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.

FBPPHM3005	Operate a concentration process
Application	This unit of competency describes the skills and knowledge required to set up, operate, monitor, adjust and shut down a concentration process in a pharmaceutical manufacturing facility. The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the concentration 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.
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 concentration equipment and process for operation	1.1 Identify production requirements from workplace documentation 1.2 Confirm materials and services meet production requirements 1.3 Confirm required facilities, storage, equipment and personnel are available 1.4 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures 1.5 Carry out line clearance procedures according to production requirements and equipment operation and maintenance manual 1.6 Follow procedures to eliminate or control the risk of cross-contamination 1.7 Conduct pre-start checks and start up concentration process according to workplace procedures
2. Operate and monitor the concentration process	2.1 Monitor concentration process to confirm that specifications are within required limits 2.2 Identify and report out of limit products 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 requirements
3. Shut down the concentration process	3.1 Confirm the workplace procedures for shutting down the process 3.2 Safely shut down the process 3.3 Report maintenance requirements according to workplace procedures 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 a concentration process
Writing	• Complete workplace documentation using appropriate language and in required format
Numeracy	• Interpret measurement information to set, monitor and adjust process parameters

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
FBPPHM3005 Operate a concentration process Release 2	FBPPHM3005 Operate a concentration 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 FBPPHM3005 Operate a concentration 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 safely operated at least one concentration process, including:

- confirmed production requirements and related facilities, storage and equipment
- selected, fitted and correctly used one of the following:
  - protective gown
  - scrubs
  - smock
  - stat coat
  - disposable coverall
- selected, fitted and correctly used personal protective equipment and contamination prevention clothing, including:
  - disposable overshoes
  - hair net
- performed batch and product changeovers, including line clearance procedures
- conducted pre-start checks required for safe operation of the concentration process, including all of the following:
  - 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 concentration process to achieve required outcomes
- conducted in-process control checks to confirm the process remains within limits
- calculated yields and determined the number of passes required to ensure concentration is within specification
- inspected product for defects
- taken corrective action in response to a non-conformance
- 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:

- types of pharmaceutical concentration processes
- stages of a concentration process, including:
  - the purpose, methods and outcomes of each stage
  - the effect of process parameters on each stage
- basic operating principles, requirements and parameters of concentration process 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
  - corrective actions required where operation is outside specified operating parameters
- services used in a concentration process, including:
  - potable and purified water
  - steam
  - compressed and instrumentation air
  - vacuum

Knowledge Evidence

- line clearance procedures, including procedures for clearing feed lines
- workplace health and safety hazards, risks and controls relevant to a concentration process, including:
  - use of solvents
  - 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 concentration process, including inspecting, measuring and testing
- product and process specifications, procedures and operating parameters for different products and materials
- quality requirements of materials and the effect of variations on the concentration process
- contamination risks associated with the concentration process
- common causes of out-of-specification product or process and corrective actions required
- concentration process shutdown procedures and responsibilities
- Good Manufacturing Practice (GMP) requirements associated with a concentration process and related control measures
- environmental issues and controls relevant to the concentration 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 extracts to be concentrated
  - concentration equipment, materials and services
  - cleaning materials and equipment associated with a concentration process
  - record keeping system
- specifications:
  - specifications, control points and processing parameters
  - recording requirements and procedures in accordance with Good Documentation Practice (GDP)
  - workplace documentation relating to concentration process and procedures that comply with GMP requirements
  - cleaning procedures associated with a concentration 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