



Australian Government

Assessment Requirements for FBPPHM3006 Operate an extraction process

Release: 2

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Modification History

Release	Comments
Release 2	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 5.0.
Release 1	This version released with FBP Food, Beverage and Pharmaceutical Training Package Version 2.0.

Performance Evidence

An individual demonstrating competency must satisfy all of the elements and performance criteria in this unit.

There must be evidence that the individual has safely operated at least one extraction process, including:

- confirmed production requirements and related facilities, storage and equipment
- correctly gown using Standard Operating Procedures for the operations performed batch and product changeovers, including line clearance procedures
- performed batch and product changeovers, including line clearance procedures
- conducted pre-start checks required for the safe operation of the extraction process, including:
 - carried out required area or line clearances
 - inspected equipment condition to identify signs of wear
 - checked all safety equipment in place and operational
 - checked equipment clean or sanitised
 - checked equipment correctly configured for processing requirements
- started, operated, monitored and adjusted a process to achieve required outcomes
- conducted in-process control checks to confirm the process remains within limits
- inspected product for defects
- taken corrective action in response to a non-conformance
- safely shut down the process according to workplace procedures
- cleaned and maintained work area to meet workplace cleaning standards and environmental requirements
- 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 extraction process, including:
 - the purpose, methods and outcomes of each stage
 - the effect of material density on filtration
 - packing processes required for different types of materials
- basic operating principles, requirements and parameters of extraction process equipment, including:
 - main equipment components, operating capacities and applications
 - typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
 - corrective actions required where operation is outside specified operating parameters
- line clearance procedures, including procedures for clearing feed lines
- workplace health and safety hazards, risks and controls relevant to an extraction process, including:
 - use of solvents
 - functions and limitations of personal protective equipment and contamination prevention clothing
- pre-start check requirements, including:
 - required area or line clearances
 - equipment condition to identify signs of wear
 - safety equipment in place and operational
 - equipment clean or sanitised
 - equipment correctly configured for processing requirements
- methods used to monitor extraction process, including:
 - inspecting
 - measuring
 - testing
 - calculating yields
- quality requirements of materials and the effect of variations on the extraction process
- product and process specifications, procedures and operating parameters for different products and materials
- contamination risks associated with the extraction process
- common causes of out-of-specification product or process and corrective actions required
- extraction process shutdown and changeover procedures and responsibilities
- Good Manufacturing Practice (GMP) requirements associated with an extraction process and related control measures
- environmental issues and controls relevant to the extraction process, including waste collection and handling procedures
- requirements for completion of workplace documentation.

Assessment Conditions

Assessment of the skills in this unit of competency 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
 - extraction solvents, material and equipment
 - cleaning materials and equipment associated with an extraction process
 - record keeping system
- specifications:
 - product and intermediate product specifications, control points and processing parameters
 - recording requirements and procedures in accordance with Good Documentation Practice
 - workplace documentation relating to an extraction process and procedures that comply with GMP requirements
 - cleaning procedures associated with an extraction process.

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>