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 | 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.  The unit applies to individuals who operate and monitor measuring and dispensing equipment in the pharmaceutical sector.  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 Inspect materials to confirm type, quality clearance, quantities and to identify obvious contamination or non-compliance issues  1.2 Select measuring and weighing equipment appropriate for dispensing requirements and confirm readiness for use  1.3 Use correctly fitted and appropriate personal protective clothing and equipment  1.4 Supply containers, bags and labels for batch and production requirements  1.5 Conduct pre-start checks according to workplace requirements |
| 2. Measure and weigh raw materials | 2.1 Weigh and measure non-bulk ingredients and additives to meet production and batch requirements  2.2 Label dispensed ingredients  2.3 Monitor accuracy of measuring and dispensing equipment  2.4 Identify variations in equipment operation  2.5 Maintain work area according to workplace housekeeping standards  2.6 Conduct activities according to workplace environmental guidelines |
| 3. Shut down the dispensing process | 3.1 Confirm shut down type and initiate shut down procedures according to workplace procedures  3.2 Clean dispensing equipment according to workplace procedures  3.3 Identify and report unacceptable equipment and utensil condition  3.4 Record and reconcile dispensed materials  3.5 Identify and report maintenance requirements in required format |

| 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 workplace procedures for dispensing pharmaceutical raw materials |
| Writing | * Complete records according to workplace guidelines using paper based and/or electronic media |
| Numeracy | * Measure materials and additives to meet batch requirements * Check raw material labels, codes and quantity |
| 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 the condition and cleanliness of equipment and utensils * taring scales * carrying out procedures to confirm that equipment is calibrated and fit for use. |

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| Unit Mapping Information | | | |
| Code and title current version | Code and title previous version | Comments | Equivalence status |
| FDFPHM3XXX 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, on at least one occasion, the individual has dispensed pharmaceutical raw materials, including:   * accessed workplace information to identify dispensing requirements * selected, fitted and used personal protective clothing and equipment * confirmed supply of necessary raw materials, including checking raw material labels, codes, quantities and quality clearances * conducted pre-start checks on dispensing equipment, including inspecting the condition and cleanliness of equipment, utensils and taring scales * confirmed equipment is accurately calibrated and fit for use * 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 * paced dispensing to meet production requirements * packed and labelled dispensed materials, according to batch requirements * followed 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 in accordance with workplace procedures to maintain integrity of materials * cleaned dispensing equipment and utensils in accordance with workplace procedures * responded to and reporting equipment failure in required format * completed dispensing records using workplace recording system * followed work health and safety procedures * maintained work area to meet housekeeping standards. | |

| 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:   * purpose and basic principles of the dispensing process, including characteristics of raw materials and related handling requirements * dangerous goods handling requirements and procedures * relevant legislative responsibilities and workplace systems for recording information about dispensed pharmaceutical materials and related workplace coding and labelling systems * purpose of pharmaceutical recording, coding and labelling systems * relationship between the dispensing process and related operations, including an understanding of accuracy, tolerance and consequences of errors * purpose, measuring, and accuracy capacity of instrumentation and related equipment * control points in the dispensing process * procedures for calculating assay and adjusting potency * procedures for reconciliation of raw materials, including reconciliation of S8 materials * Good Manufacturing Practice (GMP) requirements associated with the dispensing process and related control measures * procedures for requisitioning, receiving and returning ingredients from stores * typical equipment faults and related causes, including signs and symptoms of faulty equipment and early warning signs of potential problems * work health and safety hazards and controls, including limitations of protective clothing and equipment * cleaning, care and storage of relevant equipment and instrumentation * procedures and responsibilities for reporting production and performance information * environmental issues and controls relevant to the dispensing process, including waste and rework collection, and handling procedures related to the process. |

| 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 * dispensing process and related equipment and services * 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: * work procedures, including advice on safe work practices, GMP. SOP and environmental requirements * information on equipment capacity and operating parameters * dispensing 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 dispensing pharmaceutical raw materials * 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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