

CONTENTS OF SUPPLEMENT 5.6

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

- 2.6.27. Microbiological control of cellular products
- 2.7.23. Numeration of CD34/CD45+ cells in haematopoietic products
- 2.7.24. Flow cytometry
- 2.7.27. Flocculation value (Lf) of diphtheria and tetanus toxins and toxoids (Ramon assay)
- 2.9.31. Particle size analysis by laser light diffraction
- 2.9.33. Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD)
- 2.9.43. Apparent dissolution
- 5.12. Reference standards
- 5.14. Gene transfer medicinal products for human use

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2007 at the latest.

Vaccines for human use

- Anthrax vaccine for human use (adsorbed, prepared from culture filtrates) (2188)
- Diphtheria, tetanus and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2328)
- Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content) (2329)

Vaccines for veterinary use

- Feline chlamydiosis vaccine (inactivated) (2324)
- Mycoplasma gallisepticum vaccine (inactivated) (1942)

Monographs

- Alverine citrate (2156)
- Benzoin, Sumatra (1814)

- Benzoin tincture, Sumatra (1813)
- Capsicum oleoresin, refined and quantified (2336)
- Capsicum tincture, standardised (2337)
- Cascara dry extract, standardised (1844)
- Cefepime dihydrochloride monohydrate (2126)
- Cladribine (2174)
- Dembrexine hydrochloride monohydrate for veterinary use (2169)
- Dopexamine dihydrochloride (1748)
- Enalaprilat dihydrate (1749)
- Fluconazole (2287)
- Gemcitabine hydrochloride (2306)
- Guaiacol (1978)
- Human haematopoietic stem cells (2323)
- Human von Willebrand factor (2298)
- Letrozole (2334)
- Loratadine (2124)
- Mandarin oil (2355)
- Manganese glycerophosphate, hydrated (2163)
- Milk thistle dry extract, refined and standardised (2071)
- Modafinil (2307)
- Naproxen sodium (1702)
- Oxitropium bromide (2170)
- Purple coneflower herb (1823)
- Purple coneflower root (1824)
- Pyrrolidone (2180)
- Terazosin hydrochloride dihydrate (2021)
- Tropisetron hydrochloride (2102)
- Verbena herb (1854)

REVISED TEXTS

GENERAL CHAPTERS

- 1. General notices
- 2.2.7. Optical rotation
- 2.2.25. Absorption spectrophotometry, ultraviolet and visible
- 2.4.14. Sulphated ash
- 2.4.22. Composition of fatty acids by gas chromatography
- 2.6.7. Mycoplasmas
- 2.6.12. Microbiological examination of non-sterile products: total viable aerobic count
- 2.6.13. Microbiological examination of non-sterile products: test for specified micro-organisms
- 2.7.5. Assay of heparin
- 2.7.20. *In vivo* assay of poliomyelitis vaccine (inactivated)
- 4. Reagents (*new, revised, corrected*)
- 5.1.4. Microbiological quality of pharmaceutical preparations

MONOGRAPHS

The monographs below have been technically revised since their last publication. They will be implemented on 1 January 2007.

Dosage forms

Liquid preparations for oral use (0672)

Nasal preparations (0676)

Preparations for irrigation (1116)

Vaccines for human use

Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) (0647)

Diphtheria vaccine (adsorbed, reduced antigen content) (0646)

Vaccines for veterinary use

Marek's disease vaccine (live) (0589)

Newcastle disease vaccine (inactivated) (0870)

Tetanus vaccine for veterinary use (0697)

Monographs

Agnus castus fruit (2147)

Ascorbic acid (0253)

Ascorbyl palmitate (0807)

Azithromycin (1649)

Bendroflumethiazide (0370)

Betacarotene (1069)

Bisacodyl (0595)

Bromazepam (0879)

Bromocriptine mesilate (0596)

Buserelin (1077)

Calcitonin (salmon) (0471)

Calcium ascorbate (1182)

Cetostearyl alcohol (type A), emulsifying (0801)

Cetostearyl alcohol (type B), emulsifying (0802)

Cholecalciferol concentrate (oily form) (0575)

Cholecalciferol concentrate (powder form) (0574)

Cholecalciferol concentrate (water-dispersible form) (0598)

Cyanocobalamin (0547)

Diazepam (0022)

Glycerol mono-oleate (1430)

Human anti-D immunoglobulin (0557)

Human anti-D immunoglobulin for intravenous administration (1527)

Human coagulation factor VIII (0275)

Human fibrinogen (0024)

Human normal immunoglobulin (0338)

Human normal immunoglobulin for intravenous administration (0918)

Human plasma (pooled and treated for virus inactivation) (1646)

Human plasma for fractionation (0853)

Hydroxocobalamin acetate (0913)

Hydroxocobalamin chloride (0914)

Hydroxocobalamin sulphate (0915)

Levodopa (0038)

Lorazepam (1121)

Magnesium oxide, heavy (0041)

Magnesium oxide, light (0040)

Mannitol (0559)

Methotrexate (0560)

Phytomenadione (1036)

Phytosterol (1911)

Prednisolone acetate (0734)

Riboflavin sodium phosphate (0786)

Sodium ascorbate (1791)

Sodium sulphite, anhydrous (0775)

Sodium sulphite heptahydrate (0776)

Stannous chloride dihydrate (1266)

Stearic acid (1474)

all-*rac*- α -Tocopherol (0692)

RRR- α -Tocopherol (1256)

all-*rac*- α -Tocopheryl acetate (0439)

RRR- α -Tocopheryl acetate (1257)

α -Tocopheryl acetate concentrate (powder form) (0691)

DL- α -Tocopheryl hydrogen succinate (1258)

RRR- α -Tocopheryl hydrogen succinate (1259)

Vitamin A (0217)

Vitamin A concentrate (oily form), synthetic (0219)

Vitamin A concentrate (powder form), synthetic (0218)

Vitamin A concentrate (solubilisate/emulsion), synthetic (0220)

Zuclopenthixol decanoate (1707)

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 5.6.

GENERAL CHAPTERS

2.7.10. Assay of human coagulation factor VII

3.2. Containers

MONOGRAPHS**Monographs**

β -Acetyldigoxin (2168)

Amisulpride (1490)

Ammonio methacrylate copolymer (type A) (2081)

Ammonio methacrylate copolymer (type B) (2082)

Anti-T lymphocyte immunoglobulin for human use, animal (1928)

Artichoke leaf (1866)

Benzyl alcohol (0256)	Java tea (1229)
Bifonazole (1395)	Mitoxantrone hydrochloride (1243)
Calcium levofolinate pentahydrate (1606)	Nettle leaf (1897)
Carbamazepine (0543)	Nomegestrol acetate (1551)
Chondroitin sulphate sodium (2064)	Octyldodecanol (1136)
Chymotrypsin (0476)	Oxacillin sodium monohydrate (2260)
Docusate sodium (1418)	Pancreas powder (0350)
Epirubicin hydrochloride (1590)	Thyme (0865)
Fenofibrate (1322)	Torasemide, anhydrous (2132)
Flucloxacillin sodium (0668)	Trypsin (0694)
Flumequine (1517)	Turpentine oil, Pinus pinaster type (1627)
Folic acid (0067)	Valnemulin hydrochloride for veterinary use (2137)
Fumitory (1869)	Wormwood (1380)
Ivy leaf (2148)	Xylometazoline hydrochloride (1162)

TEXTS WHOSE TITLE HAS CHANGED

The title of the following texts has been changed in Supplement 5.6.

MONOGRAPHS

Monographs

α -Tocopheryl acetate concentrate (powder form) (0691) (*previously α -Tocopherol acetate concentrate (powder form)*)

Vaccines for human use

Diphtheria and tetanus vaccine (adsorbed, reduced antigen(s) content) (0647) (*previously Diphtheria and tetanus vaccine (adsorbed) for adults and adolescents*)

Diphtheria vaccine (adsorbed, reduced antigen content) (0646) (*previously Diphtheria vaccine (adsorbed) for adults and adolescents*)

SUPPRESSION OF TEXTS

The following text is deleted on 1 January 2007.

GENERAL CHAPTERS

2.9.13. Limit test of particle size by microscopy

The following text was deleted on 1 April 2006.

MONOGRAPHS

Monographs

Glucagon (0612)