

**MEDICINES AND HEALTHCARE PRODUCTS
REGULATORY AGENCY**

**UK HOMOEOPATHIC REGISTRATION SCHEME
GUIDANCE NOTES**

**THE CONTROL AND QUALITY OF
HOMOEOPATHIC STOCKS**

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Introduction

Applications to register homoeopathic medicinal products should be accompanied by supporting data on the production and control of the homoeopathic stock. The special nature of homoeopathic medicinal products is such that tests on the finished product are of limited value with regard to quality control. The quality and control of stocks is therefore of considerable importance in assuring the consistent quality of the finished product. This guidance note interprets Article 8 of the Homoeopathic Directive 92/73/EEC which requires that the pharmaceutical quality and batch-to-batch homogeneity of the products concerned should be demonstrated.

1. PREPARATION OF STOCKS

Homoeopathic stocks must be prepared in accordance with a manufacturing method set out in a homoeopathic pharmacopoeia. The British Homoeopathic Pharmacopoeia, the German Homoeopathic Pharmacopoeia, the Homoeopathic Pharmacopoeia of the United States and homoeopathic monographs cited in the French Pharmacopoeia may be used. Applicants should refer to the appropriate section of the homoeopathic pharmacopoeia.

Raw materials and vehicles used should be of an appropriate pharmacopoeial quality unless adequately justified. (See section below on raw materials).

The quantity of raw materials and vehicles used for each batch should be specified. If batch sizes vary, then a representative batch size should be stated.

The nature of containers used for the maceration process should be described, together with the times and conditions used.

2. CONTROL OF STARTING MATERIALS

2.1 Raw Materials

Specifications

Raw materials used should comply with the section on raw materials set out in individual monographs of a homoeopathic pharmacopoeia.

In some instances it may be necessary to include additional controls for monographed raw materials, for example:

Plant Material

- Microscopic examination
- Limit tests for pesticides
- Description of the part of the plant used

Zoological Material and Minerals of Natural Origin

- Bioburden controls or absence of pathogens

Where no monograph exists, applicants will be required to draw up a suitable monograph for the raw material, taking into account the following characteristics as appropriate to the nature of the raw material (which may be botanical, zoological or chemical in origin).

- Description, identity, name and appearance
- Assay
- Melting point, solubility
- Microbiological contamination
- Impurities (including sulphated ash, foreign material)
- Loss on drying

In some cases, for example certain minerals or organic substances, it may be appropriate to refer to monographs in the British or European Pharmacopoeias.

Where guidelines are already established (for example CPMP have provided advice on biological and botanical raw materials) these should be taken into account and additional information provided as appropriate.

Supporting Data

Applicants should provide data to demonstrate compliance with the agreed monographs (batch data or certificates of analysis for three batches). Where additional controls are necessary, evidence should be provided to show that these controls have been met.

Where it has been necessary for an applicant to establish a monograph, the controls and limits applied should be justified and analytical methods validated.

Supporting data for plant material should include details of the source of the material, cultivation and time of harvesting. Details of any drying procedure used and any treatment to reduce levels of microbial contamination should be stated. It is preferable for plant material to be grown organically.

Supporting data for zoological material should include information on the collection, treatment and storage of the source material.

2.2 Vehicles

Vehicles used for the preparation of homoeopathic stocks should be of an appropriate pharmacopoeial specification unless justified.

3. CONTROL OF STOCKS

Applicants should provide satisfactory evidence in the form of batch data or certificates of analysis to demonstrate that the stock meets the agreed specification.

Where a stock is not monographed, the specification used to control the stock should be adequately justified and analytical methods validated.

Where additional controls are used for monographed stocks, evidence should be provided to show that these are met.

4. STABILITY OF STOCKS

Evidence of stability should be provided unless stocks are freshly prepared for immediate use.

The stability of homoeopathic stocks should be established with due reference to the specification used to control the stock at the time of preparation.

Stability should be monitored over an appropriate time period in controlled conditions and a suitable shelf-life established, for example two years. This work may be carried out on an on-going basis and applicants may wish to extend the shelf-life in the light of available information.

Manufacturers of stocks should provide clear advice concerning storage conditions, for example below 25°C, protected from light. Diluted stocks should be assigned the same shelf-life (expiry date) as the original stock.

5. JUSTIFICATION OF THE HOMOEPATHIC NATURE OF THE STOCK

Reference should be made to a suitable Materia Medica such as Clarke or Boericke. Where a stock has not been included in a Materia Medica, appropriate literature references should be provided.

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