

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, professional 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. A caring and compassionate approach should be adopted in line with current healthcare guidance. Users of this standard will need to ensure that practice reflects up to date information and policies.

Performance criteria

You must be able to:

1. work within the relevant Standard Operating Procedures including the relevant health and safety procedures and within your own limits of competence
2. undertake relevant environmental monitoring checking that the parameters, where appropriate, are within the set limits
3. take appropriate action if the environmental parameters are outside the set limits
4. put on the appropriate clean room clothing and follow the correct gowning procedure
5. clean and prepare the environmental areas using the correct materials
6. disinfect starting materials and equipment prior to introduction and transfer at each stage within the work area
7. prepare the product using the correct process and equipment according to the documentation and Standard Operating Procedures
8. ensure that the appropriate in-process checks have been carried out by the relevant person
9. take corrective action, within limits of your own responsibility, in the event of an accident/incident/error during the preparation, including the completion of required documentation
10. act within the limits of your authority and refer any problems to an appropriate person
11. record and report any near misses or errors in line with organisational procedures
12. feedback any near misses or errors to colleagues to minimise potential future errors
13. clean and decontaminate all work areas using the appropriate method and equipment and remove all waste in accordance with Standard Operating Procedures
14. label product and complete documentation in line with local policy
15. quarantine product in accordance with organisational requirements
16. complete all necessary reconciliation and calculations correctly and accurately on all the relevant documentation
17. correctly store and/or transport the product, paying particular attention to maintenance of the 'cold chain' if appropriate
18. complete all relevant documentation and store appropriately in accordance with

legal and organisational requirements

Knowledge and understanding

You need to know and understand:

1. the Standard Operating Procedures and the importance of adhering to them at all times
2. the importance of working within the limits of your competence and authority, when to seek agreement or permission from others and when to refer on to an appropriate person
3. current health and safety legislation and how it applies to the working environment
4. legal, organisational and policy requirements relevant to your role, the role of others in your organisation and the activities being carried out
5. the relevant national and local guidelines, policies and procedures that are available and how and when they should be accessed
6. the importance of adhering to information governance policies and maintaining confidentiality when sharing information about individuals with others
7. the duty to report any acts or omissions that could be detrimental to individuals, yourself, colleagues or your employer
8. the principles of good manufacturing practice, including pharmaceutical quality systems and your role within that
9. the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace
10. the recognised guidelines relating to aseptic preparation
11. the importance of maintaining a clean working environment
12. the importance of personal hygiene and the correct use of protective / clean room clothing
13. the different types of environmental areas and when they should be used
14. the possible sources of contamination and the appropriate methods of prevention
15. the importance of storing products correctly especially in relation to maintaining the cold chain from both chemical and microbiological aspects
16. the various types of products
17. chemical and physical properties of ingredients relevant to formulation and compounding, including any interactions between raw materials and components
18. the different types of equipment and consumables and which products they must be used for

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19. the procedures for preparing, cleaning and decontaminating equipment and work areas
20. the importance of storing equipment safely and in a condition ready for use
21. the principles of formulae calculations, weights and measures
22. the importance of environmental parameters, how to carry out their monitoring and the referral procedures if they are outside the set limits
23. aseptic techniques and when to use the different processes to minimise any associated risks
24. the importance of carrying out accuracy and quality checks
25. the importance of label and product reconciliation
26. the reasons for safe systems of work including the quarantine requirements and the appropriate checking processes
27. the methods and materials used for packaging
28. the procedures for the safe handling and disposal of waste materials
29. the importance of using approved documentation
30. how to identify near misses and errors
31. the causes and consequences of near misses and errors
32. local and/or national error reporting procedures and communication channels
33. the importance of recording, storing and retrieving information in accordance with organisational procedures

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External Links