



Australian Government

Assessment Requirements for FBPPHM3007 Operate a separation process using chromatography

Release: 1

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Modification History

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

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
 - 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
 - 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 Volume Implementation Guides are found in VETNet: -

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