Modification history

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| Release | Comments |
| Release 1 | This version released with FBP Food, Beverage and Pharmaceuticals Training Package Version 2.0 and meets the Standards for Training Packages 2012. |

| FBPPHM3005 | Operate a concentration process |
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| 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 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 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 clothing and equipment 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, rectify or 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 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. | |
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| 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 |
| 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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| Services must include at least two of the following: | * electricity * potable water * purified water * steam * compressed and instrumentation air * vacuum. |
| Pre-start checks must include at least four of the following: | * inspecting equipment condition to identify signs of wear * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * turning on oil pumps to the evaporator * pre-running equipment in line with operating temperature requirements where required. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3005 Operate a concentration process | FDFPH2002A Operate a concentration 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 Operate a concentration 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 concentration process, including:   * confirmed production requirements and related facilities, storage, equipment * selected, fitted and correctly used personal protective clothing and equipment, including: * protective gown, scrubs, smocks, statcoats or disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair net * conducted pre-start checks required for safe operation of the concentration process, including four of the following: * inspecting equipment condition to identify signs of wear * confirming that equipment is clean and correctly configured for processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * turning on oil pumps to the evaporator * pre-running equipment in line with operating temperature requirements where required * started, operated, monitored and adjusted a concentration process to achieve required outcomes * checked control points and conducted inspections to confirm process remains within specification, including: * product and machine temperature * vacuum * distillate colour * viscosity of concentrate * calculated yields and determined the number of passes required to ensure concentration is within specification * taken corrective action in response to out-of-specification product or process 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 a concentration process, including: * the purpose, methods and outcomes of each stage * the effect of heat and vacuum on distillate volume * 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 required and actions to take if services are unavailable, including: * power * potable water * purified water * steam * compressed and instrumentation air * vacuum * line clearance procedures, including procedures for clearing feed lines * work health and safety hazards, risks and controls relevant to a concentration 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 processing requirements * positioning sensors and controls correctly * ensuring scheduled maintenance has been carried out * turning on oil pumps to the evaporator * pre-running equipment in line with operating temperature requirements where required * 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 * 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 |
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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 * liquid extracts to be concentrated * concentration equipment, materials and services * cleaning materials and equipment associated with a concentration process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to concentration process and procedures * GMP requirements relating to concentration process * 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. |

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