The International Pharmacopoeia, Sixth Edition

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New and revised texts. New and revised texts are introduced for 12 monographs on pharmaceutical substances, 12 monographs on dosage forms, one method of analysis and three texts for the section on “Supplementary information”. A list of these texts is provided as an annex.

Omitted texts. Following a decision at the 50th meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP), 18 texts were omitted from the Fifth 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

- -Clindamycin hydrochloride
- -Estradiol cipionate
- -Misoprostol
- -Misoprostol dispersion

Dosage forms

- -Carbamazepine chewable tablets
- -Carbamazepine oral suspension
- -Clindamycin hydrochloride capsules
- -Dextromethorphan oral solution
- -Flucytosine intravenous infusion
- -Misoprostol tablets
- -Norethisterone tablets

Supplementary information

- -Levomethorphan limit test for dextromethorphan containing finished pharmaceutical products

REVISED TEXTS

Pharmaceutical substances

- -Atazanavir sulfate
- -Cycloserine
- -Carbamazepine
- -Dextromethorphan hydrobromide
- -Flucytosine
- -Levonorgestrel
- -Medroxyprogesterone acetate
- -Norethisterone

Dosage forms

- -Artemether injection
- -Artesunate for injection
- -Carbamazepine tablets
- -Cycloserine capsules
- -Medroxyprogesterone injection

Methods of analysis

- -High-performance liquid chromatography (1.14.4)

Supplementary information

-Notes for guidance: Dissolution testing of tablets and capsules
-Reference substances and reference spectra

OMITTED TEXTS

Pharmaceutical substances

-Bacitracin
-Bacitracin zinc
-Bleomycin hydrochloride
-Chlortetracycline hydrochloride
-Erythromycin (base)
-Neomycin sulfate
-Oxytetracycline dehydrate
-Oxytetracycline hydrochloride

Dosage forms

-Ampicillin capsules
-Colchicine tablets
-Ergometrine hydrogen maleate tablets
-Indometacin tablets
-Pethidine hydrochloride tablets
-Piperazine adipate tablets
-Piperazine citrate tablets
-Prednisolone sodium phosphate injection
-Prednisolone sodium succinate powder for injections
-Probenecid tablets