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Intrauterine Preparations

General Notices

(Intrauterine Preparations for Veterinary Use, Ph. Eur. monograph 1806)

Intrauterine Preparations comply with the requirements of the European Pharmacopoeia. These requirements are reproduced below.

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DEFINITION

Intrauterine preparations for veterinary use are liquid, semi-solid or solid preparations intended for the direct administration to the uterus (cervix, cavity or fundus), usually in order to obtain a local effect. They contain 1 or more active substances in a suitable basis.

Where appropriate, containers for intrauterine preparations for veterinary use comply with the requirements for *Materials used for the manufacture of containers* (*3.1* and subsections) and *Containers* (*3.2* and subsections).

Several categories of intrauterine preparations for veterinary use may be distinguished:

— intrauterine tablets;

— intrauterine capsules;

— intrauterine solutions, emulsions and suspensions, concentrates for intrauterine solutions;

— tablets for intrauterine solutions and suspensions;

— semi-solid intrauterine preparations;

— intrauterine foams;

— intrauterine sticks.

PRODUCTION

During the development of an intrauterine preparation for veterinary use, the effectiveness of any added antimicrobial 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 under *Efficacy of antimicrobial preservation* (*5.1.3*).

In the manufacture, packaging, storage and distribution of intrauterine preparations for veterinary use, suitable measures are taken to ensure their microbial quality; recommendations on this aspect are provided in the text on *5.1.4*. *Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use*, see Table 5.1.4.-1. – *Cutaneous use*.

Sterile intrauterine 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*).

During development, it must be demonstrated that the nominal content can be withdrawn from the container of liquid and semi-solid intrauterine preparations for veterinary use presented in single-dose containers.

TESTS

Uniformity of dosage units (*2.9.40*)

Single-dose intrauterine preparations for veterinary use comply with the test 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 prescribed or justified and authorised, solid single-dose preparations with a content of active substance less than 2 mg or less than 2 per cent of the total mass comply with test A (intrauterine tablets) or test B (intrauterine capsules) for uniformity of content of single-dose preparations. If the preparation has more than 1 active substance, the requirement applies only to those substances which correspond to the above conditions.

Uniformity of mass (*2.9.5*)

Solid single-dose intrauterine preparations for veterinary use comply with the test for uniformity of mass of single-dose preparations. If the test for uniformity of content is prescribed or justified and authorised for all the active substances, the test for uniformity of mass is not required.

Dissolution

A suitable test may be carried out to demonstrate the appropriate release of the active substance(s) from solid single-dose intrauterine preparations for veterinary use, for example one of the tests described in *Dissolution test for solid dosage forms* (*2.9.3*).

When a dissolution test is prescribed, a disintegration test may not be required.

Sterility (*2.6.1*)

Sterile intrauterine preparations for veterinary use comply with the test for sterility. Applicators supplied with the preparation also comply with the test for sterility. Remove the applicator with aseptic precautions from its package and transfer it to a tube of culture medium so that it is completely immersed. Incubate and interpret the results as described in the test for sterility.

LABELLING

The label states:

— the name of any added antimicrobial preservative;

— where applicable, that the preparation is sterile.

INTRAUTERINE TABLETS

DEFINITION

Intrauterine tablets are solid preparations each containing a single dose of 1 or more active substances. They generally conform to the definition given in the monograph on *Tablets (0478)*.

A suitable applicator may be used for application into the uterus.

TESTS

Disintegration (*2.9.2*)

Unless intended for prolonged local action, intrauterine tablets comply with the test. Examine the state of the tablets after 30 min, unless otherwise justified and authorised.

INTRAUTERINE CAPSULES

DEFINITION

Intrauterine capsules are solid, single-dose preparations. They are generally similar to soft capsules, differing only in their shape and size. Intrauterine capsules have various shapes, usually ovoid. They are smooth and have a uniform external appearance.

A suitable applicator may be used for application into the uterus.

TESTS

Disintegration (*2.9.2*)

Unless intended for prolonged local action, intrauterine capsules comply with the test. Examine the state of the capsules after 30 min, unless otherwise justified and authorised.

INTRAUTERINE SOLUTIONS, SUSPENSIONS AND EMULSIONSCONCENTRATES FOR INTRAUTERINE SOLUTIONS

DEFINITION

Intrauterine solutions, suspensions and emulsions are liquid preparations. Concentrates for intrauterine solutions are intended for administration after dilution.

They may contain excipients, for example to adjust the viscosity of the preparation, to adjust or stabilise the pH, to increase the solubility of the active substance(s) or to stabilise the preparation. The excipients do not adversely affect the intended medical action, or, at the concentrations used, cause undue local irritation.

Intrauterine emulsions may show evidence of phase separation, but are readily redispersed on shaking. Intrauterine suspensions may show a sediment that is readily dispersed on shaking to give a suspension which remains sufficiently stable to enable a homogeneous preparation to be delivered.

They may be supplied in single-dose containers. The container is adapted to deliver the preparation to the uterus or it may be accompanied by a suitable applicator.

PRODUCTION

In the manufacture of intrauterine suspensions, measures are taken to ensure a suitable and controlled particle size with regard to the intended use.

TABLETS FOR INTRAUTERINE SOLUTIONS AND SUSPENSIONS

DEFINITION

Tablets intended for the preparation of intrauterine solutions and suspensions are single-dose preparations which are dissolved or dispersed in water at the time of administration. They may contain excipients to facilitate dissolution or dispersion or to prevent caking.

Tablets for intrauterine solutions or suspensions conform with the definition given in the monograph on *Tablets (0478)*.

After dissolution or dispersion, they comply with the requirements for intrauterine solutions or intrauterine suspensions, as appropriate.

TESTS

Disintegration (*2.9.1*)

Tablets for intrauterine solutions or suspensions disintegrate within 3 min using *water R* at 15-25 °C.

LABELLING

The label states:

— the method of preparation of the intrauterine solution or suspension;

— the conditions and duration of storage of the solution or suspension after reconstitution.

SEMI-SOLID INTRAUTERINE PREPARATIONS

DEFINITION

Semi-solid preparations for intrauterine use are ointments, creams or gels.

Semi-solid preparations for intrauterine use comply with the requirements of the monograph on *Semi-solid preparations for cutaneous application (0132)*.

They are often supplied in single-dose containers. The container is adapted to deliver the preparation to the uterus or it may be accompanied by a suitable applicator.

INTRAUTERINE FOAMS

DEFINITION

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

They are supplied in multidose containers. The container is adapted to deliver the preparation to the uterus or it may be accompanied by a suitable applicator.

INTRAUTERINE STICKS

DEFINITION

Intrauterine sticks comply with the requirements of the monograph on *Sticks (1154)*. They often produce a foam when coming into contact with physiological fluids.

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