Australian Government

Assessment Requirements for 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.

Performance Evidence

The candidate must show evidence of the ability to complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the job role. There must be evidence that the candidate has:

- followed established procedures and industry codes to accurately and safely produce 10 aseptic products:
    - worked within the requirements of sterile areas, air locks, laminar flow hoods and cytotoxic drug safety cabinet/isolators
- identified issues outside scope of practice and referred these to the authorised person

Knowledge Evidence

The candidate must be able to demonstrate essential knowledge required to effectively complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the work role. This includes knowledge of:

- legal and ethical requirements (national, state/territory) 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 clients
    - specific legislation:
        - medicines and their use

- - the practice of pharmacy
    - different schedules of medicines and pharmaceutical products
  - work role boundaries – responsibilities and limitations in manufacturing products
  - work health and safety
- key information in standard pharmaceutical references and their use in manufacturing, including:
  - *Australian pharmaceutical formulary and handbook* (APF)
  - MIMs
  - *Australian medicines handbook* (AMH)
  - Micromedex
- rationale and key features of:
  - The Society of Hospital Pharmacists (SHPA) *Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments*
  - 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)
- product identification and handling, including those for:
  - formulary medicines and non-formulary medicines
  - 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
  - cleaning and disinfection processes plus sterilisation of pharmaceuticals
  - personal hygiene and clothing standards
  - sources and types of contamination and required responses – microbial, cross-chemical, physical, environmental and corrective strategies
- 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 manufacturing
  - processes for dilution, suspension, incorporation and reconstitution
  - use of terminal filtration

- risk considerations and procedures for pharmaceutical manufacturing:
    - 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 manufacturing documentation, including:
    - different documentation types, their scope and purpose
    - worksheet processes
    - information quality 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
- features and use of pharmacy systems used for aseptic compounding
- circumstances that require compounding of the product within a laminar flow hood/clean room or cytotoxic drug safety cabinet/cytotoxic suite or room or isolator

Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
    - simulated facilities with physically separate areas for preparation/checking of product, hand washing and manipulation of produce
    - gowns, gloves and hand washing facilities
    - weighing and measuring equipment
    - materials (including simulation medicine substitutes such as coloured water) and disposable equipment

- note that a clean room environment is not required for simulated assessment
- modelling of industry operating conditions, including time constraints for completing activity

Assessors must satisfy the Standards for Registered Training Organisations (RTOs) 2015/AQTF mandatory competency 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