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 tablet coating process |
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| Application | This unit of competency describes the skills and knowledge required to set up, operate and shut down a tablet coating process.  The unit applies to individuals who are responsible for applying basic operating principles to the operation and monitoring of a tablet coating process in a pharmaceutical manufacturing environment.  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 |
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| Elements describe the essential outcomes. | Performance criteria describe the performance needed to demonstrate achievement of the element. |
| 1. Prepare the tablet coating process for operation | 1.1 Confirm availability of tablets and coating materials to meet operating requirements  1.2 Identify and confirm cleaning and maintenance requirements and status  1.3 Use correctly fitted and appropriate personal protective clothing and equipment  1.4 Fit and attach machine components and related attachments to meet operating requirements  1.5 Enter processing and operating parameters, to meet safety and production requirements  1.6 Check and adjust equipment performance according to equipment operating procedures  1.7 Conduct pre-start checks according to procedures |
| 2. Operate and monitor the tablet coating process | 2.1 Start and operate the process according to workplace procedures  2.2 Monitor equipment to identify variations in operating conditions  2.3 Monitor process to confirm that coated tablets meet specifications  2.4 Contain, remove and report spillages according to workplace procedures  2.5 Identify, rectify and report out-of-specification product and process outcomes to ensure the process remains within specifications  2.6 Maintain work area according to workplace housekeeping standards  2.7 Conduct work according to environmental standards  2.8 Maintain workplace records in required format |
| 3. Shut down the tablet coating process | 3.1 Complete end-of-batch procedures according to batch instructions and standard operating procedures (SOP)  3.2 Shut down the tablet coating process according to workplace procedures  3.3 Identify and report maintenance requirements according to workplace reporting requirements |

| 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. | |
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| Skill | Description |
| Reading | * Read and interpret standard operating procedures for the tablet coating process |
| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media |
| Numeracy | * Calculate type and number of tablets to be coated * Set coating addition rate and drying air temperature and flow |
| 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 |
| Interact with others | * Report operational and safety information to relevant personnel using required communication method |
| Get the work done | * Solve routine problems according to workplace guidelines and using experience of past solutions |

| 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. | |
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| Personal protective clothing and equipment must include: | * protective gown or scrubs * surgical masks * surgical gloves * disposable overshoes * hair net. |
| Pre start 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 that 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 tablet coating process | FDFPH2013A Operate a tablet coating 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 tablet coating 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 table coating process, including:   * accessed workplace information to identify tablet coating process requirements * selected, fitted and used personal protective equipment * confirmed supply of necessary tablets, coating materials and services to the tablet coating process * prepared coating materials in accordance with specifications * conducted all pre-start checks on coating process equipment to ensure safe start up of operations * started, operated, monitored and adjusted the tablet coating process equipment to achieve required outcomes, including monitoring control points and conducting inspections to confirm process remains within specification, for: * pan preparation and coating * coating addition rate * addition and dosing of materials * drying air temperature and flow * addition of polishing agent or gum * taken corrective action in response to out-of-specification results * monitored supply and flow of materials to and from the tablet coating process * responded to and reported equipment failure according to workplace guidelines * located emergency stop functions on equipment * followed isolation, lock out and tag out procedures, to take the tablet coating process and related equipment off-line in preparation for cleaning or 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 * collected samples and conducted tests in accordance with workplace procedures * conducted routine maintenance in accordance with workplace procedures * followed work health and safety procedures. | |

| 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 tablet coating process, including tablet preparation, conditioning procedures and requirements, coating preparation and stages in the coating process * basic operating principles of equipment, including main equipment components, status and purpose of guards, equipment operating capacities and applications, and purpose and location of sensors and related feedback instrumentation * services required and actions to take if they are unavailable * flow of the tablet coating process and the effect of outputs on downstream pharmaceutical processes * stages and changes which occur during tablet coating * types of materials used in preparation of coatings and related handling and segregation requirements * quality characteristics to be met by the tablet coating process * effects of tablet coating process on the end products * quality requirements of materials and the effect of variation on tablet coating process performance * operating requirements, parameters and corrective actions required where operation is outside of 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 tablet coating process, including inspecting, measuring and testing the process * inspection or test points (control points) in the tablet coating process and related procedures and recording requirements * Good Manufacturing Practice (GMP) requirements associated with the tablet coating process and related control measures * common causes of variation and corrective actions required * product and process changeover procedures and responsibilities * work health and safety hazards and controls, including the limitations of personal protective equipment * end-of-batch procedures, including procedures for calculating yield and material reconciliation * actions required if yield or reconciliation is not within 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, including waste collection and handling procedures * basic operating principles of process control, including the relationship between control panels and systems and the physical equipment. |

| 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 * tablet coating process and related equipment and services * materials required for the tablet coating process, including tablets and coating materials * test equipment * cleaning materials and equipment associated with tablet coating process * specifications: * work procedures, including advice on safe work practices, GMP, quality and environmental requirements * information on equipment capacity and operating parameters * production schedule/batch instructions * specifications, control points and processing parameters * sampling schedules and test procedures * documentation and recording requirements and procedures, including labels * cleaning procedures associated with tablet coating 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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