Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceuticals Training Package Version 2.0 |

| FBPPHM3006 | Operate an extraction process |
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| Application | 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 plant 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 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 |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 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 clothing and equipment 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 Rectify, identify and report out-of-specification products or processes to maintain process within specifications  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 the 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. | |
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| 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 |
| Numeracy | * Interpret specifications for rate and amount of solvent addition |
| Navigate the world of work | * Identify workplace procedures relevant to own role |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * Plan, organise and implement tasks required to achieve production outcomes * Use problem-solving skills to analyse product and process faults and decide on appropriate action |

| 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. | |
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| Pre-start checks must include at least three of the following: | * inspecting equipment condition to identify signs of wear * confirming that equipment is clean and correctly configured for extraction requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * placing sand filters or scourers in base of percolators where required. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3006 Operate an extraction process | FDFPH2003A Operate an extraction process | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | Equivalent unit |

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

| TITLE | Assessment requirements for 006 Operate an extraction process |
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| 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 extraction process, including:   * selected, fitted and correctly used one of the following: * protective gown * scrubs * smock * statcoat * disposable coverall * selected, fitted and correctly used personal protective clothing and equipment, including: * surgical mask * surgical gloves * 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 three of the following: * inspecting equipment condition to identify signs of wear * confirming that equipment is clean and correctly configured for extraction requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * placing sand filters or scourers in base of percolators where required * started, operated, monitored and adjusted a process to achieve required outcomes * checked control points and conducted inspections to confirm process remains within specification, including: * density of herbs in percolator * re-packing of percolator as required * rates and amounts of added solvent * extract collection and yield * taken corrective action in response to out-of-specification results * cleaned and maintained work area to meet workplace cleaning standards and environmental requirements. | |

| Knowledge Evidence |
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| 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 herb density on filtration * packing processes required for different types of herbs * 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 * work health and safety hazards, risks and controls relevant to an extraction process, including: * use of solvents * functions and limitations of personal protective clothing and equipment, including; protective gowns, scrubs, smocks, statcoats, disposable coveralls, surgical masks, surgical gloves, disposable overshoes, and hair nets * pre-start check requirements, including: * inspecting equipment condition to identify signs of wear * confirming that equipment is clean and correctly configured for extraction requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * placing sand filters or scourers in base of percolators where required * 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 * 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 |
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| 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 clothing and equipment * extraction solvents, material and equipment * cleaning materials and equipment associated with an extraction process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to concentration process and procedures * GMP requirements relating to extraction process * 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. |

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