— for a container with a metering dose valve, the amount of active substance in a unit-spray.

**RECTAL PREPARATIONS**

**DEFINITION**

Rectal preparations are intended for rectal use in order to obtain a systemic or local effect, or they may be intended for diagnostic purposes.

Where applicable, containers for rectal preparations comply with the requirements for manufacture of containers (3.1 and subsections) and Containers (3.2 and subsections).

Several categories of rectal preparations may be distinguished:

— suppositories,
— rectal capsules,
— rectal solutions, emulsions and suspensions,
— powders and tablets for rectal solutions and suspensions,
— semi-solid rectal preparations,
— rectal foams,
— rectal tampons.

**PRODUCTION**

During the development of a rectal preparation, 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 rectal 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).

In the manufacture of semi-solid and liquid rectal preparations containing dispersed particles measures are taken to ensure a suitable and controlled particle size with regard to the intended use.

**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 (tablets) or test B (suppositories, rectal capsules) for uniformity of content of single-dose preparations. If the preparation contains more than one active substance, this requirement applies only to those substances that correspond to the above conditions.

**Uniformity of mass** (2.9.5). Solid, single-dose preparations 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.

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

**Rectal capsules**

**DEFINITION**

Rectal capsules (shell suppositories) are solid, single-dose preparations generally similar to soft capsules as defined in the monograph on Capsules (0016) except that they may have lubricating coatings. They are of elongated shape, 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 rectal capsules intended for modified release or for prolonged local action.

**Disintegration.** A suitable test may be required to demonstrate the appropriate release of the active substance(s) from solid, single-dose preparations, for example the dissolution test for suppositories and soft capsules (2.9.3).

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

**LABELLING**

The label states the name of any added antimicrobial preservative.

**Suppositories**

**DEFINITION**

Suppositories are solid, single-dose preparations. The shape, volume and consistency of suppositories are suitable for rectal administration.

They contain one or more active substances dispersed or dissolved in a suitable basis which 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**

Suppositories are prepared by compression or moulding. If necessary, the active substance(s) are previously ground and sieved through a suitable sieve. When prepared by moulding, the medicated mass, sufficiently liquefied by heating, is poured into suitable moulds. The suppository solidifies on cooling. Various excipients are available for this process, such as hard fat, macrogols, cocoa butter, and various gelatinous mixtures consisting of, for example, gelatin, water and glycerol. Where applicable, the determination of the softening time of lipophilic suppositories (2.9.22) and/or the determination of the resistance to rupture of suppositories (2.9.24) are carried out.

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

In the manufacture of suppositories containing dispersed active substances, measures are taken to ensure a suitable and controlled particle size.

**TESTS**

**Disintegration.** Unless intended for modified release or for prolonged local action, they comply with the test for disintegration of suppositories and pessaries (2.9.2). For suppositories with a fatty base, examine after 30 min and for suppositories with a water-soluble base after 60 min, unless otherwise justified and authorised.

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**Rectal foam**

**DEFINITION**

Rectal foam is a liquid, single-dose preparation generally similar to ointments as defined in the monograph on Ointments (0015) except that the foam (emulsion) may be dispersed in a suitable basis.

**PRODUCTION**

A suitable test may be required to demonstrate the appropriate release of the active substance(s) from rectal foam intended for modified release or for prolonged local action.
Rectal solutions, emulsions and suspensions

DEFINITION
Rectal solutions, emulsions and suspensions are liquid preparations intended for rectal use in order to obtain a systemic or local effect, or they may be intended for diagnostic purposes.

Rectal solutions, emulsions and suspensions are supplied in single-dose containers and they contain one or more active substances dissolved or dispersed in water, glycerol or macrogols or other suitable solvents. Emulsions may show evidence of phase separation but are readily redispersed on shaking. Suspensions may show a sediment which is readily dispersible on shaking to give a suspension which remains sufficiently stable to enable the correct dose to be delivered. Rectal solutions, emulsions and suspensions 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. These substances do not adversely affect the intended medical action or, at the concentrations used, cause undue local irritation.

Rectal solutions, emulsions and suspensions are supplied in containers containing a volume in the range of 2.5 ml to 2000 ml. The container is adapted to deliver the preparation to the rectum or it is accompanied by a suitable applicator.

Powders and tablets for rectal solutions and suspensions

DEFINITION
Powders and tablets intended for the preparation of rectal solutions or 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 aggregation of the particles. After dissolution or suspension, they comply with the requirements for rectal solutions or rectal suspensions, as appropriate.

TESTS
Disintegration. Tablets for rectal solutions or suspensions disintegrate within 3 min when tested according to the test for disintegration of tablets and capsules (2.9.2) but using water R at 15 °C to 25 °C.

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

Semi-solid rectal preparations

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