MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

GUIDANCE NOTES FOR THE SIMPLIFIED HOMEOPATHIC REGISTRATION SCHEME & UK HOMEOPATHIC NATIONAL RULES SCHEME

THE CONTROL AND QUALITY OF HOMEOPATHIC STOCKS

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Introduction

Applications to register or authorise homeopathic medicinal products should be accompanied by supporting data on the production and control of the homeopathic stock. The special nature of homeopathic 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 document provides guidance on data required to demonstrate the pharmaceutical quality and batch-to-batch homogeneity of the products concerned.

1. PREPARATION OF STOCKS

The definition of a homeopathic medicinal product is given in the Human Medicines Regulations.

For homeopathic products marketed in the whole of the United Kingdom or Northern Ireland only: Products must be prepared from homeopathic stocks made following a homeopathic manufacturing procedure described in the European Pharmacopoeia, or in the absence of a description there, the British Pharmacopoeia or a pharmacopoeia used officially in an EEA State.

For homeopathic products marketed in Great Britain only:
Products must be prepared from homeopathic stocks made following a homeopathic manufacturing procedure described in the European Pharmacopoeia, or in the absence of a description there, the British Pharmacopoeia or a pharmacopoeia used officially in a country that is included in a list published by the MHRA.

The MHRA list can be found at the following link: https://www.gov.uk/guidance/register-a-homeopathic-medicine-or-remedy

Applicants should refer to the appropriate section of the relevant 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 the individual monographs of a homeopathic pharmacopoeia to which reference is made

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

Plant Material

- Description of the part of the plant used
- Microscopic examination
- Limit tests for pesticides
- Heavy metals
- AflatoxinsPyrrolizidine alkaloids

Zoological Material and Minerals of Natural Origin

- Bioburden controls or absence of pathogens
- Minimising the risk of transmitting animal spongiform encephalopathy (TSE)

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 European or British Pharmacopoeias, or in a pharmacopoeia used officially in an EEA State for homeopathic products marketed in the whole of the UK or Northern Ireland only. For homeopathic products marketed in Great Britain only it may be appropriate to refer to monographs in the European or British Pharmacopoeias, or in any pharmacopoeia used officially in a country that is included in a list published by the MHRA.

Where guidelines are already established 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. Plant material should be grown in accordance with Good Agricultural and Collection Practices (GACP).

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 homeopathic 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 homeopathic 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 25ºC, protected from light. Diluted stocks should be assigned the same shelf-life (expiry date) as the original stock.

5. JUSTIFICATION OF THE HOMEPATHIC NATURE OF THE STOCK FOR THE SIMPLIFIED HOMEOPATHIC REGISTRATION SCHEME.

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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