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Veterinary Semi-solid Preparations for Oral Use

General Notices

(Ph. Eur. monograph 2638)

Ph Eur

DEFINITION

Veterinary semi-solid preparations for oral use (usually pastes or gels) contain one or more active substances dissolved or dispersed in a suitable basis. They are administered to the oral cavity and are intended to be swallowed for delivery of active substances to the gastrointestinal tract.

Veterinary semi-solid preparations for oral use may contain suitable antimicrobial preservatives and other excipients such as dispersing, suspending, thickening, emulsifying, buffering, wetting, solubilising, stabilising, flavouring and sweetening agents.

Veterinary semi-solid preparations for oral use are usually supplied in multidose containers such as oral syringes, which are designed to allow the accurate dosing of animals according to their bodyweight.

Where applicable, containers for veterinary semi-solid preparations for oral use comply with the requirements described in *Materials used for the manufacture of containers* (*3.1* and subsections) and *Containers* (*3.2* and subsections).

PRODUCTION

During the development of veterinary semi-solid preparations for oral use whose formulation contains an antimicrobial preservative, the need for and the efficacy of the chosen preservative shall be demonstrated to the satisfaction of the competent authority. A suitable test method together with criteria for judging the preservative properties of the formulation are provided in general chapter *5.1.3*. *Efficacy of antimicrobial preservation*.

In the manufacture, packaging, storage and distribution of veterinary semi-solid preparations for oral use, suitable measures are taken to ensure their microbiological quality; recommendations on this are provided in general chapter *5.1.4*. *Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use*.

TESTS

Dissolution

A suitable test may be carried out to demonstrate the appropriate release of the active substance(s).

Uniformity of mass of delivered doses from multidose containers (*2.9.27*)

Unless otherwise justified and authorised, the minimum and the maximum labelled doses are tested, where possible using the same container and dosing device.

Discharge once to waste in order to prime the system, if so stated on the label and depending on the type and shape of the container.

Unless otherwise justified and authorised, the preparation complies with the test.

STORAGE

If the preparation contains water or other volatile ingredients, store in an airtight container.

LABELLING

The label states:

— the name of any added antimicrobial preservative;

— if it is necessary to prime the dosing device before administration.