

Premixes

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 'Acceptance Criteria for Microbiological Quality of Non Sterile Pharmaceutical Substances and Non Sterile Doses Forms (2.2.9)'

Active substance

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

- complies with the requirements of the relevant monograph of the [Indian Pharmacopoeia](#);
- in the case of a fermentation product that is not the subject of a monograph of the [Indian Pharmacopoeia](#), complies with the general chapter - [Drug substances Manufactured by Cell Culture/Fermentation \(2.2.22\)](#).

Tests

Loss on drying (2.4.19).

Unless otherwise justified and authorized, for premixes occurring in granulated or powdered form, maximum 15.0 per cent, determined on 3g by drying in an oven at 105° for 2 hour.

Labelling. The label states (1) the strength in terms of the amount of active ingredient(s) as a percentage; (2) the category of animal for which the premix is intended to be used; (3) the directions for the preparation of the medicated feed; (4) where applicable, the minimum interval between the stoppage of feeding of the diluted premix and the slaughter of the animal for human consumption; (5) any special precautions to be taken for use of the premix; (6) the storage conditions; (7) the date after which the preparation is not intended to be used.