



Australian Government

Department of Education, Employment and Workplace Relations

HLTPH306C Package pharmaceutical products

Release: 1

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Modification History

Not Applicable

Unit Descriptor

Descriptor

This unit of competency describes the skills and knowledge required to package and/or pre-package pharmaceutical products according to Australia's NCCTG Guidelines for Preparation of Pharmaceuticals in Hospitals and national guidelines/legislation on the filling of dose administration containers

Application of the Unit

Application

The application of knowledge and skills takes place around standards, guidelines, policies and procedures and under the supervision of a qualified person

Individuals may take responsibility for their own outputs

Work performed requires a range of well developed skills where some discretion and judgement is required

Licensing/Regulatory Information

Not Applicable

Pre-Requisites

Not Applicable

Employability Skills Information

Employability Skills

This unit contains Employability Skills

Elements and Performance Criteria Pre-Content

Elements define the essential outcomes of a unit of competency.

The Performance Criteria specify the level of performance required to demonstrate achievement of the Element. Terms in italics are elaborated in the Range Statement.

Elements and Performance Criteria

ELEMENT

PERFORMANCE CRITERIA

1. Prepare packing/pre packing process

- 1.1 Comply with dress code, safety requirements and personal hygiene procedures prior to entering the packaging/pre-packaging area
- 1.2 Clean and prepare *work area* according to work specifications
- 1.3 Obtain and interpret pre-packing documentation and instructions from authorised person according to packaging/pre-packaging specifications
- 1.4 Identify, clean, prepare and set packaging/pre-packaging *machinery*
- 1.5 Obtain appropriate *packaging/pre-packaging* materials according to stock issuing procedures

2. Allocate bulk product/medicine to machinery/pre-packing apparatus

- 2.1 Obtain and prepare approved bulk product/medicine
- 2.2 Allocate bulk product/medicine to packaging machine/pre-packing apparatus according to instructions from an authorised person
- 2.3 Allocate sufficient packaging/pre-packaging materials to the work area

ELEMENT**PERFORMANCE CRITERIA****3. Pack or pre-pack products**

- 3.1 Initiate line opening procedures
- 3.2 Pack or pre-pack *products* according to standard operating procedures
- 3.3 Apply in-process controls and record results
- 3.4 Report deviations to authorised person
- 3.5 Take corrective action according to instructions from an authorised person
- 3.6 Operate packaging machinery and equipment according to manufacturer specifications and OHS requirements

4. Conduct quality control

- 4.1 Obtain approval from authorised person at designated points in the packaging/pre-packaging process according to batch record
- 4.2 Obtain relevant documentation and check product specifications according to batch documentation
- 4.3 Reconcile and verify packaging/pre-packaging materials under supervision of an authorised person
- 4.4 Submit sample where appropriate

5. Shut down packaging/pre-packaging process

- 5.1 Complete packaging/pre-packaging documentation and forward according to standard operating procedures
- 5.2 Note discrepancies in *labels* and documentation
- 5.3 Reconcile number of labels printed with number used and discard excess
- 5.4 Note and report discrepancies in equipment functioning and take corrective action according to the instructions of an authorised person
- 5.5 Alert authorised person of excess materials
- 5.6 Clean machinery and equipment according to standard operating procedures
- 5.7 Obtain final approval from the pharmacist before releasing packed/pre-packed medicines/product to storage areas

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level required for this unit.

Essential knowledge:

The candidate must be able to demonstrate essential knowledge required to effectively do the task outlined in elements and performance criteria of this unit, manage the task and manage contingencies in the context of the identified work role

This includes knowledge of:

- Basic hygiene and the importance of maintaining a clean working environment and equipment
- Infection control policies, guidelines and symbols and their relevance to working in a hospital pharmacy
- Identification and handling of products, including
 - formulary drugs and non-formulary drugs eg clinical trial drugs and special access scheme drugs
 - products with the required integrity as well as those whose integrity has been compromised eg damaged, contaminated or deteriorated stock
 - routine handling of products and products requiring special handling, eg cytotoxics and its spill management, refrigerated and frozen items, light sensitive materials and flammables
- Legal requirements and principles of pharmaceutical product labelling eg product name, batch numbering and expiry date
 - Australia's NCCTG Guidelines for Preparation of Pharmaceuticals in Hospitals and guidelines/legislation on the filling of dose administration containers
 - specific labelling requirements for filling Webster style containers/dosette boxes
- Knowledge of and the rationale for applicable legislation, organisation policy and in-house standard operating procedures (SOPs), relating to packaging/pre-packaging of pharmaceuticals
- OHS policies, guidelines and symbols and their relevance to working in a hospital pharmacy
- Personal hygiene and the use of protective clothing
- Principles of calculations, weights and measures
- Properties of container types and principles of selection for use
- Storage requirements and rationale for different types of product

REQUIRED SKILLS AND KNOWLEDGE

- Various pack sizes and appropriateness

Essential skills:

It is critical that the candidate demonstrate the ability to:

- Effectively package and/or pre-package products in accordance with organisation requirements
- Label appropriately
- Maintain effective quality control during the packaging/pre-packaging process
- Refer issues identified outside scope of practice to authorised person
- Work in accordance with relevant organisation policy, legislative requirements, industrial awards and agreements and in-house operating procedures (SOPs)
- Work in a safe manner

In addition, the candidate must be able to effectively do the task outlined in elements and performance criteria of this unit, manage the task and manage contingencies in the context of the identified work role

This includes the ability to:

- Enter and access data on pharmacy computer system
- Maintain packaging/pre-packaging documentation
- Operate the specified equipment
- Take into account opportunities to address waste minimisation, environmental responsibility and sustainable practice issues
- Use literacy, numeracy and oral communication skills required to fulfil the position in a safe manner as specified by the health care facility
- Use problem solving skills
- Use available resources and prioritise workload

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, the Range Statement and the Assessment Guidelines for this Training Package.

EVIDENCE GUIDE

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

- The individual being assessed must provide evidence of specified essential knowledge as well as skills
- Observation of workplace performance is essential for assessment of this unit
- Consistency of performance should be demonstrated over the required range of situations relevant to the workplace
- Where, for reasons of safety, space, or access to equipment and resources, assessment takes place away from the workplace, the assessment environment should represent workplace conditions as closely as possible

Context of and specific resources for assessment:

- Assessment should replicate workplace conditions as far as possible
- Simulations may be used to represent workplace conditions as closely as possible. Acceptable simulation requires:
 - Scope to determine that work is conducted within legislative and regulatory requirements
 - Scope to determine that work is conducted within OHS and infection control requirements
- Resources essential for assessment include:
 - Access to relevant workplace or appropriately simulated environment where assessment can take place
 - Relevant legislation, regulations and guidelines
 - Weighing and measuring equipment
 - Relevant packing machinery
 - Instructions on the use of equipment

Method of assessment may include:

- Observation in the work place (if possible)
- Written assignments/projects, eg for fundamentals of microbiology and principles of cleaning and disinfection
- Interviewing and questioning
- Formal appraisal systems
- Supporting statement of supervisor(s)

EVIDENCE GUIDE

- Access and equity considerations:*
- All workers in the health industry should be aware of access and equity issues in relation to their own area of work
 - All workers should develop their ability to work in a culturally diverse environment
 - In recognition of particular health issues facing Aboriginal and Torres Strait Islander communities, workers should be aware of cultural, historical and current issues impacting on health of Aboriginal and Torres Strait Islander people
 - Assessors and trainers must take into account relevant access and equity issues, in particular relating to factors impacting on health of Aboriginal and/or Torres Strait Islander clients and communities

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. Add any 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.

- Packaging equipment/apparatus may be operated manually or automatically and may include but are not limited to::*
- Scales, measures
 - Irons, heat sealing equipment
 - Tweezers
 - Gloves

- Storage and work are conditions may include but are not limited to:*
- Correct temperature
 - Humidity, light
 - Security
 - Ventilation

RANGE STATEMENT

Packaging materials and products may include but is not limited to:

- Dosage administration aids/containers
- Tamper proof dose administration containers
- Webster style containers
- Heat seal or press seal equipment
- Durable dosette boxes
- Formulary drugs and non-formulary drugs eg special access scheme drugs
- Routine handling products and products requiring special handling and/or storage

Dose administration container labels may include but are not limited to:

- Name of client
- Pharmacy details
- Name, strength and form of all medicines supplied in the container
- Directions for use of each medicine as prescribed
- Date on which the container was filled

Products may include:

- Formulary drugs and non-formulary drugs eg clinical trial drugs and special access scheme drugs
- Products with the required integrity as well as those whose integrity have been compromised eg damaged, contaminated or deteriorated
- Routine handling products and products requiring special handling eg cytotoxics and its spill management, refrigerated and frozen items, light sensitive material and flammables

Unit Sector(s)

Not Applicable