Australian Government

Department of Education, Employment and Workplace Relations

HLTPH408A Conduct small scale compounding and labelling of pharmaceutical products

Release: 1

HLTPH408A Conduct small scale compounding and labelling of pharmaceutical products

Modification History

HLT07 Version 4	HLT07 Version 5	Comments
HLTPH407C Conduct small-scale compounding of pharmaceutical products	HLTPH408A Conduct small scale compounding and labelling of pharmaceutical products	Unit updated in V5 Competency outcome changed

Unit 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

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

This unit contains Employability Skills

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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.

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Elements and Performance Criteria

1) Source *information* on formula	1.1 Select appropriate dosage form for product, based on client need and/or against order for 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 Comply with dress code, safety and personal hygiene procedures prior to entering the work area 2.2 Clean work area and equipment correctly 2.3 Maintain inventory levels of *raw 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 *equipment*
3) Obtain and process raw materials	3.1 Acquire all materials listed on the worksheet according to stock levels and stock requisitioning procedures 3.2 Check raw materials to ensure they have been released from quarantine for use by authorised persons 3.3 Verify raw materials against manufacturing work sheet and record raw material batch numbers and expiry dates 3.4 Weigh or measure raw materials in designated area 3.5 Obtain required authorisation or checks at designated points according to work sheet

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4) Compound products	4.1 Allocate approved raw materials to equipment according to batch documentation 4.2 *Compound product* according to method on work sheet 4.3 Monitor product and adjust any necessary pharmaceutical/compounding to ensure product complies with work sheet specifications 4.4 Perform verification procedures, inspect finished product for deviations and report to authorised person 4.5 *Pack compounded product* into appropriate container as specified on the work sheet, and following approval from an authorised person 4.6 Label *containers/*units according to labelling specifications on the work sheet 4.7 Obtain required authorisation or checks at designated points
5) Complete production process	5.1 Reconcile the number of labels printed with number used and discard excess, noting and documenting discrepancies in labels 5.2 Place product in quarantine area under appropriate *storage conditions* 5.3 Clean machinery and manufacturing area and dispose of disposable equipment safely 5.4 Complete *all required documentation* and forward to an authorised person 5.5 Report all discrepancies to an authorised person 5.6 Obtain final approval from the pharmacist before releasing packed medicines to storage areas
6) Participate in quality control	6.1 Pack and *label* a retention sample and/or quality control sample if specified on the work sheet 6.2 Submit product sample and relevant documentation to quality control, where specified 6.3 Record and file product quality control assay results
7) Store and transport released product	7.1 Store products according to manufacturing documentation 7.2 Obtain released product(s) from quarantine store 7.3 Pack released product(s) into delivery containers which will maintain the required ambient conditions for the product 7.4 Deliver product to *destination* 7.5 Advise receipting area personnel of specific

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storage requirements

7.6 Complete and file records and/or work sheets

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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:

- Formulated manufacturing order / master batch sheet which must:
  - be clearly written
  - be in logical order
  - contain all required information
  - contain no ambiguous information
- Identification and handling of products, including:
  - formulary medicines and non-formulary medicines e.g. clinical trial medicines and Special Access Acheme (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. refrigerated and frozen items, light sensitive materials and flammables
- Infection control principles related to small scale manufacture of pharmaceutical products including:
  - correct disposal of sharps, drug residues etc
  - hygiene and maintaining a clean working environment and equipment, including the principles of cleaning and disinfection
  - personal hygiene and the use of protective clothing when conducting small scale compounding pharmaceutical products
  - sources and types of contamination – microbial, cross-chemical, physical, environmental; and corrective strategies
- Knowledge of and the rationale for The Society of Hospital Pharmacists (SHPA) Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments, 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 compounding of pharmaceutical 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

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

  - provide spacing for entry of batch numbers and expiry dates
- Limitations of own work role including identification and referring of issues outside scope of practice to the authorised person
- Nature and use of two different dosage forms i.e. oral and topical
- Work Health and Safety (WHS) policies, guidelines and symbols and their relevance to small scale compounding of pharmaceutical products
- Packaging methods, container materials and principles for selection
- Pharmacy or health facility computer systems related to small scale compound / manufacture of pharmaceutical products
- Preparation of worksheets
- Principles and practices of ethical and professional codes of conduct
- Principles and procedures of maintaining security of pharmaceutical products
- Principles of handling and storage of hazardous materials
- Principles and procedures for implementing a quarantine period related to pharmaceutical products
- Principles of manufacturing processes relating to small scale compounding, including:
  - chemical and physical properties of raw materials in relation to formulation and compounding
  - compounding of a product according to a work sheet
  - principles and procedures of formulae calculations, weights and measures
  - processes for dilution, suspension, incorporation and reconstitution
- Principles of record keeping and required documentation to be completed
- Purpose of information to be shown on medicine packs, e.g. product name, batch numbering and expiry date
- 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
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Essential skills:
It is critical that the candidate demonstrate the ability to:

- Complete and file required documentation
- Correctly and safely prepare, process and manufacture quality pharmaceutical products from fixed formulae
- 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 to meet requirements

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

- Work in accordance with relevant work health and safety, and infection control guidelines
- Work in accordance with The Society of Hospital Pharmacists (SHPA) Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments, 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

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 the required manner and ensure a clean work environment. Cleaning methods include:
  - de-scaling
  - disinfecting
  - soaking
  - sweeping
  - washing
  - wiping
- Complete manufacturing process including:
  - calculate medicine and other stock requirements for manufacturing
  - complete required documentation related to manufacturing task
  - compound an item 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

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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 as closely as possible

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 WHS and infection control requirements
- Resources essential for assessment include:
  - access to relevant workplace or a simulated environment where assessment can take place
  - instructions on the use of equipment
  - relevant legislation, regulations and guidelines
  - relevant manufacturing and packing machinery
  - weighing and measuring equipment

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Method of assessment may include:

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

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

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

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Raw materials may include:	• Agents considered inactive, that are required for bulking, stabilising, colouring and flavouring the final product • Therapeutic agents
Master sheet or formulae must:	• Be clearly written • Be in logical order • Contain all required information • Contain no ambiguous directions
Equipment includes equipment and machinery required for manufacturing or compounding and may include:	• Autoclaves • Balances • Beakers • Extractors • Filters • Gauges • Gloves • Goggles • Masks • Measures • Meters • Mixers • Needles • Ointment slabs • Pestle and mortar • Pumps • Spatulas • Stills • Syringes
Compound product may include:	• Aggregation • Dissolution • Emulsification • Grinding • Mixing • Suspension • Trituration

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Pack compounded product may include:	• Client ready units • Bulk containers
Containers may include:	• Bottles (medical and poison) • Glass jars • Miscellaneous individual client unit devices • Syringes • Tubes
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 records • Machinery and equipment logs
Destination may include:	• Client care area • Dispensary • Store

Unit Sector(s)

Not applicable.

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Custom Content Section

Not applicable.

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