

PHARM23.2016 Check documentation and materials prior to the preparation of aseptic products

OVERVIEW

This standard covers the checking of documentation and materials prior to the preparation 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, professional and ethical frameworks established in the context of current legislation. You will need to take a reflective approach to your work. 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. Version No 2

KNOWLEDGE AND UNDERSTANDING

You will 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.recognised guidelines for the aseptic process
- 10.the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace
- 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 environmentally controlled areas and when they should be used
- 14.the possible sources of contamination and appropriate methods of prevention
- 15.the various types of products
- 16.chemical and physical properties of ingredients relevant to formulation and compounding, including any interactions between raw materials and components
- 17.the principles of formulae calculations, weights and measures
- 18.the materials and equipment necessary for the preparation of aseptic products
- 19.aseptic techniques and when to use the different processes to minimise any associated risks
- 20.the importance of carrying out accuracy and quality checks
- 21.the reasons for safe systems of work including the quarantine requirements and the appropriate checking processes
- 22.the importance of using approved documentation
- 23.how to identify near misses and errors
- 24.the causes and consequences of near misses and errors
- 25.local and/or national error reporting procedures and communication channels
- 26.the importance of recording, storing and retrieving information in accordance with organisational procedures

PERFORMANCE CRITERIA

You must be able to do the following:

- 1.work within the relevant Standard Operating Procedures including the relevant health and safety procedures and within your own limits of competence
- 2.check that you have the correct documentation for the product
- 3.ensure that the starting materials have been collected correctly and are ready for the aseptic process
- 4.check that the transcriptions, calculations, batch numbers and expiry dates are all correct
- 5.check the allocated batch number and expiry date for the product
- 6.check that the documentation and labels generated are correct, complete, accurate, and legible
- 7.ensure the correct raw materials and equipment / consumables have been assembled for the product and are fit for purpose
- 8.quarantine product in accordance with organisational requirements
- 9.record and report any near misses or errors in line with organisational procedures
- 10.feedback any near misses or errors to colleagues to minimise potential future errors
- 11.act within the limits of your authority and refer any problems to an appropriate person
- 12.complete all relevant documentation and store appropriately in accordance with legal and organisational requirements

ADDITIONAL INFORMATION

This National Occupational Standard was developed by Skills for Health. 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