



Australian Government

FBPPHM3018 Operate a sterilisation process using an autoclave

Release: 1

FBPPHM3018 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 5.0.

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.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) or other accreditation or certification requirements if relevant in other industries/settings, and operating principles to the terminal sterilisation of product and sterilisation of goods for aseptic processing using an autoclave. Individuals work under broad direction and take responsibility for their own work.

No 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 and initiate operation of equipment	1.1 Check autoclave is operational and sterilisation load is available 1.2 Prepare items for sterilisation load by stacking, wrapping, taping or sealing according to Standard Operating Procedures (SOP) 1.3 Mark bags as required according to SOP 1.4 Load autoclave and position temperature load probe according to

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	load pattern requirements detailed in the SOP 1.5 Run pre-start leak test cycle and select the correct sterilisation cycle according to SOP 1.6 Initiate the autoclave cycle
2. Review autoclave printout at end of cycle	2.1 Review autoclave cycle printout or electronic report and confirm correct cycle was run with no faults or alarms detected 2.2 Complete documentation according to SOP
3. Remove items and follow shut down procedures	3.1 Commence shutdown of autoclave by confirming autoclave cycle is complete and autoclave is safe to open according to SOP 3.2 Remove items safely from autoclave and check contents 3.3 Check data logging or relevant indicators have been activated according to SOP 3.4 Confirm items are dry and sterilised 3.5 Clean autoclave according to SOP 3.6 Complete records according to SOP

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 - Interpret time and temperature specifications for cycle parameters - Confirm post cycle results meet sterilisation requirements

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3018 Operate a sterilisation process using an autoclave	FBPPHM3016 Operate a sterilisation process using an autoclave	Major changes to performance criteria for clarity and industry currency Foundation skills table updated Assessment requirements updated	Not equivalent

Links

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

Assessment Requirements for FBPPHM3018 Operate a sterilisation process using an autoclave

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Performance Evidence

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

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

- accessed Standard Operating Procedure (SOP) information to confirm sterilisation requirements
- confirmed supply of product or materials for the sterilisation process
- prepared items by stacking autoclave dolly with product for terminal sterilisation or wrapping, taping, or sealing in an autoclave bag product for aseptic processing
- marked bags with temperature-sensitive tape or chemical indicators
- positioned any moveable load probe and loaded items in correct orientation according to SOP and validated load pattern requirements
- conducted pre-start checks required for safe operation of the autoclave, including:
 - carried out required area or line clearances
 - inspected equipment condition to identify signs of wear
 - confirmed all safety equipment in place and operational
 - confirmed sterilising equipment clean or sanitised
 - confirmed all pre-start cycles have been run, including a leak test
- confirmed sterilising equipment correctly set up for processing requirements
- selected correct sterilisation cycle as per the SOP
- reviewed cycle print out to confirm the cycle was completed satisfactorily with no alarms or faults
- taken corrective action in response to a non-conformance
- opened autoclave and removed items from autoclave 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 SOP.

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:

- requirements for autoclaving for microbial reduction/sterility
- stages of the sterilisation process, including:
 - relationship between time, temperature and pressure as they affect kill rate
 - variables that impact effectiveness of sterilisation
- nature of items to be sterilised using an autoclave, different cycle types used and related handling and preparation requirements, including:
 - porous loads
 - non-porous loads
 - position of probes
- nature of wrapping materials suitable for use, including:
 - methods used to wrap or bag items
 - methods used to monitor whether time and temperature parameters are met, including heat-sensitive tape or markers
 - significance of validated loading patterns in achieving effective sterilisation
- basic operating principles of equipment, requirements and parameters of autoclave, including:
 - main equipment components including filters, vacuum pumps, condensers and the autoclave chamber
 - utilities requirements for a GMP autoclave including compressed air, electricity, processed water steam supply and cooling water
 - 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
 - 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 check requirements, including:
 - carrying out required area or line clearances
 - inspecting equipment condition to identify signs of wear
 - confirming all safety equipment in place and operational
 - confirming equipment is clean or sanitised
 - confirming 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 the skills in this unit of competency must take place under the following conditions:

- physical conditions:
 - a workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - autoclave and handling equipment
 - loading bags or 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
 - product and intermediate product specifications, control points and processing parameters
 - workplace documentation relating to sterilisation process and procedures that comply with GMP
 - 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.

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