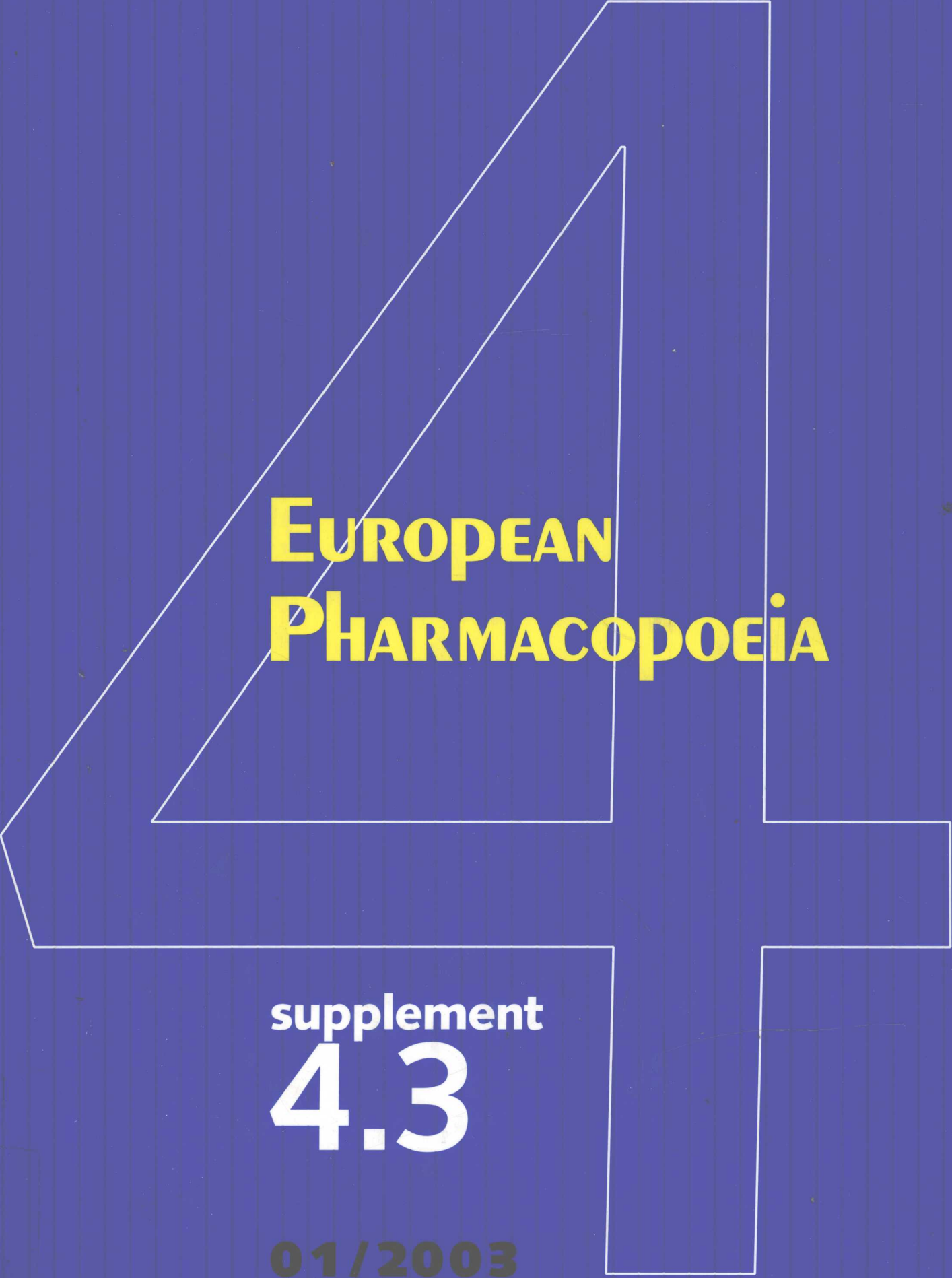




EUROPEAN PHARMACOPŌEIA

**supplement
4.3**

01/2003



EUROPEAN PHARMACOPOEIA

FOURTH EDITION

SUPPLEMENT 4.3

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



Council of Europe

Strasbourg

EUROPEAN PHARMACOPOEIA

FOURTH EDITION

SUPPLEMENT A3

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(European Treaty Series No. 20)

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CONTENTS OF SUPPLEMENT 4.3

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 emphasized 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.

NEW TEXTS

GENERAL CHAPTERS

2.4.29. Composition of fatty acids in oils rich in omega-3-acids

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2003 at the latest.

Monographs

Air, synthetic medicinal (1684)
4-Aminobenzoic acid (1687)
Cineole (1973)
Cresol, crude (1628)
Dihydrocodeine hydrogen tartrate (1776)
Erythritol (1803)
Fish oil, rich in omega-3-acids (1912)
Flubendazole (1721)
Glucagon, human (1635)
Goserelin (1636)
Hawthorn leaf and flower dry extract (1865)
Motherwort (1833)
Moxonidine (1758)
Nitrogen, low-oxygen (1685)
Omega-3-acid ethyl esters 60 (2063)
Ondansetron hydrochloride dihydrate (2016)
Opium, prepared (1840)

Pravastatin sodium (2059)
Rhatany tincture (1888)
Rutoside trihydrate (1795)
Saw palmetto fruit (1848)
Sodium glycerophosphate, hydrated (1995)
Tianeptine sodium (2022)
Wild thyme (1891)
Zinc sulphate hexahydrate (1683)

Vaccines for human use

Diphtheria, tetanus and hepatitis B (rDNA) vaccine (adsorbed) (2062)
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)
Diphtheria, tetanus, pertussis and poliomyelitis (inactivated) vaccine (adsorbed) (2061)
Diphtheria, tetanus, pertussis, poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2066)

Vaccines for veterinary use

Bovine viral diarrhoea vaccine (inactivated) (1952)
Canine parainfluenza virus vaccine (live) (1955)

Radiopharmaceutical preparations

Raclopride ($[^{11}\text{C}]$ methoxy) injection (1924)
Technetium ($^{99\text{m}}\text{Tc}$) exametazime injection (1925)

REVISED TEXTS

GENERAL CHAPTERS

1. General notices
- 2.2.6. Refractive index
- 2.2.15. Melting point – open capillary method
- 2.5.4. Iodine value
- 2.7.12. Assay of heparin in coagulation factors
- 2.9.19. Particulate contamination: sub-visible particles
- 2.9.22. Softening time determination of lipophilic suppositories
4. Reagents (*new, revised and corrected*)
- 5.1.2. Biological indicators of sterilisation

MONOGRAPHS

The monographs below have been technically revised since their last publication. They will be implemented on 1 January 2003.

General Monographs

Extracts (0765) - *this monograph now covers tinctures, previously subject of a monograph Tinctures (0792)*
Immunosera for human use, animal (0084)

Dosage Forms

Premixes for medicated feeding stuffs for veterinary use (1037)

Monographs

Aceclofenac (1281)
Acitretin (1385)
Amiodarone hydrochloride (0803)
Amphotericin B (1292)
Apomorphine hydrochloride (0136)
Calcium chloride dihydrate (0015)
Cefalexin monohydrate (0708)

Cefradine (0814)
 Cefuroxime sodium (0992)
 Cellulose acetate phthalate (0314)
 Cetrimide (0378)
 Chamomile flower, roman (0380)
 Colistimethate sodium (0319)
 Cyproheptadine hydrochloride (0817)
 Cysteine hydrochloride monohydrate (0895)
 Devil's claw root (1095)
 Dexamethasone (0388)
 Diethylene glycol monoethyl ether (1198)
 Droperidol (1010)
 Enalapril maleate (1420)
 Erythromycin ethylsuccinate (0274)
 Etoposide (0823)
 Ferrous gluconate (0493)
 Ferrous sulphate heptahydrate (0083)
 Flunitrazepam (0717)
 Flurazepam monohydrochloride (0905)
 Folic acid (0067)
 Glycine (0614)
 Haemodialysis solutions, concentrated, water for diluting (1167)
 Haemodialysis, solutions for (0128)
 Haloperidol (0616)
 Human normal immunoglobulin (0338)
 Isopropyl myristate (0725)
 Isopropyl palmitate (0839)
 Maize starch (0344)
 Metixene hydrochloride (1347)

Metoprolol succinate (1448)
 Metoprolol tartrate (1028)
 Noradrenaline hydrochloride (0732)
 Noradrenaline tartrate (0285)
 Omega-3-acid ethyl esters 90 (1250)
 Omega-3-acid triglycerides (1352)
 Paraffin, light liquid (0240)
 Paraffin, liquid (0239)
 Pilocarpine hydrochloride (0633)
 Pilocarpine nitrate (0104)
 Piperacillin (1169)
 Pivampicillin (0852)
 Pivmecillinam hydrochloride (1359)
 Poloxamers (1464)
 Potato starch (0355)
 Praziquantel (0855)
 Pyridoxine hydrochloride (0245)
 Saccharin sodium (0787)
 Sodium acetate trihydrate (0411)
 Sodium benzoate (0123)
 Sorbitan sesquioleate (1916)
 Tobramycin (0645)
 Triglycerides, medium-chain (0868)
 Wheat starch (0359)
 Wool alcohols (0593)
 Wool fat (0134)
 Zinc sulphate heptahydrate (0111)

Vaccines for veterinary use

Tetanus vaccine for veterinary use (0697)

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 4.3.

GENERAL CHAPTERS

- 2.7.19. Assay of human coagulation factor X
- 3.1.10. Materials based on non-plasticised poly(vinyl chloride) for containers for non-injectable, aqueous solutions

MONOGRAPHS

Dosage Forms

Semi-solid preparations for cutaneous application (0132)

Monographs

Aluminium magnesium silicate (1388)
 Amoxicillin trihydrate (0260)
 Ascorbic acid (0253)
 Budesonide (1075)

Calcium folinate (0978)
 Castor oil, hydrogenated (1497)
 Castor oil, virgin (0051)
 Cefamandole nafate (1402)
 Cefixime (1188)
 Cefuroxime axetil (1300)
 Chlorprothixene hydrochloride (0815)
 Cloxacillin sodium (0661)
 Docusate sodium (1418)
 Ethanol (96 per cent) (1317)
 Ethanol, anhydrous (1318)
 Fenoterol hydrobromide (0901)
 Fentanyl (1210)
 Fentanyl citrate (1103)
 Flucloxacillin sodium (0668)
 Flumazenil (1326)
 Human plasma for fractionation (0853)
 Ketoprofen (0922)
 Lactulose (1230)

Lactulose, liquid (0924)	Povidone (0685)
Metronidazole benzoate (0934)	Rosemary oil (1846)
Miconazole (0935)	Sulindac (0864)
Miconazole nitrate (0513)	Thiomersal (1625)
Norethisterone acetate (0850)	Ubidecarenone (1578)
Polysorbate 80 (0428)	Water, highly purified (1927)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 4.3.

GENERAL CHAPTERS

2.7.12. Assay of heparin in coagulation factor concentrates, becomes:

2.7.12. Assay of heparin in coagulation factors

MONOGRAPHS

Calcium chloride, becomes:

Calcium chloride dihydrate (0015)

Cefalexin, becomes:

Cefalexin monohydrate (0708)

Ferrous sulphate, becomes:

Ferrous sulphate heptahydrate (0083)

Immunosera for human use, becomes:

Immunosera for human use, animal (0084)

Omega-3-acid ethyl esters, becomes:

Omega-3-acid ethyl esters 90 (1250)

Sodium acetate, becomes:

Sodium acetate trihydrate (0411)

Zinc sulphate, becomes:

Zinc sulphate heptahydrate (0111)

SUPPRESSION OF TEXTS

The following text was deleted on 1 April 2002.

Canine contagious hepatitis vaccine (live), freeze-dried (0446)

The following texts are deleted on 1 January 2003.

2.7.3. Assay of Corticotropin

Corticotropin (0759)

Human fibrinogen, iodinated (¹²⁵I) (0604)

Tinctures (0792) - *tinctures are now covered by the monograph Extracts (0765)*

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