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Intraruminal Delivery Systems

General Notices

(Ph. Eur. monograph 1228)

Intraruminal Delivery Systems comply with the requirements of the European Pharmacopoeia. These requirements are reproduced below.

Ph Eur

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

DEFINITION

Intraruminal delivery systems are solid preparations each containing one or more active substances. They are intended for oral administration to ruminant animals, and may be administered by means of a suitable device. They 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 system.

Some intraruminal delivery systems 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 delivery system has a density appropriate for its intended purpose.

PRODUCTION

For continuous release, the intraruminal delivery system 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 delivery system 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 delivery system, leading to sequential release of the constituent units, which are usually in the form of tablets.

In the manufacture of intraruminal delivery systems, measures are taken to ensure an appropriate release of the active substance(s).

In the manufacture, packaging, storage and distribution of intraruminal delivery systems, 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*.

TESTS

Uniformity of dosage units

Constituent dosage units of intraruminal delivery systems comply with the test for uniformity of dosage units (*2.9.40*) or, where justified and authorised, with the tests for uniformity of content and/or uniformity of mass shown below. Herbal drugs and herbal drug preparations present in the dosage form are not subject to the provisions of this paragraph.

Uniformity of content (*2.9.6*)

Unless otherwise justified and authorised, constituent dosage units of intraruminal delivery systems 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 that correspond to the above conditions.

Uniformity of mass (*2.9.5*)

Unless otherwise justified and authorised, the constituent dosage units of intraruminal delivery systems 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 delivery systems, the dose released per unit time;

— for pulsatile-release delivery systems, the dose released at specified times.