Modification history

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

| FDFPHM3XXX | Operate a separation process using chromatography |
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| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a chromatography process in a production context.  The unit applies to individuals working in the pharmaceutical sector who apply basic operating principles to the operation and monitoring of a separation process using chromatography.  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 chromatography equipment for operation | 1.1 Identify workplace documentation relevant to work area activities  1.2 Use correctly fitted and appropriate personal protective clothing and equipment  1.3 Clean, assemble and adjust equipment to meet operational requirements  1.4 Set equipment components and related instrumentation to meet production requirements  1.5 Check and prepare column status for operation  1.6 Carry out pre-start checks according to workplace procedures  1.7 Complete equipment status reports in required format |
| 2. Prepare samples and load products | 2.1 Conduct pre-sampling tests according to test method to confirm column operation  2.2 Interpret test results  2.3 Identify out-of-specification results, investigate to identify cause and report according to workplace procedures  2.4 Load product into columns |
| 3. Operate and monitor column operation | 3.1 Start up and operate process according to workplace procedures  3.2 Monitor equipment to confirm that process cycles occur in correct sequence  3.3 Identify and promptly report variation in equipment operation and process outcomes according to workplace reporting procedures  3.4 Confirm separation of solution meets specifications  3.5 Maintain workplace documentation in required format  3.6 Conduct work according to environmental guidelines |
| 4. Shut down column process | 4.1 Shut down process according to workplace procedures  4.2 Identify and report maintenance requirements in accordance with workplace reporting requirements |

| 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 | * Read and interpret standard operating procedures for the chromatography process |
| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media |
| Numeracy | * Monitor the chromatography process including number of cycles and flow meters |
| Navigate the world of work | * Apply workplace procedures to own role and responsibilities * Understand main tasks, responsibilities and boundaries of own role, including use of personal protective clothing and equipment, housekeeping standards and environmental care requirements * Maintain a clean and hazard free work area |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * Solve routine problems according to workplace guidelines and using experience of past solutions |

| 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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| Personal protective clothing and equipment must include: | * protective gown or scrubs * surgical masks * surgical gloves * disposable overshoes * hair net. |
| Pre start checks must include: | * inspecting equipment condition to identify signs of wear * disinfecting and sterilising equipment and surfaces * assembling columns * confirming that connections and valves are correctly positioned * ensuring column lines have been purged * ensuring all safety guards are in place and operational * selecting instrumentation settings * cancelling isolation or lock outs where required * checking equipment readiness. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Operate a separation process using chromatography | FDFPH2004A Operate a separation process using chromatography | 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 |
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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, on at least one occasion, the individual has operated a separation process using chromatography, including:   * selected, fitted and used personal protective clothing and equipment * followed required work area entry and exit procedures and moved around work area to minimise risk of contamination * prepared equipment for the safe operation of a chromatography separation process * carried out sample testing to confirm integrity of columns * performed procedures for loading and packing product into columns * started, operated, and monitored the process to achieve required outcomes, including monitoring: * chromatography cycles * correct collection of fractions * appropriate product segregation * pump operation * taken corrective action in response to out-of-specification results * maintained security, integrity and traceability of samples, sub-samples and documentation * responded to or reported equipment failure within level of responsibility * located emergency stop functions on equipment * followed isolation and lock out procedures to take process and related equipment off-line in preparation for cleaning and maintenance in accordance with level of responsibility * performed product and process changeovers, including demonstrating column storage procedures * followed end of batch procedures, including line clearance and cleaning, yield calculation, materials reconciliation and product labelling * completed workplace records in required format * maintained work area to meet housekeeping standards * followed work health and safety procedures. | |

| 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:   * the purpose and principles of chromatography, including processes, purposes and methods used for analysis and preparation * basic operating principles of chromatography equipment, such as main equipment components, and consequences of incorrect equipment preparation, such as incorrectly positioned non-return valve, supply pump failure and air in the column * quality characteristics achievable by the separation process * operating requirements and parameters and potentially required corrective actions * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * sample test methods and actions taken if results are out-of-specification including typical tests such as Height Equivalent to Theoretical Plate (HETP) test * procedures to collect fractions as appropriate to columns and process requirements * procedures to identify traces and corrective action where traces are not within specifications * typical profile for a product cycle and events to be monitored during the cycle * procedures used to ensure product segregation * analysis and interpretation of relevant test results and implications for action required * GMP and Good Laboratory Practice (GLP) requirements associated with chromatography process and related control measures * common causes of variation and corrective actions required * work health and safety hazards and controls, including the limitations of protective clothing and equipment used * procedures and requirements of different shutdowns, including an understanding of the requirements for column storage, emergency and routine shutdowns and procedures to follow in the event of power outage * line clearance, cleaning and sanitation procedures * isolation, lock out and tag out procedures and responsibilities * procedures and responsibilities for reporting production and performance information. |

| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:   * physical conditions: * a workplace setting or an environment that accurately represents workplace conditions * resources, equipment and materials: * personal protective clothing and equipment * chromatography equipment * a typical range of samples to be tested * cleaning materials and equipment associated with a separation process using chromatography * specifications: * work procedures, including advice on safe work practices, food safety, quality and environmental requirements * workplace documentation relating to separation process and procedures * cleaning procedures associated with a separation process using chromatography * relationships: * interactions with team members and supervisors or realistic scenarios or roleplays.   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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