SFHPHARM21
Prepare documentation, materials and other items for the preparation of aseptic products

Overview

This standard covers the generation and completion of documentation and preparation of starting materials, components and other consumables necessary for the production of aseptic products. It covers aseptic preparation for both dispensing and manufacturing. 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 competence 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 SOPs including the relevant health and safety and COSHH procedures and within own limits of responsibility
- P2 ensure the appropriate clothing is worn at all times
- P3 clean the appropriate environmental areas using the correct equipment and materials
- P4 ensure that you work using the correct prescription / order
- P5 generate worksheets according to local guidelines and protocols
- P6 generate the labels and ensure that all labels produced are accounted for and complete, accurate and legible
- P7 ensure that the environmental area is always clean and tidy
- P8 monitor relevant environmental parameters and ensure that where appropriate they are within the set limits
- P9 confirm you have the correct worksheet for the product, completing any calculations as appropriate
- P10 allocate the batch number and expiry date for the product
- P11 select the correct starting materials and consumables, for the product, recording the relevant information on the worksheet
- P12 confirm the starting materials and consumables are fit for purpose
- P13 make clear and accurate entries on all the relevant documentation
- P14 disinfect the starting materials and consumables for transfer into the clean room
- P15 report any problems outside your area of responsibility to an appropriate person

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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 (cGMP)

K2 the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace

K3 the recognised guidelines relating to aseptic preparation

K4 your responsibilities under COSHH and current health and safety legislation and how it applies to the working environment

K5 the importance of SOPs 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

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 possible sources of contamination

K11 the various types of products

K12 the materials and equipment necessary for the preparation of aseptic products

K13 the principles of formulae calculations, weights and measures

K14 the safe handling of cytotoxic drugs

K15 the procedures for cleaning, decontamination, and preparing the environment and components

K16 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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