Modification history

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 3.0.
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

FBPPHM3016	Operate a sterilisation process using an autoclave
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.**Error! Use the Home tab to apply AFSA AR Code to the text that you want to appear here.**
Prerequisite Unit	Nil
Unit Sector	Pharmaceutical (PHM)

Elements	Performance Criteria
Elements describe the essential outcomes.	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
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 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

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
Writing	• Complete workplace documentation using appropriate language and in required format
Numeracy	• Confirm number of items according to loading pattern • Interpret time and temperature specifications for cycle parameters • Confirm post cycle sampling results meet sterilisation requirements

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.

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3016 Operate a sterilisation process using an autoclave Release 2	FBPPHM3016 Operate a sterilisation process using an autoclave Release 1	Foundation skills amended Knowledge Evidence clarified Assessment Conditions clarified	Equivalent unit

Links	Companion Volumes, including Implementation Guides, are available at VETNet https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4

TITLE	Assessment requirements for FBPPHM3016 Operate a sterilisation process using an autoclave

Performance Evidence

An individual demonstrating competency in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has operated at least one sterilisation process using an autoclave, including:

- accessed workplace information to confirm sterilisation requirements
- confirmed supply of necessary wrapping, cleaning and material items for the sterilisation process
- prepared items by wrapping and marking with temperature-sensitive tape or material and ensured clothing is folded correctly
- positioned load probe and loaded items in correct orientation according to workplace procedures and load pattern requirements
- conducted pre-start checks required for safe operation of the autoclave, including:
  - 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
- started, operated, monitored and adjusted autoclave to achieve required outcomes, including time and temperature parameters
- conducted in-process control checks to confirm the process remains within limits
- collected samples and conducted tests according to workplace procedures
- taken corrective action in response to a non-conformance
- opened autoclave and removed items from autoclave according to workplace procedures
- used process control systems according to workplace procedures
- safely shut down the process according to workplace procedures
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirements
- completed records according to workplace procedures.

Knowledge Evidence

An individual must be able to demonstrate the knowledge required to perform the tasks outlined in the elements and performance criteria of this unit. This includes knowledge of:

- the origin of where contamination can come from
- stages of the sterilisation process, including:
  - principles of heat transfer
  - properties of saturated steam
  - the relationship between time, temperature and pressure as they affect the kill rate
  - variables that impact the effectiveness of sterilisation
- the nature of items to be sterilised using an autoclave and related handling and preparation requirements, including:
  - porous loads
  - non-porous loads
  - position of probes
- the nature of wrapping materials suitable for use, including:
  - methods used to wrap items
  - methods used to monitor whether time and temperature parameters are met (including heat-sensitive tape or markers)
  - the significance of loading patterns in achieving effective sterilisation
- basic operating principles of equipment, requirements and parameters of autoclave, including:
  - main equipment components
  - time and temperature parameters required to achieve sterilisation and corrective actions required where operation falls outside specified parameters
  - typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems

Knowledge Evidence

- status and purpose of guards
- equipment operating capacities and applications
- purpose and location of sensors and related feedback instrumentation
- corrective actions required where operation is outside of specified parameters
- calibration schedule and procedures to confirm that instruments are within calibration

- health and safety hazards related to autoclave operation and associated control measures, including working with superheated steam and hot surfaces, manual handling and steam leaks
- pre-start checks requirements, including:
  - 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
- evaluation and in-process monitoring of sterilisation process indicators, including:
  - biological
  - chemical
  - physical
- methods used to monitor the sterilisation process, including:
  - inspecting
  - measuring
  - testing
- requirements of different shutdowns, including:
  - emergency and routine shutdowns
  - procedures to follow in the event of a power outage
- isolation, lock out and tag out procedures and responsibilities
- operating principles of process control
- Good Manufacturing Practice (GMP) requirements associated with a sterilisation process and related control measures
- environmental issues and controls relevant to the sterilisation process including waste collection and handling procedures
- requirements for completion of workplace documentation.

Assessment Conditions

Assessment of skills must take place under the following conditions:

- physical conditions:
  - a pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
  - autoclave and handling equipment
  - wrapping materials and tape/heat sensitive markers
  - materials for sterilisation
  - test equipment
  - cleaning materials and equipment associated with sterilisation process
  - record keeping system
- specifications:
  - sterilisation specifications, control points and processing parameters
  - recording requirements and procedures
  - workplace documentation relating to sterilisation process and procedures that comply with GMP and Good Documentation Practice (GDP) requirements
  - load pattern requirements
  - sampling schedules and test procedures
  - cleaning procedures associated with sterilisation process.

Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards.

Links	Companion Volumes, including Implementation Guides, are available at VETNet https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4