

SFHPHARM19 - SQA Unit Code FA32 04

Prepare aseptic products and carry out in-process checking



Overview

This standard covers the preparation of aseptic products including preparing the environment, self and in-process checking. 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.

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 undertake relevant environmental monitoring checking that the parameters, where appropriate, are within the set limits:
 - P2.1 prior to aseptic preparation
 - P2.2 during aseptic preparation
 - P2.3 following completion of aseptic preparation
 - P3 take appropriate action if the environmental parameters are outside the set limits
 - P4 put on the appropriate clean room clothing following correct gowning procedure
 - P5 clean and prepare the environmental areas using the correct materials
 - P6 disinfect starting materials, equipment prior to introduction into and within the work area into the work area
 - P7 prepare the product using the correct process and equipment according to worksheet and Standard Operating Procedures, and maintain an aseptic technique
 - P8 undertake all quality, accuracy and safety checks
 - P9 take corrective action, within limits of own responsibility, if there is an accident/incident/error during the preparation, including the completion of required documentation
 - P10 report to the appropriate person any problems outside your area of responsibility
 - P11 clean and decontaminate all work areas using the correct cleaning method and removing all waste
 - P12 ensure that waste is stored or disposed of in accordance with legal requirements
 - P13 make clear and accurate entries on all the relevant documentation
 - P14 correctly store (including any quarantine requirements) and/or transport the product, paying particular attention to maintenance of the 'cold chain' if appropriate

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 in the workplace
- K3 current health and safety legislation and how it applies to the working environment, including Control of Substances Hazardous to Health
- K4 the importance of Standard Operating Procedures and why you must always work within these procedures
- K5 the limits of your own role and the referral procedures
- 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 environmental areas and when they should be used
- K9 the possible sources of contamination and the appropriate methods of prevention
- K10 the importance of storing products correctly (including any quarantine requirements) especially in relation to maintaining the cold chain from both chemical and microbiological aspects
- K11 the different types of equipment and consumables and which products they must be used for
- K12 the procedures for preparing, cleaning and decontaminating equipment and work areas
- K13 the importance of storing equipment safely and in a condition ready for use
- K14 the principles of formulae calculations, weights and measures
- K15 aseptic techniques and when to use the different processes
- K16 the environmental parameters that govern the working area, their importance, and how to carry out their monitoring
- K17 the correct handling of cytotoxic drugs and how to minimise risks
- K18 the importance of carrying out accuracy and quality checks
- K19 the importance of label and product reconciliation
- K20 the methods and materials used for packaging
- K21 the procedures for the safe handling and disposal of waste materials
- K22 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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