



Australian Government

FBPPHM3019 Operate a chromatography manufacturing process

Release: 1

FBPPHM3019 Operate a chromatography manufacturing process

Modification History

Release	Comments
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.

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 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 prevention clothing according to workplace procedures

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	1.5 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 and pack 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 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 isolation and lock out procedures and product and process changeovers for shutting down 4.2 Safely shut down process 4.3 Clean work area according to workplace procedures 4.4 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.

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

Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3019 Operate a chromatography manufacturing process	FBPPHM3007 Operate a separation process using chromatography	Title changed Foundation skills table updated Range of Conditions deleted to remove duplication Minor change to performance criteria and assessment requirements for clarity	Equivalent

Links

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