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FORMULATED PREPARATIONS: GENERAL MONOGRAPHS

GLOSSARY

A glossary of terms relating to formulated preparations is included in the 3rd edition of the European Pharmacopoeia [1502]. This glossary is reproduced below.

Ph Eru

The following introductory text provides definitions and/or explanations of terms that may be found in, or used in association with, the general monographs on dosage forms, but that are not defined within them. Where relevant, reference is made to other equivalent terms that may be found in other publications or contexts.

This glossary is given for information.

Standard Term

Standard Terms for describing the pharmaceutical form of a medicinal product, the routes of administration and the containers used have been established by the European Pharmacopoeia Commission and are provided in a separate publication on Standard Terms.

Active substance

The active substance is any component of a medicinal product intended to furnish pharmacological activity or another direct effect in the diagnosis, treatment or prevention of disease, or to affect the structure or function of the human or animal body by pharmacological means. A medicinal product may contain more than one active substance. Equivalent terms: active ingredient, drug substance, medicinal substance.

Excipient

An excipient is any component, other than the active substance(s), present in a medicinal product or used in the manufacture of the product. The intended function of an excipient is to act as the carrier (vehicle or basis) or as a component of the carrier of the active substance(s) and, in so doing, to contribute to product attributes such as stability, biopharmaceutical profile, appearance and patient acceptability and to the ease with which the product can be manufactured. Usually, more than one excipient is used in the formulation of a medicinal product.

Vehicle

A vehicle is the carrier, composed of one or more excipients, for the active substance(s) in a liquid preparation.

Basis

A basis is the carrier, composed of one or more excipients, for the active substance(s) in semi-solid and solid preparations.

Conventional-release dosage forms

Conventional-release dosage forms are preparations showing a release of the active substance(s) which is not deliberately modified by a special formulation design and/or manufacturing method. In the case of a solid dosage form, the dissolution profile of the active substance depends essentially on its intrinsic properties. Equivalent term: immediate-release dosage form.

Modified-release dosage forms

Modified-release dosage forms are preparations where the rate and/or place of release of the active substance(s) is different from that of a conventional-release dosage form administered by the same route. This deliberate modification is achieved by a special formulation design and/or manufacturing method. Modified-release dosage forms include prolonged-release, delayed-release and pulsatile-release dosage forms.

Prolonged-release dosage forms

Prolonged-release dosage forms are modified-release dosage forms showing a slower release of the active substance(s) than that of a conventional-release dosage form administered by the same route. Prolonged-release is achieved by a special formulation design and/or manufacturing method. Equivalent term: extended-release dosage form.

Delayed-release dosage forms

Delayed-release dosage forms are modified-release dosage forms showing a release of the active substance(s) which is delayed. Delayed release is achieved by a special formulation design and/or manufacturing method. Delayed-release dosage forms include gastro-resistant preparations as defined in the general monographs on solid oral dosage forms.

Pulsatile-release dosage forms

Pulsatile-release dosage forms are modified-release dosage forms showing a sequential release of the active substance(s). Sequential release is achieved by a special formulation design and/or manufacturing method.

Large-volume parenterals

Infusions and injections supplied in containers with a nominal content of more than 100 ml.

Small-volume parenterals

Infusions and injections supplied in containers with a nominal content of 100 ml or less.

Ph Eur

CAPSULES

1/01

Capsules comply with the requirements of the 3rd edition of the European Pharmacopoeia [0016]. These requirements are reproduced below.

Ph Eur

The requirements of this monograph do not necessarily apply to preparations that are presented as capsules 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) and Vaginal preparations (1164).

Correspondence between Ph Eur general methods and Appendices of the British Pharmacopoeia is shown on page A9

DEFINITION

Capsules are solid preparations with hard or soft shells of various shapes and capacities, usually containing a single dose of active substance. They are intended for oral administration.

The capsule shells are made of gelatin or other substances, the consistency of which may be adjusted by the addition of substances such as glycerol or sorbitol. Excipients such as surface-active agents, opaque fillers, antimicrobial preservatives, sweeteners, colouring matter authorised by the competent authority and flavouring substances may be added. The capsules may bear surface markings.

The contents of capsules may be solid, liquid or of a paste-like consistency. They consist of one or more active substances with or without excipients such as solvents, diluents, lubricants and disintegrating agents. The contents do not cause deterioration of the shell. The shell, however, is attacked by the digestive fluids and the contents are released.

Where applicable, containers for capsules comply with the requirements of *Materials used for the manufacture of containers* (*3.1* and subsections) and *Containers* (*3.2* and subsections).

Several categories of capsules may be distinguished:
— hard capsules,
— soft capsules,
— gastro-resistant capsules,
— modified-release capsules,
— cachets.

PRODUCTION

In the manufacture, packaging, storage and distribution of capsules, 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, capsules with a content of active substance less than 2 mg or less than 2 per cent of the total mass comply with test B for uniformity of content of single-dose preparations. If the preparation has more than one active substance, the requirement applies only to those ingredients which correspond to the above conditions.

Uniformity of mass (*2.9.5*). Capsules 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.

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

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

STORAGE

Store in a well-closed container, at a temperature not exceeding 30°C.

LABELLING

The label states the name of any added antimicrobial preservative.

Hard Capsules

DEFINITION

Hard capsules have shells consisting of two prefabricated cylindrical sections one end of which is rounded and closed, the other being open.

PRODUCTION

The active substance(s) usually in solid form (powder or granules) are filled into one of the sections which is then closed by slipping the other section over it. The security of the closure may be strengthened by suitable means.

TESTS

Disintegration Hard capsules comply with the test for disintegration of tablets and capsules (*2.9.1*). Use *water R* as the liquid medium. When justified and authorised, *0.1M hydrochloric acid* or *artificial gastric juice R* may be used as the liquid medium. If the capsules float on the surface of the water, a disc may be added. Operate the apparatus for 30 min, unless otherwise justified and authorised and examine the state of the capsules. The capsules comply with the test if all six have disintegrated.

Soft Capsules

DEFINITION

Soft capsules have thicker shells than those of hard capsules. The shells consist of one part and are of various shapes.

PRODUCTION

Soft capsules are usually formed, filled and sealed in one operation but for extemporaneous use, the shell may be prefabricated. The shell material may contain an active substance.

Liquids may be enclosed directly; solids are usually dissolved or dispersed in a suitable vehicle to give a solution or dispersion of a paste-like consistency.

There may be partial migration of the constituents from the capsule contents into the shell and vice versa because of the nature of the materials and the surfaces in contact.

TESTS

Disintegration Soft capsules comply with the test for disintegration of tablets and capsules (*2.9.1*). Use *water R* as the liquid medium. When justified and authorised, *0.1M hydrochloric acid* or *artificial gastric juice R* may be used as the liquid medium. Add a disc to each tube. Liquid active substances dispensed in soft capsules may attack the disc; in such circumstances and where authorised, the disc may be omitted. Operate the apparatus for 30 min, unless otherwise justified and authorised and examine the state of the capsules. If the capsules fail to comply because of adherence to the discs, repeat the test on a further six capsules omitting the discs. The capsules comply with the test if all six have disintegrated.

Modified-Release Capsules

DEFINITION

Modified-release capsules are hard or soft capsules in which the contents or the shell or both contain special excipients or are prepared by a special process designed to modify the rate, the place or the time at which the active substance(s) are released.

Correspondence between Ph Eur general methods and Appendices of the British Pharmacopoeia is shown on page A9

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