Intramammary preparations for veterinary use are prepared using materials and methods designed to ensure sterility and to avoid the introduction of contaminants and the growth of micro-organisms; recommendations on this aspect are provided in the text on Methods of preparation of sterile products (5.1.1). In the manufacture of intramammary preparations for veterinary use containing dispersed particles, measures are taken to ensure a suitable and controlled particle size with regard to the intended use.

TESTS

**Deliverable mass or volume.** Squeeze out as much as possible of the contents of ten containers according to the instructions on the label. The mean mass or volume does not differ by more than 10 per cent from the nominal mass or volume.

**Sterility (2.6.1).** Intramammary preparations for veterinary use comply with the test for sterility; use the technique of membrane filtration or, in justified cases, direct inoculation of the culture media. Squeeze out the contents of ten containers and mix thoroughly. For each medium, use 0.5 g to 1 g (or 0.5 ml to 1 ml as appropriate) taken from the mixed sample.

**STORAGE**

Store in a sterile, airtight, tamper-proof container.

**LABELLING**

The label states:

- the name of the active substance(s) and the mass or number of International Units of the active substance(s) that may be delivered from the container using normal technique,
- whether the preparation is intended for use in a lactating animal or a non-lactating animal,
- in the case of multidose containers, the name of any added antimicrobial preservative.

**INTRARUMINAL DEVICES**

**Praeparationes intraruminales**

The requirements of this monograph do not apply to preparations (sometimes known as boluses), such as large conventional tablets, capsules or moulded dosage forms which give immediate or prolonged release of the active substance(s). Such preparations comply with the relevant parts of the monographs on Capsules (0016) or Tablets (0478).

**DEFINITION**

Intraruminal devices are solid preparations each containing one or more active substances. They are intended for oral administration to ruminant animals and are designed to be retained in the rumen to deliver the active substance(s) in a continuous or pulsatile manner. The period of release of the active substance(s) may vary from days to weeks according to the nature of the formulation and/or the delivery device. Intraruminal devices may be administered using a balling gun. Some intraruminal devices are intended to float on the surface of the ruminal fluid while others are intended to remain on the floor of the rumen or reticulum. Each device has a density appropriate for its intended purpose.

**PRODUCTION**

For continuous release, the intraruminal device is designed to release the active substance(s) at a defined rate over a defined period of time. This may be achieved by erosion, corrosion, diffusion, osmotic pressure or any other suitable chemical, physical or physico-chemical means.

For pulsatile-release, the intraruminal device is designed to release a specific quantity of active substance(s) at one or several defined intermediate times. This may be achieved by corrosion by ruminal fluids of the metallic elements of the intraruminal device which leads to sequential release of the constituent units which are usually in the form of tablets.

In the manufacture of intraruminal devices, means are taken to ensure an appropriate release of the active substance(s). In the manufacture, packaging, storage and distribution of intraruminal devices, suitable means are taken to ensure their microbial quality; recommendations on this aspect are provided in the text on Microbiological quality of pharmaceutical preparations (5.1.4).

**TESTS**

**Uniformity of content (2.9.6).** Unless otherwise justified and authorised, constituent tablet units of intraruminal devices in which the active substances are present at levels less than 2 mg or less than 2 per cent of the total mass comply with test A for uniformity of content of single-dose preparations. If the preparation contains more than one active substance, the requirement applies only to those substances which correspond to the above conditions.

**Uniformity of mass (2.9.5).** Unless otherwise justified and authorised, the constituent tablet units of intraruminal devices comply with the test for uniformity of mass. If the test for uniformity of content is prescribed for all active substances, the test for uniformity of mass is not required.

**LABELLING**

The label states:

- for continuous-release devices, the dose released per unit time,
- for pulsatile-release devices, the dose released at specified times.

**LIQUID PREPARATIONS FOR CUTANEOUS APPLICATION**

**Praeparationes liquidae ad usum dermicum**

Where justified and authorised, the requirements of this monograph do not apply to preparations intended for systemic and veterinary use.

**DEFINITION**

Liquid preparations for cutaneous application are preparations of a variety of viscosities intended for local or transdermal delivery of active ingredients. They are solutions, emulsions or suspensions which may contain one or more active substances in a suitable vehicle. They may contain suitable antimicrobial preservatives, antioxidants and other excipients such as stabilisers, emulsifiers and thickeners.

Emulsions may show evidence of phase separation but are readily redispersed on shaking. Suspensions may show a sediment which is readily dispersed on shaking to give a suspension which is sufficiently stable to enable a homogeneous preparation to be delivered.
Where applicable, containers for liquid preparations for cutaneous application comply with the requirements of Materials used for the manufacture of containers (3.1 and subsections) and Containers (3.2 and subsections).

When liquid preparations for cutaneous application are dispensed in pressurised containers, the containers comply with the requirements of the monograph on Pressurised pharmaceutical preparations (60523).

Preparations specifically intended for use on severely injured skin are sterile.

Several categories of liquid preparations for cutaneous application may be distinguished, for example:
- shampoos,
- cutaneous foams.

**PRODUCTION**

During the development of a liquid preparation for cutaneous application, the formulation for which contains an antimicrobial preservative, the effectiveness 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 the text on Efficacy of antimicrobial preservation (5.1.3).

In the manufacture, packaging, storage and distribution of liquid preparations for cutaneous application, suitable means are taken to ensure their microbial quality; recommendations on this aspect are provided in the text on Microbiological quality of pharmaceutical preparations (5.1.4).

Sterile liquid preparations for cutaneous application are prepared using materials and methods designed to ensure sterility and to avoid the introduction of contaminants and the growth of micro-organisms; recommendations on this aspect are provided in the text on Methods of preparation of sterile products (5.1.1).

In the manufacture of liquid preparations for cutaneous application containing dispersed particles, measures are taken to ensure a suitable and controlled particle size with regard to the intended use.

**TESTS**

**Deliverable mass or volume (2.9.28).** Liquid preparations for cutaneous application supplied in single-dose containers comply with the test.

**Sterility (2.6.1).** Where the label indicates that the preparation is sterile, it complies with the test for sterility.

**STORAGE**

If the preparation is sterile, store in a sterile, airtight, tamper-proof container.

**LABELLING**

The label states:
- the name of any added antimicrobial preservative,
- where applicable, that the preparation is sterile.

**Shampoos**

**DEFINITION**

Shampoos are liquid or, occasionally semi-solid preparations intended for application to the scalp and subsequent washing away with water. Upon rubbing with water they usually form a foam.

They are emulsions, suspensions or solutions. Shampoos normally contain surface active agents.

**Cutaneous foams**

**DEFINITION**

Cutaneous foams comply with the requirements of the monograph on Medicated foams (1105).

**LIQUID PREPARATIONS FOR ORAL USE**

**Praeparationes liquidae peroraliae**

Where justified and authorised, the requirements of this monograph do not apply to liquid preparations for oral use intended for veterinary use.

**DEFINITION**

Liquid preparations for oral use are usually solutions, emulsions or suspensions containing one or more active substances in a suitable vehicle; they may, however, consist of liquid active substances used as such (oral liquids). Some preparations for oral use are prepared by dilution of concentrated liquid preparations, or from powders or granules for the preparation of oral solutions or suspensions, for oral drops or for syrups, using a suitable vehicle.

The vehicle for any preparations for oral use is chosen having regard to the nature of the active substance(s) and to provide organoleptic characteristics appropriate to the intended use of the preparation.

Liquid preparations for oral use may contain suitable antimicrobial preservatives, antioxidants and other excipients such as dispersing, suspending, thickening, emulsifying, buffering, wetting, solubilising, stabilising, flavouring and sweetening agents and colouring matter, authorised by the competent authority.

Emulsions may show evidence of phase separation but are readily redispersed on shaking. Suspensions may show a sediment which is readily dispersed on shaking to give a suspension which remains sufficiently stable to enable the correct dose to be delivered.

Where applicable, containers for liquid preparations for oral use comply with the requirements of Materials used for the manufacture of containers (3.1 and subsections) and Containers (3.2 and subsections).

Several categories of preparations may be distinguished:
- oral solutions, emulsions and suspensions,
- powders and granules for oral solutions and suspensions,
- oral drops,
- powders for oral drops,
- syrups,
- powders and granules for syrups.

**PRODUCTION**

During the development of a preparation for oral use, the formulation for which contains an antimicrobial preservative, the effectiveness 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 the text on Efficacy of antimicrobial preservation (5.1.3).

In the manufacturing, packaging, storage and distribution of liquid preparations for oral use, suitable means are taken to ensure their microbial quality; recommendations on this aspect are provided in the text on Microbiological quality of pharmaceutical preparations (5.1.4).