The International Pharmacopoeia, Eighth Edition

This is the Eighth Edition of *The International Pharmacopoeia*, published in 2018.

New and revised texts. New and revised texts are introduced for 40 monographs on pharmaceutical substances, 13 monographs on dosage forms and one method of analysis.

As part of the activities to replace mercury salts in titrations of halide salts of weak bases, alternative titrations either with perchloric acid in anhydrous acetic acid or with sodium hydroxide in alcoholic media are introduced in 31 monographs. Two of these new titrations are based on laboratory investigations; the other provisions were based on texts found in the European Pharmacopoeia, which granted permission for reproduction in the Ph.Int. and whose support is gratefully acknowledged.

A list of new and revised texts is provided as an annex to this preface.

Omitted texts. Following a decision at the 52nd meeting of the ECSPP, one text, the monograph on Thiamine hydrobromide, was omitted from the Seventh Edition. Omitted 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.

ANNEX

NEW TEXTS

Pharmaceutical substances

-Clindamycin palmitate hydrochloride
-Ganciclovir
-Clavulanate potassium

Dosage forms

-Amoxicillin and clavulanic acid tablets
-Clindamycin palmitate powder for oral solution
-Ganciclovir for injection
-Protionamide tablets

Methods of analysis

-Capillary Electrophoresis

REVISED TEXTS

Pharmaceutical substances

-Amiloride hydrochloride
-Amitriptyline hydrochloride
-Amoxicillin trihydrate
-Atazanavir sulfate
-Atenolol
-Biperiden hydrochloride
-Capreomycin sulfate
-Chlorhexidine dihydrochloride
-Chlorpromazine hydrochloride
-Ciclosporin
-Dacarbazine
-Dopamine hydrochloride
-Edrophonium chloride
-Ephedrine hydrochloride
-Ethambutol hydrochloride
-Fluphenazine hydrochloride
-Homatropine hydrobromide
-Homatropine methylbromide

-Ketamine hydrochloride
-Lidocaine hydrochloride
-Loperamide hydrochloride
-Metoclopramide hydrochloride
-Morphine hydrochloride
-Naloxone hydrochloride
-Neostigmine bromide
-Pilocarpine hydrochloride
-Procarbazine hydrochloride
-Proguanil hydrochloride
-Propranolol hydrochloride
-Protionamide
-Pyridostigmine bromide
-Pyridoxine hydrochloride
-Quinine dihydrochloride
-Quinine hydrochloride
-Suxamethonium chloride
-Thiamine hydrochloride
-Verapamil hydrochloride

Dosage forms

-Atazanavir capsules
-Capreomycin for injection
-Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets
-Emtricitabine and tenofovir disoproxil fumerate tablets
-Ethinylestradiol and levonorgestrel tablets
-Mebendazole tablets
-Protionamide tablets
-Sulfamethoxazole and trimethoprim oral suspension
-Tenofovir disoproxil fumarate tablets

OMITTED TEXTS

Pharmaceutical substances

-Thiamine hydrobromide