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.

FBPPHM3014	Operate a liquid manufacturing process
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 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 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 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 the 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

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
FBPPHM3014 Operate a liquid manufacturing process Release 2	FBPPHM3014 Operate a liquid manufacturing process Release 1	Foundation skills amended 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 FBPPHM3014 Operate a liquid manufacturing process

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:
  - 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 a liquid manufacturing process to achieve required outcomes, including:
  - adding and loading materials in correct quantities and sequences, including monitoring automatic ingredient addition and manual addition
  - supply and flow of materials to and from the liquid manufacturing process
  - pacing the liquid manufacturing process to meet production requirements
- conducted in-process control checks to confirm the process remains within limits
- sampled and inspected 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
  - change status to dirty/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:
  - the 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 the ingredients used
  - method and sequence of addition required to achieve required mix characteristics
  - required characteristics of manufactured solutions, suspensions and emulsions
  - flow of the 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

Knowledge Evidence

- 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
- the purpose and location of sensors and related feedback instrumentation
- awareness of 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 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
- 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
  - polymer issues, such as parison formation and burning polymer
- 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 issue trouble shooting
- line clearance procedures, including cleaning and sanitation procedures
- isolation, lock out and tag out procedures and responsibilities
- operating principles of process control, including the relationship between control panels and systems and physical equipment
- 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 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:
  - personal protective equipment and contamination prevention clothing liquid manufacturing process equipment
  - materials required for the liquid manufacturing process
  - test equipment
  - cleaning materials and equipment associated with liquid manufacturing process
  - record keeping system
- specifications:

Assessment Conditions
• batch instructions including product specifications, control points and processing parameters • recording requirements and procedures according to Good Documentation Practice (GDP) • 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.

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