

CONTENTS OF SUPPLEMENT 8.6

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. However, 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.

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NEW TEXTS

The texts below appear for the first time in the European Pharmacopoeia. They will be implemented on **1 January 2016** at the latest.

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Copper tetramibi tetrafluoroborate for radiopharmaceutical preparations (2547)

Herbal drugs and herbal drug preparations

Anemarrhena asphodeloides rhizome (2661)

Hamamelis bark (2532)

Indigo plant leaf (2727)

Homoeopathic preparations

Belladonna for homoeopathic preparations (2489)

Petroleum rectificatum for homoeopathic preparations (2683)

Staphysagria for homoeopathic preparations (2289)

Monographs

Exemestane (2766)

Nicorandil (2332)

Pirfenidone (2856)

Sodium selenite (2740)

Solifenacin succinate (2779)

Somatropin solution for injection (2370)

REVISED TEXTS

The texts below have been technically revised since their last publication. They will be implemented on **1 January 2016**.

GENERAL CHAPTERS

2.2.4. Approximate pH of solutions

2.2.19. Amperometric titration

2.2.20. Potentiometric titration

2.2.34. Thermal analysis

2.2.36. Potentiometric determination of ionic concentration using ion-selective electrodes

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

2.5.5. Peroxide value

2.5.32. Water: micro determination

2.9.3. Dissolution test for solid dosage forms

2.9.40. Uniformity of dosage units

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

5.2.4. Cell cultures for the production of veterinary vaccines

5.8. Pharmacopoeial harmonisation

5.22. Names of herbal drugs used in traditional Chinese medicine

MONOGRAPHS

Vaccines for veterinary use

Brucellosis vaccine (live) (*Brucella melitensis* Rev. 1 strain) for veterinary use (0793)

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

Pentetate sodium calcium for radiopharmaceutical preparations (2353)

Technetium (^{99m}Tc) medronate injection (0641)

Herbal drugs and herbal drug preparations

Benzoin, Siam (2158)

Bilberry fruit, dried (1588)

Bilberry fruit, fresh (1602)

Centella (1498)

Fresh bilberry fruit dry extract, refined and standardised (2394)

Ginseng (1523)

Java tea (1229)

Homoeopathic preparations

Methods of preparation of homoeopathic stocks and potentisation (2371)

Monographs

Aluminium phosphate, hydrated (1598)

Amidotrizoic acid dihydrate (0873)

Amiloride hydrochloride dihydrate (0651)

Amlodipine besilate (1491)

Anticoagulant and preservative solutions for human blood (0209)

Aprotinin (0580)

Aprotinin concentrated solution (0579)

Bromhexine hydrochloride (0706)

Buserelin (1077)

Carbomers (1299)

Carnauba wax (0597)

Chymotrypsin (0476)

Crospovidone (0892)

Demeclocycline hydrochloride (0176)

Dihydralazine sulfate, hydrated (1310)

Diphenhydramine hydrochloride (0023)

Dithranol (1007)	Orphenadrine hydrochloride (1760)
Doxapram hydrochloride (1201)	Oxeladin hydrogen citrate (1761)
Filgrastim concentrated solution (2206)	Oxolinic acid (1353)
Fluticasone propionate (1750)	Pancreas powder (0350)
Fructose (0188)	Phenazone (0421)
Fulvestrant (2443)	Phentolamine mesilate (1138)
Galactose (1215)	Polysorbate 80 (0428)
Glimepiride (2223)	Potassium hydroxide (0840)
Glucose, anhydrous (0177)	Povidone, iodinated (1142)
Glucose monohydrate (0178)	Propylene glycol dicaprylocaprate (2122)
Hexylresorcinol (1437)	Quinidine sulfate (0017)
Human coagulation factor IX (rDNA) concentrated solution (2522)	Quinine hydrochloride (0018)
Hypromellose (0348)	Quinine sulfate (0019)
Iopanoic acid (0700)	Risedronate sodium 2.5-hydrate (2572)
Ioxaglic acid (2009)	Rivastigmine hydrogen tartrate (2630)
Isoleucine (0770)	Sodium amidotrizoate (1150)
Lactose, anhydrous (1061)	Sodium hydroxide (0677)
Lactose monohydrate (0187)	Sodium nitroprusside (0565)
Leucine (0771)	Sodium selenite pentahydrate (1677)
Lysine hydrochloride (0930)	Spirapril hydrochloride monohydrate (1766)
Methionine (1027)	Sucrose (0204)
Methylcellulose (0345)	Sugar spheres (1570)
Methylprednisolone acetate (0933)	Sulfacetamide sodium (0107)
Methylprednisolone hydrogen succinate (1131)	Theophylline-ethylenediamine hydrate (0301)
Methylthioninium chloride (1132)	Thiamine hydrochloride (0303)
Naftidrofuryl hydrogen oxalate (1594)	Thiamine nitrate (0531)
Nicotinamide (0047)	Thiamphenicol (0109)
Orphenadrine citrate (1759)	Tribenoside (1740)
	Trypsin (0694)

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 8.6 (1 July 2015), unless otherwise indicated.

GENERAL CHAPTERS

- 2.4.22. Composition of fatty acids by gas chromatography
- 2.5.1. Acid value
- 2.7.14. Assay of hepatitis A vaccine
- 2.8.13. Pesticide residues
- 5.7. Table of physical characteristics of radionuclides mentioned in the European Pharmacopoeia

MONOGRAPHS

Radiopharmaceutical preparations and starting materials for radiopharmaceutical preparations

- Gallium (⁶⁸Ga) edotreotide injection (2482)

Monographs

- Cimetidine (0756)

- Cimetidine hydrochloride (1500)
- Flucytosine (0766)
- Goserelin (1636)
- Human antithrombin III concentrate (0878)⁽¹⁾
- Insulin, bovine (1637)
- Insulin, human (0838)
- Insulin, porcine (1638)
- Insulin preparations, injectable (0854)
- Isomalt (1531)
- Miconazole nitrate (0513)
- Nitric acid (1549)
- Oxaliplatin (2017)
- Polyoxypropylene stearyl ether (2602)

(1) Correction to be taken into account from 1 January 2015.

HARMONISED TEXTS

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

GENERAL CHAPTERS

2.2.34. Thermal analysis

2.9.3. Dissolution test for solid dosage forms

2.9.40. Uniformity of dosage units

Glucose, anhydrous (0177)

Glucose monohydrate (0178)

Hypromellose (0348)

Methylcellulose (0345)

Polysorbate 80 (0428)

MONOGRAPHS

Monographs

Crospovidone (0892)

TEXTS WHOSE TITLE HAS CHANGED

The titles of the following texts have been changed in Supplement 8.6.

GENERAL CHAPTERS

2.2.4. Approximate pH of solutions (*previously Relationship between reaction of solution, approximate pH and colour of certain indicators*)

MONOGRAPHS

Monographs

Amiloride hydrochloride dihydrate (0651) (*previously Amiloride hydrochloride*)

DELETED TEXTS

The following texts are deleted as of 1 January 2016.

MONOGRAPHS

Immunosera for veterinary use

Clostridium novyi alpha antitoxin for veterinary use (0339)

Clostridium perfringens beta antitoxin for veterinary use (0340)

Clostridium perfringens epsilon antitoxin for veterinary use (0341)

The following text is deleted as of 1 April 2015.

MONOGRAPHS

Monographs

Liquorice ethanolic liquid extract, standardised (1536)