

SFHPHARM20 - SQA Unit Code FA33 04

Prepare documentation, materials and other items for manufacture and assembly of medicinal products



Overview

This standard covers the preparation of documentation and collection of raw materials, components and other consumables necessary to prepare medicinal products. It also covers the breaking down of large containers of medicinal products and repacking them into sizes that are convenient to use. This is known as 'assembly' and is often referred to as 'pre-packing'. Your practice will be consistent with your occupational role and carried out under the regulatory and ethical frameworks established in the context of current legislation. You will work at all times within Standard Operating Procedures that relate to the way in which a pharmacy service is provided in your place of work. Users of this standard will need to ensure that practice reflects up to date information and policies.

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Performance criteria

- You must be able to:*
- P1 work within the relevant Standard Operating Procedures including the relevant health and safety and Control of Substances Hazardous to Health procedures and within own limits of responsibility
 - P2 put on the appropriate clean room clothing following correct gowning procedure
 - P3 clean the appropriate environmental area(s) using the correct materials
 - P4 ensure that the area of work is always clean and tidy
 - P5 monitor relevant environmental parameters and ensure that where appropriate they are within the set limits
 - P6 confirm you have the correct worksheet for the product, completing any calculations as appropriate
 - P7 allocate the batch number and expiry date for the product
 - P8 generate the labels ensuring that all labels produced are complete, accurate and legible and that you account for them
 - P9 select the correct raw materials and consumables / equipment, for the product, recording the relevant information on the worksheet
 - P10 confirm the raw materials and consumables / equipment are fit for purpose
 - P11 make clear and accurate entries on all the relevant documentation
 - P12 ensure the 'first check' is carried out by the appropriate person
 - P13 disinfect the raw materials, consumables for transfer into the clean room, if applicable
 - P14 report to the appropriate person any problems outside your area of responsibility
 - P15 calculate the quantities of different raw materials
 - P16 transfer materials into the clean room, if applicable
 - P17 take appropriate action following an unusual event, within the limits of your authority

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Knowledge and understanding

You need to know and understand:

- K1 the basic principles of quality assurance including current good manufacturing practice
- K2 the difference between preparation for individual patients and preparation for stock and how this is generally implemented
- K3 the recognised guidelines relating to manufacture of medicinal products
- K4 your responsibilities under current health and safety legislation and Control of Substances Hazardous to Health and how it applies to the working environment
- K5 the importance of Standard Operating Procedures and why you must always work within these procedures
- K6 the importance of working within the limits of your own role
- K7 basic hygiene and the importance of maintaining a clean working environment including conducting a weekly and monthly clean
- K8 the importance of personal hygiene and the correct use of protective / clean room clothing
- K9 the different types of environmental areas and when they should be used
- K10 the environmental parameters that govern the working area, their importance, and how to carry out their monitoring including:
- K11 the possible sources of contamination
- K12 chemical and physical properties of raw materials relevant to formulation and compounding, this will include any interactions between raw materials and between raw materials and packaging
- K13 the principles of formulae calculations, weights and measures
- K14 the various types of products
- K15 the materials, consumables and equipment necessary for the preparation of medicinal products
- K16 the correct handling of cytotoxic drugs and how to minimise risks
- K17 the procedures for cleaning, decontamination, and preparing the environment and equipment
- K18 labelling and packaging requirements and conventions
- K19 the importance of recording information clearly, accurately and in a systematic, timely manner and of the storing of this information

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Additional Information

External links

This standard links with the following dimension within the NHS Knowledge and Skills Framework (October 2004):

Dimension: HWB10 Products to meet health and wellbeing needs

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Developed by Skills for Health

Version number 1

Date approved June 2010

Indicative review date June 2012

Validity Current

Status Original

Originating organisation Skills for Health

Original URN PHARM20

Relevant occupations Health and Social Care; Healthcare and Related Personal Services

Suite Pharmacy

Key words Sterile production, non-sterile production, manufacturing, pharmacy, production of pharmaceuticals, batch medicines, pre-packing, assembly.