Modification history

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

| FBPPHM3007 | Operate a separation process using chromatography |
| --- | --- |
| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a chromatography separation process in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) and operating principles to the chromatography separation 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 |
| --- | --- |
| 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 production requirements from workplace documentation  1.2 Confirm materials 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 Clean, assemble and adjust equipment according to workplace procedures and operation and maintenance manual  1.6 Set equipment components and related instrumentation to meet production requirements  1.7 Conduct pre-start checks according to workplace procedures  1.8 Complete equipment status reports according to workplace procedures |
| 2. Prepare samples and load products | 2.1 Conduct pre-sampling tests and interpret test results to confirm column operation  2.2 Rectify, identify and report out-of-specification test results according to workplace procedures  2.3 Load product into columns according to specifications and production requirements |
| 3. Operate and monitor separation process | 3.1 Start up and monitor separation process to confirm process cycles occur in correct sequence according to specifications and production requirements  3.2 Rectify, identify and report out-of-specification products or processes to maintain process within specifications  3.3 Confirm separation of solution meets specifications  3.4 Conduct process according to safety and environmental requirements  3.5 Completed documentation according to workplace requirements |
| 4. Shut down separation process | 4.1 Confirm the workplace procedures for shutting down the process  4.2 Safely shut down the process  4.3 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 chromatography separation process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Interpret specifications for number of cycles and flow meters |
| 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 problems-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. | |
| --- | --- |
| Pre start checks must include at least five of the following: | * 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 * preparing column status for operation * ensuring all safety guards are in place and operational * selecting instrumentation settings * cancelling isolation or lock outs where required * carried out sample testing to confirm integrity of columns. |

|  |  |  |  |
| --- | --- | --- | --- |
| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3007 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 |

|  |  |
| --- | --- |
| 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 FBPPHM3007 Error! Use the Home tab to apply AFSA Unit Title to the text that you want to appear here. |
| --- | --- |
| 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 separation process using chromatography, including:   * selected, fitted and correctly used one of the following: * protective gown * scrubs * smocks * statcoats * disposable coveralls * selected, fitted and correctly used personal protective clothing and equipment, including: * surgical masks * surgical gloves * disposable overshoes * hair net * conducted pre-start checks required for the safe operation of a chromatography separation process, including five of the following: * 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 * preparing column status for operation * ensuring all safety guards are in place and operational * selecting instrumentation settings * cancelling isolation or lock outs where required * carried out sample testing to confirm integrity of columns * performed procedures for loading and packing product into columns * started, operated, monitored and adjusted a process to achieve required outcomes * checked control points and conducted inspections to confirm process remains within specification, including: * chromatography cycles * correct collection of fractions * appropriate product segregation * pump operation * maintained security, integrity and traceability of: * samples * sub-samples * documentation * 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 according to workplace procedures * performed product and process changeovers, including demonstrating column storage procedures * followed end of batch procedures, including: * line clearance and cleaning * yield calculation * materials reconciliation * product labelling * 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 |
| --- |
| 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 chromatography separation process, including: * the purpose, methods and outcomes of each stage * quality characteristics achievable by the separation process * methods of analysis * basic operating principles, requirements and parameters of chromatography equipment, including: * main equipment components, operating capacities and applications * consequences of incorrect equipment preparation, such as incorrectly positioned non-return valve, supply pump failure and air in the column * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * line clearance, cleaning and sanitation procedures * functions and limitations of personal protective clothing and equipment, including: * protective gown, scrubs, smocks, statcoats and disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair net * pre-start checks requirements, including: * 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 * preparing column status for operation * ensuring all safety guards are in place and operational * selecting instrumentation settings * cancelling isolation or lock outs where required * carried out sample testing to confirm integrity of columns * sample test methods, including: * typical tests such as Height Equivalent to Theoretical Plate (HETP) test * analysis and interpretation of results * implications and actions taken if results are out-of-specification * procedures used for the following: * collecting fractions as appropriate to columns and process requirements * identifying traces and corrective action where traces are not within specifications * ensuring product segregation * typical profile for a product cycle and events to be monitored during the cycle * common causes of out-of-specification product or process and corrective actions required * procedures and requirements of different shutdowns, including: * an understanding of the requirements for column storage * emergency and routine shutdowns * procedures to follow in the event of power outage * isolation, lock out and tag out procedures and responsibilities * GMP requirements associated with a separation process and related control measures * 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 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: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to separation process and procedures * GMP requirements relating to separation process * cleaning procedures associated with a separation process using chromatography.   Assessors of this unit must satisfy the requirements for assessors in applicable vocational education and training legislation, frameworks and/or standards. |

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