The International Pharmacopoeia, Seventh Edition

The Seventh Edition was published in 2017 in CD-ROM format and online.

New and revised texts. New and revised texts are introduced for six monographs on pharmaceutical substances, seven monographs on dosage forms, three method of analysis and two texts for the section on “Supplementary information”. A list of these texts is provided as an annex to this preface.

Reproductions from the European Pharmacopoeia. The following revised test is based on a text published in the European Pharmacopoeia, which granted permission for reproduction in *The International Pharmacopoeia*:

Colour of liquids (*1.11*)

This support from the *European Pharmacopoeia* was gratefully acknowledged.

Omitted texts. Following a decision at the Fifty-first meeting of the ECSPP, 80 texts were omitted from the Sixth Edition; they are listed in the annex to this chapter. These texts are further accessible on the website of *The International Pharmacopoeia* (http://www.who.int/medicines/publications/pharmacopoeia/en/). Users of these texts may note that the documents are provided for information; they will neither be updated or revised nor will the prescribed International Chemical Reference Substances (ICRS) be further monitored for the analytical purpose mentioned in the monograph. Users will need to ensure that the described active pharmaceutical substances or dosage forms comply with current rules and regulations governing medicines in their respective territories and that the prescribed reference substances are still suitable for the intended use.

ANNEX

NEW TEXTS

Pharmaceutical substances

-Ceftriaxone sodium
-Chlorhexidine digluconate solution

Dosage forms

-Ceftriaxone for injection
-Chlorhexidine digluconate topical solution
-Clindamycin phosphate injection
-Mebendazole tablets
-Methylthioninium injection

Supplementary information

-Note for guidance on organic impurities in active pharmaceutical ingredients and finished pharmaceutical products.
-Monographs to be evaluated against the text “Related substances in dosage form monographs”.

REVISED TEXTS

Pharmaceutical substances

-Clindamycin phosphate
-Mebendazole
-Medroxyprogesterone acetate
-Methylthioninium chloride

Dosage forms

-Mebendazole chewable tablets
-Medroxyprogesterone injection

Methods of analysis

-Colour of liquids (*1.11*)
-Determination of pH (*1.13*)
-Non-aqueous titrations (*2.6*)

OMITTED TEXTS

Pharmaceutical substances

-Alcuronium chloride

-Aluminium hydroxide
-Aminophylline
-Anaesthetic Ether
-Artemotil
-Benzocaine
-Benzoic acid
-Bephenium hydroxynaphthoate
-Busulfan
-Captopril
-Chloral hydrate
-Chlormethine hydrochloride
-Chlortalidone
-Cimetidine
-Colchicine
-Cyanocobalamin
-Dehydroemetine dihydrochloride
-Diazoxide
-Dicloxacillin sodium
-Dicoumarol
-Digitoxin
-Diphenoxylate hydrochloride
-Dithranol
-DL-Methionine
-Emetine hydrochloride
-Gallamine triethiodide
-Glibenclamide
-Idoxuridine
-Imipramine hydrochloride
-Indinavir sulfate
-Indometacin
-Iopanoic acid
-Iotroxic acid
-Isoprenaline hydrochloride
-Isoprenaline sulfate
-Ketoconazole
-Lactic acid
-Mercuric oxycyanide
-Methylrosanilinium chloride
-Methyltestosterone
-Metrifonate
-Nelfinavir mesilate
-Niridazole
-Nitrazepam
-Nonoxinol 9
-Noscapine
-Noscapine hydrochloride
-Papaverine hydrochloride
-Pethidine hydrochloride
-Physostigmine salicylate
-Piperazine adipate
-Piperazine citrate
-Probenecid
-Procainamide hydrochloride

-Promethazine hydrochloride
-Quinidine sulfate
-Reserpine
-Silver nitrate
-Sodium cromoglicate
-Sodium salicylate
-Sodium sulfate
-Sodium sulfate anhydrous
-Sulfacetamide
-Sulfacetamide sodium
-Sulfadimidine
-Sulfadimidine sodium
-Sulfamethoxypyridazine
-Thioacetazone
-Tiabendazole
-Tolbutamide
-Trihexyphenidyl hydrochloride
-Trimethadione
-Tubocurarine chloride

Dosage forms

-Artemether capsules
-Artemotil injection
-Artenimol tablets
-Atropine sulfate tablets
-Ephedrine sulfate injection
-Nelfinavir mesilate oral powder
-Nelfinavir mesilate tablets

[1] Published in accordance with World Health Assembly Resolution WHA3.10, *WHO Handbook of Resolutions and Decisions*, Vol. 1, 1977, p. 127. This Edition is published electronically by means of incorporation into a replacement CD-ROM and online version.

[2] WHO Technical Report Series, No. 1003, 2017, Annex 2.

[3] WHO Technical Report Series, No. 994, 2015, Annex 1.

[4] WHO Technical Report Series, No. 994, 2015, Annex 2.

[5] WHO Technical Report Series, No. 992, 2015, Annex 1 and Annex 2.

[6] For the current WHO recommendations, consult the WHO Medicines website (http://www.who.int/medicines).

[7] Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. Annex 2, WHO Technical Report Series, No. 953, 2009.
Please note that Table 2 is updated on the following website upon advice from WHO Member States: http://www.who.int/medicines/areas/quality_safety/quality_assurance/regulatory_standards/en/.