

# EUROPEAN PHARMACOPŌEIA

## 6.2

supplement

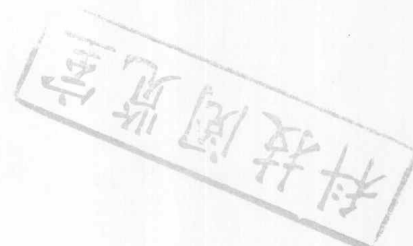
07/2008



# EUROPEAN PHARMACOPOEIA

SIXTH EDITION

Supplement 6.2



*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



Y2002551

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: 978-92-871-6059-1

# CONTENTS OF SUPPLEMENT 6.2

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 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

- 2.7.25. Assay of human plasmin inhibitor
- 2.7.30. Assay of human protein C
- 2.7.31. Assay of human protein S
- 2.7.32. Assay of human  $\alpha$ -1-proteinase inhibitor
- 2.9.32. Porosity and pore-size distribution of solids by mercury porosimetry
- 2.9.34. Bulk density and tapped density of powders
- 2.9.35. Powder fineness

### MONOGRAPHS

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

#### Vaccines for veterinary use

- Coccidiosis vaccine (live) for chickens (2326)

### Monographs

- Adrenaline (2303)
- Altizide (2185)
- Carprofen for veterinary use (2201)
- Clodronate disodium tetrahydrate (1777)
- Flucloxacillin magnesium octahydrate (2346)
- Fluvoxamine maleate (1977)
- Fresh bilberry fruit dry extract, refined and standardised (2394)
- Human  $\alpha$ -1-proteinase inhibitor (2387)
- Nilutamide (2256)
- Racecadotril (2171)
- Spanish sage oil (1849)
- St. John's wort dry extract, quantified (1874)
- Telmisartan (2154)

## REVISED TEXTS

### GENERAL CHAPTERS

- 2.6.26. Test for anti-D antibodies in human immunoglobulin for intravenous administration
- 2.8.13. Pesticide residues
- 2.9.9. Measurement of consistency by penetrometry
- 2.9.23. Gas pycnometric density of solids
- 2.9.38. Particle-size distribution estimation by analytical sieving
- 4. Reagents (*new, revised, corrected*)

### MONOGRAPHS

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

#### Vaccines for veterinary use

- Vibriosis (cold-water) vaccine (inactivated) for salmonids (1580)
- Vibriosis vaccine (inactivated) for salmonids (1581)
- Furunculosis vaccine (inactivated, oil-adjuvanted, injectable) for salmonids (1521)
- Swine-fever vaccine (live, prepared in cell cultures), classical (0065)

#### Radiopharmaceutical preparations

- Chromium ( $^{51}\text{Cr}$ ) edetate injection (0266)
- Fludeoxyglucose ( $^{18}\text{F}$ ) injection (1325)

### Monographs

- Acacia (0307)
- Acacia, spray-dried (0308)

- Aceclofenac (1281)
- Alginic acid (0591)
- Birch leaf (1174)
- Calcium carbonate (0014)
- Calcium dobesilate monohydrate (1183)
- Capsicum (1859)
- Cellulose, microcrystalline (0316)
- Cellulose, powdered (0315)
- Cinchona bark (0174)
- Cyclizine hydrochloride (1092)
- Devil's claw root (1095)
- Dihydrostreptomycin sulphate for veterinary use (0485)
- Etamsylate (1204)
- Ginger (1522)
- Glucose, liquid (1330)
- Human anti-D immunoglobulin (0557)
- Human normal immunoglobulin (0338)
- Human plasma (pooled and treated for virus inactivation) (1646)
- Human plasma for fractionation (0853)
- Hydroxypropylbetadex (1804)
- Imipramine hydrochloride (0029)
- Magnesium carbonate, heavy (0043)
- Methyltestosterone (0410)
- Metoclopramide (1348)
- Naproxen (0731)
- Norfloxacin (1248)
- Ofloxacin (1455)

Orciprenaline sulphate (1033)	Sodium hyaluronate (1472)
Oxacillin sodium monohydrate (2260)	Soya-bean oil, refined (1473)
Oxfendazole for veterinary use (1458)	St. John's wort (1438)
Paraffin, white soft (1799)	Streptokinase concentrated solution (0356)
Paraffin, yellow soft (1554)	Sulfacetamide sodium (0107)
Pseudoephedrine hydrochloride (1367)	Tinidazole (1051)
Ramipril (1368)	

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 6.2.

GENERAL CHAPTERS

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

MONOGRAPHS

Monographs

- Agnus castus fruit (2147)
- Aprotinin concentrated solution (0579)
- Arachis oil, hydrogenated (1171)
- Cetirizine dihydrochloride (1084)
- Cetostearyl alcohol (type A), emulsifying (0801)
- Cetostearyl alcohol (type B), emulsifying (0802)
- Cottonseed oil, hydrogenated (1305)
- Dimeticone (0138)

- Ipratropium bromide (0919)
- Maize oil, refined (1342)
- Methacrylic acid - ethyl acrylate copolymer (1:1) (1128)
- Morphine sulphate (1244)
- Moxifloxacin hydrochloride (2254)
- Olive oil, refined (1456)
- Olive oil, virgin (0518)
- Pancreas powder (0350)
- Poly(vinyl acetate) dispersion 30 per cent (2152)
- Potassium chloride (0185)
- Rapeseed oil, refined (1369)
- Soya-bean oil, hydrogenated (1265)
- Sulbactam sodium (2209)
- Sunflower oil, refined (1371)
- Tobramycin (0645)

TEXTS CONVERTED TO THE NEW EDITORIAL STYLE

The monographs below have been converted to the new editorial style, which does not entail any changes to their technical content, unless otherwise stated in the above section Corrected texts.

MONOGRAPHS

Monographs

- Agar (0310)
- Aloes dry extract, standardised (0259)
- Arachis oil, hydrogenated (1171)
- Belladonna leaf dry extract, standardised (1294)
- Belladonna, prepared (0222)
- Cassia oil (1496)
- Cinnamon bark oil, Ceylon (1501)
- Coconut oil, refined (1410)
- Cottonseed oil, hydrogenated (1305)
- Eucalyptus oil (0390)
- Frangula bark dry extract, standardised (1214)
- Guar (1218)
- Guar galactomannan (0908)
- Ipecacuanha, prepared (0093)

- Liquorice ethanolic liquid extract, standardised (1536)
- Maize oil, refined (1342)
- Matricaria liquid extract (1544)
- Nitric oxide (1550)
- Nitrogen (1247)
- Nutmeg oil (1552)
- Olive oil, refined (1456)
- Olive oil, virgin (0518)
- Oxygen (0417)
- Peru balsam (0754)
- Rapeseed oil, refined (1369)
- Senna leaf dry extract, standardised (1261)
- Shellac (1149)
- Soya-bean oil, hydrogenated (1265)
- Stramonium, prepared (0247)
- Sunflower oil, refined (1371)
- Tragacanth (0532)

TEXTS WHOSE TITLE HAS CHANGED

*The title of the following texts has been changed in Supplement 6.2.*

GENERAL CHAPTERS

2.9.23. Gas pycnometric density of solids (*previously Pycnometric density of solids*)

MONOGRAPHS

Vaccines for veterinary use

Swine-fever vaccine (live, prepared in cell cultures), classical (0065) (*previously Swine-fever vaccine (live), classical, freeze-dried*)

Monographs

Streptokinase concentrated solution (0356) (*previously Streptokinase bulk solution*)

DELETED TEXTS

*The following texts are deleted as of 1 April 2008.*

MONOGRAPHS

Vaccines for human use

Pertussis vaccine (0160)

Monographs

Stanozolol (1568)



TEXTS WHOSE TITLE HAS CHANGED

The title of the following text has been changed in Supplement 6.2.

GENERAL CHAPTERS

2.2.13. Gas chromatographic density of solids (previously: Factors for density of solids)

MONOGRAPHS

Procedures for veterinary use

2.9.16.1. for vaccines (not prepared in cell cultures), bacterial (0005) (previously: Bacterial vaccines (live), classical, freeze-dried)

MONOGRAPHS

2.9.16.2. for vaccines (not prepared in cell cultures), bacterial (0005) (previously: Bacterial vaccines (live), classical, freeze-dried)

DELETED TEXTS

The following texts are deleted as of 1 April 2009

MONOGRAPHS

Vaccines for human use

2.9.16.1. for vaccines (not prepared in cell cultures), bacterial (0005)

MONOGRAPHS

2.9.16.2. for vaccines (not prepared in cell cultures), bacterial (0005)

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