# European Pharmacopoeia

supplement

4.4

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# EUROPEAN PHARMACOPOEIA

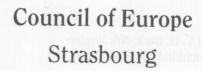
FOURTH EDITION SUPPLEMENT 4.4

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# EUROPEAN PHANIA FOURTH SUPPLEMENTAA

on the Elaboration of a European Phaniquiages (European Treaty Series No. 50)

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# CONTENTS OF SUPPLEMENT 4.4

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.

Individual copies of texts will not be supplied.

### **NEW TEXTS**

### **GENERAL CHAPTERS**

2.5.36. Anisidine value

### **MONOGRAPHS**

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

Basic butylated methacrylate copolymer (1975) Bitter-fennel fruit oil (1826) Cefapirin sodium (1650) Colophony (1862) Levomethadone hydrochloride (1787)

Linseed oil, virgin (1908)

Magnesium acetate tetrahydrate (2035)

Meadowsweet (1868)

Nicotine resinate (1792)

Nifuroxazide (1999)

Oxaliplatin (2017)

Phenylmercuric acetate (2042)

Potassium clavulanate, diluted (1653)

Proguanil hydrochloride (2002)

Ribwort plantain (1884)

Rilmenidine dihydrogen phosphate (2020)

Sodium propionate (2041)

Squalane (1630)

### **REVISED TEXTS**

### **GENERAL CHAPTERS**

2.4.22. Composition of fatty acids by gas chromatography

2.4.27. Heavy metals in herbal drugs and fatty oils

2.5.29. Sulphur dioxide

2.9.5. Uniformity of mass of single-dose preparations

2.9.6. Uniformity of content of single-dose preparations

5.1.3. Efficacy of antimicrobial preservation

### **MONOGRAPHS**

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

### Dosage forms

Eye preparations (1163)

Granules (0499)

Liquid preparations for cutaneous application (0927)

Liquid preparations for oral use (0672)

Powders, oral (1165)

Preparations for inhalation (0671)

### Monographs

Benzyl alcohol (0256)

Bromhexine hydrochloride (0706)

Carnauba wax (0597)

Chlortetracycline hydrochloride (0173)

Cholesterol (0993)

Cod-liver oil (type A) (1192)

Cod-liver oil (type B) (1193)

Colchicine (0758)

Crospovidone (0892)

Demeclocycline hydrochloride (0176)

Dextrin (1507)

Diphenhydramine hydrochloride (0023)

Disodium phosphate, anhydrous (1509)

Doxycycline hyclate (0272)

Doxycycline monohydrate (0820)

Estradiol benzoate (0139)

Estriol (1203)

Ethosuximide (0764)

Ethylcellulose (0822)

Isoconazole (1018)

Ketoconazole (0921)

Mannitol (0559)

Metformin hydrochloride (0931)

Nonoxinol 9 (1454)

Noscapine (0516)

Noscapine hydrochloride (0515)

Octoxinol 10 (1553)

Oxfendazole for veterinary use (1458)

Oxytetracycline dihydrate (0199)

Oxytetracycline hydrochloride (0198)

Paracetamol (0049)

Pentoxyverine hydrogen citrate (1621)

Phenylbutazone (0422)

Sorbitol, liquid (crystallising) (0436)

Sorbitol, liquid (non-crystallising) (0437)

Tetracycline (0211)

Tetracycline hydrochloride (0210)

Vincristine sulphate (0749)

Warfarin sodium (0698)

Warfarin sodium clathrate (0699)

Wheat-germ oil, refined (1379)

### Vaccines for veterinary use

Porcine influenza vaccine (inactivated) (0963)

### Homoeopathic preparations

Homoeopathic preparations (1038)

### **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 4.4.

### **GENERAL CHAPTERS**

2.3.2. Identification of fatty oils by thin-layer chromatography

2.9.3. Dissolution test for solid dosage forms

### MONOGRAPHS

Aprotinin (0580)

Aprotinin concentrated solution (0579)

Castor oil, hydrogenated (1497)

Castor oil, virgin (0051)

Cefadroxil monohydrate (0813)

Cefazolin sodium (0988)

Copovidone (0891)

Dexamethasone (0388)

Enalapril maleate (1420)

Framycetin sulphate (0180)

Glyceryl trinitrate solution (1331)

Hydroxyzine hydrochloride (0916)

Methacrylic acid - ethyl acrylate copolymer (1:1) (1128)

Methacrylic acid - ethyl acrylate copolymer (1:1)

dispersion 30 per cent (1129)

Methacrylic acid - methyl methacrylate copolymer

(1:1) (1127)

Methacrylic acid - methyl methacrylate copolymer

(1:2) (1130)

Naftidrofuryl hydrogen oxalate (1594)

Neomycin sulphate (0197)

Ondansetron hydrochloride dihydrate (2016)

Oxytocin (0780)

Oxytocin bulk solution (0779)

Potassium clavulanate (1140)

Rifabutin (1657)

Roselle (1623)

Simvastatin (1563)

Sodium alendronate (1564)

Tribenoside (1740)

Trimethoprim (0060)

Water for injections (0169)

### TEXTS WHOSE TITLE HAS CHANGED

The title of the following texts has been changed in Supplement 4.4.

2.4.27. Nickel in hydrogenated vegetable oils, becomes:

2.4.27. Heavy metals in herbal drugs and fatty oils

Doxycycline, becomes:

Doxycycline monohydrate (0820)

Oxytetracycline, becomes:

Oxytetracycline dihydrate (0199)

### SUPRESSION OF TEXTS

The following texts are deleted on 1 January 2003.

2.7.3. Assay of Corticotropin

2.9.21. Particulate contamination: microscope method

Corticotropin (0759)

Human fibrinogen, iodinated (125I) (0604)

Oxyphenbutazone (0418)

Sodium iodide (125I) solution (0280)

Swine erysipelas immunoserum (0342)

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

The following text was deleted on 1 April 2002.

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

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