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Tutor Support Material

Assignment briefs

The Edexcel BTEC Level 3 Diploma in Pharmaceutical Science (QCF)

To support specifications first taught from September 2010

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Contents

Introduction

These Assignment briefs support delivery of the Edexcel Level 3 BTEC Diploma in Pharmaceutical Science (QCF). It should be read in conjunction with the published specification (Publication Code B024924).

Most BTEC units include an *Essential guidance for tutors* section which brings together the unit's learning outcomes, content and grading grid, to provide an overview of how the unit could be delivered and assessed.

These Assignment briefs supplement the *Essential guidance for tutors* and provide a programme of sample assessments where unit assessment requirements have been divided into a number of manageable activities and assignments. They cover some of the assessment and grading criteria for *Unit 3: Microbiology for Pharmacy*, *Unit 9: Infections, Immunological Products and Vaccines*, *Unit 12: Eye, Ear, Nose and Dermatological Medicines*, *Unit 14: Professional Development in Pharmacy* and *Unit 19: Making Medicines for Pharmacy* which form part of the Edexcel Level 3 BTEC Diploma in Pharmaceutical Science (QCF).

Where sample assessments do not cover all of the published assessment and/or grading criteria, other assignments for the unit will need to be created by the centre. All assignments must be subject to the centre's normal quality assurance procedures.

Use of these Assignment briefs is not compulsory. Tutors may feel that the unit can be assessed more effectively in a different way. This may be because of the way the qualification is organised within their centre or after taking into consideration their learners, their learning styles and prior learning.

Sample assignment for Unit 12: Eye, Ear, Nose and Dermatological Medicines (coverage of selected assessment criteria) and Unit 14: Professional Development in Pharmacy (coverage of selected assessment criteria)

Assessment activity front sheet

This front sheet must be completed by the learner and included with the work submitted for assessment.

Learner name:	Assessor name:	
Date issued:	Completion date:	Submitted on:
Qualification: Edexcel BTEC Level 3 Diploma in Pharmaceutical Science (QCF)		
Unit 12: Eye, Ear, Nose and Dermatological Medicines (coverage of selected assessment criteria) and Unit 14: Professional Development in Pharmacy (coverage of selected assessment criteria)		

Assignment title — Helping Patients with Skin, Hair and Nail Disorders

In this assessment you will have opportunities to provide evidence against the following criteria. Indicate the page numbers where the evidence can be found.

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U12 (P17)	Describe common disorders affecting the skin, hair and nails	2	4
U12 (P18)	Explain how common medicines are used in each of the disorders		
U12 (P19)	Outline common side effects of these medicines		
U12 (P20)	Explain information that must be given to the patient about their skin, hair and nail medicines	3	5
U12 (M13)	Describe the pharmacological actions of medicines used to treat disorders affecting the skin, hair and nails	4	5
U12 (M14)	Discuss the reasons why side effects occur with medicines used to treat disorders affecting the skin, hair and nails		

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U14 (P2)	Explain the key features of effective communication in pharmacy settings	5	5
U14 (P5)	Explain the importance of customer confidentiality in pharmacy settings		
U14 (P3)	Describe customers needs and how to respond appropriately		
U12 (M15)	Explain how counselling patients with disorders affecting the skin, hair and nails improves medication compliance		
U12 (D10)	Recommend ways in which patients can manage their medication for disorders affecting the skin, hair and nails effectively		
U14 (M1)	Describe the different types of communication relevant to pharmacy customer service	6	5
U14 (M3)	Explain the term 'confidentiality' as it applies to pharmacy settings		
U12 (D9)	Analyse the factors involved in the choice of therapeutic agents for the treatment of disorders of the skin, hair and nails	7	6
U14 (P1)	Identify the different customers that use the pharmacy service	1	4
U14 (D1)	Relate communication skills to pharmacy customer service	8	6
U14 (D2)	Review pharmacy customers service policies		
U14 (P16, M11, D7)	Discuss own CPD requirements and those of their pharmacy job role Describe how to record their CPD Provide examples of recorded CPD	9	6

Learner declaration

I certify that the work submitted for this assignment is my own and that research sources are fully acknowledged.

Learner signature: Date:

Unit 12 (part) and Unit 14 (part)	Eye, Ear, Nose and Dermatological Medicines and Professional Development in Pharmacy
Start date:	
Deadline date:	
Assessment feedback will be provided by:	
Assessor:	

Assignment title — Helping Patients with Skin, Hair and Nail Disorders

The purpose of this assignment is to:

enable you to learn about medicines used in hair, nail and skin disorders, their side effects and how to communicate information about these appropriately to patients and customers. Completion of this assignment could contribute towards Continuing Professional Development (CPD).

Scenario

You have several patients who attend your pharmacy, either hospital or community, who have a range of dermatological conditions. You have been asked to investigate the medicines used to treat these conditions in a general sense and demonstrate the application of this knowledge for one particular condition. You will be required to show that you can counsel a patient appropriately about their medicine(s), help them to maximise their treatment and communicate in an effective and professional manner.

Task 1

Over a period of time, make a list that identifies the different kinds of patients who use a given pharmacy, remember patients with special needs and patients which reflect the location of your pharmacy.

This provides evidence for Unit 14 (P1)

Task 2

Draw up a display chart listing five common disorders that can affect skin, hair and nails; include a brief description of each disorder in simple, easy-to-understand language. Provide information on the common medicines, both prescription-only and those available for purchase from a community pharmacy, explaining how they could be used to treat or ameliorate each disorder. In another column outline the five most common side effects of each medicine.

This provides evidence for Unit 12 (P17, P18, P19)

Task 3

Design a leaflet for customers to complement your display chart explaining, in general terms, the essential information for patients or customers receiving five medicines for conditions related to skin, hair and nails (these could be topical and oral medicines). Information must cover demonstration of use needed, how the medicines are used and the route of administration. You need to be mindful that patients or customers may have limited knowledge of medical terminology so information, particularly that relating to side effects of the medicines, needs to be in explained in terms which are understood. Include source references where relevant.

This provides evidence for Unit 12 (P20)

Task 4

Describe how the medicines you have listed in your chart treat the human body. You could produce a table which groups medicines according to their chemical and pharmacological families. As you describe the detailed pharmacological action you should also discuss reasons why side effects occur where they are related to the actual mode of action of the drugs in their groups. Add this information to your chart.

This provides evidence for Unit 12 (M13, M14)

Task 5

Choose ONE major hair, nail or skin disease or disorder with which you are familiar, this could be related to an anonymised patient to whom you regularly supply medicines. To a suitable audience, present information on the treatment of the chosen disorder.

Explain the key features of communicating effectively in a pharmacy, particularly in relation to potentially embarrassing disorders. Explain why patient confidentiality is important within the pharmacy and describe the particular needs your chosen patient has in terms of their disorder and how to respond to them.

Explain how counselling patients with these disorders can help them to get the most out of their medicines and their treatment. Include information on ways to check patients' understanding of any counselling given.

Engage in a role play with a fellow learner, or use observed evidence from work to show that you can recommend positive ways that patients suffering from three different disorders — including the disorder you have selected, could maximise the beneficial effect of treatments. You should include reference to non-drug strategies.

This provides evidence for Unit 12 (M15, D10); Unit 14 (P2, P3, P5)

Task 6

In an observed scenario, have a discussion with others about the different types of customer communication you would find in a hospital or community pharmacy. Discuss what you understand by the term 'confidentiality' and then produce a common definition and confidentiality statement, agreed with others, for use in a workplace.

This provides evidence for Unit 14 (M1, M3)

Task 7

In your group, at a time appointed by the tutor, have a discussion about the considerations doctors or independent prescribers need to think about when making choices about which medicines to prescribe. Include considerations about issues over use and availability that a patient may have, administration and route of delivery issues as well as patient parameters. Produce a set of notes as a record of your discussion.

This provides evidence for Unit 12 (D9)

Task 8

Source a copy of your company's or hospital's customer service policy and in your group compare these policies. Draw conclusions about how good communication skills relate to good customer service and the reverse. Illustrate your piece with some examples from a given workplace.

This provides evidence for Unit 14 (D1, D2)

Task 9

Draw a diagram/algorithm to use as a basis for a discussion with your assessor about the requirements placed on you by the General Pharmaceutical Council for CPD. Describe to your tutor/mentor how you record your Continuing Professional Development providing appropriate examples of your CPD entries. This is in readiness for your registration with the General Pharmaceutical Council. This could be evidenced through an e-portfolio or work-based system.

This provides evidence for Unit 14 (P16, M11, D7)

Sources of information

Textbooks

Martindale W et al — *Martindale Extra Pharmacopoeia* (Pharmaceutical Press, 1996) ISBN 978-0853693420

Websites

bnf.org	British National Formulary
www.mhra.gov.uk	Medicines and Healthcare products Regulatory Authority

Other documents

A range of pharmacology books

Company or hospital policy documents

Unit 3: Microbiology for Pharmacy (coverage of selected assessment criteria) and Unit 9: Infections, Immunological Products and Vaccines (coverage of selected assessment criteria)

Assessment activity front sheet

This front sheet must be completed by the learner and included with the work submitted for assessment.

Learner name:		Assessor name:
Date issued:	Completion date:	Submitted on:
Qualification: Edexcel BTEC Level 3 Diploma in Pharmaceutical Science (QCF)		
Unit 3: Microbiology for Pharmacy (part) and Unit 9: Infections, Immunological Products and Vaccines (part)		

Assignment title — Designing and Running a Pharmacy Manufacturing Unit

In this assessment you will have opportunities to provide evidence against the following criteria. Indicate the page numbers where the evidence can be found.

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U9 (P1); U3 (P8)	Describe common infections caused by pathogenic micro-organisms and their associated symptoms	1	9
U3 (M3)	Discuss with reference to a named disease, details of the causative pathogen, transmission, disease symptoms, treatment and incidence	2	9
U3 (P9)	Explain the role of micro-organisms in the transmission of disease and infections	3	9

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U9 (P2, P3, P4, P5)	Explain how common medicines are used to treat infections, giving examples Summarise common side effects of these medicines used to treat infections Explain the information that must be given to patients about their infection-treating medicines Discuss the factors that influence the selection of antimicrobial medicines	4	10
U9 (M1, M2, M3, M4)	Describe the pharmacological action of the medicines used to treat infections Discuss the reasons why side effects occur with medicines used to treat infections Explain how counselling patients helps improve their compliance of anti-microbial treatments, including examples of counselling Explain how antimicrobials achieve selective toxicity	5	10
U9 (D1, D2, D3)	Recommend ways in which patients can manage their anti-microbial medication effectively, including examples of information and counselling which may be used Discuss the factors involved in the choice of therapeutic agents for the treatment of infections providing information regarding prescribing guidelines and limitation of use Explain the problems of antibiotic resistance and how it can be minimised giving examples	6	10

Learner declaration

I certify that the work submitted for this assignment is my own and that research sources are fully acknowledged.

Learner signature: Date:

Unit 3 (part) and Unit 9 (part)	Microbiology for Pharmacy and Infections, Immunological Products and Vaccines
Start date:	
Deadline date:	
Assessment feedback will be provided by:	
Assessor:	

Assignment title – Using Antibiotics

The purpose of this assignment is to:

develop your understanding of the nature of pathogenic micro-organisms that cause disease, particularly in humans and relate this to antibiotic therapy and current principles governing the use of antimicrobials and prescribing guidelines.

Scenario

You are part of a pharmacy team tasked with developing an antibiotic policy. You need to start by investigating pathogenic micro-organisms (bacteria, fungi, protozoa and viruses) that cause disease in humans. You must investigate the chemotherapeutic agents used to destroy these organisms and effect a cure. You can then develop the work by looking at side effects and concepts of antibiotic resistance and create a poster to help patients, doctors or other heathcare professionals to understand the issues around resistance and how to make a rational choice of antibiotic therapy.

Task 1

Draw up a chart listing a range of common infections, their causative organisms and the associated symptoms of the disease. Organisms should come from four categories (bacteria, fungi, viruses and protozoans) as a minimum.

This provides evidence for Unit 9 (P1); Unit 3 (P8)

Task 2

Choose ONE disease from your chart and discuss details of the causative pathogen, its transmission, the disease's symptoms, treatment and its incidence. Prepare a short report on this topic in not more than 500 words, diagrams may be used.

This provides evidence for Unit 3 (M3)

Task 3

Develop the short report from Task 2 to cover the role of micro-organisms in the transmission of disease and infections for all the different categories of micro-organisms. No more than 500 words should be added.

This provides evidence for Unit 3 (P9)

Task 4

You will be given an example of ONE drug commonly used against infections by the tutor. You are to produce a short (around 10 to 20 minutes maximum) oral presentation which you will deliver to a suitable audience explaining how your particular common medicine is used to treat infections, you must summarise the side effects of this medicine. You must cover:

- information that must be given to patients about their infection-treating medicine
- how to check patient understanding of information given
- factors that influence the selection of antimicrobial medicines in general.

This provides evidence for Unit 9 (P2, P3, P4, P5)

Task 5

Produce a poster for display in a surgery or a pharmacy waiting room that gives information on the use of antimicrobial medication. It should include a table showing:

- visual symptons of when antimicrobial medicines are and are not needed
- common antimicrobial medicines and their use
- recommended ways in which patients can manage antimicrobial medication effectively
- examples of related information and counselling available.

This provides evidence for Unit 9 (M1, M2, M3, M4)

Task 6

You must take part in a role-play situation where you are a pharmacy technician giving advice to a patient, a nurse and a carer about the choice of therapeutic agents for the treatment of three different infections. You must cover:

- choice of agents
- prescribing guidelines
- limitations of use
- reasons for chosen agents
- when to seek medical advice if symptoms persist
- problems of antibiotic resistance
- how antibiotic resistance can be minimised, giving examples.

This provides evidence for Unit 9 (D1, D2, D3)

Sources of information

Textbooks

Martindale W et al — *Martindale Extra Pharmacopoeia* (Pharmaceutical Press, 1996) ISBN 978-0853693420

A range of other pharmacology and microbiology books

Websites

bnf.org	British National Formulary
www.mhra.gov.uk	Medicines and Healthcare products Regulatory Authority

Other documents

Company or hospital policy documents on antimicrobial prescribing

National Institute for Health and Clinical Excellence (NICE) guidelines and national frameworks and standards relating to the use of antimicrobials.

Unit 3: Microbiology for Pharmacy (coverage of selected assessment criteria) and Unit 19: Making Medicines for Pharmacy (coverage of selected assessment criteria)

Assessment activity front sheet

This front sheet must be completed by the learner and included with the work submitted for assessment.

Learner name:		Assessor name:
Date issued:	Completion date:	Submitted on:
Qualification: Edexcel BTEC Level 3 Diploma in Pharmaceutical Science (QCF)		
Unit 3: Microbiology for Pharmacy (part) and Unit 19: Making Medicines for Pharmacy (part)		

Assignment title — Designing and Running a Pharmacy Manufacturing Unit

In this assessment you will have opportunities to provide evidence against the following criteria. Indicate the page numbers where the evidence can be found.

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U19 (P1, P2, P3, P6, P14, P19, M1, M2)	Explain the legislation and guidelines governing the manufacture of pharmaceutical products Discuss an individual's responsibility in relation to current health and safety regulations Describe the principles of waste disposal Discuss examples of how the legislation and guidelines governing the manufacture of pharmaceutical products are applied in practice. Explain how health and safety responsibilities can me managed in a manufacturing environment. Explain the difference between dispensing and manufacturing in pharmacy Explain product formulation in pharmacy manufacturing Explain the different environments used for pharmaceutical manufacturing	1	15

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U19 (P7, P10, P15)	Explain the importance of basic and personal hygiene in pharmaceutical manufacture Describe the procedures for preparing the manufacturing environment of medicines Describe the different methods of sterilisation	2	16
U19 (P9)	Describe the importance of Planned Preventative Maintenance in pharmaceutical manufacturing	3	16
U19 (P11, P12, P13)	Explain the difference between sterile and non-sterile manufacturing Describe documentation used in the manufacturing of medicines State the principles of labelling and packaging	4	16
U19 (P8, M5) U3(D2, P4, P5, P6)	Explain the potential consequences of different sources of contamination within pharmaceutical manufacturing Discuss the different sources of contamination which could be present in a manufacturing environment Evaluate the use of antimicrobial agents (disinfectants) in pharmacy Explain the factors that affect the growth of micro organisms Explain the uses of different growth media Describe methods used to control and monitor the microbial content of the environment, including environment and personal hygiene	5	16
U19 (P17, P18, P20, P21, P22, M7, M8)	Explain the difference between quality assurance and quality control Explain Total Quality Management Describe how manufactured products are tested Discuss the importance of validation and record keeping in quality assurance Explain the importance of quarantine in pharmacy manufacturing Examine a quality assurance system, at work or a simulation and explain the component parts and why they are in place Explain a validation system with which you are familiar or a simulation you have been given and indicate the critical parts	6	17
U19 (P16)	Describe the principles for the storage and supply of manufactured products	7	17

Criteria reference	To meet the criteria the evidence must show that the learner is able to:	Task no.	Page number
U19 (M6, D1, D2, D3)	Explain why it is important to have a robust recording system in pharmacy manufacturing Justify why pharmaceutical manufacturing is highly controlled by rules and legislation Explain how drug recall procedures work Critically evaluate the quality assurance system in your workplace or the simulation you have used	8	17

Learner declaration

I certify that the work submitted for this assignment is my own and that research sources are fully acknowledged.

Learner signature: Date:

Unit 3 (part) and Unit 19 (part)	Microbiology for Pharmacy and Making Medicines for Pharmacy
Start date:	
Deadline date:	
Assessment feedback will be provided by:	
Assessor:	

Assignment title — Designing and Running a Pharmacy Manufacturing Unit

The purpose of this assignment is to:

develop your understanding of the complexities involved in making medicines and experience the practical aspects of solving problems in a manufacturing environment. You will also be given information through a visit to a real pharmacy manufacturer as part of the briefing for this assignment.

Scenario

You have been asked to produce a simple design for a manufacturing unit that will make ONE sterile product. You will decide on fixtures and fittings, design the necessary documentation and develop a quality assurance system for your factory. This could be carried out as a group exercise.

Task 1

Develop a plan for a manufacturing unit, the plan should include the following information:

- health and safety policy for your unit (employer and employee responsibilities and how these are managed in a manufacturing environment) and how these are applied in one aspect of the unit's manufacturing
- how the product will be formulated
- the principles of waste disposal in your unit
- a mission statement for your manufacturing unit, explaining the difference between dispensing and manufacturing in pharmacy
- the different environments used for pharmaceutical manufacturing within your small unit, eg where staff change, where mixing occurs, where the product is sterilised etc.

In a group discuss and agree the legislation and guidelines governing the manufacture of pharmaceutical products.

This provides evidence for Unit 19 (P1, P2, P3, P6, P14, P19, M1, M2)

Task 2

Draw up a standard operating procedure for the donning of personal protective equipment for one area of your unit. The procedure should cover the importance of basic and personal hygiene in pharmaceutical manufacture.

Describe the procedures for preparing the manufacturing environment of medicines by creating a flow chart of the manufacturing process in your unit.

Describe the different methods of sterilisation available for injectable products as described in the British Pharmacopoeia and identify which method will be used in your unit – a chart can be used.

This provides evidence for Unit 19 (P7, P10, P15)

Task 3

Develop a plan to describe the importance of Planned Preventative Maintenance in your pharmaceutical manufacturing unit – you need do this for only one key item of equipment for example the steriliser or the air-handling unit.

This provides evidence for Unit 19 (P9)

Task 4

Prepare a batch worksheet for your product to describe the documentation used in the manufacturing of your medicine. Include the principles of labelling and packaging and a statement that shows you understand the difference between dispensing and manufacturing and between sterile and non-sterile production.

This provides evidence for Unit 19 (P11, P12, P13)

Task 5

Produce a table which gives details of the microbiological monitoring and management required at your unit over a five-day period, covering:

- different environments and the restrictions on the work/staff/cleaning etc
- use of antimicrobial agents
- factors that affect the growth of micro-organisms
- uses of different growth media
- methods of control and monitoring.

Using your table, discuss the different sources of contamination which could be present in your manufacturing environment. Explain the potential consequences of different sources of contamination within pharmaceutical manufacturing.

Describe how you would control and monitor the microbial content of the environment, including personal hygiene of the staff working there.

This provides evidence for Unit 19 (P8, M5, U3;D2, P4, P5, P6)

Task 6

Draw up a validation and record-keeping procedure for quality assurance in your unit and explain the importance of quarantine in pharmacy manufacturing.

Take part in a group discussion and agree on what needs to be included in Quality Assurance:

- the rationale for the difference between quality assurance/quality contol and Total Quality Management
- the validation and record-keeping procedure for QA
- components of the quality assurance system
- highlight of the critical parts of the validation system
- how the product manufactured in your unit will be tested.

This provides evidence for Unit 19 (P17, P18, P20, P21, P22, M7, M8)

Task 7

Describe how your product will be stored and supplied to end users, including the underlying principles. 500 words maximum.

This provides evidence for Unit 19 (P16)

Task 8

Explain why it is important to have a robust recording system in pharmacy manufacturing and how your drug recall procedures work.

Argue the reasons why pharmaceutical manufacturing is so highly controlled by rules and legislation and critically evaluate the quality assurance system in your manufacturing unit.

This provides evidence for Unit 19 (M6, D1, D2, D3)

Sources of information

Textbooks

Martindale W et al — *Martindale Extra Pharmacopoeia* (Pharmaceutical Press, 1996) ISBN 978-0853693420

Websites

bnf.org	British National Formulary
www.mhra.gov.uk	Medicines and Healthcare products Regulatory Authority

Other documents

Company or hospital policy documents

Rules and guidance for pharmacy manufacturers and wholesalers

Other references can be found in workplaces, from tutors and from site visits.

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