BTEC Level 3

Specification

BTEC Nationals

Pearson BTEC Level 3 Diploma in Pharmaceutical Science

For first teaching September 2010

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Issue 2

Edexcel, BTEC and LCCI qualifications

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This specification is Issue 2. Key changes are sidelined. We will inform centres of any changes to this issue. The latest issue can be found on the Edexcel website: www.edexcel.com

These qualifications were previously entitled:

Edexcel BTEC Level 3 Diploma in Pharmaceutical Science (QCF)

The QN remains the same.

References to third party material made in this specification are made in good faith. We not endorse, approve or accept responsibility for the content of materials, which may be subject to change, or any opinions expressed therein. (Material may include textbooks, journals, magazines and other publications and websites.)

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Contents

The units for the BTEC Nationals in Pharmaceutical Science are on the CD ROM contained within the specification pack.

BTEC National qualification titles covered by this specification

Pearson BTEC Level 3 Diploma in Pharmaceutical Science

This qualification has been accredited to the National Framework and is eligible for public funding as determined by the Department for Education (DfE) under Sections 96 and 97 of the Learning and Skills Act 2000.

The qualification title listed above features in the funding lists published annually by the DfE and the regularly updated website. The Qualifications Number (QN) should be used by centres when they wish to seek public funding for their learners. Each unit within a qualification will also have a unit code.

The qualification and unit codes will appear on learners' final certification documentation.

The QN for the qualification in this publication is:

Pearson BTEC Level 3 Diploma in Pharmaceutical Science	500/9939/5

This qualification title will appear on learners' certificates. Learners need to be made aware of this when they are recruited by the centre and registered with Edexcel.

What are BTEC Nationals?

BTEC National qualifications are undertaken in further education and sixth-form colleges, schools and other training providers, and have been since they were introduced in 1984. Their purpose, approaches to teaching, learning and assessment are established and understood by teaching professionals, employers and learners alike.

The title is:

Pearson BTEC Level 3 Diploma in Pharmaceutical Science.

The qualification maintains the same equivalences, benchmarks and other articulations (for example SCAAT points, UCAS Tariff points) as its predecessor qualification. The following identifies the titling conventions and variations between the predecessor and new specifications:

Predecessor BTEC Nationals (accredited 2007)	BTEC Nationals (for delivery from September 2010)
Not applicable	Pearson BTEC Level 3 Certificate
Edexcel Level 3 BTEC National Award	Pearson BTEC Level 3 Subsidiary Diploma
Edexcel Level 3 BTEC National Certificate	Pearson BTEC Level 3 Diploma
Edexcel Level 3 BTEC National Diploma	Pearson BTEC Level 3 Extended Diploma

BTEC Nationals are Level 3 qualifications designed to provide highly specialist work-related qualifications in a range of vocational sectors. They give learners the knowledge, understanding and skills that they need to prepare for employment. The qualifications also provide career development opportunities for those already in work, and through articulation to higher education, degree and professional development programmes provide progression opportunities within the same cognate or related areas of study within universities and other institutions. BTEC Nationals accredit the achievement for courses and programmes of study for full-time or part-time learners in schools, colleges and other training provider organisations.

BTEC Nationals provide much of the underpinning knowledge and understanding for the National Occupational Standards for the sector, where these are appropriate. They are supported by the relevant Sector Skills Councils (SSCs) and/or Standards Setting Bodies (SSBs). Certain BTEC Nationals are recognised as Technical Certificates and form part of the Apprenticeship Framework. They attract UCAS points that equate to similar-sized general qualifications within education institutions within the UK.

On successful completion of a BTEC National qualification, a learner can progress to or within employment and/or continue their study in the same or related vocational area.

Total Qualification Time

For all regulated qualifications, Pearson specifies a total number of hours that it is expected the average learner will be required to undertake in order to complete and show achievement for the qualification: this is the Total Qualification Time (TQT).

Within this, Pearson will also identify the number of Guided Learning Hours (GLH) that we expect a centre delivering the qualification will need to provide. Guided learning means activities that directly or immediately involve tutors and assessors in teaching, supervising, and invigilating learners, such as lessons, tutorials, online instruction, supervised study giving feedback on performance.

In addition to guided learning, other required learning directed by tutors or assessors will include private study, preparation for assessment and undertaking assessment when not under supervision, such as preparatory reading, revision and independent research.

These qualifications also have a credit value, which is equal to one tenth of TQT. Pearson consults with users of these qualifications in assigning TQT and credit values.

This suite of BTEC Level 3 qualifications is available in the following sizes:

- Certificate – 300 TQT (30 credits, 180 GLH)
- Subsidiary Diploma – 600 TQT (60 credits, 360 GLH)
- 90-credit Diploma – 900 TQT (90 credits, 540 GLH)
- Diploma – 1200 TQT (120 credits, 720 GLH)
- Extended Diploma – 1800 TQT (180 credits, 1080 GLH)

Pearson BTEC Level 3 Certificate – 30 credits

The 30-credit BTEC Level 3 Certificate offers a specialist qualification that focuses on particular aspects of employment within the appropriate vocational sector. The BTEC Level 3 Certificate is a qualification which can extend a learner's programme of study and give vocational emphasis. The BTEC Level 3 Certificate is broadly equivalent to one GCE AS Level.

The BTEC Level 3 Certificate is also suitable for more mature learners, who wish to follow a vocational programme of study as part of their continued professional development or who want to move to a different area of employment.

Pearson BTEC Level 3 Subsidiary Diploma – 60 credits

The 60-credit BTEC Level 3 Subsidiary Diploma extends the specialist work-related focus from the BTEC Level 3 Certificate and covers the key knowledge and practical skills required in the appropriate vocational sector. The BTEC Level 3 Subsidiary Diploma offers greater flexibility and a choice of emphasis through the optional units. It is broadly equivalent to one GCE A Level.

The BTEC Level 3 Subsidiary Diploma offers an engaging programme for those who are clear about the area of employment that they wish to enter. These learners may wish to extend their programme through the study of general qualifications such as GCE AS Levels, additional specialist learning (for example through another BTEC qualification) or a complementary NVQ. These learning programmes can be developed to allow learners to study related and complementary qualifications without duplication of content.

For adult learners the BTEC Level 3 Subsidiary Diploma can extend their experience of work in a particular sector. It may also be a suitable qualification for those wishing to change career or move into a particular area of employment following a career break.

Pearson BTEC Level 3 Diploma – 120 credits

The 120-credit BTEC Level 3 Diploma broadens and expands the specialist work-related focus from the BTEC Level 3 Subsidiary Diploma. There is potential for the qualification to prepare learners for employment in the appropriate vocational sector and it is suitable for those who have decided that they wish to enter a particular area of work. It is broadly equivalent to two GCE A Levels.

Some learners may wish to gain the qualification in order to enter a specialist area of employment or to progress to a Level 3 programme. Other learners may want to extend the specialism they studied on the BTEC Level 3 Certificate or the BTEC Level 3 Subsidiary Diploma programme.

Pearson BTEC Level 3 Extended Diploma – 180 credits

The 180-credit BTEC Level 3 Extended Diploma extends and deepens the specialist work-related focus from the BTEC Level 3 Diploma. There is potential for the qualification to prepare learners for appropriate direct employment in the vocational sector and it is suitable for those who have decided that they clearly wish to enter a particular specialist area of work. It is broadly equivalent to three GCE A Levels.

Some learners may wish to gain the qualification in order to enter a specialist area of employment or to progress to a higher education foundation degree, HND or other professional development programme. Other learners may want to extend the specialist nature of the subjects they studied on the BTEC Level 3 Diploma or another programme of study.

Key features of the Pearson BTEC Level 3 Diploma in Pharmaceutical Science

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science has been developed in the Pharmacy Services sector to:

- give education and training for pharmacy employees
- give opportunities for pharmacy employees to achieve a nationally recognised Level 3 vocationally-specific qualification
- give full-time learners the opportunity to enter employment in the pharmacy sector
- give learners the opportunity to develop a range of skills and techniques, personal skills and attributes essential for successful performance in working life.

Rationale for the BTEC National in Pharmaceutical Science

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science has been designed for those wishing to work in a pharmacy setting, either in the community or in a non-community setting. The qualification can be taken as a stand-alone knowledge qualification. It can also be taken in conjunction with the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills and will contribute to the Level 3 Apprenticeship in Pharmacy as specified by the Sector Skills Council, Skills for Health. Learners who achieve both the Pearson BTEC Level 3 Diploma in Pharmaceutical Science and the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills will satisfy the requirements for registration to work as a pharmacy technician, (provided they meet all other registration criteria) as required by the General Pharmaceutical Council.

Centres should note that the General Pharmaceutical Council have set out requirements for staff delivering the qualifications leading to registration of candidates as pharmacy technicians. It is a requirement of the General Pharmaceutical Council that centres must have a pharmacist or pharmacy technician, who has professional responsibility and sufficient authority to deliver outcomes. There is also an expectation that units dealing with aspects of pharmacology, pharmacy practice, ethics or legislation will be taught by a registered pharmacist or pharmacy technician. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland. Further information is available from the General Pharmaceutical Council website: www.pharmacyregulation.org

National Occupational Standards

BTEC Nationals are designed to provide much of the underpinning knowledge and understanding for the National Occupational Standards (NOS), as well as developing practical skills in preparation for work and possible achievement of NVQs in due course. NOS form the basis of National Vocational Qualifications (NVQs). BTEC Nationals do not purport to deliver occupational competence in the sector, which should be demonstrated in a work context.

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science is based on the requirements of the General Pharmaceutical Council Standards for the Initial Education and Training of Pharmacy Technicians (June 2010). See Annexe F for detailed mapping of this qualification to the General Pharmaceutical Council Standards for the Initial Education and Training of Pharmacy Technicians (June 2010).

Rules of combination for Pearson BTEC Level 3 National qualifications

The rules of combination specify the:

- total credit value of the qualification
- minimum credit to be achieved at the level or above the level of the qualification
- mandatory unit credit
- optional unit credit
- maximum credit that can come from other BTEC units.

When combining units for a BTEC National qualification, it is the centre's responsibility to ensure that the following rules of combination are adhered to.

Pearson BTEC Level 3 Diploma

1 Qualification credit value: a minimum of 120 credits.

2 Minimum credit to be achieved at, or above, the level of the qualification: 90 credits.

3 Mandatory unit credit: 120 credits.

4 Optional unit credit: *there are no optional units in this qualification.*

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science is a 120-credit and 720-guided-learning-hour (GLH) qualification that consists of 19 mandatory units. Learners must achieve all 19 mandatory units in order to achieve a total of 120 credits. There are no optional units in this qualification.

Pearson BTEC Level 3 Diploma in Pharmaceutical Science			
Unit	**Mandatory units**	**Credit**	**Level**
1	Chemical Principles for Pharmacy Technicians	5	3
2	Biological Principles for Pharmacy	5	3
3	Microbiology for Pharmacy	5	3
4	Human Physiology for Pharmacy	10	3
5	Action and Uses of Medicines	10	3
6	Gastrointestinal and Nutritional Medicines	5	3
7	Cardio-Respiratory Medicines	5	3
8	Central Nervous System Medicines and Anaesthesia	5	3
9	Infections, Immunological Products and Vaccines	5	3
10	Endocrine and Genito-Urinary Medicines	5	3
11	Malignant Disease, Immunosuppressive and Musculoskeletal Medicines	5	3
12	Eye, Ear, Nose and Dermatological Medicines	5	3
13	Community Pharmacy Practice	5	3
14	Professional Development in Pharmacy	5	3
15	Communicating in Pharmacy	5	3
16	Dispensing and Supply of Medicines	5	3
17	Pharmaceutics	10	3
18	Pharmacy Law, Ethics and Practice	10	3
19	Making Medicines for Pharmacy	10	3

Assessment and grading

In BTEC Nationals, all units are internally assessed

All assessment for BTEC Nationals is criterion referenced, based on the achievement of specified learning outcomes. Each unit within the qualification has specified assessment and grading criteria which are to be used for grading purposes. A summative unit grade can be awarded at pass, merit or distinction:

- to achieve a 'pass' a learner must have satisfied **all** the pass assessment criteria
- to achieve a 'merit' a learner must additionally have satisfied **all** the merit grading criteria
- to achieve a 'distinction' a learner must additionally have satisfied **all** the distinction grading criteria.

Learners who complete the unit but who do not meet all the pass criteria are graded 'unclassified'.

Grading domains

The grading criteria are developed in relation to grading domains which are exemplified by a number of indicative characteristics at the level of the qualification.

There are four BTEC National grading domains:

- application of knowledge and understanding
- development of practical and technical skills
- personal development for occupational roles
- application of generic skills.

Please refer to *Annexe B* which shows the merit and distinction indicative characteristics.

Guidance

The purpose of assessment is to ensure that effective learning has taken place to give learners the opportunity to:

- meet the assessment and grading criteria and
- achieve the learning outcomes within the units.

All the assignments created by centres should be reliable and fit for purpose, and should build on the assessment and grading criteria. Assessment tasks and activities should enable learners to produce valid, sufficient and reliable evidence that relates directly to the specified criteria. Centres should enable learners to produce evidence in a variety of different forms and including, written reports, graphs and posters, along with projects, performance observation and time-constrained assessments.

Centres are encouraged to emphasise the practical application of the assessment and grading criteria, providing a realistic scenario for learners to adopt, and making maximum use of practical activities and work experience. The creation of assignments that are fit for purpose is vital to achievement and their importance cannot be over-emphasised.

The assessment and grading criteria must be clearly indicated in the fit-for-purpose assignments. This gives learners focus and helps with internal verification and standardisation processes. It will also help to ensure that learner feedback is specific to the assessment and grading criteria.

When looking at the assessment and grading grids and designing assignments, centres are encouraged to identify common topics and themes.

The units include guidance on appropriate assessment methodology. A central feature of vocational assessment is that it allows for assessment to be:

- current, ie to reflect the most recent developments and issues
- local, ie to reflect the employment context of the delivering centre
- flexible to reflect learner needs, ie at a time and in a way that matches the learner's requirements so that they can demonstrate achievement.

Calculation of the qualification grade

Pass qualification grade

Learners who achieve the minimum eligible credit value specified by the rule of combination will achieve the qualification at pass grade (see *Rules of combination for Pearson BTEC Level 3 National qualifications*).

Qualification grades above pass grade

Learners will be awarded a merit or distinction or distinction* qualification grade (or combination of these grades appropriate to the qualification) by the aggregation of points gained through the successful achievement of individual units. The number of points available is dependent on the unit level and grade achieved, and the credit size of the unit (as shown in the 'points available for credits achieved at different Levels and unit grades' below).

Points available for credits achieved at different Levels and unit grades

The table below shows the **number of points scored per credit** at the unit level and grade.

Unit level	Points per credit		
	Pass	Merit	Distinction
Level 2	5	6	7
Level 3	**7**	**8**	**9**
Level 4	9	10	11

Learners who achieve the correct number of points within the ranges shown in the 'qualification grade' table will achieve the qualification merit or distinction or distinction* grade (or combinations of these grades appropriate to the qualification).

Qualification grade

BTEC Level 3 Certificate

Points range above pass grade	Grade	
230-249	**Merit**	**M**
250-259	Distinction	D
260 and above	Distinction*	D*

BTEC Level 3 Subsidiary Diploma

Points range above pass grade	Grade	
460-499	**Merit**	**M**
500-519	Distinction	D
520 and above	Distinction*	D*

BTEC Level 3 Diploma

Points range above pass grade	Grade
880-919	**MP**
920-959	MM
960-999	DM
1000-1029	DD
1030-1059	DD*
1060 and above	D*D*

BTEC Level 3 Extended Diploma

Points range above pass grade	Grade
1300-1339	**MPP**
1340-1379	MMP
1380-1419	MMM
1420-1459	DMM
1460-1499	DDM
1500-1529	DDD
1530-1559	DDD*
1560-1589	DD*D*
1590 and above	D*D*D*

Please refer to *Annexe H* for examples of calculation of qualification grade above pass grade.

Quality assurance of centres

Pearson's qualification specifications set out the standard to be achieved by each learner in order to be awarded the qualification. This is covered in the statement of learning outcomes, and assessment and grading criteria in each unit. Further guidance on delivery and assessment is given in the *Essential guidance for tutors* section in each unit. This section is designed to provide additional guidance and amplification related to the unit to support tutors, deliverers and assessors and to provide for a coherence of understanding and a consistency of delivery and assessment.

Approval

Centres that have not previously offered BTEC qualifications will first need to apply for, and be granted, centre approval before they can apply for approval to offer the programme.

When a centre applies for approval to offer a BTEC qualification they are required to enter into an approvals agreement.

The approvals agreement is a formal commitment by the head or principal of a centre to meet all the requirements of the specification and any linked codes or regulations. Sanctions and tariffs may be applied if centres do not comply with the agreement. Ultimately, this could result in the suspension of certification or withdrawal of approval.

Centres will be allowed 'accelerated approval' for a new programme where the centre already has approval for a programme that is being replaced by the new programme.

The key principles of quality assurance are that:

- a centre delivering BTEC programmes must be an approved centre and must have approval for programmes or groups of programmes that it is operating
- the centre agrees as part of gaining approval to abide by specific terms and conditions around the effective delivery and quality assurance of assessment; it must abide by these conditions throughout the period of delivery
- Pearson makes available to approved centres a range of materials and opportunities intended to exemplify the processes required for effective assessment and examples of effective standards. Approved centres must use the materials and services to ensure that all staff delivering BTEC qualifications keep up to date with the guidance on assessment
- an approved centre must follow agreed protocols for standardisation of assessors and verifiers; planning, monitoring and recording of assessment processes; and for dealing with special circumstances, appeals and malpractice.

The approach of quality assured assessment is made through a partnership between an approved centre and Pearson. Pearson is committed to ensuring that it follows best practice and employs appropriate technology to support quality assurance processes where practicable. Therefore, the specific arrangements for working with centres will vary. Edexcel seeks to ensure that the quality assurance processes that it uses do not place undue bureaucratic processes on centres and works to support centres in providing robust quality assurance processes.

Pearson monitors and supports centres in the effective operation of assessment and quality assurance. The methods which it uses to do this for BTEC First and National programmes include:

- ensuring that all centres have completed appropriate declarations at the time of approval undertaking approval visits to centres where necessary

- requiring all centres to appoint a Lead Internal Verifier for designated groups of programmes and to ensure that this person is trained and supported in carrying out that role
- requiring that the Lead Internal Verifier completes compulsory online standardisation related to assessment and verification decisions for the designated programme
- assessment sampling and verification, through requested samples of assessments, completed assessed learner work and associated documentation
- overarching review and assessment of a centre's strategy for assessing and quality assuring its BTEC programmes.

Pearson Quality Assurance Handbook

Centres should refer to the *Handbook for Quality Assurance for BTEC Qualifications*, issued annually, for detailed guidance.

An approved centre must make certification claims only when authorised by Edexcel and strictly in accordance with requirements for reporting.

Centres that do not fully address and maintain rigorous approaches to quality assurance will be prevented from seeking certification for individual programmes or for all BTEC First and National programmes. Centres that do not comply with remedial action plans may have their approval to deliver qualifications removed.

Programme design and delivery

BTEC National qualifications consist of mandatory units and optional units. Optional units are designed to provide a focus to the qualification and give more specialist opportunities in the sector. (Note: Some BTEC National qualifications do not offer optional units).

In BTEC Nationals each unit has a number of guided learning hours and Centres are advised to consider this definition when planning the programme of study associated with this specification.

Mode of delivery

Edexcel does not define the mode of study for BTEC Nationals. Centres are free to offer the qualifications using any mode of delivery (such as full time, part time, evening only, distance learning) that meets their learners' needs. Whichever mode of delivery is used, centres must ensure that learners have appropriate access to the resources identified in the specification and to the subject specialists delivering the units. This is particularly important for learners studying for the qualification through open or distance learning.

Learners studying for the qualification on a part-time basis bring with them a wealth of experience that should be utilised to maximum effect by tutors and assessors. The use of assessment evidence drawn from learners' work environments should be encouraged. Those planning the programme should aim to enhance the vocational nature of the qualification by:

- liaising with employers to ensure a course relevant to learners' specific needs
- accessing and using non-confidential data and documents from learners' workplaces
- including sponsoring employers in the delivery of the programme and, where appropriate, in the assessment
- linking with company-based/workplace training programmes
- making full use of the variety of experience of work and life that learners bring to the programme.

Resources

BTEC Nationals are designed to prepare learners for employment in specific occupational sectors. Physical resources need to support the delivery of the programme and the proper assessment of the learning outcomes and should, therefore, normally be of industry standard. Staff delivering programmes and conducting the assessments should be familiar with current practice and standards in the sector concerned. Centres will need to meet any specific resource requirements to gain approval from Edexcel.

Where specific resources are required these have been indicated in individual units in the Essential resources sections.

Delivery approach

It is important that centres develop an approach to teaching and learning that supports the specialist vocational nature of BTEC National qualifications and the mode of delivery. Specifications give a balance of practical skill development and knowledge requirements, some of which can be theoretical in nature. Tutors and assessors need to ensure that appropriate links are made between theory and practical application and that the knowledge base is applied to the sector. This requires the development of relevant and up-to-date teaching materials that allow learners to apply their learning to actual events and activity within the sector. Maximum use should be made of the learner's experience.

An outline learning plan is included in every unit as guidance which demonstrates one way in planning the delivery and assessment of the unit. The outline learning plan can be used in conjunction with the programme of suggested assignments.

Where the qualification has been designated and approved as a Technical Certificate and forms part of an Apprenticeship scheme, particular care needs to be taken to build strong links between the learning and assessment for the BTEC National qualification and the related NVQs and Functional Skills that also contribute to the scheme.

Meeting local needs

Centres should note that the qualifications set out in this specification have been developed in consultation with centres and employers and the Sector Skills Councils or the Standards Setting Bodies for the relevant sector. Centres should make maximum use of the choice available to them within the optional units to meet the needs of their learners, and local skills and training needs.

In certain circumstances, units in this specification might not allow centres to meet a local need. In this situation, Edexcel will ensure that the rule of combination allows centres to make use of units from other standard BTEC specifications. Centres are required to ensure that the coherence and purpose of the qualification is retained and to ensure that the vocational focus is not diluted.

Limitations on variations from standard specifications

The flexibility to import standard units from other BTEC Nationals is limited to a total of 25 per cent of the qualification credit value (see *Rules of combination for Pearson BTEC Level 3 National qualifications*).

These units cannot be used at the expense of the mandatory units in any qualification.

Additional and specialist learning

Additional and specialist learning (ASL) consists of accredited qualifications at the same level as, or one level above, the Diploma course of study. The ASL may include BTEC qualifications which are also available to learners not following a Diploma course of study.

Qualifications for ASL must be selected from the ASL catalogue through the National Database of Accredited Qualifications (NDAQ). The catalogue includes qualifications which have the approval of the Diploma Development Partnership (DDP) and will expand over time as more qualifications are approved. To access the catalogue go to www.ndaq.org.uk and select 'Browse Diploma Qualifications'.

Functional Skills

BTEC Nationals give learners opportunities to develop and apply Functional Skills.

Functional Skills are offered as stand-alone qualifications at Level 2. See individual units for opportunities to cover ICT, Mathematics and English Functional Skills.

Personal, learning and thinking skills

Opportunities are available to develop personal, learning and thinking skills (PLTS) within sector-related context. PLTS are identified in brackets after the unit pass criteria to which they are associated and they are also mapped in *Annexe C*. Further opportunities for learners to demonstrate these skills may also be apparent as learners progress throughout their learning.

Access and recruitment

Pearson's policy regarding access to its qualifications is that:

- they should be available to everyone who is capable of reaching the required standards
- they should be free from any barriers that restrict access and progression
- there should be equal opportunities for all wishing to access the qualifications.

Centres are required to recruit learners to BTEC qualifications with integrity. This will include ensuring that applicants have appropriate information and advice about the qualifications and that the qualification will meet their needs. Centres should take appropriate steps to assess each applicant's potential and make a professional judgement about their ability to successfully complete the programme of study and achieve the qualification. This assessment will need to take account of the support available to the learner within the centre during their programme of study and any specific support that might be necessary to allow the learner to access the assessment for the qualification. Centres should consult Pearson's policy on learners with particular requirements.

Centres will need to review the entry profile of qualifications and/or experience held by applicants, considering whether this profile shows an ability to progress to a Level 3 qualification. For learners who have recently been in education, the profile is likely to include one of the following:

- a BTEC Level 2 qualification in Pharmaceutical Science or a related vocational area
- a standard of literacy and numeracy supported by a general education equivalent to four GCSEs at grade A*-C
- other related Level 2 qualifications
- related work experience.

More mature learners may present a more varied profile of achievement that is likely to include experience of paid and/or unpaid employment.

Restrictions on learner entry

Most BTEC National qualifications are accredited for learners aged 16 years and over.

In particular sectors the restrictions on learner entry might also relate to any physical or legal barriers, for example people working in health, care or education are likely to be subject to police checks.

Pearson BTEC Level 3 Nationals are listed on the DfE funding lists under Section 96 and Section 97 of the Learning and Skills Act 2000.

Access arrangements and special considerations

Pearson's policy on access arrangements and special considerations for BTEC and Edexcel NVQ qualifications aims to enhance access to the qualifications for learners with disabilities and other difficulties (as defined by the 1995 Disability Discrimination Act and the amendments to the Act) without compromising the assessment of skills, knowledge, understanding or competence.

Further details are given in the policy *Access Arrangements and Special Considerations for BTEC and Edexcel NVQ Qualifications*, which can be found on the Pearson website (qualifications.pearson.com). This policy replaces the previous Edexcel policy (Assessment of Vocationally Related Qualification: Regulations and Guidance Relating to Learners with Special Requirements, 2002) concerning learners with particular requirements.

Recognition of Prior Learning

Recognition of Prior Learning (RPL) is a method of assessment (leading to the award of credit) that considers whether a learner can demonstrate that they can meet the assessment requirements for a unit through knowledge, understanding or skills they already possess and so do not need to develop through a course of learning.

Pearson encourages centres to recognise learners' previous achievements and experiences whether at work, home and at leisure, as well as in the classroom. RPL provides a route for the recognition of the achievements resulting from continuous learning.

RPL enables recognition of achievement from a range of activities using any valid assessment methodology. Provided that the assessment requirements of a given unit or qualification have been met, the use of RPL is acceptable for accrediting a unit, units or a whole qualification. Evidence of learning must be valid and reliable.

Unit format

All units in Pearson BTEC Level 3 National qualifications have a standard format. The unit format is designed to give guidance on the requirements of the qualification for learners, tutors, assessors and those responsible for monitoring national standards.

Each unit has the following sections.

Unit title

The unit title will appear on the learner's Notification of Performance (NOP).

Unit code

Each unit is assigned a unit code that appears with the unit title on the National Database of Accredited Qualifications.

Level

All units and qualifications will have a level assigned to them, which represents the level of achievement. There are nine levels of achievement, from Entry Level to Level 8. The level of the unit has been informed by level descriptors and, where appropriate, the National Occupational Standards (NOS) and/or other sector/professional benchmarks.

Credit value

Each unit in BTEC National qualifications has a credit value; learners will be awarded credits for the successful completion of whole units.

A credit value specifies the number of credits that will be awarded to a learner who has achieved all the learning outcomes of the unit.

Guided learning hours

Guided learning hours for the unit are shown on page 3.

Aim and purpose

The aim provides a clear summary of the purpose of the unit and is a succinct statement that summarises the learning outcomes of the unit.

Unit introduction

The unit introduction gives the reader an appreciation of the unit in the vocational setting of the qualification, as well as highlighting the focus of the unit. It gives the reader a snapshot of the unit and the key knowledge, skills and understanding gained while studying the unit. The unit introduction also highlights any links to the appropriate vocational sector by describing how the unit relates to that sector.

Learning outcomes

Learning outcomes state exactly what a learner should 'know, understand or be able to do' as a result of completing the unit.

Unit content

The unit content identifies the breadth of knowledge, skills and understanding needed to design and deliver a programme of learning to achieve each of the learning outcomes. This is informed by the underpinning knowledge and understanding requirements of the related NOS. The content provides the range of subject material for the programme of learning and specifies the skills, knowledge and understanding required for achievement of the pass, merit and distinction grading criteria.

Each learning outcome is stated in full and then the key phrases or concepts related to that learning outcome are listed in italics followed by the subsequent range of related topics.

Relationship between content and assessment criteria

The learner must have the opportunity within the delivery of the unit to cover all of the unit content.

It is not a requirement of the unit specification that all of the content is assessed. However, the indicative content will need to be covered in a programme of learning in order for learners to be able to meet the standard determined in the assessment and grading criteria. The merit and distinction grading criteria enable the learner to achieve higher levels of performance in acquisition of knowledge, understanding and skills.

Content structure and terminology

The information below shows how unit content is structured and gives the terminology used to explain the different components within the content.

- Learning outcome: this is given and in bold at the beginning of each section of content.
- Italicised sub-heading: it contains a key phrase or concept. This is content which must be covered in the delivery of the unit. Colons mark the end of an italicised sub-heading.
- Elements of content: the elements are in plain text and amplify the sub-heading. The elements must also be covered in the delivery of the unit. Semi-colons mark the end of an element.
- Brackets contain amplification of elements of content which must be covered in the delivery of the unit.
- 'eg' is a list of examples used for indicative amplification of an element (that is, the content specified in this amplification that could be covered or that could be replaced by other, similar material).

Assessment and grading grid

Each grading grid gives the assessment and grading criteria used to determine the evidence that each learner must produce in order to receive a pass, merit or distinction grade. It is important to note that the merit and distinction grading criteria require a qualitative improvement in a learner's evidence and not simply the production of more evidence at the same level.

Essential guidance for tutors

This section gives tutors additional guidance and amplification to aid understanding and a consistent level of delivery and assessment. It is divided into the following sections.

- *Delivery* – explains the content's relationship with the learning outcomes and offers guidance about possible approaches to delivery. This section is based on the more usual delivery modes but is not intended to rule out alternative approaches.
- *Outline learning plan* – the outline learning plan has been included in every unit as guidance and demonstrates one way in planning the delivery and assessment of a unit. The outline learning plan can be used in conjunction with the programme of suggested assignments.
- *Assessment* – gives amplification about the nature and type of evidence that learners need to produce in order to pass the unit or achieve the higher grades. This section should be read in conjunction with the grading criteria.
- *Programme of suggested assignments* – the table shows how the suggested assignments match and cover the assessment grading criteria.
- *Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications* – sets out links with other units within the qualification. These links can be used to ensure that learners make connections between units, resulting in a coherent programme of learning. The links show opportunities for integration of learning, delivery and assessment.

- *Essential resources* – identifies any specialist resources needed to allow learners to generate the evidence required for each unit. The centre will be asked to ensure that any requirements are in place when it seeks approval from Pearson to offer the qualification.
- *Employer engagement and vocational contexts* – provides a short list of agencies, networks and other useful contacts for employer engagement and for sources of vocational contexts.
- *Indicative reading for learners* – gives a short list of learner resource material that benchmarks the level of study.

Units

Unit 1: Chemical Principles for Pharmacy Technicians

Unit code: Y/601/7562

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

The aim of this unit is to give learners the underpinning knowledge of the fundamental principles of chemistry needed for the understanding of pharmaceutical concepts.

Unit introduction

This unit enables learners to gain the theoretical knowledge of the chemistry that forms the basis of the pharmaceutical concepts they will study in other units and which will also be applied in the workplace.

The study of atomic structure gives learners an understanding of how electron configuration accounts for the arrangement of elements in the periodic table. Learners will develop an understanding that electronic structure determines the chemical properties of an element. The unit covers the periodical trends in physical properties in terms of electronic configuration. Learners will consider the main types of atomic bonding and hydrogen bonding and the physical properties of their associated structures.

This unit enables learners to carry out simple quantitative and qualitative experiments and assessments to increase their understanding of chemical reactions. Learners will investigate the principles behind chemical reactions such as the factors affecting rate of reaction and the formation of salts in neutralisation reactions. The basic principles of organic chemistry are also introduced.

Learners will develop the basic chemical skills of equation writing and calculating chemical quantities. Relative atomic and molecular masses will be introduced, along with the concept of molar quantities. Learners will investigate the use of balanced equations to calculate reacting masses using the concepts of amount of substance and molar mass. This will include calculations of the amount of substance in a solution of known concentration and vice versa, including conversion between different units of concentration.

Learning outcomes

On completion of this unit a learner should:

1 Understand how the atomic and electronic structure of elements influences the arrangement of the periodic table and bonding

2 Understand the principles behind chemical reactions

3 Be able to carry out calculations involving quantities and concentrations.

Unit content

1 Understand how the atomic and electronic structure of elements influences the arrangement of the periodic table and bonding.

The nuclear model of the atom: protons, neutrons and electrons; atomic number; mass number

The electronic structures of atoms: arrangement of electrons around the nucleus; electronic configurations of the first 20 elements; s, p, and d sub-orbitals

The periodic table: organisation of elements in the periodic table; periodicity of physical and chemical properties

Bonding: ionic compounds (electron transfer common examples, common properties); covalent compounds (electron sharing common examples, common properties); metallic bonding; tetrahedral basis of organic chemistry; electro-negativity and polar bonding; hydrogen bonding.

2 Understand the principles behind chemical reactions

Reaction rates: how reaction rates are affected by changes in concentration, temperature, pressure, surface area and catalysts

Solutions: the concept of solutions and dissolution

pH and neutralization reactions: description of acids and bases; common laboratory acids and bases; pharmaceutical examples of acids and bases; pH scale; indicators, pH meter and measurement of pH; neutralisation reactions; preparation of simple salts

Hydrocarbons and the basic principles of organic chemistry: formulae; structural formulae; displayed formulae; isomers and their biological and pharmaceutical importance; homologous series and associated properties; simple reactions of organic compounds (addition reactions for alkenes, oxidation of alcohols to aldehydes and ketones, oxidation of aldehydes to acids, carboxylic acids as acids, esterification, amines as bases, formation of amides)

3 Be able to carry out calculations involving quantities and concentrations

SI and metric units used in pharmacy: weights (kg, g, mg, mcg); volumes (l, ml); concentrations (g/l, mg/l, mg/ml etc); percentages (%w/w, %w/v, %v/v)

Chemical quantities: relative atomic mass and relative molecular mass; relationship between atomic quantities and grams

Molar quantities: the mole concept; molarity; calculation of amounts of substance in moles using equations such as moles = mass/relative molecular mass

Molar concentrations: mol/l; mmol/l; mmol/ml

Proportions in chemical reactions: balanced equations for chemical reactions; reacting masses

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	explain the periodic table in terms of the atomic structure of the elements[IE1]	**M1**	explain the physical and chemical properties of elements and compounds in terms of the type of bonding present	**D1**	explain the influence of electro-negativity and molecular size on the bonding and intermolecular forces in pure substances and solutions
P2	explain inter and intramolecular forces of attraction [IE1,IE2, IE4,TW1,TW2,TW3, EP3]	**M2**	analyse variation in rates of reaction as a function of concentration, particle size, temperature and presence of a catalyst	**D2**	explain how the nature of a chemical's pharmacological activity is governed by its chemical properties or its structure
P3	explain chemical bonding between atoms and between molecules	**M3**	relate the reactions of organic molecules to the properties of their functional groups		
P4	explain how chemical and physical factors affect the rates of reactions [IE1]	**M4**	write balanced equations to solve problems involving mole/mass conversions.	**D3**	carry out complex calculations involving the conversion of different concentration units.
P5	explain the concept of pH [IE1]				
P6	categorise the different functional groups for homologous series				
P7	accurately balance chemical equations				
P8	accurately carry out calculations involving molar quantities.				

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

In this unit, emphasis should be placed on the relevance of chemistry to pharmacy. The use of pharmaceutically relevant examples is important as chemistry is often difficult to relate to everyday practice. Tutors should maximise every opportunity to relate fundamental concepts to applications in the pharmacy sector. This will help to contextualise the knowledge and understanding of this unit for learners.

Teaching will often be tutor led, and the key to learner-centred learning success will be in the practical opportunities that chemistry presents. The unit should be delivered so that it allows the learner to approach many of the concepts through scientific investigation wherever possible. Learners should have access to a full chemistry laboratory.

Learning outcomes 1 and 2 are likely to be delivered through a combination of formal lectures, active learning techniques and practical work. Tutor-led study must also be supplemented by independent research. Learning outcome 3 could be taught through the activities undertaken in the delivery of learning outcomes 1 and 2, rather than delivered separately.

In learning outcome 1, learners need to review and develop their understanding of atomic structure and electronic configuration and how this relates to the periodic table and chemical bonding.

In working towards P1, learners should be able to recognise diagrammatical representations of atoms and bonding between atoms and ions. The electronic structure of atoms should be related to the position of the element in the periodic table. Learners should be able to recall that the periodic table is divided into s, p and d blocks and that this relates to different electron orbitals. Activities related to atomic structure and periodicity should concentrate on the first 20 elements.

Learners could carry out practical work to investigate the physical and chemical properties of ionic, simple covalent, giant covalent and metallic structures in order to satisfy M1. They need to explain the properties observed in terms of the type of bonding present and relate this back to electronic configuration.

More advanced learners will be able to explain the role of electro-negativity and size on bonding and intermolecular forces such as hydrogen bonding. Learners should be able to distinguish between polar

bonds and polar molecules and be able to predict whether or not a given molecule is likely to be polar. Learners should become familiar with theories of bonding, allowing an understanding of the behaviour of water and solutes to be developed. The concept of polarity is central to understanding the solubility of drugs. The target in the body for the drug determines what type of solubility is required and thus solubility is a key factor in drug design.

For learning outcome 2, it is important for learners to carry out experimental investigations on the factors affecting rate of reaction. They should also be able to make and test predictions based on changes in concentration, particle size, temperature and the use of a catalyst. Although it is important for learners to understand that enzymes are biological catalysts, it is not necessary to describe details of a range of reactions catalysed by enzymes.

Learners should investigate pH and ways to measure pH. The concept of strength of acids and bases should be investigated practically, as should the behaviour of buffer solutions and links made to biological buffer systems in the body.

Learners should know that there are many classes of organic compound, and should understand the concept of a functional group. It is important that learners are made aware that more than one functional group may be present in a molecule of biological significance. The emphasis should be on learners understanding the structure and function of the various organic chemicals, as opposed to memorising chemical names and structures. This section is likely to involve practical laboratory synthesis, for example preparation of aspirin, which would also provide an ideal opportunity to develop learning outcome 3. Since certain aspects of biological activity depend on isomerism, it is important that learners are able to recognise different types of isomers.

Physical properties, such as solubility, should be explored. Learners should investigate the oxidation of alcohols, aldehydes and esterification in a practical way. The biological significance of reactions should be explained for example oxidation of reducing sugars, fats as examples of esters, formation of amide linkages in proteins.

Calculations are an important part of this unit, as aspects such as dilution and molar calculations form a basis of pharmaceutics (formulation studies). In learning outcome 3, calculation of quantities used in chemical reactions should be introduced through the use of balanced equations and learners should have the opportunity to develop their understanding of the terms and use of relative molecular mass, moles and units of concentration. The balancing of chemical equations and the correct use of different units should be applied to pharmaceutical applications whenever possible. Pharmacy technicians frequently have to make up solutions and perform dilutions. It is therefore important for learners to understand how concentration is calculated. Learners must be able to calculate the mass of substance needed to make a given volume at a given concentration of solution. This should be linked as much as possible to practical work.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and/assessment
Introduction to unit, programme of assignments, safety and ICT briefing.
Learning outcome 1 Examine atomic structure and sub atomic particles, elements and atoms. Examine electronic configuration and orbitals. Explain the periodic table – organisation and periodicity. Explain bonding in terms of electronic configuration. Explain electro- negativity and intermolecular bonds. Investigate properties of structures theory. Practical work. **Assignment 1: Electronic Structure, The Periodic Table and Bonding** (P1, P2, M1)
Learning outcome 3 Preparation for the delivery of learning outcome 2 – equations, masses and moles.
Learning outcome 2 Factors affecting rates of reaction – theory and practical work. pH and neutralisation reactions. Preparation of simple salts – include work for learning outcome 3 – equations and calculations. Solutions and dissolution – include work for learning outcome 3 – concentrations. Practical work. **Assignment 2: Rates of Reaction** (P3, P4, P6, P7, P8, M2, M4) Introduction to organic compounds – naming, structures and isomers. Explain properties of functional groups. Explain simple reactions of organic compounds. Practical work. **Assignment 3: The Importance of Organic Synthesis** (P5, M3, D1, D2, D3)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should apply the following guidelines.

'Substantial guidance': Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

'Limited guidance': The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

'Independently': The tutor supports learners initially, as in for instance, in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

To achieve P1, learners are required to explain the electronic structure of an atom and identify the relationship between the atom's position in the periodic table and its electronic configuration. Learners need to be able to recall that the periodic table is divided into s, p and d blocks and the relationship to orbitals.

For P2, learners need to explain inter and intra molecular forces of attraction.

For P3, learners need to be able to explain chemical bonding between atoms and molecules using diagrammatical representations of covalent, ionic, metallic and hydrogen bonds.

For P4, learners need to explain the factors affecting reaction rates. There is opportunity for learners to write balanced equations and carry out quantitive evaluation, thereby meeting P7 and P8.

For P5, learners need to be able to explain pH in terms of acids and bases and the methods used to measure pH and the pH scale.

For P6, learners are required to demonstrate a basic understanding of functional groups in organic compounds by categorising the various functional groups present on different biological chemicals or drugs. Learners should be presented with models of organic compounds and be able to identify isomers.

P7 requires learners to balance simple chemical equations.

For P8, learners are required to carry out calculations to convert from moles to mass and vice-versa.

M1 requires learners to relate the physical and chemical properties of the elements and compounds to the type of bonding, including discussion of melting points, boiling points and solubility in terms of the size of the intramolecular forces which exist in the substances.

For M2, learners need to analyse the effects of the factors identified for P2 in terms of collision theory and activation energy.

For M3, learners need to identify the properties of functional groups and relate this to their reactions.

For M4, learners need to be able to write balanced equations in solving problems involving mole/mass conversions. For example, in the synthesis of aspirin, the theoretical yield in grams could be calculated from a given weight of starting material.

To achieve D1, learners are required to use their understanding of electro-negativity to explain the phenomena of hydrogen bonding and bond polarisation and the effect these have on intermolecular forces and solubility. Learners should be able to explain high melting points/boiling points and solubility in terms of strong intermolecular forces resulting from dipole-dipole interactions and hydrogen bonding, due to high electro- negativity of one of the atoms in the molecule. Learners should also explain the effect of molecular size on the interaction between molecules. Additionally, learners should include discussion of water as a polar solvent and its biological importance.

D2 requires learners to evaluate a substance used in pharmacological applications and explain how the substance's chemical properties and/or its structure affect its pharmacological activity. Examples include relating rates of reaction to drug metabolism or the importance of isomerism on biological activity of organic compounds.

For D3, learners need to carry out complex calculations involving concentrations and the conversion between different units.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P2, M1	Electronic Structure, The Periodic Table and Bonding	You have been asked to write training materials about atomic structure, the periodic table and chemical bonding for pharmacy technicians starting the first year of their training. Produce a poster or presentation to show the link between electronic configuration and the arrangement of the periodic table and bonding.	Poster. Presentations. Observation records.
P3, P4, P6, P7, P8, M2, M4	Rates of Reaction	You are a pharmacology technician working as part of a team to develop a new antacid formulation. You have been asked by your supervisor to investigate the factors that will affect how quickly the product will be effective. Carry out experiments to investigate the factors which affect the rate of neutralisation and present the results in a written report or in a presentation.	Written report. Presentations. Observation records.
P5, M3, D1, D2, D3	The Importance of Organic Synthesis	You are a researcher for a pharmaceutical company which manufactures aspirin and paracetamol. You have been asked to investigate how they are synthesised and how the solubility of aspirin can be improved. To do this, you will need to identify the functional groups involved in the two syntheses and explain the type of reactions occurring. Carry out the synthesis of aspirin in the lab and calculate the percentage yield. Consider the solubility of aspirin and why solubility is a key factor in drug design.	Practical experiment. Written report.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 17: Pharmaceutics
Unit 19: Making Medicines for Pharmacy

Essential resources

Learners should have access to a range of chemistry resources, similar to those used for GCSE and GCE in Science.

Learners will need access to a chemistry/science laboratory equipped with a fume cupboard and standard laboratory chemistry apparatus. Access to a range of information resources to complete investigative assignments and case studies will be essential, including relevant CD ROMs and the internet.

Learners will also require access to a library with a range of relevant books, journals and electronic resources, for example *Chemistry Review*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

AS-Level Chemistry Revision Guide (CGP, 2005) ISBN 9781847621252

Conoley C – *Edexcel GCSE Chemistry* (Hodder Arnold, 2009) ISBN 9780340914793

Hutchings K – *Classic Chemistry Experiments* (The Royal Society of Chemistry, 2000) ISBN 97808540491196

M. Fry & E. Page – *Catch Up Chemistry: For the Life and Medical Sciences* (Scion Publishing, 2005) 1904842100

Ryan L – *New Chemistry for You* (Nelson Thornes, 2006) ISBN 9780748783236

Safeguards Committee – *Safeguards in the School Laboratory* (Association for Science Education, 2006) ISBN 9780863574085

Journals

New Scientist (Reed Business Information Ltd, published weekly)

Chemistry Review (Philip Allan Updates, Hodder Education Group)

Websites

www.alka-seltzer.com/as/student_experiment.html	Alka-Seltzer Experiments
www.chemguide.co.uk	Online Guide for chemistry terms and concepts
www.creative-chemistry.org.uk	Online Resources for chemistry teachers and students
www.docbrown.info	Chemistry revision resources

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Independent enquirers	[IE1, IE2, IE4] carrying out experiments to show the effect of factors on the rate of reaction, balancing equations, carrying out mole/mass conversions, identifying the link between atomic structure, the periodic table and bonding
Reflective learners	[RL2] setting goals with success criteria when carrying out experiments
Team workers	[TW1,TW2,TW3] carrying out experiments to show the effect of factors on the rate of reaction
Self-managers	[SM2, SM3, SM5] completing coursework [SM4] carrying out experiments
Effective participators	[EP3] proposing practical ways forward when carrying out experiments.

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE4, IIE6] explaining bonding; explaining the affect of electro negativity on intermolecular forces; explaining pharmacological activity in terms of chemical properties and structure
Creative thinkers	[CT1] explaining bonding [CT2] explaining the affect of electro negativity on intermolecular forces [CT6] explaining pharmacological activity in terms of chemical properties and structure
Reflective learners	[RL3, RL4, RL5] preparing coursework to meet the constraints of the scenarios and grading criteria; acting on feedback
Team workers	[TW1,TW4,TW6] sharing and comparing experimental data.
Self-managers	[SM2, SM3, SM5] completing coursework [SM4] carrying out experiments
Effective participators	[EP4] taking part in discussions and question and answer sessions [EP5]carrying out experimental work.

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using data logging to monitor pH or temperature during a reaction
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	preparing coursework documentation carrying out internet-based research
Manage information storage to enable efficient retrieval	saving internet searches and coursework documentation
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	using the internet to complete assignment tasks
Select information from a variety of sources to meet requirements of a complex task	using the internet to complete assignment tasks
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	preparing coursework and assignments writing experimental reports and presenting results producing presentations as part of coursework.
Use appropriate software to meet the requirements of a complex data-handling task	preparing written assignments and presentations
Use communications software to meet requirements of a complex task	using virtual learning environments and message boards contacting course tutors and other learners
Combine and present information in ways that are fit for purpose and audience	preparing written assignments and presentations
Mathematics – representing	
Understand routine and non-routine problems in familiar and unfamiliar contexts and situations	participating in the treatment and manipulation of numerical experimental data balancing equations and calculating amounts
Identify the situation or problems and identify the mathematical methods needed to solve them	dealing with quantitative experiments balancing equations and calculating amounts
Choose from a range of mathematics to find solutions	involved in the treatment and manipulation of numerical experimental data balancing equations and calculating amounts
Mathematics – analysing	

Skill	When learners are ...
Use appropriate checking procedures and evaluate their effectiveness at each stage	involved in the treatment and manipulation of numerical experimental data balancing equations and calculating amounts
Mathematics – interpreting	
Interpret and communicate solutions to multistage practical problems in familiar and unfamiliar contexts and situations	presenting numerical experimental data balancing equations and calculating amounts
Draw conclusions and provide mathematical justifications	presenting numerical experimental data balancing equations and calculating amounts
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions presenting experimental results presenting information where required by the assignment brief
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	doing background reading to support studies
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing lab reports and all supporting coursework documentation for their assignments

Unit 2: Biological Principles for Pharmacy

Unit code: M/601/7566

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

The aim of this unit is for learners to develop knowledge of biological principles applicable to pharmacy. This unit will give the learner knowledge and understanding of the basic structure and functions of biological chemicals.

Unit introduction

This unit covers the basic biological principles for pharmacy. These principles build understanding of the structure and functions of basic biological chemicals, including carbohydrates, lipids and proteins, enzymes and nucleic acids and water.

Learners will be introduced to the biological principles associated with pharmacy. The unit will enable learners to develop practical biological skills, underpinning knowledge and understanding of biology, including preparation for *Unit 4: Human Physiology for Pharmacy*.

Learning outcomes

On completion of this unit a learner should:

1 Understand the basic structure and function of carbohydrates, lipids and proteins

2 Understand the structure and functions of enzymes

3 Understand the structure and functions of nucleic acids

4 Understand the biological significance of water.

Unit content

1 Understand the basic structure and function of carbohydrates, lipids and proteins

Structure and function of carbohydrates: forms of monosaccharides eg simple ring, straight chain; formation and breakdown of glycosidic bonds; anabolism and catabolism of mono- di- and polysaccharides; catabolism of carbohydrates as a source of energy

Structure and function of lipids: structure of lipids; saturated and unsaturated fatty acids; triglycerides; phospholipids; lipids as a source of energy; lipids as structural tissue components; insulation; physical protection

Structure and function of proteins: essential and non-essential amino acids; formation of peptide bonds, formation of dipeptides and polypeptide chains (primary structure); basic secondary, tertiary and quaternary structure of proteins; effects of conformational change on protein functions; basic protein groups eg enzyme transport proteins, contractile proteins, immunoproteins, membrane proteins, structural proteins, hormones

2 Understand the structure and functions of enzymes

Structure: active sites; role as biological catalysts; hypothesis of enzyme action eg simple lock and key, induced fit; properties of specificity; importance of optimum conditions; causes and effects of denaturation; inhibitors; activators; cofactors, prosthetic groups

3 Understand the structure and functions of nucleic acids

Structure: nucleotides as subunits of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA); DNA structure; RNA structure

Function: genetic information, storage, transmission; transcription; translation; basic protein synthesis; effects of genetic changes on variation; mutation (causes, effects on normal functions of cells and tissues)

4 Understand the biological significance of water

Structure: water molecule structure

Function: water as a biological solvent; polarisation; hydrogen bonding; lubricant; temperature buffer

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe the basic structure of carbohydrates, lipids and proteins [RL3]	**M1**	discuss specific examples of the structure of carbohydrates, lipids and proteins	**D1**	relate the structure of carbohydrates, lipids and proteins to their function
P2	explain the functions of carbohydrates [CT2]				
P3	explain the functions of lipids				
P4	explain the functions of proteins				
P5	describe the structure of enzymes	**M2**	compare the structure of different enzymes	**D2**	relate the structure of enzymes to their function
P6	explain the role, functions and actions of enzymes [RL3]				
P7	explain the formation and structure of DNA and RNA	**M3**	compare the structure of nucleic acids	**D3**	relate the structure of nucleic acids to their function.
P8	describe the causes of mutations and their effects on the human body	**M4**	discuss, with specific examples, the structure of the water molecule.		
P9	explain the biological functions of water in the human body. [CT2]				

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Introduction to the materials and equipment used in biological principles. Tutorials and/or workbook assignments on carbohydrate, lipids and proteins. Learners carry out theory and practical work on the structure and function of carbohydrates, lipids and proteins. Personal study time and research. **Assignment 1: Carbohydrates, Lipids and Proteins** (P1, P2, P3, P4, M1, D1)
Learning outcome 2 Formal teaching of enzymes. Tutorials and discussion on functions of enzymes. Learners carry out theory and practical work on the structure and function of enzymes. **Assignment 2: Enzymes** (P5, P6, M2, D2)
Learning outcome 3 Formal teaching of nucleic acids. Tutorials and discussion on nucleic acid function. Learners carry out theory and practical work on the structure and function of nucleic acids. Personal study time and research. **Assignment 3: Nucleic Acids** (P7, P8, M3, D3)
Learning outcome 4 Introduction to the materials and equipment used in biological principles. Formal teaching of the biological significance of water. Tutorials and discussion on water function. Learners carry out theory and practical work on the structure and function of the water molecule. Personal study time and research. **Assignment 4: Water** (P9, M4, D4)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of

support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

P1 requires learners to describe the basic structure of carbohydrates, lipids and proteins. This could be assessed using diagrams of a selection of biological molecules, (for example monosaccharides and amino acids) which could be labelled by the learner and supported by appropriate descriptions.

For P2, learners are required to explain the functions of carbohydrates. This could be evidenced by the learner completing tables outlining the physiological importance of these biological molecules, supported by an explanation of the relevant functions.

For P3, learners need to explain the functions of lipids. This could be evidenced by the learner completing tables outlining the physiological importance of these biological molecules, supported by an explanation of the relevant functions.

P4 requires learners to explain the functions of proteins. This could be evidenced by the learner completing tables outlining the physiological importance of these biological molecules, supported by an explanation of the relevant functions.

For P5, learners need to describe the basic structure of enzymes. This could be assessed by the learner presenting and describing diagrams to show they understand the theory of both the lock-and-key and induced-fit hypotheses.

For P6, learners need to explain the role, function and actions of enzymes. This could be assessed by the completion of a graph to show how enzymes lower the activation energy required for a reaction to occur. Learners should relate the graph to a clear explanation of how the graph shows the role, function and actions of enzymes.

For P7, learners need to explain the formation and structure of DNA and RNA. This could be assessed using appropriate diagrams to support a basic explanation of the main structural components of DNA and RNA (for example sugar-phosphate backbone, complimentary base pairing).

To achieve P8, learners need to describe the causes of genetic mutations and their effects on the human body. This could be assessed concomitantly with P7. Any description should be brief and generic.

For P9, learners need to explain the biological functions of water in the human body. This could be evidenced by a written explanation with supporting diagrams as necessary.

For M1, learners need to discuss specific examples of the structure of carbohydrates, lipids and proteins. This could be evidenced by a series of diagrams and relevant comments showing the anabolism and catabolism of carbohydrates, lipids and proteins (one for each group).

For M2, learners are required to compare the structure of different enzymes. This could be assessed through the production of a table (accompanied by supporting notes) showing a number of biologically relevant enzyme catalysed reactions, their substrates, products, and the catalysing enzyme.

M3 requires learners must be able to compare the structure of nucleic acids. This could be evidenced by the production of a 'similarities and differences' table to show the key biological features of DNA and RNA.

M4 requires learners to discuss the structure of the water molecule, making reference to specific examples. This could be assessed by the production of a written assignment, with supporting diagrams to show the types of bonding undergone by the water molecule, in biological systems.

For D1, learners need to relate the structure of carbohydrates, lipids and proteins to their function. This could be evidenced by a written assignment containing images showing structure to function relationships.

For D2, learners are required to relate the structure of enzymes to their function. This could be assessed by a practical report containing images and showing the effects of enzyme denaturation on enzyme function (eg heat/pH).

For D3, learners need to relate the structure of nucleic acids to their function. This could be evidenced by a written assignment containing images to show DNA replication and protein synthesis as discreet processes.

For D4, learners need to discuss the biological functions of water. This could be evidenced by the production of diagrams to show how water is biologically active as a solvent eg in condensation and hydrolysis reactions with mono- and disaccharides. Any information presented should extend that provided by the learner in P7, P8 and M5.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P2, P3, P4, M1, D1	Carbohydrates, Lipids and Proteins	You are a dietician and are required to give informed advice to clients about the essential nutrients required to maintain a positive lifestyle. Prepare suitable documents and presentations that you could use as resources to help you provide the relevant information to clients.	Presentations. Written assignment containing images. Observation records.
P5, P6, M2, D2	Enzymes	You are preparing a new biological washing powder, and have been asked to prepare a report which shows the effects of the temperature of the water on the efficiency of the washing powder.	Written report.
P7, P8, M3, D3	Nucleic Acids	You work for the Human Genome Project, and have been asked to produce an explanatory leaflet to give to A-level students to explain how DNA and RNA work.	Leaflet. Written assignment containing images.
P9, M4, D4	Water	You are training a group of athletes and are required to give a presentation explaining the biological necessity of proper hydration.	Presentations. Written assignment containing images. Observation records.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 6: Gastrointestinal and Nutritional Medicines
Unit 7: Cardio-Respiratory Medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 9: Infections, Immunological Products and Vaccines
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines
Unit 12: Eye, Ear, Nose and Dermatological Medicines
Unit 17: Pharmaceutics

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Learners will need access to a library with a range of relevant books, journals and electronic resources, for example *MedicinesComplete* and a range of general AS/A2 biology and human biology books.

Relevant information is also available on CD ROMs such as those available from Plato Learning (www.new-media.co.uk).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Bailey M and Hirst K – *Biology Core* (Collins Educational, 1995) ISBN 0003223817

Boyle M and Indge B – *Human Biology* (Collins Educational, 2002) ISBN 0007135998

Hames B D and Hooper N M – *Instant Notes in Biochemistry* (Bios Scientific Publishers Ltd, 2005) ISBN 0415367786

Jones A et al – *Practical Skills in Biology* (Pearson Higher Education, 2002) ISBN 013045141X

Jones M et al – *Biology 1* (Cambridge University Press, 2000) ISBN 052178719X

Jones M and Jones G – *Human Biology for AS Level* (Cambridge University Press, 2004) ISBN 0521548918

Junqueira et al – *Basic Histology* (McGraw-Hill Publishing Co, 2005) ISBN 0071440917

Reiss M J et al – *Advanced Biology* (Nelson Thornes, 2000) ISBN 0174387326

Simpkins J and Williams J I – *Advanced Biology* (Collins Educational, 1987) ISBN 000322290X

Websites

www.ase.org.uk	The Association for Science Education
www.bbc.co.uk/science/humanbody	BBC – Science & Nature: Human Body & Mind
www.biochem4schools.org	Biochem4schools
www.biochemistry.org	Biochemical Society
www.biology4all.com	Biology4all
www.mrothery.co.uk	Mark Rothery's Biology Website
www.s-cool.co.uk	S-Cool! Revision Resources
www.sheffcol.ac.uk/links/science	Sheffield College Science Web Links

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Creative thinkers	[CT2] asking questions to extend thinking on biological structures and functions
Reflective learners	[RL3] inviting feedback and using it as a means of improving their work

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Self-managers	[SM3] organising their time and resources when carrying out tasks

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from books and journals
Select information from a variety of sources to meet requirements of a complex task	obtaining information from identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	preparing diagrams of basic biological structures
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that has all the information for their work
Use communications software to meet requirements of a complex task	creating a contact list
Combine and present information in ways that are fit for purpose and audience	preparing presentations designing a leaflet
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how the documents could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions
English – Reading	

Skill	When learners are ...
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given from formal teaching reading information from a range of resources
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments

Unit 3: Microbiology for Pharmacy

Unit code: L/601/9177

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

The aim of this unit is to give learners an understanding of the relevance of microbiology to pharmacy.

Unit introduction

This unit will help learners understand the importance of micro-organisms in pharmacy. Learners will gain general knowledge of the properties of micro-organisms and how these relate to pharmaceutical processes and procedures.

The unit also enables learners to understand how the environment in the workplace may be controlled in order to minimise the risk to patients and pharmaceutical products. Learners will gain knowledge of sterilisation and antimicrobial agents (disinfectant solutions) and how they may be used to control microbial contamination.

Additionally, learners will be introduced to the process of transmission of pathogenic micro-organisms, infections and diseases.

Learning outcomes

On completion of this unit a learner should:

1 Understand the structure and function of micro-organisms, including their classification

2 Understand the growth of micro-organisms, including the biological, chemical, and physical requirements for growth

3 Understand microbial control of the environment

4 Understand the transmission of infectious disease.

Unit content

1 Understand the structure and function of micro-organisms, including their classification

Micro-organisms: bacteria; viruses; microscopic fungi; chlamydia; protozoa

Classification of micro-organisms: bacteria; viruses, microscopic fungi

Microscopy: light microscope; electron microscope; other types of microscopy including phase contrast; dark ground, fluorescent

Form and structure: prokaryotic and eukaryotic cells; size; shape; cell arrangements; cellular structure

2 Understand the growth of micro-organisms, including the biological, chemical, and physical requirements for growth

Growth and reproduction of micro-organisms: binary fission; asexual reproduction; growth curves; bacterial counting including viable and total counts

Cultural requirements of micro-organisms; physical and chemical factors affecting growth (including pH, temperature, osmotic and atmospheric pressure, water, carbon, nitrogen, energy, trace nutrients and the nutritional classification of micro-organisms)

Laboratory media: types including liquid, semi-solid, selective/differential, enriched; use; advantages and disadvantages

3 Understand microbial control of the environment

Environmental control: methods used to control and monitor the microbial content of the environment; basic principles of hygiene including the environment and personnel; hospital acquired infections

Antimicrobial agents: types, use and mode of action of disinfectants and antiseptics

Sterilisation: methods; uses

Contamination: spoilage of medicines; cross contamination

4 Understand the transmission of infectious disease

Causes and transmission of infection: routes and modes of transmission

Pathogenic micro-organisms: obligate and opportunistic pathogens, indigenous body flora; infections and diseases

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	explain the classification of micro-organisms [IE1]	**M1**	discuss how to investigate, by laboratory experiment, the effect of various factors on the growth of micro-organisms	**D1**	explain the relevance of different types of micro-organisms to pharmacy
P2	explain how the structure of micro- organisms relates to their function				
P3	explain the growth and reproduction of micro-organisms				
P4	explain the factors that affect the growth of micro-organisms [IE1, CT2]	**M2**	explain how disinfectant activity may be tested in the laboratory	**D2**	evaluate the use of antimicrobial agents (disinfectants) in pharmacy.
P5	explain the uses of different growth media [RL4]				
P6	describe methods used to control and monitor the microbial content of the environment, including environmental and personal hygiene [IE1, RL4, SM3]	**M3**	with reference to a named disease, discuss details of the causative pathogen, transmission, disease symptoms, treatment and incidence.		
P7	describe the different groups of disinfectants				
P8	describe diseases caused by pathogenic micro-organisms				
P9	explain the role of micro-organisms in the transmission of disease and infections.				

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF))and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

The delivery of this unit should provide appropriate pharmacy examples to support the microbiological information. If possible, the theoretical content of the unit should be supported by practical sessions which need to be delivered in a laboratory setting suitable for the use of micro-organisms.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of suggested assignments.
Learning outcome 1 Explain the different groups of micro-organisms. Discuss the differences between the prokaryotic and eukaryotic cells. Describe the different micro-organisms including bacteria, viruses, microscopic fungi, Chlamydia and protozoa having relevance to pharmacy. Explain the size, shape, cell arrangements and cellular structure of micro-organisms. Tutorials and/or workbook assignments to investigate the different types of microscopy in relationship to micro-organisms. Learners, if possible, carry out some microscopic examination of micro-organisms to include staining techniques. **Assignment 1: Classification and Structure of Micro-organisms** (P1, P2, D1)
Learning outcome 2 Explain the growth and reproduction of micro-organisms. Discuss the cultural requirements of micro-organisms. Tutorials and/or workbook assignments to investigate the different types of microbiological media for use in the laboratory and in practice. **Assignment 2: Growth and Cultural Requirements of Micro-organisms** (P3, P4, P5, M1)
Learning outcome 3 Discuss the microbial control of the environment. Explain how the environment may be sampled for the presence of micro-organisms. Discuss the importance of hygiene in the working environment. Explain how hygiene may be established and maintained. Discuss the various groups of disinfectants and how they are used in pharmacy. Consider sterilisation methods and their use in pharmacy and microbiology. Discuss the possible spoilage and contamination of medicines by micro-organisms. **Assignment 3: Microbial Control of the Environment and Antimicrobial Agents** (P3, P4, P6, P7, M2, D2)
Explain the routes and transmission of infection. Consider different pathogenic micro-organisms. Explain the normal flora of the human body. Tutorials and/or workbook assignments to discuss diseases caused by pathogenic micro-organisms. **Assignment 4: Transmission of Pathogens, Infections and Diseases** (P8, P9, M3)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners are required to explain the different types of micro-organisms and show their familial inter-relationships. These should include bacteria, microscopic fungi (moulds and yeasts), viruses, protozoa and Chlamydia. The learner should give a named example of each type of micro-organism.

To achieve P2, learners should describe the structure of the different types of micro-organisms and explain how this relates this to function. These should include bacteria, microscopic fungi, viruses, protozoa and chlamydia.

For P3, learners need to explain both the chemical and physical factors that affect the growth and reproduction of micro-organisms, in particular bacteria and microscopic fungi.

For P4, learners need to be able to explain the chemical, biological and environmental factors which affect microbial growth and why they are significant.

To achieve P5, learners need to show good understanding of different growth media and explain how they can be used to good effect for the identification and culture of bacteria and moulds.

For P6, learners are required to describe how the pharmacy environment may be microbiologically controlled. Examples should be drawn from the workplace, if possible, and should include control of the air and personnel. Learners should describe how the pharmacy environment may be sampled for the presence of micro-organisms using examples from the workplace. These should include examples of the various microbiological techniques used for sampling, namely settle plates, air samplers and other relevant techniques for sampling for example swabs and contact plates.

For P7, learners need to describe the different groups of disinfectants, illustrating this with suitable examples of named disinfectants. Examples of disinfectants should be those used in the workplace, if possible.

To achieve P8, learners need to describe named pathogens and the diseases caused by them.

For P9, learners are required to explain the transmission of micro-organisms in relation to disease and infections.

For M1, learners are required to discuss how to investigate, in a laboratory, the effect of various factors

(including both chemical and physical factors) on the growth of micro-organisms. Learners should consider how this may be achieved, designed and carried out in a laboratory experiment to determine the effects.

For M2, learners need to discuss how the activity of disinfectants may be determined by laboratory experiment. Learners should, if possible, carry out such laboratory experiments.

For M3, learners need to explain, with reference to a named disease, details of the causative pathogen, transmission, disease symptoms, treatment and incidence.

For D1, learners are required to explain the relevance of different types of micro-organisms to pharmacy. This should include all the relevant procedures and practices where micro-organisms have an impact on pharmacy.

D2 requires learners to evaluate the use of disinfectants used in pharmacy and explain why rotational patterns of use are favoured. Examples should be provided from the workplace.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P2, D1	Classification and Structure of Micro-organisms	You have been asked by a pharmacist to provide a brief illustrated account on the classification and structure of micro-organisms for the junior staff in the pharmacy.	Written account. Labelled diagrams or illustrations. Oral presentation.
P3, P4, P5, M1	Growth and Cultural Requirements of Micro-organisms	A work colleague has asked you to explain what substances and conditions micro- organisms require in order to grow. Your explanation could be in the form of written information or a presentation.	Written account. Poster presentation.
P3, P4, P6, P7, M2, D2	Microbial Control of the Environment and Antimicrobial Agents	You have been asked by your pharmacy manager to explain the microbial control of the environment to staff. Your explanation should illustrate good hygiene in the pharmacy and inform the staff about the main groups of disinfectants. Prepare the relevant resources you will need to help you with your explanation.	Written account. Illustrated list. Departmental diagram of micro-monitoring. Schedule of disinfectant use.
P8, P9, M3	Transmission of Pathogens, Infections and Diseases	You have been asked by your pharmacy manager to provide an illustrated talk to the medicines counter assistants about some of the more common and current microbial diseases.	Written illustrated account. Verbal illustrated presentation.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 2: Biological Principles for Pharmacy
Unit 4: Human Physiology for Pharmacy
Unit 9: Infections, Immunological Products and Vaccines
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 17: Pharmaceutics
Unit 19: Making Medicines for Pharmacy

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, *eg MedicinesComplete.*

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Cappuccino J G and Sherman N – *Microbiology: A Laboratory Manual, 9th Edition* (Pearson, 2010) ISBN 10: 0321673875

Clegg C J – *Microbes in Action, 1st Edition* (John Murray, 2001) ISBN10: 03121488202

Denyer S P, Hodges N A and Gorman S P – *Hugo and Russell's Pharmaceutical Microbiology, 7th Edition* (Blackwell, 2004) ISBN 0632064676

Goering R, Dockrell H Roitt I, Zuckerman M and Wakelin D – *Miims Medical Microbiology, 4th Edition* (Mosby, 2008) ISBN 9780323044752

Greenwood D, Slack R C B and Peutherer J F – *Medical Microbiology, 17th Edition* (Church Livingstone, 2007) ISBN 97804431020 97

Inglis T J – *Microbiology and Infection, 3rd Edition* (Churchill Livingstone, 2007) ISBN 9780443102899

Madigan M T, Martinko J M, Dunlap P V and Clark D P –*Brock Biology of Micro organisms, 12th Edition* (Pearson, 2009) ISBN 13: 9780321536150

Mannion K and Hudson T – *Microbes and Disease, 2nd Edition* (Harper and Collins 2001) ISBN 9780003277425

Journals

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.microbes.info	Microbiology Information Portal
www.nhs.uk	National Health Service

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Independent enquirers	[IE1] identifying factors affecting microbial growth; controlling the pharmacy environment; identifying pathogens and diseases
Creative thinkers	[CT2] asking questions to identify how the pharmacy environment is microbiologically sampled and controlled
Reflective learners	[RL4] inviting feedback and using it as a means of improving their skills to develop independent investigation of diseases
Self-managers	[SM3] organising their time and resources and prioritising their actions in relationship to the pharmacy environment.

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE3] exploring issues, events or problems from different perspectives in the pharmacy
Creative thinkers	[CT2] asking questions to extend their thinking with the integration of skills and knowledge obtained in the pharmacy and their educational course
Reflective learners	[RL4] reviewing their progress both in the pharmacy and in their educational course
Team workers	[TW1] collaborating with others both in the pharmacy and in their educational course to work towards common goals
Self-managers	[SM2] working towards goals, showing initiative, commitment and perseverance both in the pharmacy and in their educational course.

Functional Skills – Level 2

Skill	When learners are ...
ICT – Use ICT systems	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	obtaining information from identified websites
Select information from a variety of sources to meet requirements of a complex task	collecting information from online journals
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if all the information they require is obtainable from a website eg diagrams of micro-organisms or charts about disinfectants
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that has all the information for their work
Use communications software to meet requirements of a complex task	creating a contact list keeping their own messages safely in a folder using email to send centre-produced work to own email address
Combine and present information in ways that are fit for purpose and audience	presenting information from the document as requested in the assignment briefs
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how the documents can be improved
Identify the situation or problems and identify the mathematical methods needed to solve them	
Choose from a range of mathematics to find solutions	
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions
English – Reading	

Skill	When learners are ...
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given from formal teaching reading information from a range of resources
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments

Unit 4: Human Physiology for Pharmacy

Unit code: K/601/7789

Level 3: BTEC National

Credit value: 10

Guided learning hours: 60

Aim and purpose

This unit aims to provide the learner with a broad knowledge of the structure and function of the human body as a basis for learning about the use of medicines.

Unit introduction

The unit covers human physiology for pharmacy. Building on learners' practical biological skills, underpinning knowledge and understanding of biology gained in *Unit 2: Biological Principles for Pharmacy,* the unit looks at the functioning of the human body and structure of the various body systems.

Learners will gain an understanding of various aspects of different tissue types and also of the structure and function of the musculoskeletal and digestive systems. The roles of the cardiovascular, respiratory and lymphatic systems are also covered.

The importance of physiological homeostasis and the co-ordination of the body's activities by the nervous and endocrine systems are considered, along with the importance of the sensory organs and genito-urinary system.

Learning outcomes

On completion of this unit a learner should:

1 Know different types of human cells and tissue

2 Understand the structure and function of the musculoskeletal system and the digestive system

3 Understand the cardiovascular, respiratory and lymphatic systems in the human body

4 Know how the human body's nervous system and sensory organs function

5 Know how the endocrine system and the genito-urinary system function.

Unit content

1 Know different types of human cells and tissue

Tissues: differentiation of cells to form tissues; structure and function of tissues; epithelial, connective, muscle and nerve tissues; organisation of tissues to form organs

2 Understand the structure and function of the musculoskeletal system and the digestive system

Musculoskeletal system: major bones; muscles; cartilage; tendons; membranes; joints

Essential dietary components: vitamins; minerals; carbohydrates; proteins; fibre; water

Structure of the digestive system: mouth; pharynx; oesophagus; stomach; pancreas; liver; gall bladder; small intestine; large intestine

Functions of the digestive system: ingestion; mechanical digestion, chemical digestion; absorption;

Metabolism and energy: the body's energy requirements; glucose and cellular respiration; regulation of blood glucose (insulin, glucagon, adrenaline, glucocorticoids)

3 Understand the circulatory, respiratory and lymphatic systems in the human body

Structure of the cardiovascular system: blood; heart; blood vessels (arteries, veins, arterioles, venules, capillaries)

Functions of the cardiovascular system: transport; temperature regulation

Structure of the respiratory system: nasal cavities; pharynx; larynx; trachea; bronchi; bronchioles; alveoli; capillary networks

Structure of the lymphatic system: lymphatic vessels; lymph nodes; spleen

Functions of lymphatic system: drainage of tissue fluid and formation of lymph; defence

Functions of the respiratory system: breathing; gaseous exchange

4 Know how the human body's nervous system and sensory organs function

Organisation of the nervous system: central nervous system; peripheral nervous system; structure of a neurone; structure of a nerve; sense organs; effector organs

Functions of the nervous system: initiation and transmission of the nerve impulse; synapses; sensory (afferent) and motor (efferent) neurones; reflex arc; somatic and autonomic (sympathetic and parasympathetic) control; co-ordination

Sensory organs: Skin; ear; eye; oropharynx

5 Know how the endocrine system and the genito-urinary system function

Organisation of the endocrine system: pituitary gland; hypothalamus; thyroid; parathyroid; pancreas; adrenal medulla; adrenal cortex; gonads

Functions of the endocrine system: significance of homeostatic regulation by hormones; characteristics of hormones; endocrine control and feedback; names and actions of principal hormones produced by each gland

Urinary system: structure (gross anatomy and location of kidneys, ureters, bladder, blood supply to kidneys); functions (fluid and electrolyte balance, pH balance); regulation of fluid balance by ADH; nephron structure; significance of maintaining fluid, filtration, absorption, urine production, storage and release; regulation of urine volume and composition

Structure of the reproductive system: in male (testis, epididymis, scrotum, sperm duct, penis, accessory glands); in female (ovary, oviduct, uterus, vagina, external genitalia, mammary glands)

Functions of the reproductive system: production of gametes (gametogenesis); hormonal regulation of sperm production in the male; hormonal regulation of the female ovarian and menstrual cycles; fertilisation, pregnancy and birth, lactation

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 describe the structure of human cells [CT2]	**M1** compare different cells	**D1** relate cellular differentiation to tissue function
P2 describe the main types of human tissues	**M2** explain how cells join to form human tissue of different types	
P3 describe the function of the main human tissue types [CT2]		
P4 describe the structure of the musculoskeletal system [CT2]	**M3** relate the structure of the musculoskeletal system to its function	**D2** discuss the pathophysiology of a common musculoskeletal disorder
P5 explain the function of the musculoskeletal system		
P6 describe the structure of the digestive system [CT2]	**M4** discuss possible causes of failure of the digestive system	**D3** explain the consequences for the human body if the digestive system fails, with reference to a specific digestive disorder
P7 explain the function of the digestive system		
P8 describe the structure of the cardiovascular system	**M5** explain the way the respiratory and circulatory systems interact to maintain cellular and body function	**D4** explain the consequences for the human body if the respiratory or circulatory system fails
P9 explain the function of the cardiovascular system		
P10 explain how the structure of the respiratory system aids gaseous exchange		
P11 explain how the structure of the lymphatic system contributes towards the body's defence mechanisms		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P12 describe how the organisation of the nervous system affects its function	**M6** explain the roles of the endocrine and nervous system in the maintenance of homeostasis	**D5** describe the causes of common homeostatic disorder by analysis of relevant physiological information
P13 describe the structure of the body's sensory organs [CT2]		
P14 explain the function of the sensory organs		
P15 describe the structure of the endocrine system [CT2]		
P16 explain the function of each endocrine gland		
P17 define homeostasis		
P18 describe how the urinary system assists the regulation of body fluids in the body [CT2]	**M7** explain the consequences of failure in the urinary system	
P19 describe the structure of the reproductive system [CT2]	**M8** describe gametogenesis in the male and female.	**D6** explain the way conception is controlled using replacement hormones.
P20 explain the function of the reproductive system		
P21 describe foetal development from conception to birth. [CT2]		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF))and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Introduction to the unit and materials and equipment used. Formal teaching on human cells and tissues. Tutor to give examples of different cells and tissues – diagrams. Learners carry out theory and practical work on the structure and function of human cells and tissues. **Assignment 1: Cells and Tissues** (P1, P2, P3, M1, M2, D1)
Learning outcome 2 Introduction to the unit. Formal teaching of the musculoskeletal system. Discussion on the function of the musculoskeletal system. Tutor to show the structure of the musculoskeletal system. Learners carry out theory and practical work on the structure and function of human cells and tissues. Formal teaching of the digestive system. Discussion on the digestive system and metabolism. Learners carry out theory and practical work on the structure and function of the digestive system. **Assignment 2: Digestion, Excretion and Respiration** (P6, P7, P10, P18, M4, M7, D3) **Assignment 3: Co-ordination** (P4, P5, M3, D2)
Learning outcome 3 Introduction to the unit and materials and equipment used. Formal teaching of cardiovascular system. Tutor to show structure of cardiovascular system (heart dissection). Discussion on the function of the cardiovascular system. Formal teaching of the respiratory system. Discussion on the structure and function of the respiratory system. Learners carry out theory and practical work on the cardiovascular and respiratory systems. Formal teaching of the lymphatic system. Discussion on the structure and function of the lymphatic system. Learners research the body's defence mechanisms.
Assignment 4: Transport and Immunity (P8, P9, P11, P15, M5, M6, D4)
Learning outcome 4 Formal teaching on the nervous system. Discussion on the function of the nervous system and its structure. Discussion on sensory organs. Learners research the function of sensory organs.

Topic and suggested assignments/activities and/assessment
Learning outcome 5
Formal teaching on the endocrine system.
Formal teaching on homeostasis.
Discussion on the function of endocrine glands.
Learners research the function of the endocrine system in homeostasis.
Formal teaching on the reproductive system.
Discussion on the reproductive system structure and function.
Assignment 5: Control (P12, P13, P14, P15, P16, P17, P18, M6, D5)
Assignment 6: Reproduction (P19, P20, P21, M8, D6)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners need to describe the structure of human cells. This could be evidenced by labelling diagrams of a cell, accompanied by basic explanations of major component functions.

For P2, learners need to describe the main types of human tissue. This should be limited to the four major tissue classes (connective, muscular, nervous, epithelial) and could be evidenced by a compare and contrast table which includes examples of each tissue type.

To achieve P3, learners need to describe the function of the main human tissue types. This could be evidenced by short answer questions or appended to a similar table as for P2.

For P4, learners need to describe the structure of the musculoskeletal system. A poster showing the main anatomical structures of muscle could be used. A descriptive account of the organisation of the skeleton and its main functions would attain P4 in relation to the skeletal system.

P5 requires learners to explain the function of the musculoskeletal system. This could be evidenced by short answer questions, or by extension of the account referenced in P4.

To achieve P6, learners need to describe the structure of the digestive system. This could be evidenced by a 'virtual-tour' written account of the major organs of the digestive system, including the teeth, tongue, oesophagus, stomach and divisions of the small and large intestines.

For P7, learners are required to explain the function of the digestive system. This could be evidenced by short answer questions, or by extension on the account referenced in P6.

For P8, learners need to describe the structure of the cardiovascular system. This could be evidenced by short answer questions that include the labelling of a stylised diagram of the circulatory system, the heart and cross sections of the blood vessels.

For P9, learners are required to explain the function of the cardiovascular system. This could be evidenced by the learner explaining the effects of exercise on the body. Any information provided by the learner regarding gaseous exchange need only be an outline.

For P10, learners need to explain how the structure of the respiratory system aids gaseous exchange. The learner could evidence this by identification of structures within the respiratory system and by giving explanations of their role in gaseous exchange.

P11 requires learners to explain how the structure of the lymphatic system contributes to the body's defence system. This could be evidenced by an assignment outlining the immune responses to disease, including basic information on both humoral and cell-mediated responses.

P12 requires learners to describe how the organisation of the nervous system affects its function. This could be evidenced by a written assignment with illustrations showing the specific organisation of afferent/efferent fibres and highlighting differences between autonomic responses, voluntary responses and reflex arcs.

To achieve P13, learners need to describe the structure of the body's sensory organs. This could be evidenced by the production of labelled diagrams indicating gross anatomy, with accompanying text describing basic macroscopic structure.

For P14, learners need to explain the function of the sensory organs. This could be evidenced by an extension of the evidence produced for P10.

For P15, learners are required to describe the structure of the endocrine system. This could be evidenced by description of endocrine control, along with a brief description of a specific example of endocrine control for example regulation of blood glucose.

For P16, learners need to explain the function of the major endocrine glands, including the pituitary, pineal, adrenals and reproductive organs. Evidence for this could be a detailed table, indicating location, principle hormones, target organs and the substance or process regulated or controlled for each gland.

For P17, learners need to define homeostasis. This could be evidenced by a written assignment which includes a specific example of homeostatic control. Examples should be linked to P12.

For P18, learners need to describe the urinary system and its assistance in the regulation of body fluids. This could be evidenced by the production of a flow diagram with illustrations and explanations.

For P19, learners need to describe the structure of the reproductive system. This could be evidenced by a poster describing key organs and processes, including basic male and female gametogenesis.

For P20, learners are required to explain the function of the reproductive system. This could be evidenced by written assignment, with a flow diagram to indicate key roles in conception and pregnancy.

For P21, learners are required to describe foetal development from conception to birth. This could be evidenced by the production of a chronological flow diagram, appended to the evidence submitted for P17.

For M1, learners need to compare different cells. This could be evidenced by a written assignment

comparing cell specialisations.

For M2, learners need to explain how cells join to form human tissue of different types. This could be evidenced by the identification of examples of different human tissues, supported by a commentary explaining levels of organisation.

For M3, learners are required to relate the structure of the musculoskeletal system to its function. This could be evidenced by a written assignment commenting on the interdependency of the skeletal and muscular systems, including tendons and ligaments.

For M4, learners need to discuss possible causes of the failure of the digestive system. This could be evidenced by the production of lists of common digestive disorders and an outline of the patho-physiology.

For M5, learners are required to explain the interaction between the circulatory and respiratory system in maintaining cellular and body function. This could be evidenced by a written assignment which includes detailed reference to gaseous exchange.

For M6, learners need to explain the role of the endocrine and nervous systems in maintaining homeostasis. This could be evidenced by a written assignment with a focus on the interdependence of the two systems. Alternatively, a "compare and contrast" style table of information could be used.

For M7, learners need to explain the consequences of the failure of the urinary system. This could be evidenced by short answer questions.

M8 requires learners to describe gametogenesis. This could be evidenced by a written assignment with illustrations.

For D1, learners need to relate cellular differentiation to tissue function. This could be evidenced by a written assignment with diagrams.

For D2, learners are required to discuss the patho-physiology of a common musculoskeletal disorder. This could be evidenced by a presentation on a given disorder.

D3 requires learners to explain the consequences for the human body if the digestive system fails. The explanation need to make reference to a specific disorder. This could be evidenced by a presentation on a specific disorder.

For D4, learners need to explain the consequence for the human body if the respiratory or circulatory system fails. This could be evidenced by a written assignment covering a specific failure of each system.

D5 requires learners to describe causes of common homeostatic disorders. This could be evidenced by analysing relevant physiological data and producing a report. For clarity, any examples should relate to conditions or disorders described for the relevant P and M criteria.

D6 requires learners to explain the way conception is controlled using replacement hormones. This could be evidenced by the production of a leaflet.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P2, P3, M1, M2, D1	Cells and Tissues	You are a scientist working in the pathology laboratory. You are required to produce an illustrated guide for trainee MLAs allowing them to identify basic tissue types and understand their structure, function and generation.	Written assignment with illustrations.
P6, P7, P10, P18, M4, M7, D3	Digestion, Excretion and Respiration	You are a dietician, working to promote healthy lifestyles. You have been asked to produce a presentation that explains the process of a healthy lifestyle. The presentation is to be made to a group of unfit children.	Presentations. Handout to accompany presentations. Observation records.
P4, P5, M3, D2	Co-ordination	The British Osteopathic Association (BOA) has asked you to provide training to their junior osteopaths on the causes, symptoms and treatments of scoliosis.	Presentations. Leaflet. Written assignment. Observation records.
P8, P9, P11, P15, M5, M6, D4	Transport and Immunity	Working for a leukaemia charity, you must produce an information pack for leukaemia patients. The information pack should explain how the cardiovascular and lymphatic systems work, including their inter-dependence.	Written assignment with illustrations. Leaflet.
P12, P13, P14, P15, P16, P17, P18, M6, D5	Control	As a health professional, prepare an advice leaflet for newly- diagnosed diabetics. The leaflet should explain the medical condition in terms of the different types, their differing aetiologies and treatments.	Leaflet. Written assignment with illustrations.
P19, P20, P21, M8, D6	Reproduction	You are a clinician, working in an assisted conception unit. You have been asked to produce a poster for patients outlining gametogenesis in the male and female, showing the process of conception, foetal development and birth. Included in the poster should be information about how and when each major ART would be employed.	Poster.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy Technicians
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 6: Gastrointestinal and Nutritional Medicines
Unit 7: Cardio-respiratory Medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 9: Infections, Immunological products and Vaccines
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 11: Malignant disease, Immunosuppressive and Musculoskeletal Medicines
Unit 12: Eye, Ear, Nose and Dermatological Medicines

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this underpinning knowledge unit should be competent and experienced biologists, with appropriate qualifications in their field, and preferably with allied health links. They should show evidence of continuing professional development.

Learners will need access to a library with a range of relevant books, journals and electronic resources, eg *MedicinesComplete* and a range of general AS/A2 biology or human biology books.

Relevant information is also available on CD ROMs such as those available from Plato Learning (www.new-media.co.uk).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners

to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Bailey M and Hirst K – *Biology Core* (Collins Educational, 1995) ISBN 0003223817

Boyle M and Indge B – *Human Biology* (Collins Educational, 2002) ISBN 0007135998

Hames B D and Hooper N M – *Instant Notes in Biochemistry* (Bios Scientific Publishers Ltd, 2005) ISBN 0415367786

Jones A et al – *Practical Skills in Biology* (Pearson Higher Education, 2002) ISBN 013045141X

Jones M et al – *Biology 1* (Cambridge University Press, 2000) ISBN 052178719X

Jones M and Jones G – *Human Biology for AS Level* (Cambridge University Press, 2004) ISBN 0521548918

Junqueira et al – *Basic Histology* (McGraw-Hill Publishing Co, 2005) ISBN 0071440917

Reiss M J et al – *Advanced Biology* (Nelson Thornes, 2000) ISBN 0174387326

Simpkins J and Williams J I – *Advanced Biology* (Collins Educational, 1987) ISBN 000322290X

Websites

www.ase.org.uk	The Association for Science Education
www.bbc.co.uk/science/humanbody	BBC Science & Nature: Human Body & Mind
www.biochem4schools.org	Biochem4schools
www.biochemistry.org	Biochemical Society
www.biology4all.com	Biology4all
www.mrothery.co.uk	Mark Rothery's Biology website
www.s-cool.co.uk	S-Cool! Online Revision Resources
www.sheffcol.ac.uk/links/science	Sheffield College Science Web Links

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Creative thinkers	[CT2] asking tutors questions to help with descriptions of systems

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Reflective learners	[RL3] inviting feedback and using it as a means of improving their work
Team workers	[TW2] working in groups on assignments
Self-managers	[SM3] organising their time and resources when carrying out tasks

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	obtaining information from identified websites
Select information from a variety of sources to meet requirements of a complex task	collecting information from online journals
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	creating a single document that contains all the information for their work checking if the information they require is obtainable from a website eg diagrams of body systems
Use appropriate software to meet the requirements of a complex data-handling task	using tables to record analysis
Use communications software to meet requirements of a complex task	using email to communicate with other learners, tutors and colleagues keeping their own messages safely in a folder creating a contact list
Combine and present information in ways that are fit for purpose and audience	presenting information from the document as requested in the assignment briefs
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how the documents can be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions giving presentations
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given from formal teaching reading information from a range of resources

Skill	When learners are ...
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments

Unit 5: Action and Uses of Medicines§

Unit code: L/601/9180

Level 3: BTEC National

Credit value: 10

Guided learning hours: 60

Aim and purpose

This unit provides learners with basic information and concepts to help them understand how medicines work. It relates physiological function with disease and eventual treatment to help learners with their work in the Pharmacy.

Unit introduction

Much of a pharmacy technician's role is concerned with supplying medicines and helping patients and health care professionals to manage their use. This includes advising patients on the correct use of their medicines. This introductory unit forms the basis for the other units concerned with the action and uses of medicines in this qualification.

In this unit, learners will be introduced to the underlying principles behind the way medicines work on the human body. The unit extends learners' knowledge from physiology in health to disease processes. It also explains the appropriate use and limitations of therapeutic agents.

The fundamental principles of drug action are expanded so that learners can apply these concepts in their workplace to provide appropriate dispensing, consultation with customers and over the counter sales. This unit also forms the basis for medicines management skills, highlighting the need for pharmacy technicians to demonstrate awareness of their own limitations and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

The unit highlights the need for pharmacy technicians to support their practice with sound research skills. Learners will gain knowledge of how to use pharmaceutical resources both to help with studies later in the course but also in their professional lives when dealing with queries from the public and healthcare professionals.

Learning outcomes

On completion of this unit a learner should:

1 Understand the basic principles of how medicines work in the human body

2 Know about the uses and limitations of medicines, including their management in practice.

3 Know how to use standard pharmacy resources to research answers to pharmaceutical queries.

Unit content

1 Understand the basic principles of how medicines work in the human body

Disease: its nature and causes

Medical terminology: introduction to medical terminology and drug nomenclature

Routes of drug delivery: routes by which drugs are delivered to the body including oral, rectal, injectable, transdermal, inhaled; advantages and disadvantages of each route

Fate of medicines: route by which drugs travel through the body to the site of action; factors that influence the amount of drug that reaches the site of action and the final fate of therapeutic agents; influence of factors such as absorption, metabolism, excretion

Basic principles of action of medicines in the body: drug actions at receptor site; agonists and antagonists; drug action on enzymes; drug influence on ion channels; non-specific drug action; genetic mechanisms

Adverse drug reactions (ADR): how drugs are brought to market; clinical trials, design and phases of trials, predictable and idiosyncratic adverse reactions; pharmacovigilance and the ADR reporting scheme (yellow card)

2 Know about the uses and limitations of medicines, including their management in practice

Basic Pharmacokinetics: clearance; volume of distribution; half-life; bioavailability; protein binding; clearance by the liver and kidneys; how dosage regimens are designed; purpose of therapeutic drug monitoring

Mechanisms of medicines interactions: chemical incompatibilities; nutrition/drug incompatibilities; genetic factors causing incompatibilities; pharmacokinetic and pharmacodynamic interactions

Medicine history taking: principles of medicine history taking; identification of patient medication; medication administration record sheets (MARS); previous hospital records/charts, GP printouts, patient summaries, repeat prescriptions, patient's own medication (PODs), referral letters, community pharmacy, patient's relatives/carers

Medication use reviews (MURs): principles and purpose of MURs; common groups for MURs; patients on long-term medication eg epileptics, diabetics; patients with mental health difficulties; patients on multiple drug regimens; patients with compliance issues eg the elderly, stroke patients; national and local guidelines and policies relating to the use of medicines

Communication: patient confidentiality; talking to patients eg use of open questions, checking patient alertness, body language; talking to other healthcare professionals to comply with the limitations of own job role and knowing when to refer; dealing with patients with special requirements eg deaf, hard of hearing, visually impaired, English as a second language, mental illness, learning disabilities

Problems with medication: allergies; adverse drug reactions; compliance problems, ensuring safe storage and use of medicines

Documentation: procedures and policies, endorsing prescriptions, prescription intervention forms

3 Know how to use standard pharmacy resources to research answers to pharmaceutical queries

British National Formulary: steps to be taken in order to retrieve information quickly and accurately from this resource

Other pharmaceutical texts: searching for information and evaluating its usefulness in the particular context necessary, appropriate texts eg Martindale, British Pharmacopoeia, Pharmaceutical Codex, Pharmaceutical Journal, other medical journals

Online resources: retrieval and evaluation of information found on the internet, appropriate resources eg Medline, eBNF

Evidence-based practice: its significance and use in the pharmacy; advising health professionals and the public

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe the basic modes of actions of medicines on the human body	**M1**	explain, with examples, how agonists, antagonists, drugs acting on enzyme systems and ion channels modulators/ blockers exert their mode of action		
P2	explain the reasons for using different routes for the administration of medicines. [IE1, IE2, CT2, RL4]	**M2**	describe the advantages and disadvantages of the different routes of administration of medicines	**D1**	discuss the effect pharmacokinetics can have on how medicines work in humans and how this affects dosage regimens
P3	describe the common drug-drug and drug- food interactions	**M3**	explain why it is important to take an accurate medication history from a patient		
P4	describe the factors which lead to the successful medicinal treatment of disorders [IE2, CT2, RL4, SM6]	**M4**	discuss the limitations inherent in the use of medicines and how these can be mitigated to maximise patient benefit from their treatment	**D2**	examine what should be done to help a patient maximise the benefit of their treatment with medicines and minimise any adverse effects they might experience
P5	describe the main sources of pharmaceutical information	**M5**	using an appropriate source of information, respond to a work- related pharmaceutical query	**D3**	evaluate the usefulness and quality of information retrieved to answer a pharmaceutical query in a work- related context
P6	describe how to select and use the appropriate sources of information in order to correctly answer pharmaceutical queries [IE1, CT2, RL3]				

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and suggested assessment activities
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Lecture on disease: its nature and causes. Revision quiz on categories of disease (formative only). An introduction to medical terminology and drug nomenclature. Group work with medical dictionaries to learn how to sort out meanings of medical words and abbreviations. Worksheet completed in groups, exploring routes by which drugs are delivered to the body – oral, rectal, injectable, transdermal, inhaled etc; advantages and disadvantages of all routes. **Assignment 1: Routes of Administration of Medicines** (P2 M2) Lectures on the outcome of medicines and the routes by which drugs travel through the body to the site of action. Lectures on factors that influence the amount of drug that reaches the site of action and the final outcome of therapeutic agents eg influence of absorption, metabolism and excretion. Lecture on drug interactions and mechanisms operating. Workshop on identification of common interactions. Lectures, DVDs and other ways of exploring how drugs act at receptor sites, agonists and antagonists, drug action on enzymes, drug influence on ion channels, non-specific drug action, genetic mechanisms. DVD on how drugs are brought to market. Workshop on clinical trials, including design and phases of trials. Lecture on adverse drug reactions –how they arise, predictable and idiosyncratic adverse reactions. DVD on the pharmacovigilance system in the UK and the ADR reporting scheme (yellow card).

Topic and suggested assignments/activities and suggested assessment activities

Learning outcome 2

Lectures on aspects of Pharmacokinetics and pharmacodynamics – including clearance, volume of distribution, half life, bioavailability, protein binding, clearance by the liver and kidneys, how dosage regimens are designed, the purpose of therapeutic drug monitoring.

Lectures on drug interactions, chemical incompatibilities, nutrition/drug incompatibilities, genetic factors causing incompatibilities, pharmacokinetic and pharmacodynamic interactions.

Assignment 2: Pharmacokinetics and its role in Dosage Regimen Design (D1)

Workshop on medicine history taking, identification of patient medication; medication administration record sheets (MARS), previous hospital records/charts, GP printouts, patient summaries, repeat prescriptions, patient's own medication (PODs), referral letters, community pharmacy, patient's relatives/carers.

Role plays in class – formative assessment only.

Observation of a medication use review in community or hospital pharmacy – simulated, with a class discussion – formative assessment only.

Lecture on principles and purpose of MURs, common groups for MURs; patients on long-term medication (eg epileptics, diabetics); patients with mental health problems; patients on multiple drug regimens; patients with compliance issues (eg elderly, stroke patients), national and local guidelines and policies relating to the use of medicines.

Communications workshop on patient confidentiality, talking to patients (eg use of open questions, checking patient alertness, body language), talking to other healthcare professionals (eg limitations of your job role, when to refer), dealing with patients with special requirements (eg deaf and hard of hearing, visually impaired, English as a second language, mental illness and learning disabilities).

Assignment 3: Taking Medication Histories and Talking to Patients (P1, P3, P4, M1, M3, M4, D2)

Lecture on issues related to allergies, adverse drug reactions, compliance problems, ensuring safe storage and use of medicines.

Workshop comparing student's workplace procedures and policies, endorsing prescriptions, prescription intervention forms.

Learning outcome 3

Explanation of how the British National formulary is constructed.

Open learning work pack allowing the students to practice being be able to retrieve information quickly and accurately (formative assessment only).

Demonstration of other pharmaceutical texts: Martindale, British Pharmacopoeia, Pharmaceutical Codex, Pharmaceutical Journal, medical journals.

Discussion on how to search for information and evaluate its usefulness in the particular context necessary.

Demonstration of online resources and retrieval eg Medline, eBNF.

Discussion on how to evaluate information found on the internet.

Assignment 4: Medicines Information Query (P5, P6, M5, D3)

Lecture on evidence-based practice: its significance and use in the pharmacy, advising health professionals and the public.

Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction

This unit forms the basis for all the other units on the action and uses of medicines. Learners need to be secure in their understanding of the fundamental principles of drug action in the human body. They need to be aware of the types of questions they are likely to get from patients and how to respond to these.

Where possible, connections should be made with other units and the learner's workplace to allow for naturally-occurring evidence to form part of the assessment.

To achieve P1, learners need to be able to describe the basic modes of actions of medicines in the human body. This could be evidenced by drawing diagrams or describing the main mechanisms such as receptor sites, enzyme reactions, ion channel modulators for instance.

For P2, learners need to be aware of all the different ways in which medicines can be administered to human beings and be able to explain why a particular route is chosen. This could be evidenced by diagrams, records of discussions in relation to their work experience and personal experience, resulting in a chart or poster.

For P3, learners are required to describe common drug-drug and drug-food interactions and briefly describe these reactions. This could be evidenced by role play exercises with simulated patients or by means of a written exercise where the learner uses reference books to determine what is taking place in the reaction. In deciding which interactions to select, tutors might wish to focus on only the most common and serious examples.

For P4, learners need to be able to describe the factors relating to the patient, their circumstances and feelings, which will have an impact on the success of treatments. This could be evidenced through group discussions, written exercises or case study material.

For P5, the learner needs to describe the main sources of information available to them in their workplace. They could evidence this by means of a table, or by using the sources of information in the context of an assignment. The assignment could take the form of answering a real or simulated pharmaceutical query.

For P6, the description provided by the learner should show that they know how to access appropriate pharmacy resources in order to find accurate answers to pharmaceutical queries.

For M1, the learner is required to build on the work done for P1 by explaining the mechanisms, agonists, antagonists, drugs acting on enzyme systems and ion channel modulator and blockers and by providing examples for real pharmaceuticals which work in these ways. Learners can evidence this by creating a chart with diagrams supported by additional written or discursive material. Since the science of pharmacy is evolving rapidly, tutors should include new mechanisms as they become identified. Tutors might also wish to consider the future importance of genetic medicines and their mode of action.

For M2, learners need to describe the different ways in which medicines can be administered to human beings and be able to discuss the advantages and disadvantages of the different routes from the perspective of both patient and doctor. This could be evidenced by learners taking part in a debate on the advantages and disadvantages of the routes, using case study materials or by means of a written assignment.

To achieve M3, learners need to explain why taking a medication history from a patient is important. It is expected that learners would appreciate the positive and negative aspects flowing from such an exercise. Learners should also show an appreciation of the types of situations in which they would need to refer matters to a higher authority. Case studies and role plays could form the evidence for this activity.

M4 is the converse of P4. Learners should be able to discuss the negative aspects of using medicines as well as the positive ones. Learners should also discuss how they would help patients deal with the negative aspects of medicines in order to maximise treatment. Case studies and role plays could provide effective evidence for this.

For M5, learners need to use an appropriate source of information in order to answer a pharmaceutical query, either real or simulated. This could be evidenced as a written piece of work or the learner could use real life examples of when they have answered patient's queries by using reference sources.

For D1, learners need to build on what they have learned about the totality of how medicines work in humans and about how the mechanisms of action, along with the patient factors involved, work together to allow a medicine to exert its effect (either alone or in tandem with other medicines). Learners also need to discuss how dosage regimens are designed. This could be evidenced in a written assignment or through an exercise on simulation of drug development and design.

D2 requires the learner to synthesise the negative and positive aspects inherent in taking a medicine and determine how they can assist a patient to get the maximum benefit from their treatment whilst minimising harm. This could be evidenced through case studies or pharmaceutical queries, real or simulated.

Learners aiming to achieve D3 need to have the ability to critically evaluate the information they have gathered to answer a work-related pharmaceutical query.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P2, M2	Routes of Administration of Medicines	You have been asked to design a worksheet for your colleagues, exploring routes of administration and their advantages and disadvantages.	Worksheet.
D1	Pharmacokinetics and its Role in Dosage Regimen Design	You have been asked to write comprehensive notes to evaluate the role of pharmacokinetics in the design of dose regimens.	Written assignment.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P3, P4, M1, M3, M4, D2	Taking Medication Histories and Talking to Patients	You have been asked to take a medication history from a patient. A patient has asked you to explain how one of their medicines work and how they can get the greatest benefit from their drug treatment.	Completing written documentation. Verbal discussion.
P5, P6, M5, D3	Medicines Information Query	Respond to a pharmaceutical query from a health professional using a real life scenario.	Report. Email. Telephone conversation. Face to face dialogue.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 4: Human Physiology for Pharmacy
Unit 13: Community Pharmacy Practice
Unit 14: Professional Development in Pharmacy
Unit 15: Communicating in Pharmacy
Unit 16: Dispensing and Supply of Medicines
Unit 18: Pharmacy Law, Ethics and Practice

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, for example *MedicinesComplete*. It would also be useful for learners to have access to a current medical dictionary (nursing level is suitable).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Pharmacology and clinical pharmacology textbooks

Clayton B and Stock Y – *Basic Pharmacology for Nurses, 13th Edition* (Mosby, 2004) ISBN 0323023592

Laurence DR, Bennett PN and Brown MJ – *Clinical Pharmacology, 8th Edition* (Churchill Livingstone, 1997) ISBN 0443049904

Minneman KP and Wecker L – *Brody's Human Pharmacology, 4th Edition* (Mosby, 2005) ISBN 0323032869

Neal MJ – *Medical Pharmacology at a Glance, 5th Edition* (Blackwell Science, London, 2005) ISBN 1405133600

Rang HP, Dale MM and Ritter JM – *Pharmacology, 5th Edition* (Churchill Livingstone, Edinburgh, 2003) ISBN 0443071454

Stringer J – *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2001) ISBN 0071356991

Walker R and Edwards C (Editors) – *Clinical Pharmacy and Therapeutics, 3rd Edition* (Churchill Livingstone, Edinburgh, 2002) ISBN 0443071373

Drug use textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P – *Symptoms in the Pharmacy, 4th Edition* (Blackwell Science, 2005) ISBN 1405122226

Dodds L (Editor) – *Drugs in Use, 3rd Edition* (Pharmaceutical Press, 2004) ISBN 0853695415

Harman RJ and Mason P (Editors) – *Handbook of Pharmacy Healthcare, 2nd Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry JA – *The British Medical Association's Concise Guide to Medicines and Drugs, 2nd Edition* (Dorling Kindersley, 2005) ISBN 1405306947

McGavock H – *How Drugs Work, 2nd Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A – *Non-Prescription Medicines, 2nd Edition* (Pharmaceutical Press, 2002) ISBN 0853695067

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

Websites

www.medicines.org.uk Electronic Data Sheet Compendium

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Independent enquirers	[IE1, IE2] exploring the different routes of administration for medicines [IE1, IE2] investigating the effects of various aspects of a medicine and its administration on the outcome for the patient
Creative thinkers	[CT2] asking questions to find out why different routes are used to administer medicines or to find out why a medicine taken in a certain way exerts its effect
Reflective learners	[RL4] assessing why routes of administration and other factors influence treatment [RL3] reviewing collected information and deciding which they should use to answer pharmaceutical queries
Team workers	[TW1] collaborating with others to work towards common goals during group work, eg working with others to enable patients to get the most out of their treatment
Self-managers	[SM3, SM5] organising their time and resources and prioritising their actions in relation to working with patients, dispensing, speaking to patients and researching answers to questions [SM6] able to anticipate and respond in a professional way to the risks associated with not giving patients or healthcare staff correct information

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1, IE3] asking questions and exploring solutions about how to answer pharmaceutical queries
Creative thinkers	[CT2] asking questions of their pharmacy team to extend their understanding of the uses and limitations of medicines or the methods used to answer pharmaceutical queries
Reflective learners	[RL3] reviewing information [R2, R3, R4] reviewing progress with tutors and mentors [RL4] evaluating literature and practical work done on observation of patients and in the workplace, and considering how these could be used to identify their own developmental needs
Team workers	[TW1] collaborating with others to work towards common goals during group work
Self-managers	[SM3] organising their time, resources and prioritising actions for assessments
Effective participators	[IE1] discussing deadlines and other task-related issues with tutors and colleagues

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	searching for resources on the internet in order to respond to pharmaceutical queries
Manage information storage to enable efficient retrieval	maintaining their own storage systems for work they have done
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	searching for resources on the internet in order to respond to pharmaceutical queries
Select information from a variety of sources to meet requirements of a complex task	searching for resources on the internet in order to respond to pharmaceutical queries
ICT – developing, presenting and communicating information	
Use appropriate software to meet the requirements of a complex data-handling task	showing they are able to use ICT resources to find a response to a pharmaceutical query
Use communications software to meet requirements of a complex task	showing they are able to use ICT resources to find a response to a pharmaceutical query in order to meet the needs of the enquirer using an electronic method of communication to find a response to a pharmaceutical query
Use appropriate checking procedures and evaluate their effectiveness at each stage	
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	participating in discussions listening to patient requests
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading a range of resources for own research reading a range of resources in order to find out how to provide a response to a pharmaceutical query
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing essays eg on pharmacokinetics completing worksheets for formative assessment completing "Medicines History Taking" sheets

Unit 6: Gastrointestinal and Nutritional Medicines

Unit code: A/601/7568

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit examines the main medicine categories and their actions in the treatment of gastrointestinal, nutritional and blood disorders.

Unit introduction

This unit, along with *Unit 5: Action and Uses of Medicines*, *Unit 7: Cardio-Respiratory Medicines*, *Unit 8: Central Nervous System Medicines and Anaesthesia*, *Unit 9: Infections, Immunological Products and Vaccines*, *Unit 10: Endocrine and Genito-Urinary Medicines*, *Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines* and *Unit 12: Eye, Ear, Nose and Dermatological Medicines*, covers all the sections found in the British National Formulary (BNF).

This unit provides learners with an understanding of the underlying principles behind the way medicines work on the human body. The unit extends the learner's knowledge from physiology in health to disease processes. It explains the appropriate use and limitations of therapeutic agents. The role of the pharmacy technician is expanding so learners will require a good knowledge of therapeutics and must be able to demonstrate good communication skills.

The unit develops general concepts around knowledge of gastrointestinal, nutritional and blood disorders and the principles of drug action in these conditions. The fundamental principles are expanded so that learners can apply the concepts of drug action in their workplace to provide appropriate dispensing, consultation with patients and over the counter sales. This unit also forms the basis for other medicine management training. The pharmacy technician should also demonstrate that they are aware of their own limitations, and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

Learning outcomes

On completion of this unit a learner should:

1 Understand how medicines are used to treat disorders of the gastrointestinal tract

2 Understand how medicines are used to treat nutritional disorders

3 Understand how medicines are used in the treatment of blood disorders.

Unit content

1 Understand how medicines are used to treat disorders of the gastrointestinal tract

Antacids and ulcer healing agents: the nature of dyspepsia, peptic ulceration, helicobacter pylori eradication and gastro-oesophageal reflux disorders (GORD); drug treatment of the conditions, their benefits and limitations; non-prescription medicines treatment of indigestion and heartburn

Diarrhoea and constipation: gut motility; causes of diarrhoea and constipation; drug treatment of the conditions, agents and their actions, side effects, contra-indications; non-prescription medicines treatment of diarrhoea and constipation, limitations of non-prescription medicines treatment

Inflammatory bowel disease: irritable bowel syndrome and inflammatory bowel disease; drug treatment of the conditions, agents and their actions, side effects, contra-indications

Miscellaneous GI conditions: haemorrhoids, stoma care, anal fissures, emesis and antiemetics, diet and gastro-intestinal health

2 Understand how medicines are used to treat nutritional disorders

Intravenous nutrition: reasons for feeding intravenously, problems, methods, home care, constituents of fluids; re-feeding syndrome

Enteral nutrition including PEGs (percutaneous endoscopic gastrostomy), nasogastric and sip feeds; reason for use and types of preparation

Vitamins and minerals: causes, symptoms and treatment of deficiencies

Special diets: coeliac and intolerance, other disorders eg irritable bowel syndrome, weight reduction, food substitutes
Metabolic disorders: causes, symptoms, treatment

3 Understand how medicines are used in the treatment of blood disorders

Deficiency anaemias: symptoms and treatment of iron deficiency anaemia, glucose 6-phosphate dehydrogenase (G6PD) deficiency; other types of anaemia (pernicious anaemia, megaloblastic, platelet disorders, idiopathic thrombocytopenia purpura)

Drugs used to treat neutropenia: use of recombinant human granulocyte-colony stimulating factor (rhG-CSF)

Fluid and electrolyte imbalance: oral re-hydration therapy, intravenous fluids, reasons for and hazards of intravenous routes; uses of common infusion fluids and plasma substitutes

Erythropoietin deficiency: in patients undergoing renal dialysis; in patients undergoing chemotherapy

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe common disorders affecting the gastrointestinal tract	**M1**	describe the pharmacological action of medicines used to treat gastro intestinal disorders	**D1**	analyse the factors involved in the choice of therapeutic agents for gastrointestinal disorders
P2	explain how common medicines are used in each of the gastrointestinal tract disorders				
P3	summarise common side effects of medicines used to treat disorders of the gastrointestinal tract	**M2**	discuss the reasons why side effects may occur with medicines used in the treatment of gastrointestinal disorders	**D2**	recommend ways in which patients can effectively manage their medication for gastrointestinal disorders
P4	explain the information that must be given to patients about their gastrointestinal medicines [EP3, EP4]	**M3**	explain how counselling patients helps improve compliance with gastrointestinal disorder treatment		
P5	describe the problems arising from nutritional disorders	**M4**	describe the pharmacological action of medicines used to treat nutritional disorders	**D3**	analyse the factors involved in the choice of therapeutic agents for the treatment of nutritional disorders
P6	compare the routes used to provide artificial nutrition [IE4]				
P7	explain how common medicines or foods are used in each of the nutritional disorders				
P8	summarise common side effects of medicines used to treat nutritional disorders	**M5**	discuss the reasons why side effects may occur with medicines used to treat nutritional disorders	**D4**	recommend ways in which patients can manage their nutritional disorder conditions effectively

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P9 describe common disorders affecting the blood	**M6** describe the pharmacological action of medicines used to treat disorders of the blood	**D5** analyse the factors involved in the choice of therapeutic agents for the treatment of blood disorders
P10 explain how common medicines are used in each of the blood disorders		
P11 summarise common side effects of medicines used to treat blood disorders	**M7** discuss the reasons why side effects may occur with medicines used to treat blood disorders	**D6** recommend ways in which patients with blood disorders can manage their medication effectively
P12 explain information given to patients about their blood disorder medicines [EP3, EP4]	**M8** explain how counselling patients with blood disorders helps improve their compliance	

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Formal teaching on gastrointestinal disorders and common medicines used to treat these disorders. Tutor led discussion on how and why medicines used, including common side effects. Case studies to be used to identify the importance of patient consultation and how to improve compliance. Personal study time and research. **Assignment 1: Gastrointestinal Disorders** (P1, P2, P3, P4, M1, M2, M3, D1, D2)
Learning outcome 2 Formal teaching on nutritional disorders and common medicines used to treat these disorders. Tutor led discussion on common medicines and foods used to treat these disorders. Tutor led discussion on routes used to provide artificial nutrition. Case studies used to investigate common side effects and the importance of consultation with patients. Personal study time and research. **Assignment 2: Nutritional Disorders** (P5, P6, P7, P8, M4, M5, D3, D4)
Learning outcome 3 Formal teaching on blood disorders and common medicines used to treat these disorders. Tutor led discussion on common medicines and foods used to treat these disorders. Group case studies used to investigate common side effects and the importance of consulting with patients. Personal study time and research. **Assignment 3: Disorders Affecting the Blood** (P9, P10, P11, P12, M6, M7, M8, D5, D6)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction

For P1, learners need to describe common disorders affecting the gastro-intestinal tract. This could be evidenced by the learner completing a presentation on a common disorder selected by the tutor. The tutor should select the examples carefully so the unit is covered sufficiently.

For P2, learners need to explain how common medicines are used in each of the gastrointestinal disorders. This could be evidenced by the learner completing a written assignment.

For P3, learners are required to summarise common side effects of the medicines referred to in P2. This could be evidenced by the learner completing a presentation or written assignment, building on P2.

For P4, learners are required to explain information given to the patient about their gastrointestinal medicines. This could be evidenced by the learner producing a patient information leaflet.

For P5, learners need to describe the problems arising from nutritional disorders. This could be evidenced by the learner completing a written assignment on a common nutritional disorder selected by the tutor. The tutor should select the examples carefully so the unit is covered sufficiently.

For P6, learners need to compare the routes used to provide artificial nutrition. This could be evidenced by the learner completing tables or labelling diagrams.

For P7, learners are required to explain how common medicines or foods are used in each of the nutritional disorders. This could be evidenced by the learner completing a presentation and producing accompanying handout notes.

For P8, learners need to summarise the common side effects of the medicines identified in P7. This could be evidenced by the learner completing a table or building on assessments from P7.

For P9, learners need to describe common disorders affecting the blood. This could be evidenced by the learner completing a written assignment containing the relevant images.

For P10, learners need to explain how common medicines are used in each of the disorders identified in P9. This could be evidenced by the learner completing a written assignment containing the relevant images.

For P11, learners are required to summarise the common side effects of the medicines identified in P10. This could be evidenced by the learner producing a leaflet or building on assessments from P10.

For P12, learners need to explain information given to the patient about their blood disorder medicines. This could be evidenced by the learner producing a leaflet.

For M1, learners need to describe the pharmacological action of medicines used to treat gastrointestinal disorders. This may be evidenced by the learner completing a written assignment containing the relevant images.

For M2, learners are required to discuss the reasons why side effects may occur with medicines used to treat gastrointestinal disorders. This could be evidenced by the learner completing a presentation or written assignment.

M3 requires learners to explain how counselling patients on gastrointestinal medicines helps improve their compliance. This could be evidenced by the learner completing a presentation or written assignment.

For M4, learners need to describe the pharmacological action of medicines used to treat nutritional disorders. This may be evidenced by the learner completing a presentation and producing accompanying

handout notes.

For M5, learners need to discuss the reasons why side effects may occur with medicines used to treat nutritional disorders. This may be evidenced by the learner completing a presentation and answering questions.

For M6, learners are required to describe the pharmacological action of medicines used to treat blood disorders. This may be evidenced by the learner completing a written assignment containing the relevant images.

M7 requires learners to discuss the reasons why side effects may occur with medicines used to treat blood disorders. This could be evidenced by the learner completing a written assignment.

For M8, learners need to explain how counselling patients who have blood disorders helps improve their compliance. This may be evidenced by the learner completing a written assignment or leaflet.

To achieve D1, learners need to analyse the factors involved in the choice of therapeutic agents for gastrointestinal disorders. This may be evidenced by the learner completing a presentation or written assignment.

For D2, learners are required to recommend ways in which patients can effectively manage their medication for gastrointestinal disorders. This could be evidenced by the learner completing a presentation and leaflet.

For D3, learners need to analyse the factors involved in the choice of therapeutic agents for the treatment of nutritional disorders. This may be evidenced by the learner completing a written assignment.

D4 requires learners to recommend ways in which patients can effectively manage their nutritional disorders. This could be evidenced by the learner producing a presentation along with accompanying handout notes.

For D5, learners need to analyse the factors involved in the choice of therapeutic agents for treatments of blood disorders. This could be evidenced by the learner completing a written assignment.

For D6, learners need to recommend ways in which patients who have blood disorders could manage their medication effectively. This may be evidenced by the learner completing a leaflet.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P2, P3, P4, M1, M2, M3, D1, D2	Gastrointestinal Disorders	You have been asked by a doctor's surgery to provide a coaching session to staff on common gastrointestinal disorders, their treatment and patient advice.	Presentations. Written Assignment. Leaflet. Observation records.
P5, P6, P7, P8, M4, M5, D3, D4	Nutritional Disorders	You have been asked by the nutritional team to prepare a brief presentation on a given common nutritional disorder to a group of colleagues.	Presentations. Handout notes to accompany presentation. Written assignment. Observation records.

P9, P10, P11, P12, M6, M7, M8, D5, D6	Disorders Affecting the Blood	You have been asked by a pathology unit to produce a leaflet showing the services available for patients with a variety of blood disorders.	Written assignment Leaflet with images

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy Technicians
Unit 2: Biological Principles for Pharmacy
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 7: Cardio-Respiratory Medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 9: Infections, Immunological products and Vaccines
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines
Unit 12: Eye, Ear, Nose and Dermatological Medicines
Unit 17: Pharmaceutics

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Pharmacology and clinical pharmacology textbooks

Clayton B, Stock Y, Cooper S – *Basic Pharmacology for Nurses, 15th Edition* (Mosby, 2009) ISBN 0323057802

Bennett PN and Brown MJ – *Clinical Pharmacology, 10th Edition* (Churchill Livingstone, 2008) ISBN 978-0-443-10244-8

Wecker L, Crespo L, Dunaway G, Faingold C and Watts S – *Brody's Human Pharmacology, 5th Edition* (Mosby, 2010) ISBN 978-0-323-05374-7

Neal MJ – *Medical Pharmacology at a Glance, 6th Edition* (Wiley-Blackwell 2009) ISBN 978-1-4051-8197-6

Rang HP, Dale MM, Ritter JM and Flower RJ – *Pharmacology, 6th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 04430691 15

Stringer J – *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2005) ISBN 0071458182

Walker R and Whittlesea C – *Clinical Pharmacy and Therapeutics, 4th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 0443102856

Drug use textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P – *Symptoms in the Pharmacy a guide to the management of common illness, 6th Edition*(Blackwell Science, 2005) ISBN 140518079X

Dodds L (Editor) – *Drugs in Use: Clinical Case Studies for Pharmacists, 3rd Edition*(Pharmaceutical Press, 2003) ISBN 0853695415

Harman RJ and Mason P (Editors) – *Handbook of Pharmacy Healthcare, 2nd Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry JA – *The British Medical Association's Concise Guide to Medicines and Drugs, 7th Edition* (Dorling Kindersley, 2007) ISBN 1405317779

McGavock H – *How Drugs Work, 2nd Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A – *Non-Prescription Medicines, 3rd Edition* (Pharmaceutical Press, 2006) ISBN 0853696446

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

A current medical dictionary (nursing level is suitable)

Websites

Electronic Data Sheet Compendium	www.emc.vhn.net
Medicines Guides	www.medicines.org.uk

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Independent enquirers	[IE4] comparing the routes used to provide artificial nutrition
Effective participators	[EP3, EP4] explaining information given to the patient about their medicines.

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE2] planning and carrying out research for assessments
Creative thinkers	[CT2] asking questions during discussion to extend their thinking
Reflective learners	[RL6] communicating their learning in relevant ways for different audiences
Team workers	[TW1] collaborating with others to work towards common goals during group work
Self-managers	[SM3] organising their time, resources and prioritising actions for assessments.

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from online journals
Select information from a variety of sources to meet requirements of a complex task	obtaining relevant information from identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if the information they require is obtainable from a website eg images for patient information leaflets
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that contains all the information for their work
Use communications software to meet requirements of a complex task	using email to send centre-produced work to their own address keeping their own messages safely in a folder creating a contact list
Combine and present information in ways that are fit for purpose and audience	presenting the information from the document as requested in the assessment brief
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how documents and presentations can be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions presenting to a group
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given during formal teaching reading information from a range of resources

Skill	When learners are ...
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments writing information leaflets and handouts

Unit 7: Cardio-Respiratory Medicines

Unit code: T/601/7570

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit examines the main medicine categories and their actions in the treatment of cardiovascular and respiratory disorders.

Unit introduction

This unit enables learners to develop an understanding of the physiology and disorders of the cardio-respiratory system. The unit explains the appropriate use and limitations of medicines prescribed for disorders of the cardio-respiratory system. The principles of drug action are studied and enable the learner to apply this knowledge to appropriate consultations with patients and over the counter sales.

Learning outcomes

On completion of this unit a learner should:

1 Understand how medicines are used to treat disorders of the respiratory system

2 Understand how medicines are used to treat disorders of the cardiovascular system

3 Understand how to advise patients to manage their conditions.

Unit content

1 Understand how medicines are used to treat disorders of the respiratory system

Asthma: nature of the asthmatic condition

Treatment of asthma: drug treatment, beta 2 agonists, antimuscarinic bronchodilators, theophylline, corticosteroids, cromoglicate and nedocromil, leukotriene receptor antagonists, and newer therapies; British Thoracic Society guidelines for the management of acute and chronic asthma

Medication for coughs and colds: the common cold and influenza; coughs and nasal congestion; drug treatment of the conditions including mode of action, side effects, contra-indications; non-prescription medicines treatment of coughs and colds eg giving advice and guidance to patients; uses and limitations of non-prescription medicines preparations

Chronic obstructive pulmonary disease (COPD): bronchitis, emphysema and their treatment including use of short-acting and regular beta 2 agonist and antimuscarinic bronchodilator, corticosteroids; oxygen at home

Allergy, hypo sensitisation and hay fever: allergy; allergic emergencies and hypo- sensitisation (anaphylaxis, angioedema); hay fever; drug treatment, oral and topical antihistamines, non-prescription medicines treatment of hayfever eg giving advice and guidance to patients; uses and limitations of non-prescription medicines preparations

2 Understand how medicines are used to treat disorders of the cardiovascular system

Congestive heart failure: cardiac glycosides and other positive inotropics; diuretics (thiazides and related diuretics, loop and potassium-sparing diuretics)

Blood pressure regulation: hypertension, symptoms, thresholds and targets for treatments according to the British Hypertension Society recommendations; beta blockers; vasodilators (thiazides, calcium blockers, ACE inhibitors and blockers, potassium channel activators, alpha blockers and central acting); hypotension, symptoms, treatments (inotropic sympathomimetics, vasoconstrictor sympathomimetics)

Cardiac arrhythmias: symptoms and treatments; membrane stabilising drugs (lidocaine, flecainide and derivatives); beta blockers; amiodarone; calcium channel blockers and digoxin

Angina: symptoms and treatments; nitrates, beta blockers, calcium channel blocker, anti-platelet drugs

Lipid regulation: cholesterol testing; low-density lipoprotein (LDL), high-density lipoprotein (HDL); hypercholesterolemia; hyperlipidaemia; anion-exchange resins; fibrates; statins; nicotinic acid group

Myocardial infarction: symptoms and treatments, anticoagulants including warfarin and heparin; anti-platelet drugs including aspirin and clopidogrel; fibrinolytics

Cardiac arrest: symptoms; risk factors; cardiac stimulants including sympathomimetics, atropine and calcium; cardioversion

3 Understand how to advise patients to manage their conditions

Airway function: use of devices in airway disease; advising patients in the use of inhalation devices eg metered dose inhalers, breath-actuated inhalers, dry powder inhalers, pacers, nebulisers, other devices; peak flow meters; assessment of lung function

Lifestyles changes: dietary changes; smoking cessation; exercise; lipid-lowering foods

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe common disorders affecting the respiratory system	**M1**	discuss the physiological changes that trigger disorders affecting the respiratory system	**D1**	analyse the factors involved in the choice of therapeutic agent for respiratory system disorders
P2	explain how common medicines are used in each of the respiratory disorders [CT2]	**M2**	describe the therapeutic action of medicines used in the treatment of respiratory disorders		
P3	summarise common side effects of medicines used to treat disorders of the respiratory system	**M3**	discuss the reasons why side effects may occur with medicines used to treat respiratory system disorders	**D2**	recommend ways in which patients can manage their disorder and medication and reduce the side effects that occur with respiratory disorder medicine
P4	explain information that must be given to patients about their respiratory medicines [CT2, EP3]	**M4**	explain how counselling patients helps improve compliance with respiratory medicines		
P5	describe common disorders affecting the cardiovascular system	**M5**	discuss the physiological changes that trigger cardiovascular disorders	**D3**	analyse the factors involved in the choice of cardiovascular drug treatment
P6	explain how common medicines are used in each of the cardiovascular disorders [CT2]	**M6**	describe the pharmacological action of medicines used to treat cardiovascular disorders		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P7 summarise common side effects of medicines used to treat disorders of the cardiovascular system	**M7** discuss the reasons why side effects may occur with medicines used in the treatment of cardiovascular disorders	**D4** recommend ways in which patientscould manage their cardiovascular disorder and medication, including the side effects of cardiovascular disorder medicines
P8 explain the information that must be given to patients about their cardiovascular medicines [CT2, EP3]	**M8** explain how counselling patients helps improve compliance with cardiovascular medicines	
P9 safely and accurately demonstrate the use of devices used in airways disease	**M9** provide counselling information to patients covering a range of devices used in airways disease	
P10 produce a safe and effective plan to improve the lifestyle of a selected patient [CT2, EP3]		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF))and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1
Lectures on asthma, its signs and symptoms, effect on patients, the range of treatment for asthma and British National Formulary (BNF) step- up prescribing guidelines.
Tutorial on the action of the range of drug treatments.
Learners access and research the British Thoracic Society guidelines for the management of acute and chronic asthma.
Lectures on the symptoms of Chronic obstructive pulmonary disease (COPD) bronchitis, emphysema; the action, use and limitations of short-acting and regular beta 2 agonist, antimuscarinic bronchodilator, corticosteroid drugs.
Lecturer to explain the cautions associated with prescribing corticosteroids and the need for oxygen treatment at home.
Learners simulate an order for domiciliary oxygen delivery.
Discussion on comparison of the symptoms of the common cold and influenza; how nasal congestion and coughs occur.
Discussion on the action and limitation of drug treatments for the common cold, influenza and nasal congestion, including mode of action and side effects and reference to influenza epidemics of previous years.
Explanation of the importance of WWHAM when cold preparations are sold Over the Counter (OTC).
Learners research and recall examples of non-prescription medicinal treatment of coughs and colds.
Learners simulate patient consultation session giving advice on uses and limitations of non-prescription medicinal preparations. (Guidance required by tutor).
Description of the symptoms of respiratory allergic reactions.
Learners identify the signs of allergic emergencies/hypo-sensitisation.
Description of the action and use of drug treatment or respiratory allergic response.
Explanation of the action and side effects of antihistamines (oral and topical).
Learners simulate patient consultation session giving advice on uses and limitations of non-prescription medicinal preparations for hayfever. (Guidance required by tutor).

Topic and suggested assignments/activities and/assessment
Learning outcome 2
Description of the symptoms of hypertension.
Learners research British Hypertension Society recommendations for thresholds and targets for treatments.
Description of the action and use of treatments of hypertension.
Discussion on hypotension, its symptoms, the action of treatments (inotropic sympathomimetics, vasoconstrictor sympathomimetics).
Discussion on the importance of lipid regulation.
Learners research cholesterol testing in their community.
Describe the difference between low-density lipoprotein (LDL), and high-density lipoprotein (HDL).
Describe the symptoms of hypercholesterolemia and hyperlipidaemia.
Discuss action and use of treatments anion-exchange resins, fibrates, statins, nicotinic acid group.
Learners to suggest lifestyle changes to reduce risks of hypercholesterolemia.
Describe the symptoms of differing types of cardiac arrhythmias.
Describe the action and use of treatments in relation to the type of arrhythmia including membrane stabilising drugs (lidocaine, flecainide and derivatives), beta blockers, amiodarone, calcium channel blockers and digoxin.
Describe the symptoms of angina.
Describe the action and use of treatments in relation to angina to include nitrates, beta blockers, calcium channel blockers, anti-platelet drugs.
Describe the symptoms of congestive heart failure, the action of treatments in relation to congestive heart failure including cardiac glycosides and other positive inotropics; diuretics (thiazides and related diuretics, loop and potassium-sparing diuretics).
Learners to show understanding of polypharmacy and concept of combination treatments to increase compliance.
Describe the signs and symptoms of myocardial infarction and the action and use of emergency and stabilising treatments, including anti-coagulants.
Describe antiplatelet- drugs.
Describe fibrinolytics.
Describe the symptoms of a cardiac arrest, the risk factors; the action and use of emergency and stabilising treatments.
Assignment 1: Treating Respiratory and Cardiovascular Disorders (P1, P2, P3, P4, M1, M2, M3, M4, D1, D2)
Assignment 2: Treating Cardiovascular Disorders (P5, P6, P7, P8, M5, M6, M7, M8, D3, D4)
Learning outcome 3
Learners demonstrate the use of devices used in airway disease (practice with placebo inhalers).
Learners simulate advising patients in the use of inhalation devices.
Learners use peak flow meters and measure and asses lung function.
Learners create a poster/information leaflet outlining advice for lifestyles changes.
Assignment 3: Counselling Patients to Manage their Conditions (P9, M9, P10)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners need to describe the disorders affecting the respiratory system. This could be evidenced by the learner verbally presenting the information (documented by the tutor in an observation record) or by means of a written assignment.

For M1, learners need to discuss the changes that occur within the respiratory system which produce the symptoms of the disorder. This could be evidenced by the learner verbally presenting the information (documented by the tutor in an observation record) or by means of a detailed diagram or a written assignment.

For D1, learners are required to analyse the factors that may be involved in the choice of therapeutic agent for respiratory disorders. The factors could include age and severity of the disorder. This could be evidenced within a presentation of a defined case study by the learner or by means of a written assignment.

For P2, learners need to explain how common medicines are used to treat the respiratory disorders identified in P1. This could be linked to P9 and evidenced by a demonstration of different devices. The learner could present the information as part of a case study or as a written assignment.

For M2, learners need to describe the action of the common medicines on the respiratory system. This could be evidenced as part of a verbal presentation (documented by the tutor in an observation record) or by means of a written assignment.

For P3, learners need to summarise the side effects of the medicines used to treat respiratory disorders. This could be evidenced as part of a verbal presentation (documented by the tutor in an observation record), a simulated patient consultation session or presented as a written assignment.

For M3, learners need to discuss the reasons the side effects occur with medicines used to treat the respiratory system. This could be evidenced as part of a verbal presentation relating the side effect to the action of the medicine (and documented by the tutor in an observation record), or by means of a simulated patient consultation session or as a written assignment.

For D2, learners are required to recommend ways in which the patient could effectively manage their respiratory disorder for example by the patient recognising trigger factors, taking regular medication or

changing lifestyle. The learner's understanding of D2 could be evidenced as part of a verbal presentation (documented by the tutor in an observation record) or by means of a simulated patient consultation session or as a written assignment.

P4 requires learners to explain the information given to the patient about their respiratory disorder medicines. This could include how to take the medicines for example dosage, frequency, storage and any other appropriate information relating to the medicine such as to take with food, or to avoid certain foods whilst taking the medicine. This could be evidenced as a verbal presentation (documented by the tutor in an observation record) or by means of a simulated patient consultation session or as a written assignment.

For M4, learners are required to explain how counselling helps patients to manage their respiratory disorder. This could include advice given over the counter, providing such information as regular dosing, regular exercise, recognition and avoidance of trigger factors for the respiratory disorder. This could be evidenced as part of a simulated patient consultation session or as a written assignment. The learner could design a patient information leaflet.

To achieve P5, learners need to describe the common disorders affecting the cardiovascular system. This could be evidenced by a verbal description to the tutor (documented by the tutor in an observation record), a presentation with anatomical diagrams or as a written assignment.

For M5, learners need to discuss the changes that occur within the cardiovascular system in order to produce the symptoms of the disorder. This could be evidenced by a verbal presentation (documented by the tutor in an observation record) or as a written assignment.

To achieve D3, learners are required to analyse the factors that may be involved in the choice of cardiovascular drug treatment. Learners should show that they understand why specific medication is prescribed for each cardiovascular disorder. This could include an explanation of the action of each medicine and the advantages of taking synergistic medicines. Learners could research local and national guidelines such as NICE guidelines or PCT contracts for the choice of treatments.

For P6, learners need to explain how common medicines are used in each of the cardiovascular disorders identified in P5. This could be linked to P5, M5 and D3. The learner could explain the importance of giving injections or infusions to gain control over the disorder then maintenance with oral treatment. This could be evidenced as part of a presentation of a case study or as a written assignment.

For M6, learners need to describe the pharmacological action of the medicines used on the cardiovascular system. This could be linked to M5 and D4 and evidenced as part of a verbal presentation (documented by the tutor in an observation record) or as a written assignment.

For P7, learners are required to summarise the common side effects of the cardiovascular medicines. This could be evidenced as part of a simulated patient consultation session, a verbal presentation (documented by the tutor in an observation record) or as a written assignment.

M7 requires learners to discuss reasons why side effects occur with cardiovascular medicines, relating this to the action of the medicine. This could link M7 to P6, P7 and M6 as part of a presentation of a case study or written assignment.

For D4, learners need to recommend ways in which patients could manage the cardio-vascular condition, including side effects of the medication. The recommendations should include dietary changes and regular exercise. This could be evidenced by a simulated patient consultation session, verbal presentation (documented by the tutor in an observation record) or written assignment.

For P8, learners need to explain the information given to the patient about their cardiovascular medicines. This could include how to take the medicines for example dosage, frequency and storage and any other appropriate information relating to the medicine such as to take with food, or to avoid certain foods or activities whilst taking the medicine. This could be evidenced as a verbal presentation (documented by the tutor in an observation record), or by means of a simulated presentation or as a written assignment.

For M8, learners are required to explain how counselling helps patients to manage their cardiovascular disorder. This could include advice on healthy lifestyles, increasing exercise tolerance and helping the patient to recognise early warning signs of disorders for example angina pains or arrhythmias. Evidence could be provided as part of a simulated patient consultation session, verbal presentation (documented by the tutor in an observation record) or by means of written assignment.

To achieve P9, learners need to demonstrate the safe and accurate application of devices used in airways disease. This could be evidenced as part of a simulated patient consultation session using placebo inhalers documented on a generic tick sheet by the tutor.

For M9, learners need to provide advice and information to patients covering a range of airways devices. This evidence could be linked to P9.

For P10, learners need to plan changes with a selected patient to improve the patient's lifestyle and produce evidence of the plan. This evidence could be linked to P9 and M9.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P3, P4, M1, M2, M3, M4, D1, D2	Treating Respiratory Disorders	You are required to help inform the nurses in an asthma clinic about the patients' disorders. Devise a presentation that will cover the following points: • describe the symptoms of asthma and the changes within the respiratory system that produce these symptoms • describe the medicines used to treat asthma and how they work • discuss the possible side effects the medicines could produce • discuss how patients could be encouraged to manage their own disorder effectively.	Observed presentation. Report
P5, P6, P7, P8, M5, M6, M7, M8, D3, D4	Treating Cardiovascular Disorders	You are required to help inform a group of nurses about cardiovascular disorders. Devise a presentation that will cover the following points: • describe the symptoms of hypertension • describe the medicines used to treat hypertension and how they work • discuss the possible side effects the medicines could produce • discuss how patients could be encouraged to manage their own disorder effectively.	Observed presentation.

Criteria covered	Assignment Title	Scenario	Assessment Method
P9,M9,P10	Counselling Patients to Manage their Conditions	You are required to advise a patient on the use of their inhaler device. Your advice to the patient should include the following components: • demonstrate to the patient how the device should be used. • give advice and guidance to the patient regarding use of the device • provide advice to the patient on how to incorporate the treatment into their daily routine • help the patient to plan lifestyle changes to improve their condition.	Observed simulated patient consultation session. Report.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 13: Community Pharmacy Practice
Unit 15: Communicating in Pharmacy

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Greenstein B & Greenstein – *A Concise Clinical Pharmacology* (Pharmaceutical Press 2007) ISBN 9780853695769

Horton-Szar D – *Crash Course Pharmacology* (Mosby 2007) ISBN 97807234341 60

Neal M J – *Medical Pharmacology at a Glance* (John Wiley & Sons Ltd, 2009) ISBN 9781405181976

Rang HP Dale MM and Ritter J M – *Pharmacology* (Churchill Livingstone, 2007) ISBN 97804430691 16

Journals

British Journal of Pharmacology (British Pharmacological Society/Wiley-Blackwell, 2010)

The British Medical Journal (BMJ Publishing Group Ltd, 2010)

The Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.medicines.org.uk	The Electronic Medicines Compendium
www.netdoctor.co.uk	Net Doctor Website

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1] identifying assignment questions, resolving problems and answering patient queries [IE2] planning research for assignments including the content, length and design of presentations [IE3] exploring patient issues eg different ways of giving medicines if a patient is unable to swallow
Creative thinkers	[CT2] asking questions to check understanding has taken place when communicating with patients about their medicines
Effective Participators	[EP3] explaining the information to be given to patients about their medicines.

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1] identifying questions to resolve assignment difficulties or patient problems [IE2] planning research for assignments or patient advice sessions [IE2] planning daily activities within the vocational placement [IE3] exploring patient issues, medicine administration problems, formulation of medicines or concordance issues
Creative thinkers	[CT2] asking questions of the tutor or workplace mentor to expand learning and understanding [CT6] adapting explanations given to patients when understanding has not taken place to show they are able to explain things in a variety of ways
Reflective learners	[RL2] setting targets for assignment work [RL3] reviewing information for inclusion on assignment work [RL6] communicating with tutors, mentors and colleagues to support learning [RL6] communicating with patients and staff in a variety of ways eg if hard of hearing or patient doesn't speak English
Self-managers	[SM3] organising time for research and assignment deadlines [SM6] able to behave in a professional manner when faced with a variety of medical situations.

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	accessing ICT systems to research information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using an electronic calendar to time manage self- directed study able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information on a removable data storage device aware of keeping their password confidential
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching information online from books, journals and other relevant electronic sources
Select information from a variety of sources to meet requirements of a complex task	obtaining relevant information from websites and electronic journals
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if the information they require is available on the internet or intranet
Use appropriate software to meet the requirements of a complex data-handling task	creating a single assignment that contains all the information required for the criteria
Use communications software to meet requirements of a complex task	using email to send the assignment to their tutor
Combine and present information in ways that are fit for purpose and audience	presenting information as required for their assignments
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	receiving feedback and discussing how the assignment could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions during formal learning communicating with patients and customers
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts during discussions reading research material
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing assignments and presentations,

Unit 8: Central Nervous System Medicines and Anaesthesia

Unit code: J/601/7573

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit examines the main medicine categories and their actions affecting the central nervous system.

Unit introduction

This unit enables learners to understand how the activity of the central nervous system is controlled by the release and uptake of neurotransmitters. Learners will gain knowledge of the medical disorders resulting from an increase or decrease in the release or uptake of neurotransmitters.

Learners will be introduced to the action and use of medications used to treat disorders of the central nervous system and how medicines are used in anaesthesia.

Learning outcomes

On completion of this unit a learner should:

1 Understand how medicines are used to treat disorders of the central nervous system

2 Understand how medicines are used to treat mental health disorders

3 Understand how medicines are used in the treatment and management of pain

4 Understand how medicines are used in anaesthesia.

Unit content

1 Understand how medicines are used to treat disorders of the central nervous system

Anti-epileptics: types of epilepsy and their symptoms; diagnosis and treatment of epilepsy; action and use of medications used to treat epilepsy

Parkinson's disease and related disorders: Parkinsonism and symptoms; action and use of medications used to treat Parkinsonism

CNS stimulants and drugs used for attention deficit hyperactivity disorder: symptoms of ADHD and narcolepsy; actions and use of amphetamines and related drugs

Obesity: causes and symptoms of obesity; actions and use of medications used to treat obesity

2 Understand how medicines are used to treat mental health disorders

Hypnotics and anxiolytics: symptoms of anxiety and sleep disorders; prescribing cautions; dependence and withdrawal; cognitive behaviour therapy

Psychoses and related disorders: symptoms of affective disorders eg unipolar, bipolar, depression; symptoms of psychotic disorders eg schizophrenia, delusional disorders, mania; action and use of medications used to treat psychoses and related disorders eg antipsychotic, lithium, antidepressants, neuroleptics; adjuvant therapy interactions

Substance dependence: misuse and consequences of alcohol, cigarettes, opioid drugs and related substances; medications and treatments used in the management of related substance dependence

Dementia: management and assessment of dementia and Alzheimer's disease; disease progression; action and use of drugs used to treat Alzheimer's disease

3 Understand how medicines are used in the treatment and management of pain

Analgesics: pain mechanism; psychological aspect of chronic pain; the need for regular pain control and the analgesic ladder; action and use of non opioids and opioids; action and use of adjuvant drugs; limitations of analgesia; dangers and treatment of overdose

Migraine: types of migraine, their symptoms and trigger factors; action and use of treatments used for migraine; prophylaxis of migraine

Nausea and vertigo: epidemiology of nausea and vertigo; action, use and limitations of antiemetics; mediation and treatments for vertigo and associated disorders

4 Understand how medicines are used in anaesthesia

General anaesthesia: concept of general anaesthesia; stages of anaesthesia; intravenous anaesthetics; inhalation anaesthetics; antimuscurinic, anxiolytic, analgesia, antiemetic perioperative drugs; muscle relaxants; reversal

Local anaesthesia: routes of administration including epidural and intrathecal; use of vasoconstrictors; action of local anaesthetic

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 describe common disorders affecting the central nervous system	**M1** discuss the physiological changes that trigger disorders affecting the central nervous system	**D1** analyse the factors involved in the choice of therapeutic agent for central nervous system disorders
P2 explain how common medicines are used in each of the central nervous system disorders [CT2]	**M2** describe the therapeutic action of medicines used in the treatment of central nervous system disorders	
P3 summarise common side effects of medicines used to treat disorders of the central nervous system	**M3** discuss the reasons why side effects may occur with medicines used to treat disorders of the central nervous system	**D2** recommend ways in which the patient could manage their disorder and reduce the side effects experience of medicines used for central nervous system disorders
P4 explain the information that must be given to patients about their central nervous system medicines	**M4** provide information to the patient to manage their central nervous system disorder effectively	
P5 describe common disorders affecting mental health, including addiction and substance misuse	**M5** discuss the physiological changes that trigger common mental health disorders	**D3** analyse the factors involved in the choice of treatment for mental health disorders
P6 explain how common medicines are used in each of the mental health disorders [CT2]	**M6** describe the therapeutic action of medicines used in the treatment of mental health disorders	
P7 summarise common side effects of medicines used to treat mental health disorders	**M7** discuss the reasons why side effects may occur with medicines used to treat mental health disorders	**D4** recommend ways in which the patient could manage their disorder and reduce the side effects that occur with mental health disorder treatments
P8 explain the information that must be given to patients about their medicines for the treatment of their mental health disorder [CT2, EP3]	**M8** provide information to the patient to manage their mental health disorder effectively	

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P9 discuss the prescribing of pain control in relation to the analgesic ladder	**M9** describe how the addition of adjuvant drugs can effectively improve pain management	**D5** recommend ways, including cognitive behaviour therapy, which the patient can use to provide effective pain management
P10 summarise common side effects of medicines used in the treatment and management of pain	**M10** discuss the reasons why side effects may occur with medicines used in the treatment and management of pain	
P11 explain the information that must be given to patients about their medicines for pain treatment and management [CT2, EP3]	**M11** provide information to the patient to manage their pain effectively	
P12 explain the requirement for combination drug use in general anaesthesia [IE3]	**M12** using named drug examples, discuss the action of the drugs used in combination	**D6** discuss the action of anaesthetic agents and combination drugs used during all stages of anaesthesia from induction to reversal
P13 explain the reasons for the different administration routes for local anaesthetics. [IE3]	**M13** discuss the advantages and disadvantages of the different routes for local anaesthetics.	**D7** evaluate how the addition of adrenaline can affect and/or limit the use of the local anaesthetic.

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

The unit subject needs to be regularly updated. Learners should be encouraged to take part in the review of clinical case studies, role plays and simulated patient consultation sessions. This unit should be taught by a pharmacist, pharmacy technician or persons having a relevant qualification in pharmacology.

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF))and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Introduction to the different types of epilepsy, the physiological basis of the different types of epilepsy and the symptoms of each type of epilepsy. Describe the breakdown of pathways and neurotransmitter problems that cause Parkinsonism and its symptoms. Describe the action and use of medicines used to treat Parkinson's disease. Introduction to miscellaneous CNS disorders including ADHD, narcolepsy, and obesity. Describe the action and use of drugs used to treat the miscellaneous disorders.
Assignment 1: Parkinson's Disease and its Treatment (P1, P2, P3, P4, P5, M1, M2, M3, M4, D3)
Learning outcome 2 Describe the symptoms of anxiety and sleep disorders. Explain the action and use of hypnotics and anxiolytics. Discuss the importance of prescribing cautions, dependence, tolerance and withdrawal. Introduction to alternative therapies for anxiety, including cognitive behaviour therapy. Describe the symptoms of affective disorders and symptoms of psychotic disorders. Explain the action and use of medications used to treat psychoses and related disorders. Use a case study to demonstrate the management and assessment of dementia and Alzheimer's disease. Follow the case study showing progression of the disease. Learners take the dementia test. Explain the action and use of drugs to treat Alzheimer's disease. Discuss NICE guidelines for treatment of dementia and Alzheimer's disease. Learners devise an information leaflet showing the consequences of alcohol, opioid or related substance misuse. Learners to include information on the action and use of treatments for substance dependence.
Assignment 2: Alzheimer's Disease and its Treatment (P6, P7, P8, M6, M7, M8, D4)

Topic and suggested assignments/activities and/assessment
Learning outcome 3
Explain the pain mechanism.
Discuss the psychological aspect of chronic pain and the need for regular pain control.
Draw the analgesic ladder and explain the difference in potency and action of drugs on differing levels.
Describe action and use of non opioids and opioids.
Explain why adjuvant drugs are prescribed, their action and use.
Discuss the limitations of analgesia.
Demonstrate the dangers and treatment of overdose.
Describe the types of migraine, symptoms experienced and trigger factors.
Explain the action and use of treatments used for migraine.
Learners investigate and recommend therapies to provide prophylaxis of migraine.
Define epidemiology of nausea and vertigo, making reference to vomiting centre and chemoreceptor trigger zone.
Describe the action, use and limitations of anti-emetics; mediation and treatments for vertigo and associated disorders.
Learning outcome 4
Describe the concept of general anaesthesia.
Define the stages of anaesthesia.
Introduction to intravenous anaesthetics and inhalation anaesthetics.
Tutorials and/or workbook assignments to investigate why antimuscurinic, anxiolytic, analgesia, antiemetic perioperative drugs, muscle relaxants are given during anaesthesia.
Diagram to demonstrate the routes of administration (including epidural and intrathecal).
Discus the inclusion of vasoconstrictors.
Explain the action of local anaesthetics.
Assignment 3: Anaesthetic Medicines (P9, P10, P11, P12, M9, M10, M11, M12, D5, D12)
Assignment 4: Local Anaesthetics (P13, M13, D7)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners need to describe common disorders of the central nervous system. This could be evidenced verbally as a presentation or discussion (documented by the tutor in an observation record) or as a written description assessed by the tutor using a generic check sheet.

For M1, learners should discuss the physiological changes that trigger disorders affecting the central nervous system. Learners must be able to identify the neurotransmitter affecting the disorder and describe the effect of increase or decrease of the neurotransmission pathway. This could be evidenced verbally as a presentation or discussion (documented by the tutor in an observation record) or as a written description.

For D1, learners are required to analyse contributing factors that would affect the choice of therapeutic agent for central nervous system disorders. This may be age, severity of disease or NICE guidelines. D1 could be evidenced as a presentation of a case study or as a written assignment assessed by the tutor.

For P2, learners need to explain how common medicines are used in the treatment of central nervous system disorders. For example, learners could explain how a short course of anxiolytics may give some relief without causing dependence but longer term therapy may need to be in the form of a different treatment. The evidence could be linked with P1 as part of a presentation or written description.

For M2, learners need to describe the therapeutic action of the common medicines used in the treatment of central nervous system disorders. The learner's description should include the neurotransmission pathway and the antagonistic or agonistic action of the medicine. This could be linked to P1 and M1 as part of an assessed presentation or written assignment.

For P3, learners are required to summarise the side effects the patient may experience when taking medication for the treatment of central nervous system disorders. This could be linked to P1 and P2 as part of an assessed presentation or written assignment.

For M3, learners are required to discuss the reasons why side effects may occur and relate the side effects to the action of the medication used for the treatment of central nervous system disorders. This could be linked to P2, M2 and P3 and assessed as part of a presentation or written assignment.

For D2, learners need to recommend ways in which patients can effectively manage the CNS disorder and reduce the side effects. For example, the learner could recommend cognitive behavioural therapy or relaxation therapy alongside the prescribed medicines. This could be evidenced as a simulated patient consultation session or linked to P2, P3, M2 and M3 as part of a presentation or written assignment.

For P4, learners need to explain the information that is given to patients about their medication. This could be advice given to the patient over the counter, providing information on dosage, whether to take the medication with food or regarding the avoidance of foods or activities such as alcohol or driving. This could be linked to P2, P3, M2 and M3 and assessed as part of a presentation or a simulated patient consultation session.

For M4, learners are required to provide information to help the patient manage their condition effectively. This could be evidenced by linking to P3, M3 and D3 as part of a case study, patient consultation scenario, assessed presentation or written assignment.

P5 requires learners to describe common mental health disorders. Learners should describe the reasons why a substance can become addictive and continue to be misused. This could be evidenced by designing promotional material or as part of a presented case study or written assignment assessed by the tutor.

For M5, learners need to discuss the physiological reasons why mental health disorders are experienced. This could be linked to P5 and evidenced as part of a case study, presentation or written assignment.

For D3, learners need to analyse the factors involved in the choice of treatment of mental health disorders. The learner should relate their analysis to the symptoms and severity of symptoms. Evidence for D3 could form part of a case study, presentation or written assignment linked to P5 and M5.

For P6, learners are required to explain how common medicines are used to treat mental health disorders. This could be linked to P5, M5 and D3. The learner could explain the importance of giving depot injections to improve compliance and to gain control over the disorder, followed by maintenance with oral treatment. This could be evidenced as part of a presentation of a case study or written assignment.

For M6, learners need to describe the therapeutic action of medication used to treat mental health disorders. This could be linked to P6, describing the route and site of action of the medication as part of a case study, presentation or written assignment.

P7 requires learners to summarise the side effects the patient may experience when taking medication for the treatment of mental health disorders. This could be linked to P6 and M6 as part of an assessed presentation or written assignment.

For M7, learners are required to discuss the reasons side effects may occur with mental health disorder treatments and relate the side effects to the action of the medication. This could be linked to P6, P7 and M6 and assessed as part of a presentation or written assignment.

For D4, learners are required to recommend ways in which patients can effectively manage the mental health disorder and reduce the side effects. This could be evidenced as a simulated patient consultation session or linked to P6, P7, M6 and M7 as part of a presentation or written assignment.

For P8, learners need to explain the information that is given to patients about their medication for treating mental health disorders. This could include how to take the medicines, for example information on dosage, frequency and storage and any other appropriate information relating to the medicine, such as whether to take the medication with food, or to avoid certain foods or activities whilst taking the medicine (for example alcohol or driving). This could be evidenced as a verbal presentation (documented by the tutor in an observation record) or by means of a simulated presentation or a written assignment.

For M8, learners need to provide information to help the patient manage their mental health disorder effectively. The learner should demonstrate how this information can be tailored to the patient's needs and their ability to understand or retain information. This could be evidenced by linking M8 to P7 and M7 and D4 as part of a case study, a patient consultation scenario, assessed presentation or written assignment.

P9 requires learners to discuss the prescribing of pain control in relation to the analgesic ladder. The learner could complete a diagram of the pain ladder with analgesic drugs as part of a written assignment.

For M9, learners need to describe how adjuvant drugs can effectively improve pain management. This could be evidenced as part of a case study, presentation or written assignment.

D5 requires the learner to recommend ways in which the patient can optimise pain management. The learner should demonstrate how this could be tailored to a patient's ability to understand or retain information. This could be related to behavioural therapy and, in this regard, the learner could visit a pain clinic. Evidence could be provided as part of a case study, presentation or written assignment.

For P10, learners need to summarise the side effects the patient may experience when taking medication for pain management. This could be part of an assessed presentation or written assignment.

For M10, learners are required to discuss the side effects of medication used in pain management and relate the side effects to the action of the medication. This could be assessed as part of a presentation or written assignment.

P11 requires learners to explain the information that is given to patients about their medication. This could include how to take the medicines, for example information on dosage, frequency and storage and any other appropriate information relating to the medicine, such as taking NSAID's regularly will manage pain as well as reduce inflammation. This could be evidenced as a verbal presentation (documented by the tutor in an observation record), or by means of a simulated presentation or a written assignment.

For M11, learners are required to provide information to help the patient manage their pain effectively. This could be evidenced by linking M11 to P9, M9 and D5 as part of a case study, simulated patient consultation session, assessed presentation or written assignment.

For P12, learners need to explain when combination drugs can be used for general anaesthesia.

For M12, learners need to use named examples of the combination drugs to discuss the reason for the inclusion of each agent.

For D6, learners need to discuss the action of anaesthetic agents and combination drugs used at each stage of anaesthesia to include induction with pre-meds, maintenance with inhalation agents and reversal agents. This could be evidenced in the form of an informative flow chart.

For P13, learners are required to explain the reasons for using different routes for local anaesthetics. Particular attention may be given to the risks associated with some routes of administration.

M13 requires learners to discuss the advantages and disadvantages of the different local anaesthetic routes. This could be evidenced as a comparison table and assessed by the tutor.

For D7, learners need to evaluate the addition of adrenaline to a local anaesthetic injection site and the effect this may have on the surrounding area.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P3, P4, P5, M1, M2, M3, M4, D3	Parkinson's Disease and its Treatment	A pharmacy customer tells you her father has been diagnosed with Parkinson's disease. She hasn't heard of this disease and doesn't know how to look after her father. You are required to advise Mrs X with the following explanation: • Describe the neurochemical imbalance in the brains of people suffering from Parkinson's disease • Suggest, by name, some medicines that her father may be prescribed and how these medicines will work in his body • Give examples of side- effects that her father may experience from the prescribed medicines • Suggest ways in which she may support her father during the progression of his illness.	Simulated patient consultation session with tutor. Written assignment.
P6, P7, P8, M6, M7, M8, D4,	Alzheimer's Disease and its Treatment	You are required to help inform a group of nurses about Alzheimer's disease. Devise a presentation that will cover the following points: • Common medicines used in the treatment of Alzheimer's disease and how they work in the body • Examples of any side- effects that could be experienced as a result of prescribed medicines, why side effects occur and how these could be minimised • Information that should be given to patients regarding their medicines for the treatment of Alzheimer's disease and how to manage their condition	Observed Presentation.

Criteria covered	Assignment Title	Scenario	Assessment Method
P9, P10, P11, P12, M9, M10, M11, M12, D5, D12	Anaesthetic Medicines	A patient has been highlighted for major surgery. The pre- meds on the front of the drug chart include an anxiolytic and H2 receptor blocker. The patient will be induced by intravenous anaesthesia and maintained by inhalation anaesthesia. A muscle relaxant, anti-muscarinic and analgesia are also prescribed during surgery. Using named drug examples: • Explain why each drug has been included • Describe the action of each drug included and any possible side effects • Describe the stage of anaesthesia in which the drug is used • Information to be given to the patient about the medication they will be given for pain management and any other appropriate ways in which the patient can achieve effective pain management.	Written assignment.
P13, M13, D7	Local Anaesthetics	You are required to help inform a group of nurses about local anaesthetics. Devise a presentation that will cover the following points: • the reasons for the different administration routes for local anaesthetics and the advantages and disadvantages • the effect of adrenalin on local anaesthetic.	Observed Presentation.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 15: Communicating in Pharmacy
Unit 16: Dispensing and Supply of Medicines

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Greenstein B & Greenstein – *A Concise Clinical Pharmacology* (Pharmaceutical Press, 2007) ISBN 9780853695769

Horton-Szar D – *Crash Course Pharmacology* (Mosby, 2007) ISBN 978-0723434160

Neal M J – *Medical Pharmacology at a Glance* (John Wiley & Sons Ltd, 2009) ISBN 9781405181976

Rang HP Dale MM and Ritter J M – *Pharmacology* (Churchill Livingstone, 2007) ISBN 04430691115

Journals

British Journal of Pharmacology (British Pharmacological Society/Wiley-Blackwell, 2010)

Pharmaceutical Journal (Pharmaceutical Press, 2010)

The British Medical Journal (BMJ Publishing Group Ltd, 2010)

Websites

www.medicines.org.uk	The Electronic Medicines Compendium
www.netdoctor.co.uk	Net Doctor Website

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1] identifying assignment questions, resolving problems or answering patient queries. [IE2] planning research for assignment, including the content, length and design of presentations [IE3] exploring patient issues eg different ways of giving medicines where a patient has a mental health condition or a particular medical condition that affects the administration of medicines
Creative thinkers	[CT2] asking questions to clarify understanding has taken place and receiving feedback from the patient during simulated exercises [CT6] adapting learning to incorporate depth of experience
Reflective learners	[RL6] communicating with patients and a variety of staff disciplines in order to gain the correct information about the patient and their treatment
Self-managers	[SM2] working towards the completion of units and awards [SM3] organising their time for research purposes and assignment deadlines [SM5] managing their time effectively within a dispensing area
Effective Participators	[EP3] explaining the information to be given to patients about their medicines.

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1] identifying the answers to assignment questions [IE1] identifying the correct questions to ask a patient to ensure his/her understanding of what has been communicated to him/her [IE2] planning research for assignments, presentations or a placement for vocational experience [IE3] exploring patient issues eg how, when and for how long the medication should be taken
Reflective learners	[RL2] setting targets for assignment work [RL3] reviewing information for inclusion on assignment work [RL6]communicating with a tutor to support learning
Self-managers	[SM3] organising their time for research and assignment deadlines [SM4] receiving feedback from tutors to improve assignment grades

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using ICT systems to plan assignments in a coherent and logical way able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	accessing and saving information for assignment work aware of the need for passwords to ensure secure and safe access to ICT systems
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	using a variety of online resources, books, journals and websites to research information
Select information from a variety of sources to meet requirements of a complex task	using websites and electronic journals to access information
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	making sure information can be downloaded from websites for inclusion in assignments
Use appropriate software to meet the requirements of a complex data-handling task	collating and creating a single document for an assignment
Use communications software to meet requirements of a complex task	using email to send their assignment work to a tutor
Combine and present information in ways that are fit for purpose and audience	presenting information as written work or as a presentation
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how a document could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	participating in discussions when advising patients
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts during directed study
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing assignments.

Unit 9: Infections, Immunological Products and Vaccines

Unit code: L/601/7574

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit will provide learners with an understanding of the main medicine categories, including immunological products and vaccines used in the treatment and prevention of infections.

Unit introduction

This unit provides learners with an understanding of the underlying principles behind the way medicines work on the human body in treating infections. This unit extends learners' knowledge from physiology of health to disease processes. It explains the appropriate use and limitations of therapeutic agents.

The unit develops general concepts around knowledge of disease states and the principles of drug actions in these conditions. The fundamental principles are expanded so that the learner can apply the concepts of drug action in their workplace to provide appropriate dispensing, customer advice and over- the-counter sales.

Learning outcomes

On completion of this unit a learner should:

1 Understand how medicines are used to treat infections

2 Understand the uses of commonly available immunological products.

Unit content

1 Understand how medicines are used to treat infections

General principles: factors which govern the choice of anti-infective agents spectrum of action, organism factors, disease factors, patient factors, drug factors; wider implications of use

Resistance: mechanisms of resistance; innate and acquired resistance; avoiding resistance; problems associated with resistance

Antibacterials: blind therapy, sampling of cultures, knowledge of prevalent organisms; mode of action, use, limitations of drugs; commonly used groups antibacterial antibiotics and their target organisms; antimicrobial policies

Tuberculosis: phases of treatment, anti-tubercular drugs; difficulties of treatment eg duration of treatment, patient compliance and resistance

Antifungals: systemic infections; superficial infection; treatment of fungal infections; mode of action, use, limitation of drugs

Antivirals: common viral infections; herpes simplex, human immunodeficiency virus, viral hepatitis; influenza, severe acute respiratory syndrome (SARS), avian flu, H1N1 influenza (swine flu); mode of action, use, limitations of drugs

Antiprotozoals: malignant malaria, benign malaria, prophylaxis; listed centres for advice; other protozoal infections

Anthelmintics: roundworm, tapeworm and hookworm infestations, schistosomiasis; action, use, limitations

2 Understand the uses of commonly available immunological products

Response to invasion: non-specific response; specific immune response; acquisition of immunity (natural, artificial, active, passive)

General principles of vaccination: vaccination and immune response; reasons for immunisation; immunisation schedule; immunisation of high-risk groups; immunisation procedures for international travel; immunisation procedures in the event of pandemics

Vaccines in common use: diseases; symptoms; reasons for vaccination; vaccines and antisera available and limitations for each disease; care of vaccines (records, storage, transport, disposal, cold chain)

Immunoglobulins: normal immunoglobulins; specific immunoglobulins; anti-D immunoglobulin; interferons; availability; reasons for use

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe common infections and their associated symptoms	**M1**	describe the pharmacological action of the medicines used to treat infections	**D1**	discuss the factors involved in the choice of therapeutic agents for the treatment of infections, providing information regarding prescribing guidelines and limitation of use
P2	explain how common medicines are used to treat infections, giving examples of those in common use [CT2]				
P3	summarise common side effects ofmedicines used to treat infections	**M2**	discuss the reasons why side effects occur with medicines used to treat infections	**D2**	recommend ways in which patients can manage their anti-microbial medication effectively, including examples of information and counselling which may be used
P4	explain the information that must be given to patients about their infection-treating medicines [CT2, EP3]	**M3**	explain how counselling patients helps improve their compliance of anti-microbial treatments, including examples of counselling		
P5	discuss the factors that influence the selection of antimicrobial medicines	**M4**	explain how antimicrobials achieve selective toxicity	**D3**	through the use of examples, explain the problems of antibiotic resistance and how it can be minimised
P6	explain the general principles and benefits of vaccination	**M5**	describe the pharmacological action of vaccines used	**D4**	discuss natural, artificial, active and passive immunity.
P7	discuss vaccines in the current UK vaccination schedule, giving examples of the current schedule [IE4]	**M6**	provide examples of when vaccination is used apart from in the vaccination schedule and the benefit of such vaccination.		
P8	explain why correct storage of immunological products is vital, providing examples of best practice and workplace policies.				

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included in this unit as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan demonstrates one way of planning the delivery and assessment of this unit.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Formal teaching on infectious diseases and common medicines used to treat these infections. Tutor led discussion on how and why medicines are used, including common side effects. Case used studies to identify the importance of consulting with patients and how to improve patient compliance. Personal study time and research.
Assignment 1: Infectious Diseases (P1, P2, P3, P4, P5, M1, M2, M3, M4, D1, D2, D3)
Learning outcome 2 Formal teaching on vaccination and immune response. Tutor-led discussion on commonly used vaccinations and immunoglobulin products, vaccination in the case of pandemics. Case studies used to identify the common problems relating to vaccination and the importance of consulting with patients. Personal study time and research.
Assignment 2:Vaccination and Immune Response (P6, P7, P8, M5, M6, D4)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners need to describe common infections and their associated symptoms. This could be evidenced by the learner completing a presentation on common infections, selected by the tutor. The tutor should select the examples given carefully, to ensure the unit is covered sufficiently.

For P2, learners need to explain how antimicrobials are used in common infections and give examples of specific infection and the antimicrobial of choice. Evidence could be presented in a written assignment.

For P3, learners are required to summarise common side effects of antimicrobial medicines. Evidence could be presented in a written assignment which included examples of side effects.

For P4, learners need to explain information given to patients about their antimicrobial medicines. Evidence could be presented in the form of a patient information leaflet design.

For P5, learners are required to discuss the factors that influence the selection of antimicrobial medicines. Evidence could be presented in a written assignment.

For P6, learners are required to explain the general principles of vaccination and the benefits of vaccination. Evidence could be presented in a written assignment.

P7 requires learners to discuss vaccines in the current UK schedule and give examples of the current infant vaccination schedule. Evidence could be presented in an information leaflet developed by the learner.

For P8, learners need to be able to identify the correct storage conditions for immunological products and explain why correct storage is vital. Evidence could be presented in a written assignment and/or information leaflet which gives details of best practice for storage.

For M1, learners are required to describe the pharmacological action of antimicrobials used to treat infection. Learners should give examples of antimicrobial use. Evidence could be presented in a presentation.

For M2, learners need to discuss the reasons why side effects occur, referring to examples of common side effects in the use of antimicrobials. Evidence could be presented in a written assignment.

For M3, learners need to explain how counselling patients improves patient compliance with antimicrobial treatments. The explanation should include examples of counselling. Evidence could be presented in the form of a patient information leaflet design with supporting information.

For M4, learners are required to explain how antimicrobials achieve selective toxicity. Evidence could be presented in a written assignment.

For M5, learners need to describe the pharmacological action of vaccines. Evidence could take the form of a presentation to peers on the topic of vaccination.

For M6, learners are required to produce examples of when vaccination is used apart from in the vaccination schedule and the benefits of such vaccination. Evidence could be presented in an information leaflet developed by the learner.

For D1, learners need to discuss the factors involved in the choice of therapeutic agents and provide information regarding prescribing guidelines and limited-use antimicrobials. Evidence could be presented in a presentation.

For D2, learners need to recommend ways in which patients can manage their antimicrobial medication effectively, including examples of information and counselling points. Evidence could be presented in the form of a patient information leaflet.

For D3, learners should explain the problems of antibiotic resistance and also explain how it can be minimised. Learners should illustrate their explanation with examples of antibiotic resistance and how it can be minimised. Evidence could be presented in a written assignment.

D4 requires learners to discuss natural, artificial, active and passive immunity. Evidence could be presented in a written assignment.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the assessment and grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment title	Scenario	Assessment method
P1, P2, P3, P4, P5, M1, M2, M3, M4, D1, D2, D3	Infectious Diseases	You have been asked by your pharmacist to provide a briefing session to untrained junior members of staff. The session should cover common infections, their treatment and side effects.	Presentations. Written assignment. Patient information leaflet. Observation records.
P6, P7, P8, M5, M6, D4	Vaccination and Immune Response	You have been asked by a doctor's surgery to produce a patient information leaflet on vaccinations and facilitate a short presentation to their staff.	Presentations. Written assignment. Patient information leaflet. Observation records.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy Technicians
Unit 2: Biological Principles for Pharmacy
Unit 4: Human Physiology for Pharmacy
Unit 5: Actions and Uses of Medicines
Unit 7: Cardio-Respiratory Medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines
Unit 12: Eye, Ear, Nose and Dermatological Medicines
Unit 17: Pharmaceutics

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, for example *MedicinesComplete*. It would useful for learners to have access to a current medical dictionary (nursing level would be suitable).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Pharmacology and Clinical Pharmacology Textbooks

Bennett PN and Brown MJ – *Clinical Pharmacology, 10th Edition* (Churchill Livingstone, 2008) ISBN 978-0-443-10244-8

Clayton B, Stock Y, Cooper S – *Basic Pharmacology for Nurses, 15th Edition* (Mosby, 2009) ISBN 0323057802

Neal MJ – *Medical Pharmacology at a Glance, 6th Edition* (Wiley-Blackwell, 2009) ISBN 978-1-4051-8197-6

Rang HP, Dale MM, Ritter JM and Flower RJ – *Pharmacology, 6th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 04430691 15

Stringer J – *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2005) ISBN 0071458182

Walker R and Whittlesea C – *Clinical Pharmacy and Therapeutics, 4th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 0443102856

Wecker L, Crespo L, Dunaway G, Faingold C and Watts S – *Brody's Human Pharmacology, 5th Edition* (Mosby, 2010) ISBN 978-0-323-05374-7

Drug Use Textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P – *Symptoms in the Pharmacy: A Guide to the Management of Common Illness, 6th Edition* (Blackwell Science, 2005) ISBN 140518079X

Dodds L (Editor) – *Drugs in Use: Clinical Case Studies for Pharmacists, 3rd Edition* (Pharmaceutical Press, 2003) ISBN 0853695415

Harman RJ and Mason P (Editors) – *Handbook of Pharmacy Healthcare, 2nd Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry JA – *The British Medical Association's Concise Guide to Medicines and Drugs, 7th Edition* (Dorling Kindersley, 2007) ISBN 1405317779

McGavock H – *How Drugs Work, 2nd Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A – *Non-Prescription Medicines, 3rd Edition* (Pharmaceutical Press, 2006) ISBN 0853696446

Salisbury D, Ramsay M (editors), Noakes K, Immunisation Against Infectious Disease, 3rd Edition (The Stationary Office, 2006) ISBN -13-978-0-11-322528-6

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

Websites

www.emc.vhn.net	Electronic Data Sheet Compendium
www.medicines.org.uk	Medicines Guide
www.doh.gov.uk/green book	Department of Health Immunisation Updates

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Independent enquirers	[IE4] finding out information about immunisation schedules
Creative thinkers	[CT2] asking questions to check understanding has taken place when communicating with patients about their medicines
Effective participators	[EP3] explaining information given to patients about their medicines

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE2] planning and carrying out research for assignments
Creative thinkers	[CT2] asking questions during discussion to extend their thinking
Reflective learners	[RL6] communicating their learning in relevant ways to different audiences
Team workers	[TW1] collaborating with others to work towards common goals in group work
Self-managers	[SM3] organising their time, resources and prioritising actions for assessments

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	saving information and assignment work in a folder for future use
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using ICT systems to find information for assignments
Manage information storage to enable efficient retrieval	aware of keeping passwords safe and non-disclosure to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from online books and journals
Select information from a variety of sources to meet requirements of a complex task	accessing information from identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	making sure the information they require can be obtained from a website
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that contains all the information required for their work
Use communications software to meet requirements of a complex task	using email to communicate with other learners, colleagues and tutors
Combine and present information in ways that are fit for purpose and audience	presenting information from a document as requested in the assessment brief
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how documents and presentations could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in group discussions
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading and compiling information from books and journals
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing assignments

Unit 10: Endocrine and Genito-Urinary Medicines

Unit code: Y/601/7576

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit examines the main medicine categories and their actions in the treatment of endocrine genito-urinary disorders.

Unit introduction

This unit provides learners with knowledge of the action and uses of drugs in the treatment of endocrine and genito-urinary disorders. The unit also introduces learners to the use of medicines in obstetrics and in treating gynaecological disorders. Learners will acquire knowledge and skills to enable them to identify different disease states and the different treatment options available.

Learning outcomes

On completion of this unit a learner should:

1 Understand how medicines are used to treat disorders of the endocrine system

2 Understand how medicines are used to treat gynaecological disorders and in obstetrics

3 Understand how medicines are used to treat genito-urinary disorders.

Unit content

1 Understand how medicines are used to treat disorders of the endocrine system

Thyroid gland: hypothyroidism; hyperthyroidism; symptoms; treatment eg thyroid replacement therapy, antithyroid drugs, radio-iodine therapy, surgery, symptomatic treatment

Pancreas: diabetes; insulins; oral anti-diabetics; complications of diabetes and its treatment; patient monitoring of the disease; treatment of hypoglycaemia; pancreatitis, symptoms and treatment

Sex hormones: oestrogens and anti-oestrogens; progesterones; male sex hormones and antagonists; hormone replacement therapy and its use in the treatment of osteoporosis

Hypothalamic and pituitary hormones: corticotrophins and gonadotrophins; growth hormone; antidiuretic hormone analogues

Corticosteroids: mineralocorticoids; mode of action, use and limitations (replacement therapy); glucocorticoids; replacement, anti-inflammatory use, adverse effects, steroid warning cards, consulting with patients and offering advice, CSM advice, immunosuppressant use

2 Understand how medicines are used to treat gynaecological disorders and in obstetrics

Reproductive system: hormonal contraceptives (combined and progesterone only); alternatives to hormonal contraception; emergency contraception (hormonal and IUD)

Medicines used in obstetrics: induction of abortion; induction or augmentation of labour; prevention and treatment of haemorrhage; myometrial relaxants used to inhibit premature labour

3 Understand how medicines are used in the treatment of genito-urinary disorders

Genital system: infections of the genitals; symptoms and treatment of sexually transmitted diseases; symptoms and treatment of vaginal and vulval candidiasis

Genito-urinary system; medicines used in the treatment of urinary retention, urinary incontinence and nocturnal enuresis; medicines used in benign prostatic hyperplasia (BPH); uses and limitations of medicines used in the treatment of erectile disorders

Kidney dialysis; types; reasons for use; fate of medicines used in dialysis patients

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe common disorders affecting the endocrine system	**M1**	discuss the physiological changes that produce the symptoms of endocrine disorders	**D1**	analyse the factors involved in the choice of therapeutic agent for the treatment of endocrine disorders
P2	explain how common medicines are used in each of the endocrine system disorders [CT2]	**M2**	describe the therapeutic action of medicines used in the treatment of endocrine disorders	**D2**	recommend ways in which the patient could manage their endocrine disorder and reduce the side effects of treatments
P3	summarise common side effects of medicines used to treat disorders of the endocrine system	**M3**	discuss the reasons why side effects may occur with medicines used to treat endocrine system disorders		
P4	explain the information given to patients about their medicines for the treatment of their endocrine disorder [CT2, EP3]	**M4**	provide information to the patient to manage their endocrine disorder effectively		
P5	describe common gynaecological and obstetric disorders	**M5**	discuss the physiological changes that occur to produce the symptoms of gynaecological and obstetric disorders	**D3**	analyse the factors involved in the choice of therapeutic agent for gynaecological and obstetric disorders
P6	explain how common medicines are used in each of the gynaecological and obstetric disorders [CT2]	**M6**	describe the therapeutic action of medicines used in the treatment of gynaecological and obstetric disorders		
P7	summarise common side effects ofmedicines used to treat gynaecological and obstetric disorders	**M7**	discuss the reasons why side effects may occur with medicines used to treat gynaecological and obstetric disorders	**D4**	recommend ways in which the patient could manage their gynaecological or obstetric disorder and reduce the side effects experienced
P8	explain the information that must be given to patients about their gynaecological or obstetrics medicines [CT2, EP3]	**M8**	provide information to patients to manage their gynaecological or obstetric condition effectively		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P9 describe the use, limitations and side effects of the main methods of contraception	**M9** provide information about contraception to the patient to ensure the most effective method is chosen	
P10 describe common disorders affecting the genito-urinary system	**M10** discuss the physiological changes that produce the symptoms of disorders of the genito-urinary system	
P11 explain how common medicines are used in each of the genito-urinary disorders [CT2]	**M11** describe the therapeutic action of medicines used in the treatment of genito-urinary disorders	
P12 summarise common side effects of medicines used to treat genito-urinary disorders	**M12** discuss the reasons why side effects may occur with medicines used to treat genito-urinary disorders	**D5** recommend ways in which the patient could manage their genitourinary disorder and reduce side effects
P13 explain the information that must be given to patients about their genito-urinary medicines [CT2, EP3]	**M13** provide information to the patient to manage their genito-urinary disorder effectively	
P14 describe the effect that renal dialysis will have on patient medication		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments
Learning outcome 1 Describe the signs and symptoms of hypothyroidism and the action of treatments prescribed for hypothyroidism. Describe the signs of hyperthyroidism, the action of treatments used for hyperthyroidism. Describe the signs and symptoms of types of diabetes and the complications of the disease. Use of tutorials, workbooks, self-study or research to investigate the action and use of treatments for diabetes, including the importance of patient monitoring of diabetes. Describe the signs symptoms and treatment of hypoglycaemia and hyperglycaemia. Describe the signs and symptoms of pancreatitis and the action and use of treatments for the disease. Describe the symptoms experienced with over or underproduction of the common sex hormones. Describe the treatments given to increase or decrease the production of the common sex hormones. Describe the use of hormone replacement therapy and its use in the treatment of osteoporosis. Describe the signs and symptoms of overproduction or decreased production of corticotrophins, gonadotrophins and growth hormone. Describe the signs and symptoms of over production or decreased production of mineralocorticoids and glucocorticoids. Learners investigate the mode of action of replacement therapy and its use and limitations. Discuss the action and use of corticosteroids for anti-inflammatory use. Use of tutorials, workbooks, self-study or research to investigate the importance of recognising adverse effects of corticosteroids, giving steroid warning cards, consulting with patients and CSM advice. Describe the immunosuppressant use of corticosteroids. **Assignment 1: Endocrine Disorders** (P1, P2, P3, P4, M1, M2, M3, M4, D1, D2)
Learning outcome 2 Describe the action and use of hormonal contraceptives (combined and progesterone only). Discuss alternatives to hormonal contraception. Discuss the action of emergency contraception. Describe the medicines used to induce abortion. Describe the action and use of medicines used to induce or augment labour. Describe how medicines can be used to prevent and treat haemorrhage. Describe the action of myometrial relaxants when used to inhibit premature labour. **Assignment 2: Methods of Contraception** (P9, M9) **Assignment 3: Gynaecological and Obstetric Disorders** (P5, P6, P7, P8, M5, M6, M7, M8, D3, D4)

Topic and suggested assignments/activities and/assessment
Learning outcome 3
Identify organisms that cause infections of the genitals.
Describe the signs and symptoms of sexually transmitted diseases.
Describe the action and use of treatments for sexually transmitted diseases.
Describe the symptoms and treatment of vaginal and vulval candidiasis.
Describe the symptoms of urinary retention, urinary incontinence and nocturnal enuresis.
Describe the action and use of treatments for urinary retention, urinary incontinence and nocturnal enuresis.
Describe the symptoms of benign prostatic hyperplasia (BPH) and the action and limitations of medicines used to treat this condition.
Describe the medicines used to treat erectile disorders.
Discuss reasons why a patient may receive kidney dialysis.
Tutorials and/or workbook assignments on the different types of dialysis used and what happens to medicines when a patient is receiving dialysis.
Assignment 4: Disorders of the Genito-Urinary system (P10, P11, P12, P13, P14, M10, M11, M12, M13, D5)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners should describe the common disorders affecting the endocrine system. This could be evidenced by a verbal presentation (documented by the tutor in an observation record) or by means of a written assignment.

For M1, learners should discuss how the body changes to produce the symptoms of the endocrine disorders. This could be evidenced by a verbal presentation (documented by the tutor in an observation record) or by means of a written assignment.

For D1, learners are required to analyse the factors involved in the choice of therapeutic agents for endocrine disorders. This could be evidenced as part of a verbal presentation of a case study (documented by the tutor in an observation record) or as a written assignment.

For P2, learners need to explain how common medicines are used in treating endocrine disorders. This could include information on how to take the medicines for example dosage and frequency. The learner could also make reference to different medicines for endocrine disorders for example injected insulin, inhaled insulin, oral medicines or pre-op solution for thyrotoxicosis. This could be evidenced as a verbal presentation (documented by the tutor in an observation record) or by means of a simulated patient consultation session or a written assignment.

For M2, learners are required to describe the therapeutic action of common medicines used to treat the endocrine disorders. Learners should relate the action of the medicines to homeostasis and symptoms of the disorder. This could be evidenced as part of a verbal presentation of a case study (documented by the tutor in an observation record) or as a written assignment.

For D2, learners are required to recommend ways in which the patient could manage their endocrine disorder and the side effects of treatments. The learner could provide information on recognising the symptoms of hyperglycaemia or hypoglycaemia and give advice on how to reduce these effects. This could be evidenced by a simulated patient consultation session or as part of verbal presentation of a case study (documented by the tutor in an observation record) or written assignment.

For P3, learners need to summarise the common side effects of medicines prescribed for the endocrine disorders. This could be evidenced as part of verbal presentation of a case study (documented by the tutor in an observation record) or as a written assignment.

For M3, learners need to discuss the reasons why side effects occur with treatments for endocrine disorders. The learner could relate the side effects to the action of the medicines, which would link to the evidence for P1, P2, P3, M1 and M2. This could be evidenced as part of a verbal presentation of a case study (documented by the tutor in an observation record) or as a written assignment.

For P4, learners need to explain information to patients about their medicines for the treatment of endocrine disorders. This could include information on how to take the medicines for example how to use a pen device, frequency, storage and other appropriate information. This could be evidenced by a simulated patient consultation session marked by the tutor using a generic check sheet.

For M4, learners are required to provide information to the patient to manage their endocrine disorder effectively. This could be linked to D2. The learner could produce evidence for M4 in the form of a patient information leaflet or as part of a verbal presentation (documented by the tutor in an observation record) or written assignment.

P5 requires learners to describe common gynaecological and obstetric disorders. This could be evidenced by a verbal presentation (documented by the tutor in an observation record) or written assignment.

For M5, learners need to discuss the changes within the body which produce the symptoms of gynaecological and obstetric disorders. This could be evidenced by a verbal presentation (documented by the tutor in an observation record) or written assignment.

For D3, learners need to analyse the factors involved in the choice of therapeutic agent for the treatment of gynaecological or obstetric disorders. This could depend, for example, on the age and choice of the patient. This could be evidenced as part a case study presented verbally (documented by the tutor in an observation record) or as part of a written assignment.

For P6, learners are required to explain how medicines are used in each of the disorders. The learner should explain the range of devices used for gynaecological and obstetric disorders. The medicines could be presented as oral tablets, gels, patch implants and injections. P6 could be linked to the evidence for P7, M6, M7 and D3. P6 could also be evidenced as part of a presentation or written assignment.

For M6, learners need to describe the therapeutic action of medicines used in the treatment of gynaecological and obstetric disorders. This could be evidenced as part of a verbal presentation (documented by the tutor in an observation record) or a written assignment.

For P7, learners need to summarise the common side effects of medicines used to treat gynaecological and obstetric disorders. This could be evidenced as a simulated patient consultation session or as part of a presentation or written assignment.

M7 requires learners to discuss why side effects occur with medicines used to treat gynaecological and obstetric disorders, relating the side effects to the action of the medicine. This could be linked to the evidence for P7.

For D4, learners are required to recommend ways in which the patient could manage the gynaecological disorder. This could be evidenced as presentation of a case study or as part of verbal presentation (documented by the tutor in an observation record) or written assignment.

P8 requires learners to explain the information given to the patient about their gynaecological and obstetric medicines. This could be linked to P6, P7, M6 and M7. P8 could be evidenced as part of a simulated patient consultation session or verbal presentation (documented by the tutor in an observation record) or by means of a written assignment.

For M8, learners need to provide information to patients to manage their gynaecological or obstetric condition effectively. The learner could provide information on alternative non-drug therapies which may alleviate symptoms for example relaxation techniques used during labour. Learners could create a patient information leaflet as evidence.

For P9, learners are required to describe the use and limitations of the main methods of contraception. This could be evidenced by the creation of a poster display.

For M9, learners need to provide information to patients about contraception methods. This could be linked to P9 and presented as an information leaflet.

P10 requires learners to describe the common disorders affecting the genito-urinary system. Disorders could include infections, infestations of the genitals and disorders of the genito-urinary system. This could be evidenced as a verbal presentation (documented by the tutor in an observation record) or written assignment.

For M10, learners need to discuss the changes within the genito-urinary system that produce the symptoms of the disorders. This could be evidenced as a verbal presentation (documented by the tutor in an observation record) or a written assignment.

For P11, learners are required to explain how common medicines for genito- urinary system disorders are used. The learner could offer advice on different types of medicines including applications, paints and oral therapy. This could be evidenced as a simulated patient consultation session, presentation or written assignment.

For M11, learners need to describe how common medicines act within the genito- urinary system. The learner could relate the action to the type of disorder for example the use of antibacterials for infections, applications for infestations, or nasal sprays for nocturnal enuresis. This could be evidenced as part of a case study, verbal presentation (documented by the tutor in an observation record) or written assignment.

For P12, learners need to summarise the common side effects experienced by patients undergoing genito-urinary disorder treatments. The learner could relate the side effects to the medicine and how it is used or applied. This could be evidenced by a simulated patient consultation session or as part of a written assignment.

For M12, learners need to discuss why the side effects occur with treatments for genito-urinary disorders and relate the side effect to the action and type of medicine used. This could be evidenced during a simulated patient consultation session, presentation or written assignment.

P13 requires learners to explain information given to patients about their treatments for genito-urinary disorders. Learners could evidence P13 by means of a patient information leaflet.

For M13, learners need to provide information to the patient to manage their genito-urinary system condition effectively. This could be evidenced as part of a simulated patient consultation session, presentation of a case study or as part of a written assignment.

For P14, learners need to describe the effect that renal dialysis will have on patient medication. Learners should make references to the appendix in the BNF and could present the relevant evidence as part of a written assignment.

For D5, learners need to recommend ways in which the patient could manage their genito-urinary disorder and reduce side effects. This could be evidenced by a simulated patient consultation session, verbal presentation (documented by the tutor in an observation record) or written assignment.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P3, P4, M1, M2, M3, M4, D1, D2	Endocrine Disorders	Ms Z is suffering from excessive tiredness, she has gained weight, her hair has thinned dramatically and she has ridged and brittle nails. Suggest which endocrine disorder Ms Z is suffering from. Suggest a program of treatment for Ms Z, including an explanation of how any medication would treat symptoms, any side effects she may suffer from during the treatment and recommend ways in which she could reduce the symptoms and side effects herself. Explain clearly what information she should be given to help her effectively manage her disorder.	Case study.
P9, M9	Methods of Contraception	You have been asked to create an A3 poster for display in a doctor's surgery. The poster should depict the main methods of contraception, their use and limitations. Ensure the poster provides information to the patients to enable them to make an informed choice about contraception.	Written display.

Criteria covered	Assignment Title	Scenario	Assessment Method
P5, P6, P7, P8, M5, M6, M7, M8, D3, D4	Gynaecological and Obstetric Disorders	You are required to help inform a group of nurses about gynaecological and obstetric disorders. Devise a presentation that will cover the following points: • Common gynaecological and obstetric disorders • Common medicines used in the treatment of gynaecological and obstetric disorders and how they work in the body • Examples of any side- effects that could be experienced as a result of prescribed medicines, why side effects occur and how these could be minimised • Information that should be given to patients regarding their gynaecological or obstetric medicine and how to manage their condition.	Observed Presentation.
P10, P11, P12, P13, P14, M10, M11, M12, M13, D5	Disorders of the Genito-Urinary system	You are required to help inform a group of nurses about disorders of the genito-urinary system. Devise a presentation that will cover the following points: • Common disorders affecting the genito-urinary system and associated symptoms • Common medicines used in the treatment of genito-urinary disorders and how they work in the body • Examples of any side- effects that could be experienced as a result of prescribed medicines, why side effects occur and how these could be minimised • Information that should be given to patients regarding their medicines for their genito-urinary disorder and how to manage their condition • The effects of renal dialysis on patient medication.	Observed Presentation.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 15: Communicating in Pharmacy

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Greenstein B & Greenstein – *A Concise Clinical Pharmacology* (Pharmaceutical Press, 2007) ISBN 9780853695769

Horton-Szar D – *Crash Course Pharmacology* (Mosby, 2007) ISBN 978-0723434160

Neal M J – *Medical Pharmacology at a Glance* (John Wiley & Sons Ltd, 2009) ISBN 9781405181976

Rang HP Dale MM and Ritter J M – *Pharmacology* (Churchill Livingstone, 2007) ISBN 0443069115

Journals

British Journal of Pharmacology (British Pharmacological Society/Wiley-Blackwell, 2010)

Pharmaceutical Journal (Pharmaceutical Press, 2010)

The British Medical Journal (BMJ Publishing Group Ltd, 2010)

Websites

www.medicines.org.uk	The Electronic Medicines Compendium
www.netdoctor.co.uk	Net Doctor Website

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1] identifying assignment questions, resolving problems and answering patients' queries [IE2] planning research for assignments including the content, length and design of presentations [IE3] exploring patient issues eg different ways of giving medicines such as oral, injection
Creative thinkers	[CT2] asking questions to check understanding has taken place when communicating with patients about their medicine
Effective Participators	[EP3] explaining the information to be given to patients about their medicines.

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1] identifying questions to resolve problems [IE2] planning research for assignments [IE3] exploring patient issues
Creative thinkers	[CT2] asking questions to clarify understanding
Reflective learners	[RL2] setting targets for assignment work [RL3] reviewing information for inclusion in assignment work [RL6] communicating with tutors to support learning [RL6] communicating with patients and staff in a variety of ways eg if hard of hearing or patient doesn't speak English
Self-managers	[SM3] organising their time for research and planning for assignment deadlines [SM5] dealing effectively with time constraints when working in a busy dispensary or hospital Trust [SM6] able to behave in a professional manner when faced with a variety of medical situations.

Functional Skills – Level 2

Skill	When learners are ...
ICT – Using ICT systems	
Plan solutions to complex tasks by analysing the necessary stages	accessing ICT systems to research information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using an electronic calendar to time manage self -directed study able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information on a removable data storage device aware of keeping their password confidential
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching information from online books and journals
Select information from a variety of sources to meet requirements of a complex task	obtaining relevant information from websites and electronic journals
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if the information they require can be obtained from a website
Use appropriate software to meet the requirements of a complex data-handling task	creating a single assignment that has all the information required for the criteria
Use communications software to meet requirements of a complex task	using email to send an assignment to their tutor
Combine and present information in ways that are fit for purpose and audience	presenting information as required for their assignment
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	receiving feedback and discussing how the assignment could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions during formal learning, communicating with patients
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts during discussions reading research material
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing assignments and presentations

Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines

Unit code: D/601/7577

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit aims to provide learners with knowledge of the action and uses of drugs in the treatment of malignancy, immunosuppressive and musculoskeletal disorders.

Unit introduction

This unit will equip learners with the knowledge and skills to enable them to identify different disease states and identify the different treatment options available.

This unit provides learners with an understanding of the underlying principles behind the way medicines work on the human body. The unit extends learners' knowledge from physiology in health to disease processes. It also explains the appropriate use and limitations of therapeutic agents, examining the main medicine categories and their actions in the treatment of malignant disease, immuno-suppression and musculoskeletal disorders.

The unit develops general concepts around knowledge of disease states and the principles of drug action in these conditions. The fundamental principles are expanded so that learners can apply the concepts of drug action in their workplace to provide appropriate dispensing, consulting with patients and over the counter sales.

Learning outcomes

On completion of this unit a learner should:

1 Know the behavioural difference between normal cells and malignant cells

2 Understand the treatments used for malignant diseases

3 Understand how medicines are used to treat musculoskeletal disorders.

Unit content

1 Know the behavioural difference between normal and malignant cells

Difference: normal cells; malignant cells; metastasis

2 Understand the treatments used for malignant diseases

Classification: alkylating agents; antimetabolites; cytotoxic antibiotics; platinum compounds; vinca alkaloids; other antineoplastic drugs

Use: drug regimens

Limitations: toxicity; side effects

Hormones: sex hormones; hormone antagonists

Drugs affecting immune response: eg antiproliferative immunosuppressants, corticosteroids, immunomodulating drugs

Monoclonal antibodies: eg Rituximab, Alemtuzemab

Basic principles of cancer treatment: techniques eg different types of surgery, radiotherapy, combination treatment; use of drugs eg pre-operatively, post-operatively

3 Understand how medicines are used to treat musculoskeletal disorders

Drugs used in arthritis and other inflammatory disorders: non-steroidal anti-inflammatory agents (NSAIDs); corticosteroids, disease modifying anti-rheumatic agents(DMARDs)

Drugs used in the treatment of gout: long term treatment; short term treatment

Drugs used in the treatment of miscellaneous skeletal disorders: drugs used in thetreatment of eg osteoporosis, Padget's disease, osteoarthritis, rheumatoid arthritis

Drugs used in soft tissue disorders: rubefacients; topical antirheumatics

Drugs used in neuromuscular disorders: enhancement of neuromuscular transmission;muscle relaxants

Consulting with patients: advising patients on medication taken for differentmusculoskeletal disorders

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 describe the behavioural differences between normal and malignant cells	**M1** explain the use of combination therapy	**D1** evaluate, with examples, how anti-cancer drug choice and the cell cycle affect treatment for cancer
P2 describe the common malignant diseases	**M2** describe the pharmacological action of medicines used to treat malignant diseases	**D2** analyse the factors involved in the choice of therapeutic agents used in the treatment of malignancy
P3 explain how common treatments are used in the treatment of malignant diseases [CT2]		
P4 summarise common side effects oftreatments used for malignant diseases [IE2]	**M3** discuss the reasons why side effects may occur with medicines used to treat malignant diseases	**D3** recommend ways in which patients could manage their malignancy medication effectively
P5 explain the information that must be given to patients about their medicines for the treatment of malignant diseases [CT2, EP3]	**M4** explain how counselling patients with malignant diseases helps improve their compliance	
P6 describe common disorders affecting the musculoskeletal system	**M5** describe the pharmacological action of medicines used to treat musculoskeletal disorders	**D4** analyse the factors involved in the choice of therapeutic agents for musculoskeletal disorders
P7 explain how common treatments are used in the treatment of musculoskeletal disorders [CT2]		
P8 summarise common side effects of treatments used for musculoskeletal disorders [IE2]	**M6** discuss the reasons why side effects may occur with medicines used to treat musculoskeletal disorders	**D5** recommend ways in which patients can manage their musculoskeletal condition and medication effectively.
P9 explain the information that must be given to patients about their musculoskeletal medicines. [CT2, EP3]	**M7** explain how counselling patients helps improve their compliance with musculoskeletal medicines.	

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Formal teaching on the behavioural differences between normal and malignant cells. Tutor led discussion: how combination therapy targets different stages of the cell cycle. Personal study time and research. **Assignment 1: Behavioural Differences between Normal and Malignant Cells and Links to Cancer Treatment** (P1, M1, D1)
Learning outcome 2 Formal teaching on malignant diseases and common medicines used to treat these diseases. Tutor led discussion: How and why medicines used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research. **Assignment 2: Malignant Disease and Treatments** (P2, P3, P4, P5, M2, M3, M4, D2, D3)
Learning outcome 3 Formal teaching on musculoskeletal disorders and common medicines used to treat these disorders. Tutor led discussion: how and why medicines used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research. **Assignment 3: Musculoskeletal Disorders** (P6, P7, P8, P9, M5, M6, M7, D4, D5)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners are required to describe the behavioural differences between normal and malignant cells. This could be evidenced by the learner producing a written assignment containing relevant images.

For P2, learners are required to describe common malignant diseases. This could be evidenced by the learner completing a presentation on a common disorder selected by the tutor. The tutor should select the given examples carefully so the unit is covered sufficiently.

For P3, learners need to explain how common treatments are used in the treatment of malignant diseases. This could be evidenced by the learner completing a table or a written assignment.

For P4, learners are required to summarise the common side effects of treatments for malignant diseases. This could be evidenced by the learner completing a table or a written assignment.

For P5, learners need to explain information given to patients on the treatment of their malignant disease. This could be evidenced by the learner producing a patient information leaflet.

For P6, learners are required to describe the common disorders affecting the musculoskeletal system. This could be evidenced by the learner completing a presentation on a common disorder selected by the tutor. The tutor should select any given examples carefully so the unit is covered sufficiently.

For P7, learners need to explain how common treatments used in musculoskeletal disorders. This could be evidenced by the learner building on the evidence for P6, completing a written assignment or producing a table.

For P8, learners need to summarise common side effects of musculoskeletal disorder treatments. This could be evidenced by the learner building on P6 and P7 and producing a written assignment.

For P9, learners need to show that they can explain information to be given to patients about their treatment for musculoskeletal disorders. This could be evidenced by role play, a patient information leaflet or a table. The tutor should select any given examples carefully so the unit is covered sufficiently.

For M1, learners need to explain the use of combination therapy used in malignant disease. This could be evidenced by the learner producing a written assignment containing images or by means of a presentation. The tutor should select any given examples carefully so the unit is covered sufficiently.

For M2, learners need to describe the pharmacological action of the medicines used to treat malignancy. This could be evidenced by the learner producing a written assignment containing images or by means of a presentation. The tutor should select any given examples carefully so the unit is covered sufficiently.

M3 requires learners to discuss the reasons why side effects occur with medicines used to treat malignancies. This could be evidenced by the learner producing a written assignment or a presentation on a particular medicine. The presentation should include handout notes.

For M4, learners need to explain how patient counselling improves compliance with malignancy treatments. This could be evidenced by the learner producing a written assignment or a presentation.

For M5, learners are required to describe the pharmacological action of medicines used to treat musculoskeletal disorders. This could be evidenced by the learner producing a written assignment containing images or by means of a presentation to the class on a particular medicine chosen by the tutor. The tutor should select any given examples carefully so the unit is covered sufficiently.

For M6, learners need to discuss the reasons why side effects may occur with medicines used in musculoskeletal disorders. This could be evidenced by the learner producing a written assignment, completing a presentation or taking part in a question and answer session.

For M7, learners need to explain how counselling patients helps improve compliance with their musculoskeletal medication. This could be evidenced by the learner producing a written assignment or a presentation.

To achieve D1, learners need to evaluate how anti-cancer drug choice and the cell cycle affect treatment for cancer. Their evaluation should be supported by appropriate examples. This could be evidenced by the learner producing a flow chart or table.

For D2, learners need to analyse the factors involved in the choice of therapeutic agents used in malignancy. This could be evidenced by the learner producing a written assignment or a presentation with handout notes.

For D3, learners are required to recommend ways in which patients could manage their anti-cancer medications effectively. This could be evidenced by the learner producing a leaflet.

For D4, learners need to analyse the factors involved in the choice of therapeutic agents used in musculoskeletal disorders. This could be evidenced by the learner completing a written assignment or presenting to the class on a topic chosen by the tutor. The tutor should select any given examples carefully so the unit is covered sufficiently.

For D5, learners are required to recommend ways in which patients could manage their musculoskeletal medications effectively. This could be evidenced by the learner producing a leaflet on a disorder chosen by the tutor. The tutor should select any given examples carefully so the unit is covered sufficiently.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, M1, D1	Behavioural Differences between Normal and Malignant Cells and Links to Cancer Treatment	You have been asked by the matron of the oncology ward to produce a handout explaining the behavioural differences between normal and malignant cells and how this relates to treatment. This will be given to patients who wish to know more about how cancer develops.	Written assignment including images.

Criteria covered	Assignment Title	Scenario	Assessment Method
P2, P3, P4, P5, M2, M3, M4, D2, D3	Malignant Disease and Treatments	You have been asked by the oncology/ haematology pharmacist to prepare a brief presentation on the pharmacological action of the common treatments used in malignancy. The presentation is aimed at a group of student nurses newly rotating onto the oncology wards. Your presentation should cover the following areas: • Common malignant diseases • Common medicines used in the treatment of malignant diseases, considerations in choosing therapeutic agents and how they work in the body • Examples of any side- effects that could be experienced as a result of prescribed treatments, why side effects occur and how these could be minimised • Information that should be given to patients regarding their medicines • How patient counselling improves compliance.	Presentations. Handout to accompany presentation. Written assignment. Observation records.
P6, P7, P8, P9, M5, M6, M7, D4, D5	Musculoskeletal Disorders	You have been asked by the rheumatology department to give a short presentation about a given musculoskeletal disorder to a group of auxiliary nurses. Your presentation should cover the following areas: • Common disorders affecting the musculoskeletal system • Common treatments for musculoskeletal disorders, considerations in choosing therapeutic agents and how they work in the body • Examples of any side- effects that could be experienced as a result of prescribed treatments, why side effects occur and how these could be minimised • Information that should be given to patients regarding their medicines • How patients can manage their medication and condition effectively • How patient counselling improves compliance.	Written assignment. Presentations with handout notes. Leaflet with images.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 4: Human Physiology for Pharmacy Technicians
Unit 5: Action and Uses of Medicines
Unit 6: Gastrointestinal and Nutritional Medicines
Unit 7: Cardio-Respiratory Medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 9: Infections, Immunological Products and Vaccines
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 12: Eye, Ear, Nose and Dermatological Medicines
Unit 15: Communicating in Pharmacy
Unit 17: Pharmaceutics

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*. It would be useful for learners to have access to a current medical dictionary (nursing level would be suitable).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of

health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Pharmacology and Clinical Pharmacology Textbooks

Bennett PN and Brown MJ – *Clinical Pharmacology, 10th Edition* (Churchill Livingstone, 2008) ISBN 978-0-443-10244-8

Clayton B, Stock Y, Cooper S – *Basic Pharmacology for Nurses, 15th Edition* (Mosby, 2009) ISBN 0323057802

Neal MJ – *Medical Pharmacology at a Glance, 6th Edition* (Wiley-Blackwell 2009) ISBN 978-1-4051-8197-6

Rang HP, Dale MM, Ritter JM and Flower RJ – *Pharmacology, 6th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 04430691115

Stringer J – *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2005) ISBN 0071458182

Walker R and Whittlesea C – *Clinical Pharmacy and Therapeutics, 4th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 0443102856

Wecker L, Crespo L, Dunaway G, Faingold C and Watts S – *Brody's Human Pharmacology, 5th Edition* (Mosby, 2010) ISBN 978-0-323-05374-7

Drug Use Textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P – *Symptoms in the Pharmacy: a guide to the management of common illness, 6th Edition* (Blackwell Science, 2005) ISBN 140518079X

Dodds L (Editor) – *Drugs in Use: Clinical case studies for Pharmacists, 3rd Edition* (Pharmaceutical Press, 2003) ISBN 0853695415

Harman RJ and Mason P (Editors) – *Handbook of Pharmacy Healthcare, 2nd Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry JA – *The British Medical Association's Concise Guide to Medicines and Drugs, 7th Edition* (Dorling Kindersley, 2007) ISBN 1405317779

McGavock H – *How Drugs Work, 2nd Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A – *Non-Prescription Medicines, 3rd Edition* (Pharmaceutical Press, 2006) ISBN 0853696446

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

Websites

www.emc.vhn.net	Electronic Data Sheet Compendium
www.medicines.org.uk	Medicine Guides

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE2] planning and carrying out research for assessments on the side effects of treatments
Creative thinkers	[CT1] considering the factors involved in the choice of therapeutic agents [CT2] asking questions during discussion to extend their thinking on ways which patients could manage their medication effectively
Team workers	[TW1] collaborating with others to work towards common goals during group work
Self-managers	[SM3] organising their time and resources and prioritising actions for assessments
Effective participators	[EP3] explaining information given to the patient about their medicines.

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1] identifying questions to resolve problems [IE3] exploring patient issues
Reflective learners	[RL2] setting targets for assignment work [RL3] reviewing information for inclusion in assignment work [RL6] communicating with tutors to support learning [RL6] communicating with patients and staff in a variety of ways eg if hard of hearing or patient doesn't speak English
Self-managers	[SM5] dealing effectively with time constraints when working in a busy dispensary or hospital Trust [SM6] able to behave in a professional manner when faced with a variety of medical situations.

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from online books and journals
Select information from a variety of sources to meet requirements of a complex task	finding information on identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if the information they require (eg diagrams) can be obtained from a website
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that contains all the information for their work
Use communications software to meet requirements of a complex task	using email to send centre-produced work to their own address keeping their own messages safely in a folder creating a contact list
Combine and present information in ways that are fit for purpose and audience	presenting information from a document as requested in an assignment brief
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how the documents could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given from formal teaching reading information from a range of resources

Skill	When learners are ...
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments

Unit 12: Eye, Ear, Nose and Dermatological Medicines

Unit code: T/601/7794

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit examines the main medicine categories and their actions in the treatment of disorders of the eye, ear, nose, throat, skin, hair and nails.

Unit introduction

This unit provides learners with an understanding of the underlying principles behind the way medicines work on the human body. This unit extends learners' knowledge from physiology of health to disease processes. It explains the appropriate use and limitations of therapeutic agents. It examines the main medicine categories and their actions in the treatment of disorders of the eye, ear, nose and skin.

The unit develops general concepts around knowledge of disease states and the principles of drug actions in these conditions. The fundamental principles are expanded so that learners can apply the concepts of drug action in their workplace to provide appropriate dispensing, consulting with patients and over the counter sales.

Learning outcomes

On completion of this unit a learner should:

1 Understand how medicines are used to treat disorders of the eye

2 Understand how medicines are used to treat disorders of the ear

3 Understand how medicines are used to treat disorders of the nose

4 Understand how medicines are used to treat disorders affecting the mouth and the throat

5 Understand how medicines are used in the treatment of dermatological disorders.

Unit content

1 Understand how medicines are used to treat disorders of the eye

Diseases, disorders and symptoms: glaucoma (closed and open angled, steroid induced); infective and allergic conjunctivitis, hayfever; tear deficiency (tired or dry eyes); inflammatory disorders, simple eye disorders; contact lens care

Drug therapies and their mechanisms of actions for diseases and disorders: therapies for glaucoma eg beta blockers, anti-cholinergic miotics, carbonic anhydrase inhibitors, prostaglandin analogues; therapies for infective and allergic conjunctivitis eg antimicrobial; therapies for tear deficiency eg ocular lubricants; therapies for inflammatory disorders eg corticosteroids

Diagnostic preparations: mydriatics; cycloplegics; stains

Consulting with patients: instillation of eye drops; cross infection; storage; expiry dates; own limitations and referral

2 Understand how medicines are used to treat disorders of the ear

Diseases, disorders and symptoms: otitis externa; otitis media; ear wax

Drug therapies and their mechanisms of actions for diseases and disorders: astringent preparations; anti-inflammatory preparations eg corticosteroids, mast cell stabilisers, antihistamines, NSAIDs, sympathomimetic decongestants, local anaesthetics and counter irritants; anti-infective preparations; antimicrobial drugs including antiseptics, antibiotics, antiviral and antifungal; removal of ear wax

Consulting with patients:: instillation of ear drops; cross infection; storage; expiry dates; own limitations and referral; advice when systemic products are necessary

3 Understand how medicines are used to treat disorders of the nose

Diseases, disorders and symptoms: allergic rhinitis; rhinitis and nasal congestion; staphylococcal infections

Drug therapies and their mechanisms of actions for diseases and disorders: nasal allergy preparations; topical nasal decongestions; anti-infective preparations; nasal infections

Consulting with patients: instillation of nose drops; storage; expiry dates; own limitations and referral; advice when systemic products are necessary; advice on rebound nasal congestion

4 Understand how medicines are used to treat disorders affecting the mouth and the throat

Diseases, disorders and symptoms: gingivitis; mouth ulcers; cold sores; oral thrush

Drug therapies and their mechanisms of actions for diseases and disorders: drugs for oral ulceration and inflammation; oropharyngeal anti-infective drugs; lozenges and sprays, oral hygiene mouthwashes, gargles and dentifrices; treatments for dry mouth

Consulting with patients: application and use of mouth and throat medicines; storage; expiry dates; own limitations and referral

5 Understand how medicines are used in the treatment of dermatological disorders

Diseases, disorders and symptoms: eczema; psoriasis; dry skin; dermatitis; acne; rosaceae; dandruff; fungal infections eg impetigo, tinea, athlete's foot, ringworm; infestations eg lice, scabies; warts; veruccas; first aid; pruritis; bites, stings and rashes

Drug therapies and their mechanisms of actions for diseases and disorders: antiseptics; antipruritics; antihistamines; sun- protection treatment rating; keratolytics; antifungals; emollients and barrier preparations; local anaesthetics; topical preparations for eczema and psoriasis; drugs affecting the immune response; antiproliferative eg alicipitriol, dithranol and coal tar, retinoids and cytotoxics, PUVA; antibiotics including mupirocin, topical and oral antibacterials; anti-infective skin preparations; parasitical preparations egorganophosphate insecticides, resistant lice products

Consulting with patients: safe and effective use; properties and uses of creams, ointments, gels, pastes, collodions, powders, lotions and applications; use of corticosteroids; 'fingertip method' for dosing; systemic treatment; correct use of moisturizers; steroid storage; expiry dates; own limitations and referral; creams and other non-prescription medicines products

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe common disorders affecting the eye	**M1**	describe the pharmacological actions of medicines used to treat disorders affecting the eye	**D1**	analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the eye
P2	explain how common medicines are used in each of the disorders [CT2]				
P3	outline common side effects of these medicines	**M2**	discuss the reasons why side effects occur with medicines used to treat disorders affecting the eye	**D2**	recommend ways in which patients can manage their eye disorder medication effectively
P4	explain the information that must be given to the patient about their medicines and contact lens products [CT2, EP3]	**M3**	explain how counselling patients with disorders affecting the eye improves medication compliance		
P5	describe the problems arising from ear disorders	**M4**	describe the pharmacological actions of medicines used to treat disorders affecting the ear	**D3**	analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the ear
P6	explain how common medicines are used in each of the disorders [CT2]				
P7	outline common side effects of these medicines	**M5**	discuss the reasons why side-effects occur with medicines used to treat disorders affecting the ear	**D4**	recommend ways in which patients can manage their ear disorder medication effectively
P8	explain information that must be given to the patient about their ear medicines [CT2, EP3]	**M6**	explain how counselling patients with disorders affecting the ear improves medication compliance		
P9	describe the problems arising from disorders of the nose	**M7**	describe the pharmacological actions of medicines used to treat disorders affecting the nose	**D5**	analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the nose
P10	explain how common medicines are used in each of the disorders [CT2]				

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P11 outline common side effects of these medicines	**M8** discuss the reasons why side effects occur with medicines used to treat disorders affecting the nose	**D6** recommend ways in which patients can manage their nose disorder medication effectively
P12 explain information that must be given to the patient about their nose medicines [CT2, EP3]	**M9** explain how counselling patients with disorders affecting the nose improves medication compliance	
P13 describe the problems arising from disorders of the mouth and throat	**M10** describe the pharmacological actions of medicines used to treat disorders affecting the mouth and throat	**D7** analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the mouth and throat
P14 explain how common medicines are used in each of the disorders [CT2]		
P15 outline common side effects of these medicines	**M11** discuss the reasons why side effects occur with medicines used to treat disorders affecting the mouth and throat	**D8** recommend ways in which patients can manage medication for mouth and throat disorders effectively
P16 explain information that must be given to the patient about their mouth and throat medicines [CT2, EP3]	**M12** explain how counselling patients with disorders affecting the mouth and throat improves medication compliance	
P17 describe common disorders affecting the skin, hair and nails	**M13** describe the pharmacological actions of medicines used to treat disorders affecting the skin, hair and nails	**D9** analyse the factors involved in the choice of therapeutic agents for the treatment of disorders of the skin, hair and nails
P18 explain how common medicines are used in each of the disorders [CT2]		
P19 outline common side effects of these medicines	**M14** discuss the reasons why side effects occur with medicines used to treat disorders affecting the skin, hair and nails	**D10** recommend ways in which patients can manage their medication for disorders affecting the skin, hair and nails effectively
P20 explain information that must be given to the patient about their skin, hair and nail medicines [CT2, EP3]	**M15** explain how counselling patients with disorders affecting the skin, hair and nails improves medication compliance	

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Formal teaching on disorders of the eye and common medicines used to treat these disorders. Tutor led discussion: how and why these medicines are used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research.
Learning outcome 2 Formal teaching on disorders of the ear and common medicines used to treat these disorders. Tutor led discussion: how and why these medicines are used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research. **Assignment 1: Disorders of the Eye and Ear** (P1, P2, P3, P4, P5, P6, P7, P8, M1, M2, M3, M4, M5, M6, D1, D2, D3, D4)
Learning outcome 3 Formal teaching on disorders of the nose and common medicines used to treat these disorders. Tutor led discussion: how and why these medicines are used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research.
Learning outcome 4 Formal teaching on disorders of the mouth and throat and common medicines used to treat these disorders. Tutor led discussion: how and why these medicines are used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research. **Assignment 2: Disorders of the Nose, Mouth and Throat** (P9, P10, P11, P12, P13, P14, P15, P16, M7, M8, M9, M10, M11, M12, D5, D6, D7, D8)
Learning outcome 5 Formal teaching on disorders of the skin, hair and nails and common medicines used to treat these disorders. Tutor led discussion: how and why these medicines are used, including common side effects. Case studies used to identify importance of consulting with patients and how to improve patient compliance. Personal study time and research. **Assignment 3: Disorders of the Skin, Hair and Nails** (P17, P18, P19, P20, M13, M14, M15, D9, D10)

Topic and suggested assignments/activities and/assessment
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners should describe common disorders affecting the eye. This could be evidenced by the learner completing a presentation on a common eye disorder selected by the tutor. The tutor should select any given examples carefully so the unit is covered sufficiently.

For P2, learners are required to explain how medicines are used in common disorders of the eye and give examples of specific disorders and the medicine of choice. Evidence could be presented on completion of a written assignment.

For P3, learners need to outline common side effects of medicines used to treat disorders affecting the eye. Evidence could be presented in a written assignment which includes relevant examples of side effects.

For P4, learners need to explain information given to patients about their eye disorder medicines, including contact lens products. Evidence could be presented in the form of a patient information leaflet design.

For P5, learners are required to describe the problems arising from disorders of the ear. Evidence could be presented by the learner completing a presentation on common ear disorders which may present in a community pharmacy setting.

For P6, learners need to explain how medicines are used in common disorders of the ear. Learners should also give examples of specific disorders and the medicine of choice. Evidence could be presented on completion of a written assignment.

For P7, learners need to outline common side effects of medicines used to treat disorders of the ear. Evidence could be presented in a written assignment which includes relevant examples of side effects.

For P8, learners are required to explain information given to patients about their ear disorder medicines. Evidence could be presented in the form of a patient information leaflet design which shows the use of

over- the-counter ear preparations.

For P9, learners need to describe the problems arising from disorders of the nose. Evidence could be presented by the learner completing a presentation on common nasal disorders which may present in a community pharmacy setting. This would probably include references to allergic rhinitis and hayfever.

For P10, learners need to explain how medicines are used in common disorders of the nose. Learners should also give examples of specific disorders and the medicine of choice. Evidence could be presented on completion of a written assignment.

For P11, learners need to outline common side effects of medicines used to treat disorders of the nose. Evidence could be presented in a written assignment which includes relevant examples of side effects.

For P12, learners need to explain information given to patients about their medication for the treatment of disorders affecting the nose. Evidence could be presented in the form of a patient information leaflet design.

For P13, learners are required to describe the problems arising from disorders of the mouth and throat. This could be evidenced by the learner completing a presentation on a common mouth or throat disorder selected by the tutor. The tutor should select any given examples carefully so the unit is covered sufficiently.

For P14, learners are required to explain how medicines are used in common disorders of the mouth and throat. Learners should also give examples of specific disorders and the medicine of choice. Evidence could be presented on completion of a written assignment.

For P15, learners are required to outline common side effects of medicines used in the treatment of disorders affecting the mouth and throat. Evidence could be presented in a written assignment which includes relevant examples of side effects.

For P16, learners need to explain information given to patients about their medicines used to treat disorders of the mouth and throat. Evidence could be presented in the form of a patient information leaflet design.

For P17, learners are required to describe common disorders of the skin, hair and nails. Evidence could be presented by the learner completing a presentation on common disorders which may present in a community pharmacy setting.

For P18, learners need to explain how medicines are used in common disorders of the skin, hair and nails. Learners should also give examples of specific disorders and the medicine of choice. Evidence could be presented on completion of a written assignment.

For P19, learners need to outline common side effects of medicines used in the treatment of disorders of the skin, hair and nails. Evidence could be presented in a written assignment which includes relevant examples of side effects.

For P20, learners need to explain information given to patients about their medicines used for the treatment of disorders affecting the skin, hair and nails. Evidence could be presented in the form of a patient information leaflet design.

For M1, learners need to describe the pharmacological action of medicines used to treat disorders of the eye. The learner's description should include relevant examples. Evidence could be presented in a presentation or written assignment.

For M2, learners are required to discuss the reasons why side effects occur as a result of the use of eye preparations. Learners should also provide relevant examples of common side effects. Evidence could be presented in a written assignment.

For M3, learners need to explain how counselling patients improves compliance with treatments for disorders affecting the eye. Evidence could be presented in the form of a patient information leaflet design with supporting information.

For M4, learners need to describe the pharmacological action of medicines used to treat disorders of the ear. Learners should also provide relevant examples in their description. Evidence could be presented in a presentation or written assignment.

For M5, learners are required to discuss the reasons why side effects occur as a result of the use of ear preparations. Learners should also provide relevant examples of common side effects. Evidence could be presented in a written assignment.

For M6, learners need to explain how counselling patients improves compliance with treatments for disorders of the ear. Evidence could be presented in the form of a patient information leaflet design with supporting information.

For M7, learners need to describe the pharmacological action of medicines used to treat disorders of the nose. Learners should also provide relevant examples in their description. Evidence could be presented in a presentation or written assignment.

For M8, learners are required to discuss the reasons why side effects occur as a result of the use of nasal preparations. Learners should also provide relevant examples of common side effects. Evidence could be presented in a written assignment.

For M9, learners need to explain how counselling patients improves compliance with treatments for disorders affecting the nose. Evidence could be presented in the form of a patient information leaflet design with supporting information.

For M10, learners need to describe the pharmacological action of medicines used to treat disorders of the mouth and throat. Learners should also provide relevant examples in their description. Evidence could be presented in a presentation or written assignment.

For M11, learners are required to discuss the reasons why side effects occur as a result of the use of preparations for the mouth and throat. Learners should also provide relevant examples of common side effects. Evidence could be presented in a written assignment.

For M12, learners are required to explain how counselling patients improves compliance with treatments for disorders affecting the mouth and throat. Evidence could be presented in the form of a patient information leaflet design with supporting information.

For M13, learners need to describe the pharmacological action of medicines used to treat disorders of the skin, hair and nails. Learners should also provide relevant examples in their description. Evidence could be presented in a presentation or written assignment.

For M14, learners are required to discuss the reasons why side effects occur as a result of the use of skin, hair and nail preparations. Learners should also provide relevant examples of common side effects. Evidence could be presented in a written assignment.

For M15, learners are required to explain how counselling patients improves compliance with treatments for disorders affecting the skin, hair and nails. Evidence could be presented in the form of a patient information leaflet design with supporting information.

For D1, learners need to analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the eye and information regarding prescribing guidelines. Evidence could be presented in a presentation or written assignment.

For D2, learners need to recommend ways in which patients could manage their eye disorder medication effectively. Learners should also include examples of information and counselling points. Evidence could be presented in the form of a patient information leaflet.

For D3, learners need to analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the ear and information regarding prescribing guidelines. Evidence could be presented in a presentation or written assignment.

For D4, learners need to recommend ways in which patients could manage their ear disorder medication effectively. Learners should also include examples of information and counselling points. Evidence could be presented in the form of a patient information leaflet.

For D5, learners need to analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the nose and information regarding prescribing guidelines. Evidence could be presented in a presentation or written assignment.

For D6, learners need to recommend ways in which patients could manage their nose disorder medication effectively. Learners should also include examples of information and counselling points. Evidence could be presented in the form of a patient information leaflet.

For D7, learners need to analyse the factors involved in the choice of therapeutic agents for the treatment of disorders affecting the mouth and throat and information regarding prescribing guidelines. Evidence could be presented in a presentation or written assignment.

For D8, learners are required to recommend ways in which patients can manage their medication for mouth and throat disorders effectively. Learners should also include examples of information and counselling points. Evidence could be presented in the form of a patient information leaflet.

For D9, learners need to analyse the factors involved in the choice of therapeutic agents for the treatment of disorders of the skin, hair and nails and information regarding prescribing guidelines. Evidence could be presented in a presentation or written assignment.

For D10, learners need to recommend ways in which patients can manage their medication for the treatment of disorders affecting the skin, hair and nails effectively. Learners should also include examples of information and counselling points. Evidence could be presented in the form of a patient information leaflet.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P3, P4, P5, P6, P7, P8, M1, M2, M3, M4, M5, M6, D1, D2, D3, D4	Disorders of the Eye and Ear	You are asked by the tutor for first year student nurses to provide a learning session on common disorders of the eye and ear and the medicines available to treat them.	Presentations. Accompanying handout for reference. Information leaflets. Observation records.
P9, P10, P11, P12, P13, P14, P15, P16, M7, M8, M9, M10, M11, M12, D5, D6, D7, D8	Disorders of the Nose, Mouth and Throat	You have been asked by your lead technician in the outpatient department to prepare a brief presentation and supporting information about disorders of the nose, mouth and throat. The presentation and supporting documents will be used for pharmacy support staff in their development meetings.	Short presentations. Written assignment. Short information leaflets on each separate disorder. Observation records.
P17, P18, P19, P20, M13, M14, M15, D9, D10	Disorders of the Skin, Hair and Nails	You have been asked by the dermatology department to produce information for patients about common conditions affecting the skin, hair and nails and over the counter preparations they may be able to use.	Patient information leaflet. Supporting written documentation. Information cards.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy Technicians
Unit 2: Biological Principles for Pharmacy
Unit 4: Human Physiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 7: Cardio-Respiratory medicines
Unit 8: Central Nervous System Medicines and Anaesthesia
Unit 9: Infections, Immunological Products and Vaccines
Unit 10: Endocrine and Genito-Urinary Medicines
Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines
Unit 17: Pharmaceutics

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*. It would be useful if learners had access to a current medical dictionary (nursing level would be suitable).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of

health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Pharmacology and Clinical Pharmacology Textbooks

Bennett PN and Brown MJ – *Clinical Pharmacology, 10th Edition* (Churchill Livingstone, 2008) ISBN 978-0-443-10244-8

Clayton B, Stock Y, Cooper S – *Basic Pharmacology for Nurses, 15th Edition* (Mosby, 2009) ISBN 0323057802

Neal MJ – *Medical Pharmacology at a Glance, 6th Edition* (Wiley-Blackwell 2009) ISBN 978-1-4051-8197-6

Rang HP, Dale MM, Ritter JM and Flower RJ – *Pharmacology, 6th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 04430691115

Stringer J – *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2005) ISBN 0071458182

Walker R and Whittlesea C – *Clinical Pharmacy and Therapeutics, 4th Edition* (Churchill Livingstone, Edinburgh, 2007) ISBN 0443102856

Wecker L, Crespo L, Dunaway G, Faingold C and Watts S – *Brody's Human Pharmacology, 5th Edition* (Mosby, 2010) ISBN 978-0-323-05374-7

Drug Use Textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P – *Symptoms in the Pharmacy a guide to the management of common illness, 6th Edition* (Blackwell Science, 2005) ISBN 140518079X

Dodds L (Editor) – *Drugs in Use: Clinical Case studies for Pharmacists, 3rd Edition* (Pharmaceutical Press, 2003) ISBN 0853695415

Harman RJ and Mason P (Editors) – *Handbook of Pharmacy Healthcare, 2nd Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry JA – *The British Medical Association's Concise Guide to Medicines and Drugs, 7th Edition* (Dorling Kindersley, 2007) ISBN 1405317779

McGavock H – *How Drugs Work, 2nd Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A – *Non-Prescription Medicines, 3rd Edition* (Pharmaceutical Press, 2006) ISBN 0853696446

Salisbury D, Ramsay M (editors), Noakes K, Immunisation Against Infectious Disease, 3rd Edition (The Stationary Office, 2006) ISBN -13-978-0-11-322528-6

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

Websites

www.emc.vhn.net	Electronic Data Sheet Compendium
www.medicines.org.uk	Medicines Guide

Delivery of personal, learning and thinking skills

The table below identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit.

Skill	When learners are ...
Independent enquirers	[IE1] identifying assignment questions, resolving problems and answering patient queries [IE3] exploring patient issues eg different ways of giving medicines if a patient is unable to swallow
Creative thinkers	[CT2] asking questions to check understanding has taken place when communicating with patients about their medicines
Effective Participators	[EP3] explaining the information to be given to patients about their medicines

Although PLTS are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE2] planning and carrying out research for assignments
Creative thinkers	[CT2] asking questions during discussion to extend their thinking
Reflective learners	[RL6] communicating their learning in relevant ways to different audiences
Team workers	[TW1] collaborating with others to work towards common goals in group work
Self-managers	[SM3] organising their time and resources and prioritising actions for assessments

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder for future use aware of keeping passwords safe and non-disclosure to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from online books and journals
Select information from a variety of sources to meet requirements of a complex task	accessing information from identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if the information they require can be obtained from a website
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that contains all the information required for their work
Use communications software to meet requirements of a complex task	saving messages in appropriate folders using email and online communications tools to communicate with tutors, colleagues and other learners
Combine and present information in ways that are fit for purpose and audience	presenting the information from the document as requested in the assessment brief
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how documents and presentations can be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in group discussions

Skill	When learners are ...
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	collecting and reading information from books and journals
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing assignments

Unit 13: Community Pharmacy Practice

Unit code: R/601/9181

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit provides the knowledge required to assist in the supply of appliances, dressings and other non-medicinal products, and the provision of services outside of the pharmacy.

Unit introduction

This unit delivers knowledge and understanding that can be used by learners involved with the provision of community specialist services to colleagues, clients and other healthcare professionals. The impact of the role of pharmacy within the community healthcare environment is also considered.

Following completion of this unit, learners will know how medication is supplied to care homes and the equipment and documentation involved. Learners will acquire knowledge to assist in the supply of appliances, dressings and other non-medicinal products using standard operating procedures, ensuring that payment for the product is processed as appropriate.

The unit highlights the importance of correctly preparing for the delivery of services outside the pharmacy, including health and safety requirements, as well as the importance of working at all times within the limits of one's own role.

Learning outcomes

On completion of this unit a learner should:

1 Understand how to assist in the provision of appliances, dressings and other non-medicinal products

2 Understand how to assist in the provision of services outside of the pharmacy

3 Know the national and local regulations and policies regarding supply of medicines to patients in care.

Unit content

1 Understand how to assist in the provision of appliances, dressings and other non-medicinal products

Wound management: features of commercial wound dressings; primary and secondary dressings; external factors involved in wound healing; unconventional methods to aid wound healing eg maggot therapy, leeches, herbal remedies

Surgical hosiery: therapeutic use; varicose veins; measurement and fitting; care and maintenance of products

Stoma care: reasons for use of urostomy, ilieostomy and colostomy; care and maintenance; management and supply of ostomy products and accessories

Continence care: causes of incontinence; treatments, medical and non-medical; available products

Inhaler devices: technique to use; care and maintenance

Compliance aids: available products and their use eg dossette boxes

Correct documentation and record keeping: electronic and paper; Patient Medication Records (PMR's); endorsement, processing payment

Use of resources: drug tariff, products allowed on prescription; appropriate endorsement; different types of prescriptions; prescriber formularies

2 Understand how to assist in the provision of services outside of the pharmacy

Communication skills: identifying the needs of others; confidentiality; questioning, listening, sensitivity

Services: collection and delivery service, collection of prescriptions; delivery of dispensed items; domiciliary visits; Standards Operating Procedures (SOPs); guidelines in code of ethics; legal and ethical requirements for patient safety

Health and safety: personal and product safety

Correct documentation and record keeping: manual, electronic

3 Know the national and local regulations and policies regarding supply of medicines to patients in care

Monitored dosage systems: different products available; purpose for use; dispensing and labelling; difference between compliance aids and MDS

Documentation: Medication Administration Records (MARs); manual and electronic record keeping; prescriptions; endorsement

Regulation and policy: National Standards; Medicines, Ethics and Practice guidance; Audit (external, internal); SOPs

Unused medication: returned medication; registered nursing homes, residential care homes

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	explain how to prepare for the supply of appliances, dressings, and surgical hosiery, meeting individual and prescriber requirements	**M1**	categorise different types of dressings and surgical hosiery	**D1**	explain factors to be considered when choosing an appropriate product
P2	explain the information required by an individual or healthcare professional when supplying appliances, dressings and surgical hosiery [E1, E3]				
P3	explain how to prepare for and deliver a service to individuals that are unable to attend the pharmacy [E3]	**M2**	discuss how risks to personal and product safety can be minimised when delivering a service outside of the pharmacy	**D2**	evaluate a service delivered outside of the pharmacy including the suitability of clients
P4	describe health and safety risks when delivering services outside of the pharmacy				
P5	describe the regulations and policies for the supply of medicines to care homes	**M3**	explain the responsibilities of individuals involved in the supply of medicines to care homes	**D3**	explain how to plan for the supply of medicines to a care home
P6	describe the use of Monitored Dosage Systems	**M4**	compare different types of Monitored Dosage Systems		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on knowledge of wound care management, stoma care, incontinence and surgical hosiery. Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on products and treatment available. Explain information required by individuals and procedures to be followed for supply of products. **Assignment 1: The Supply of Appliances, Dressings and other Non-medicinal Products** (P1, P2, M1, D1) **Assignment 2: Wound Care Management** (P1, P2, M1, D1)
Learning outcome 2 Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions on services available to clients outside of the pharmacy. Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions on how to prepare to deliver these services outside of the pharmacy, including procedures to be followed, and consideration of health and safety issues. **Assignment 3: Assisting in the Delivery of Services Outside of the Pharmacy** (P3, P4, M2, D2)
Learning outcome 3 Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions on regulations governing supply of medicines to care homes, the use of MDS's, different products available and SOPs. **Assignment 4: The Supply of Medicines to Care Homes** (P5, P6, M3, M4, D3)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

A variety of assessment methods can be used in this unit to allow learners the opportunity to make use of all delivery resources available. Assignments may be delivered through blended learning programmes.

Most of the evidence from this unit will be generated from a series of assignments that encompass the grading criteria for all learning outcomes, although separate assignments could be used for distinction criteria. Professional discussion could be used by tutors where there are opportunities for learners to improve their grade. There may be opportunities for learners to use evidence from work experience as evidence of knowledge criteria being met. Holistic assessment should be used where appropriate and evidence could be used from assignments in other units within the qualification framework. Tutors should ensure that suitable assignment guidance is provided, indicating the requirements for assessment criteria.

For P1, learners need to explain how to prepare for the supply of appliances, dressings and surgical hosiery. Evidence produced by the learner should show clearly how this meets individual and prescriber requirements. Workplace assessment could be used or case studies and simulated situations. Some of the evidence will be generic to the supply of all products and therefore holistic assessment could be used. Other evidence required will relate to specific products and therefore knowledge of the product groups and their use will be required.

For P2, learners are required to demonstrate that they know the information required in order to supply appliances, dressings and surgical hosiery to individuals and healthcare professionals. Learners should demonstrate that they can provide the correct information required, including care and maintenance of products and the required techniques. This criterion is linked to P1 and could be evidenced through case studies, workplace assessment or written assignments. Product knowledge for different appliances and dressings could be assessed through additional questions.

For both P1 and P2, learners will be required to know the correct documentation to be completed and how to use appropriate resources. Learners should know what action to take to ensure that the needs of the individuals are met. Workplace evidence could be used for P1 and P2 and may compliment written assignments.

For M1, learners are required to demonstrate further product knowledge relating to wound care and hosiery and learners should be able to categorise different products into their relevant groups. This could be evidenced through a standalone assignment using tables. Alternatively it may be demonstrated as part of the evidence produced for P1 and P2.

D1 may require a separate assignment requiring demonstration of extended knowledge relating to the reasons for use of a variety of the products listed in P1 and P2 and M1.

For P3, learners need to explain how to prepare for delivery of a service outside of the pharmacy. This could be linked to evidence for P4.

For P4, learners are required to describe health and safety issues and the procedures that should be followed when delivering services outside of the pharmacy. This could be evidenced through a written assignment or case study.

For M2, learners are required to consider personal and product safety when delivering a service outside of the pharmacy and discuss how the risks could be minimised. This may be evidenced through explanation of the preparation and delivery of the services for P3 and P4 but may require an additional assignment or tutor questions.

For D2, learners are required to evaluate services that are delivered outside of the pharmacy. They should assess the preparation procedures, provision and suitability of clients. This could be evidenced through a separate written assignment.

For P5, learners are required to describe the regulations and policies for the supply of medicines to care homes. This should include the supply of medicines and the destruction of unused medicines. A written assignment may be used. Alternatively, questions and case studies could be used to assess understanding.

For M3, learners are required to explain the responsibilities of individuals who are involved in the supply of medicines to care homes. This may be evidenced through assignments produced for P5.

For P6, learners are required to describe how and why Monitored Dosage Systems are used for the supply of medicines to care homes. This may be assessed as part of evidence from assignments to cover other pass and merit criteria in this learning outcome.

For M4, learners are required to demonstrate further knowledge from P6 by comparing different types of MDS that are currently available. This could be assessed through an assignment designed to cover all criteria within this unit.

For D3, learners are required to explain how they would plan to supply medicines to a care home. Workplace evidence could be presented along with written assignments, or answers to questions to demonstrate understanding of the factors involved in the preparation and facilitation.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, M1, D1	The Supply of Appliances, Dressings and Other Non-medicinal Products Wound Care Management	You have been asked by your line manager to write a procedure to be used in a pharmacy for the supply of appliance, dressings and surgical hosiery. Your procedure should include all information required by individuals for preparation and supply. Design a table to categorise wound care products. This table will be used by colleagues in your pharmacy.	Written assignment.
P3, P4, M2, D2	Assisting in the Delivery of Services Outside of the Pharmacy	Produce an information leaflet detailing a service offered by your pharmacy. Include criteria to be met by the client and documentation to be completed. Write a report on a service provided outside of the pharmacy.	Written assignment. Product evidence.
P5, P6, M3, M4, D3	The Supply of Medicines to Care Homes	A 50-bed nursing home has approached your pharmacy to supply medicines using a MDS of your choice. Write an action plan that includes identification of roles, responsibilities and guidelines to be followed.	Written account. Simulated scenario.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *BTEC Pharmaceutical Science* sector suite. This unit has particular links with:

Level 2	Level 3
Unit 1: Communicating with Pharmacy Customers	Unit 4: Human Physiology for Pharmacy
Unit 4: Ordering and Issuing Stock in the Pharmacy	Unit 5: Action and Uses of Medicines
Unit 9: Processing a Prescription	Unit 14: Professional Development in Pharmacy
	Unit 15: Communicating in Pharmacy
	Unit 18: Pharmacy Law, Ethics and Practice

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

British National Formulary (Pharmaceutical Press, 2010) ISBN 9780853699279

Royal Pharmaceutical Society – *Medicines, Ethics and Practice* (Pharmaceutical Press, current, published annually in July)

Journals

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.bladderandbowelfoundation.org	Bladder and Bowel Foundation
www.chemistanddruggist.co.uk	Chemist and Druggist
www.doh.gov.uk	Department of Health
www.medicinescomplete.com	MedicinesComplete
www.ppa.org.uk	The Prescription Pricing Authority
www.isdscotland.org	The Prescription Pricing Authority (Scotland)

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1] identifying health and safety risks
Effective participators	[E3, E4] explaining information to patients or health care professionals

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[E1] explaining information to patients or healthcare professionals
Creative thinkers	[CT1, CT2] discussing topics with tutors and mentors and asking them questions in order to develop the knowledge and skills required
Reflective learners	[R1, R3] reflecting on workplace scenarios and using the knowledge acquired for assignments [R3] reviewing course progress
Team workers	[T1,T3] developing knowledge and skills in the workplace whilst working within the pharmacy team
Self-managers	[SM] planning and organising work and study

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	doing research via the internet completing blended learning assignments word processing assignments or homework
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using a computer to produce individual learning plans
Manage information storage to enable efficient retrieval	storing assignments in electronic files and folders using workplace systems which contain confidential information
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching online data to assist with assignments
Select information from a variety of sources to meet requirements of a complex task	developing an understanding of the appropriate websites to use for research
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	collating various information and files appropriately for use in this unit
Use appropriate software to meet the requirements of a complex data-handling task	using electronic data to produce text and tables, images and numbers in assignments or in self study
Use communications software to meet requirements of a complex task	using ICT to communicate and network with colleagues, other learners and tutors
Combine and present information in ways that are fit for purpose and audience	choosing appropriate tools to present assignments presenting information in the formats requested in assignments
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	evaluating how presentations and documents could be improved
Mathematics – representing	
Identify the situation or problems and identify the mathematical methods needed to solve them	costing and evaluating services
Mathematics – analysing	
English – Speaking, Listening and Communication	

Skill	When learners are ...
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	participating in discussions with mentors, tutors and colleagues
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading text provided by tutors, using a variety of delivery methods
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing reports and assignments

Unit 14: Professional Development in Pharmacy

Unit code: A/601/7795

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit aims to provide the learner with the knowledge and understanding to function as a professional in the pharmacy environment and give them the necessary skills to support their own learning and that of others.

Unit introduction

This unit introduces learners to the professional aspects of their career. It will enable learners to develop effective communication skills which need to operate alongside their customer service knowledge. Learners will be given the underpinning knowledge to support their understanding of the nature of teamwork and how to work effectively within a pharmacy team.

This unit also covers learning and development skills, helping learners to understand how they and others learn, and how they can to pass on knowledge to others. It will also prepare them for qualification and registration and help them to understand the requirements of being a registered pharmacy professional.

Learning outcomes

On completion of this unit a learner should:

1 Understand the importance of effective communications with the customers of the pharmacy

2 Know how to perform as part of an effective pharmacy team

3 Understand the importance of supporting own learning and that of others

4 Understand the importance of continuing professional development.

Unit content

1 Understand the importance of effective communications with the customers of the pharmacy

Policies and procedures: workplace customer care training; internal customers; Standard Operating Procedures (SOPs); organisation induction; mandatory training; code of ethics

2 Know how to perform as part of an effective pharmacy team

Tools, standards and guidelines: teamwork; types of teams; team-building activities; workplace training; standard operating procedures (SOPs); code of ethics

3 Understand the importance of supporting own learning and that of others

Tools that support learning: learning styles eg learning styles questionnaires, SWOT analysis, 'Train the Trainers'; Personal Development Plans; feedback skills and workshops; descriptions of the learning cycle eg Kolb; presentation skills, instruction, demonstration; critical incident, error reporting

4 Understand the importance of continuing professional development

Engaging in CPD: CPD cycle; SMART objectives; RPSGB Code of Ethics; plan and record; local or regional support for CPD activities

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	identify the different customers that use the pharmacy service	**M1**	describe different types of communication relevant to pharmacy customer service	**D1**	relate communication skills to pharmacy customer service
P2	explain the key features of effective communication in pharmacy settings	**M2**	describecomplaints or conflict procedures relevant to pharmacy settings	**D2**	review pharmacy customer service policies
P3	describe customers needs and how to respond appropriately	**M3**	explain the term 'confidentiality' as it applies to pharmacy settings		
P4	explain how to deal with complaints or conflict in pharmacy settings [IE4, TW3]				
P5	explain the importance of customer confidentiality in pharmacy settings				
P6	explain the principles of effective team working in a pharmacy setting [IE4, CT2]	**M4**	describe the contributions that different members of a pharmacy team can make to the overall effectiveness of the team	**D3**	analyse apharmacy team in terms of its effectiveness in team work
P7	recognise styles of interactions between pharmacy team members [TW3]	**M5**	discuss the different working relationships within a pharmacy team		
P8	outline strategies for handling problem relationships within the pharmacy team				
P9	describe different learning styles	**M6**	relate learning styles to different methods of training or teaching	**D4**	analyse own learning style
P10	compare different learning environments				

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P11 explain the use of different instructional techniques	**M7** compare different instructional techniques	**D5** evaluate instructional techniques
P12 describe how demonstrations are structured	**M8** compare different demonstration techniques	
P13 discuss development opportunities to improve practice	**M9** discuss own development needs	**D6** review own development needs
P14 review successful interventions and learn from these [RL4]	**M10** compare different ways to highlight developmental needs	
P15 explain how to learn from errors, critical incidents and enquiries into serious failings		
P16 describe how to record their CPD.	**M11** discuss own CPD requirements and those of their pharmacy job role.	**D7** provide examples of own recorded CPD.

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Introduction to types of customers. Learners research different customer types. Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions, DVDs, role plays, demonstrations and case studies on communication skills and examples of communication skills. Learners demonstrate communication skills. Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions, DVDs, role plays, demonstrations and case studies on the subject of complaints and conflict, and how to deal effectively with complaints and conflict. Learners demonstrate dealing with conflict or complaints. Discuss confidentiality requirements. **Assignment 1: Communication in a Pharmacy Setting** (P2, P3, P4, M1, D1) **Assignment 2: Customer Service in a Pharmacy Setting** (P1, P3, P5, M2, M3, D1, D2)
Learning outcome 2 Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions, DVDs, role plays, demonstrations and case studies on teamwork and examples of different types of teams. Discuss effective ways of dealing with team issues. Demonstration of handling difficult situations. Learners research teamwork. **Assignment 3: Teamwork in a Pharmacy Setting** (P6, P7, P8, M4, M5, M6, D3)
Learning outcome 3 Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions, DVDs, role plays, demonstrations and case studies on the subject of learning styles. Discuss instruction and demonstration. Discuss learning environments. Learners research learning styles. Learners demonstrate different techniques relevant to different learning styles. Learners review techniques. **Assignment 4: Giving a Presentation** (P9, P10, P11, P12, M6, M7, M8, D4, D5)
Learning outcome 4 Introduction to personal and professional development. Discuss professional development requirements. Learners research developmental needs. Demonstration of CPD recording systems (online). Discuss different ways of identifying developmental needs. Learners demonstrate recording of CPD. **Assignment 5: Recording CPD** (P13, P14, P15, P16, M9, M10, M11, D6, D7)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners need to identify different types of pharmacy customers. This could be evidenced by the completion of tables identifying customers that use the pharmacy service.

For P2, learners need to explain the key features of effective communication in a pharmacy setting. This could be evidenced by short answer questions to identify good and poor communication skills and the possible impact of good communication skills and poor ones.

For P3, learners need to describe customer needs and how to appropriately respond to those needs, including the aspect of referral. This could be evidenced by multiple choice questions covering different situations and customer needs.

P4 requires learners to explain ways to deal with complaints and potential conflict situations within a pharmacy setting. The learner's explanation should include the referral process and could be linked to evidence for P2.

For P5, learners need to explain the importance of confidentiality when dealing with pharmacy customers and patient data. This could be evidenced by a written assignment.

P6 requires the learner to explain effective teamwork. The explanation should include the advantages of working well in a team, and explanation of the limitations of poor teamwork.

For P7, learners are required to recognise styles of interactions between colleagues who are team members. This could be evidenced by multiple choice questions or completion of tables indicating professional interactions between different members of a team.

P8 requires learners to outline strategies for dealing with problems within a team. This should include the referral process and should also identify any appropriate polices.

For P9, learners need to describe different learning styles. This could be evidenced by short answer questions or completion of tables.

For P10, learners need to compare different learning environments.

For P11, learners need to explain the use of different instructional techniques. This could be evidenced by

using witness statements and peer review of different techniques used.

P12 requires learners to describe how demonstrations are structured. This could be evidenced by using witness statements or completing flow diagrams.

For P13, learners need to discuss the development opportunities to improve their practice and that of their team or service. This could be evidenced by professional discussion or written assignment.

For P14, learners are required to review successful interventions and demonstrate that they have built on the knowledge evidenced for P13. This could be demonstrated as a written assignment linked to the evidence for P13.

For P15, learners are required to explain how to learn from errors or critical incidents. This could be evidenced by professional discussion or written assignment.

For P16, learners need to describe how to record their CPD. This could be evidenced by professional discussion or multiple choice questions.

For M1, learners need to describe different types of communication. This could be evidenced by the learner completing a table or diagram supported by relevant comments.

For M2, learners need to describe the complaints or conflict procedures that may be used in the situations identified in P4. This could be evidenced by flow chart or written assignment.

For M3, learners need to explain the concept of confidentiality as it applies to pharmacy settings. This could be evidenced by short answer questions, answers to multiple choice questions or by professional discussion.

For M4, learners need to describe the contributions that different members of a pharmacy team (identified in P7) could make to the overall effectiveness of the team. This could be linked to evidence for P7 and M5.

For M5, learners are required to discuss different working relationships within the pharmacy team identified in P7. This could be evidenced by short answer questions or linked in an assignment to P7 and M4.

For M6, learners need to relate learning styles to different methods of training or teaching, indicating that some methods of training and teaching are more suited to certain learning styles than others.

For M7, learners are required to compare the different instructional techniques identified in P11. This could be evidenced by the completion of tables.

For M8, learners need to compare different demonstration techniques. This could be evidenced by the completion of tables.

For M9, learners are required to discuss their own development needs. This could be evidenced by the learner producing a training needs analysis or a professional development plan.

M10 requires the learner to compare different ways of identifying developmental needs when undertaking M9. This could be evidenced by the completion of tables.

M11 requires learners to discuss their own CPD requirements and those of their job role. This could be evidenced by a professional discussion or written assignment.

For D1, learners need to relate communication skills to customer service and could build on skills identified in P2 and M1. Evidence for D1 could be linked to evidence for P2 and M1.

D2 requires learners to review pharmacy customer service policies.

D3 requires learners to analyse a pharmacy team in terms of its effectiveness and skill in working as a team. D3 can build on information obtained from P7, M4 and M5. This could be evidenced by producing a report.

For D4, learners need to analyse their own learning style; this could be evidenced by completing a learning style questionnaire and analysis.

For D5, learners need to evaluate instructional techniques. This could be evidenced by the learner producing

a reflective account of instructional techniques which they have used or which trainers have used with them.

For D6, learners need to review their own developmental needs. This could be evidenced by a reflective account or appraisal.

D7 requires learners to provide examples of their recorded CPD. This could be evidenced by the production of CPD records online or by means of written CPD accounts.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P2, P3, P4, M1, D1	Communication in a Pharmacy Setting	You are working for a drug company and have a new and exciting drug to advertise. Put together a job description for the new role as drug rep for this product. Indicate all the communication skills that will be required and how you will assess these.	Written assignment. Completion of job description.
P1, P3, P5, M2, M3, D1, D2	Customer Service in a Pharmacy Setting	You are the head of a hospital complaints department. When being discharged, many patients complained about the pharmacy department. Consequently, a training need for those working in the pharmacy department has been identified. It has also been identified that patients require improved information about the role of pharmacy services in the hospital. You have been asked to produce a leaflet on effective customer service for the pharmacy team to use in training and with patients.	Leaflet. Written assignment.
P6, P7, P8, M4, M5, M6, D3	Teamwork in a Pharmacy Setting	You have been asked to put together a team of explorers for an expedition to the Amazon river to look for new medicinal plants. Write a report on the attributes the team needs and what skills are required within the team.	Presentations. Written report. Observation records.
P9, P10, P11, P12, M6, M7, M8, D4, D5	Giving a Presentation	You have been asked to make a presentation to a group of adults who attend evening study classes. The presentation will be on a subject you are well qualified or experienced in. Produce the learning materials and deliver a training session to this group.	Presentations. Planning documents. Peer review. Observation records.
P13, P14, P15, P16, M9, M10, M11, D6, D7	Recording CPD	You are a qualified pharmacy technician and in this capacity, you are required to record your CPD activities. Produce a record of your CPD activities according to organisational guidelines.	Report. Written assignment.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3	Level 3
Unit 1: Communicating with Pharmacy Customers	Unit 15: Communicating in Pharmacy
Unit 3: Working in a Pharmacy Team	

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Caviglioli, O and Harris, I – *Thinking Visually: Step by Step Exercises that Promote Visual, Auditory and Kinesthetic Learning* (Pembroke Publishers, 2003) ISBN 1551381559

Gravells, A – *Delivering Adult Learning* (Learning Matters, 2006) ISBN 1844450643

Parker, G – *Team Players and Teamwork: New Strategies for Developing Successful Collaboration, 2nd Edition* (Jossey Bass, 2008) ISBN 0787998117

Petty, G – *Teaching Today: A Practical Guide* (Nelson Thornes, 1998) ISBN 0748735070

Reece, I and Walker, S – *Teaching, Training and Learning: A Practical Guide, 6th Edition* (Business Education Publishers Ltd, 2007) ISBN 9781901888560

Roffey-Barentsen, J and Malthouse, R – *Reflective Practice in the Lifelong Learning Sector* (Learning Matters, 2009) ISBN 9781844451845

Websites

www.aptuk.org	Association of Pharmacy Technicians UK
www. businessballs.com	Business Balls
www.cppe.ac.uk	Centre for Pharmacy Postgraduate Education
www.npa.co.uk	National Pharmacy Association
www.open2.net/survey/learningstyles	BBC Learning Styles
www.pharmj.com	Pharmacy Journal Online
www.rpharms.com	Royal Pharmaceutical Society
www.teachers.tv	Teachers TV Website
www.teamtechnology.co.uk	Team Technology
www.studyskills.soton.ac.uk	Study Skills

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE4] resolving teamwork and conflict issues within their own pharmacy team
Creative thinkers	[CT2] asking questions of their pharmacy team to extend their understanding of their interactions in relation to good teamwork
Reflective learners	[RL4] assessing different interventions and how these can be used to identify their own developmental needs
Team workers	[TW3] showing consideration and reaching agreements in conflict situations with pharmacy customer services

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Self-managers	[SM4] managing time and resources in giving a presentation
Effective participators	[EP5] identifying improvements in their professional development and presentation skills

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments using ICT to deliver presentations
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from online books and journals
Select information from a variety of sources to meet requirements of a complex task	obtaining relevant information from identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	using images in presentations
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that contains all the information for their work
Use communications software to meet requirements of a complex task	using email to send centre-produced work to their own address keeping their own messages safely in a folder creating a contact list
Combine and present information in ways that are fit for purpose and audience	presenting information from a document as requested in the assignment briefs
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how the documents could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions presenting to a group
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given from formal teaching reading information from a range of resources

Skill	When learners are ...
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments.

Unit 15: Communicating in Pharmacy

Unit code: Y/601/9182

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit delivers the knowledge required by pharmacy technicians to effectively communicate in a Pharmacy environment.

Unit introduction

Learners completing this unit will develop the knowledge required to communicate effectively with colleagues, clients and healthcare professionals in a variety of different contexts. Learners will find out how to use different questions and techniques to obtain relevant information required for the safe supply of medicines, the provision of appropriate information and advice, and onward referral to an appropriate authority.

This unit will consolidate and build upon *Unit 14: Professional Development in Pharmacy*, and provides opportunities to consider how to refine and use this knowledge in a variety of contexts. Learners will be required to use their knowledge of the uses and side effects of commonly used medicines including over the counter (OTC) products, and know how to advise clients to take their medicines in a way that ensures compliance, concordance and safe use. They will learn the role of pharmacy in health promotion and how to identify suitable clients for referral. Learners will also learn how to communicate effectively when preparing for a review of medicines taken by an individual.

The unit highlights the importance of working at all times within the limits of one's own role, following standard operating procedures (SOPs).

The unit also identifies the developing role of the pharmacy technician, how pharmacy contributes to medicines management, and how this fits in with local and national policy.

Learning outcomes

On completion of this unit a learner should:

1 Understand how to provide relevant information and advice on medicines and products

2 Understand the correct procedures for the sale and supply of OTC medicines

3 Know about health and health promotion

4 Understand how to prepare for a review of medicines taken by an individual.

Unit content

1 Understand how to provide relevant information and advice on medicines and products

Communication skills: identifying the needs of others; questions and questioning techniques eg open and closed; listening, sensitivity; confidentiality

Resources: standard operating procedures; Protocols; MIMS, BNF; information from suppliers or manufacturers; healthcare leaflets

Different formats: verbal; written eg Patient Information Leaflets (PILs), electronic formats

Individuals: customers, patient, carer, health care professional

Information: side effects or adverse effects; storage requirements; safe use; compliance; concordance; compliance aids; sundries

Referral to appropriate authority: pharmacist, doctor, other healthcare professional

Medicines: General Sales Medicines (GSM), Pharmacy (P), Prescription Only Medicines (POM), herbal, homeopathic, vitamin and dietary supplements, clinical trials medicines, CDs, prescribed

Medicines management: concordance/compliance, adherence, pharmacy intervention, factors causing poor concordance

2 Understand the correct procedures for the sale and supply of OTC medicines

Questions: 2WHAM and/or alternatives

Questioning techniques: open and closed questions

Individuals: those with special requirements, those with no idea of their needs, those with clear idea of their needs, customer's representative, those presenting with symptoms

Classes of medicines: General Sales Medicines (GSL); Pharmacy (P); Prescription Only Medicines (POM)

When to refer: requests for product or advice outside limits of learner's authority; medicines with the same/similar active ingredients; regular quantities of medicines requested liable to abuse or misuse; sale of medicines to those with special circumstances eg elderly, children, pregnant

Legal and ethical responsibilities: when medicines may not be sold; confidentiality; SOPs, pharmacy protocol; responsible pharmacist, staff training requirements

Local policy: eg minor ailment schemes, head lice policy

Commonly used non-prescription medicines: products available for coughs and colds, indigestion and heartburn, constipation, diarrhoea, pain, hayfever, skin, dental, women's health, men's health

3 Know about health and health promotion

Healthy lifestyle advice: diet; exercise; stress reduction

Health promotion in the pharmacy: information that can be provided within the pharmacy, methods used for the dissemination of health messages eg health promotion leaflets, information relating to a full range of Health Promotion activities and services; the role of the Pharmacist, pharmacy technician and other support staff in promoting health; drug misuse, impact on the practice of pharmacy, local support organisations

National regional and local targets for the health community: local campaigns, government campaigns

Health risk factors: identifying risk factors and relevant measurements; interpreting relevant data

4 Understand how to prepare for a review of medicines taken by an individual

Health related knowledge: classes of medicines; General Sales Medicines (GSL); Pharmacy (P); Prescription Only Medicines (POM)

Different levels or types of reviews: compliance reviews, clinical reviews

Purpose of individual review of medicines: concordance; compliance; target groups; primary care organisation policies and guidance

Records and documentation: maintenance of records; completion of documentation

Identification of patient medication: PMR; Patient Own Drugs (PODs); repeat prescriptions; pharmacy intervention forms, hospital records; MARS

Current legislation, policy, good practice and ethical standards: valid consent in England, Wales, Northern Ireland; SOPs (including equality, diversity and confidentiality); working within limitations of the job role

Individual: patient, carer, representative

Care and support of the individual: preparing a clean and safe environment; appropriate questioning techniques; how to encourage an individual to ask questions; discuss understanding of their medicines; respect of individual's privacy, dignity, wishes and beliefs

Reasons why medicines are not taken correctly: eg concern regarding side effects, forgetting to take the medicine, beliefs, misunderstanding

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	explain how to advise patients to take their medicines in a way that ensures cost -effective compliance, concordance and safe use [IE1, IE2, IE4, IE5]	**M1**	discuss counselling points required for a range of medicines	**D1**	evaluate advice given to patients on how to take their medicines
P2	explain how to work within the parameters of own role when providing information and advice to individuals	**M2**	assess situations requiring referral to an appropriate authority		
P3	describe the different classes of medicines	**M3**	describe OTC products that potentially may be misused or abused	**D2**	interpret different legislation relevant to the sale of medicines over the counter
P4	describe the pharmacy protocol				
P5	discuss the questions and techniques used to obtain relevant information before recommending products or referring to an appropriate authority [TW1, TW4, SM7]	**M4**	following SOPs, recommend suitable commonly used non-prescription items	**D3**	evaluate different questions and techniques used to meet the needs of individuals
P6	define the term 'health promotion'	**M5**	discuss the role of pharmacy in promoting public health	**D4**	assess different types of health information available in the pharmacy
P7	define the components of a healthy lifestyle				
P8	describe the predictors used for managing common conditions [EP1]	**M6**	interpret data and use information to refer when further action is required		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P9 explain the purpose of reviewing an individual's medication	**M7** describe the processes followed when preparing for an individual's medication review	**D5** evaluate different medication reviews.
P10 explain the importance of the completion and maintenance of documentation and records		
P11 discuss legal and ethical requirements when preparing for a 'Medicines Use Review' (MUR).	**M8** compare different roles and responsibilities of pharmacy staff involved in medication reviews.	

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

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Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions and case studies on medicines management. Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions and case studies on compliance, concordance and adherence. Tutorials and self study using a variety of resources, workplace tasks, research, multiple choice questions and case studies on classes of medicines and how to obtain and provide relevant information. Role play or workshop on communication skills, choosing questions and questioning techniques. **Assignment 1: Promoting Compliance, Concordance and Safe Use when Counselling Patients** (P1, P2, P5, M1, M2, D1)
Learning outcome 2 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on the legal requirements for the sale of OTC medicines and SOPs. Investigating case studies: questions and techniques used, referral process. **Assignment 2: The sale of Over The Counter Medicines and Products** (P3, P4, P5, M2, M3, M4, D2, D3, D5)
Learning outcome 3 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on health promotion in pharmacy, methods of promoting health, services provided by pharmacy. Case studies and workshop on health risk factors, predictors and measurements, lifestyle advice. **Assignment 3: The Role of Pharmacy in Promoting Healthy Living to Customers** (P6, P7, P8, M5, M6, D4)
Learning outcome 4 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on different types of medicines review, reasons for review, documentation, identifying patients for review, legislation. Role play or case studies: preparation for review of an individual's medicines. **Assignment 4: Preparing for a Review of an Individual's Medicines** (P9, P10, P11, M7, M8, D5)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

A variety of assessment methods can be used in this unit to allow learners the opportunity to make use of all delivery resources available. Assignments may be delivered through blended learning programmes and may include the use of multiple choice questions and case studies.

Most of the evidence from this unit will be generated from a series of assignments that encompass the grading criteria for all learning outcomes although separate assignments could be used for merit and Distinction Criteria. There may be opportunities for learners to use evidence from work experience as evidence of knowledge criteria being met. Holistic assessment should be use where appropriate and evidence could be used from assignments in other units within the qualification framework. Tutors should ensure that suitable assignment guidance is provided indicating the requirements for assessment criteria.

For Learning Outcome 2, APL should be provided for learners that have recently completed a medicine counter assistant qualification meeting the professional minimum requirements.

For P1, learners are required to explain how they would advise patients to take their medicines in a way that ensures compliance and concordance and considers cost effectiveness and safe use. They should demonstrate an understanding of the reasons why patients do not adhere to medicine regimens. This may be evidenced using case studies or workplace assessment.

For M1, learners need to discuss the counselling points that they would use to meet P1. The learner's discussion should cover a range of different medicines. An assignment linked to P1 may provide evidence. Alternatively, additional questions or evaluation of case studies could be used.

For D1, learners are required to evaluate advice given to patients. This may be evidenced through reflection of previous case studies or through workplace evidence used to meet P1 and M1.

For P2, learners are required to explain how they would work within the limits of their own role and the importance of doing so. Learners could reference evidence from P1 or an additional assignment could be used.

For M2, learners are required to assess situations requiring referral to an authority. This could be done as an extension of the assignment used to cover P2.

For P3, learners need to describe the classes of medicine. Multiple choice questions could be used. Alternatively, inferred knowledge from previously assessed assignments could provide evidence.

For P4, learners are required to describe the pharmacy protocol. The description should include how the protocol is used and the information it contains. A written assignment or questions could be used to provide evidence for P4.

For M3, learners are required to describe the OTC medicines that could potentially be misused or abused. Learners should demonstrate that they understand the difference between abuse and misuse. Assessment may be evidenced from earlier assignments or in a separate written assignment.

For D2, learners are required to be able to interpret the different legislation relating to the sale of OTC medicines and relate this to practice. This may be evidenced though case studies or a separate assignment using real life or simulated situations.

For P5, learners are required to discuss the different questions and techniques used to meet individual needs, namely knowing how to recommend a suitable product. This could be demonstrated through simulated situations, workplace evidence or a written assignment that includes case studies.

For M4, in recommending suitable commonly used non-prescription items, learners need to consider different medication reviews and the suitability of clients for these reviews. This might require a separate assignment and could include case studies. Some evidence could however be drawn from the evidence produced for M8, where learners will have identified different staff involved in reviews.

For D3, learners are required to evaluate situations where different questions and techniques have been used in order to meet the needs of individuals. Reflective accounts drawing on previous evidence could be used.

To achieve P6 and P7, learners are required to define 'health promotion' and the components of a healthy lifestyle.

For M5, learners are required to discuss the role of pharmacy in health promotion. A separate assignment could be used, allowing evaluation of evidence for the criteria in this unit and reviewing the roles of pharmacy staff involved in the promotion of health.

For P8, learners are required to demonstrate that they can describe the predictors and measurements used in the management of common conditions. Evidence may come from simulated situations or case studies.

For M6, learners need to build on P8 and be able to interpret data from health assessments and take appropriate action to refer where necessary. Case studies could be used as evidence and may be a development of an assignment to meet other pass criteria in this learning outcome.

For D4, learners are required to build on knowledge for P6 and P7 and assess the different types of health information available. They should consider the advantages and disadvantages of different types of information and formats, and consider how the information and formats are used. Evidence could be in the form of a written assignment, linking to P6 and P7.

For P9, learners need to explain the purpose of reviewing an individual's medication. A written assignment could be used and may link to evidence for P10.

For P10, learners are required to explain the importance of completing and maintaining documentation used when preparing for a review. This could include reference to particular documents and their use. A written assignment could be used as evidence for both P9 and P10.

For M7, learners need to build on knowledge evidenced for P9 and P10 and describe details of the processes to be followed when preparing for an individual's medication review. This could take the form of a separate assignment, although some evidence is likely to be referenced from P10.

For P11, learners need to discuss legal and ethical requirements when preparing for an MUR. Learners will need to demonstrate that they understand their impact on the processes followed. This could link to evidence presented to satisfy M7.

For M8, learners are required to compare the different roles and responsibilities of staff involved in medication reviews. This may be evidenced through reflective accounts relating to working practice. Alternatively, it could be covered in an assignment linked to M7.

For D5, learners need to use the knowledge demonstrated in P5 and be able to evaluate different medication reviews, recommending suitable products if required. Depending on evidence produced for previous criteria, this might require an additional assignment.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Educe assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P5, M1 M2 D1	Promoting Compliance, Concordance and Safe Use when Counselling Patients	Using case studies, provide examples of how you would offer advice to patients to ensure compliance, concordance and safe use of their medicines. Using real life or simulated situations, assess information provided to individuals to ensure compliance, concordance and safe use of their medicines.	Written assignment. Case studies. Work place evidence.
P3, P4, P5, M2, M3,M4, D2 D3 D5	The Sale of Over The Counter Medicines and Products	Produce a training guide to be used for the induction of new members of the pharmacy team involved in the sale of OTC medicines. Case Study – example A businessman aged 55 years wants something for a congested nose and a sore throat. He needs to work and go to a meeting. • List the questions you would ask and why you would ask them • State how you would ask the questions and why • Describe different questions and techniques that you would have used for a request for a named product, and a request from a representative You identify that he is taking medication for high blood pressure • What action would you take? • What medicines or products could you recommend?	Written assignment. Case study. Assignment.
P6, M5, D4 P7, P8, M6	The Role of Pharmacy in Promoting Healthy Living to Customers	Write a report for two services that a pharmacy is involved in. Include the public health targets set for a GP practice or primary care organisation relevant to these services. Define a range of health risk factors. Include examples of how to assess risk by using predictors and measurements.	Written assignment. Tutor questions. Case studies. Written Assignment. Workplace evidence.

Criteria covered	Assignment Title	Scenario	Assessment Method
P10, P11, M7 P9, M8, D5	Preparing for a Review of an Individual's Medicines	Design a form that could be used to prepare for a review of an individual's medicines For each case study explain the following: • Why this individual is suitable for a review. • How compliance and/or concordance issues have been identified. • What type of review will be required. • What information you need to prepare for the review.	Written assignment. Case studies. Assignment.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the Pharmaceutical Science. sector suite. This unit has particular links with:

Level 2	Level 3
Unit 1: Communicating with Pharmacy Customers	Unit 5: Action and Uses of Medicines
Unit 8: Selling Over the Counter Medicines in the Pharmacy	Unit 13: Community Pharmacy Practice
	Unit 14: Professional Development in Pharmacy
	Unit 16: Dispensing and Supply of Medicines
	Unit 18: Pharmacy Law, Ethics and Practice

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources, for example *MedicinesComplete*. It would be useful if learners had access to a medical dictionary (nursing level would be suitable).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

British National Formulary (Pharmaceutical Press, 2010) ISBN 9780853699279

Royal Pharmaceutical Society – *Medicines, Ethics and Practice* (Pharmaceutical Press, current, published annually in July)

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.chemistanddruggist.co.uk	Chemist and Druggist
www.dh.gov.uk	Department of Health
www.emc.vhn.net	Electronic data sheet compendium
www.isdscotland.org	The Prescription Pricing Authority (Scotland)
www.medicines.org.uk	Medicines Guides
www.nice.org.uk	National Institute for Clinical Excellence
www.npc.co.uk	National Prescribing Centr
www.ppa.org.uk	The Prescription Pricing Authority
www.psnc.org.uk	Pharmaceutical Services Negotiating Committee
www.rpharms.com	Royal Pharmaceutical Society

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	
Independent enquirers	[IE1, IE2, IE4 IE5] providing medicines management services which require asking customers questions and evaluating information
Team workers	[T1, T2, T3, T4] obtaining and providing information and referring to the appropriate authority when required
Self-managers	[SM7] discussing sensitive issues with others
Effective participators	[E1, E4] identifying health risks and suggesting improvements that could be made

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1, IE2] preparing and researching information for assignments
Creative thinkers	[C2] asking questions during tutorials or in the workplace
Reflective learners	[R2, R3, R4] reviewing progress with tutors and mentors
Self-managers	[SM2, SM3, SM5] organising and planning assignments and self study
Effective participators	[E1] discussing issues with tutors and colleagues during tutorials

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using the internet to do research completing blended learning assignments word processing assignments or homework
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using a computer to produce individual learning plans identifying a fault and following the correct procedure for reporting it dealing with simple IT problems
Manage information storage to enable efficient retrieval	storing assignments in electronic files and folders using workplace systems that confidential information
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching online data to assist with assignments
Select information from a variety of sources to meet requirements of a complex task	developing an understanding of appropriate websites to use for research
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	collating various information and files appropriately for use in their work for this unit
Use appropriate software to meet the requirements of a complex data-handling task	using electronic data to produce text and tables, images and numbers in assignments or in self- study
Use communications software to meet requirements of a complex task	using ICT to communicate and network with colleagues and tutors
Combine and present information in ways that are fit for purpose and audience	choosing appropriate tools to present assignments presenting information in the formats requested in assignments
Mathematics – interpreting	
Draw conclusions and provide mathematical justifications	interpreting the data required for referral to other health professionals
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions with mentors, tutors and colleagues communicating with customers and colleagues providing information and advice on products and healthcare
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading text provided by tutors using a variety of delivery methods

Skill	When learners are ...
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing reports and assignments

Unit 16: Dispensing and Supply of Medicines

Unit code: J/601/7797

Level 3: BTEC National

Credit value: 5

Guided learning hours: 30

Aim and purpose

This unit aims to provide the learner with the knowledge and understanding to dispense prescriptions appropriately and to be able to order, receive, dispose and return pharmaceutical stock.

Unit introduction

This unit aims to equip learners with the knowledge and skills that will enable them to dispense and supply medicines in the correct way. The role of the pharmacy technician is expanding, so learners must be able to demonstrate good communication skills in this regard.

Learners will also be introduced to the laws and the underlying principles behind the dispensing and supply of medicines. The unit also highlights the need for pharmacy technicians to demonstrate that they are aware of the limitations of their own role and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

Learning outcomes

On completion of this unit a learner should:

1 Understand the organisational policies and standard operating procedures within the pharmacy working environment

2 Understand the processes involved when dispensing prescriptions

3 Know how to order, receive, store and maintain pharmaceutical stock.

Unit content

1 Understand the organisational policies and standard operating procedures within the pharmacy working environment

Policies and procedures: induction programme; mandatory training; current Pharmacy Professional Regulation; General Pharmaceutical Council (GPhC) Code of Ethics; Health and Safety at Work Act (HASAWA); Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR); Medicines Act, licensing of medicines, classifications of medicines; Misuse of Drugs Act; Poisons Act; error reporting procedures, near miss, incidents; factors which cause errors, implications of errors, roles and responsibilities, referral process

2 Understand the processes involved when dispensing prescriptions

Policies: standard operating procedures (SOPs); purpose, receipt of prescriptions; exemptions; payment methods; national and local guidelines; ethical and legal requirements; safe handling of hazardous materials

Types of prescription checks: clinical; in-process; final

Types of prescriptions: general practitioners; discharge; in-patients; out-patients; clinical trial; dental; nursing prescribers; pharmacist prescribers

Types of prescribers: general practitioners; pharmacist, nurse; dentist; veterinarians

Assembling: information required; branded and generic names; abbreviations; conventions; route of administration; strengths; dose form; calculations; reconstitution; patient information leaflets (PILS); record cards; automated supply

Equipment: uses; counting and transfer equipment; consumables

Containers: uses; types of container

3 Know how to order, receive, store and maintain pharmaceutical stock

Policies: purpose; standard operating procedures; waste disposal policies; Control of Substances Hazardous to Health (COSHH); national and local guidelines; ethical and legal requirements;

Drug alerts: purpose; standard operating procedures; company recalls; Medicines and Healthcare Products Regulatory Agency (MHRA); shared information, National Patient Safety Alerts (NPSA)

Stock: standard operating procedures; sources; ordering; maintenance; storage requirements; disposal; stock rotation; records; formulations; discrepancies

Roles and responsibilities: referral process; appropriate person

NOTE

Tutors should ensure that the most current legislation is used when delivering the content for this unit.

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 explain the principles and practices for dispensing, including organisational policies [IE2]	**M1** discuss the referral process and the responsibilities of different staff in ownworkplace	
P2 explain the importance and use of SOPs [IE2]		
P3 describe the consequences of near misses and dispensing errors [RL6]	**M2** describe where potential errors could occur in the dispensing process	**D1** explain how errors can be minimised in the dispensing procedure
P4 explain the importance of recording errors within the pharmacy working environment [IE2]		
P5 explain the importance of keeping accurate records within the pharmacy working environment		
P6 explain the processes for prescription receipt	**M3** validate a range of prescription forms	**D2** detect errors on prescriptions and explain remedial procedures before dispensing
P7 discuss the types of check that need to be performed on a prescription		
P8 define branded and generic medicines		
P9 explain the processes for prescription collection		
P10 describe automated supply procedures [IE2]		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P11 outline procedures for the ordering and receipt of stock	**M4** explain the different wholesalers and other suppliers of stock, detailing why stock is ordered from different suppliers	**D3** explain the different types of stock that need to be ordered on a seasonal basis
P12 describe appropriate storage conditions for stock		
P13 explain the guidelines for stock control [CT2]		
P14 describe the procedures for dealing with breakages/ spillages	**M5** referring to the laws governing the safe disposal of stock, discuss why stock must be disposed of in a certain way	**D4** explain ways to minimise wastage of stock
P15 describe the process for stock rotation and dealing with expired items		
P16 describe the process for returns and disposal of stock		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Formal teaching on the policies and procedures governing the dispensing and supply of medicine. Tutor led discussion on the professional responsibilities of different levels of staff within the workplace. Personal study time and research.
Learning outcome 2 Formal teaching on the processes for dispensing prescriptions, including prescribing limitations. Tutor led discussion on the types of containers and equipment used in the dispensing process. Use of case studies to identify the different types of prescriber and different types of prescription used in the workplace. Personal study time and research. **Assignment 1: Policies and Procedures Governing the Dispensing and Supply of Medicines** (P1, P2, P3, P4, P5, P6, P7, P8, P9, P10, M1, M2, M3, D1, D2)
Learning outcome 3 Formal teaching on the process of stock control within pharmacy. Tutor led discussion on the different types of suppliers of stock in the pharmacy. Personal study time and research. **Assignment 2: Stock Control in the Pharmacy** (P11, P12, P13, P14, P15, P16, M4, M5, D3, D4)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress

throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners should explain the principles, practices and organisational policies for dispensing medicines. This could be evidenced by the learner producing a written assignment.

For P2, learners need to explain the importance and the use of standard operating procedures. This could be evidenced by the learner producing a simple standard operating procedure.

For P3, learners are required to describe the consequences of near misses and dispensing errors. This could be evidenced by the learner producing a written assignment or producing a flow chart containing relevant images.

For P4, learners are required to explain the importance of recording errors in the pharmacy environment. This could be evidenced by the learner producing an error report form detailing a fictitious incident, a flow chart containing images or by means of a written assignment.

For P5, learners are required to explain the importance of keeping accurate records in the pharmacy environment. This could be evidenced by the learner producing a flow chart containing images or a written assignment.

For P6, learners need to explain the processes for the receipt of prescriptions. This could be evidenced by the learner producing a flow chart with images or explaining the process to an assessor through professional discussion.

For P7, learners need to discuss the types of checks that need to be performed on a prescription. This could be evidenced by the learner performing different checks on prescriptions. The checks carried out by the learner should be documented.

For P8, the learner is required to define branded and generic drugs. This could be evidenced by the learner producing a written assignment.

For P9, learners need to explain the processes for prescription collection. This could be evidenced by the learner producing a written assignment or carrying out a role play scenario with colleagues.

For P10, learners need to describe automated supply procedures. This could be evidenced by the learner completing a diagram of an automated supply system with an accompanying flow chart or a written assignment.

For P11, learners are required to outline the procedures for the ordering and receipt of stock. This could be evidenced by the learner producing a written assignment or a poster with an explanation for the ordering and the receipt of stock.

For P12, learners are required to describe appropriate conditions for the storage of stock. This could be evidenced by the learner completing multiple choice questions, a written assignment or a poster as in P11.

P13 requires learners to explain the guidelines for stock control. This could be evidenced by the learner giving a poster presentation with an explanation as in P11 and P12. Alternatively, a written assignment could be used as evidence.

For P14, learners need to describe the procedures for dealing with breakages or spillages. This could be evidenced by completing a written assignment with images or a simulation of a spillage.

For P15, learners need to describe the process of stock rotation, including how to deal with expired items. This could be evidenced by the learner completing a written assignment with images or answering multiple choice questions.

P16 requires learners to describe the process for the return and disposal of stock. This could be evidenced by the learner completing a written assignment with images, a simulation or answering multiple choice questions.

For M1, learners need to discuss the referral procedures in their workplace, including the responsibilities of staff in this regard. The learner will need to research workplace policies and procedures and this could be evidenced by producing a flow chart indicating different steps in the procedures and the different staff involved.

For M2, learners need to describe where errors could occur in the dispensing process. This could be built on from the evidence produced for P3, P4 and P5. This could be evidenced by a written assignment, a flow chart with images or by the learner completing a error report form for a fictitious incident with supporting explanation.

To achieve M3, learners are required to validate a range of prescription items. This could be evidenced by the learner being assessed or witnessed in the workplace whilst they are validating a number of prescriptions. Alternatively, assessment could take place under simulated conditions.

For M4, learners are required to explain the different wholesalers used by their workplace, the stock supplied by different wholesalers and why different types of stock are ordered from different suppliers. This could be evidenced by the learner producing a flow chart identifying different suppliers and stock.

For M5, learners need to discuss why stock must be disposed of in a certain way, detailing the laws relating to the safe disposal of stock. This could be evidenced by the learner producing a written assignment with images or having a professional discussion with a tutor.

For D1, learners need to explain how errors can be minimised during the dispensing process. This could be evidenced by the learner producing a poster or a written assignment identifying the risk areas and explaining how to minimise errors.

For D2, learners need to detect errors on prescriptions and explain remedial procedures before dispensing. This could be evidenced by the learner producing a flow chart or a written assignment.

For D3, learners need to explain different types of stock ordered on a seasonal basis and ways in which wastage can be minimised. This could be evidenced by the learner producing a flow chart with supporting explanation.

For D4, learners need to explain ways to minimise wastage of stock. This could be linked to the evidence produced for D3.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P3, P4, P5, P6, P7, P8, P9, P10, M1, M2, M3, D1, D2	Policies and Procedures Governing the Dispensing and Supply of Medicines	You have been asked to produce a poster as part of a short presentation to a group of new members of staff. The subject of the presentation is how errors occur in your workplace.	Poster presentation. Handout notes.
P11, P12, P13, P14, P15, P16, M4, M5, D3, D4	Stock Control in the Pharmacy	You have been asked by your manager to write a standard operating procedure on the ordering, receipt, storage and disposal of stock in your workplace.	Standard operating procedure documents. Handout notes. Flowchart.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *Pharmaceutical Science* sector suite. This unit has particular links with:

Level 2	Level 3
Unit 2: Law, Regulation, Health and Safety in Pharmacy	Unit 14: Professional Development in Pharmacy
Unit 3: Working in the Pharmacy Team	Unit 16: Dispensing and Supply of Medicines
Unit 9: Processing a Prescription	Unit 18: Pharmacy Law, Ethics and Practice
Unit 10: Assemble Prescriptions Safely	

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*. It would be useful if learners had access to a current medical dictionary (nursing level would be suitable).

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Applebe G E and Wingfield J – *Pharmacy Law and Ethics, 8th Edition* (Pharmaceutical Press, 2005) ISBN 0853696047

Merrill J and Fisher J – *Pharmacy Law and Practice, 4th Edition* (Blackwell Science, 2006) ISBN 0444522018

Royal Pharmaceutical Society – *Medicines, Ethics and Practice* (Pharmaceutical Press, current, published annually in July)

Journals

MIMS (Monthly Index of Medical Specialities) (Haymarket Group, published monthly)

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.emc.vhn.net	Electronic Data Sheet Compendium
www.medicines.org.uk	Medicines Guide
www.mhra.gov.uk/index.htm	Medicines and Healthcare Products Regulatory Agency

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Effective participators	[EP3, EP4] explaining information given to health practitioners on prescribing errors
Independent enquirers	[IE2] planning and carrying out research for assessments on explaining the principles and practices for dispensing [IE4] researching the roles and responsibilities of staff in the workplace
Creative thinkers	[CT2] asking questions during discussions with workplace supervisors and tutors to extend their thinking on seasonal stock ordering and minimising wastage
Reflective learners	[RL6] communicating their learning in relevant ways for different audiences by validating a range of prescription forms [RL3] inviting feedback and using it as a means of improving their work when detecting errors on prescriptions

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Team workers	[TW1] collaborating with others to work towards common goals during group work
Self-managers	[SM3] organising their time and resources and prioritising actions for assessments

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using ICT systems to find information for assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	able to identify a fault and know the procedure to report it
Manage information storage to enable efficient retrieval	saving information and assignment work in a folder aware of keeping their password safe and not disclosing it to others
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	collecting information from online books and journals
Select information from a variety of sources to meet requirements of a complex task	obtaining relevant information from identified websites
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	checking if the information they require (eg diagrams) is obtainable from a website
Use appropriate software to meet the requirements of a complex data-handling task	creating a single document that contains all the information for their work
Use communications software to meet requirements of a complex task	using email to send centre-produced work to their own address keeping own messages safely in a folder creating a contact list
Combine and present information in ways that are fit for purpose and audience	presenting information from a document as requested in their assignment briefs
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how the documents could be improved
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	taking part in discussions presenting to a group
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading handouts given during formal teaching reading information from a range of resources

Skill	When learners are ...
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing their assignments writing information leaflets and handouts

Unit 17: Pharmaceutics

Unit code: A/601/7800

Level 3: BTEC National

Credit value: 10

Guided learning hours: 60

Aim and purpose

This unit prepares the learner to be able to produce extemporaneous medicinal products for patients. The learner will be able to calculate formulae and use techniques that will ensure a safe and accurate product is produced.

Unit introduction

Pharmaceutics is concerned with the preparation and dispensing of pharmaceutical products (medicines) from the initial formulation stage to the final issuing to a patient. This unit enables learners to develop practical skills in fundamental dispensing procedures, measurements and calculations. Learners will also examine the theoretical aspects and apply practical skills to ensure the safe and accurate preparation of effective, acceptable dispensed medicines.

It is important that those employed in a pharmaceutical workplace have the knowledge and skills to undertake all these activities safely and accurately in order to ensure the safety of both themselves and the patient. It is important that learners gain an appreciation of pharmaceutical and other factors that can result in inaccuracy and poor quality medicines and understand the harm that could result to the health of patients.

Learners will, through the course of the unit, become familiar with the equipment, materials and practical techniques required to make a range of medicines.

Learning outcomes

On completion of this unit a learner should:

1 Understand how to perform accurate calculations for pharmaceutical formulae

2 Understand how to accurately weigh and measure ingredients for pharmaceutical products

3 Understand factors that affect the formulation of pharmaceutical products

4 Know how to prepare pharmaceutical products.

Unit content

1 Understand how to perform accurate calculations for pharmaceutical formulae

Calculations: weights; volumes; percentages; ratios; dilutions; displacement values; small quantity calculations; concentration; use of formulae for extemporaneous dispensing

Dosages and quantities for patients: based on age, weight, surface area and blood volume; quantity of medicine based on number of prescribed doses and time intervals

2 Understand how to accurately weigh and measure ingredients for pharmaceutical products

Weighing and measuring: metric system (SI units); balances; measuring cylinders; conical measures; pipettes; syringes; maintenance of equipment; setting up balances; limitation of errors and limits of tolerance

3 Understand factors that affect the formulation of pharmaceutical products

Pharmaceutical products: solutions; suspensions; mixtures; linctuses; elixirs; emulsions; ointments; creams; pastes; capsules; suppositories; pessaries; lotions; liniments; mouth washes; gargles; powders

Types of water: potable; distilled; de-ionised; purified; water for preparations; water for injections; sterile water; pyrogen free

Pharmaceutical techniques: mixing; comminution; levigation; size reduction; doubling up; filtration

Chemical and physical properties: solubility; solute; solvent; saturated; super saturated; isotonicity; factors affecting rate of solution; characteristics of emulsions, characteristics of suspensions; solid dose forms; chemical and physical purity of raw materials; quality standards applied to materials; contamination of raw materials

Shelf life of dispensed medicines: factors affecting shelf life; determination of shelf life, microbial, chemical and physical contamination and their effects on shelf life

4 Know how to prepare pharmaceutical products

Pharmaceutical products: solutions; suspensions; mixtures; linctuses; elixirs; emulsions; ointments; creams; pastes; capsules; suppositories; pessaries; lotions; liniments; mouth washes; gargles; powders

Packaging materials: types, advantages and disadvantages, their effect on shelf life;giving patients advice on the correct storage of medicines

Labelling requirements: for pharmacopoeial products; for non-formulary products

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	explain the importance of performing accurate calculations	**M1**	accurately perform simple pharmaceutical calculations	**D1**	accurately perform complex pharmaceutical calculations
P2	explain how to calculate accurate dosages and quantities for patients in accordance with prescriptions [IE1,CT1]	**M2**	calculate accurate dosages and quantities for patients in accordance with prescriptions, showing evidence of the ability to check own work	**D2**	identify errors in calculations performed by others
P3	explain the importance of selecting the correct weighing and measuring equipment	**M3**	competently and safely prepare a range of extemporaneous pharmaceutical products	**D3**	working independently, competently and safely, prepare a range of extemporaneous pharmaceutical products using a selection of different compounding techniques
P4	describe weighing and measuring procedures	**M4**	describe sources of error in weighing and measuring techniques	**D4**	calculate limits of tolerance in products made as part of the dispensing process
P5	describe how to use metric system and SI system accurately [IE2]				
P6	describe types of water used in pharmaceutical products	**M5**	explain why products require different types of water in their manufacture		
P7	discuss the properties of different forms of pharmaceutical products [IE3]	**M6**	explain how the requirements of products determine the compounding techniques used		
P8	describe different pharmaceutical compounding techniques [IE3]				

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P9 describe factors affecting the quality and stability of pharmaceutical products [IE2, CT1]	**M7** explain measures used to maximise the stability and quality of dispensed pharmaceutical products	
P10 list the chemical and physical properties of ingredients for pharmaceutical products		
P11 describe different types of pharmaceutical equipment used in compounding [IE3, CT2]		
P12 describe how to prepare a range of pharmaceutical products [IE2, CT3]		
P13 describe how to produce accurate labels	**M8** explain reasons for the legal and safety information required on labels for dispensed products	**D5** provide additional information and advice required for the recipient of extemporaneously dispensed medicines
P14 describe storage requirements for pharmaceutical products [IE2, CT1, CT2]		
P15 explain how to complete and store accurate records [IE2]		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Lectures and workshops on weights, volumes, percentages, ratios, dilutions, displacement values, small quantity calculations, concentration and use of formulae for extemporaneous dispensing. Lectures and workshops on specific types of pharmaceutical calculations based on age, weight, surface area and blood volume. Lectures and workshops on quantity of medicine based on number of prescribed doses and time intervals. Ideally, these lectures and workshops should take place in short bursts interleaved with practical dispensing work so that students can develop their mathematical skills gradually within a pharmaceutical context. **Assignment 1: Pharmaceutical Calculations** (P1, P2, P5, M1, M2, D1, D2)
Learning outcome 2 Explanation of the metric system (SI units), balances, measuring cylinders, conical measures, pipettes, syringes, maintenance of equipment, setting up balances. Demonstration of the above in practice. Students use their own pharmaceutical equipment. Explanation of limitation of errors and limits of tolerance.
Learning outcome 3 Lectures on the background to common pharmaceutical techniques eg mixing, comminution, levigation, size reduction, doubling up, filtration. Lecture on and demonstrations of solutions solubility, solute, solvent, saturated, super saturated, isotonicity, factors affecting rate of solution. Lecture on and demonstrations of suspensions and characteristics of suspensions. Explanation of the background to making mixtures, linctuses and elixirs. Lecture on and demonstrations of emulsions and characteristics of emulsions. Lecture on and demonstrations of ointments, creams and pastes. Lecture on and demonstrations of capsules and solid dose forms. Lecture on and demonstrations of suppositories and pessaries. Lecture on and demonstrations of lotions, liniments, mouth washes and gargles. Lecture on and demonstrations of powders. Workshop on water: potable, distilled, deionised, purified, water for preparations, water for injections, sterile water, pyrogen free. Lecture on chemical and physical purity of raw materials and quality standards applied to materials. Lecture on contamination of raw materials. Workshop on shelf life of dispensed medicines, factors affecting this and determination of shelf life. Workshop on microbial, chemical and physical contamination and their effects on shelf life. **Assignment 2: Pharmaceutical Formulation** (P6, P7, P9, P10, M5, M6, M7,M8)

Topic and suggested assignments/activities and/assessment
Learning outcome 4
Practical class on making solutions.
Practical class on suspensions.
Practical class on mixtures, linctuses and elixirs.
Practical class on emulsions.
Practical class on ointments.
Practical class on creams and pastes.
Practical class on capsules.
Practical class on suppositories and pessaries.
Practical class on lotions, liniments, mouth washes and gargles.
Practical class on powders.
Ideally these practical classes should be run immediately after the lecture and demonstration describing the theoretical aspects of these products so that learners have an immediate opportunity to apply their learning.
Workshop on types of packaging, advantages and disadvantages, their effect on shelf life and giving patients advice on the correct storage of medicines.
Workshop on labelling requirements for pharmacopoeial products and for non- formulary products.
Assignment 3: Practical Dispensing of Pharmaceutical Products (P3, P4, P8, P11, P12, P13, P14, P15, M3, M4, M8, D3, D4, D5) – write up of laboratory work
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners need to explain why it is important to accurately perform a range of basic calculations. The calculations could involve percentages, decimals, serial dilutions as well as the basic scaling up and down of formulae and recipes for medicines.

For P2, learners need to explain how to calculate accurate dosages and quantities for patients in accordance with prescriptions. Learners will need to understand calculations in a pharmaceutical context, for example quantities for a period of time supply, and doses involving children where adjustments to dose are made on the basis of body weight. Calculations centred on body surface area and blood volume should also be included.

For P3, learners need to explain why it is important to correctly select a range of weighing and measuring equipment, for example equipment used for solid and liquid materials, and equipment used to measure a range of liquids, both aqueous and viscous or oily in nature.

For P4, learners need to describe weighing and measuring procedures. The learner could produce a written account of how they weighed and measured materials, following a template for a practical activity or method.

For P5, learners need to describe how they would use balances and measures in their calculations.

P6 requires learners to be aware of the different types of water and to be able to describe the different types of water used routinely in pharmacy both for cleaning, clinical and manufacturing purposes. It would aid learners' understanding if they could also outline how the various types of water are produced and processed.

P7 requires learners to describe the fundamental properties of different types of pharmaceutical formulations for example how an emulsion is made up of a mixture of an oil in water with an emulgent present to provide stability.

For P8, learners are required to describe the various techniques they have used when making medicines for example filtering out extraneous particles to clarify a mixture. This would usually be in the context of a practical lesson write-up.

For P9, learners need to describe which factors can affect the quality and stability of the medicines they make, for example what will cause a cream to curdle, an emulsion to crack or a clear mixture to precipitate a flocculate.

For P10, learners need to list the chemical and physical properties of ingredients for pharmaceutical products. As part of their practical activities, learners will use a range of pharmaceutical ingredients and so it is important that they are aware of the qualities of these items, for example a hygroscopic solid or a ground resin of a South American tree.

For P11, learners need to show that they have become familiar with equipment as they have learned how to do their dispensing. As part of their practical write- ups, they should be able to describe the equipment they have used and the way in which they used that equipment.

For P12, learners are expected to show knowledge of a range of methods for preparing different types of dispensed medicines such as oral solutions, suppositories, capsules and creams. The learner's descriptions should be presented in such a way that others could follow their instructions and make those products themselves.

P13 requires learners to describe the process for producing elegant, legal and pharmaceutically accurate labels to affix to relevant products.

Storage of the finished product is critical to its shelf life and, in order to achieve P14, learners need to describe the storage requirements for the products they have made, most usually on the product label. They also should be able to give patients advice on how to store the medicine in their own home.

P15 requires learners to explain the process for completing and storing accurate records. In their explanation, the learner could refer to records such as prescriptions and prescription books, logbooks or worksheets.

Learners aiming to achieve M1 need to demonstrate that they can cope with not just mathematical calculations but simple calculations within a pharmaceutical context. These are the type of calculations they need to be able to deal with confidently in the workplace.

Dispensing prescriptions requires a great deal of care. Learners aiming to achieve M2 need to demonstrate that they can accurately perform calculations relating to dosages and quantities in a pharmaceutical environment. They should also show evidence of their ability to check their own work before passing it on to a senior person.

M3 provides opportunity for learners to build on the following criteria: P2, P3, P4, P5, P8 P11, P12, P13, P14 and P15. To achieve M3, the learner should show that they have been able to develop their skills and work in a confident and safe way over a range of different situations. The learner should competently and safely prepare a range of extemporaneous pharmaceutical products.

For M4, learners need to show, in some form of description or calculation, that they can describe weighing and measuring errors. They should also be able to describe the point(s) in the dispensing process where these errors arise.

M5 could be demonstrated in a written exercise where the learner articulates explanations for why different types of water are used in the different types of extemporaneous products.

For M6, learners could demonstrate their understanding by means of a written exercise within which they explain how the different properties of the final dispensed products determine their mixing and compounding techniques.

M7 could be demonstrated by learners explaining how they can maximise the stability of their products by considerations regarding storage, preservatives or stabilising agents. This could be part of a written assignment or part of a practical write-up.

For M8, learners need to be able to explain the need for the various legal and safety requirements provided, usually by a computer, on dispensing labels.

To achieve D1, learners need to demonstrate consistent accuracy in their calculations and need to show they can cope with complicated multi-factorial calculations such as isotonicity and depression of freezing point determinations.

To achieve D2, learners need to show that they can identify errors made by others either in their own workplace or in simulated examples. This will demonstrate a good grounding in pharmaceutical calculations and thereby point towards safe practice.

D3 allows learners to build on all their practical dispensing work. They must show that they have been able to develop their skills and work in a confident and safe way, preparing a wide range of different products. Some should be non-routine, for example named patient requests for patients with nasogastric access only.

To achieve D4, learners must calculate limits of tolerance in products made as part of the dispensing process. This could be demonstrated on a dispensed product where tolerance limits are significant. Weights of suppositories, pessaries or capsules and powders would all be suitable examples.

D5 gives the learner an opportunity to show that they understand and can review the type of information they need to give to the patient recipients regarding the medicines they have made. This develops the dispensing process from making a good product to advising the patient in order to maximise their treatment. It also builds on material taught in the *Unit 5: Action and Uses of Medicines*.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P5, M1, M2, D1, D2	Pharmaceutical Calculations	You are presented with a series of pharmaceutical calculations drawn from real life examples in the workplace and will be required to carry out various tasks in this regard.	Homework assignment or a timed assessment.
P6, P7, P9, P10, M5, M6, M7, M8	Pharmaceutical Formulation	You have been asked to produce a new formulation to carry an active ingredient (drug). You are given the specifications by your supervisor and the clinical details by the doctor. You need to research the literature and produce a rationale for the production of this new medicine, including what constituents have gone into it and why, how it will be compounded and labelled and how you maximise its stability.	Research leading to a written report. Production of a real product.
P3, P4, P8, P11, P12, P13, P14, P15, M3, M4, M8, D3, D4, D5	Practical Dispensing of Pharmaceutical Products	You have been asked to prepare, over a significant time period to allow for skill development to occur, a series of commonly used products in pharmacy. The products could include: Compound Sodium Chloride Mouthwash B.P. Chalk Mixture Paediatric B.P. Menthol and Eucalyptus Inhalation B.P. Cod liver Oil Emulsion 30% Aqueous Cream B.P. Zinc Ointment B.P. Aspirin Suppositories 150mg Carmine Capsules Zinc Starch and Talc Dusting powder BPC	Practical dispensing work in a laboratory or workplace.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the Pharmaceutical Science sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy Technicians
Unit 3: Microbiology for Pharmacy
Unit 5: Action and Uses of Medicines
Unit 13: Community Pharmacy Practice
Unit 14: Professional Development in Pharmacy
Unit 15: Communicating in Pharmacy
Unit 16: Dispensing and Supply of Medicines
Unit 18: Pharmacy Law, Ethics and Practice
Unit 19: Making Medicines for Pharmacy

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Bonner MC, Wright DJ and George B – *Practical Pharmaceutical Calculations* (Petroc Press, 1999) ISBN 1900603578

Lapham R and Agar H – *Drug Calculations for Nurses* (Arnold, 2003) ISBN 0340604794

Marriott J, Wilson K, Langley C and Belcher D – *Pharmaceutical Compounding and Dispensing, 1st Edition* (Pharmaceutical Press, 2005) ISBN 085369575X

Rees J and Smith I – *Pharmaceutical Calculations Workbook, 1st Edition* (Pharmaceutical Press, 2005) ISBN 0853696020

Rees J, Smith I and Smith B – *Introduction to Pharmaceutical Calculations, 2nd Edition* (Pharmaceutical Press, 2004) ISBN 0853696039

Winfield AJ and Richards RME – *Pharmaceutical Practice, 4th Edition* (Churchill Livingstone, 2009) ISBN 0443069069

Journals

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.mhra.gov.uk	Medicines and Healthcare Products Regulatory Agency
www.pjonline.com	Pharmaceutical Journal Online
www.rpharms.com	Royal Pharmaceutical Society

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1,IE2,IE3] researching methods and formulae for dispensing and planning how they will prepare a medicine
Creative thinkers	[CT1]trying out new ways of making medicines if they don't succeed the first time [CT2] asking questions to develop their ideas [CT6] adapting their work in response to changing circumstances

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[IE1] asking questions to challenge other learners about why they have chosen a particular course of action [IE6] supporting other learners' conclusions and decisions where appropriate
Reflective learners	[RL2]setting goals for the achievement of practical dispensing exercises [RL5] evaluating progress in learning and making action plans for the future
Team workers	[EP6] encouraging a responsible attitude to their work and their patients [EP5] providing feedback on performance in dispensing
Self-managers	[SM1] challenging self and others and providing new opportunities to try out new methods of dispensing
Effective participators	[EP3] helping other learners to break the dispensing down to manageable steps, particularly in relation to the development of mathematical skills in a pharmaceutical context and to the development of confidence in practical skills

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	preparing dispensing labels writing up assignment work
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	researching materials for practical and theoretical assignments
Manage information storage to enable efficient retrieval	storing their materials and research in electronic formats
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching materials for practical and theoretical assignments
Select information from a variety of sources to meet requirements of a complex task	researching materials for practical and theoretical assignments
ICT – developing, presenting and communicating information	
Use appropriate software to meet the requirements of a complex data-handling task	writing up assignment work
Use communications software to meet requirements of a complex task	using email to network and communicate with others
Combine and present information in ways that are fit for purpose and audience	presenting information according to the requirements of an assignment brief
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	discussing how documents and presentations could be improved
Mathematics – representing	
Understand routine and non-routine problems in familiar and unfamiliar contexts and situations	performing pharmaceutical calculations
Identify the situation or problems and identify the mathematical methods needed to solve them	performing pharmaceutical calculations deciding how to approach a particular practical exercise
Mathematics – analysing	
Use appropriate checking procedures and evaluate their effectiveness at each stage	checking weights and measures used by others and checking their own work
Mathematics – interpreting	
Interpret and communicate solutions to multistage practical problems in familiar and unfamiliar contexts and situations	preparing materials for dispensing medicines
Draw conclusions and provide mathematical justifications	calculating limits of tolerance for products evaluating possible sources of error

Skill	When learners are ...
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	participating in discussions with tutors and other learners
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	using pharmaceutical reference texts to gain information to help them in their dispensing
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	completing worksheets in a logical, clear manner writing up assignments.

Unit 18: Pharmacy Law, Ethics and Practice

Unit code: L/601/7803

Level 3: BTEC National

Credit value: 10

Guided learning hours: 60

Aim and purpose

This unit will ensure that the learner will have the necessary knowledge and understanding to be able to supply and issue medicines ethically, legally and safely.

Unit introduction

In order to practise safely and legally, it is crucial for pharmacy technicians to understand the law relating to pharmacy and how pharmacy works within the National Health Service (NHS), the private sector and industry. This has become increasingly important as pharmacy technicians assume greater responsibility and autonomy. As registered professionals, it is important that they understand the responsibilities that this will bring, and how to make reasoned judgements based on legal and ethical requirements.

This unit provides the knowledge and understanding of laws that relate to pharmacy practice and the pharmacy profession. It identifies all roles within the pharmacy and healthcare professions and considers professional codes of ethics and conduct, and how legislation relates to the safety of patients, the public and other health care workers.

Laws relating to medicines, controlled drugs (CDs), and dangerous substances are examined in this unit, along with other laws that impact on pharmacy practice. Learners are required to relate their knowledge to their own working practice in order to demonstrate further understanding.

The unit identifies and explains NHS organisations and various other pharmacy organisations. Additionally, learners will develop an understanding of the factors that affect standards in health care (particularly in pharmacy practice) and how these are monitored.

Learning outcomes

On completion of this unit a learner should:

1 Understand the laws regulating the sale and supply of medicines and non-medicinal poisons

2 Understand the laws governing the supply of controlled drugs

3 Know other laws that relate to the legal and safe delivery of pharmacy services

4 Know the organisations and staff groups relating to the delivery of pharmacy services

5 Understand the factors affecting standards in pharmacy services.

Unit content

1 Understand the laws regulating the sale and supply of medicines and non-medicinal poisons

Current pharmacy legislation: Medicines Act 1968 (purpose, scope, administration, enforcement); licensing of medicines

Manufacturers and Wholesale Dealers Licence: section 10 dispensing; 'specials'; parallel imports; counterfeit medicines; good distribution practice; records

Classification of medicines: GSL; P; POMs; definitions; pack size restrictions; retail sale; strength variables; supervision of sale and supply

POMs: legal prescriptions and supply; types of prescribers; electronic prescribing; prescribing conventions; prescription types; charges and exemptions; patient group directions; emergency supply; provision of service in a pandemic or other national emergency; forged prescriptions; records; hospital and healthcare professional exemptions

Drug Tariff: payment for supply of medicines; allowable products; endorsing of prescriptions

Labelling and packaging regulations: patient information leaflets; child resistant closures; fluted bottles

Sales promotion of medicines: advertising and promoting; codes of practice

Homeopathic medicines and herbal remedies: licences and classifications

Poisons Act 1972: definitions; poisons list, poison rules (schedules); labelling and storage; sale and supply of poisons; inspection and enforcement

Schedule 1 poisons: sale and supply; storage; records; signed orders; exemptions from requirements

Veterinary regulations: classification; prescription requirements; cascade process; labelling dispensed medicines; records

Denatured alcohol: types and retail sale; supply

2 Understand the laws governing the supply of controlled drugs

Current controlled drugs laws: Misuse of Drugs Act 1971; Misuse of Drugs Regulations 2001 (and amendments); possession; supply; accountable officers; standard operating procedures; classes and schedules; prescriptions; independent and supplementary prescribers; technical errors; midwives; requisition; labelling requirements; patient group directions; safe custody, records and electronic records; collections; returned patients own controlled drugs; destruction requirements; controlled drugs in hospitals; operating department practitioners

Treatment of misusers: drug dependence; tolerance; instalment prescriptions and dispensing; supply of paraphernalia to misusers; supervised consumption; needle and syringe exchange schemes

3 Understand other laws that relate to the legal and safe delivery of pharmacy services

Current legislation: trade descriptions; consumer protection; weights and measures; data protection (Caldicott principles); hazardous substances; Control of Substances Hazardous to Health (COSHH); risk assessment; CHIP4 (classification, labelling and packaging of substances and mixtures (CLP) regulations); health and safety; equality and diversity, equal opportunities, disability discrimination, employment law; adult and child protection; Freedom of information; environment and waste disposal

4 Understand the organisations and staff groups relating to the delivery of pharmacy services

NHS Organisations: Department of Health; Strategic Health Authorities; Primary and Secondary Care; Primary Care Trusts; NHS Trusts; NHS Foundation Trusts; Mental Health Trusts

Other NHS bodies and organizations: Special Health Authorities; NHS Direct; NHSBSA; Local Pharmaceutical Committees; Pharmaceutical Services Negotiating Committee

Other pharmacy organizations: National Pharmacy Association; Guild of Healthcare Pharmacists; Association of Pharmacy Technicians United Kingdom

Current pharmacy professional regulation: structure and function of General Pharmaceutical Council (GPhC) including regulation and registration of pharmacists and pharmacy technicians, registers (standards of entry and fitness to practise); standards of practice; professional discipline; statutory committees; codes of conduct and ethics; continuing professional development (CPD)

Pharmacy professional leadership bodies: Association of Pharmacy Technicians United Kingdom (for pharmacy technicians); Royal Pharmaceutical Society: English, Welsh and Scottish Boards (for pharmacists); Prospectus (APTUK and RPS); practice guidance; professional decision making; continuing professional development support; fitness to practice; professional support

Roles of Pharmacy staff and other healthcare professionals: working as a professional; duty of care; Local Practice Forums; legal and ethical requirements for confidentiality (including the NHS Confidentiality Code of Practice); continuing professional development for pharmacists, including responsible pharmacist, supervision and provision of service in the absence of a pharmacist; continuing professional development for pharmacy technicians, including extended roles and career progression; roles of pharmacy assistants and other healthcare professionals eg doctors, nurses, dentists, veterinarians, opticians

5 Understand the factors affecting standards in pharmacy services

Retail pharmacy business: registered premise (ownership, restricted titles and descriptions, administration, inspection)

Clinical Governance: DoH guidance; New Pharmacy Contract, 3 levels of services

Audit and quality improvement: RPSGB audit resources; clinical audit; risk assessment and management; DoH "High quality care for all"; Quality, Innovation, Productivity, Prevention (QUIPP)

National standards: National Service Frameworks NSFs; National Institute for Health and Clinical Excellence (NICE); National Patient Safety Agency; Care Quality Commission

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria					
To achieve a pass grade the evidence must show that the learner is able to:		**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**		**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**	
P1	describe the key principles and requirements of current legislation relating to the use of drugs and medicines	**M1**	explain how current legislation relating to the use of drugs and medicines is implemented in pharmacy	**D1**	evaluate the implementation of legislation relating to the use of drugs and medicines in different situations
P2	explain the uses of the Drug Tariff	**M2**	interpret information in the Drug Tariff to endorse prescriptions, ensuring correct payment		
P3	describe the main requirements of current legislation relating to the sale or supply of non-medicinal poisons	**M3**	explain how current legislation relating to the sale or supply of non-medicinal poisons is implemented in pharmacy		
P4	outline the current legal requirements for the sale or supply of veterinary medicines	**M4**	explain how current legal requirements for the sale or supply of veterinary medicines are implemented in pharmacy		
P5	summarise the current legal requirements relating to the provision of denatured alcohol	**M5**	explain how current legal requirements relating to the provisions of denatured alcohol are implemented in pharmacy		
P6	describe the key principles and requirements of current legislation relating to the use of controlled drugs	**M6**	interpret legislation for the use of controlled drugs in relation to working practice	**D2**	discuss how legislation relating to the use of controlled drugs impacts on patient care
P7	describe the additional requirements for use of controlled drugs in hospitals	**M7**	explain how the additional requirements for the use of controlled drugs in hospitals are implemented		
P8	explain how drug dependence treatments are supplied to drug misusers [IE1]	**M8**	assess how drug dependence treatments are supplied to drug misusers		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P9 summarise the key principles of legislation within the pharmacy context	**M9** explain how other laws relate to the legal and safe delivery of pharmacy services	**D3** evaluate the implementation of legislation that relates to the safe delivery of pharmacy services
P10 explain how legislation impacts on pharmacy services [CT3]		
P11 describe the structure and function of the National Health Service and other NHS bodies and organisations connected with pharmacy [IE2]	**M10** explain how pharmacy works in conjunction with different NHS organisations	
P12 explain the role of the professional regulator for pharmacy technicians	**M11** compare the roles of the professional regulator and professional leadership body for pharmacy technicians	**D4** assess how the regulation of pharmacy professionals impacts on the pharmacy work place and profession
P13 describe the role of the professional leadership bodies for pharmacists and pharmacy technicians		
P14 compare the roles and responsibilities of the pharmacist, pharmacy support staff and other healthcare professionals within pharmacy practice [IE3]	**M12** discuss how pharmacy staff work with other healthcare professionals to provide effective pharmacy services	
P15 describe the requirements for conducting a retail pharmacy business [CT1]	**M13** explain how the requirements for conducting a retail pharmacy business are monitored	**D5** discuss how pharmacy contracts affect the provision of pharmacy services
P16 explain the principles of clinical governance	**M14** discuss how pharmacy contributes to clinical governance	
P17 explain the importance of standard operating procedures	**M15** explain how audits lead to quality improvement within pharmacy	**D6** discuss how risk assessment in pharmacy contributes to patient care
P18 describe the key principles of audit and quality improvement		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P19 explain how National Health Care Standards contribute to improving patient care [CT2]	**M16** discuss how pharmacy contributes to improvements to patient care using National Standards	

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key			
	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 and Learning outcome 3 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on legislation relating to the use of drugs and medicines, non-medicinal poisons, the sale or supply of veterinary medicines, the provision of denatured alcohol. Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on other laws that impact on pharmacy practice. Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on the use of the drug tariff and how to endorse appropriately to ensure correct payment. **Assignment 1: Legislation Relating to the Use of Drugs and Medicines in Current Pharmacy Practice** (P1, P2, P3, P4, P5, P9,M1, M2, M3, M4, M5,M9, D1, D3)
Learning outcome 2 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on current legislation relating to the supply and use of controlled drugs including additional requirements for hospitals, and services to misusers. **Assignment 2: Laws Governing the Use of Controlled Drugs in Pharmacy** (P6, P7, P8, P10, M6, M7 M8, D2)
Learning outcome 4 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on the following aspects of the NHS: structure, function, organisations, roles. Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on the roles and responsibilities of pharmacy staff and other healthcare professionals. Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on the following aspects of the pharmacy profession: regulation, professional leadership, relevant organisations, roles and responsibilities, code of ethics. **Assignment 3:The Roles of Organisations and Staff Groups Connected with Pharmacy** (P11, P12, P13, P14, M10, M11, M12, D4)
Learning Outcome 5 Tutorials and self study using a variety of resources, workplace tasks, research and multiple choice questions on requirements for retail pharmacy business, clinical governance, audit, quality improvement and the importance of SOPs. Tutorials, self study using a variety of resources, workplace tasks, research, multiple choice questions on National Healthcare Standards and pharmacy's role. **Assignment 4: Factors Affecting Standards in Pharmacy Services** (P15, P16, P17 P18, P19, M13, M14, M15, M16, D5, D6)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/ calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should

be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

A variety of assessment methods can be used in this unit to allow learners the opportunity to make use of all delivery resources available. Assignments may be delivered through blended learning programmes and may include the use of multiple choice questions and case studies.

Most of the evidence from this unit will be generated from a series of assignments that encompass the grading criteria for all learning outcomes although separate assignments could be used for merit and distinction criteria. There may be opportunities for learners to use evidence from work experience as evidence of knowledge criteria being met. Holistic assessment should be use where appropriate and evidence could be used from assignments in other units within the qualification framework. Tutors should ensure that suitable assignment guidance is provided, indicating the requirements for assessment criteria.

For P1, learners need to describe and show sound understanding of legislation relating to the use of drugs and medicines in pharmacy practice. This could be assessed through an assignment linked to other criteria within this unit and could involve the use of case studies.

For M1, learners are required to explain how current legislation relates to current practice. They should be able to interpret how legal requirements apply in working practice, giving relevant examples. This could be assessed using a written assignment to meet other pass and merit criteria.

For D1, learners are required to evaluate the implementation of legislation relating to the use of drugs and medicines in different situations. Evidence may come from a separate written assignment that discusses different situations.

For P2, learners are required to explain the use of the Drug Tariff, including the endorsing of prescriptions and how payment is processed. An assignment for P2 may provide opportunities for the learner to also cover M2.

For M2, learners are required to demonstrate that they know how to use the Drug Tariff to endorse prescriptions appropriately. This could be assessed using an assignment that includes example prescriptions.

For P3, learners need to describe legislation relating to the sale or supply of non-medicinal poisons. This could be assessed using an assignment linked to other pass and merit criteria for learning outcome 1.

For M3, learners are required to explain how current legislation is implemented in current practice. They should be able to interpret legal requirements using examples. This may be linked to an assignment to cover other pass and merit criteria covering legislation in learning outcome 1.

For P4, learners are required to outline the current legal requirements for the sale and supply of veterinary medicines. This may be linked to assignment covering other legislation to meet earlier pass criteria. Alternatively, multiple choice questions could be used.

For M4, learners are required to use the knowledge demonstrated in P4 and further explain how this is implemented in practice. They should be able to interpret legal requirements into working practice, explaining examples of how this takes place.

For P5, learners are required to summarise the current legal requirements relating to the provision of denatured alcohol. This could be linked to an assignment covering other legislation to meet earlier pass criteria. Alternatively, multiple choice questions could be used.

For M5, learners are required to use the knowledge demonstrated in P5 and further explain how this is implemented in practice. They should be able to interpret legal requirements into working practice, explaining examples of how this takes place.

For P6 and P7, learners are required to describe the key principles of current legislation relating to the use of controlled drugs. Additional requirements for the use of controlled drugs in hospital should also be described. An assignment that covers both pass criteria could be used and may including the use of example prescriptions and requisitions.

For M6 and M7, learners are required to show that they are able to apply, in practice, the laws that control the use of controlled drugs. For M6, learners should show understanding of how the laws relating to controlled drugs affect practice. For M7, learners should explain how the additional requirements for the use of controlled drugs are implemented in the hospital workplace. An assignment that covers both P6 and P7 may be used to provide evidence. Relevant workplace examples could also be provided by the learner to show evidence of knowledge.

For D2, learners need to discuss how legislation relating to the use of controlled drugs impacts on patient care. Assessment may lend itself to discussion of real life case studies.

For P8, learners need to explain how drug dependence treatments are supplied to misusers. Learners could produce a written assignment that provides opportunities to also meet the requirements for M8.

For M8, learners need to assess how drug dependence treatments are supplied to misusers. Learners will need to give consideration to all factors involved in the relevant services and consider the most important issues.

For P9 and P10, learners need to show good understanding of other legislation relating to pharmacy practice (namely, non-pharmacy specific laws). For P10, they should explain how legislation impacts on pharmacy services. This could be assessed using an assignment linked to other pass and merit criteria for learning outcome 1.

For M9, learners are required to explain how other legislation relates to the safe delivery of pharmacy services. They should be able to interpret legal requirements in working practice, giving relevant examples. This could be linked to an assignment to cover M1, M3, M4 and M5 in learning outcome 1.

For D3, learners are required to demonstrate further understanding of other legal requirements and how this relates to patient safety. This could be evidenced as an extension to an assignment used for M9 or as a stand-alone assessment.

For P11, learners need to describe the structure and function of the NHS and other NHS bodies associated with pharmacy. Learners could be asked to produce a structure chart identifying different organisations, or they could be asked to produce a written assignment that may also provide evidence to cover M10.

For M10, learners are required to explain how the pharmacy profession works with different organisations. Evidence could be used from an assignment linked to P11.

For P12, learners need to explain the role of the professional regulator for pharmacy technicians. For P13, learners need to describe the role of the professional leadership body. A single written assignment for P12 and P13 could be used, comparing the roles. This would also provide opportunities to cover the requirements of M11.

For M11, learners need to use the knowledge demonstrated for P12 and P13 by comparing the roles of the professional regulator and the professional leadership bodies for pharmacy technicians. This could be linked to an assignment to cover P12 and P13.

For P14, learners need to demonstrate that they can compare different roles and responsibilities of pharmacy staff and other healthcare professionals within pharmacy practice. This could be assessed using evidence from case studies or real life situations.

M12 requires learners to discuss how pharmacy staff work with other healthcare professionals to provide effective pharmacy services. This could be linked to an assignment for P14 or covered by a separate assignment for criteria in learning outcome 5.

For D4, learners are required to assess how the regulation of pharmacy professionals impacts on the pharmacy workplace and profession. This could be assessed in a separate assignment using real life case studies.

For P15, learners need to describe the requirements for conducting a retail pharmacy business. This may be assessed using short answer questions. Alternatively, it could be linked to an assignment that also provides opportunities to present evidence for M13.

For M13, learners are required to explain how the requirements listed in P15 are audited and by whom they are audited. This may be evidenced thorough an assignment linked to P15.

For P16, learners need to explain the principles of clinical governance. This could be evidenced through an assignment covering other criteria in this learning outcome.

For M14, learners need to expand the knowledge demonstrated for P16 and discuss how pharmacy contributes to clinical governance.

For D5, learners need to discuss how pharmacy contracts affect the provision of pharmacy services. This could be assessed using an extension to an assignment which also covers the corresponding pass and merit criteria. Alternatively, the learner could produce a separate assignment for D5.

For P17 and P18, learners are required to explain the importance of standard operating procedures and describe the key principles of audit. This is likely to be linked into evidence for other assignments throughout this unit.

For M15, learners are required to explain how audits lead to improvements within pharmacy. Workplace evidence or simulated situations could be used as an assignment to meet this criterion.

For D6, learners need to discuss how risk assessment contributes to patient care. This may lend itself to a separate assignment. Alternatively, assessment may be demonstrated though other assignments relating to risk management.

For P19, learners need to explain how National Healthcare Standards contribute to improving patient care. An assignment related to a specific national standard could be used to meet this criterion.

For M16, learners need to discuss how pharmacy contributes to the improvement of patient care through healthcare standards. This may be evidenced through an assignment linked to P18.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P3, P4, P5, P9, M1, M3, M4, M5, M9, P2, M2, D1, D3	Legislation Relating to the Use of Drugs and Medicines in Current Pharmacy Practice How to Use the Drug Tariff Other Laws that Relate to the Delivery of Pharmacy Services	You have been asked to produce a table of legislation to be displayed in your work area as a reference for staff. Use the table to categorise legislation into the following sections: Laws that protect the public Laws that protect the profession Care of equipment, use of machines and care with stock Safe pharmacy practice Legal maintenance of the quality of pharmaceutical products and materials For each section, provide an example of how your working practice demonstrates adherence to this legislation. Using the Drug Tariff, detail how you would endorse a variety of example prescriptions ensuring correct payment is processed as applicable. Your work is to be included in a training guide for new members of the team. Your supervisor has asked you to consider an 'emergency' situation eg a national emergency or a one -off emergency request for medication. You are required to write an account discussing how legislation impacts on the provision of pharmacy services required to meet the needs of the public in this particular situation. You have been asked to write a report evaluating other laws that relate to the delivery of pharmacy services. Your report should be illustrated with relevant examples.	Written assignment. Written assignment using example prescriptions. Written account. Written assignment. Written assignment.
P6, P7, P8, P10, M6, M7, M8 D2 P8, M8	Laws Governing the Use of Controlled Drugs in Pharmacy	Using example prescriptions and requisitions for controlled drugs: Validate the prescription identify any issues describe further action required Using case studies, discuss the impact that the legal requirements relating to the supply and use of controlled drugs has on patient care. Your supervisor has asked you to write a report on a service provided by pharmacy for drug misusers.	Written assignment or simulated situation Case study or written assignment Written assignment

Criteria covered	Assignment Title	Scenario	Assessment Method
P11, M10, P14, 12, D4, P12, P13, M11 D4	The Roles of Organisations and Staff Groups Connected with Pharmacy	Your supervisor has asked you to write a report on one NHS organisation and one other organisation. Detail their role within healthcare and how pharmacy contributes to this. You are required to produce a training guide to be used for the induction of new members of the pharmacy team. This should include the following: roles and responsibilities the referral process SOPs As part of your development records, write an account detailing what registration for pharmacy technicians means for you in the workplace and how you think it will change the profession. Write a leaflet for new staff to compare the role of professional regulator for pharmacists and pharmacy technicians and their leadership bodies. Produce a flowchart for new staff members to illustrate the procedure that follows a complaint to the professional regulator.	Report or written assignment. Training guide. Written account. Written leaflet. Flowchart.

Criteria covered	Assignment Title	Scenario	Assessment Method
P19, M16, P16, P17, P18, M14, M15, D6, P15, P19, M13, D5	Factors Affecting Standards in Pharmacy Service	Choose a national service framework and describe the role of pharmacy in the delivery of this framework. Your manager has asked you to produce a report on 'near misses' that occur in your area of work. Record 'near misses' that occur in your pharmacy over a set period using the appropriate documentation. After the set period, analyse the data and identify any trends. Produce a report to show the following: Reasons why this activity is being undertaken Days on which errors occurred Times at which errors occurred The types of errors that have occurred The reasons why the errors occurred. Report any suggestions to improve systems/SOPs. Discuss how risk assessment in Pharmacy contributes to patient care. Your manager has asked you to produce a report on a pharmacy service. Choose a service provided by a pharmacy and write a report detailing the following: Why the service was chosen How the service is facilitated The legal requirements that must be in place for the provision of the service How the pharmacy will be paid for the service provided How this service contributes to improvements to patient care How the service will be monitored.	Written assignment. Workplace activity or written assignment. Written assignment. Written report.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *Pharmaceutical Science* sector suite. This unit has particular links with:

Level 2	Level 3
Unit 1: Communicating with Pharmacy Customers	Unit 13: Community Pharmacy Practice
Unit 2: Law, Regulation Health and Safety in Pharmacy	Unit 14: Professional Development in Pharmacy
Unit 4: Ordering and Issuing Stock in the Pharmacy	Unit 15: Communicating in Pharmacy
Unit 5: Receiving, Storing and Maintaining Stock in the Pharmacy	Unit 16: Dispensing and Supply of Medicines
Unit 6: Preparing for and Manufacture of Aseptic Products	Unit 17: Pharmaceutics
Unit 7: Assisting in the Preparation, Manufacture and Assembly of Medicinal Products	Unit 19: Making Medicines for Pharmacy
Unit 8: Selling Over the Counter Medicines in the Pharmacy	
Unit 9: Processing a Prescription	
Unit 10: Assemble Prescriptions Safely	

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy

is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Applebe G E and Wingfield J – *Pharmacy Law and Ethics, Eighth Edition* (Pharmaceutical Press, 2005) ISBN 0853696047

British National Formulary (Pharmaceutical Press, 2010) ISBN 9780853699279

Royal Pharmaceutical Society – *Medicines, Ethics and Practice* (Pharmaceutical Press, current, published annually in July)

Merrill J and Fisher J – *Pharmacy Law and Practice, Fourth Edition* (Blackwell Science, 2006) ISBN 0444522018

Royal Pharmaceutical Society – *Medicines, Ethics and Practice* (Pharmaceutical Press, current, published annually in July)

The Drug Tariff (HMSO, published monthly)

Journals

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.aptuk.org	Association of Pharmacy Technicians UK
www.dh.gov.uk	Department of Health
www.hse.gov.uk	Health and Safety Executive
www.isdscotland.org	The Prescription Pricing Authority (Scotland)
www.nice.org.uk	National Institute for Clinical Excellence
www.npc.co.uk	National Prescribing Centre
www.ppa.org.uk	The Prescription Pricing Authority
www.psnc.org.uk	Pharmaceutical Services Negotiating Committee
www.rpharms.com	Royal Pharmaceutical Society

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1] explaining supply of drug dependence treatments to drug misusers [IE2] describing the structure and function of various NHS bodies connected with pharmacy [IE3] comparing the roles and responsibilities of various staff within pharmacy practice
Creative thinkers	[CT1] describing the requirements for conducting a retail pharmacy business [CT2] explaining how National Health Care Standards contribute to improving patient care [CT3] explaining the impact of legislation on pharmacy services

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Reflective learners	[R2, R3, R4] reviewing progress with tutors and mentors
Self-managers	[SM2, SM3, SM5] organising and planning assignments and self study
Effective participators	[E1] discussing issues with tutors and colleagues during tutorials

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using the internet to do research completing blended learning assignments word processing assignments or homework
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	using a computer to produce individual learning plans
Manage information storage to enable efficient retrieval	storing assignments in files and folders using workplace systems that contain confidential information
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching online data to assist with assignments
Select information from a variety of sources to meet requirements of a complex task	developing an understanding of appropriate websites to use for research
ICT – Develop, present and communicate information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	
Use appropriate software to meet the requirements of a complex data-handling task	using electronic data to produce text and tables, images and numbers in assignments or in self -study collating various information and files appropriately for their work on this unit
Use communications software to meet requirements of a complex task	using ICT to communicate and network with colleagues and tutors
Combine and present information in ways that are fit for purpose and audience	choosing appropriate tools to present assignments presenting information in the formats requested in assignments
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information	
Mathematics – representing	
Identify the situation or problems and identify the mathematical methods needed to solve them	identifying risks and evaluating data
Mathematics – analysing	
Use appropriate checking procedures and evaluate their effectiveness at each stage	identifying risks and evaluating data

Skill	When learners are ...
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	participating in discussions with mentors, tutors and colleagues
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	reading text provided by tutors using a variety of delivery methods
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing reports and assignments

Unit 19: Making Medicines for Pharmacy

Unit code: Y/601/7805

Level 3: BTEC National

Credit value: 10

Guided learning hours: 60

Aim and purpose

The unit will ensure the learner will have the necessary knowledge and understanding to be able to work safely in the pharmaceutical manufacturing environment.

Unit introduction

This unit is designed to give learners an insight into the complex and varied aspects of the work involved in medicines manufacture. It is important for pharmacy technicians to know how medicines are made. Learners will therefore consider the manufacture of medicines in order to develop an understanding of the concepts of batch formulation, stability, shelf life, drug recall and the need to work in a systematic and auditable way according to standard operating procedures. The unit also covers the principles behind quality assurance of medicines.

The unit aims to provide learners with the knowledge they need to work in sterile/non-sterile pharmacy manufacturing units, either in the hospital sector, in specialised pharmacy manufacturing units (PMU), or in the pharmaceutical industry. This knowledge will be of use to hospital technicians working in aseptic or centralised intravenous additive services (CIVAS). It will also be invaluable for community pharmacy technicians and others working in a pharmaceutical role as it will enable them to understand these areas of pharmacy work.

Learning outcomes

On completion of this unit a learner should:

1 Understand the legislation and guidelines controlling pharmaceutical manufacture

2 Know about the environment and equipment for pharmaceutical manufacture

3 Understand how medicines are manufactured

4 Understand the principles of quality assurance and quality control

5 Understand the aseptic preparation of pharmaceutical products.

Unit content

1 Understand the legislation and guidelines controlling pharmaceutical manufacture

Current legislation and guidance: rules and guidance for pharmaceutical manufacturers

Objectives and related legislation: understand and apply the EEC Directive on Good Manufacturing Practice for Human Medication; the role of the European Medicines Agency (EMEA); the Rules and Guidance for Pharmaceutical Manufacturers and Distributors and current appendices thereof (orange guide); Health and Safety at Work Act (HASAWA), Chemicals Hazard Information and Packaging Regulations (CHIP2) and Control of Substances Hazardous to Health (COSHH) regulations; Aseptic Dispensing for NHS Patients Report; Quality Assurance of Aseptic Preparation Services EL(97) 52; The Medicines Act from the perspective of the licensing system and bringing medicines to market.; environmental and waste regulations

Clinical trials: purpose, design of trials, different types of trials, phases of trials, protection of the public; role of the Medicines and Healthcare Regulatory Authority; role of the qualified person (QP), Intermediate Medicinal Products (IMP)

Organisational procedures and practical application of rules and legislation: the role of the qualified person (QP); production manager and quality controller; product specification file, site master file; selection and training of personnel; hygiene requirements; use and development of local standard operating procedures (SOPs); protective clothing and equipment (PPE)

2 Know about the environment and equipment for pharmaceutical manufacture

The manufacturing environment: manufacturing equipment; use and maintenance of manufacturing equipment including planned preventative maintenance (PPM); essential requirements for sterile and non-sterile products in the manufacturing environment, fabric and fittings of buildings and layout of sterile and non-sterile units; general considerations as indicated in COSHH and HASAWA

Environmental control: sources of contamination in manufacturing practice; environmental and product monitoring in relation to product quality; how design and systems affect product quality

Documentation and system control in pharmacy manufacturing: Local Standard Operating Procedures; the application of legislation to documentation; working procedure manuals, batch worksheets or records and associated documents; storage, distribution and transport of pharmaceutical products; packaging and labelling requirements for manufactured products and work practices in manufacturing and aseptic dispensing units; recording systems using computer systems (GAMP)

3 Understand how medicines are manufactured

Dispensing versus production for stock: the difference between named patient dispensing of extemporaneous and aseptic items and licensed manufacturing; how this is implemented in the workplace; Section 10 exemptions of the Medicines Act and its application in the work environment

Methods employed in non-sterile, sterile and aseptic areas: preparation of areas prior to work; changing requirements; SOPs; training records; sterilisation methods;cleaning, packaging and labelling; storage and delivery, maintenance of optimum storage conditions

Equipment: practical use of autoclaves, stills, mixing equipment, filling and sealing equipment, pumps, unidirectional air flow and isolator cabinets, filters; planned preventative maintenance systems for equipment

Industrial batch production: scaling up of quantities; scaling up of methods of manufacture; scaling up of packaging and transport operations; quality assurance issues particular to large scale production

4 Understand the principles of quality assurance and quality control

Quality control: contamination or impurities in pharmaceutical materials and formulated products, their sources and control; in-process testing, degradation of pharmaceutical products; chemical analysis of raw materials and final products; reasons for product sampling and reliability, sterility and pyrogen testing

Quality assurance: standards in the dispensing or manufacturing process, master formulae and worksheets, official standards relating to containers, raw materials and finished products, quality and freedom from toxicity; product contamination by personnel, environment and personnel monitoring; labelling requirements for manufactured products; shelf life and accelerated stability testing; statutory requirements on quality of pharmaceutical raw materials and formulated products; packaging, labelling and quarantine of completed products, release procedure; batch reconciliation and product recall procedures

Total Quality Management (TQM): implementation of TQM; philosophy or operations management; process control, process validation eg manned counts in work areas; product definition, specifications for chemicals and packaging materials, sterilisation control, steriliser validation, record keeping; health and safety and COSHH reporting procedures; staff training, records, SOPs and work/procedure files, validation, personnel competence validation eg broth and process validation

The audit process: the basis of audit; EEC directives, official guidance notes, ISO and British Standards, Investors in People; internal and external audit; self-inspection; the role of the Medicines and Healthcare Products Regulatory Agency (MHRA)

5 Understand the aseptic preparation of pharmaceutical products

Current Legislation: Rules and Guidance for Pharmaceutical Manufacturers and Distributors (2007); Medicines Act 1968; current health and safety policies; current COSHH polices; CIVAS handbook; Cytotoxic Handbook; Quality Assurance of Aseptic Preparation Services (4th Edition)

Basic aseptic dispensing manipulations of a range of sterile products: different formulations eg eye drops, injections; antibiotic reconstitutions; cytotoxic products; total parenteral nutrition (TPN); radiopharmaceutical products; CIVAS (Centralised Intravenous Additive Service); materials for syringe drivers

Asepsis: the maintenance of sterility during the preparation of dispensed items; potential contaminants of aseptically dispensed items in terms of the environment, equipment, materials and personnel

Health and safety: COSHH and RIDDOR regulations and standard operating procedures; aseptic dispensing for NHS patients, the quality assurance of aseptic services; waste disposal, contamination risk and how to prevent it occurring; calculations eg body surface area calculations, parenteral nutrition calculations, radiopharmacy calculations

Precautions taken: waste disposal regulations and procedures in relation to aseptic dispensing; the environment and equipment eg unidirectional flow cabinets and isolators, raw materials and personnel; preparation prior to dispensing; pharmaceutical packaging and labelling regulations

Quality assurance: its role in the process of aseptic dispensing in terms of microbiological monitoring and process or personnel validation; documentation sterility testing; Section 10 exemptions under the Medicines Act; the differences between aseptic manufacturing and aseptic dispensing

Transport and secure storage arrangements: maintenance of cold chain, documentation associated with transport; special arrangements for cytotoxic/radiopharmaceutical materials; labelling and packaging requirements

NOTE:

In some cases in this description of underpinning knowledge, dates of publication have been included. This is an area of pharmacy where legislation changes frequently. It is incumbent upon tutors to ensure they are teaching the most up-to-date pieces of legislation and the most up-to-date rules and guidance published by the government so that learners are not disadvantaged in their work places.

Assessment and grading criteria

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria for a pass grade describe the level of achievement required to pass this unit.

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 explain the legislation and guidelines governing the manufacture of pharmaceutical products	**M1** discuss examples of how the legislation and guidelines governing the manufacture of pharmaceutical products are applied in practice	**D1** justify why pharmaceutical manufacturing is highly controlled by rules and legislation
P2 discuss an individual's responsibility in relation to current health and safety regulations [IE2]	**M2** explain how health and safety responsibilities can be managed in a manufacturing environment	
P3 explain the difference between dispensing and manufacturing in pharmacy		
P4 explain error reduction strategies in a manufacturing context [IE1]	**M3** discuss the value of error reporting in pharmacy manufacturing	
P5 explain the legislation on manufacture and supply of clinical trial materials	**M4** discuss the different phases and stages in the clinical trial process	
P6 explain the different environments used for pharmaceutical manufacturing [IE3]		
P7 explain the importance of basic and personal hygiene in pharmaceutical manufacture		
P8 explain the potential consequences of different sources of contamination within pharmaceutical manufacturing	**M5** discuss the different sources of contamination which could be present in a manufacturing environment	
P9 describe the importance of planned preventative maintenance in pharmaceutical manufacturing		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P10 describe the procedures for preparing the manufacturing environment of medicines		
P11 explain the difference between sterile and non-sterile manufacturing		
P12 describe documentation used in the manufacturing of medicines	**M6** explain why it is important to have a robust recording system in pharmacy manufacturing	**D2** explain how drug recall procedures are implemented
P13 state the principles of labelling and packaging		
P14 describe the principles of waste disposal		
P15 describe the different methods of sterilisation		
P16 describe the principles for the storage and supply of manufactured products		
P17 explain the difference between quality assurance and quality control [CT2]	**M7** examine a workplace or simulated quality assurance system, explaining the component parts and why they are in place	**D3** critically evaluate the quality assurance system in your workplace or in the simulation you have used
P18 describe how manufactured products are tested		
P19 explain product formulation in pharmacy manufacturing		
P20 discuss the importance of validation and record keeping in quality assurance	**M8** explain a validation system with which you are familiar or a simulation you have been given, and indicate the critical parts	
P21 explain 'Total Quality Management'		
P22 explain the importance of quarantine in pharmacy manufacturing		
P23 describe the different types of products made by aseptic units		
P24 explain the safe disposal of hazardous materials and waste		

Assessment and grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P25 explain the importance of validation in aseptic preparation		

PLTS: This summary references where applicable, in the square brackets, the elements of the personal, learning and thinking skills applicable in the pass criteria. It identifies opportunities for learners to demonstrate effective application of the referenced elements of the skills.

Key	IE – independent enquirers	RL – reflective learners	SM – self-managers
	CT – creative thinkers	TW – team workers	EP – effective participators

Essential guidance for tutors

Delivery

Learners who achieve this qualification will be eligible to register with the General Pharmaceutical Council, providing they meet the other registration criteria. These criteria include simultaneously achieving the complementary competence-based qualification (the Edexcel Level 3 NVQ Diploma in Pharmacy Service Skills (QCF)) and the required current minimum number of hours of work experience in a pharmacy in the role of pre-registration trainee pharmacy technician. Learners who are taking this qualification with a view to registration with the General Pharmaceutical Council should therefore have a portfolio in which to keep a record of activities as this could provide evidence for assessment on either or both qualifications.

Where learners are taking this qualification with a view to registration with the General Pharmaceutical Council, an integrated approach to delivery and assessment will help learners develop the required practical skills whilst acquiring underpinning knowledge and confidence in a pharmacy environment. Tutors should consider integrating the delivery, private study and assessment for this unit with other units and assessment instruments that learners will be taking as part of their programme of study intended to lead to registration with the General Pharmaceutical Council. Learners should have access to a pharmacy department and work with a pharmacist and other members of the pharmacy team to enable them to acquire the skills to develop into competent pharmacy technicians. It is recommended that learners have access within their workplace to sufficient variety in their day–to-day work to enable them to experience most aspects of pharmacy work.

Learners should be encouraged to work independently but should also know when it is necessary to seek advice or guidance.

Health and safety issues relating to working in a pharmacy environment must be regularly reinforced. Risk assessments must be carried out both in the training laboratory and the work environment before the start of any practical activities.

Tutors delivering this unit have opportunities to use a wide variety of delivery methods. Lectures, practical demonstrations, discussions, seminar presentations, research using the internet and/or library resources and the use of workplace pharmacy experience would all be suitable. Delivery should encourage learners to be enthusiastic about their new profession and motivate them to find out more information and improve their skills through questioning and practice.

Pharmacy workplaces should be monitored regularly in order to ensure the quality of the learning experience. Learners and supervisors should be made aware of the requirements of this unit before any work–related activities take place, so that naturally occurring evidence can be collected at the time. Activities provided on the underpinning knowledge programme may be linked and provide evidence for the learner's competency-based qualification, (where the competency-based qualification is being undertaken).

Learners will become aware of the health and safety requirements and quality assurance procedures necessary to ensure patient safety and satisfaction. Visits to clinical environments, other than a pharmacy, to meet with patients and other health care professionals, would be beneficial at this stage of the learning process.

Since this unit is about the manufacture of medicines, it would enhance learners' experience if they could visit one or more of the following: a manufacturing unit in a hospital, industrial pharmacy manufacturing premises, a large aseptic unit or CIVAS unit in a hospital, possibly a radiopharmacy. It would be ideal if these were licensed units but units operating under Section 10 of the Medicines Act would also be valuable.

This is a specialist unit and learners would benefit greatly from input from a range of outside speakers such as a production manager or quality controller, the manager of an aseptic unit, specialist pharmacy technicians from hospital aseptic units, clinical trials laboratories and Centralised Intravenous Additive Services or those

delivering a cytotoxic service to patients.

Outline learning plan

The outline learning plan has been included as guidance and can be used in conjunction with the programme of suggested assignments.

The outline learning plan gives **an indication of the volume of learning it would take the average learner** to achieve the learning outcomes. It is **indicative and is one way of achieving the credit value**.

Learning time should address all learning (including assessment) relevant to the learning outcomes, regardless of where, when and how the learning has taken place.

Topic and suggested assignments/activities and/assessment
Introduction to the unit and structure of the programme of assignments.
Learning outcome 1 Lectures on legislation associated with pharmacy manufacturing, rules and guidance for pharmacy manufacturers, EEC Directive, HASWA and COSHH. Practical applications of the legislation in the workplace, using students' own experiences. Talk by visiting speaker on role of the production manager and quality controller and QP. Workshop: How clinical trials operate. **Assignment 1: Legislation Controlling Pharmacy Manufacturing** (P1, P2, P3, P5, P11, M1, M2, M4, D1)
Learning outcome 2 Lectures on premises design, fabric and materials. Discussion about sources of contamination and how design can minimise this. Investigation of documentation systems in pharmacy manufacturing, standard operating procedures and document control systems. Visit to a manufacturing unit. **Assignment 2: Designing a Manufacturing Unit** (P6, P7, P10, P16)
Learning outcome 3 Lecture on dispensing versus manufacturing. Student led workshop: different types of environment. Lecture on equipment used in manufacturing, including its use and cleaning and maintenance. Lecture should include isolators and laminar flow cabinets, sterilisers and mixers. Lecture and DVD on personal hygiene and garments used in manufacturing. Calculations workshop on scaling up to batch production and manufacturing considerations. **Assignment 3: Design Your Own Manufacturing Process** (P8, P9, P15, P19, P23, M5) **Assignment 4: Create Your Own Documentation** (P10, P12, P13, P16, M6, D2)

Topic and suggested assignments/activities and/assessment
Learning outcome 4
Concepts of quality control, quality assurance and total quality management explained.
Standards of raw materials and packaging materials.
Environmental monitoring – types available, sterility, pyrogen testing etc.
Record keeping and how these relate to documentation.
Product recall and batch reconciliation.
Audit, its purpose and importance in manufacturing.
Inspection systems and the MHRA.
Assignment 5: Understanding Quality Systems (P4, P17, P18, P20, P21, P22, P25, M3, M7, M8, D3)
Learning outcome 5
Asepsis and what it means – concepts of sterility and microbial and particulate contamination.
Application of legislation and inspection regimens to this aspect of the work.
Practical workshop using typical products involved in making aseptic products.
Health and safety issues, waste disposal.
Calculations workshop on cytotoxic and total parenteral nutrition products.
Transport and security regulations.
Assignment 6: Waste Disposal in Manufacturing (P2, P14, P24)
Assignment 7: Aseptic Dispensing (P7, P8, P20, P23, P25, M5)
Review of unit and programme of assignments.

Assessment

Because significant harm can result to patients as a consequence of incorrect actions or incorrect information being given to a patient or their representative, it is vital to ensure that correct answers/calculations/formulations are provided by learners in their assessments.

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. Learners who wish to become registered pharmacy technicians will be required to work independently and make professional decisions themselves. This needs to be taken into account when assessing learners and so the terms working with 'substantial guidance', with 'limited guidance' and 'independently' should be used. When assessing the work, assessors should follow the guidelines given below:

Substantial guidance: Learners have to be guided and advised throughout to ensure that progress is made. Learners rely on the support of the tutor, who has to assist in most aspects of the work. This level of support restricts learners to a pass grade, irrespective of the quality of the evidence.

Limited guidance: The tutor supports learners initially, for instance, in the choice of topic for investigation. Thereafter, the tutor reacts to questions from learners and suggests a range of ideas that they can act upon. Learners frequently check matters of detail. The tutor needs to assist in some aspects of the work. This level of support restricts learners to a pass or a merit grade, irrespective of the quality of the evidence.

Independently: The tutor supports learners initially, for instance in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists learners and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

For P1, learners are required to explain the legislation that governs the manufacture of pharmaceuticals and how it is underpinned by official guidelines. This could be evidenced by a written assignment.

For P2, learners need to discuss their own responsibility and their employer's responsibility in respect of health and safety in a manufacturing environment. This could be evidenced in a written assignment or a professional discussion with a competency assessor.

To achieve P3, learners need to show they understand the legal and practical differences between dispensing and manufacturing in pharmacy. This could be assessed as a written assignment which also covers P1.

For P4, learners need to draw on the knowledge of errors and error reporting which they have gained from other units in this qualification. In achieving P4, learners need to explain how to reduce errors in a manufacturing context. This could be done either by using a real error reporting system or by explaining how such a system could operate.

Clinical trials are a complex, specialist area in manufacturing and subject to large amounts of legislation. To achieve P5, learners' explanations need to show a sound understanding of the relevant laws and issues involved in supply of materials for clinical trials. This could be achieved as part of a group discussion, the design of a simulated clinical trial or as part of a written assignment.

To achieve P6, learners need to explain the nature of different pharmacy manufacturing environments and explain why they are structured in particular ways. The learner could do this after a visit to a real manufacturing unit or in response to a slide show or simulated exercise involving design of a manufacturing facility.

Personal hygiene is very important in manufacturing units and can have a significant effect on the final products. To achieve P7, learners need to be able to explain the importance of this aspect. Evidence could be presented by means of a written exercise or a simulated activity.

For P8, the learner will need to explain the potential consequences of different sources of contamination within pharmaceutical manufacturing. Learners will already have examined examples of contamination in *Unit 3: Microbiology for Pharmacy* and *Unit 17: Pharmaceutics*, so they could therefore extrapolate these findings to a manufacturing rather than a dispensing environment in order to achieve P8. This could be evidenced as a written assignment or as a discussion with a tutor.

For P9, learners are required to describe the importance of Planned Preventative Maintenance in pharmaceutical manufacturing. The learner should show that they understand that equipment maintenance is vital if product quality is to meet pharmacopoeial standards. The learner could evidence this by discussing a real system for planned preventative maintenance or by doing a written or design exercise.

P10 requires learners to describe how to prepare a medicines manufacturing environment, including stock preparation, consumables, facilities and personnel. This could be done as a part of a design exercise or as a consequence of a visit to a manufacturing facility or alternatively, drawn from the learner's own professional practice.

For P11, learners explanations need to show a clear understanding of the difference between sterile and non-sterile products. This could be achieved in a written assignment, possibly in combination with the evidenced produced for P1.

For P12, learners need to describe the different types of documentation they will encounter in pharmacy manufacturing. They could do this by constructing a poster display of different documents types, supported by an explanation of the use of their items. Alternatively, the learner could design a series of documents which could be used in a department with which they are familiar or used in a simulated department.

For P13, learners need to state the principles of labelling and packaging. In achieving P13, learners need to draw on the knowledge they have gained about labelling and packaging in *Unit 18: Pharmacy Law, Ethics and Practice*. This knowledge should be applied to a manufacturing context for P13 so the learner shows their

understanding of labelling and packaging principles in manufacturing.

Waste disposal processes are vital to help ensure a decent and safe environment, and they are enshrined in law. For P14, learners need to describe the principles of waste disposal. This could be evidenced through a written assignment.

For P15, learners need to draw on their knowledge of micro-organisms as covered in *Unit 3: Microbiology for Pharmacy*. P15 requires learners to describe the different B.P. methods of sterilisation and explain how these achieve kill. This could be evidenced as a written assignment which could be linked to Unit 3.

For P16, learners need to describe the general principles of storage and supply of manufactured products. P16 draws on the knowledge acquired through *Unit 13: Community Pharmacy Practice* and *Unit 16: Dispensing and Supply of Medicines*. In achieving P16, learners could therefore progress to a description of how these principles apply in a manufacturing context. This could be evidenced as a written assignment.

P17 requires learners to explain the difference between quality assurance and quality control. A written assignment or exercise could demonstrate that the learner has an understanding of the difference between these two concepts.

P18 requires learners to provide a description of how chemical raw materials, intermediate products and finished products are tested using pharmacopoeial methods.

For P19, learners need to explain how pharmaceutical products are formulated. In this regard, learners should draw on the knowledge gained in *Unit 17: Pharmaceutics*, to consider the large scale considerations of pharmaceutical manufacturing. This could be evidenced as a written assignment.

For P20, learners need to discuss the importance of validation in pharmaceutical manufacturing. This could be evidenced through discussion of an existing validation system or by the learner designing their own process.

P21 requires the learner to explain 'Total Quality Management'. This is an additional concept relating to quality of pharmaceutical products and could be discussed in combination with P17 and linked to the evidence produced for P17.

For P22, learners need to show that they understand that manufactured pharmaceuticals cannot be used until they are fully tested and this requires them to be quarantined until they can be safely used. Learners could demonstrate this as part of the evidence produced for P17. Alternatively, they could describe a system with which they currently work.

For P23, learners need to describe a range of different products made in aseptic units to show they have grasped the difference between manufacturing and aseptic dispensing, and the types of products they are likely to find. Learners working in an aseptic environment could describe products they make. Alternatively, learners could carry out research to discover the types of products and complete a written exercise about their findings.

For P24, learners could explain a waste disposal system with which they are familiar and how they are involved in that process, where applicable. Alternatively, learners could produce evidence using a simulated or theoretical situation.

For P25, learners need to explain the importance of validation in aseptic preparation. P25 links logically to P20 and could be incorporated as part of the evidence produced for P20. Alternatively, learners working in aseptic units could participate in validation procedures and could provide evidence of competence and a description of their work.

For M1, learners need to draw upon the knowledge they demonstrated for P1 regarding the legislation and guidelines applying to manufacturing. M1 requires learners to develop that knowledge and apply it to the real work situation by discussing examples they have seen, participated in or learned about.

For M2, learners need to be able to relate health and safety to the manufacturing environment and progress beyond personal responsibility to explain how this can be built in as part of systems and site design. This could be achieved through a design or poster exercise.

M3 requires learners to discuss why error reporting is of critical importance in pharmacy. This could be done as a written exercise. Alternatively, the learner could use an error reporting system and fill in a justification for the system.

In achieving M4, learners could use a chart or form to discuss the phases of trials and the different stages and types found in the potential pharmaceutical marketplace.

For M5, learners need to draw on knowledge obtained through *Unit 3: Microbiology for Pharmacy* and *Unit 17: Pharmaceutics*, and P8. M5 links with P8 and could be assessed concurrently. To achieve M5, learners could, in a workplace or laboratory, demonstrate in practice the examples of contamination in a manufacturing or aseptic environment and discuss their source.

For M6, learners need to explain the importance of a robust recording system in pharmacy. Learners will already have addressed the concepts underpinning standard operating procedures in other units in this qualification. In achieving M6, learners should therefore build on this knowledge by emphasising the importance of robust recording, with particular focus on pharmaceutical manufacturing.

Having learned about quality assurance in a theoretical way, M7 requires learners to examine a QA system and explain why the component parts exist and what purposes they fulfil. Learners could make use of a real QA system in their workplace or use a simulated system provided for assessment purposes.

Having learned about validation in a theoretical way, M8 requires learners to examine a validation system and explain why the component parts exist and what purposes they fulfil. Learners should show they have taken note of the critical parts of this process. Learners could make use of a real validation system in their workplace or use a simulated system provided for assessment purposes.

D1 requires learners to produce a set of reasons why pharmaceutical manufacturing is subject to such strict control. Learners need to think about the advantages and disadvantages of this level of control in terms of manufacturers, the regulatory agencies and the patient or recipient of the product.

D2 could be evidenced by building on a documentation system learners have studied and written about, or designed themselves. In order to achieve D2, the learner need to show evidence of how these documents support a drug recall event. The evidence should also show that the learner understands the drug recall process.

D3 requires learners to critically evaluate a quality assurance system, either a real one from their workplace or a simulated one provided for the purposes of assessment. This could take the form of a written exercise.

Programme of suggested assignments

The table below shows a programme of suggested assignments that cover the pass, merit and distinction criteria in the grading grid. This is for guidance and it is recommended that centres either write their own assignments or adapt any Edexcel assignments to meet local needs and resources.

Criteria covered	Assignment Title	Scenario	Assessment Method
P1, P2, P3, P5 P11, M1, M2, M4, D1	Legislation Controlling Pharmacy Manufacturing	Your supervisor has asked you to write a report which reviews the legislation related to pharmacy manufacturing and aseptic processing.	Written timed assessment or multiple choice test.

Criteria covered	Assignment Title	Scenario	Assessment Method
P6, P7, P10, P16	Designing a Manufacturing Unit	You have been asked to design a unit in which pharmaceuticals can be prepared. Your design should consider materials, fixtures and fittings, how you could minimise contamination and produce a product of high quality.	Written report or creation of a model or representation of a manufacturing unit.
P8, P9, P15, P19, P23, M5	Design Your Own Manufacturing Process	You have been given a product to make. Design the process by which its manufacture will be achieved.	Poster or flow chart.
P10, P12, P13, P16, M6, D2	Create Your Own Documentation	Produce an example of the documentation, including that for packaging and labelling for the product you made in Assignment 3.	Pharmaceutical documentation for real product.
P4, P17, P18, P20, P21, P22, P25, M3, M7, M8, D3	Understanding Quality Systems	Your supervisor has asked you to write a brief report on the quality assurance system in your workplace, identifying the key components of the system and describing whether or not these key components are effective.	Written report.
P2, P14, P24	Waste Disposal in Manufacturing	Your supervisor has asked you to write a report describing the underpinning principles of waste disposal, explaining how it can be disposed of safely and describing the responsibilities of individuals involved.	Written report or standard operating procedure.
P7, P8, P20, P23, P25, M5	Aseptic Dispensing	Your supervisor has asked you to write a report describing the products made in an aseptic unit and how they and the operators are validated. Your report should describe how contamination can be minimised. It should also highlight the importance of personal hygiene.	Written assignment.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit forms part of the *Pharmaceutical Science* sector suite. This unit has particular links with:

Level 3
Unit 1: Chemical Principles for Pharmacy Technicians
Unit 3: Microbiology for Pharmacy
Unit 14: Professional Development in Pharmacy
Unit 16: Dispensing and Supply of Medicines
Unit 17: Pharmaceutics

Essential resources

Facilities required for this unit include learner access to a pharmacy fulfilling the necessary requirements of the General Pharmaceutical Council. Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council should have access to a registered pharmacist and, if possible, other members of the pharmacy team to act as a support or mentor.

Staff delivering this unit should be competent, experienced and registered with the General Pharmaceutical Council. They should have recent experience of pharmacy practice and show evidence of contact with the profession and continuing professional development in order to maintain their registration with the General Pharmaceutical Council. Exceptions to the requirement for registration with the General Pharmaceutical Council may apply in Northern Ireland.

Learners will need access to a library with a range of relevant books, journals and electronic resources for example *MedicinesComplete*.

Employer engagement and vocational contexts

Learners undertaking this qualification as part of the requirements for registration with the General Pharmaceutical Council must be employed in a pharmacy while gaining their qualification. The number of hours required per week in a pharmacy is specified by the General Pharmaceutical Council (see www.pharmacyregulation.org for further information). Learners' workplaces should comply with all relevant health and safety legislation.

Learners may work in any kind of pharmacy for example community, hospital, prison but they must have access to a registered pharmacist and, where possible, other members of the wider pharmacy team. Learners must also be given opportunities to experience a variety of different aspects of pharmacy service provision while they are classed as **pre-registration trainee pharmacy technicians**.

Some learners will be taking this qualification as a stand-alone knowledge-based qualification without the intention of registration with the General Pharmaceutical Council. Access to work placement in a pharmacy is strongly recommended for these learners. Where possible, all learners should visit other related areas of health care, for example a doctor's surgery or a ward or department in a hospital, as this will enable learners to obtain a balanced overview of how the pharmacy service relates to other healthcare environments.

Indicative reading for learners

Textbooks

Beaney AM – *Quality Assurance of Aseptic Preparation Services* (Pharmaceutical Press, 2005) ISBN 0853696155

Blaine, Templar and Smith (Ed) – *Nuclear Pharmacy 1st Edition* (Pharmaceutical Press, 2010) ISBN 9788853698661

Collett DM and Aulton ME – *Pharmaceutical Practice* (Churchill Livingstone, 1990) ISBN 0443036446

Denyer SP, Hodges NA and Gorman SP – *Hugo and Russell's Pharmaceutical Microbiology, 7th Edition* (Blackwell, 2004) ISBN 0632064676

Lund W – *The Pharmaceutical Codex, 12th Edition* (The Pharmaceutical Press, 1994) ISBN 0853692904

Medicines Control Agency – *Rules and Guidance for Pharmaceutical Manufacturers and Distributors* (The Stationery Office, 2007) ISBN 9780853687190

Sampson's Textbook of Radiopharmacy, 5th Edition (edited by Theobald, T) (Pharmaceutical Press, 2010) ISBN 978 0 85369 789 3

Winfield AJ and Richards RME – *Pharmaceutical Practice, 4th Edition* (Churchill Livingstone, 2009) ISBN 0443069069

Journals

Pharmaceutical Journal (Pharmaceutical Press, 2010)

Websites

www.emea.europa.eu	European Medicines Agency
www.essentialscience.co.uk	Essential Science Support Website
www.mhra.gov.uk	Medicines and Healthcare Products Regulatory Agency

Delivery of personal, learning and thinking skills

The following table identifies the opportunities for personal, learning and thinking skills (PLTS) that have been included within the pass assessment criteria of this unit:

Skill	When learners are ...
Independent enquirers	[IE1] explaining error reduction strategies in a manufacturing context [IE2] discussing an individual's responsibility concerning health and safety regulations [IE3] explaining the different environments used for pharmaceutical manufacturing
Creative thinkers	[CT2] explaining the difference between quality assurance and quality control

Although PLTS opportunities are identified within this unit as an inherent part of the assessment criteria, there are further opportunities to develop a range of PLTS through various approaches to teaching and learning.

Skill	When learners are ...
Independent enquirers	[CT1] exploring new ideas and issues in respect of pharmaceutical manufacturing and the legislation which constrains it
Reflective learners	[RL1] evaluating their workplace systems and those of others
Team workers	[CT1] working with others to design systems and premises
Self-managers	[SM2, SM5] working towards goals, assessment deadlines and grading criteria whilst dealing with competing pressures from their personal lives and their workplaces

Functional Skills – Level 2

Skill	When learners are ...
ICT – using ICT	
Plan solutions to complex tasks by analysing the necessary stages	using CAD and drawing packages to execute design assignments
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	developing flow charts for quality systems
Manage information storage to enable efficient retrieval	storing their materials and research in electronic formats
ICT – finding and selecting information	
Use appropriate search techniques to locate and select relevant information	researching aspects of pharmaceutical manufacturing
ICT – developing, presenting and communicating information	
Enter, develop and refine information using appropriate software to meet requirements of a complex task	designing posters producing written assignments
Use appropriate software to meet the requirements of a complex data-handling task	designing an assignment
Use communications software to meet requirements of a complex task	creating contact records for communication purposes using email and other online communication methods
Combine and present information in ways that are fit for purpose and audience	designing posters
Mathematics – representing	
Understand routine and non-routine problems in familiar and unfamiliar contexts and situations	calculating measurements for scaling in design projects
English – Speaking, Listening and Communication	
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	participating in discussions about validation, quality assurance systems or error reporting systems
English – Reading	
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	researching various aspects of pharmaceutical manufacturing and the rules and guidance document (Orange Guide)
English – Writing	
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	writing answers to questions communicating ideas through flow charts, posters and three dimensional models

Further information

For further information please call Customer Services on 020 701 02188 (calls may be recorded for training purposes) or email: TeachingScience@pearson.com.

Useful publications

Further copies of this document and related publications can be obtained by contacting us:

Telephone: 0845 172 0205
Email: publication.orders@edexcel.com

Related information and publications include:

- Functional Skills publications – specifications, tutor support materials and question papers
- the current Edexcel publications catalogue and update catalogue.

Edexcel publications concerning the Quality Assurance System and the internal and external verification of vocationally related programmes can be found on the Edexcel website and in the Edexcel publications catalogue.

NB: Most of our publications are priced. There is also a charge for postage and packing. Please check the cost when you order.

How to obtain National Occupational Standards

Skills for Health

(Head office)
2nd Floor
Goldsmiths House
Broad Plain
Bristol BS2 0JP
Tel: 0117 922 1155

Fax: 0117 925 1800

Email: office@skillsforhealth.org.uk

www.skillsforhealth.org.uk

Professional development and training

Pearson supports UK and international customers with training related to BTEC qualifications. This support is available through a choice of training options offered in our published training directory or through customised training at your centre.

The support we offer focuses on a range of issues including:

- planning for the delivery of a new programme
- planning for assessment and grading
- developing effective assignments
- building your team and teamwork skills
- developing student-centred learning and teaching approaches
- building Functional Skills into your programme
- building in effective and efficient quality assurance systems.

The national programme of training we offer can be viewed on our website (www.edexcel.com/training). You can request customised training through the website or by contacting one of our advisers in the Training from Pearson UK to discuss your training needs.

Calls may be recorded for training purposes.

The training we provide:

- is active – ideas are developed and applied
- is designed to be supportive and thought provoking
- builds on best practice.

Our training is underpinned by the LLUK standards for those preparing to teach and for those seeking evidence for their continuing professional development.

Annexe A

The Pearson BTEC qualification framework for the Pharmacy Services sector

Progression opportunities within the framework:

Level	General qualifications		BTEC full vocationally-related qualifications	BTEC Short Courses	NVQ/occupational
5			BTEC Level 5 HND Diploma in Applied Biology BTEC Level 4 HND Diploma in Applied Chemistry		
4			BTEC Level 4 HNC Diploma in Applied Biology BTEC Level 4 HNC Diploma in Applied Chemistry		
3	GCSE Sciences: Chemistry, Physics, Biology/Human Perspectives on Science; Psychology		Pearson BTEC Level 3 Diploma in Pharmaceutical Science		Edexcel Level 3 NVQ Diploma in Pharmacy Services Skills
2	GCSE Science; Additional Science; Astronomy; Chemistry; Physics; Biology; Psychology	GCSE Science	Pearson BTEC Level 2 Certificate in Pharmaceutical Science		Edexcel Level 2 NVQ Certificate in Pharmacy Services Skills
1			Pearson BTEC Level 1 Award, Certificate and Diploma in Applied Science		
Entry			Foundation Learning Tier (Applied Science)		

Annexe B

Grading domain 1	Indicative characteristics – merit	Indicative characteristics – distinction
Application of knowledge and understanding (Learning outcome stem *understand* or *know*)	• Shows depth of knowledge and development of understanding in familiar and unfamiliar situations (for example explain why, makes judgements based on analysis). • Applies and/or selects concepts showing comprehension of often complex theories. • Applies knowledge in often familiar and unfamiliar contexts. • Applies knowledge to non-routine contexts (eg assessor selection). • Makes reasoned analytical judgements. • Shows relationships between pass criteria.	• Synthesises knowledge and understanding across pass/merit criteria. • Evaluates complex concepts/ideas/ actions and makes reasoned and confident judgements. • Uses analysis, research and evaluation to make recommendations and influence proposals. • Analyses implications of application of knowledge/understanding. • Accesses and evaluates knowledge and understanding to advance complex activities/contexts. • Shows relationships with p/m criteria. • Responds positively to evaluation.
Grading domain 2	**Indicative characteristics – merit**	**Indicative characteristics – distinction**
Development of practical and technical skills (Learning outcome stem *be able to*)	• Deploys appropriate advanced techniques/processes/skills. • Applies technical skill to advance non-routine activities. • Advances practical activities within resource constraints. • Produces varied solutions (including non-routine). • Modifies techniques/processes to situations. • Shows relationship between p criteria.	• Demonstrates creativity/originality/ own ideas. • Applies skill(s) to achieve higher order outcome. • Selects and uses successfully from a range of advanced techniques/ processes/skills. • Reflects on skill acquisition and application. • Justifies application of skills/methods. • Makes judgements about risks and limitations of techniques/processes. • Innovates or generates new techniques/processes for new situations. • Shows relationship with p and m criteria.

Grading domain 3	Indicative characteristics – merit	Indicative characteristics – distinction
Personal development for occupational roles (Any learning outcome stem)	• Takes responsibility in planning and undertaking activities. • Reviews own development needs. • Finds and uses relevant information sources. • Acts within a given work-related context showing understanding of responsibilities. • Identifies responsibilities of employers to the community and the environment. • Applies qualities related to the vocational sector. • Internalises skills/attributes (creating confidence).	• Manages self to achieve outcomes successfully. • Plans for own learning and development through the activities. • Analyses and manipulates information to draw conclusions. • Applies initiative appropriately. • Assesses how different work-related contexts or constraints would change performance. • Reacts positively to changing work-related contexts • Operates ethically in work-related environments. • Takes decisions related to work contexts. • Applies divergent and lateral thinking in work-related contexts. • Understands interdependence.
Grading domain 4	**Indicative characteristics – merit**	**Indicative characteristics – distinction**
Application of generic skills (Any learning outcome stem)	• Communicates effectively using appropriate behavioural and language registers. • Communicates with clarity and influence. • Makes judgements in contexts with explanations. • Explains how to contribute within a team. • Demonstrates positive contribution to team(s). • Makes adjustments to meet the needs/ expectations of others (negotiation skills). • Selects and justifies solutions for specified problems.	• Presents self and communicates information to meet the needs of a variety of audience. • Identifies strategies for communication. • Shows innovative approaches to dealing with individuals and groups. • Takes decisions in contexts with justifications. • Produces outputs subject to time/ resource constraints. • Reflects on own contribution to working within a team. • Generates new or alternative solutions to specified problems. • Explores entrepreneurial attributes.

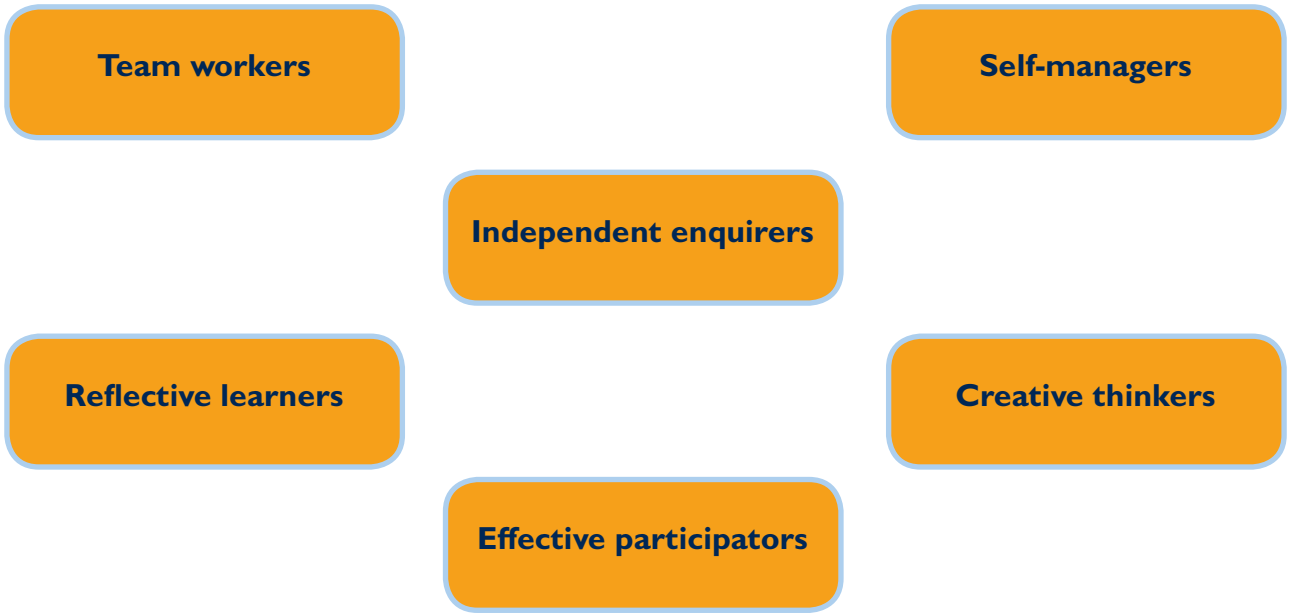
Annexe C

Personal, learning and thinking skills

A FRAMEWORK OF PERSONAL, LEARNING AND THINKING SKILLS 11–19 IN ENGLAND

The framework comprises six groups of skills that, together with the Functional Skills of English, mathematics and ICT, are essential to success in learning, life and work. In essence the framework captures the essential skills of: managing self; managing relationships with others; and managing own learning, performance and work. It is these skills that will enable young people to enter work and adult life confident and capable.

The titles of the six groups of skills are set out below.



For each group there is a focus statement that sums up the range of skills. This is followed by a set of outcome statements that are indicative of the skills, behaviours and personal qualities associated with each group.

Each group is distinctive and coherent. The groups are also inter-connected. Young people are likely to encounter skills from several groups in any one learning experience. For example an independent enquirer would set goals for their research with clear success criteria (reflective learner) and organise and manage their time and resources effectively to achieve these (self-manager). In order to acquire and develop fundamental concepts such as organising oneself, managing change, taking responsibility and perseverance, learners will need to apply skills from all six groups in a wide range of learning contexts 11-19.

The Skills

Independent enquirers

Focus:

Young people process and evaluate information in their investigations, planning what to do and how to go about it. They take informed and well-reasoned decisions, recognising that others have different beliefs and attitudes.

Young people:

- identify questions to answer and problems to resolve
- plan and carry out research, appreciating the consequences of decisions
- explore issues, events or problems from different perspectives
- analyse and evaluate information, judging its relevance and value
- consider the influence of circumstances, beliefs and feelings on decisions and events
- support conclusions, using reasoned arguments and evidence.

Creative thinkers

Focus:

Young people think creatively by generating and exploring ideas, making original connections. They try different ways to tackle a problem, working with others to find imaginative solutions and outcomes that are of value.

Young people:

- generate ideas and explore possibilities
- ask questions to extend their thinking
- connect their own and others' ideas and experiences in inventive ways
- question their own and others' assumptions
- try out alternatives or new solutions and follow ideas through
- adapt ideas as circumstances change.

Reflective learners

Focus:

Young people evaluate their strengths and limitations, setting themselves realistic goals with criteria for success. They monitor their own performance and progress, inviting feedback from others and making changes to further their learning.

Young people:

- assess themselves and others, identifying opportunities and achievements
- set goals with success criteria for their development and work
- review progress, acting on the outcomes
- invite feedback and deal positively with praise, setbacks and criticism
- evaluate experiences and learning to inform future progress
- communicate their learning in relevant ways for different audiences.

Team workers

Focus:

Young people work confidently with others, adapting to different contexts and taking responsibility for their own part. They listen to and take account of different views. They form collaborative relationships, resolving issues to reach agreed outcomes.

Young people:

- collaborate with others to work towards common goals
- reach agreements, managing discussions to achieve results
- adapt behaviour to suit different roles and situations, including leadership role
- show fairness and consideration to others
- take responsibility, showing confidence in themselves and their contribution
- provide constructive support and feedback to others.

Self-managers

Focus:

Young people organise themselves, showing personal responsibility, initiative, creativity and enterprise with a commitment to learning and self-improvement. They actively embrace change, responding positively to new priorities, coping with challenges and looking for opportunities.

Young people:

- seek out challenges or new responsibilities and show flexibility when priorities change
- work towards goals, showing initiative, commitment and perseverance
- organise time and resources, prioritising actions
- anticipate, take and manage risks
- deal with competing pressures, including personal and work-related demands
- respond positively to change, seeking advice and support when needed
- manage their emotions, and build and maintain relationships.

Effective participators

Focus:

Young people actively engage with issues that affect them and those around them. They play a full part in the life of their school, college, workplace or wider community by taking responsible action to bring improvements for others as well as themselves.

Young people:

- discuss issues of concern, seeking resolution where needed
- present a persuasive case for action
- propose practical ways forward, breaking these down into manageable steps
- identify improvements that would benefit others as well as themselves
- try to influence others, negotiating and balancing diverse views to reach workable solutions
- act as an advocate for views and beliefs that may differ from their own.

PLTS performance indicator (suggested recording sheet)

Name:	Date:				
	Level of success 1 = low, 5 = high				
Independent enquirers					
Identify questions to answer and problems to resolve	1	2	3	4	5
Plan and carry out research, appreciating the consequences of decisions	1	2	3	4	5
Explore issues, events or problems from different perspectives	1	2	3	4	5
Analyse and evaluate information, judging its relevance and value	1	2	3	4	5
Consider the influence of circumstances, beliefs and feelings on decisions and events	1	2	3	4	5
Support conclusions, using reasoned arguments and evidence	1	2	3	4	5
Creative thinkers					
Generate ideas and explore possibilities	1	2	3	4	5
Ask questions to extend their thinking	1	2	3	4	5
Connect their own and others' ideas and experiences in inventive ways	1	2	3	4	5
Question their own and others' assumptions	1	2	3	4	5
Try out alternatives or new solutions and follow ideas through	1	2	3	4	5
Adapt ideas as circumstances change	1	2	3	4	5
Reflective learners					
Assess themselves and others, identifying opportunities and achievements	1	2	3	4	5
Set goals with success criteria for their development and work	1	2	3	4	5
Review progress, acting on the outcomes	1	2	3	4	5
Invite feedback and deal positively with praise, setbacks and criticism	1	2	3	4	5
Evaluate experiences and learning to inform future progress	1	2	3	4	5
Communicate their learning in relevant ways for different audiences	1	2	3	4	5

Team workers					
Collaborate with others to work towards common goals	1	2	3	4	5
Reach agreements, managing discussions to achieve results	1	2	3	4	5
Adapt behaviour to suit different roles and situations, including leadership roles	1	2	3	4	5
Show fairness and consideration to others	1	2	3	4	5
Take responsibility, showing confidence in themselves and their contribution	1	2	3	4	5
Provide constructive support and feedback to others	1	2	3	4	5
Self-managers					
Seek out challenges or new responsibilities and show flexibility when priorities change	1	2	3	4	5
Work towards goals, showing initiative, commitment and perseverance	1	2	3	4	5
Organise time and resources, prioritising actions	1	2	3	4	5
Anticipate, take and manage risks	1	2	3	4	5
Deal with competing pressures, including personal and work-related demands	1	2	3	4	5
Respond positively to change, seeking advice and support when needed	1	2	3	4	5
Manage their emotions, and build and maintain relationships.	1	2	3	4	5
Effective participators					
Discuss issues of concern, seeking resolution where needed	1	2	3	4	5
Present a persuasive case for action	1	2	3	4	5
Propose practical ways forward, breaking these down into manageable steps	1	2	3	4	5
Identify improvements that would benefit others as well as themselves	1	2	3	4	5
Try to influence others, negotiating and balancing diverse views to reach workable solutions	1	2	3	4	5
Act as an advocate for views and beliefs that may differ from their own	1	2	3	4	5

Note to learner: The circled number represents an indication of your PLTS performance so far.

Note to tutor: Indicate the level of success by circling the appropriate number during your feedback with the learner.

Summary of the PLTS coverage throughout the programme

Personal, learning and thinking skills	Unit								
	1	2	3	4	5	6	7	8	9
Independent enquirers	✓		✓		✓	✓	✓	✓	✓
Creative thinkers	✓	✓	✓	✓	✓	✓	✓	✓	✓
Reflective learners	✓	✓	✓	✓	✓	✓	✓	✓	✓
Team workers	✓		✓	✓	✓	✓			✓
Self-managers	✓	✓	✓	✓	✓	✓	✓	✓	✓
Effective participators	✓				✓	✓	✓	✓	✓
✓ – opportunities for development									

Personal, learning and thinking skills	Unit									
	10	11	12	13	14	15	16	17	18	19
Independent enquirers	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Creative thinkers	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Reflective learners	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Team workers		✓	✓	✓	✓	✓	✓	✓		✓
Self-managers	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Effective participators	✓	✓	✓	✓	✓	✓	✓		✓	
✓ – opportunities for development										

Annexe D

Wider curriculum mapping

Study of the Pearson BTEC Level 3 Diploma in Pharmaceutical Science gives learners opportunities to develop an understanding of spiritual, moral, ethical, social and cultural issues as well as an awareness of citizenship, environmental issues, European developments, health and safety considerations and equal opportunities issues.

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science makes a positive contribution to wider curricular areas as appropriate.

Spiritual, moral, ethical, social and cultural issues

The qualification contributes to an understanding of:

- spiritual issues – for example in *Unit 13: Community Pharmacy Practice* where learners consider how the moral and ethical issues of patients in the community are taken into account and the various sources of resources for providing a service to patients in care
- moral and ethical issues – for example in *Unit 11: Malignant Disease, Immunosuppressive and Musculoskeletal Medicines* where learners become aware of ethical considerations involved in the treatment of patients
- social and cultural issues – for example in *Unit 15: Communicating in Pharmacy* where learners consider the sociological, environmental and economic factors which contribute to healthcare and healthcare promotion.

Citizenship issues

Learners undertaking the Pearson BTEC Level 3 Diploma in Pharmaceutical Science will have the opportunity to develop their understanding of citizenship issues, for example in terms of their rights and responsibilities in a pharmacy workplace.

Environmental issues

Learners undertaking the Pearson BTEC Level 3 Diploma in Pharmaceutical Science will have the opportunity to develop their understanding of environmental issues for example through the experience of the pharmacy sector in many units.

European developments

Much of the content of the Pearson BTEC Level 3 Diploma in Pharmaceutical Science applies throughout Europe even though delivery is in a UK context.

Health and safety considerations

The Pearson BTEC Level 3 Diploma in Pharmaceutical Science is practically based and health and safety issues are encountered throughout the units.

Equal opportunities issues

Equal opportunities issues are implicit throughout the Pearson BTEC Level 3 Diploma in Pharmaceutical Science.

Wider curriculum mapping

Level 3

	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8	Unit 9
Spiritual					✓			✓	
Moral and ethical				✓	✓	✓	✓	✓	✓
Social and cultural				✓	✓	✓	✓	✓	✓
Citizenship issues									✓
Environmental issues	✓	✓	✓	✓	✓	✓	✓	✓	✓
European developments				✓	✓	✓	✓	✓	✓
Health and safety considerations	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equal opportunities issues	✓	✓	✓	✓	✓	✓	✓	✓	✓

	Unit 10	Unit 11	Unit 12	Unit 13	Unit 14	Unit 15	Unit 16	Unit 17	Unit 18	Unit 19
Spiritual	✓	✓		✓	✓	✓	✓			
Moral and ethical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Social and cultural	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Citizenship issues				✓	✓	✓	✓		✓	
Environmental issues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
European developments	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Health and safety considerations	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equal opportunities issues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Annexe E

Mapping to Level 2 Functional Skills

	Unit number																		
English – Speaking, Listening and Communication	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Make a range of contributions to discussions in a range of contexts, including those that are unfamiliar, and make effective presentations	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
English – Reading	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Select, read, understand and compare texts and use them to gather information, ideas, arguments and opinions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
English – Writing	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Write a range of texts, including extended written documents, communicating information, ideas and opinions, effectively and persuasively	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mathematics – representing:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Understand routine and non-routine problems in familiar and unfamiliar contexts and situations	✓																✓		✓
Identify the situation or problems and identify the mathematical methods needed to solve them	✓												✓	✓			✓	✓	
Choose from a range of mathematics to find solutions	✓																		
Mathematics – analysing	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Apply a range of mathematics to find solutions	✓																		
Use appropriate checking procedures and evaluate their effectiveness at each stage	✓																✓	✓	

	Unit number																		
Mathematics – interpreting	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Interpret and communicate solutions to multistage practical problems in familiar and unfamiliar contexts and situations	✓																✓		
Draw conclusions and provide mathematical justifications	✓												✓				✓		
ICT – using ICT	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Plan solutions to complex tasks by analysing the necessary stages	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Select, interact with and use ICT systems safely and securely for a complex task in non-routine and unfamiliar contexts	✓	✓	✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Manage information storage to enable efficient retrieval	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ICT – finding and selecting information	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Use appropriate search techniques to locate and select relevant information	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Select information from a variety of sources to meet requirements of a complex task	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
ICT – developing, presenting and communicating information	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
Enter, develop and refine information using appropriate software to meet requirements of a complex task	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓
Use appropriate software to meet the requirements of a complex data-handling task	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Use communications software to meet requirements of a complex task	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Combine and present information in ways that are fit for purpose and audience	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Evaluate the selection, use and effectiveness of ICT tools and facilities used to present information		✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		

Annexe F

Mapping with the General Pharmaceutical Council (GPhC) Standards for the Initial Education and Training of Pharmacy Technicians, June 2010

The grid below maps the knowledge covered in the Pearson BTEC Level 3 Diploma in Pharmaceutical Science (QCF)/General Pharmaceutical Council (GPhC) Standards for the Initial Education and Training of Pharmacy Technicians, June 2010

KEY

✓ indicates that the BTEC National covers all of the underpinning knowledge of the GPhC Standard

# indicates partial coverage of the GPhC Standard

a blank space indicates no coverage of the GPhC Standard

	Units																		
GPhC Standards Document	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**
B3.1 Chemistry	✓																		
B3.2 Microbiology			✓																
B3.3 Biology, human physiology and action and uses of medicines and other pharmaceutical products	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓							
B3.4 Interpersonal skills													✓	✓	✓				
B3.5 Dispensing procedures and practices																✓	✓		
B3.6 Pharmacy law and ethics																	✓	✓	
B3.7 Pharmaceutical production and aseptic procedures																	✓		✓

Annexe G

Examples of calculation of qualification grade above pass grade

Edexcel will automatically calculate the qualification grade for your learners when your learner unit grades are submitted.

The generic examples below demonstrate how the qualification grade above pass is calculated using the following two tables which are also shown in the section earlier on in the specification *Calculation of the qualification grades above pass grade*.

Points available for credits achieved at different levels and unit grades

The table below shows the **number of points scored per credit** at the unit level and grade.

Unit Level	Points per credit		
	Pass	Merit	Distinction
Level 2	5	6	7
Level 3	**7**	**8**	**9**
Level 4	9	10	11

Learners who achieve the correct number of points within the ranges shown in the 'qualification grade' table below will achieve the qualification merit, distinction or distinction* grades (or combinations of these grades appropriate to the qualification).

Qualification grade

BTEC Level 3 Certificate

Points range above pass grade	Grade	
230-249	Merit	M
250-259	Distinction	D
260 and above	Distinction*	D*

BTEC Level 3 Subsidiary Diploma

Points range above pass grade	Grade	
460-499	Merit	M
500-519	Distinction	D
520 and above	Distinction*	D*

BTEC Level 3 Diploma

Points range above pass grade	Grade
880-919	MP
920-959	MM
960-999	DM
1000-1029	DD
1030-1059	DD*
1060 and above	D*D*

BTEC Level 3 Extended Diploma

Points range above pass grade	Grade
1300-1339	MPP
1340-1379	MMP
1380-1419	MMM
1420-1459	DMM
1460-1499	DDM
1500-1529	DDD
1530-1559	DDD*
1560-1589	DD*D*
1590 and above	D*D*D*

Example 1

Achievement of pass qualification grade

A learner completing a 30-credit Pearson BTEC Level 3 Certificate **does not** achieve the points required to gain a merit qualification grade.

	Level	Credit	Grade	Grade points	Points per unit = credit x grade
Unit 1	3	10	Pass	7	10 × 7 = 70
Unit 2	3	10	Pass	7	10 × 7 = 70
Unit 3	3	10	Merit	8	10 × 8 = 80
Qualification grade totals		**30**	**Pass**		**220**

Example 2

Achievement of merit qualification grade

A learner completing a 30-credit Pearson BTEC Level 3 Certificate achieves the points required to gain a merit qualification grade.

	Level	Credit	Grade	Grade points	Points per unit = credit x grade
Unit 1	3	10	Pass	7	10 × 7 = 70
Unit 2	3	10	Merit	8	10 × 8 = 80
Unit 3	3	10	Merit	8	10 × 8 = 80
Qualification grade totals			**Merit**		**230**

Example 3

Achievement of distinction qualification grade

A learner completing a 60-credit Pearson BTEC Level 3 Subsidiary Diploma achieves the points required to gain a distinction qualification grade.

	Level	Credit	Grade	Grade points	Points per unit = credit x grade
Unit 1	3	10	Merit	8	10 × 8 = 80
Unit 2	3	10	Distinction	9	10 × 9 = 90
Unit 3	3	10	Distinction	9	10 × 9 = 90
Unit 5	3	10	Merit	8	10 × 8 = 80
Unit 6	2	10	Distinction	7	10 × 7 = 70
Unit 11	3	10	Distinction	9	10 × 9 = 90
Qualification grade totals		**60**	**Distinction**		**500**

Example 4

Achievement of distinction merit qualification grade

A learner completing a 120-credit Pearson BTEC Level 3 Diploma achieves the points required to gain a distinction merit qualification grade.

	Level	Credit	Grade	Grade points	Points per unit = credit x grade
Unit 1	3	10	Merit	8	10 × 8 = 80
Unit 2	3	10	Distinction	9	10 × 9 = 90
Unit 3	3	10	Distinction	9	10 × 9 = 90
Unit 4	3	10	Merit	8	10 × 8 = 80
Unit 5	3	10	Merit	8	10 × 8 = 80
Unit 6	2	10	Distinction	7	10 × 7 = 70
Unit 11	3	10	Distinction	9	10 × 9 = 90
Unit 15	4	10	Merit	10	10 × 10 = 100
Unit 17	3	10	Pass	7	10 × 7 = 70
Unit 18	3	10	Pass	7	10 × 7 = 70
Unit 25	3	20	Merit	8	20 × 8 = 160
Qualification grade totals		**120**	**Distinction Merit**		**980**

Example 5

Achievement of merit merit merit qualification grade

A learner completing a 180-credit Pearson BTEC Level 3 Extended Diploma achieves the points required to gain a merit merit merit qualification grade.

	Level	Credit	Grade	Grade points	Points per unit = credit x grade
Unit 1	3	10	Merit	8	10 × 8 = 80
Unit 2	3	10	Pass	7	10 × 7 = 70
Unit 3	3	10	Distinction	9	10 × 9 = 90
Unit 4	3	10	Merit	8	10 × 8 = 80
Unit 5	3	10	Pass	7	10 × 7 = 70
Unit 6	2	10	Distinction	7	10 × 7 = 70
Unit 11	3	10	Distinction	9	10 × 9 = 90
Unit 12	3	10	Merit	8	10 × 8 = 80
Unit 15	4	10	Pass	9	10 × 9 = 90
Unit 17	3	10	Pass	7	10 × 7 = 70
Unit 18	3	10	Pass	7	10 × 7 = 70
Unit 20	3	10	Pass	7	10 × 7 = 70
Unit 22	3	10	Merit	8	10 × 8 = 80
Unit 25	3	20	Pass	7	20 × 7 = 140
Unit 35	3	10	Distinction	9	10 × 9 = 90
Unit 36	3	10	Merit	8	10 × 8 = 80
Unit 38	3	10	Distinction	9	10 × 9 = 90
Qualification grade totals		**180**	**Merit Merit Merit**		**1410**

Unit mapping overview

The Edexcel Level 3 BTEC National Certificate in Pharmacy Services (specification end date 31/08/2010)/ new version of the Pearson BTEC Level 3 Diploma in Pharmaceutical Science:

Old units / New units	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12	Unit 13	Unit 14	Unit 15	Unit 16	Unit 17	Unit 18	Unit 19
Unit 1	P											P							
Unit 2	F																		
Unit 3									F										
Unit 4								X											
Unit 5			P			P													
Unit 6			P	P															
Unit 7						P													
Unit 8					P														
Unit 9				P															
Unit 10				P	P	P													
Unit 11			P	P															
Unit 12					P														
Unit 13										P									
Unit 14																			
Unit 15										P									
Unit 16																			
Unit 17							X												
Unit 18		X																	
Unit 19											X								

KEY

P – Partial mapping (some topics from the old unit appear in the new unit)

F – Full mapping (topics in old unit match new unit exactly or almost exactly)

X – Full mapping + new (all the topics from the old unit appear in the new unit, but new unit also contains new topic(s))

Unit mapping in depth

The Edexcel Level 3 BTEC National Certificate in Pharmacy Services (specification end date 31/08/2010)/new QCF version of the Pearson BTEC Level 3 Diploma in Pharmaceutical Science (QCF)

New units		Old units		Mapping/comments
Number	**Name**	**Number**	**Name**	
Unit 1	Chemical Principles for Pharmacy Technicians	**1** **12**	Scientific Principles for Pharmacy Chemistry for Pharmacy	Learning outcome 1 is as old Learning outcome 2 except experimental investigations have been removed Learning outcome 2 as part of old Unit 12 Learning outcome 2 and Learning outcome 3 Learning outcome 3 is the same as old Unit 1 Learning outcome 3
Unit 2	Biological Principles for Pharmacy	**1**	Scientific Principles for Pharmacy	Same as old unit 1 except metabolism removed
Unit 3	Microbiology for Pharmacy	**9**	Microbiology for Pharmacy	Same as old unit 3 except microbiological techniques removed
Unit 4	Human Physiology for Pharmacy	**8**	Human Physiology for Pharmacy	Same as old unit 8 but has addition of musculoskeletal systems and more detail specified on urinary systems and sensory organs
Unit 5	Action and Uses of Medicines	**3** **6**	An Introduction to Action and Uses of Medicines Cardio-Respiratory and Genito-Urinary medicines and Medicines Management	Same as old unit 3 for Learning outcome 1 and Learning outcome 3 Gastrointestinal and musculoskeletal medicines have been relocated into another unit. Learning outcome 2 is the same as old unit 6 Learning outcome 4

New units		Old units		Mapping/comments
Number	**Name**	**Number**	**Name**	
Unit 6	Gastrointestinal and Nutritional Medicines	**3** **4**	An introduction to Action and Uses of Medicines Cytotoxic, Endocrine and Nutritional Medicines	Learning outcome 1 is the same as old unit 3 Learning outcome 2 Learning outcome 2 is the same as old unit 4 Learning outcome 1 for nutrition except that dialysis has been relocated to another unit and metabolic disorders has been added to new unit 6 Learning outcome 3 is the same as old unit 4 Learning outcome 3 for blood disorders
Unit 7	Cardio-Respiratory Medicines	**6**	Cardio-Respiratory and Genito-urinary Medicines and Medicines Management	Same as old unit 6 Learning outcome 1 for Cardio-Respiratory medicines
Unit 8	Central Nervous System Medicines and Anaesthesia	**5**	Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines	Same as old unit 5 Learning outcome 1 except for the addition of CNS stimulants, ADHD and obesity
Unit 9	Infections, Immunological Products and Vaccines	**4**	Cytotoxic, Endocrine and Nutritional Medicines	Learning outcome 1 is the same as old unit 4 Learning outcome 1 except for the addition of H1N1 influenza Learning outcome 2 is the same as old unit 4 Learning outcome 5 except for the addition of vaccination in pandemics
Unit 10	Endocrine and Genito-Urinary Medicines	**4** **5** **6**	Cytotoxic, Endocrine and Nutritional Medicines Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines Cardio-Respiratory and Genito-urinary Medicines and Medicines Management	Learning outcome 1 is the same as old unit 4 Learning outcome 2 Learning outcome 2 is the same as old unit 5 Learning outcome 5 Learning outcome 3 is the same as old unit 6 Learning outcome 2 except for the addition of kidney dialysis

New units		Old units		Mapping/comments
Number	**Name**	**Number**	**Name**	
Unit 11	Malignant Disease, Immunosuppressive and Musculoskeletal medicines	**3** **4**	An Introduction to Action and Uses of Medicines Cytotoxic, Endocrine and Nutritional Medicines	Learning outcome 1 is a new addition Learning outcome 2 is the same as old unit 4 Learning outcome 4 Learning outcome 3 is the same as old unit 3 Learning outcome 3 except for the addition of drugs used in soft tissue and neuromuscular disorders
Unit 12	Eye, Ear, Nose and Dermatological Medicines	**5**	Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines	Learning outcome 1 is the same as old unit 5 Learning outcome 2 Learning outcome 2, Learning outcome 3 and Learning outcome 4 are the same as old unit 5 Learning outcome 3 except for the addition of more specific detail on diseases, drug therapies and patient consultation Learning outcome 5 is the same as old unit 5 Learning outcome 4
Unit 13	Community Pharmacy Practice	**10**	Pharmacy Practice	Most of this unit is new, however Learning outcome 1 has partial coverage of old unit 10 Learning outcome 3

New units		Old units		Mapping/comments
Number	**Name**	**Number**	**Name**	
Unit 14	Professional Development in Pharmacy			This is a new unit
Unit 15	Communicating in Pharmacy	**10**	Pharmacy Practice	Most of this unit is new but it does partially cover old unit 10
Unit 16	Dispensing and Supply of Medicines			This is a new unit
Unit 17	Pharmaceutics	**7**	Pharmaceutics	Unit covers old unit 7 Learning outcome 2, Learning outcome 3 and Learning outcome 4 Calculations for patients is a new addition to the unit
Unit 18	Pharmacy Law, Ethics and Practice	**2**	Pharmacy Law, Ethics and Practice	This unit is the same as old unit 2 except that references to staff groups have been added and legislation has been updated Learning outcome 5 has been added to cover clinical governance, audit and quality improvement and national standards
Unit 19	Making Medicines for Pharmacy	**11**	Pharmacy Production	This unit is the same as old unit 11 except for the addition of clinical trials, environmental controls and industrial batch productions Legislation and guidelines have been updated

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