Edition: BP 2025 (Ph. Eur. 11.6 update)

Premixes

General Notices

(Premixes for Medicated Feeding Stuffs for Veterinary Use, Ph. Eur. monograph 1037)

Premixes comply with the requirements of the European Pharmacopoeia monograph for Premises for Medicated Feeding Stuffs for Veterinary Use. These requirements are reproduced below.

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DEFINITION

Mixtures of one or more active substances, usually in a suitable basis or vehicle, that are prepared to facilitate feeding the active substances to animals. They are used exclusively in the preparation of medicated feeding stuffs.

Premixes occur in granulated, powdered, semi-solid or liquid form. Used as powders or granules, they are free-flowing and homogeneous; any aggregates break apart during normal handling. Used in liquid form, they are homogeneous suspensions or solutions that may be obtained from thixotropic gels or structured liquids. The particle size and other properties are such as to ensure uniform distribution of the active substance(s) in the final feed. Unless otherwise justified and authorised, the instructions for use state that the concentration of a premix in granulated or powdered form is at least 0.5 per cent in the medicated feeding stuff.

PRODUCTION

In the manufacture, packaging, storage and distribution of premixes for medicated feeding stuffs for veterinary use, suitable measures are taken to ensure their microbial quality; recommendations on this aspect are provided in general chapter *5.1.4*. *Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use*.

Active substance

Unless already otherwise justified and authorised for existing premixes, an active substance intended for incorporation into a medicated premix:

— complies with the requirements of the relevant monograph of the European Pharmacopoeia;

— in the case of a fermentation product that is not the subject of a monograph of the European Pharmacopoeia, complies with the monograph *Products of fermentation (1468)*, notably with the section Down-stream processing.

TESTS

Loss on drying (*2.2.32*)

Unless otherwise justified and authorised, for premixes occurring in granulated or powdered form, maximum 15.0 per cent, determined on 3.000 g by drying in an oven at 105 °C for 2 h.

LABELLING

The label states the instructions for the preparation of the medicated feeding stuffs from the premix and the basic feed, including information on whether or not the premix can be granulated with the feed and the critical parameters (e.g. maximum temperature) that may be applied during the process.

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