[Unique Reference Number]
Manufacture and assembly of medicinal products

Overview

This standard covers the processes and procedures for the manufacture and assembly of batch medicinal products including preparing the environment and self. It also covers the breaking down of large containers of medicinal products and repacking them into sizes that are convenient to use. 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.

[Unique Reference Number]

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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 before you start the preparation, confirm that the correct worksheet, labels, raw materials, equipment and consumables are available and ready for use
- P3 monitor relevant environmental parameters and ensure that where appropriate they are within the set limits:
  - P3.1 prior to preparation
  - P3.2 during preparation
  - P3.3 following completion of preparation
- P4 take appropriate action if the environmental parameters are outside the set limits
- P5 put on the appropriate clean room clothing following correct gowning procedure
- P6 ensure the environmental areas are clean and prepared using the correct materials
- P7 prepare products in accordance with the batch sheet using the correct process and equipment and undertaking all process checks at the relevant stages
- P8 complete any necessary sterilisation processes to meet the quality assurance
- P9 label product, pack and if necessary label into any secondary packaging and prepare quality assurance samples as appropriate
- P10 complete all necessary reconciliation calculations correctly and accurately for the product and the labels
- P11 complete all documentation clearly and accurately, ready for checking
- P12 quarantine product following the final check by the appropriate person
- P13 ensure that the environmental areas are cleaned and decontaminated using the correct cleaning method
- P14 ensure that all equipment is dismantled, cleaned, decontaminated and correctly stored or disposed of correctly
- P15 report any defects to an appropriate person
- P16 record and report any out of specification results/unusual events where appropriate
- P17 record and report any near misses or errors to colleagues (to minimise potential future errors)
- P18 take appropriate action following an unusual event, within the limits of your authority

[Unique Reference Number]

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Knowledge and understanding

You need to know and understand:

- K1 the basic principles of quality assurance relating to manufacture of medicinal products
- K2 the principles of current good manufacturing practice
- K3 the difference between preparation for individual patients and preparation for stock and how this is generally implemented in the workplace
- K4 understanding of the recognised guidelines relating to manufacture of medicinal products
- K5 current health and safety legislation and how it applies to the working environment, including Control of Substances Hazardous to Health
- K6 the principles of Standard Operating Procedures and why it is important to work within these procedures
- K7 the limits of your own role and the referral procedures
- K8 local error reporting and exception procedures and communication channels
- K9 national error reduction policies/strategies
- K10 basic hygiene and the importance of maintaining a clean working environment
- K11 personal hygiene and the use of protective / clean room clothing
- K12 the possible sources of contamination and the appropriate methods of prevention
- K13 environmental parameters, their importance and how to carry out their monitoring
- K14 chemical and physical properties of ingredients relevant to formulation and compounding, this will include any interactions between ingredients
- K15 the principles of formulae calculations, weights and measures
- K16 the preparation, assembly and maintenance of equipment
- K17 the principles and properties of different types of containers and when to use the various types
- K18 the nature and use of different product forms
- K19 the preparation and use of environmental areas
- K20 principles and procedure for preparing medicinal products including:
  - K20.1 mixing
  - K20.2 filtration
  - K20.3 reconstitution
  - K20.4 trituration
  - K20.5 filling
  - K20.6 assembly
- K21 labelling and packaging requirements

K22 the reasons for safe systems of work and importance of carrying out in-process checks, end product quality checks and quarantine requirements

K23 principles and procedures for sterilisation of products, including, autoclave, dry heat, microbial filtration

K24 the principles and procedures for:

- K24.1 disposal of waste products and cleaning material
- K24.2 dismantling, cleaning and storing equipment
- K24.3 cleaning and decontamination of preparation area and equipment
- K24.4 a working knowledge of principles and procedures for the safe disposal of waste materials

K25 the importance of recording information clearly, accurately and in a systematic, timely manner and of the storing of this information including records that are:

- K25.1 paper based
- K25.2 electronic

[Unique Reference Number]

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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 well being needs

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