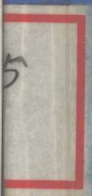


# EUROPEAN PHARMACOPOEIA

4. 2 supplement  
07/2002



# EUROPEAN PHARMACOPOEIA

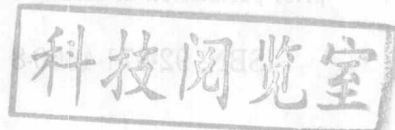
FOURTH EDITION

SUPPLEMENT 4.2

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



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**Council of Europe**  
Strasbourg

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

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# CONTENTS OF SUPPLEMENT 4.2

*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 changes, which are not necessarily exhaustive, are indicated for information and do not form an official part of the texts. Editorial changes are not indicated.*

## NEW TEXTS

### GENERAL CHAPTERS

- 2.7.22. Assay of human coagulation factor XI

### MONOGRAPHS

*The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 July 2002 at the latest.*

#### Monographs

- Ammonium glycyrrhizate (1772)  
Black horehound (1858)  
Butcher's broom (1847)  
Carteolol hydrochloride (1972)  
Cinnamon tincture (1819)  
Enilconazole for veterinary use (1720)

- Equisetum stem (1825)  
Human coagulation factor XI (1644)  
Ipecacuanha liquid extract, standardised (1875)  
Mastic (1876)  
Nadolol (1789)  
Pygeum africanum bark (1886)  
Red poppy petals (1881)  
Rifabutin (1657)  
Tramadol hydrochloride (1681)  
Tribenoside (1740)

#### Vaccines for human use

- Hepatitis A vaccine (inactivated, virosome) (1935)

#### Radiopharmaceutical preparations

- Iodinated ( $^{125}\text{I}$ ) human albumin injection (1922)

## REVISED TEXTS

### GENERAL CHAPTERS

- 2.6.13. Microbiological examination of non-sterile products (test for specified micro-organisms)  
2.7.6. Assay of diphtheria vaccine (adsorbed)  
2.7.8. Assay of tetanus vaccine (adsorbed)  
3.1.11. Materials based on non-plasticised poly(vinyl chloride) for containers for dry dosage forms for oral administration  
4. Reagents (*new, revised and corrected*)

### MONOGRAPHS

*The monographs below have been technically revised since their last publication. They will be implemented on 1 July 2002.*

#### General Monographs

- Vaccines for human use (0153)

#### Monographs

- Acebutolol hydrochloride (0871)  
Ammonium bromide (1389)  
Angelica root (1857)

- Butyl parahydroxybenzoate (0881)  
Carbomers (1299)  
Cefadroxil monohydrate (0813)  
Cefazolin sodium (0988)  
Cefoxitin sodium (0990)  
Ceftazidime (1405)  
Cholesterol (0993)  
Cinchona bark (0174)  
Clindamycin hydrochloride (0582)  
Cyanocobalamin (0547)  
Dexamethasone (0388)  
Erythromycin (0179)  
Erythromycin stearate (0490)  
Ethyl parahydroxybenzoate (0900)  
Etoposide (0823)  
Glyceryl trinitrate solution (1331)  
Human albumin solution (0255)  
Human anti-D immunoglobulin for intravenous administration (1527)  
Human coagulation factor VIII (0275)  
Human coagulation factor IX (1223)  
Ibuprofen (0721)  
Ipecacuanha liquid extract, standardised (1875)



Isomalt (1531)  
 Ivermectin (1336)  
 Lovage root (1233)  
 Mebendazole (0845)  
 Methyl parahydroxybenzoate (0409)  
 Mexiletine hydrochloride (1029)  
 Norethisterone acetate (0850)  
 Pethidine hydrochloride (0420)  
 Phenylbutazone (0422)  
 Potassium bromide (0184)  
 Potassium clavulanate (1140)  
 Povidone (0685)  
 Povidone, iodinated (1142)  
 Propyl parahydroxybenzoate (0431)  
 Riboflavine (0292)  
 Sodium bromide (0190)  
 Sodium sulphate, anhydrous (0099)  
 Sodium sulphate decahydrate (0100)  
 Sorbitol (0435)  
 Testosterone propionate (0297)

Thiamine hydrochloride (0303)  
 Thiamine nitrate (0531)  
 Trolamine (1577)  
 Water for injections (0169)  
 Water, highly purified (1927)  
 Water, purified (0008)  
 Xylitol (1381)

#### Vaccines for human use

Diphtheria and tetanus vaccine (adsorbed) (0444)  
 Diphtheria and tetanus vaccine (adsorbed) for adults and adolescents (0647)  
 Diphtheria, tetanus and pertussis vaccine (adsorbed) (0445)  
 Diphtheria vaccine (adsorbed) (0443)  
 Diphtheria vaccine (adsorbed) for adults and adolescents (0646)  
 Pertussis vaccine (0160)  
 Pertussis vaccine (adsorbed) (0161)  
 Tetanus vaccine (adsorbed) (0452)  
 Typhoid polysaccharide vaccine (1160)

## 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 the present supplement.*

#### GENERAL CHAPTERS

- 2.7.2. Microbiological assay of antibiotics  
 2.9.1. Disintegration of tablets and capsules (*correction of Figure 2.9.1.-2*)

#### MONOGRAPHS

##### Monographs

Alfacalcidol (1286)  
 Amlodipine besilate (1491)  
 Carmellose calcium (0886)  
 Cellulose, microcrystalline (0316)  
 Cellulose, powdered (0315)

Cetyl palmitate (1906)  
 Crotamiton (1194)  
 Framycetin sulphate (0180)  
 Insulin, human (0838)  
 Lobeline hydrochloride (1988)  
 Neomycin sulphate (0197)  
 Nitrogen (1247)  
 Oxytocin (0780)  
 Oxytocin bulk solution (0779)  
 Sotalol hydrochloride (2004)  
 Tiapride hydrochloride (1575)  
 Tramazoline hydrochloride monohydrate (1597)  
 Vitamin A (0217)  
 Vitamin A concentrate (oily form), synthetic (0219)  
 Vitamin A concentrate (powder form), synthetic (0218)  
 Vitamin A concentrate (solubilisate/emulsion), synthetic (0220)

## TEXTS WHOSE TITLE HAS CHANGED

*The title of the following text has been changed in Supplement 4.2.*

Cefadroxil, becomes:

Cefadroxil monohydrate (0813)

## SUPPRESSION OF TEXTS

*The following text is deleted on 1 April 2002.*

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

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

























