



Australian Government

FBPPHM3006 Operate an extraction process

Release: 2

FBPPHM3006 Operate an extraction 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 an extraction process used to isolate organic materials using solvents in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the extraction 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 extraction equipment and process for operation	1.1 Confirm, blend and prepare materials to meet production requirements 1.2 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>
	1.3 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures 1.4 Carry out line clearance procedures according to production requirements and equipment operation and maintenance manual 1.5 Follow procedures to eliminate or control the risk of cross-contamination 1.6 Conduct pre-start checks according to workplace procedures 1.7 Load material into percolator
2. Operate and monitor the extraction process	2.1 Start up and monitor extraction 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 extraction process	3.1 Confirm workplace procedures for shutting down the process 3.2 Safely shut down the process 3.3 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 extraction process
Writing	Complete workplace documentation using appropriate language and in required format

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3006 Operate an extraction process Release 2	FBPPHM3006 Operate an extraction process Release 1	Minor changes to application, knowledge evidence and assessment conditions for clarity Foundation skills table updated Range of conditions deleted to remove duplication	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 FBPPHM3006 Operate an extraction 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 extraction process, including:

- confirmed production requirements and related facilities, storage and equipment
- correctly gown using Standard Operating Procedures for the operations performed batch and product changeovers, including line clearance procedures
- performed batch and product changeovers, including line clearance procedures
- conducted pre-start checks required for the safe operation of the extraction 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 process to achieve required outcomes
- conducted in-process control checks to confirm the process remains within limits
- 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:

- stages of the extraction process, including:
 - the purpose, methods and outcomes of each stage
 - the effect of material density on filtration
 - packing processes required for different types of materials
- basic operating principles, requirements and parameters of extraction 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
- line clearance procedures, including procedures for clearing feed lines
- workplace health and safety hazards, risks and controls relevant to an extraction 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 extraction process, including:
 - inspecting
 - measuring
 - testing
 - calculating yields
- quality requirements of materials and the effect of variations on the extraction process
- product and process specifications, procedures and operating parameters for different products and materials
- contamination risks associated with the extraction process
- common causes of out-of-specification product or process and corrective actions required
- extraction process shutdown and changeover procedures and responsibilities
- Good Manufacturing Practice (GMP) requirements associated with an extraction process and related control measures
- environmental issues and controls relevant to the extraction 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
 - extraction solvents, material and equipment
 - cleaning materials and equipment associated with an extraction process
 - record keeping system
- specifications:
 - product and intermediate product specifications, control points and processing parameters
 - recording requirements and procedures in accordance with Good Documentation Practice
 - workplace documentation relating to an extraction process and procedures that comply with GMP requirements
 - cleaning procedures associated with an extraction 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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