



Australian Government

HLTPHA005 Conduct small scale compounding and labelling of pharmaceutical products

Release: 1

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Modification History

Release	Comments
Release 1	This version was released in <i>HLT Health Training Package release 2.0</i> and meets the requirements of the 2012 Standards for Training Packages. Minimal changes to the elements and performance criteria. New evidence requirements for assessment, including volume and frequency. Significant changes to knowledge evidence.

Application

This unit describes the skills and knowledge required to complete small scale compounding of non-sterile pharmaceutical products from predetermined formulae, including extemporaneous dispensing.

This unit applies to pharmacy assistants and technicians working under the supervision of a pharmacist.

The skills in this unit must be applied in accordance with Commonwealth and State/Territory legislation, Australian/New Zealand standards and industry codes of practice.

Elements and Performance Criteria

ELEMENT

PERFORMANCE CRITERIA

Elements define the essential outcomes

Performance criteria describe the performance needed to demonstrate achievement of the element

1. Source information on formula

1.1 Select appropriate formula and master batch sheet for product, based on correct interpretation of the medication order or prescription

1.2 Confirm suitability of chosen master work sheet and availability of resources

1.3 Obtain authority of pharmacist to proceed

2. Prepare for production

2.1 Comply with dress code, safety and personal hygiene

ELEMENT

PERFORMANCE CRITERIA

Elements define the essential outcomes

Performance criteria describe the performance needed to demonstrate achievement of the element

process

procedures prior to entering the work area

2.2 Clean work area and equipment correctly

2.3 Confirm inventory levels of raw materials and disposable equipment

2.4 Prepare a work sheet referenced from a master work sheet

2.5 Verify that batch/work sheets are clearly written in logical order with clear directions and contains all the required information

2.6 Assign product batch number

2.7 Generate the product labels referenced from the master label detailed on the master work sheet

2.8 Check and note the number of labels generated

2.9 Submit work sheet and labels to pharmacist for approval

2.10 Check and set up compounding requirements and equipment

3. Obtain equipment and supplies

3.1 Acquire materials listed on the work sheet according to stock levels and stock requisitioning procedures

3.2 Check raw materials to ensure they have been released from quarantine for use by authorised persons

3.3 Verify raw materials against batch work sheet and record raw material batch numbers and expiry dates

3.4 Weigh or measure raw materials in designated area

3.5 Obtain required authorisation or checks at designated points according to work sheet

4. Compound products

4.1 Allocate approved raw materials to equipment according to batch work sheet

4.2 Compound product according to method on work sheet

4.3 Monitor and adjust compounding to comply with

ELEMENT

PERFORMANCE CRITERIA

Elements define the essential outcomes

Performance criteria describe the performance needed to demonstrate achievement of the element

work sheet specifications

4.4 Perform verification procedures, inspect finished product for deviations and report to authorised person

4.5 Pack compounded product as specified on the work sheet, and following approval from an authorised person

4.6 Label containers/units according to labelling specifications on the work sheet

4.7 Obtain required authorisation or checks at designated points

5. Complete production process

5.1 Reconcile number of labels printed with number used and report discrepancies to the pharmacist

5.2 Place product in quarantine area under appropriate storage conditions

5.3 Clean machinery and manufacturing area and dispose of disposable equipment safely

5.4 Complete all required documentation and forward to an authorised person

5.5 Report all discrepancies to an authorised person

5.6 Obtain final approval from the pharmacist before releasing packed medicines to storage areas

6. Participate in quality control

6.1 Pack and label a retention sample and/or quality control sample if specified on the work sheet

6.2 Submit product sample and relevant documentation to quality control, where specified

6.3 Record and file product quality control assay results

7. Store and transport released product

7.1 Store products according to work sheet documentation

7.2 Obtain released product(s) from quarantine store

7.3 Pack released product(s) into delivery containers which will maintain the required ambient conditions for

ELEMENT

Elements define the essential outcomes

PERFORMANCE CRITERIA

Performance criteria describe the performance needed to demonstrate achievement of the element

the product

7.4 Deliver product to destination

7.5 Advise receipting area personnel of specific storage requirements

7.6 Complete and file records and/or work sheets

Foundation Skills

The Foundation Skills describe those required skills (language, literacy, numeracy and employment skills) that are essential to performance.

Foundation skills essential to performance are explicit in the performance criteria of this unit of competency.

Unit Mapping Information

No equivalent unit.

Links

Companion Volume implementation guides are found in VETNet -

<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=ced1390f-48d9-4ab0-bd50-b015e5485705>

Assessment Requirements for HLTPHA005 Conduct small scale compounding and labelling of pharmaceutical products

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Performance Evidence

The candidate must show evidence of the ability to complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the job role. There must be evidence that the candidate has:

- followed workplace procedures and industry codes to correctly and safely compound and label at least 5 different batches of pharmaceutical products listed in the *Australian pharmaceutical formulary and handbook* (APF)
- identified issues outside scope of own practice and referred to the authorised person

Knowledge Evidence

The candidate must be able to demonstrate essential knowledge required to effectively complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the work role. This includes knowledge of:

- legal and ethical requirements (national, state/territory) for pharmacy work, and how these are applied in organisations, including:
 - codes of conduct
 - duty of care (and implications of negligence)
 - privacy, confidentiality and disclosure
 - records management
 - rights and responsibilities of workers, employers and clients
 - specific legislation:
 - medicines and their use
 - the practice of pharmacy
 - different schedules of medicines and pharmaceutical products

- work role boundaries – responsibilities and limitations in manufacturing products
- work health and safety
- key information in standard pharmaceutical references and their use in manufacturing, including:
 - APF
 - MIMs
 - *Australian medicines handbook (AMH)*
 - Micromedex
- rationale for, and key features of:
 - The Society of Hospital Pharmacists (SHPA) *Guidelines for medicines prepared in Australian hospital pharmacy departments*
 - Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) *Guide to good practices for the preparation of medicinal products in healthcare establishments*
- product identification and handling, including those for:
 - formulary medicines and non-formulary medicines
 - products with the required integrity as well as those whose integrity has been compromised
 - routine of handling products and products requiring special handling
- nature and use of different dosage forms including:
 - oral
 - parenteral products
 - topical
- infection control requirements for small scale compounding of pharmaceutical products, including:
 - correct disposal of sharps and residues
 - cleaning and disinfection processes
 - personal hygiene
 - sources and types of contamination and required responses (microbial, cross-chemical, physical, environmental; and corrective strategies)
- manufacturing processes relating to small scale compounding, including:
 - nature and use of oral and topical dosage forms
 - chemical and physical properties of raw materials in relation to formulation and compounding
 - types of equipment, their key features and use
 - compounding of a product according to a work sheet
 - principles and procedures of formulae calculations, weights and measures
 - processes for dilution, suspension, incorporation and reconstitution
- risk considerations and procedures for pharmaceutical manufacturing:
 - product security
 - handling and storage of hazardous materials

- quarantine periods
- requirements for formulated manufacturing documentation
 - different documentation types, their scope and purpose
 - worksheet processes
 - information quality requirements including clarity, logic and completeness
- labelling requirements for compounded products, including:
 - adherence to legislative requirements
 - name, form and strength of product
 - ancillary labels as part of label details
 - hazard warnings
 - spacing for entry of batch numbers and expiry dates
- packaging methods, container materials and principles for selection
- storage and transport requirements and rationale for different types of product including:
 - hazardous materials
 - special storage considerations:
 - humidity
 - isolation
 - light
 - temperature
 - ventilation
- features and use of pharmacy systems used for small scale compounding

Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
 - weighing and measuring equipment
 - utensils
 - raw materials
 - pharmaceutical references
- modelling of industry operating conditions, including presence of time constraints for activities

Assessors must satisfy the Standards for Registered Training Organisations (RTOs) 2015/AQTF mandatory competency requirements for assessors.

Links

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<https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=ced1390f-48d9-4ab0-bd50-b015e5485705>

