



Australian Government

Department of Education, Employment and Workplace Relations

HLTPH410C Prepare batch and work sheets and labels for compounding

Release: 1

HLTPH410C Prepare batch and work sheets and labels for compounding

Modification History

Not Applicable

Unit Descriptor

Descriptor

This unit of competency describes the skills and knowledge required to prepare master work sheets for use in batch or extemporaneous product manufacture

Application of the Unit

Application

All tasks are conducted according to NCCTG Guidelines for the Preparation of Pharmaceuticals in Hospitals and standard operating procedures (SOPs) and the Australian Pharmaceutical Formulary and Handbook

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

1. Source *information* on formula

PERFORMANCE CRITERIA

- 1.1 Select appropriate dosage form for product, based on client need and/or against application of drug
- 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

ELEMENT**PERFORMANCE CRITERIA****2. Design master batch/work sheet and labels**

- 2.1 Use template to create a *master batch/work sheet*, if available
- 2.2 Create a master batch/work sheet based on existing institutional format if a template is not available
- 2.3 Verify that master batch/work sheets are clearly written in logical order with no ambiguous directions
- 2.4 Verify that master batch/work sheets contain all the required information
- 2.5 Create a *master label* that is within legislative requirements; contains name, form and strength of product; provides spacing for entry of batch numbers and expiry date and includes hazard warnings
- 2.6 Include ancillary labels as part of label details, according to organisation policy
- 2.7 Where specified, create batch record sheet for recording details of dates and quantities of products to be made and released for use

3. Seek approval and release of batch/work sheets for use

- 3.1 Submit master batch/work sheet and labels to pharmacist for approval
- 3.2 Once released by pharmacist, make copies of master batch/work sheet and store in designated work sheet storage file
- 3.3 File master batch/work sheet

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

REQUIRED SKILLS AND KNOWLEDGE

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
- Formulation resources
- Hospital or health facility in-house computer system
- Infection control policies, guidelines and symbols and their relevance to working in a hospital pharmacy
- 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
- Issues of pharmaceutical procedures, relevant to formulation and calculation
- Knowledge of and the rationale for applicable legislation, organisation policy and in-house standard operating procedures (SOPs), relating to preparing batch and extemporaneous master work sheets and labels
- Nature and usage of different drug dosage forms
- OHS policies, guidelines and symbols and their relevance to working in a hospital pharmacy
- Principles and procedures of maintaining security of pharmaceutical products
- Principles and procedures of stock control and maintenance
- Principles of good manufacturing practice as per NCCTG Guidelines for the Preparation of Pharmaceuticals in Hospitals
- Principles of mathematics in relation to formulation calculations
- Purpose of batch numbering and expiry date on medicines
- Storage requirements and rationale for different types of product

Essential skills:

It is critical that the candidate demonstrate the ability to:

- Design master batch/work sheet and labels to meet organisation and legislative requirements
- File master and copied documents according to organisation requirements
- Refer issues identified outside scope of practice to an authorised person
- Work in a safe manner
- Work in accordance with relevant organisation policy, legislative requirements, industrial awards and agreements and in-house operating procedures (SOPs)

REQUIRED SKILLS AND KNOWLEDGE

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:

- Enter and access data on pharmacy computer system
- Take into account opportunities to address waste minimisation, environmental responsibility and sustainable practice issues
- Use available resources and prioritise workload
- Use formulation resources to prepare a master batch sheet
- 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
- Use validated formulation resources to formulate a stable, pharmaceutically correct, quality product

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

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
 - Documents/references on pharmaceutical formulations
 - 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)

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:

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

RANGE STATEMENT

Master batch/work sheets must:

- Be clearly written
- Be in logical order
- Contain all required information
- Contain no ambiguous directions

Master label must:

- Be within legislative requirements
- Contain name, form and strength of product
- Provide spacing for entry of batch numbers and expiry dates
- Include hazard warnings
- Include ancillary labels as part of label details

Unit Sector(s)

Not Applicable