



Australian Government

HLTPHA014 Conduct small-scale compounding and labelling of pharmaceutical products

Release: 1

HLTPHA014 Conduct small-scale compounding and labelling of pharmaceutical products

Modification History

Not applicable.

Application

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

This unit applies to hospital or health services pharmacy assistants and technicians working under the supervision of an authorised person.

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

No occupational licensing, certification or specific legislative requirements apply to this unit at the time of publication.

Pre-requisite Unit

Nil

Competency Field

Pharmacy

Unit Sector

Health

Elements and Performance Criteria

ELEMENTS

Elements describe the essential outcomes

1. Source information on formula.
2. Prepare for production

PERFORMANCE CRITERIA

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

- 1.1. Interpret medication orders and prescriptions to select formula and master batch sheet for product.
- 1.2. Confirm suitability of chosen master work sheet and availability of resources.
- 1.3. Obtain approval from an authorised person to proceed.
- 2.1. Comply with personal protection equipment (PPE), safety

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| process. | and personal hygiene 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 or work sheets are clearly written in logical order with clear directions and containing 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 an authorised person 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 work sheet specifications. |
| | 4.4. Perform verification procedures, inspect finished product for deviations and report to an authorised person. |
| | 4.5. Pack compounded product as specified on the work sheet and following approval from an authorised person. |
| | 4.6. Label containers or 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 an authorised person. |
| | 5.2. Place product in quarantine area under appropriate storage |

- conditions.
- 5.3. Clean equipment and compounding 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 an authorised person before releasing packed medication to storage areas.
6. Participate in quality control.
- 6.1. Pack and label a retention sample 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 products.
- 7.1. Store products according to work sheet documentation.
 - 7.2. Obtain released products from quarantine store.
 - 7.3. Pack released products into delivery containers which will maintain the required ambient conditions for the product.
 - 7.4. Deliver product to destination.
 - 7.5. Advise receipting area personnel of specific storage requirements.
 - 7.6. Complete and file records or work sheets.

Foundation Skills

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

Unit Mapping Information

Supersedes and is not equivalent to HLTPHA005 Conduct small scale compounding and labelling of pharmaceutical products.

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 HLTPHA014 Conduct small-scale compounding and labelling of pharmaceutical products

Modification History

Not applicable.

Performance Evidence

Evidence of the ability to complete tasks outlined in elements and performance criteria of this unit in the context of the job role, and:

- follow 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)
- interpret standard pharmaceutical references
- identify issues outside scope of own practice and refer to an authorised person
- perform the activities outlined in the performance criteria of this unit during a period of at least 240 hours of work related to hospital or health services pharmacy support in a clinical workplace environment. These 240 hours may be applied collectively across all units of competency that include the requirement for workplace hours for the purposes of assessment.

Knowledge Evidence

Demonstrated knowledge required to complete the tasks outlined in elements and performance criteria of this unit:

- National, State or Territory legal and ethical requirements for pharmacy work, and how these are applied in organisations, including:
 - codes of conduct
 - personal protection equipment (PPE)
 - duty of care and implications of negligence
 - privacy, confidentiality and disclosure
 - records management
 - rights and responsibilities of workers, employers and patients
 - specific legislation:
 - medication and their use
 - the practice of pharmacy
 - different schedules of medication and pharmaceutical products
 - work role boundaries including responsibilities and limitations in compounding products
 - work health and safety

- key information in standard pharmaceutical references and their use in compounding, including:
 - Australian Pharmaceutical Formulary Handbook (APF)
 - Monthly Index of Medical Specialities (MIMS) or AusDI Advanced
 - 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 medication and non-formulary medication
 - 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 including microbial, cross-chemical, physical, environmental and corrective strategies
- compounding 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 compounding:
 - product security
 - handling and storage of hazardous materials
 - quarantine periods
- requirements for formulated compounding 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 be demonstrated in the workplace with the addition of simulations and scenarios where the full range of contexts and situations have not been provided in the workplace.

Assessment must ensure access to:

- 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
- authorised person with whom to consult.

Assessors must satisfy the Standards for Registered Training Organisations' requirements for assessors.

Links

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