

Modification history

| Release | Comments |
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| 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. |

| FBPPHM3006 | Operate an extraction process |
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| Application | <p>This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down an extraction process used to extract phytochemicals from organic materials using solvents in a pharmaceutical manufacturing facility.</p> <p>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.</p> <p>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.</p> |
| Prerequisite Unit | Nil |
| Unit Sector | Pharmaceutical (PHM) |

| Elements | Performance Criteria |
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| <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 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 and add solvents according to specifications |
| 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 | |
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| <i>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.</i> | |
| Skill | Description |
| Reading | <ul style="list-style-type: none"> Identify relevant information from workplace documentation and interpret requirements for the extraction process |
| Writing | <ul style="list-style-type: none"> Complete workplace documentation using appropriate language and in required format |
| Numeracy | <ul style="list-style-type: none"> Interpret specifications for rate and amount of solvent addition |

| Range of Conditions | |
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| <i>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.</i> | |
| Pre-start checks must include: | <ul style="list-style-type: none"> 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 | | | |
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| 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 | Foundation skills updated Knowledge Evidence updated Assessment Conditions updated | Equivalent unit |

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| Links | Companion Volumes, including Implementation Guides, are available at VETNet https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4 |
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| <p>TITLE</p> | <p>Assessment requirements for Error! Use the Home tab to apply AFSA Unit Code to the text that you want to appear here.006 Error! Use the Home tab to apply AFSA Unit Title to the text that you want to appear here.Error! Use the Home tab to apply AFSA Unit Title to the text that you want to appear here.Error! Use the Home tab to apply AFSA Unit Title to the text that you want to appear here.</p> |
| <p>Performance Evidence</p> | |
| <p>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 extraction process, including:</p> <ul style="list-style-type: none"> • confirmed production requirements and related facilities, storage and equipment • selected, fitted and correctly used one of the following: <ul style="list-style-type: none"> • protective gown • scrubs • smock • stat coat • disposable coverall • selected, fitted and correctly used personal protective equipment and contamination prevention clothing, including: <ul style="list-style-type: none"> • disposable overshoes • hair net • performed batch and product changeovers, including line clearance procedures • conducted pre-start checks required for the safe operation of the extraction process, including: <ul style="list-style-type: none"> • 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 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:
 - 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 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 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
 - extraction solvents, material and equipment
 - cleaning materials and equipment associated with an extraction process
 - record keeping system
- specifications:
 - 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.

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| Assessment Conditions |
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| 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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