



Australian Government

Department of Education, Employment and Workplace Relations

HLTPH415B Conduct small-scale compounding of aseptic pharmaceutical products

Release: 1

HLTPH415B Conduct small-scale compounding of aseptic pharmaceutical products

Modification History

Not Applicable

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

All tasks are conducted according to NCCTG Guidelines for the Preparation of Pharmaceuticals in Australian Hospitals and standard operating procedures (SOPs)
It should be noted that assessment for this unit of competency does not replace initial and ongoing validation processes required in the workplace to undertake aseptic and cytotoxic production
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

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

ELEMENT

PERFORMANCE CRITERIA

1. Prepare for production process

- 1.1 Identify 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
- 1.2 Confirm relevant legal, quality and hospital policy factors in sterile production
- 1.3 Follow *correct dress code*, safety and personal hygiene procedures and Personal Protective Equipment (PPE)
- 1.4 Maintain preparation areas at NCCTG requirements and Australian Standards for area classification
- 1.5 Clean work area and equipment correctly
- 1.6 Maintain inventory levels of materials and disposable equipment
- 1.7 Obtain and clarify the confirmed and formulated manufacturing order from pharmacist
- 1.8 Prepare production work sheet from formulated manufacturing order/master batch sheet
- 1.9 Interpret manufacture work sheet and assign appropriate product batch number
- 1.10 Check and set up compounding machinery or disposable equipment and any specialist equipment and clothing required for the compounding of sterile pharmaceutical products (e.g. cytotoxic spill cleaning kits)
- 1.11 Prepare labels and check number of labels generated

2. Prepare for cytotoxic production

- 2.1 Apply an understanding of cytotoxic drugs and their basic pharmacology to the preparation of products
- 2.2 Apply an understanding of SHPA Standards for preparation of cytotoxic drugs and relevant State legislation
- 2.3 Make cytotoxic spill cleaning kits available in all production areas
- 2.4 Use specialist equipment and clothing for the safe handling and preparation of cytotoxic drugs
- 2.5 Identify exposure hazards and mitigation requirements related to cytotoxic drugs

ELEMENT**PERFORMANCE CRITERIA**

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|---|---|
| 3. Obtain equipment, consumables, containers required for manufacturing process | 3.1 Acquire <i>all materials</i> 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 <i>batch numbers</i>
3.4 Weigh and measure materials in designated weighing area
3.5 Allocate raw <i>materials</i> to appropriate <i>manufacturing machinery</i> , where applicable
3.6 Select appropriate types, size and features of containers and packaging in sterile manufacturing
3.7 Obtain appropriate authorisation/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 appropriate gloving procedures
4.3 Disinfect and transfer materials, disposable equipment and work sheet to sterile production area |

ELEMENT

5. Manufacture/compound products using aseptic techniques

PERFORMANCE CRITERIA

- 5.1 Comply with NCCTG Guidelines for the Preparation of Pharmaceuticals in Hospitals and Australian Standards for operator safety when cleaning, setting up work station and transference of materials
- 5.2 Allocate approved bulk materials, intermediary products and containers to appropriate machinery / equipment where required
- 5.3 Incorporate materials according to batch documentation
- 5.4 *Compound* product according to method on manufacturing work sheet (e.g. aseptically transfer materials from one vessel to another) and in compliance with standard operating procedures for any measuring device or machinery use
- 5.5 Prepare cytotoxic products using procedures for handling cytotoxic drugs.
- 5.6 Work within the requirements of sterile areas, air locks, laminar flow hoods and cytotoxic drug safety cabinet / isolator
- 5.7 Operate specialist equipment and use specialist supplies in sterile production preparation
- 5.8 Obtain required authorisation/checks at designated points
- 5.9 Monitor *product* and adjust any necessary pharmaceutical/compounding to ensure product complies with work sheet specifications
- 5.10 Perform checking procedure and inspect finished product for deviations
- 5.11 Pack product using appropriate *packaging* devices/machinery as specified on the work sheet, and following approval from an authorised person
- 5.12 Label *containers*/units according to labelling specifications on the work sheet
- 5.13 Pack and *label* a retention sample and/or quality control sample if specified on the work sheet

ELEMENT**PERFORMANCE CRITERIA**

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|-----------------------------------|--|
| 6. Complete production process | 6.1 Place product in <i>quarantine</i> area under appropriate <i>storage conditions</i> , where specified |
| | 6.2 <i>Clean</i> machinery and manufacturing area |
| | 6.3 Identify procedures for cleaning cytotoxic spills and the course of action taken after accidental contact with cytotoxic drugs and their safe disposal |
| | 6.4 Complete machinery and equipment records and/or logs |
| | 6.5 Reconcile the number of labels printed with the number used and discard excess. Note discrepancies in labels and documentation |
| | 6.6 Complete documentation and forward to appropriate person |
| | 6.7 Report discrepancies to an authorised person |
| | 6.8 Obtain final clearance from an authorised person |
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| 7. Participate in quality control | 7.1 Perform environmental monitoring according to organisation requirements and report abnormal readings to an authorised person |
| | 7.2 Submit product sample and relevant documentation to quality control, where specified |
| | 7.3 Record and file product quality control assay results and manufacturing area environmental monitoring results |

ELEMENT**PERFORMANCE CRITERIA****8. Transport and store release product**

- 8.1 Store products according to manufacturing documentation
- 8.2 Obtain released product(s) from quarantine store
- 8.3 Pack released product(s) into appropriate delivery containers
- 8.4 Deliver product to store/dispensary by appropriate means, ensuring safe transport of cytotoxic products
- 8.5 Advise receipting area personnel of any *special storage requirements*
- 8.6 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:

- Basic hygiene and the importance of maintaining a clean working environment and equipment
- Calculations and content rationale for all sterile admixtures
- Chemical and physical properties of materials in relation to formulation and compounding
- Circumstances requiring sterile medication
- Correct disposal of sharps, drug residues, cytotoxics etc.
- Cytotoxic use and therapeutic effect
- Different types of filters/compatibility of filters with pharmaceutical products.
- Hazards related to cytotoxic manufacture
- 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 drugs and non-formulary drugs eg clinical trial drugs and special access scheme drugs
 - products with the required integrity as well as those whose integrity has been compromised eg damaged, contaminated or deteriorated stock
 - routine handling of products and products requiring special handling, eg cytotoxics

REQUIRED SKILLS AND KNOWLEDGE

and its spill management, refrigerated and frozen items, light sensitive materials and flammables

- Infection control policies, guidelines and symbols and their relevance to working in a hospital pharmacy
- Knowledge of and the rationale for applicable legislation, organisation policy and in-house standard operating procedures (SOPs), relating to the small scale manufacture of aseptic pharmaceutical products, including cytotoxic products
- Maintenance principles and procedures of clean work environments
- Management of cytotoxic spills
- Nature and use of different dosage forms
- OHS policies, guidelines and symbols and their relevance to working in a hospital pharmacy
- Packaging methods, container materials and principles for selection
- Personal hygiene and clothing standards for manufacture
- Pharmacy computer systems
- Preparation of worksheets
- Principles and procedures of formulae calculations, weights and measures
- Principles and procedures of maintaining security of pharmaceutical products

continued ...

Essential knowledge (contd):

- Principles of aseptic technique and cytotoxic manufacturing aseptic technique
- Principles of handling and storage of hazardous materials
- Principles of record keeping
- Processes for dilution, suspension, incorporation and reconstitution
- Purpose of batch numbering and expiry date on medicines
- Purpose of information to be shown on medicine packs, eg product name, batch numbering and expiry date Basic principles of manufacturing processes
- Sources and types of contamination - microbial, cross-chemical, physical, environmental and corrective strategies
- Specific labelling requirements for aseptically prepared products
- Sterilisation of pharmaceuticals, use of terminal filtration
- Storage requirements and rationale for different types of product
- Transport of cytotoxic medications
- Use of dosage forms relating to parenteral products ie intrathecal, epidural injections

Essential skills:

It is critical that the candidate demonstrate the ability to:

- Complete and file documentation
- Compound raw materials correctly and safely to achieve a quality product

REQUIRED SKILLS AND KNOWLEDGE

- Perform aseptic cleaning and waste management
- Perform correct aseptic techniques, including general aseptic techniques and cytotoxic aseptic technique
- Perform quality assurance monitoring
- Prepare, process and manufacture quality pharmaceutical products for fixed formulae
- Produce a product free from microbial or cross contamination
- Refer issues identified outside scope of practice to an authorised person
- Transport and store product according to NCCTG Guidelines for the Preparation of Pharmaceuticals in Hospitals
- Use personal protective equipment appropriately
- Work in a safe manner
- Work in accordance with relevant organisation policy, legislative requirements, industrial awards and agreements and in-house operating procedures (SOPs)

In addition, the candidate must be able 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 the ability to:

- Assemble, maintain, clean and use all equipment used in manufacturing process in a correct and safe manner and ensure a clean work environments
- Calculate drug requirements for manufacturing
- Perform aseptic techniques and aseptic transfers
- Perform cytotoxic aseptic technique
- 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.

EVIDENCE GUIDE

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 essential 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 as closely as possible

EVIDENCE GUIDE

Context of and specific resources for assessment:

- Assessment should replicate workplace conditions as far as possible. It may be necessary to undertake the assessment in another workplace or hospital that has the required facilities
- Simulations may be used to represent workplace conditions as closely as possible
Acceptable simulation requires:
 - Scope to determine that work is conducted within legislative and regulatory requirements
 - Scope to determine that work is conducted within OHS and infection control requirements
- Resources essential for assessment include:
 - Access to relevant workplace or appropriately simulated environment where assessment can take place
 - Relevant legislation, regulations and guidelines
 - Weighing and measuring equipment
 - Relevant manufacturing and packing machinery
 - Instructions on the use of equipment
 - Aseptic/cytotoxic facilities

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)

EVIDENCE GUIDE

Method of assessment may include:

- Observation in the work place (if possible)
- Written assignments/projects, eg for fundamentals of microbiology and principles of cleaning and disinfection
- Interviewing and questioning
- Formal appraisal systems
- Supporting statement of supervisor(s)

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

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.

Personal protective equipment may include:

- Gowns
- Gloves
- Masks
- Shoes
- Goggles

Environmental conditions may include:

- Clean areas
- Laminar flow hoods / clean rooms
- Cytoguard cabinets / cytotoxic drug safety cabinets isolators / cytotoxic rooms

Materials may include:

- Therapeutic agents
- Agents considered inactive, that are required for bulking, stabilising, colouring and flavouring the final product

Batch numbers can include:

- Batch numbers can consist of any combination of numerals and digits as specified in standard operating procedures that can uniquely identify an individual product or batch for recording and identification purposes.

RANGE STATEMENT

Materials, manufacturing equipment and packaging devices:

- The range of materials, manufacturing equipment and packaging devices to be used is specified by the batch/work sheet

Equipment and machinery used in manufacturing may be disposable or non-disposable and may include:

- Balances
- Meters
- Gauges
- Pumps
- Spatulas
- Ointment slabs
- Filters
- Syringes
- Needles

Compounding may include:

- Trituration
- Aggregation
- Dissolution
- Mixing

Dose forms may include:

- Parental
- Topical

Product may include:

- Formulary drugs and non-formulary drugs eg. clinical trial drugs & special access scheme drugs
- Products with the required integrity as well as those whose integrity have been compromised eg. damaged, contaminated or deteriorated
- Routine handling products and products requiring special handling eg. cytotoxics and its spill management, refrigerated and frozen items, light sensitive material and flammables

Product packing may include:

- Bulk containers
- Client ready units

RANGE STATEMENT

Containers may include:

- Small&large volume infusions bags
- Eye droppers
- Vials
- Syringes
- Miscellaneous individual client unit devices

Labels may include:

- Typed
- Written
- Electronically produced

Quarantine period

- Quarantine period may be defined as time taken to obtain confirmation of suitability of product/batch for human use.

Storage conditions may include:

- Correct temperature
- Humidity
- Light
- Secured
- Ventilated
- Ambient
- Isolated
- Correct storage of hazardous substances
- Secure and safe storage for controlled drugs

Cleaning methods may include:

- Swabbing
- Washing
- Wiping
- Disinfecting

Special storage conditions may include:

- Refrigeration
- Inflammable store

Unit Sector(s)

Not Applicable

