SFHCHHM6
Prepare herbal medicines in batches

Overview

This standard covers the processes and procedures for the production of batched herbal products which may be derived from herbal materials that you have grown yourself or that have been bought from a supplier. It also covers the breaking down of large containers of herbal products and re packing them to sizes that are convenient to use, this is often referred to as `pre-packing' and is included in the assembly section of this standard. This area of herbal medicine is governed by strict regulations, you will need to understand these regulations and demonstrate that you are able to work competently within them. You will at all times work within Standard Operating Procedures (SOPs) that relate to the way in which you provide the herbal medicine service.

The first element requires you to demonstrate that you can collect together all the equipment and materials you would need, perform any calculations accurately and ensure that the environment you will be working in is safe and to the correct identified standard.

The second element covers the preparation and assembly of herbal medicine products. You will need to show that you can use and understand different processes and different types of equipment. Particular attention will need to be paid to the properties of the raw materials and consideration given to the use of the final product. These factors have a particular bearing on the way you will make certain products, the types of containers and labels used so that you produce a product that is of the required quality.

The third element requires you to complete the process ensuring that all the relevant documentation and records are correct. You will need to make sure that all equipment and areas are clean and are left ready to be used the next time. It is important that you can dispose of any waste material safely in accordance with procedures.

Users of this standard will need to ensure that practice reflects up to date information and policies.

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Performance criteria

You must be able to:

P1 select the correct preparation area for the product being made
P2 ensure that all areas of work are always clean and free from contamination
P3 select the correct equipment for the product and the process
P4 ensure that the equipment is maintained in good working order, is clean and free from contamination
P5 follow the correct Health and Safety guidelines
P6 check the environmental parameters and ensure they are within the correct working standard
P7 check the correct formula has been selected and that all calculations are correct and have been checked
P8 check that all the necessary labels are complete, accurate and legible
P9 ensure that the correct ingredients have been selected, they are of a suitable quality and are within the expiry date of the expected date of the final product
P10 complete all the relevant documentation clearly and accurately
P11 select the correct preparation area for the product being made
P12 ensure that all areas of work are always clean and free from contamination
P13 select the correct equipment for the product and the process
P14 ensure that the equipment is maintained in good working order, is clean and free from contamination
P15 follow the correct Health and Safety guidelines
P16 check the environmental parameters and ensure they are within the correct working standard
P17 check the correct formula has been selected and that all calculations are correct and have been checked
P18 check that all the necessary labels are complete, accurate and legible
P19 ensure that the correct ingredients have been selected, they are of a suitable quality and are within the expiry date of the expected date of the final product
P20 complete all the relevant documentation clearly and accurately
P21 ensure that all the relevant documentation is completed clearly and accurately and is ready for checking
P22 ensure that all equipment is dismantled, cleaned, decontaminated and stored correctly
P23 ensure that the reconciliation of ingredients and materials is carried out correctly
P24 ensure that prepared herbal medicines, materials and waste are labelled clearly and are stored or disposed of appropriately
P25 clean or decontaminate all work areas using the appropriate cleaning method

P26	complete all documentation clearly and accurately and ensure it is stored correctly
P27	prepare quality control (QC) samples as appropriate and quarantine products where relevant

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Knowledge and understanding

You need to know and understand:

K1 current Health and Safety legislation including COSHH
K2 principles of Standard Operating Procedures and why it is important to work within these procedures
K3 basic hygiene and the importance of maintaining a clean working environment
K4 personal hygiene and the use of protective clothing
K5 current legislation relating to the manufacture of herbal medicine products
- K5.1 current EC Directives
- K5.2 rules and Guidance for Pharmaceutical Manufacturers – Good Manufacturing Practice (GMP)
- K5.3 packaging of medicinal products, including methods and materials

K6 the factors that affect and cause microbial and cross-chemical contamination
K7 the maintenance of records e.g. updating, version number
K8 the importance of using and keeping the correct documentation
K9 principles and procedures of formulae calculations
K10 the preparation and use of environmental areas
K11 the assembly and maintenance of equipment
K12 the principles and properties of different types of containers and when to use the various types
K13 environmental parameters e.g. air pressure, temperature, air flow
K14 principles and procedures for preparing herbal medicine products
K15 labelling requirements and conventions
K16 chemical and physical properties of ingredients relevant to formulation and compounding, this will include any interactions between ingredients
K17 sources of contamination and the appropriate corrective action
K18 principles of formulae calculations, weights and measures
K19 principles and procedures for:
- K19.1 mixing
- K19.2 filtration
- K19.3 reconstitution
- K19.4 incorporation
- K19.5 filling
- K19.6 assembly
- K19.7 dissolving
- K19.8 pressing

K20 the reasons for and how to carry out `in-process' checks, end product quality checks and quarantine requirements
K21 nature and use of different products:
- K21.1 topical fluids e.g. eye drops, ear drops, nasal drops
- K21.2 solid dose forms e.g. capsules, tablets, suppositories, powders

K21.3 oral liquids
K21.4 ointments and creams

K22 principles and procedures for sterilisation of products, including, autoclave, dry heat, microbial filtration

K23 the procedures for the disposal of waste products and cleaning material

K24 principles and procedures for storing the prepared herbal medicines and for dismantling and storing equipment

K25 principles and procedures for decontamination and the records that need to be kept

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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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