Australian Government

Department of Education, Employment and Workplace Relations

HLTPH407C Conduct small-scale compounding of pharmaceutical products

Release: 1

HLTPH407C Conduct small-scale compounding of pharmaceutical products

Modification History

Not Applicable

Unit Descriptor

Descriptor	This unit of competency describes the skills and knowledge required to manufacture and small scale compounding of non-sterile pharmaceutical products from fixed formulas, including extemporaneous dispensing

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) 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

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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 Follow correct dress code, safety and personal hygiene procedures 1.2 Maintain preparation areas at NCCTG Guidelines for the Preparation of Pharmaceuticals in Hospitals requirements 1.3 Clean work area and equipment correctly 1.4 Maintain inventory levels of raw materials and disposable equipment 1.5 Obtain and clarify the confirmed and formulated manufacturing order/master batch sheet from pharmacist 1.6 Prepare production work sheet from formulated manufacturing order/master batch sheet 1.7 Interpret manufacture work sheet and assign appropriate product batch number 1.8 Check and set up manufacturing/compounding machinery 1.9 Prepare production work sheet from master batch sheet / formulated manufacturing order

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ELEMENT	PERFORMANCE CRITERIA
2. Obtain and process raw materials	2.1 Acquire all materials listed on the worksheet according to stock levels and stock requisitioning procedures 2.2 Check raw materials to ensure they have been released from quarantine for use by authorised persons 2.3 Verify raw materials against manufacturing work sheet and record raw material *batch numbers* 2.4 Weigh and measure raw materials in designated weighing area 2.5 Allocate *raw materials* to appropriate *manufacturing machinery*, where applicable 2.6 Obtain appropriate authorisation/checks at designated points

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ELEMENT	PERFORMANCE CRITERIA
3. Manufacture/compound products	3.1 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 all materials 3.2 Allocate approved raw materials to appropriate *machinery*, where required 3.3 Incorporate raw materials according to batch documentation 3.4 *Compound* product according to method on work sheet and in compliance with standard operating procedures for any machinery use 3.5 Obtain required authorisation/checks at designated points 3.6 Monitor *product* and adjust any necessary pharmaceutical/compounding to ensure product complies with work sheet specifications 3.7 Perform checking procedures and inspect finished product for deviations 3.8 Pack product using appropriate *packaging* devices/machinery as specified on the work sheet, and following approval from an authorised person 3.9 Label *containers*/units according to labelling specifications on the work sheet 3.10 Pack and *label* a retention sample and/or quality control sample if specified on the work sheet

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ELEMENT	PERFORMANCE CRITERIA
4. Complete production process	4.1 Place product in *quarantine* area under appropriate *storage conditions*, where specified 4.2 *Clean* machinery and manufacturing area and dispose of disposable equipment safely 4.3 Complete machinery and equipment records and/or logs 4.4 Complete documentation and forward to appropriate person 4.5 Complete machinery and equipment records and/or logs 4.6 Reconcile the number of labels printed with number used and discard excess, noting and documenting discrepancies in labels 4.7 Complete documentation and forward to an authorised person 4.8 Report all discrepancies to an authorised person 4.9 Obtain final clearance from an authorised person
5. Participate in quality control	5.1 Submit product sample and relevant documentation to quality control, where specified 5.2 Record and file product quality control assay results
6. Store and transport released product	6.1 Store products according to manufacturing documentation 6.2 Obtain released product(s) from quarantine store 6.3 Pack released product(s) into appropriate delivery containers 6.4 Deliver product to store/dispensary/client care area by appropriate means 6.5 Advise receipting area personnel of any *special storage requirements* 6.6 Complete and file records and/or work sheets

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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:

- Basic hygiene and the importance of maintaining a clean working environment and equipment
- Basic principles of manufacturing processes
- Chemical and physical properties of raw materials in relation to formulation and compounding
- Compound of a product according to a work sheet
- Correct disposal of sharps, drug residues etc
- 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 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 small scale compound/manufacture of pharmaceutical products
- Labelling requirements for compounded products
- Maintenance principles and procedures of clean work environments
- 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 the use of protective clothing
- Pharmacy computer systems
- Preparation of worksheets

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REQUIRED SKILLS AND KNOWLEDGE

- Principles and procedures of formulae calculations, weights and measures
- Principles and procedures of maintaining security of pharmaceutical products
- Principles of handling and storage of hazardous materials

continued ...

Essential knowledge (*contd*):

- Principles of record keeping and required documentation to be completed
- 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
- Sources and types of contamination - microbial, cross-chemical, physical, environmental and corrective strategies
- Storage requirements and rationale for different types of product

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
- Perform quality assurance monitoring
- Prepare, process and manufacture quality pharmaceutical products from 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 when necessary
- Work in a safe manner
- Work in accordance with relevant organisation policy, legislative requirements, industrial awards and agreements and in-house operating procedures (SOPs)

continued ...

Essential skills (*contd*):

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

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REQUIRED SKILLS AND KNOWLEDGE

correct and safe manner and ensure a clean work environments

- Calculate drug and non-drug stock requirements for manufacturing
- Complete required documentation
- Compound a product according to master batch/work sheet
- 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 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

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EVIDENCE GUIDE

Context of and specific resources for assessment:

- Assessment should replicate workplace conditions as far as possible
- 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

Method of assessment may include:

- Observation in the work place (if possible)
- Written assignments/projects
- Interviewing and questioning
- Formal appraisal systems
- Supporting statement of supervisor(s)

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

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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.

Raw 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.
Raw materials, manufacturing equipment and packaging devices:	• The range of raw materials, manufacturing equipment and packaging devices to be used is specified by the batch/work sheet

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RANGE STATEMENT

Equipment and machinery used in manufacturing may be disposable or non-disposable and may include:	• Balances • Meters • Gauges • Measures • Beakers • Mixers • Pumps • Spatulas • Ointment slabs • Filters • Extractors • Stills • Syringes • Needles • Pestle and mortar • Autoclaves • Gloves • Masks • Goggles
Compounding may include:	• Trituration • Aggregation • Grinding • Dissolution • Mixing • Emulsification • Suspension
Dose forms may include:	• Oral • Topical

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RANGE STATEMENT

Product may include:	• 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 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
Containers may include:	• Bottles (medical and poison) • Glass jars • Tubes • 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

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RANGE STATEMENT

Cleaning methods may include:	• Washing • Sweeping • Wiping • Disinfecting • Soaking • De-scaling
Special storage conditions may include:	• Refrigeration • Inflammable store

Unit Sector(s)

Not Applicable

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