Australian Government

HLTPHA007 Conduct small-scale compounding and labelling of aseptic pharmaceutical products

Release: 1

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Modification History

Release	Comments
Release 1	This version was released in *HLT Health Training Package release 2.0* 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 sterile pharmaceutical products from pre-determined formulae, including extemporaneous dispensing. This includes cytotoxic and total parental nutrition (TPN) products.

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 work sheet for the product, based on correct interpretation of the prescription or medication order 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 Confirm the availability of the appropriate laminar

ELEMENT	PERFORMANCE CRITERIA
Elements define the essential outcomes	*Performance criteria describe the performance needed to demonstrate achievement of the element*
process	flow hood/clean room or cytotoxic drug safety cabinet/cytotoxic suite or room or isolator required to compound the product according to the work sheet
	2.2 Comply with dress code, safety and personal hygiene procedures prior to entering the work area
	2.3 Clean work area and equipment correctly
	2.4 Maintain inventory levels of materials and disposable equipment
	2.5 Prepare a work sheet referenced from a master work sheet
	2.6 Assign product batch number
	2.7 Verify that the work sheets are clearly written in logical order with clear directions and contain all the required information
	2.8 Generate the product labels referenced from the master label detailed on the master work sheet
	2.9 Check and note the number of labels generated
	2.10 Submit work sheet and labels to pharmacist for approval
	2.11 Check and set up compounding requirements and disposable equipment
3. Obtain equipment and supplies	3.1 Assemble materials used in aseptic compounding as listed in the work sheet, according to stock levels and stock requisitioning procedures
	3.2 Check materials to ensure they have been released from quarantine for use by authorised persons
	3.3 Verify materials against manufacturing work sheet and record material batch numbers and expiry dates
	3.4 Select appropriate types, size and features of containers and packaging listed in the work sheet
	3.5 Weigh or measure materials in designated area
	3.6 Obtain required authorisation or checks at designated points according to the work sheet

ELEMENT	PERFORMANCE CRITERIA
Elements define the essential outcomes	*Performance criteria describe the performance needed to demonstrate achievement of the element*
4. Prepare for sterile manufacturing	4.1 Transfer raw materials, disposable equipment, required containers or packaging and covered work sheet to pre-production area 4.2 Follow hand washing, gowning and gloving procedures 4.3 Disinfect and transfer materials, disposable equipment and work sheet to sterile production area
5. Prepare for cytotoxic production	5.1 Check that cytotoxic spill cleaning kits are available in all production areas 5.2 Select and use appropriate sterile personal protective equipment for safe handling and preparation of cytotoxic drugs as required 5.3 Follow specific procedures to minimise risk of exposure to cytotoxic drugs
6. Compound products using aseptic techniques	6.1 Allocate approved bulk materials, intermediary products and containers to appropriate equipment 6.2 Incorporate materials according to work sheet using appropriate manipulation technique 6.3 Compound product according to method on manufacturing work sheet 6.4 Prepare cytotoxic products using procedures for safe handling of cytotoxic drugs 6.5 Operate specialist equipment and use specialist supplies in sterile production preparation 6.6 Perform verification procedures and inspect finished product for deviations and report to authorised person 6.7 Pack compounded product into appropriate container as specified on the work sheet, and following approval from an authorised person 6.8 Label containers according to labelling specifications

ELEMENT	PERFORMANCE CRITERIA
Elements define the essential outcomes	*Performance criteria describe the performance needed to demonstrate achievement of the element*
	on the work sheet
	6.9 Obtain required authorisation or checks at designated points
7. Complete production process	7.1 Reconcile the number of labels printed with number used and report discrepancies to the pharmacist
	7.2 Place product in quarantine area under appropriate storage conditions
	7.3 Clean machinery and manufacturing area and dispose of disposable equipment safely
	7.4 Follow procedures for cleaning cytotoxic spills, and exposure to cytotoxic drugs
	7.5 Complete required documentation and forward to an authorised person
	7.6 Report discrepancies to an authorised person
	7.7 Obtain final approval from pharmacist before releasing compounded medicines to storage areas
	7.8 Discard waste materials appropriately
8. Participate in quality control	8.1 Pack and label a retention sample and/or quality control sample if specified on the work sheet
	8.2 Perform environmental monitoring and report abnormal readings to an authorised person
	8.3 Submit product sample and relevant documentation to quality control
	8.4 Record and file product quality control assay results and manufacturing area environmental monitoring results
9. Store and transport released product	9.1 Store products according to the work sheet
	9.2 Obtain released product(s) from quarantine store
	9.3 Pack released product(s) into delivery containers which will maintain the required ambient conditions for

ELEMENT	PERFORMANCE CRITERIA
Elements define the essential outcomes	*Performance criteria describe the performance needed to demonstrate achievement of the element*
	the product
	9.4 Deliver product to destination ensuring safe transport of cytotoxic products
	9.5 Advise receipting area personnel of storage requirements
	9.6 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