

CONTENTS OF SUPPLEMENT 6.3

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 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

5.1.9. Guidelines for using the test for sterility

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2009 at the latest.

Vaccines for human use

Shingles (herpes zoster) vaccine (live) (2418)

Radiopharmaceutical preparations

Pentetate sodium calcium for radiopharmaceutical preparations (2353)

Technetium (^{99m}Tc) mebrofenin injection (2393)

Tetra-*O*-acetyl-mannose triflate for radiopharmaceutical preparations (2294)

Monographs

Aluminium sodium silicate (1676)

Artichoke leaf dry extract (2389)

Benazepril hydrochloride (2388)

Calcium gluconate, anhydrous (2364)

Citalopram hydrobromide (2288)

Citalopram hydrochloride (2203)

Cod-liver oil, farmed (2398)

Dydrogesterone (2357)

Esomeprazole magnesium trihydrate (2372)

Filgrastim concentrated solution (2206)

Interferon beta-1a concentrated solution (1639)

Lamotrigine (1756)

Lauromacrogol 400 (2046)

Mallow leaf (2391)

Meloxicam (2373)

Methylphenidate hydrochloride (2235)

Omeprazole magnesium (2374)

Pea starch (2403)

Saquinavir mesilate (2267)

Schisandra fruit (2428)

Sevoflurane (2269)

Teicoplanin (2358)

REVISED TEXTS

GENERAL CHAPTERS

2.2.33. Nuclear magnetic resonance spectrometry

2.2.42. Density of solids

2.5.24. Carbon dioxide in gases

2.5.25. Carbon monoxide in gases

2.5.27. Oxygen in gases

2.6.1. Sterility

2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests

2.6.13. Microbiological examination of non-sterile products: test for specified micro-organisms

2.7.2. Microbiological assay of antibiotics

2.9.1. Disintegration of tablets and capsules

2.9.33. Characterisation of crystalline and partially crystalline solids by X-ray powder diffraction (XRPD)

4. Reagents (*new, revised, corrected*)

5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use

5.1.5. Application of the F_0 concept to steam sterilisation of aqueous preparations

5.2.3. Cell substrates for the production of vaccines for human use

MONOGRAPHS

The monographs below have been technically revised since their last publication. They will be implemented on 1 January 2009.

General monographs

Substances for pharmaceutical use (2034)

Vaccines for human use (0153)

Dosage forms

Powders for cutaneous application (1166)

Semi-solid preparations for cutaneous application (0132)

Vaccines for human use

BCG for immunotherapy (1929) (*published in error under letter B in the monographs section*)

Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (2065)

Haemophilus type b conjugate vaccine (1219)

Poliomyelitis vaccine (inactivated) (0214)

Varicella vaccine (live) (0648)

Radiopharmaceutical preparations

Technetium (^{99m}Tc) colloidal rhenium sulphide injection (0126)

Technetium (^{99m}Tc) macrosalb injection (0296)

Technetium (^{99m}Tc) microspheres injection (0570)

Technetium (^{99m}Tc) tin pyrophosphate injection (0129)

Monographs

- Acacia (0307)
 Acacia, spray-dried (0308)
N-Acetyltryptophan (1383)
 Adenosine (1486)
 Agar (0310)
 Air, medicinal (1238)
 Alginic acid (0591)
 Almagate (2010)
 Aluminium magnesium silicate (1388)
 Aluminium oxide, hydrated (0311)
 Aluminium phosphate gel (2166)
 Amphotericin B (1292)
 Aprotinin (0580)
 Aprotinin concentrated solution (0579)
 Ascorbic acid (0253)
 BCG for immunotherapy (1929)
 Beclometasone dipropionate, anhydrous (0654)
 Beclometasone dipropionate monohydrate (1709)
 Belladonna leaf dry extract, standardised (1294)
 Bentonite (0467)
 Betamethasone valerate (0811)
 Bitter-orange epicarp and mesocarp (1603)
 Bitter-orange flower (1810)
 Calcium folinate (0978)
 Calcium gluconate (0172)
 Calcium gluconate for injection (0979)
 Calcium stearate (0882)
 Cellulose acetate (0887)
 Cellulose acetate phthalate (0314)
 Cellulose, microcrystalline (0316)
 Cellulose, powdered (0315)
 Charcoal, activated (0313)
 Chondroitin sulphate sodium (2064)
 Cisplatin (0599)
 Cod-liver oil (type A) (1192)
 Cod-liver oil (type B) (1193)
 Croscarmellose sodium (0985)
 Crospovidone (0892)
 Dextran 1 for injection (1506)
 Dextran 40 for injection (0999)
 Dextran 60 for injection (1000)
 Dextran 70 for injection (1001)
 Erythritol (1803)
 Ferrous gluconate (0493)
 Frangula bark dry extract, standardised (1214)
 Galactose (1215)
 Gelatin (0330)
 Glucose, liquid, spray-dried (1525)
 Guar (1218)
 Guar galactomannan (0908)
 Haemodialysis solutions, concentrated, water for diluting (1167)
 Hard fat (0462)
 Human normal immunoglobulin for intravenous administration (0918)
 Human plasma (pooled and treated for virus inactivation) (1646)
 Hydroxypropylbetadex (1804)
 Kaolin, heavy (0503)
 Lactitol monohydrate (1337)
 Lactose, anhydrous (1061)
 Lactose monohydrate (0187)
 Lactulose (1230)
 Lactulose, liquid (0924)
 Levodropropizine (1535)
 Lynestrenol (0558)
 Magnesium carbonate, light (0042)
 Magnesium oxide, heavy (0041)
 Magnesium oxide, light (0040)
 Magnesium stearate (0229)
 Maize starch (0344)
 Maltitol (1235)
 Maltodextrin (1542)
 Mannitol (0559)
 Mefenamic acid (1240)
 Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent (1129)
 Methotrexate (0560)
 Mianserin hydrochloride (0846)
 Naphazoline hydrochloride (0730)
 Nicotine (1452)
 Nicotine resinate (1792)
 Olive leaf (1878)
 Omega-3-acid ethyl esters 60 (2063)
 Omega-3-acid ethyl esters 90 (1250)
 Omega-3-acid triglycerides (1352)
 Oxaliplatin (2017)
 Oxymetazoline hydrochloride (0943)
 Paclitaxel (1794)
 Pancreas powder (0350)
 Pepsin powder (0682)
 Perphenazine (0629)
 Polyacrylate dispersion 30 per cent (0733)
 Poly(vinyl acetate) dispersion 30 per cent (2152)
 Potassium citrate (0400)
 Potato starch (0355)
 Pravastatin sodium (2059)
 Rice starch (0349)
 Senna leaf dry extract, standardised (1261)
 Sodium alginate (0625)
 Sodium ascorbate (1791)
 Sodium glycerophosphate, hydrated (1995)
 Sodium hyaluronate (1472)
 Sodium polystyrene sulphonate (1909)
 Sodium stearate (2058)
 Sorbitol (0435)
 Sorbitol, liquid, partially dehydrated (2048)
 Starch, pregelatinised (1267)
 Sucrose (0204)
 Sugar spheres (1570)
 Sumatriptan succinate (1573)
 Talc (0438)

Tetracosactide (0644)
 Tragacanth (0532)
 Tributyl acetylcitrate (1770)
 Trypsin (0694)
 Tryptophan (1272)
 Water for injections (0169)

Water, highly purified (1927)
 Water, purified (0008)
 Wheat starch (0359)
 Xanthan gum (1277)
 Xylitol (1381)

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 6.3 (10 June 2008).

MONOGRAPHS

Dosage forms

Intrauterine preparations for veterinary use (1806)

Vaccines for veterinary use

Clostridium chauvoei vaccine for veterinary use (0361)

Monographs

Acemetacin (1686)
 Amiodarone hydrochloride (0803)
 Amitriptyline hydrochloride (0464)
 Arnica flower (1391)
 Arnica tincture (1809)
 Atropine (2056)
 Atropine sulphate (0068)
 Azithromycin (1649)
 Buserelin (1077)
 Carprofen for veterinary use (2201)
 Cholecalciferol concentrate (oily form) (0575)
 Cholecalciferol concentrate (powder form) (0574)
 Cholecalciferol concentrate (water-dispersible form) (0598)
 Clonidine hydrochloride (0477)
 Codergocrine mesilate (2060)
 Dexamethasone acetate (0548)
 Disodium phosphate, anhydrous (1509)
 Ergocalciferol (0082)
 Ethacridine lactate monohydrate (1591)
 Fluvoxamine maleate (1977)
 Glucose, anhydrous (0177)
 Glucose monohydrate (0178)

Glycerol mono-oleate (1430)
 Granisetron hydrochloride (1695)
 Human haematopoietic stem cells (2323)
 Hypromellose (0348)
 Hypromellose phthalate (0347)
 Ichthammol (0917)
 Lemon verbena leaf (1834)
 Macrogol 40 sorbitol heptaoleate (2396)
 Magaldrate (1539)
 Methylcellulose (0345)
 Methyltestosterone (0410)
 Moxidectin for veterinary use (1656)
 Phenol (0631)
 Pholcodine (0522)
 Pilocarpine hydrochloride (0633)
 Pilocarpine nitrate (0104)
 Polysorbate 20 (0426)
 Polysorbate 40 (1914)
 Polysorbate 60 (0427)
 Polysorbate 80 (0428)
 Potassium dihydrogen phosphate (0920)
 Racecadotril (2171)
 Sertraline hydrochloride (1705)
 Sesame oil, refined (0433)
 Sodium alendronate (1564)
 Sodium molybdate dihydrate (1565)
 St. John's wort dry extract, quantified (1874)
 Sultamicillin tosilate dihydrate (2212)
 Telmisartan (2154)
 Triamterene (0058)

TEXTS WHOSE TITLE HAS CHANGED

The title of the following texts has been changed in Supplement 6.3.

GENERAL CHAPTERS

- 2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests (*previously Microbiological examination of non-sterile products: total viable aerobic count*)
 5.1.4. Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use (*previously Microbiological quality of pharmaceutical preparations*)

DELETED TEXTS

*The following text was deleted on **1 April 2008**.*

MONOGRAPHS

Vaccines for human use

Pertussis vaccine (0160)

REINSTATED TEXTS

*The following text was deleted on **1 April 2008**, but has been reinstated and is reintroduced unchanged in Supplement 6.3. It is to be taken into account from the publication date of Supplement 6.3 (**10 June 2008**)*

MONOGRAPHS

Monographs

Stanozolol (1568)