

EUROPEAN PHARMACOPŌEIA

6.1
supplement

04/2008



EUROPEAN PHARMACOPOEIA

SIXTH EDITION

Supplement 6.1

*Published in accordance with the
Convention on the Elaboration of a European Pharmacopoeia
(European Treaty Series No. 50)*



European Directorate for the
Quality of Medicines & HealthCare



Y2002469

Council of Europe

Strasbourg

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The European Pharmacopoeia is published by the Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM).

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ISBN: 978-92-871-6057-7

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CONTENTS OF SUPPLEMENT 6.1

A vertical line in the margin indicates where part of a text has been revised or corrected. A horizontal line in the margin indicates where part of a text has been deleted. It is to be emphasised that these indications, which are not necessarily exhaustive, are given for information and do not form an official part of the texts. Editorial changes are not indicated. Individual copies of texts will not be supplied.

NEW TEXTS

GENERAL CHAPTERS

- 2.2.60. Melting point - instrumental method
5.15. Functionality-related characteristics of excipients

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 April 2008 at the latest.

Monographs

- Acemetacin (1686)
Bisoprolol fumarate (1710)
Boldo leaf dry extract (1816)
Clopamide (1747)
Desflurane (1666)
Ginkgo dry extract, refined and quantified (1827)

- Liquorice dry extract for flavouring purposes (2378)
Magnesium gluconate (2161)
Manganese gluconate (2162)
Marbofloxacin for veterinary use (2233)
Molsidomine (1701)
Niflumic acid (2115)
Pantoprazole sodium sesquihydrate (2296)
Sanguisorba root (2385)
Selamectin for veterinary use (2268)
Sertraline hydrochloride (1705)
Sodium phenylbutyrate (2183)
Sucrose monopalmitate (2319)
Sucrose stearate (2318)
Willow bark dry extract (2312)

REVISED TEXTS

GENERAL CHAPTERS

- 2.9.40. Uniformity of dosage units
4. Reagents (*new, revised, corrected*)
5.2.7. Evaluation of efficacy of veterinary vaccines and immunosera

MONOGRAPHS

The monographs below have been technically revised since their last publication. They will be implemented on 1 April 2008.

General monographs

Extracts (0765)

Vaccines for human use

- Measles, mumps and rubella vaccine (live) (1057)
Measles vaccine (live) (0213)
Mumps vaccine (live) (0538)
Poliomyelitis vaccine (oral) (0215)
Rabies vaccine for human use prepared in cell cultures (0216)
Rubella vaccine (live) (0162)
Smallpox vaccine (live) (0164)
Varicella vaccine (live) (0648)
Yellow fever vaccine (live) (0537)

Vaccines for veterinary use

- Avian infectious bronchitis vaccine (live) (0442)
Rabies vaccine (inactivated) for veterinary use (0451)

Monographs

- Alfuzosin hydrochloride (1287)
Aluminium hydroxide, hydrated, for adsorption (1664)
Arnica flower (1391)
Atropine (2056)
Atropine sulphate (0068)

- Bearberry leaf (1054)
Butcher's broom (1847)
Caffeine (0267)
Carbomers (1299)
Cefadroxil monohydrate (0813)
Cefalexin monohydrate (0708)
Chlorphenamine maleate (0386)
Clotrimazole (0757)
Codeine (0076)
Devil's claw root (1095)
Diethyl phthalate (0897)
Dihydroergotamine mesilate (0551)
Diltiazem hydrochloride (1004)
Disodium phosphate dodecahydrate (0118)
Doxepin hydrochloride (1096)
Estradiol benzoate (0139)
Ethambutol hydrochloride (0553)
Glutathione (1670)
Goldenseal rhizome (1831)
Hamamelis leaf (0909)
Hop strobile (1222)
Hypromellose phthalate (0347)
Ibuprofen (0721)
Lidocaine (0727)
Liothyronine sodium (0728)
Lymecycline (1654)
Morphine hydrochloride (0097)
Morphine sulphate (1244)
Nifuroxazide (1999)
Povidone (0685)
Roselle (1623)

Spiramycin (0293)
Sultamicillin (2211)
Tetracaine hydrochloride (0057)

Triamterene (0058)
Triglycerol diisostearate (2032)
Willow bark (1583)

CORRECTED TEXTS

The texts below have been corrected and are republished in their entirety. These corrections are to be taken into account from the publication date of Supplement 6.1.

GENERAL CHAPTERS

2.2.34. Thermal analysis
2.6.7. Mycoplasmas
2.9.43. Apparent dissolution

MONOGRAPHS

Vaccines for veterinary use

Porcine progressive atrophic rhinitis vaccine (inactivated) (1361)

Radiopharmaceutical preparations

Iobenguane sulphate for radiopharmaceutical preparations (2351)

Homoeopathic preparations

Methods of preparation of homoeopathic stocks and potentisation (2371)

Monographs

Amikacin (1289)
Amikacin sulphate (1290)

Bacampicillin hydrochloride (0808)
Bilberry fruit, fresh (1602)
Cilastatin sodium (1408)
Clemastine fumarate (1190)
Dihydralazine sulphate, hydrated (1310)
Dirithromycin (1313)
Doxylamine hydrogen succinate (1589)
Glyceryl trinitrate solution (1331)
Hypromellose (0348)
Methylcellulose (0345)
Naproxen sodium (1702)
Paclitaxel (1794)
Phenoxyethylpenicillin (0148)
Phenoxyethylpenicillin potassium (0149)
Sertaconazole nitrate (1148)
Sultamicillin tosilate dihydrate (2212)
Terconazole (1270)
Terfenadine (0955)
Xanthan gum (1277)

DELETED TEXTS

The following texts are deleted as of 1 April 2008.

MONOGRAPHS

Vaccines for human use

Pertussis vaccine (0160)

Monographs

Stanozolol (1568)

CONTENTS

| | |
|---|------|
| CONTENTS OF SUPPLEMENT 6.1 | xxxi |
| GENERAL CHAPTERS | 3309 |
| 2. Methods of Analysis | 3309 |
| 2.2. Physical and physicochemical methods | 3309 |
| 2.2.34. Thermal analysis | 3311 |
| 2.2.60. Melting point - instrumental method | 3313 |
| 2.6. Biological tests | 3315 |
| 2.6.7. Mycoplasmas | 3317 |
| 2.9. Pharmaceutical technical procedures | 3323 |
| 2.9.40. Uniformity of dosage units | 3325 |
| 2.9.43. Apparent dissolution | 3327 |
| 4. Reagents | 3329 |
| 4.1.1. Reagents | 3331 |
| 4.1.3. Buffer solutions | 3331 |
| 5. General Texts | 3333 |
| 5.2.7. Evaluation of efficacy of veterinary vaccines and immunosera | 3335 |
| 5.15. Functionality-related characteristics of excipients | 3339 |
| GENERAL MONOGRAPHS | 3341 |
| MONOGRAPHS ON VACCINES FOR HUMAN USE | 3345 |
| MONOGRAPHS ON VACCINES FOR VETERINARY USE | 3369 |
| MONOGRAPHS ON RADIOPHARMACEUTICAL PREPARATIONS | 3379 |
| MONOGRAPHS ON HOMOEOPATHIC PREPARATIONS | 3383 |
| MONOGRAPHS | 3391 |
| INDEX | 3571 |

Note: on the first page of each chapter/section there is a list of contents.

