Australian Government

HLTPHA016 Conduct small-scale compounding and labelling of aseptic 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 sterile pharmaceutical products from pre-determined formulae, including extemporaneous dispensing. This includes cytotoxic and Total Parental Nutrition (TPN) products.

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. 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 approval from an authorised person to proceed.
2. Prepare for production process.	2.1. Confirm availability of appropriate cleanroom and containment device required to compound the item.
	2.2. Comply with personal protection equipment (PPE), safety and personal hygiene procedures prior to entering the work area.
	2.3. Clean work area and equipment correctly according to organisational standards.
	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 according to organisational numbering system.
	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 an authorised person 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 compounding 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.
4. Prepare for sterile compounding.	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 compounding 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 an 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 on the work sheet.
	6.9. Obtain required authorisation or checks at designated points according to organisational procedures.
7. Complete production process.	7.1. Reconcile the number of labels printed with number used and report discrepancies to an authorised person.
	7.2. Place product in quarantine area under appropriate storage conditions.
	7.3. Clean equipment and compounding area and dispose of disposable equipment safely and according to organisational requirements.
	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. Obtain final approval and report any discrepancies to an authorised person before releasing compounded medication to storage areas.
	7.7. Discard waste materials appropriately according to workplace health and safety (WHS) and environmental standards.
8. Participate in quality control.	8.1. Pack and label a retention sample or quality control sample if specified on the work sheet.

	8.2. Submit product sample and relevant documentation to quality control. 8.3. Conduct sessional, weekly and monthly cleaning of containment devices and cleanroom as per cleanroom standards. 8.4. Perform environmental monitoring and report abnormal readings to an authorised person. 8.5. Record and file product quality control assay results and compounding area environmental monitoring results.
9. Store and transport released products.	9.1.Store products according to the work sheet. 9.2. Obtain released products from quarantine store. 9.3. Pack released products into delivery containers which will maintain the required ambient conditions for the products. 9.4. Deliver products to destination ensuring safe transport of cytotoxic products. 9.5. Advise receipting area personnel of storage requirements. 9.6. Complete and file records or work sheets according to organisational requirements.

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

Links

Companion Volume implementation guides are found in VETNet - https://vetnet.gov.au/Pages/TrainingDocs.aspx?q=ced1390f-48d9-4ab0-bd50-b015e5485705