**VAGINAL PREPARATIONS**

**Vaginalia**

**DEFINITION**
Vaginal preparations are liquid, semi-solid or solid preparations intended for administration to the vagina usually in order to obtain a local effect. They contain one or more active substances in a suitable basis.

Where appropriate, containers for vaginal preparations 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 vaginal preparations may be distinguished:

- pessaries,
- vaginal tablets,
- vaginal capsules,
- vaginal solutions, emulsions and suspensions,
- tablets for vaginal solutions and suspensions,
- semi-solid vaginal preparations,
- vaginal foams,
- medicated vaginal tampons.

**PRODUCTION**

In the manufacturing, packaging, storage and distribution of vaginal preparations, 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 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 (vaginal tablets) or test B (pessaries, vaginal capsules) for uniformity of content of single-dose preparations. If the preparation has more than one active substance, the requirement applies only to those substances which correspond to the above conditions.

**Uniformity of mass** (2.9.5). Solid single-dose vaginal preparations comply with the test for uniformity of mass of single-dose preparations. If the test for uniformity of content is prescribed for all the active substances, the test for uniformity of mass is not required.

**Deliverable mass or volume** (2.9.28). Liquid and semi-solid vaginal preparations supplied in single-dose containers comply with the test.

**Dissolution.** A suitable test may be carried out to demonstrate the appropriate release of the active substance(s) from solid single-dose preparations, 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.

**Pessaries**

**DEFINITION**
Pessaries are solid, single-dose preparations. They have various shapes, usually ovoid, with a volume and consistency suitable for insertion into the vagina. They contain one or more active substances dispersed or dissolved in a suitable basis that may be soluble or dispersible in water or may melt at body temperature. Excipients such as diluents, adsorbents, surface-active agents, lubricants, antimicrobial preservatives and colouring matter authorised by the competent authority may be added, if necessary.

**PRODUCTION**
Pessaries are usually prepared by moulding. Where appropriate in the manufacture of pessaries, measures are taken to ensure a suitable and controlled particle size of the active substance(s). If necessary, the active substance(s) are previously ground and sieved through a suitable sieve. Pessaries are moulded into any suitable shape, suitable for insertion into the vagina. They are usually in order to obtain a local effect. They contain one or more active substances in a suitable basis.

When prepared by moulding, the medicated mass, sufficiently liquified by heating, is poured into suitable moulds. The pessary solidifies on cooling. Various excipients are available for this process, such as hard fat, macrogols, cocoa butter, and various gelatinous mixtures consisting, for example, of gelatin, water and glycerol.

A suitable test is carried out to demonstrate the appropriate release of the active substance(s) from pessaries intended for prolonged local action.

Where appropriate, the determination of the resistance to rupture of pessaries (2.9.24) is carried out.

**TESTS**

**Disintegration.** Unless intended for prolonged local action, they comply with the test for disintegration of suppositories and pessaries (2.9.2). Examine the state of the pessaries after 60 min, unless otherwise justified and authorised.

**Vaginal tablets**

**DEFINITION**
Vaginal tablets are solid, single-dose preparations. They generally conform to the definitions of uncoated or film-coated tablets given in the monograph on Tablets (0478).

**PRODUCTION**

A suitable test is carried out to demonstrate the appropriate release of the active substance(s) from vaginal tablets intended for prolonged local action.

**TESTS**

**Disintegration.** Unless intended for prolonged local action, they comply with the test for disintegration of suppositories and pessaries (special method for vaginal tablets, 2.9.2). Examine the state of the tablets after 30 min, unless otherwise justified and authorised.

**Vaginal capsules**

**DEFINITION**
Vaginal capsules (shell pessaries) are solid, single-dose preparations. They are generally similar to soft capsules, differing only in their shape and size. Vaginal capsules have various shapes, usually ovoid. They are smooth and have a uniform external appearance.

**PRODUCTION**

A suitable test is carried out to demonstrate the appropriate release of the active substance(s) from vaginal capsules intended for prolonged local action.

**TESTS**

**Disintegration.** Unless intended for prolonged local action, they comply with the test for disintegration of suppositories and pessaries (2.9.2). Examine the state of the capsules after 30 min, unless otherwise justified and authorised.
**Vaginal solutions, emulsions and suspensions**

**DEFINITION**
Vaginal solutions, emulsions and suspensions are liquid preparations intended for a local effect, for irrigation or for diagnostic purposes. 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.

Vaginal emulsions may show evidence of phase separation but are readily redispersed on shaking. Vaginal 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 are supplied in single-dose containers. The container is adapted to deliver the preparation to the vagina or it is accompanied by a suitable applicator.

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

**Tablets for vaginal solutions and suspensions**

**DEFINITION**
Tablets intended for the preparation of vaginal 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.

Apart from the test for disintegration, tablets for vaginal solutions or suspensions conform with the definition for Tablets (0478).

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

**TESTS**
**Disintegration.** Tablets for vaginal solutions or suspensions disintegrate within 3 min when tested according to the test for disintegration of tablets and capsules (2.9.1), but using water R at 15 °C to 25 °C.

**LABELLING**
The label states:
- the method of preparation of the vaginal solution or suspension,
- the conditions and duration of storage of the solution or suspension after constitution.

**Semi-solid vaginal preparations**

**DEFINITION**
Semi-solid vaginal preparations are ointments, creams or gels.

They are often supplied in single-dose containers. The container is provided with a suitable applicator.

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

**Vaginal foams**

**DEFINITION**
Vaginal foams comply with the requirements of the monograph on Medicated foams (1165).

**Medicated vaginal tampons**

**DEFINITION**
Medicated vaginal tampons are solid, single-dose preparations intended to be inserted in the vagina for a limited time.

They comply with the requirements of the monograph on Medicated tampons (1155).

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**VETERINARY LIQUID PREPARATIONS FOR CUTANEOUS APPLICATION**

Praeparationes liquidae veterinariae ad usum dermicum

*Unless otherwise justified and authorised, veterinary liquid preparations for cutaneous application comply with the requirements of the monograph on Liquid preparations for cutaneous application (0927). In addition to these requirements, the following statements apply to veterinary liquid preparations for cutaneous application.*

**DEFINITION**
Veterinary liquid preparations for cutaneous application are liquid preparations intended to be applied to the skin to obtain a local and/or systemic effect. They are solutions, suspensions or emulsions which may contain one or more active substances in a suitable vehicle. They may be presented as concentrates in the form of wettable powders, pastes, solutions or suspensions, which are used to prepare diluted suspensions or emulsions of active substances. They may contain suitable antimicrobial preservatives, antioxidants and other excipients such as stabilisers, emulsifiers and thickeners.

Several categories of veterinary liquid preparations for cutaneous application may be distinguished:
- cutaneous foams (see Liquid preparations for cutaneous application (0927)),
- dip concentrates,
- pour-on preparations,
- shampoos (see Liquid preparations for cutaneous application (0927)),
- spot-on preparations,
- sprays,
- teat dips,
- teat sprays,
- udder-washes.

**Dip concentrates**

**DEFINITION**
Dip concentrates are preparations containing one or more active substances, usually in the form of wettable powders, pastes, solutions or suspensions, which are used to prepare diluted solutions, suspensions or emulsions of active substances. The diluted preparations are applied by complete immersion of the animal.