

SFHPHARM18 - SQA Unit Code FA2L 04

Prepare aseptic products



Overview

This standard covers the preparation of aseptic products including preparing the environment and self. 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 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 e.g. air pressure differentials 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
- P7 prepare the product using the correct process and equipment according to worksheet and Standard Operating Procedures, and maintain aseptic technique
- P8 take the corrective action within limits of own responsibility in the event of an accident/incident/error during the preparation, including the completion of required documentation
- P9 report to the appropriate person any problems outside your area of responsibility
- P10 clean and decontaminate all work areas using the correct cleaning method and removing all waste
- P11 label product, making all necessary accuracy checks and complete documentation in line with local policy
- P12 ensure that waste is stored or disposed of in accordance with legal requirements
- P13 complete all necessary reconciliation calculations correctly and accurately on all the relevant documentation
- P14 feedback any near misses or errors to colleagues to minimise future errors
- P15 make clear and accurate entries on all the relevant documentation

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 the recognised guidelines relating to aseptic preparation
- K4 current health and safety legislation and how it applies to the working environment, including Control of Substances Hazardous to Health
- K5 the importance of Standard Operating Procedures and why you must always work within these procedures
- K6 the limits of your own role and the referral procedures to an appropriate person
- K7 basic hygiene and the importance of maintaining a clean working environment
- K8 a working knowledge of 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 and the appropriate methods of prevention
- K11 the importance of storing products correctly (including any quarantine requirements) especially in relation to maintaining the cold chain from both chemical and microbiological aspects
- K12 the various types of products
- K13 the different types of equipment and consumables and which products they must be used for
- K14 the procedures for preparing, cleaning and decontaminating equipment and environmental areas
- K15 the importance of storing equipment safely and in a condition ready for use
- K16 the principles of formulae calculations, weights and measures
- K17 the environmental parameters that govern the working area, their importance, and how to carry out their monitoring
- K18 the correct handling of cytotoxic drugs and how to minimise the risks
- K19 the importance of carrying out accuracy and quality checks
- K20 the importance of label and product reconciliation
- K21 the methods and materials used for packaging
- K22 the procedures for the safe handling and disposal of waste materials
- K23 importance of recording information clearly, accurately and in a systematic, timely manner and of the storing information that includes:
 - K23.1 paper based
 - K23.2 electronic

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- K24 the importance of using validated documentation
- K25 local error reporting procedures and communication channels
- K26 national error reduction policies/strategies

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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 PHARM18

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

Suite Pharmacy

Key words Aseptic production, pharmacy manufacturing, sterile production, manufacturing pharmaceuticals, pharmacy production.