Australian Government

Department of Education, Employment and Workplace Relations

HLTPH409A Conduct small-scale compounding and labelling of aseptic pharmaceutical products

Release: 1

HLTPH409A Conduct small-scale compounding and labelling of aseptic pharmaceutical products

Modification History

HLT07 Version 4	HLT07 Version 5
HLTPH415B Conduct small-scale compounding of aseptic pharmaceutical products	HLTPH409A Conduct small-scale compounding and labelling of aseptic pharmaceutical products

Unit Descriptor

Descriptor

This unit of competency describes the skills and knowledge required to manufacture and compound sterile pharmaceutical products from fixed formulae. This includes cytotoxic and total parental nutrition (TPN) products

Application of the Unit

Application

Work is completed in accordance with standards, guidelines / legislation, policies and procedures
Work performed requires a range of well developed skills where discretion and judgement is required
Individuals will take responsibility for their own outputs and limited responsibility for the outputs of others

Licensing/Regulatory Information

Not applicable.

Pre-Requisites

Not applicable.

Employability Skills Information

Employability Skills This unit contains Employability Skills

Elements and Performance Criteria Pre-Content

ELEMENT	PERFORMANCE CRITERIA
Elements define the essential outcomes of a unit of competency.	The Performance Criteria specify the level of performance required to demonstrate achievement of the Element. Terms in italics are elaborated in the Range Statement.

Elements and Performance Criteria

1) Source *information* on formula	1.1 Select appropriate dosage form for product, based on client need and/or against application of medicine 1.2 Use validated resources to source available formulae for required product 1.3 Consolidate and make relevant information available 1.4 Confirm suitability of chosen formula and availability of resources 1.5 Obtain authority of pharmacist to proceed 1.6 Obtain and clarify the confirmed and formulated manufacturing order or master batch sheet from pharmacist, when required
2) Prepare for production process	2.1 Confirm the need to use the appropriate laminar flow hood/clean room or cytotoxic drug safety cabinet/cytotoxic suite or room or isolator to compound the product 2.2 Clean work area and equipment correctly 2.3 Maintain inventory levels of materials and disposable equipment 2.4 Prepare a batch/work sheet referenced from a *master sheet or formulae* 2.5 Assign product batch number, if required 2.6 Verify that batch/work sheets are clearly written in logical order with clear directions and contain all the required information 2.7 Generate the product labels referenced from a master label 2.8 Check and note the number of labels generated 2.9 Submit batch/work sheet and labels to pharmacist for approval 2.10 Check and set up compounding machinery or disposable equipment
3) Obtain equipment, consumables, containers required for manufacturing process	3.1 Acquire *all materials* used in aseptic production 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 Weigh or measure materials in designated area 3.5 Select appropriate types, size and features of containers and packaging in sterile manufacturing

3.6 Obtain required authorisation or checks at designated points

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 specialist equipment and clothing for the safe handling and preparation of cytotoxic drugs 5.3 Follow specific procedures to minimise risk of exposure to cytotoxic drugs
6) Compound products using correct aseptic techniques	6.1 Allocate approved bulk materials, intermediary products and containers to appropriate machinery / equipment where required 6.2 Incorporate materials according to batch documentation 6.3 *Compound product* according to method on manufacturing work sheet 6.4 Prepare cytotoxic products using procedures for handling cytotoxic drugs 6.5 Operate specialist equipment and use specialist supplies in sterile production preparation 6.6 Monitor product and adjust any necessary pharmaceutical/compounding to ensure product complies with work sheet specifications 6.7 Perform verification procedures and inspect finished product for deviations and report to authorised person 6.8 *Pack compounded product* into appropriate container as specified on the work sheet, and following approval from an authorised person 6.9 Label *containers/*units according to labelling specifications on the work sheet 6.10 Obtain required authorisation or checks at designated points
7) Complete production process	7.1 Reconcile the number of *labels* printed with number used and discard excess, noting and documenting discrepancies in labels 7.2 Place product in quarantine area under appropriate *storage conditions*, where specified

	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 *all required documentation* and forward to an authorised person 7.6 Report discrepancies to an authorised person 7.7 Obtain final approval from the pharmacist before releasing packed medicines to storage areas
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, where specified 8.4 Record and file product quality control assay results and manufacturing area environmental monitoring results
9) Transport and store release product	9.1 Store products according to manufacturing documentation 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 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

Required Skills and Knowledge

REQUIRED SKILLS AND KNOWLEDGE

This describes the essential skills and knowledge and their level required for this unit.

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

- Circumstances requiring the compounding of sterile medicine
- Cytotoxic medicines – their use and therapeutic effect
- Different types of clean rooms and laminar flow cabinets for aseptic compounding
- Different types of filters/compatibility of filters with pharmaceutical products
- Formulated manufacturing order / master batch sheet which must:
  - be clearly written
  - be in logical order
  - contain all required information
  - contain no ambiguous information
- Identification of the 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
- Identification and handling of products, including:
  - formulary medicines and non-formulary medicines e.g. clinical trial medicines and Special Access Scheme (SAS) medicines
  - products with the required integrity as well as those whose integrity has been compromised e.g. damaged, contaminated or deteriorated stock
  - routine handling of products and products requiring special handling, e.g. cytotoxics and their spill management, refrigerated and frozen items, light sensitive materials and flammables
- Infection control principles related to small scale manufacture of aseptic pharmaceutical products, including cytotoxic products, including:
  - aseptic technique
  - correct disposal of sharps, drug residues, cytotoxics etc
  - correct use of personal protective equipment
  - hygiene and the importance of maintaining a clean working environment and equipment, including the principles of cleaning and disinfection
  - personal hygiene and clothing standards related to small scale manufacture of aseptic pharmaceutical products

REQUIRED SKILLS AND KNOWLEDGE

  - sources and types of contamination – microbial, cross-chemical, physical, environmental and corrective strategies
  - sterilisation of pharmaceuticals
- Knowledge of and the rationale for The Society of Hospital Pharmacists (SHPA) Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments and, the 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) and applicable legislation, organisation policy and in-house standard operating procedures (SOPs) relating to small scale manufacture of aseptic pharmaceutical products, including cytotoxic products
- Labelling requirements for compounded products, including:
  - adherence to legislative requirements
  - contain name, form and strength of product
  - include ancillary labels as part of label details
  - include hazard warnings
  - provide spacing for entry of batch numbers and expiry dates
  - specific labelling requirements for aseptically prepared products
- Nature and use of different dosage forms including:
  - oral
  - parenteral products i.e. intrathecal, epidural injections
  - topical
- Work Health and Safety (WHS) policies, guidelines and symbols and their relevance to small scale manufacture of aseptic pharmaceutical products, including cytotoxic products including:
  - management of cytotoxic spills
  - principles of handling and storage of hazardous materials
  - specific hazards related to cytotoxic manufacture
  - transport of cytotoxic medications
- Packaging methods, container materials and principles for selection
- Pharmacy or health facility computer system related to small scale manufacture of aseptic pharmaceutical products, including cytotoxic products
- Preparation of worksheets
- Principles and practices of ethical and professional codes of conduct
- Principles and procedures for implementing a quarantine period related to pharmaceutical products
- Principles and procedures of maintaining security of pharmaceutical products
- Principles of manufacturing processes relating to small scale compounding of aseptic pharmaceutical products, including:
  - calculations and content rationale for all sterile admixtures

REQUIRED SKILLS AND KNOWLEDGE

  - 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
- Purpose of information to be shown on medicine packs, e.g. product name, batch numbering and expiry date
- Principles of record keeping and required documentation to be completed
- Standard pharmaceutical references including Australian Pharmaceutical Formulary (APF), MIMs, AMH and Micromedex
- Storage requirements and rationale for different types of product including hazardous materials, special storage conditions include inflammable store, refrigeration

Essential skills:
It is critical that the candidate demonstrate the ability to:

- Complete and file documentation
- Correctly and safely prepare, process and manufacture quality pharmaceutical products for fixed formulae using aseptic technique and cytotoxic aseptic technique
- Identify issues outside scope of practice and refer to the authorised person
- Perform quality assurance monitoring
- Prepare batch/work sheet and labels
- Produce a product free from microbial or cross contamination
- Transport and store products related to small scale manufacture of aseptic pharmaceutical products, including cytotoxic products
- Work in accordance with The Society of Hospital Pharmacists (SHPA) Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments (PIC/S) Guide to good practices for the preparation of medicinal products in healthcare establishments (PE010-3) and, the 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) and with relevant organisation policy, legislative requirements, industrial awards and agreements and in-house standard operating procedures (SOPs)
- Work in accordance with relevant work health and safety, and infection control guidelines including:
  - perform aseptic cleaning and waste management
  - use personal protective equipment correctly
- Assemble, maintain, clean and use all equipment used in manufacturing process in a correct and safe manner and ensure and maintain a clean work environment. Cleaning

REQUIRED SKILLS AND KNOWLEDGE

methods include:
- disinfecting
- swabbing
- washing
- wiping

- Calculate drug requirements for manufacturing
- Perform aseptic techniques and aseptic transfers including cytotoxic aseptic technique and work within the requirements of sterile areas, air locks, laminar flow hoods and cytotoxic drug safety cabinet / isolator
- Select and maintain appropriate equipment for manufacturing task
- Take into account opportunities to address waste minimisation, environmental responsibility and sustainable practice issues
- Use available resources and prioritise workload
- Use literacy, numeracy and oral communication skills required to fulfil the position in a safe manner as specified by the health care facility
- Use problem solving skills

Evidence Guide

EVIDENCE GUIDE

The evidence guide provides advice on assessment and must be read in conjunction with the Performance Criteria, Required Skills and Knowledge, the Range Statement and the Assessment Guidelines for this Training Package.

Critical aspects for assessment and evidence required to demonstrate this competency unit:	• The individual being assessed must provide evidence of specified essential knowledge as well as skills • Observation of workplace performance is desirable for assessment of this unit • Consistency of performance should be demonstrated over the required range of situations relevant to the workplace • Where, for reasons of safety, space, or access to equipment and resources, assessment takes place away from the workplace, the assessment environment should represent workplace conditions

EVIDENCE GUIDE

as closely as possible

Context of and specific resources for assessment:

- Simulations may be used to represent workplace conditions
  Acceptable simulation requires:
  - Scope to determine that work is conducted within legislative and regulatory requirements
  - Scope to determine that work is conducted within WHS and infection control requirements
- Resources essential for assessment include:
  - Equipment that demonstrates an understanding of aseptic/cytotoxic production processes
  - Instructions on the use of equipment
  - Relevant legislation, regulations and guidelines
  - Relevant manufacturing and packing machinery
  - Weighing and measuring equipment

*Note that assessment for this competency unit does **not** replace initial and ongoing formal validation processes required in the workplace to undertake aseptic or cytotoxic production (This usually requires the preparation and microbiological sampling of a number of prepared products for initial validation and at regular future intervals, as part of ongoing validation)*

Method of assessment may include:

- Formal appraisal systems
- Interviewing and questioning
- Observation in the work place (if possible) or simulated laminar flow hood/clean room or cytotoxic drug safety cabinet/cytotoxic suite or room
- Supporting statement of supervisor(s)
- Written assignments/projects, e.g. for fundamentals of microbiology and principles of cleaning and disinfection

Formal validation processes required in the workplace to undertake aseptic or cytotoxic production are outside the assessment for this competency unit.

EVIDENCE GUIDE

Access and equity considerations:

- All workers in the health industry should be aware of access and equity issues in relation to their own area of work
- All workers should develop their ability to work in a culturally diverse environment
- In recognition of particular health issues facing Aboriginal and Torres Strait Islander communities, workers should be aware of cultural, historical and current issues impacting on health of Aboriginal and Torres Strait Islander people
- Assessors and trainers must take into account relevant access and equity issues, in particular relating to factors impacting on health of Aboriginal and/or Torres Strait Islander clients and communities

Range Statement

RANGE STATEMENT

The Range Statement relates to the unit of competency as a whole. It allows for different work environments and situations that may affect performance. Add any essential operating conditions that may be present with training and assessment depending on the work situation, needs of the candidate, accessibility of the item, and local industry and regional contexts.

Information may include:

- Equipment required
- Packaging and label requirements
- Preparation instructions
- Raw drug materials list
- Storage and stability data

RANGE STATEMENT

Master sheet or formulae must:	• Be clearly written • Be in logical order • Contain all required information • Contain no ambiguous directions
All materials used in manufacturing may be disposable or non-disposable and may include:	• Automated compounding machines • Balances • Closing caps • Filters • Gauges • Meters • Mini spikes • Needles • Ointment slabs • Pumps • Spatulas • Syringes • Syringe connectors • Three way taps
Compound product may include:	• Aggregation • Aseptic admixture • Aseptic transfer of materials from one vessel to another • Dilution • Dissolution • Mixing • Trituration

RANGE STATEMENT

Pack product may include:	• Bulk containers • Client ready units •
Containers may include:	• Eye droppers • Miscellaneous individual client unit devices • Small and large volume infusions bags • Syringes • Vials
Labels may be:	• Electronically produced • Typed • Written
Storage conditions may include:	• Ambient • Correct storage of hazardous substances • Correct temperature • Humidity • Isolated • Light • Secure and safe storage for controlled drugs • Secured • Ventilated
All required documentation may include:	• Machinery and equipment logs • Machinery and equipment records
Destination may include:	• Client care area • Dispensary • Store

Unit Sector(s)

Not applicable.

Custom Content Section

Not applicable.