Modification history

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

| FBPPHM3015 | Operate a tablet coating 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 tablet coating process in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) and operating principles to the tablet coating process 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. |
| 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 tablets, coating materials and equipment are available and meet production requirements  1.2 Select and fit personal protective clothing and equipment 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 and production requirements  1.5 Conduct pre-start checks according to workplace requirements |
| 2. Operate and monitor the tablet coating process | 2.1 Start up and monitor tablet coating process to confirm specifications are within required limits  2.2 Rectify, identify and report out-of-specification coated tablet products or processes to maintain process within specifications  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 requirements |
| 3. Shut down the tablet coating 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. | |
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| Skill | Description |
| Reading | * Identify relevant information from workplace documentation and interpret requirements for the tablet coating process |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Confirm type and number of tablets to be coated meet batch requirements * Interpret specifications for coating addition rate and drying air temperature and flow |
| Navigate the world of work | * Identify workplace procedures relevant to own role |
| 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. | |
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| Pre start checks must include at least five of the following: | * 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 |
| FBPPHM3015 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 FBPPHM3015 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 the individual has safely operated at least one tablet coating process, including:   * accessed workplace information to confirm production requirements for the tablet coating process * confirmed supply of necessary tablets, coating materials and services for the tablet coating process * selected, fitted and correctly used one of the following: * protective gown * scrubs * smocks * statcoats * disposable coveralls * selected, fitted and correctly used personal protective clothing and equipment, including: * surgical masks * surgical gloves * disposable overshoes * hair net * conducted pre-start checks required for the safe operation of the tablet coating process equipment, including five of the following: * 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 * preparing coating materials in accordance with specifications * started, operated, monitored and adjusted the tablet coating process to achieve required outcomes * checked control points and conducted inspections to confirm process remains within specification, including: * pan preparation and coating * coating addition rate * addition and dosing of materials * drying air temperature and flow * addition of polishing agent or gum * supply and flow of materials to and from tablet coating process * collected samples and conducted tests according to workplace procedures * taken corrective action in response to out-of-specification results * located emergency stop functions on equipment * followed isolation and lock out and tag out procedures to take 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 * materials reconciliation * product labelling * used process control systems according to workplace procedures * cleaned and maintained work area to meet workplace cleaning standards and environmental requirements. | |

| 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:   * stages of the tablet coating process, including: * the purpose, methods and outcomes of each stage * control points * quality characteristics to be met by the tablet coating process * stages and changes which occur during tablet coating * effects of tablet coating process on the end product * types of materials used in preparation of coatings and related handling and segregation requirements * flow of the tablet coating process and the effect of outputs on downstream pharmaceutical processes * basic operating principles of equipment, requirements and parameters of tablet coating 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 of specified parameters * functions and the limitations of personal protective clothing and equipment, including: * protective gown, scrubs, smocks, statcoats and disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair net * pre-start checks requirements, including: * 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 * preparing coating materials in accordance with specifications * methods used to monitor the tablet coating process, including: * inspecting * measuring * testing * product and process changeover procedures and responsibilities * end-of-batch procedures, including: * calculating yield * material 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 the physical equipment * GMP requirements associated with a tablet coating process and related control measures * environmental issues and controls relevant to the tablet coating process, including waste collection and handling procedures * requirements for completion of workplace documentation. |

| Assessment Conditions |
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| 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 clothing and equipment * tablet coating process equipment * materials required for the tablet coating process, including tablets, coating materials and labels * test equipment * cleaning materials and equipment associated with tablet coating process * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to tablet coating process and procedures * GMP requirements relating to tablet coating process * production schedule/batch instructions * sampling schedules and test procedures * cleaning procedures associated with tablet coating 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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