Australian Government

Assessment Requirements for FBPPHM3013 Operate a granulation process

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 granulation process, including:

- accessed workplace information to confirm production requirements for the granulation process
- confirmed supply of necessary materials and services, including checking raw materials meet batch requirements
- selected, fitted and used personal protective equipment and contamination prevention clothing
- conducted pre-start checks required for the safe operation of the granulation process:
  - carrying out required area or line clearances
  - inspecting equipment condition to identify signs of wear
  - confirming all safety equipment are in place and operational
  - confirming that equipment is clean or sanitised
  - confirming that equipment is correctly configured for processing requirements
- started, operated, monitored and adjusted a granulation process to achieve required outcomes, including:
  - interpreting and implementing batch instructions
  - supply and flow of materials to and from the granulation process
- conducted in-process control checks to confirm the process remains within limits
- sampled and inspected product for conformance to specifications, including granule size
- taken corrective action in response to a non-conformance
- followed end-of-batch procedures, including:
  - line clearance and cleaning
  - yield calculation
  - materials reconciliation

    - product labelling
- 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 granulation process, including:
    - the purpose, methods and outcomes of each stage
    - control points
    - quality characteristics to be met by the granulation process
    - stages and changes which occur during granulation
    - types of raw materials used in the granulation process and related handling and segregation requirements, including handling hazardous goods
    - flow of the granulation process and the effect of outputs on downstream pharmaceutical processes
- basic operating principles of equipment, requirements and parameters of granulation 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
    - status and purpose of guards
    - the purpose and location of sensors and related feedback instrumentation
    - corrective actions required where operation is outside specified parameters
- functions and limitations of personal protective clothing 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 are in place and operational
    - confirming that equipment is clean or sanitised
    - confirming that equipment is correctly configured for processing requirements
- methods used to monitor granulation process, including:
    - inspecting
    - measuring
    - testing
- product and process changeover procedures and responsibilities
- end-of-batch procedures, including:

  - calculating yield
  - materials reconciliation
- product labelling responsibilities and procedures
- requirements of different shutdowns, including:
  - emergency and routine shutdowns
  - procedures to follow in the event of a power outage
- line clearance procedures, including cleaning and sanitation procedures
- isolation, lock out and tag out procedures and responsibilities
- operating principles of process control, including the relationship between control panels and systems and physical equipment
- Good Manufacturing Practice (GMP) requirements associated with a granulation process and related control measures
- environmental issues and controls relevant to the granulation process, including waste collection and handling procedures
- 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
  - granulation process equipment
  - materials required for the granulation process
  - test equipment
  - cleaning materials and equipment associated with granulation process
  - record keeping system
- specifications:
  - batch instructions including product specifications, control points and processing parameters
  - recording requirements and procedures
  - workplace documentation relating to granulation process and procedures that comply with GMP requirements
  - sampling schedules and test procedures
  - cleaning procedures associated with granulation 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