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.

DEFINITION
Powders and tablets for rectal 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 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 (2.9.7) 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. They are often supplied as single-dose preparations in containers provided with a suitable applicator.

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

Rectal solutions, emulsions and suspensions

Rectal tampons

DEFINITION
Rectal tampons are solid, single-dose preparations intended to be inserted into the lower part of the rectum for a limited time.

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

SEMI-SOLID PREPARATIONS FOR CUTANEOUS APPLICATION

Praeparationes molles ad usum dermicum

The requirements of this monograph apply to all semi-solid preparations for cutaneous application. Where appropriate, additional requirements specific to semi-solid preparations intended to be applied to particular surfaces or mucous membranes may be found in other general monographs, for example Ear preparations (0652), Nasal preparations (0676), Rectal preparations (1145), Eye preparations (1163) and Vaginal preparations (1164).

DEFINITION
Semi-solid preparations for cutaneous application are intended for local or transdermal delivery of active substances, or for their emollient or protective action. They are of homogeneous appearance.

Semi-solid preparations for cutaneous application consist of a simple or compound basis in which, usually, one or more active substances are dissolved or dispersed. According to its composition, the basis may influence the activity of the preparation.

The basis may consist of natural or synthetic substances and may be single phase or multiphase. According to the nature of the basis, the preparation may have hydrophilic or hydrophobic properties; it may contain suitable excipients such as antimicrobial preservatives, antioxidants, stabilisers, emulsifiers, thickeners and penetration enhancers.

Semi-solid preparations for cutaneous application intended for use on severely injured skin are sterile.

Where applicable, containers for semi-solid preparations for cutaneous application 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 semi-solid preparations for cutaneous application may be distinguished:
– ointments,
– creams,
– gels,
– pastes,
Semi-solid preparations for cutaneous application

— poultes,
— medicated plasters.

According to their structure, ointments, creams and gels generally show viscoelastic behaviour and are non-newtonian in character e.g. plastic, pseudoplastic or thixotropic type flow at high shear rates. Pastes frequently exhibit dilatancy.

**PRODUCTION**

During the development of semi-solid preparations for cutaneous application whose formulation contains an antimicrobial preservative, the necessity for and 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 *Efficacy of antimicrobial preservation (5.1.3)*. In the manufacture, packaging, storage and distribution of semi-solid preparations for cutaneous application, suitable steps are taken to ensure their microbiological quality; recommendations on this are provided in *Microbiological Quality of Pharmaceutical Preparations (5.1.4)*. Sterile semi-solid 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 are provided in *Methods of Preparation of Sterile Products (5.1.1)*.

In the manufacture of semi-solid preparations for cutaneous application, suitable measures are taken to ensure that the defined rheological properties are fulfilled. Where appropriate, the following non-mandatory tests may be carried out: measurement of consistency by penetrometry (2.9.28), viscosity (apparent viscosity) (2.2.10) and a suitable test to demonstrate the appropriate release of the active substance(s).

In the manufacture of semi-solid preparations for cutaneous application containing (an) active substance(s) which is/are not dissolved in the basis (e.g. emulsions or suspensions), measures are taken to ensure appropriate homogeneity of the preparation to be delivered.

In the manufacture of semi-solid 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).** Semi-solid 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 contains water or other volatile ingredients, store in an airtight container. 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.

**Ointments**

**DEFINITION**

An ointment consists of a single-phase basis in which solids or liquids may be dispersed.

**Hydrophobic Ointments**

Hydrophobic ointments can absorb only small amounts of water. Typical bases used for their formulation are hard, liquid and light liquid paraffins, vegetable oils, animal fats, synthetic glycereides, waxes and liquid polyalkylsiloxanes.

**Water-emulsifying Ointments**

Water-emulsifying ointments can absorb larger amounts of water and thereby produce water-in-oil or oil-in-water emulsions depending on the nature of the emulsifiers: water-in-oil emulsifying agents such as wool alcohols, sorbitan esters, monoglycerides and fatty alcohols, or oil-in-water emulsifying agents such as sulphated fatty alcohols, polycarbols, macrogel cetosteryl ether or esters of fatty acids with macrogols may be used for this purpose. Their bases are those of the hydrophobic ointments.

**Hydrophilic Ointments**

Hydrophilic ointments are preparations having bases that are miscible with water. The bases usually consist of mixtures of liquid and solid macrogols (polyethylene glycols). They may contain appropriate amounts of water.

**Creams**

**DEFINITION**

Creams are multiphase preparations consisting of a lipophilic phase and an aqueous phase.

**Lipophilic Creams**

Lipophilic creams have as the continuous phase the lipophilic phase. They contain water-in-oil emulsifying agents such as wool alcohols, sorbitan esters and monoglycerides.

**Hydrophilic Creams**

Hydrophilic creams have as the continuous phase the aqueous phase. They contain oil-in-water emulsifying agents such as sodium or trolamine soaps, sulphated fatty alcohols, polycarbols and polyoxy fatty acid and fatty alcohol esters combined, if necessary, with water-in-oil emulsifying agents.

**Gels**

**DEFINITION**

Gels consist of liquids gelled by means of suitable gelling agents.

**Lipophilic Gels**

Lipophilic gels (oleogels) are preparations whose bases usually consist of liquid paraffin with polyethylene or fatty oils gelled with colloidal silica or aluminium or zinc soaps.

**Hydrophilic Gels**

Hydrophilic gels (hydrogels) are preparations whose bases usually consist of water, glycerol or propylene glycol gelled with suitable gelling agents such as starch, cellulose derivatives, caromers and magnesium-aluminium silicates.

**Pastes**

**DEFINITION**

Pastes are semi-solid preparations for cutaneous application containing large proportions of solids finely dispersed in the basis.

**Poultes**

**DEFINITION**

Poultes consist of a hydrophilic heat-retentive basis in which solid or liquid active substances are dispersed. They are usually spread thickly on a suitable dressing and heated before application to the skin.
Medicated plasters

DEFINITION
Medicated plasters are flexible preparations containing one or more active substances. They are intended to be applied to the skin. They are designed to maintain the active substance(s) in close contact with the skin such that these may be absorbed slowly, or act as protective or keratolytic agents.

Medicated plasters consist of an adhesive basis, which may be coloured, containing one or more active substances, spread as a uniform layer on an appropriate support made of natural or synthetic material. It is not irritant or sensitising to the skin. The adhesive layer is covered by a suitable protective liner, which is removed before applying the plaster to the skin. When removed, the protective liner does not detach the preparation from the outer, supporting layer.

Medicated plasters are presented in a range of sizes directly adapted to their intended use or as larger sheets to be cut to the size required. Medicated plasters adhere firmly to the skin. When removed, the protective liner does not cause appreciable injury to the skin or detachment of the preparation from the outer, supporting layer.

TESTS

Dissolution. A suitable test may be required to demonstrate the appropriate release of the active substance(s), for example one of the tests described in Dissolution test for transdermal patches (2.9.4).

STICKS

Styli

Additional requirements for sticks may be found, where appropriate, in other general monographs, for example Nasal preparations (0676).

DEFINITION

Sticks are solid preparations intended for local application. They are rod-shaped or conical preparations consisting of one or more active substances alone or which are dissolved or dispersed in a suitable basis which may dissolve or melt at body temperature.

Urethral sticks and sticks for insertion into wounds are sterile.

PRODUCTION

In the manufacture, packaging, storage and distribution of sticks, 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).

Urethral sticks and other sterile sticks 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 sticks means are taken to ensure that the preparation complies with a test for mass uniformity or, where appropriate, a test for uniformity of content.

TESTS

Sterility (2.6.1). Urethral sticks and sticks for insertion into wounds comply with the test for sterility.

LABELLING

The label states:

- the quantity of active substance(s) per stick,
- for urethral sticks and sticks to be inserted into wounds that they are sterile.

01/2005:0478

TABLETS

Compressi

The requirements of this monograph do not necessarily apply to preparations that are presented as tablets intended for use other than by oral administration. Requirements for such preparations may be found, where appropriate, in other general monographs; for example Rectal preparations (1145), Vaginal preparations (1164) and Oromucosal preparations (1807). This monograph does not apply to lozenges, oral lyophilisates, oral pastes and oral gums. Where justified and authorised, the requirements of this monograph do not apply to tablets for veterinary use.

DEFINITION

Tablets are solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volumes of particles. Tablets are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is liberated.

The particles consist of one or more active substances with or without excipients such as diluents, binders, disintegrating agents, glidants, lubricants, substances capable of modifying the behaviour of the preparation in the digestive tract, colouring matter authorised by the competent authority and flavouring substances.

Tablets are usually right, circular solid cylinders, the end surfaces of which are flat or convex and the edges of which may be bevelled. They may have lines or break-marks and may bear a symbol or other markings. Tablets may be coated. Where applicable, containers for tablets 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 tablets for oral use may be distinguished:

- uncoated tablets,
- coated tablets,
- effervescent tablets,
- soluble tablets,
- dispersible tablets,
- orodispersible tablets,
- gastro-resistant tablets,
- modified-release tablets.

PRODUCTION

Tablets are usually prepared by compressing uniform volumes of particles or particle aggregates produced by granulation methods. In the manufacture of tablets, means are taken to ensure that they possess a suitable mechanical strength to avoid crumbling or breaking on handling or subsequent processing. This may be demonstrated by examining the Friability of uncoated tablets (2.9.7) and the Resistance to crushing of tablets (2.9.8). Chewable tablets are prepared to ensure that they are easily crushed by chewing.