Modification history

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

| FDFPHM3XXX | Operate a granulation process |
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| Application | This unit of competency describes the skills and knowledge required to set up, operate, adjust and shut down a granulation process.The unit is applicable to individuals who are responsible for operating and monitoring a granulation process and related equipment in pharmaceutical manufacturing environments.No occupational licensing, legislative or certification requirements apply to this unit at the time of publication. |
| Prerequisite Unit | Nil |
| Unit Sector | Pharmaceutical (PHM) |

| Elements | Performance Criteria |
| --- | --- |
| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Prepare granulation process for operation | 1.1 Confirm availability of materials to meet operating requirements1.2 Identify and confirm cleaning and maintenance requirements and status 1.3 Use appropriate personal protective clothing and equipment1.4 Fit and adjust machine components and related attachments to meet operating requirements1.5 Enter processing and operating parameters to meet safety and production requirements1.6 Check and adjust equipment performance according to equipment operating procedures1.7 Conduct out pre-start checks according to procedures |
| 2. Operate and monitor granulation process | 2.1 Start up and operate granulation process according to workplace procedures2.2 Monitor equipment to identify variations in operating conditions2.3 Monitor process to confirm granulated products meet specifications2.4 Identify, rectify, and report out-of-specification products and process outcomes to ensure the process operates within specifications2.5 Maintain work area according to workplace housekeeping standards2.6 Conduct work according to environmental standards2.7 Contain, remove and report spillages according to workplace procedures2.8 Maintain workplace records in required format |
| 3. Shut down the granulation process | 3.1 Complete end-of-batch procedures according to batch instructions and SOPs3.2 Shut down the granulation process according to workplace procedures3.3 Identify and report maintenance requirements according to workplace reporting requirements |

| Foundation SkillsThis 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. |
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| Skill | Description |
| Reading | * Read and interpret standard operating procedures for the granulation process
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| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media
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| Numeracy | * Verify raw materials with batch instructions
* Monitor supply and flow of materials to and from the granulation process
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| Navigate the world of work | * Apply workplace procedures to own role and responsibilities
* Understand main tasks, responsibilities and boundaries of own role, including use of personal protective clothing and equipment, housekeeping standards and environmental care requirements
* Maintain a clean and hazard free work area
* Maintain hygiene standards
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| Interact with others | * Report operational and safety information to relevant personnel using required communication method
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| Get the work done | * Solve routine problems according to workplace guidelines and using experience of past solutions
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| Range Of ConditionsThis 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. |
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| Personal protective clothing and equipment must include: | * protective gown or scrubs
* surgical masks
* surgical gloves
* disposable overshoes
* hair net.
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| Pre start up checks must include: | * inspecting equipment condition to identify signs of wear
* selecting appropriate settings and/or related parameters
* cancelling isolation or lock outs
* confirming line clearance and cleaning status
* confirming that equipment is clean and correctly configured for processing requirements
* positioning sensors and controls correctly
* ensuring scheduled maintenance has been carried out
* confirming all safety guards are in place and operational.
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| Unit Mapping Information |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX Operate a granulation process | FDFPH2011A Operate a granulation process | Updated to meet Standards for Training Packages. Code changed to reflect AQF alignment. | Equivalent unit |

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| Links | Companion Volumes, including Implementation Guides, are available at VETNet <https://vetnet.education.gov.au/Pages/TrainingDocs.aspx?q=78b15323-cd38-483e-aad7-1159b570a5c4> |

| TITLE | Assessment requirements for FDFPHM3XXX 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, on at least one occasion, the individual has operated a granulation process, including:* accessed workplace information to identify production requirements for the granulation process
* selected, fitted and used personal protective clothing and equipment
* confirmed supply of necessary materials and services
* conducted pre-start checks required to ensure safe start-up of the granulation process
* verified raw materials with batch instructions
* started, operated, monitored and adjusted granulation process equipment, including interpreting and implementing batch instructions, labelling products, calculating yields, monitoring control points and conducting inspections to confirm the process remains within specification, including:
* granule size
* moisture content
* taken corrective action in response to out-of-specification results
* monitored the supply and flow of materials to and from the granulation process
* responded to or reported equipment failure according to workplace guidelines
* located emergency stop functions on equipment
* followed isolation, lock out and tag out procedures, to take the granulation process and related equipment off-line in preparation for cleaning and maintenance
* followed end-of-batch procedures, including line clearance and cleaning, yield calculation, material reconciliation and product labelling
* completed workplace records in required format
* maintained work area to meet workplace housekeeping standards
* used process control systems in accordance with workplace procedures
* followed work health and safety procedures.
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| Knowledge Evidence |
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| 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:* the purpose and basic principles of the granulation process
* basic operating principles of equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, and the purpose and location of sensors and related feedback instrumentation
* services required and actions to take if they are unavailable
* the types of raw materials used in the granulation process and related handling and segregation requirements, including handling hazardous goods
* stages and changes which occur during granulation
* quality characteristics to be met by the granulation process
* flow of the granulation process and the effect of outputs on downstream pharmaceutical processes
* operating requirements, parameters and corrective actions required where operation is outside specified parameters
* typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems
* methods used to monitor the granulation process, including inspecting, measuring and testing
* inspection or test points (control points) in the granulation process, related procedures and recording requirements
* Good Manufacturing Practice (GMP) requirements associated with the granulation process and related control measures
* common causes of variation and corrective action required
* product and process changeover procedures and responsibilities
* work health and safety hazards and controls, including limitations of protective clothing and equipment
* end-of-batch procedures, including procedures for calculating yield and materials reconciliation
* actions required if yield or reconciliation is outside of prescribed limits
* product labelling responsibilities and procedures
* requirements of different shutdowns, including emergency and routine shutdowns and procedures to follow in the event of a power outage
* line clearance, cleaning and sanitation procedures
* isolation, lock out and tag out procedures and responsibilities
* procedures and responsibilities for reporting production and performance information
* environmental issues and controls pertinent to the granulation process, including waste collection and handling procedures
* basic operating principles of process control, including the relationship between control panels and systems and physical equipment.
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| Assessment Conditions |
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| Assessment of skills must take place under the following conditions:* physical conditions:
* a workplace setting or an environment that accurately represents workplace conditions
* resources, equipment and materials:
* personal protective clothing and equipment
* granulation process and related equipment and services
* materials required for the granulation process
* test equipment
* cleaning materials and equipment associated with granulation process
* specifications:
* work procedures, including advice on safe work practices, GMP, SOPs and environmental requirements
* information on equipment capacity and operating parameters
* production schedule or batch instructions
* specifications, control points and processing parameters
* sampling schedules and test procedures
* documentation and recording requirements and procedures
* cleaning procedures associated with granulation process
* relationships:
* interactions with team members and supervisors or realistic scenarios or roleplays.

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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