



Australian Government

FBPPHM3013 Operate a granulation process

Release: 1

FBPPHM3013 Operate a granulation process

Modification History

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

Application

This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a granulation process in a pharmaceutical manufacturing facility.

The unit applies to individuals who apply Good Manufacturing Practice (GMP) and operating principles to the granulation process. Individuals work under broad direction and take responsibility for their own work.

No occupational 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 granulation process for operation	1.1 Confirm materials and equipment are available and meet production requirements 1.2 Select and fit personal protective equipment and contamination prevention clothing according to workplace procedures 1.3 Fit and adjust machine components and attachments according to production requirements and equipment operation and maintenance manual 1.4 Enter processing and operating parameters according to safety

Elements	Performance Criteria
<i>Elements describe the essential outcomes.</i>	<i>Performance criteria describe the performance needed to demonstrate achievement of the element.</i>
	and production requirements 1.5 Conduct pre-start checks according to workplace requirements
2. Operate and monitor granulation process	2.1 Start up and monitor granulation process to confirm specifications are within required limits 2.2 Identify and report out of limit granulated products or processes according to workplace procedures 2.3 Maintain work area according to workplace cleaning standards 2.4 Conduct process according to safety and environmental requirements 2.5 Contain, remove and report spillages according to workplace procedures 2.6 Complete documentation according to workplace procedures
3. Shut down the granulation process	3.1 Confirm the workplace procedures for shutting down the process 3.2 Complete end-of-batch procedures according to batch instructions and workplace procedures 3.3 Safely shut down the process 3.4 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 granulation process
Writing	Complete workplace documentation using appropriate language and in required format
Numeracy	Interpret specifications for flow rates and product quantity
Navigate the world	Identify workplace procedures relevant to own role

Skill	Description
of work	
Interact with others	Report operational and safety information to relevant personnel using required communication method
Get the work done	- Plan, organise and implement tasks required to achieve production outcomes - Use problem-solving skills to analyse product and process faults and decide on appropriate action

Range of Conditions

This section specifies different work environments and conditions that may affect performance. Essential operating conditions that may be present (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) are included.

Pre-start checks must include:	- 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.
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Unit Mapping Information

Code and title current version	Code and title previous version	Comments	Equivalence status
FBPPHM3013 Operate a granulation process	FDFPH2011A Operate a granulation process	Updated to meet Standards for Training Packages Changes to performance criteria for clarity Code changed to reflect AQF alignment	Equivalent unit

Links

Companion Volume Implementation Guides are found in VETNet: -

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

Assessment Requirements for FBPPHM3013 Operate a granulation process

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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.

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