

EUROPEAN PHARMACOPOEIA

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01/2002:1502 Prolonged-release dosage forms

GLOSSARY

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 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.

The following monographs on dosage forms are presented, in alphabetical order, in this chapter.

Capsules (0016)

Chewing gums, medicated (1239)

Ear preparations (0652)

Eye preparations (1163)

Foams, medicated (1105)

Granules (0499)

Intramammary preparations for veterinary use (0945)

Intraruminal devices (1228)

Liquid preparations for cutaneous application (0927)

Liquid preparations for oral use (0672)

Nasal preparations (0676)

Parenteral preparations (0520)

Patches, transdermal (1011)

Powders for cutaneous application (1166)

Powders, oral (1165)

Premixes for medicated feeding stuffs for veterinary use (1037)

Preparations for inhalation (0671)

Preparations for irrigation (1116)

Pressurised pharmaceutical preparations (0523)

Rectal preparations (1145)

Semi-solid preparations for cutaneous application (0132)

Sticks (1154)

Tablets (0478)

Tampons, medicated (1155)

Vaginal preparations (1164)

General Notices (1) apply to all monographs and other texts