



Australian Government

FBPPHM3005 Operate a concentration process

Release: 2

FBPPHM3005 Operate a concentration 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, 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 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 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

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	1.4 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 process parameters 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 shutting down process according to workplace procedures 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

Skill	Description
Numeracy	Interpret measurement information to set, monitor and adjust process parameters

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 table updated Range of conditions deleted to remove duplication Minor changes to performance evidence and assessment conditions 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 FBPPHM3005 Operate a concentration process

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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 safely operated at least one concentration process, including:

- confirmed production requirements and related facilities, storage and equipment
- correctly gown using Standard Operating Procedures (SOP) for the operations performed batch and product changeovers, including line clearance procedures
- conducted pre-start checks required for safe operation of the concentration process, including:
 - carried out required area or line clearances
 - inspected equipment condition to identify signs of wear
 - checked all safety equipment in place and operational
 - checked equipment clean or sanitised
 - checked equipment 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 process parameters required to ensure concentration is within specification
- taken samples for product testing in accordance with SOP
- taken corrective action in response to a non-conformance according to SOP
- 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
- 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:
 - required area or line clearances
 - equipment condition to identify signs of wear
 - safety equipment in place and operational
 - equipment clean or sanitised
 - equipment 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 including microbiological and cross contamination
- 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, restriction of movement 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
 - liquid extracts to be concentrated
 - concentration equipment, materials and services
 - cleaning materials and equipment associated with a concentration process
 - record keeping system
- specifications:
 - product and intermediate product specifications, control points and processing parameters
 - recording requirements and procedures in accordance with GMP requirements
 - 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

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