SFHPHARM23
Check documentation, starting materials, components and other consumables for the production of aseptic products

Overview

This standard covers the checking of documentation, 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 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 check that you have the correct worksheets for the product
- P3 ensure that the starting materials have been collected correctly and are ready for the aseptic process
- P4 check that the transcriptions, calculations, batch numbers and expiry dates are all correct
- P5 check that the entries on the worksheets and labels are correct
- P6 check the label(s) against worksheet which has the individual's details on it and on the master worksheet
- P7 check the allocated batch number and expiry date for the product
- P8 check that the labels generated are correct, complete, accurate, and legible
- P9 ensure the correct raw materials and equipment / consumables have been assembled for the product, and the relevant information has been recorded on the worksheet
- P10 check the raw materials and consumables / equipment are ensure that they are fit for purpose
- P11 make clear and accurate entries on all the relevant documentation
- P12 feedback any near misses or errors to colleagues to minimise future errors
- P13 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 and recognised guidelines for the aseptic process

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

K3 your responsibilities under Control of Substances Hazardous to Health and the current health and safety legislation and how it applies to the working environment

K4 the importance of Standard Operating Procedures and why you must always work within these procedures

K5 the importance of working within the limits of your own role

K6 basic hygiene and the importance of maintaining a clean working environment

K7 the importance of personal hygiene and the correct use of protective / clean room clothing

K8 the different types of work/environmental areas and when they should be used

K9 the possible sources of contamination

K10 the materials and equipment necessary for the preparation of aseptic products

K11 the safe handling of cytotoxic drugs

K12 the principles of formulae calculations, weights and measures

K13 the procedures for cleaning, decontamination, and preparing the environment and components

K14 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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