Australian Government

Assessment Requirements for FBPPHM3011 Dispense pharmaceutical raw materials

Release: 2

Assessment Requirements for FBPPHM3011 Dispense pharmaceutical raw materials

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 in this unit must satisfy all the elements and performance criteria of this unit.

There must be evidence that the individual has safely dispensed pharmaceutical raw materials at least once, including:

- accessed workplace information to confirm dispensing requirements
- checked supply of necessary raw materials, including:
  - raw material labels and codes for status and type
  - quantities
  - quality clearances
- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks on dispensing equipment, including:
  - condition and cleanliness of equipment and shared or dedicated utensils
  - confirmed equipment correctly configured for dispensing requirements
- measured materials and additives within a specified accuracy range to meet batch requirements
- calculated assay or potency adjustment
- verified accuracy of raw materials dispensed with raw materials records
- taken corrective action in response to a non-conformance
- applied segregation and cross contamination prevention procedures
- paced dispensing to meet production requirements
- packed and labelled dispensed materials, according to batch requirements and labelling procedures
- reconciled and recorded materials dispensed against materials released and returned unused materials to storage

- stacked dispensed materials for transfer to designated location, ensuring required material segregation
- handled containers and maintained integrity of materials according to workplace procedures
- safely cleared the process area according to workplace procedures
- cleaned and maintained dispensing equipment, utensils and 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 dispensing process, including:
  - purpose, methods and outcomes of each stage
  - control points
  - types of raw materials and related handling requirements including handling of hazardous goods
- basic operating principles, requirements and parameters of dispensing equipment, including:
  - measuring, and accuracy capacity of instrumentation and related equipment
  - 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
- functions and limitations of personal protective equipment and contamination prevention clothing
- pre-start checks requirements, including:
  - condition and cleanliness of equipment and shared or dedicated utensils
  - confirming that equipment is correctly configured for dispensing requirements
- operational considerations that impact on the quality of the dispensing process, including:
  - product accuracy
  - equipment tolerances
  - consequences of errors and variations
- workplace procedures for:
  - calculating assay and adjusting potency
  - reconciliation of raw materials, including Schedule 8 materials
  - requisitioning, receiving and returning ingredients from stores
- Good Manufacturing Practice (GMP) requirements associated with dispensing pharmaceutical raw materials
- environmental issues and controls relevant to the dispensing process, including waste and rework collection, and handling procedures

- workplace systems for recording information about dispensed pharmaceutical materials, including coding and labelling systems
- 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
  - dispensing process equipment and utensils
  - materials required for the dispensing process
  - containers or bags, labelling and storage facilities
  - test equipment
  - cleaning materials and equipment associated with dispensing pharmaceutical raw materials
  - record keeping system
- specifications:
  - product and intermediate product specifications, control points and processing parameters
  - specifications, control points and processing parameters
  - recording requirements and procedures
  - workplace documentation relating to the dispensing process and procedures that comply with GMP requirements
  - sampling schedules and test procedures
  - cleaning procedures associated with dispensing pharmaceutical raw materials.

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