

Unit 48: Prepare Aseptic Products

Level:	2
Unit type:	Optional (Life Sciences)
Credit value:	10
Guided learning hours:	40

Unit summary

This unit aims to give learners the skills they need to be able to prepare, maintain and monitor working environments and prepare aseptic products. They will know and understand how to comply with appropriate legislation and codes of practice, and how to work within the limits of their role.

Unit assessment requirements

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe B*.

Additional information

AC1.3 e.g., air pressure differentials.

Learning outcomes and assessment criteria

To pass this unit, learners need to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements that the learner is expected to meet to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Be able to monitor the working environment	1.1	Carry out relevant environmental monitoring within an aseptic setting following standard operating procedures at all times			
		1.2	Check that the parameters are within the set limits			
		1.3	Take appropriate action if the environmental monitoring identifies conditions outside set limits as per standard operating procedures			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to prepare and maintain suitable working environments	2.1	Put on the appropriate clean room clothing following specific gowning and standard operating procedures			
		2.2	Clean, sanitise, and prepare the working area, prior to use following standard operating procedures, at all times			
		2.3	Inspect and review all starting materials, equipment, and consumables to ensure that they have been sanitised or sterilised prior to their introduction into the working area, following standard operating procedures at all times			
		2.4	Following production, clean and decontaminate the working area, following standard operating procedures at all times			
		2.5	Following production, store and dispose of waste materials following standard operating procedures at all times			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
3	Be able to prepare a range of aseptic products	3.1	Prepare the product using the processes and equipment as stated in the worksheet and by following standard operating procedures at all times			
		3.2	Label the product, making all necessary accuracy checks and complete documentation as per standard operating procedures			
4	Be able to operate within the limitations of the job role	4.1	Take the corrective action within limits of own responsibility in the event of an accident/incident/error during the preparation			
		4.2	Complete required documentation in this case			
		4.3	Report to the appropriate person any problems outside the area of responsibility			
		4.4	Feed back any near misses or errors to appropriate person to minimise future errors			

Learner name: _____

Date: _____

Learner signature: _____

Date: _____

Assessor signature: _____

Date: _____

Internal verifier signature: _____

Date: _____

(if sampled)