



Australian Government

FBPPHM3007 Operate a separation process using chromatography

Release: 1

FBPPHM3007 Operate a separation process using chromatography

Modification History

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

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.

Pre-requisite Unit

Nil

Unit Sector

Pharmaceutical (PHM)

Elements and Performance Criteria

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
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

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	<p>prevention clothing according to workplace procedures</p> <p>1.5 Clean, assemble and adjust equipment according to workplace procedures and operation and maintenance manual</p> <p>1.6 Set equipment components and related instrumentation to meet production requirements</p> <p>1.7 Conduct pre-start checks according to workplace procedures</p> <p>1.8 Complete equipment status reports according to workplace procedures</p>
2. Prepare samples and load products	<p>2.1 Conduct pre-sampling tests and interpret test results to confirm column operation</p> <p>2.2 Identify and report out of limit test results according to workplace procedures</p> <p>2.3 Load product into columns according to specifications and production requirements</p>
3. Operate and monitor separation process	<p>3.1 Start up and monitor separation process to confirm process cycles occur in correct sequence according to specifications and production requirements</p> <p>3.2 Identify and report out of limit products or processes according to workplace procedures</p> <p>3.3 Confirm separation of solution meets specifications</p> <p>3.4 Conduct process according to safety and environmental requirements</p> <p>3.5 Complete documentation according to workplace requirements</p>
4. Shut down separation process	<p>4.1 Confirm the workplace procedures for shutting down the process</p> <p>4.2 Safely shut down the process</p> <p>4.3 Complete records according to workplace procedures</p>

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	<ul style="list-style-type: none"> Identify relevant information from workplace documentation and interpret requirements for the chromatography separation process
Writing	<ul style="list-style-type: none"> Complete workplace documentation using appropriate language and in required format
Numeracy	<ul style="list-style-type: none"> Interpret specifications for number of cycles and flow meters
Navigate the world of work	<ul style="list-style-type: none"> Identify workplace procedures relevant to own role
Interact with others	<ul style="list-style-type: none"> Report operational and safety information to relevant personnel using required communication method
Get the work done	<ul style="list-style-type: none"> 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.

Pre start checks must include:	<ul style="list-style-type: none"> 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
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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 Changes to performance criteria	Equivalent unit

		for clarity Code changed to reflect AQF alignment	
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Links

Companion Volume Implementation Guides are found in VETNet: -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4>