



Australian Government

Department of Education, Employment and Workplace Relations

FDFPH2009A Dispense pharmaceutical raw materials

Revision Number: 1

FDFPH2009A Dispense pharmaceutical raw materials

Modification History

Not applicable.

Unit Descriptor

Unit descriptor	This unit of competency covers the skills and knowledge required to weigh, measure and label non-bulk ingredients to meet batch requirements.
------------------------	---

Application of the Unit

Application of the unit	This unit applies to production operators working in the pharmaceutical sector. This person would typically work within defined Good Manufacturing Practice (GMP) programs and procedures. This unit typically targets the production worker responsible for applying basic operating principles to the operation and monitoring of measuring and dispensing equipment. When batch or product changeover procedures are part of this work process, the procedures should be used to customise the application of this unit. Where more detailed changeovers are carried out, FDFOP2011A Conduct routine maintenance, should be considered.
--------------------------------	--

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Prerequisite units		

Prerequisite units		

Employability Skills Information

Employability skills	This unit contains employability skills.
-----------------------------	--

Elements and Performance Criteria Pre-Content

Elements describe the essential outcomes of a unit of competency.	Performance criteria describe the performance needed to demonstrate achievement of the element. Where bold italicised text is used, further information is detailed in the required skills and knowledge section and the range statement. Assessment of performance is to be consistent with the evidence guide.
---	--

Elements and Performance Criteria

ELEMENT	PERFORMANCE CRITERIA
1. Prepare to dispense raw materials	1.1. Materials are inspected to confirm type, quality clearance, quantities and identify any obvious contamination or non-compliance 1.2. Measuring and weighing equipment is selected appropriate to dispensing requirements and checked to confirm readiness for use 1.3. Containers/bags and labels are available as required 1.4. Pre-start checks are carried out as required by workplace requirements
2. Measure and/or weigh raw materials	2.1. Non-bulk ingredients and additives are weighed/measured to meet production requirements 2.2. Dispensed ingredients are labelled according to workplace procedure 2.3. Accuracy of measuring/dispensing equipment is monitored to identify variation in operating conditions 2.4. Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements 2.5. The work area is maintained according to housekeeping standards 2.6. Work is conducted in accordance with workplace environmental guidelines
3. Shut down the dispensing process	3.1. Dispensing equipment is cleaned according to workplace procedure 3.2. Unacceptable equipment/utensil condition is identified and reported 3.3. Dispensed materials are recorded and reconciled 3.4. Maintenance requirements are identified and reported

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This section describes the skills and knowledge required for this unit.

Required skills

Ability to:

- access workplace information to identify dispensing requirements
- select, fit and use personal protective clothing and/or equipment, such as breathing apparatus and fume cabinets as required
- confirm supply of necessary raw materials, such as checking raw material labels and codes, quantity and quality clearance
- conduct pre-start checks on equipment, such as inspecting the condition and cleanliness of equipment and utensils, taring scales and carrying out any related procedures to confirm that equipment is accurately calibrated and fit for use
- measure materials and additives within specified accuracy range to meet batch requirements
- calculate assay/potency adjustment
- verify accuracy of raw materials dispensed with raw materials records
- take corrective action in response to out-of-specification results
- pace dispensing to meet production requirements
- pack and label dispensed materials as required
- follow labelling procedures
- reconcile and record materials dispensed against materials released and return unused materials to storage as required
- stack dispensed materials for transfer to designated location ensuring required material segregation
- handle containers according to workplace procedures to maintain integrity of materials
- clean dispensing equipment and utensils according to workplace procedures
- respond to and/or report equipment failure within level of responsibility
- complete dispensing records as required by workplace recording system
- maintain work area to meet housekeeping standards
- collect samples and conduct test according to enterprise procedures
- use oral communication skills/language competence to fulfil the job role as specified by the organisation, including questioning, active listening, asking for clarification and seeking advice from supervisor
- work cooperatively within a culturally diverse workforce

Required knowledge

Knowledge of:

- purpose and basic principles of the dispensing process, including the characteristics

REQUIRED SKILLS AND KNOWLEDGE

- of raw materials and related handling requirements
- dangerous goods handling requirements and procedures
- relevant legislative responsibilities and workplace systems for recording information on dispensed pharmaceutical materials and related workplace coding and labelling systems and purpose
- the relationship between the dispensing process and related operations, including an understanding of accuracy/tolerance and consequence of error
- purpose, measuring/accuracy capacity of instrumentation and related equipment calibration responsibilities and procedures
- control points in the dispensing process
- procedures for calculating assay and adjusting potency
- raw materials reconciliation purpose and procedures, such as reconciliation of S8 materials
- 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
- occupational health and safety (OHS) hazards and controls, including the limitations of protective clothing and equipment relevant to the work process
- cleaning, care and storage of equipment and instrumentation used
- procedures and responsibility for reporting production and performance information
- environmental issues and controls relevant to the dispensing process, including waste/rework collection and handling procedures related to the process
- sampling and testing associated with process monitoring and control where relevant

Evidence Guide

EVIDENCE GUIDE

The Evidence Guide provides advice on assessment and must be read in conjunction with the performance criteria, required skills and knowledge, range statement and the Assessment Guidelines for the Training Package.

Overview of assessment

Assessment must be carried out in a manner that recognises the cultural and literacy requirements of the assessee and is appropriate to the work performed. Competence in this unit must be achieved in accordance with food safety standards and regulations.

Critical aspects for assessment and evidence required to demonstrate competency in this unit

Evidence of ability to:

- weigh and measure materials to achieve required quantities
- start, operate, monitor and adjust dispensing equipment to achieve required quality outcomes
- take corrective action in response to typical faults and inconsistencies
- complete workplace records as required
- apply safe work practices and identify OHS hazards and controls
- apply food safety procedures to work practices.

Context of and specific resources for assessment

Assessment must occur in a real or simulated workplace where assessee has access to:

- personal protective clothing and equipment
- work procedures, including advice on safe work practices, GMP, SOPs and environmental requirements
- information on equipment capacity and operating parameters
- dispensing schedule, batch instructions
- specifications, control points and processing parameters
- dispensing process and related equipment and services
- materials required for the dispensing process
- containers/bags, labelling and storage facilities
- sampling schedules and test procedures and equipment as required
- documentation and recording requirements and procedures
- cleaning procedures, materials and equipment as

EVIDENCE GUIDE	
	required.
Method of assessment	This unit should be assessed together with core units and other units of competency relevant to the function or work role. Examples could be: • FDFOP2004A Clean and sanitise equipment • FDFOP2013A Apply sampling procedures • MSL973001A Perform basic tests.
Guidance information for assessment	To ensure consistency in one's performance, competency should be demonstrated on more than one occasion over a period of time in order to cover a variety of circumstances, cases and responsibilities, and where possible, over a number of assessment activities.

Range Statement

RANGE STATEMENT

The range statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Bold italicised wording, if used in the performance criteria, is detailed below. Essential operating conditions that may be present with training and assessment (depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts) may also be included.

Policies and procedures	Work is carried out according to company policies and procedures, regulatory and licensing requirements, legislative requirements, and industrial awards and agreements
Legislative requirements	Legislative requirements are typically reflected in procedures and specifications. Legislation relevant to this industry includes: • relevant Good Manufacturing Practice (GMP) codes • the Therapeutic Goods Act and/or other relevant legislation • legislation covering environmental management, OHS, anti-discrimination and equal opportunity
Workplace information	Workplace information may include: • standard operating procedures (SOPs) • specifications • production/dispensing schedules and instructions • batch/recipe instructions • manufacturers' advice • standard forms and reports
Dispensing equipment	Dispensing equipment may include: • scales • pipettes • calibrated measuring containers • fume cabinets • labels/printers and related dispensary instrumentation
Raw materials	Raw materials may include: • drugs of addiction classified as S8

RANGE STATEMENT**Operation of equipment and processes**

Operation of equipment and processes may require:

- the use of process control panels and systems

Unit Sector(s)**Unit sector**

Pharmaceutical manufacturing

Competency field**Competency field****Co-requisite units****Co-requisite units**