SFHPHARM20

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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