



Australian Government

HLTPHA016 Conduct small-scale compounding and labelling of aseptic pharmaceutical products

Release: 1

HLTPHA016 Conduct small-scale compounding and labelling of aseptic 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 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

Elements describe the essential outcomes

1. Source information on formula.

PERFORMANCE CRITERIA

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

- 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>

Assessment Requirements for HLTPHA016 Conduct small-scale compounding and labelling of aseptic 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 established procedures and industry codes to produce 10 aseptic products accurately and safely working within the requirements of sterile areas, air locks and containment devices and in the course of the above:
 - perform regular quality control activities pertaining to the cleanroom including on at least one occasion:
 - weekly and monthly cleaning
 - environmental monitoring
 - validate at least one Aseptic Technique including training and validation record and aseptic technique assessment
 - complete finger dab or glove prints on at least one occasion
 - 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
 - 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 and key features of:
 - The Society of Hospital Pharmacists (SHPA) Standards of Practice for Compounding and Aseptic Preparation in Pharmacy
 - Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to good practices for the preparation of medicinal products in healthcare establishments (PE010-3)
 - USP-NF 797 Pharmaceutical Compounding - Sterile Preparations guidelines as required by the Pharmacy Board of Australia
- 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 aseptic pharmaceutical products, including:
 - aseptic technique
 - correct disposal of sharps and residues
 - regular cleaning and disinfection processes plus sterilisation of pharmaceuticals
 - personal hygiene and clothing standards
 - sources and types of contamination and required responses including microbial and environmental monitoring
- processes relating to aseptic, including:
 - calculations for all sterile admixtures
 - chemical and physical properties of materials in relation to formulation and compounding
 - principles and procedures of formulae calculations, weights and measures
 - principles of aseptic technique, including cytotoxic compounding

- processes for dilution, suspension, incorporation and reconstitution
- use of terminal filtration
- risk considerations and procedures for pharmaceutical compounding:
 - product security
 - handling and storage of hazardous materials
 - quarantine periods
 - management of cytotoxic spills
 - specific hazards related to cytotoxic manufacture
 - transport of cytotoxic medications
- requirements for formulated compounding documentation, including:
 - different documentation types, their scope and purpose
 - worksheet processes
 - information quality control requirements including clarity, logic and completeness
- specific 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
- Operation and function of a clean room or isolator room:
 - differences between aseptic and hazardous including Cytotoxic or Biological cleanrooms
 - airflows and pressures
 - environmental grades of each cleanroom
 - cleanroom behaviour
 - quality control processes involved in maintenance of cleanroom
- knowledge to successfully operate the containment devices within a cleanroom or isolator room:
 - understand the differences between:
 - laminar flow cabinets
 - biological safety cabinets

- cytotoxic drug safety cabinets
- Isolators including Type 1 and Type 2
- cabinet airflows
- action to be taken in event of alarm or malfunction
- features and use of pharmacy systems used for aseptic compounding
- circumstances that require compounding of the product within a containment device
- environmental and WHS standards for waste disposal.

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:
 - facilities with physically separate areas for preparation or checking of product, hand washing and manipulation of products
 - gowns, gloves and hand washing facilities
 - weighing and measuring equipment
 - materials including simulation medication substitutes such as coloured water and disposable equipment
- modelling of industry operating conditions, including time constraints for completing activity
- authorised person with whom to consult.

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

Links

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