



CH HM6 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.

Version No 1

KNOWLEDGE AND UNDERSTANDING

You need to know and understand:

1. current Health and Safety legislation including COSHH
2. principles of Standard Operating Procedures and why it is important to work within these procedures
3. basic hygiene and the importance of maintaining a clean working environment
4. personal hygiene and the use of protective clothing
5. current legislation relating to the manufacture of herbal medicine products
 1. current EC Directives
 2. rules and Guidance for Pharmaceutical Manufacturers – Good Manufacturing Practice (GMP)
 3. packaging of medicinal products, including methods and materials
6. the factors that affect and cause microbial and cross-chemical contamination
7. the maintenance of records e.g. updating, version number
8. the importance of using and keeping the correct documentation
9. principles and procedures of formulae calculations
10. the preparation and use of environmental areas
11. the assembly and maintenance of equipment
12. the principles and properties of different types of containers and when to use the various types
13. environmental parameters e.g. air pressure, temperature, air flow
14. principles and procedures for preparing herbal medicine products
15. labelling requirements and conventions
16. chemical and physical properties of ingredients relevant to formulation and compounding, this will include any interactions between ingredients
17. sources of contamination and the appropriate corrective action
18. principles of formulae calculations, weights and measures
19. principles and procedures for:
 1. mixing
 2. filtration
 3. reconstitution
 4. incorporation
 5. filling
 6. assembly
 7. dissolving
 8. pressing
20. the reasons for and how to carry out 'in-process' checks, end product quality checks and quarantine requirements
21. nature and use of different products:
 1. topical fluids e.g. eye drops, ear drops, nasal drops
 2. solid dose forms e.g. capsules, tablets, suppositories, powders
 3. oral liquids
 4. ointments and creams
22. principles and procedures for sterilisation of products, including, autoclave, dry heat, microbial filtration
23. the procedures for the disposal of waste products and cleaning material
24. principles and procedures for storing the prepared herbal medicines and for dismantling and storing equipment
25. principles and procedures for decontamination and the records that need to be kept

PERFORMANCE CRITERIA

You must be able to do the following:

1. select the correct preparation area for the product being made
2. ensure that all areas of work are always clean and free from contamination
3. select the correct equipment for the product and the process
4. ensure that the equipment is maintained in good working order, is clean and free from contamination
5. follow the correct Health and Safety guidelines
6. check the environmental parameters and ensure they are within the correct working standard
7. check the correct formula has been selected and that all calculations are correct and have been checked
8. check that all the necessary labels are complete, accurate and legible
9. 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
10. complete all the relevant documentation clearly and accurately
11. select the correct preparation area for the product being made
12. ensure that all areas of work are always clean and free from contamination
13. select the correct equipment for the product and the process
14. ensure that the equipment is maintained in good working order, is clean and free from contamination
15. follow the correct Health and Safety guidelines
16. check the environmental parameters and ensure they are within the correct working standard
17. check the correct formula has been selected and that all calculations are correct and have been checked
18. check that all the necessary labels are complete, accurate and legible
19. 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
20. complete all the relevant documentation clearly and accurately
21. ensure that all the relevant documentation is completed clearly and accurately and is ready for checking
22. ensure that all equipment is dismantled, cleaned, decontaminated and stored correctly
23. ensure that the reconciliation of ingredients and materials is carried out correctly
24. ensure that prepared herbal medicines, materials and waste are labelled clearly and are stored or disposed of appropriately
25. clean or decontaminate all work areas using the appropriate cleaning method
26. complete all documentation clearly and accurately and ensure it is stored correctly
27. prepare quality control (QC) samples as appropriate and quarantine products where relevant

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