



Australian Government

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

Release: 1

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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

Companion Volume implementation guides are found in VETNet -

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