

CONTENTS OF SUPPLEMENT 6.6

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

2.8.21. Test for aristolochic acids in herbal drugs

2.8.22. Determination of ochratoxin A in herbal drugs

5.1.10. Guidelines for using the test for bacterial endotoxins

MONOGRAPHS

The monographs below appear for the first time in the European Pharmacopoeia. They will be implemented on 1 January 2010 at the latest.

Vaccines for human use

Human papillomavirus vaccine (rDNA) (2441)

Measles, mumps, rubella and varicella vaccine (live) (2442)

Monographs

Adapalene (2445)

Carrageenan (2138)

Dandelion root (1852)

Docetaxel trihydrate (2449)

Epinastine hydrochloride (2411)

Ganciclovir (1752)

Magnesium citrate dodecahydrate (2401)

Magnesium citrate nonahydrate (2402)

Melissa leaf dry extract (2524)

Orbifloxacin for veterinary use (2259)

Raloxifene hydrochloride (2375)

Valsartan (2423)

REVISED TEXTS

GENERAL CHAPTERS

2.2.31. Electrophoresis

2.2.42. Density of solids

2.2.47. Capillary electrophoresis

2.2.54. Isoelectric focusing

2.2.55. Peptide mapping

2.2.56. Amino acid analysis

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

2.6.14. Bacterial endotoxins

2.6.17. Test for anticomplementary activity of immunoglobulin

2.9.3. Dissolution test for solid dosage forms

2.9.7. Friability of uncoated tablets

2.9.26. Specific surface area by gas adsorption

2.9.31. Particle size analysis by laser light diffraction

2.9.36. Powder flow

2.9.37. Optical microscopy

2.9.38. Particle-size distribution estimation by analytical sieving

5.2.2. Chicken flocks free from specified pathogens for the production and quality control of vaccines

5.8. Pharmacopoeial harmonisation

— Electrophoresis (2.2.31)

— Capillary electrophoresis (2.2.47)

— Isoelectric focusing (2.2.54)

— Peptide mapping (2.2.55)

— Amino acid analysis (2.2.56)

— Friability of uncoated tablets (2.9.7)

— Specific surface area by gas adsorption (2.9.26)

- Powder flow (2.9.36)
- Optical microscopy (2.9.37)
- Particle-size distribution estimation by analytical sieving (2.9.38)

5.14. Gene transfer medicinal products for human use

MONOGRAPHS

The monographs below have been technically revised since their last publication in the European Pharmacopoeia.

They will be implemented on 1 January 2010.

General monographs

Allergen products (1063)

Vaccines for human use

Hepatitis A vaccine (inactivated, adsorbed) (1107)

Hepatitis A vaccine (inactivated, virosome) (1935)

Pertussis vaccine (whole cell, adsorbed) (0161)

Vaccines for veterinary use

Clostridium novyi (type B) vaccine for veterinary use (0362)

Radiopharmaceutical preparations

Iobenguane sulphate for radiopharmaceutical preparations (2351)

Monographs

Almond oil, refined (1064)

Almond oil, virgin (0261)

Amikacin (1289)

Amikacin sulphate (1290)

Arachis oil, refined (0263)

Artichoke leaf (1866)

Artichoke leaf dry extract (2389)

Borage (starflower) oil, refined (2105)

Budesonide (1075)

Cimetidine (0756)

Cimetidine hydrochloride (1500)

Clobetasone butyrate (1090)

Coconut oil, refined (1410)

Dandelion herb with root (1851)

Evening primrose oil, refined (2104)

Ferrous sulphate heptahydrate (0083)

Gemfibrozil (1694)

Glipizide (0906)

Goldenseal rhizome (1831)

Guar (1218)

Guar galactomannan (0908)

Hawthorn leaf and flower (1432)

Hawthorn leaf and flower dry extract (1865)

Human albumin solution (0255)

Human coagulation factor VIII (0275)

Human normal immunoglobulin (0338)

Human normal immunoglobulin for intravenous administration (0918)

Lansoprazole (2219)

Linseed oil, virgin (1908)

Liquorice root (0277)

Loratadine (2124)

Lovastatin (1538)

Maize oil, refined (1342)

Mefenamic acid (1240)

Nortriptyline hydrochloride (0941)

Olive oil, refined (1456)

Olive oil, virgin (0518)

Oxygen (0417)

Peppermint leaf (0406)

Phenazone (0421)

Potassium clavulanate (1140)

Potassium clavulanate, diluted (1653)

Pravastatin sodium (2059)

Pyridoxine hydrochloride (0245)

Rapeseed oil, refined (1369)

Safflower oil, refined (2088)

Sesame oil, refined (0433)

Sodium alginate (0625)

Soya-bean oil, refined (1473)	Theophylline-ethylenediamine hydrate (0301)
Starch, pregelatinised (1267)	Triglycerides, medium-chain (0868)
Sunflower oil, refined (1371)	Wheat-germ oil, refined (1379)
Terbinafine hydrochloride (1734)	Wheat-germ oil, virgin (1480)
Theophylline-ethylenediamine, anhydrous (0300)	Zinc sulphate monohydrate (2159)

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 6.6 (1 July 2009).

GENERAL CHAPTERS

- 2.3.2. Identification of fatty oils by thin-layer chromatography
- 2.4.22. Composition of fatty acids by gas chromatography
- 3.2.1. Glass containers for pharmaceutical use
- 5.1.3. Efficacy of antimicrobial preservation

MONOGRAPHS

Monographs

- Amphotericin B (1292)
- Ascorbic acid (0253)
- Buprenorphine (1180)
- Buprenorphine hydrochloride (1181)
- Cefamandole nafate (1402)
- Digoxin (0079)

- Fenugreek (1323)
- Lamotrigine (1756)
- Methylphenidate hydrochloride (2235)
- Nicotine (1452)
- Nicotine resinate (1792)
- Polysorbate 80 (0428)
- Poly(vinyl acetate) dispersion 30 per cent (2152)
- Sodium ascorbate (1791)
- Sodium glycerophosphate, hydrated (1995)
- Talc (0438)
- Teicoplanin (2358)
- Tributyl acetyl citrate (1770)
- Zinc chloride (0110)

HARMONISED TEXTS

The texts below have undergone pharmacopoeial harmonisation (see chapter 5.8. Pharmacopoeial harmonisation).

GENERAL CHAPTERS

- | | |
|-----------------------------------|---|
| 2.2.31. Electrophoresis | 2.9.7. Friability of uncoated tablets |
| 2.2.47. Capillary electrophoresis | 2.9.26. Specific surface area by gas adsorption |
| 2.2.54. Isoelectric focusing | 2.9.36. Powder flow |
| 2.2.55. Peptide mapping | 2.9.37. Optical microscopy |
| 2.2.56. Amino acid analysis | 2.9.38. Particle-size distribution estimation by analytical sieving |

TEXTS WHOSE TITLE HAS CHANGED

The title of the following texts has been changed in Supplement 6.6.

MONOGRAPHS

Vaccines for human use

Pertussis vaccine (whole cell, adsorbed) (0161)
(previously Pertussis vaccine (adsorbed))

Monographs

Theophylline-ethylenediamine, anhydrous (0300)
(previously Theophylline-ethylenediamine)

DELETED TEXTS

The following texts are deleted as of 1 April 2009.

GENERAL CHAPTERS

2.9.15. Apparent volume

MONOGRAPHS

Monographs

Lindane (0772)

The following text was deleted on 1 April 2008.

MONOGRAPHS

Vaccines for human use

Pertussis vaccine (0160)