Modification history

Release	Comments
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.

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 use Good Manufacturing Practice (GMP) and operating principles in the chromatography separation process. Individuals work 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 equipment and contamination prevention clothing 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 process operation 2.2 Identify and report out of limit test results according to workplace procedures 2.3 Load product 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 Identify and report out of limit products or processes according to workplace procedures 3.3 Confirm separation of solution meets specifications 3.4 Conduct process according to safety and environmental requirements 3.5 Complete 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

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:	• 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

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3007 Operate a separation process using chromatography Release 2	FBPPHM3007 Operate a separation process using chromatography Release 1	Foundation skills amended Performance criteria clarified Assessment Conditions updated	Equivalent unit

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

TITLE	Assessment requirements for FBPPHM3007 Operate a separation process using chromatography

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:

- accessed workplace information to confirm requirements for the process
- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks required for the safe operation of a chromatography separation process, 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
- performed procedures for loading and packing product into columns
- started, operated, monitored and adjusted a process to achieve required outcomes
- conducted in-process control checks to confirm the process remains within limits
- maintained security, integrity and traceability of:
  - samples
  - sub-samples
  - documentation
- 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
- taken corrective action in response to out-of-specification results
- safely shut down the process according to workplace procedures
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirement
- 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 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 equipment and contamination prevention clothing pre-start checks 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
- sample test methods, including:
  - typical tests such as Height Equivalent to Theoretical Plate (HETP) test

Knowledge Evidence

- analysis and interpretation of results
- implications and actions taken if results are out-of-specification

- procedures used for:
  - 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
- Good Manufacturing Practice (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 equipment and contamination prevention clothing
  - chromatography equipment
  - a typical range of samples to be tested
  - cleaning materials and equipment associated with a separation process using chromatography
  - record keeping system
- specifications:
  - product specifications, control points and processing parameters
  - recording requirements and procedures according to Good Documentation Practice (GDP)
  - workplace documentation relating to separation process and procedures that comply with GMP requirements
  - 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.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4