## Fourth Edition, *Fourth Supplement*

The Fourth Supplement to the Fourth Edition of *The International Pharmacopoeia* was published in 2014 in CD-ROM format and online. It comprises the two main volumes published in 2006, the First Supplement published in 2008, the Second Supplement published in 2011, the Third Supplement published in 2013 and the Fourth Supplement.

**New and revised texts.** New and revised texts are introduced for eight monographs on pharmaceutical substances, 15 monographs on dosage forms, one general monograph, three methods of analysis and three texts for the section on *Supplementary information*. The new, revised and withdrawn texts are as follows:

### NEW TEXTS

#### Pharmaceutical substances

- -Aciclovir
- -Capreomycin sulfate
- -Fluconazole

#### Dosage forms

- -Aciclovir for injection
- -Aciclovir tablets
- -Albendazole chewable tablets
- -Sulfamethoxazole and trimethoprim intravenous infusion
- -Sulfamethoxazole and trimethoprim oral suspension

#### Supplementary information

- -Notes on guidance: dissolution testing of tablets and capsules
- -Recommendations for quality requirements when plant derived artemisinin is used as a starting material in the production of antimalarial active pharmaceutical ingredients
  (This document was first published in: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-sixth report.* Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 6.)

### REVISED TEXTS

#### Pharmaceutical substances

- -Artemisinin
- -Medroxyprogesterone acetate
- -Niclosamide
- -Pentamidine isetionate
- -Testosterone enantate

#### Dosage forms

- -Capreomycin for injection
- -Chloroquine phosphate tablets
- -Chloroquine sulfate oral solution
- -Chloroquine sulfate tablets
- -Levonorgestrel tablets
- -Medroxyprogesteron injection
- -Niclosamide tablets
- -Pentamidine isetionate for injection
- -Streptomycin injection
- -Tenofovir tablets

#### General monographs

- -Parenteral preparations

#### Methods of analysis

- -Dissolution test for solid oral dosage forms (5.5)

-Melting temperature and melting range (1.2.1)
-Spectrophotometry in the infrared region (1.7)

**Supplementary information**

-Reference substances and reference spectra

**Pharmacopoeial Discussion Group (PDG)-harmonized general texts.** The PDG text on

-Dissolution test for solid oral dosage forms

was adapted to the editorial style of *The International Pharmacopoeia* and is included in this Supplement.

This support from the PDG is gratefully acknowledged.

**Version date.** Starting with texts newly published or revised for the Fourth Supplement, the year of publication together with a two digit number (for example 2014-01 for a text that is new or revised for the Fourth Supplement) is added above the title of each text (monograph, general chapter or text for the supplementary information). The version date makes it possible to identify the successive versions of texts in different volumes and supplements.

**Infrared reference spectra.** Many monographs in *The International Pharmacopoeia* include an identification test using infrared spectroscopy; these tests usually allow comparison either with a spectrum obtained from the ICRS or with an IIRS. Eight additional spectra of the following substances are added to the IIRS collection with this supplement:

-Biperiden HCl
-Cytarabine
-Metoclopramide HCl
-Pentamidine isetionate
-Quinidine sulfate
-Salbutamol sulfate
-Tiabendazole
-Valproic acid.

**Editorial changes** . Following a decision at the forty-fifth meeting of the Expert Committee the title of monographs on injections intended to be reconstituted before use from a powder was changed from “powder for injections” to “for injection”. Following the publication of the 18th edition of the EML information given on the strength of medicines under the section *Additional information* was updated in several monographs. Information provided in the reagent section was reviewed as to whether the listed reagents are still invoked in monographs. As a consequence, several editorial changes were made in this section.