

# 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

- 2.8.22. 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  
5.8. Electrophoresis (2.2.31)  
5.8. Capillary electrophoresis (2.2.47)  
5.8. Isoelectric focusing (2.2.54)  
5.8. Peptide mapping (2.2.55)  
5.8. Amino acid analysis (2.2.56)

- 5.8. Friability of uncoated tablets (2.9.7)  
5.8. Specific surface area by gas adsorption (2.9.26)  
5.8. Powder flow (2.9.36)  
5.8. Optical microscopy (2.9.37)  
5.8. 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)	Mefenamic acid (1240)
Cimetidine (0756)	Nortriptyline hydrochloride (0941)
Cimetidine hydrochloride (1500)	Olive oil, refined (1456)
Clobetasone butyrate (1090)	Olive oil, virgin (0518)
Coconut oil, refined (1410)	Oxygen (0417)
Dandelion herb with root (1851)	Peppermint leaf (0406)
Dextropropoxyphene hydrochloride (0713)	Phenazone (0421)
Evening primrose oil, refined (2104)	Potassium clavulanate (1140)
Ferrous sulphate heptahydrate (0083)	Potassium clavulanate, diluted (1653)
Gemfibrozil (1694)	Pravastatin sodium (2059)
Glipizide (0906)	Pyridoxine hydrochloride (0245)
Goldenseal rhizome (1831)	Rapeseed oil, refined (1369)
Guar (1218)	Safflower oil, refined (2088)
Guar galactomannan (0908)	Sesame oil, refined (0433)
Hawthorn leaf and flower (1432)	Sodium alginate (0625)
Hawthorn leaf and flower dry extract (1865)	Soya-bean oil, refined (1473)
Human albumin solution (0255)	Starch, pregelatinised (1267)
Human coagulation factor VIII (0275)	Sunflower oil, refined (1371)
Human normal immunoglobulin (0338)	Terbinafine hydrochloride (1734)
Human normal immunoglobulin for intravenous administration (0918)	Theophylline-ethylenediamine, anhydrous (0300)
Lansoprazole (2219)	Theophylline-ethylenediamine hydrate (0301)
Linseed oil, virgin (1908)	Triglycerides, medium-chain (0868)
Liquorice root (0277)	Wheat-germ oil, refined (1379)
Loratadine (2124)	Wheat-germ oil, virgin (1480)
Lovastatin (1538)	Zinc sulphate monohydrate (2159)
Maize oil, refined (1342)	

## 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)              | Digoxin (0079)                                    |
| Ascorbic acid (0253)               | Fenugreek (1323)                                  |
| Buprenorphine (1180)               | Lamotrigine (1756)                                |
| Buprenorphine hydrochloride (1181) | Methylphenidate hydrochloride (2235)              |
| Cefamandole nafate (1402)          | 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 acetylcitrate (1770)                     |
|                                    | Zinc chloride (0110)                              |

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## HARMONISED TEXTS

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

### GENERAL CHAPTERS

2.2.31. Electrophoresis

2.2.47. Capillary electrophoresis

2.2.54. Isoelectric focusing

2.2.55. Peptide mapping

2.2.56. Amino acid analysis

2.9.7. Friability of uncoated tablets

2.9.26. Specific surface area by gas adsorption

2.9.36. Powder flow

2.9.37. Optical microscopy

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)