Australian Government

HLTPHA014 Conduct small-scale compounding and labelling of pharmaceutical products

Release: 1

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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	PERFORMANCE CRITERIA
Elements describe the essential outcomes	*Performance criteria describe the performance needed to demonstrate achievement of the element.*
1. Source information on formula.	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. Prepare for production	2.1. Comply with personal protection equipment (PPE), safety

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