



Australian Government

FBPPHM3016 Operate a sterilisation process using an autoclave

Release: 1

FBPPHM3016 Operate a sterilisation process using an autoclave

Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Application

This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a sterilisation process using an autoclave in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the sterilisation process using an autoclave. Individuals work under broad direction and take responsibility for their own work.

No occupational licensing, legislative or certification requirements apply to this unit at the time of publication.

Pre-requisite Unit

Nil

Unit Sector

Pharmaceutical (PHM)

Elements and Performance Criteria

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
1. Prepare equipment and process for operation	1.1 Confirm autoclave and wrapping, cleaning and material items are available and meet load pattern requirements 1.2 Prepare autoclave and position load probe according to load pattern requirements and standard operating procedure 1.3 Enter operating parameters according to safety and sterilisation requirements 1.4 Conduct pre-start checks according to workplace

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	requirements 1.5 Load wrapping, cleaning and material items according to load pattern requirements
2. Operate autoclave to terminally sterilise items	2.1 Start up and monitor autoclave to confirm specifications are within required limits 2.2 Identify and report out of limit materials or processes according to workplace procedures 2.3 Maintain work area according to workplace cleaning standards 2.4 Conduct process according to safety and environmental requirements 2.5 Complete documentation according to workplace procedures
3. Remove items and follow shut down procedures	3.1 Confirm the workplace procedures for shutting down the process 3.2 Safely shut down the process 3.3 Remove items from autoclave 3.4 Check chemical indication to confirm items are dry 3.5 Ensure segregation of sterile and non-sterile items 3.6 Complete records according to workplace procedures

Foundation Skills

This section describes those language, literacy, numeracy and employment skills that are essential for performance in this unit of competency but are not explicit in the performance criteria.

Skill	Description
Reading	Identify relevant information from workplace documentation and interpret requirements for the sterilisation process
Writing	Complete workplace documentation using appropriate language and in required format
Numeracy	Confirm number of items according to loading pattern

Skill	Description
	- Interpret time and temperature specifications for cycle parameters - Confirm post cycle sampling results meet sterilisation requirements
Navigate the world of work	Identify workplace procedures relevant to own role
Interact with others	Report operational and safety information to relevant personnel using required communication method
Get the work done	- Plan, organise and implement tasks required to achieve sterilisation process outcomes - Use problem-solving skills to analyse product and process faults and decide on appropriate action

Range of Conditions

This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Pre-start checks must include:	- carrying out required area or line clearances - inspecting equipment condition to identify signs of wear - confirming all safety equipment is in place and operational - confirming that equipment is clean or sanitised - confirming that equipment is correctly configured for processing requirements.
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Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3016 Operate a sterilisation process using an autoclave	FDFPH2014A Operate a terminal sterilisation process	Updated to meet Standards for Training Packages Changes to performance criteria for clarity Code changed to reflect AQF	Equivalent unit

Code and title current version	Code and title previous version	Comments	Equivalence status
		alignment	

Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>