



Australian Government

FBPPHM3014 Operate a liquid manufacturing process

Release: 2

FBPPHM3014 Operate a liquid manufacturing process

Modification History

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.
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 liquid manufacturing process in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the liquid manufacturing process. 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 the liquid manufacturing process for operation	1.1 Confirm materials and equipment are available and meet production requirements 1.2 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures 1.3 Fit and adjust machine components and attachments 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>
	production requirements and equipment operation and maintenance manual 1.4 Enter processing and operating parameters according to safety and production requirements 1.5 Check and adjust equipment performance according to equipment operating procedures 1.6 Conduct pre-start checks according to workplace requirements
2. Operate and monitor the liquid manufacturing process	2.1 Deliver raw materials in required quantities and sequence according to recipe specifications, batch and production requirements 2.2 Start up and monitor liquid manufacturing process to confirm specifications are within required limits 2.3 Identify, rectify and report out-of-specification liquid products or process outcomes to maintain process within specifications 2.4 Conduct in process testing 2.5 Transfer liquid mix according to production requirements 2.6 Maintain work area according to workplace cleaning standards 2.7 Conduct process according to safety and environmental requirements 2.8 Contain, remove and report spillages according to workplace procedures 2.9 Complete documentation according to workplace procedures
3. Shut down the liquid manufacturing process	3.1 Confirm workplace procedures for shutting down the process 3.2 Complete end-of-batch procedures according to batch instructions and workplace procedures 3.3 Safely shut down the process 3.4 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 liquid manufacturing process
Writing	Complete workplace documentation using appropriate language and in required format
Numeracy	- Interpret recipe specifications for loading materials in correct quantities and sequence - Confirm equipment timers, product weights and mixing times

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3014 Operate a liquid manufacturing process Release 2	FBPPHM3014 Operate a liquid manufacturing process Release 1	Foundation skills table updated Range of conditions deleted to remove duplication Minor changes to assessment requirements for clarity	Equivalent

Links

Companion Volume Implementation Guides are found in VETNet: -

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

Assessment Requirements for FBPPHM3014 Operate a liquid manufacturing process

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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 liquid manufacturing process, including:

- accessed workplace information to confirm production requirements for the liquid manufacturing process
- confirmed supply of necessary materials and services to the liquid manufacturing process
- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks required for the safe operation of the liquid manufacturing process, 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 equipment was clean or sanitised
 - confirming equipment correctly configured for processing requirements
- started, operated, monitored and adjusted a liquid manufacturing process to achieve required outcomes, including:
 - added and loaded materials in correct quantities and sequences, including monitored automatic ingredient addition and manual addition
 - supplied flow of materials to and from the liquid manufacturing process
 - operated process to meet production requirements
- conducted in-process control checks to confirm process remained within limits
- sampled and tested product for conformance to specifications
- taken corrective action in response to a non-conformance
- followed end-of-batch procedures, including:

- line clearance and cleaning
- yield calculation
- materials reconciliation
- product labelling
- changed status to 'to be cleaned/ non-sterile'
- 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:

- stages of the liquid manufacturing process, including:
 - purpose, methods and outcomes of each stage
 - control points
 - quality characteristics to be met by the liquid manufacturing process
 - stages and changes which occur during liquid manufacturing
 - types of raw materials used in the liquid manufacturing process
 - specific gravity and bulk density properties of ingredients used
 - method and sequence of addition required to achieve required mix characteristics
 - required characteristics of manufactured solutions, suspensions and emulsions
 - flow of liquid manufacturing process and the effect of outputs on downstream pharmaceutical processes
- basic operating principles of equipment, requirements and parameters of liquid manufacturing equipment, including:
 - main equipment components, operating capacities and applications
 - 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
 - purpose and location of sensors and related feedback instrumentation
 - calibration schedules for scales and related weighing and measuring equipment
 - corrective actions required where operation falls outside specified parameters
- functions and limitations of personal protective equipment and contamination prevention clothing
- pre-start check 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
- methods used to monitor a liquid manufacturing process, including:
 - inspecting
 - measuring
 - testing
 - flow rates
 - materials addition sequence
 - times, temperatures and agitator speeds
 - spills and leaks during filling
- product and process changeover procedures and responsibilities
- end-of-batch procedures, including:
 - calculating yield
 - materials reconciliation
 - product labelling
 - change status to dirty/non-sterile
- requirements of different shutdowns, including:
 - emergency and routine shutdowns
 - procedures to follow in the event of a power outage
 - loss of environmental conditions
- filter system establishment as appropriate to batch requirements
- filter issue trouble shooting
- line clearance procedures, including cleaning and sanitation procedures
- isolation, lock out and tag out procedures and responsibilities
- Good Manufacturing Practice (GMP) requirements associated with a liquid manufacturing process and related control measures
- environmental issues and controls relevant to the liquid manufacturing 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 pharmaceutical manufacturing workplace or an environment that accurately represents workplace conditions
- resources, equipment and materials:
 - personal protective equipment and contamination prevention clothing for a liquid manufacturing process
 - materials required for the liquid manufacturing process
 - test equipment

- cleaning materials and equipment associated with liquid manufacturing process
- record keeping system
- specifications:
 - product and intermediate product specifications, control points and processing parameters
 - product specifications, control points and processing parameters
 - workplace documentation relating to liquid manufacturing process and procedures that comply with GMP requirements
 - information on equipment capacity and operating parameters
 - sampling schedules and test procedures
 - cleaning procedures associated with liquid manufacturing 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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