



Australian Government

FBPPHM3004 Clean and sanitise facilities and equipment

Release: 1

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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 plan, prepare, clean and sanitise processing facilities and equipment in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) requirements and operating principles to the cleaning and sanitising of facilities and equipment. 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. Plan and prepare to clean pharmaceutical processing areas and equipment	1.1 Obtain cleaning task requirements, including job specifications and workplace procedures for sampling and testing cleaning outcomes 1.2 Identify surfaces and soil and dirt types and select appropriate cleaning techniques 1.3 Select and prepare cleaning chemicals required for job 1.4 Select and check cleaning equipment and consumables for serviceability and compliance with cleaning and sanitation

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 of GMP cleaning program 1.5 Rectify or report faults before starting work 1.6 Confirm services are available and ready for operation 1.7 Source and fit personal protective equipment (PPE) according to procedures for health and safety in the workplace 1.8 Obtain cleaning consumables to meet anticipated usage patterns 1.9 Select and install signs and barricades according workplace procedures 1.10 Set the plant for automated cleaning cycle or initiate a manual clean
2. Remove waste	2.1 Collect and dispose of waste according to procedures and legislative requirements for the environment and health and safety in the workplace 2.2 Clean and sanitise rubbish bins and insert new replacement bin liners according to workplace procedures
3. Clean and sanitise pharmaceutical processing surfaces	3.1 Change status label of area and equipment and check status prior to cleaning 3.2 Remove loose dirt and debris from pharmaceutical processing surfaces prior to applying cleaning treatment 3.3 Follow cleaning steps according to workplace procedures 3.4 Apply cleaning chemicals to pharmaceutical surfaces according to manufacturers' specifications and workplace procedures 3.5 Thoroughly rinse and dry surfaces according to workplace procedures 3.6 Apply chemical disinfectants and sanitisers to surfaces according to workplace procedures 3.7 Report practices inconsistent with GMP according to workplace procedures
4. Clean and sanitise pharmaceutical processing equipment	4.1 Clean and sanitise processing equipment according to GMP requirements and workplace procedures 4.2 Monitor the cleaning process and identify and report deviations from job specifications according to workplace procedures 4.3 Inspect and confirm equipment cleanliness status against acceptance criteria and take appropriate action to rectify

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	<p>non-conformances</p> <p>4.4 Confirm relevant sampling or testing methods including sampling or testing points, types of samples and measurements requirements</p> <p>4.5 Take, collect, store and transport samples according to sampling plan, relevant methods and standards</p> <p>4.6 Return equipment to operating order</p> <p>4.7 Record and certify data and information about equipment cleaning and sanitising, including cleaning status, sampling and testing according to workplace procedures and GMP requirements</p>
5. Return plant to operating condition	<p>5.1 Remove signs and barricades according to workplace procedures and work health and safety</p> <p>5.2 Clean, check and store cleaning equipment and PPE according to manufacturers' specifications, environmental and workplace health and safety requirements</p> <p>5.3 Store and dispose of unused chemicals according to manufacturers' specifications, and workplace health and safety requirements</p> <p>5.4 Order and replenish cleaning consumables</p> <p>5.5 Document tasks completed according to workplace procedures</p>

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	<ul style="list-style-type: none"> Identify and follow signs, symbols, checklists, production schedules, cleaning schedules and other technical information relevant to cleaning and sanitising facilities and equipment Identify and follow workplace information, specifications and safety data sheets (SDS) Identify and interpret GMP information relevant to cleaning and sanitising facilities and equipment
Writing	<ul style="list-style-type: none"> Complete checklists, standard forms and reports relating to practices inconsistent with GMP

Skill	Description
Oral communication	<ul style="list-style-type: none"> Use clear language to report contamination risks and practices inconsistent with GMP Participate in verbal exchanges to respond to questions and clarify information
Numeracy	<ul style="list-style-type: none"> Interpret measurements and numerical symbols in SDSs Record data and information using mathematical symbols and conventions
Navigate the world of work	<ul style="list-style-type: none"> Recognise and follow workplace requirements, including safety requirements and GMP, associated with own role and area of responsibility

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.

PPE must include:	<ul style="list-style-type: none"> one of the following: <ul style="list-style-type: none"> protective gown scrubs smock statcoat cleanroom coverall disposable coverall plus all of the following: <ul style="list-style-type: none"> disposable overshoes or cleanroom boots hair net goggles or safety glasses.
Waste must include:	<ul style="list-style-type: none"> cleaning material or product waste hazardous waste general processing and laboratory waste.
Monitoring of the cleaning process must include:	<ul style="list-style-type: none"> chemical strength cycle time(s) temperature contact time rinse water quality.
Sampling or testing	<ul style="list-style-type: none"> visual inspection pH tests of final rinse water

methods must include:	<ul style="list-style-type: none"> swabbing of equipment surfaces for presence of contamination.
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Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3004 Clean and sanitise facilities and equipment	Not applicable	New unit	No equivalent unit

Links

Companion Volume Implementation Guides are found in VETNet: -

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