Modification history

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

| FBPPHM3011 | Dispense pharmaceutical raw materials |
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| Application | This unit of competency describes the skills and knowledge required to weigh, measure and label non-bulk ingredients to meet batch requirements in a pharmaceutical manufacturing facility.  The unit applies to individuals who apply good manufacturing practice (GMP) and operating principles to the dispensing of raw material 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 to dispense raw materials | 1.1 Confirm material status, type, quality clearance and quantities  1.2 Rectify, identify and report contamination or non-compliance issues to maintain process within specifications  1.3 Confirm measuring and weighing equipment are available according to dispensing requirements  1.4 Select and fit personal protective clothing and equipment according to workplace procedures  1.5 Supply containers, bags and labels according to batch and production requirements  1.6 Conduct pre-start checks according to workplace requirements |
| 2. Measure and weigh raw materials | 2.1 Weigh and measure non-bulk ingredients and additives according to batch and production requirements  2.2 Monitor accuracy of measuring and dispensing equipment  2.3 Rectify, identify and report variations in equipment operation to maintain process within specifications  2.4 Label dispensed ingredients according to batch and production requirements  2.5 Maintain work area according to workplace cleaning standards  2.6 Conduct process according to workplace safety and environmental requirements |
| 3. Shut down the dispensing process | 3.1 Confirm the workplace procedures for shutting down the process  3.2 Safely shut down the process  3.3 Clean dispensing equipment according to workplace procedures  3.4 Report unacceptable equipment and utensil condition  3.5 Reconcile dispensed materials  3.6 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 | * Interpret workplace procedures for dispensing pharmaceutical raw materials |
| Writing | * Complete workplace documentation using appropriate language and in required format |
| Numeracy | * Extract and interpret mathematical information embedded in job specifications and stock control data to meet production requirements * Use equipment to measure and weigh materials and additives to meet batch requirements * Check and interpret raw material labels, codes and quantity |
| 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 dispensing 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: | * inspecting the condition and cleanliness of equipment and shared or dedicated utensils * taring of shared or dedicated scales * carrying out procedures to confirm that equipment is calibrated and within specification. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FBPPHM3011 Dispense pharmaceutical raw materials | FDFPH2009A Dispense pharmaceutical raw materials | 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 Dispense pharmaceutical raw materials |
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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 dispensed pharmaceutical raw materials at least once, including:   * accessed workplace information to confirm dispensing requirements * confirmed supply of necessary raw materials, including: * checking raw material labels and codes for status and type * quantities * quality clearances * selected, fitted and used one of the following: * protective gown * scrubs * smock * statcoat * disposable coverall * selected, fitted and used personal protective clothing and equipment, including: * surgical mask * surgical gloves * disposable overshoes * hair net * conducted pre-start checks on dispensing equipment, including: * condition and cleanliness of equipment and shared or dedicated utensils * taring of shared or dedicated scales * procedures to confirm that equipment is calibrated and within specification * measured materials and additives within a specified accuracy range to meet batch requirements * calculated assay or potency adjustment * verified accuracy of raw materials dispensed with raw materials records * taken corrective action in response to out-of-specification results * applied segregation and cross contamination prevention procedures * paced dispensing to meet production requirements * packed and labelled dispensed materials, according to batch requirements and labelling procedures * reconciled and recorded materials dispensed against materials released and returned unused materials to storage * stacked dispensed materials for transfer to designated location, ensuring required material segregation * handled containers and maintained integrity of materials according to workplace procedures * cleaned and maintained dispensing equipment, utensils and 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 dispensing process, including: * the purpose, methods and outcomes of each stage * control points * types of raw materials and related handling requirements including handling of hazardous goods * basic operating principles, requirements and parameters of dispensing equipment, including: * measuring, and accuracy capacity of instrumentation and related equipment * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * corrective actions required where operation is outside specified operating parameters * Functions and limitations of personal protective clothing and equipment, including: * protective gown, scrubs, smocks, statcoats, or disposable coveralls * surgical masks * surgical gloves * disposable overshoes * hair nets * pre-start checks requirements, including: * condition and cleanliness of equipment and shared or dedicated utensils * taring of shared or dedicated scales * procedures to confirm that equipment is calibrated and within specification * workplace systems for recording information about dispensed pharmaceutical materials, including coding and labelling systems * operational considerations that impact on the quality of the dispensing process, including: * product accuracy * equipment tolerances * consequences of errors and variations * workplace procedures for the following: * calculating assay and adjusting potency * reconciliation of raw materials, including S8 materials * requisitioning, receiving and returning ingredients from stores * GMP requirements associated with dispensing pharmaceutical raw materials * environmental issues and controls relevant to the dispensing process, including waste and rework 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 * dispensing process equipment and utensils * materials required for the dispensing process * containers or bags, labelling and storage facilities * test equipment * cleaning materials and equipment associated with dispensing pharmaceutical raw materials * specifications: * specifications, control points and processing parameters * recording requirements and procedures * workplace documentation relating to dispensing process and procedures * GMP requirements relating to dispensing process * dispensing schedule/batch instructions * sampling schedules and test procedures * cleaning procedures associated with dispensing pharmaceutical raw materials.   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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