WHO DRUG INFORMATION

Volume 34 • Number 2 • 2020

Proposed INN: List 123

International Nonproprietary Names for Pharmaceutical Substances

World Health Organization

WHO Drug Information

WHO Drug Information provides an overview of topics relating to medicines development, regulation, quality and safety. The journal also publishes and reports on guidance documents and includes lists of International Nonproprietary Names for Pharmaceutical Substances (INN), ATC/DDD classification and monographs for The International Pharmacopoeia. It presents and describes WHO policies and activities while reflecting on technical and pharmaceutical topics of international and regional interest.

WHO Drug Information is published four times a year and can be ordered from:
WHO Press, World Health Organization, 1211 Geneva 27, Switzerland.
e-mail: bookorders@who.int or on line at http://www.who.int/bookorders

WHO Drug Information can be viewed at:
http://www.who.int/druginformation

WHO Drug Information, Vol. 34, No. 2, 2020

ISBN 978-92-4-000968-4 (electronic version)
ISBN 978-92-4-000969-1 (print version)
ISSN 1010-9609

Printed in France

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International Nonproprietary Names (INN)

Abbreviations and websites

CHMP	Committee for Medicinal Products for Human Use (EMA)
EMA	European Medicines Agency (www.ema.europa.eu)
EU	European Union
FDA	U.S. Food and Drug Administration (www.fda.gov)
Health Canada	Federal department responsible for health product regulation in Canada (www.hc-sc.gc.ca)
HPRA	Health Products Regulatory Authority, Ireland (www.hpra.ie)
HSA	Health Sciences Authority, Singapore (www.hsa.gov.sg)
ICDRA	International Conference of Drug Regulatory Authorities
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (www.ich.org)
IGDRP	International Generic Drug Regulators Programme (https://www.igdrp.com)
MHLW	Ministry of Health, Labour and Welfare, Japan
MHRA	Medicines and Healthcare Products Regulatory Agency, United Kingdom (www.mhra.gov.uk)
Medsafe	New Zealand Medicines and Medical Devices Safety Authority (www.medsafe.govt.nz)
Ph. Int	*The International Pharmacopoeia* (http://apps.who.int/phint/)
PRAC	Pharmacovigilance Risk Assessment Committee (EMA)
PMDA	Pharmaceuticals and Medical Devices Agency, Japan (www.pmda.go.jp/english/index.htm)
Swissmedic	Swiss Agency for Therapeutic Products (www.swissmedic.ch)
TGA	Therapeutic Goods Administration, Australia (www.tga.gov.au)
U.S.	United States of America
WHO	World Health Organization (www.who.int)
WHO MHP	WHO Access to Medicines and Health Products Division (www.who.int/medicines/en/)
WHO RPQ	WHO Regulation and Prequalification Department
WHO PQT	WHO Prequalification Unit (https://www.who.int/topics/prequalification/en/)
WHO HPS	WHO Health Product Policy and Standards Department

Note: The online version of this issue (freely available at www.who.int/medicines/publications/druginformation) has

Publication News

Publication of the ***54th report of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) (WHO Technical Series, N° 1025).***
https://www.who.int/publications/i/item/978-92-4-000182-4

The WHO ECSPP advises the Director-General of WHO in the area of medicines quality assurance. It oversees the maintenance of *The International Pharmacopoeia* (*3*) and provides guidance for use by relevant WHO units and regulatory authorities in WHO Member States to ensure that medicines meet unified standards of quality, safety and efficacy. The ECSPP's guidance documents are developed through a broad consensus-building process, including iterative public consultation. Representatives from international organizations, state actors, non-state actors, pharmacopoeias and relevant WHO departments are invited to the ECSPP's annual meetings, to provide updates and input to the Expert Committee's discussions.

At its Fifty-fourth meeting, held from 14 to 18 October 2019 in Geneva, Switzerland, the ECSPP heard updates on cross-cutting issues from other WHO bodies, including the ECBS, the Expert Committee on the Selection and Use of Essential Medicines, the Local Production Programme, the MSM on substandard and falsified medical products, the PQT, the RSS unit and the INN team. Updates were also presented by partner organizations, including the IAEA, the PDG and UNICEF.

The EDQM updated the ECSPP on its activities as the custodian centre in charge of ICRS for use with monographs of *The International Pharmacopoeia*. Results from the latest phase of the EQAAS, which is organized by WHO with the assistance of the EDQM, were also presented.

The ECSPP reviewed new and revised specifications and general texts for quality control testing of medicines for inclusion in *The International Pharmacopoeia*. The Expert Committee adopted 13 guidelines and 16 pharmacopoeial texts (two general chapters, 13 new and revised monographs and one correction), omitted three pharmacopoeial texts, and confirmed the release of six new ICRS established by the custodial centre for use in connection with *The International Pharmacopoeia*.

The ECSPP also agreed to publish the outcomes of the WHO Biowaiver Project as an annex to its report; this will be a living document that will be updated as data become available.

The sections that follow summarize the specific decisions and recommendations made by the ECSPP during its Fifty-fourth meeting in 2019.

Guidelines and decisions adopted and recommended for use:

The following guidelines and decisions were adopted and recommended for use:

- Procedure for the elaboration, revision and omission of monographs and other texts for The International Pharmacopoeia (Annex 1);
- International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceuticals (Annex 2);
- Production of water for injection by means other than distillation (Annex 3);
- Good chromatography practices (Annex 4);
- Quality management system requirements for national inspectorates (Annex 5);
- Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance (Annex 6);
- Good storage and distribution practices for medical products (Annex 7);
- Points to consider for setting the remaining shelf-life of medical products upon delivery (Annex 8);
- World Health Organization/United Nations Population Fund Prequalification Programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices (Annex 9);
- World Health Organization/United Nations Population Fund technical specifications for male latex condoms (Annex 10);
- World Health Organization/United Nations Population Fund specifications for plain lubricants (Annex 11);
- WHO "Biowaiver List": proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate- release, solid oral dosage forms (Annex 12); and
- WHO guideline on the implementation of quality management systems for national regulatory authorities (Annex 13).

Texts adopted for inclusion in *The International Pharmacopoeia*

The ECSPP adopted a series of texts, chapters and monograph, as listed next:

General texts

- Workplan 2020–2021

General chapters

- Polymorphism (new)
- Capillary electrophoresis (revision)

Monographs

General monographs for dosage forms and associated method texts

- Water for injections (revision)
- Ethanol/water mixtures in the reagent section (correction)

For antimalarial medicines

- doxycycline hyclate (revision)
- doxycycline capsules (revision)
- doxycycline tablets (revision)
- pyrimethamine (revision)
- pyrimethamine tablets (new)

For antibacterials, including antituberculosis medicines

- levofloxacin hemihydrate (revision)
- levofloxacin tablets (revision)

Other medicines for infectious diseases

- ciprofloxacin hydrochloride (revision)
- ciprofloxacin tablets (new)

Omissions

The ECSPP agreed to omit the following texts from *The International Pharmacopoeia*:

- undue toxicity (including the whole of Chapter 3.7 and all reference to the undue toxicity test in the monographs on kanamycin acid sulfate and kanamycin monosulfate);
- chlorpheniramine hydrogen maleate (monograph); and
- chlorpheniramine hydrogen maleate tablets (monograph).

International Chemical Reference Substances

The ECSPP confirmed the release of the following ICRS that have been newly characterized by the custodial centre, EDQM:

- metacycline ICRS 1
- artemether ICRS 3
- albendazole ICRS 1
- ethinylestradiol ICRS 4

The ECSPP also authorized the following chemical reference substances, established by the EDQM, for use according to the respective monographs in *The International Pharmacopoeia*:

- ciprofloxacin hydrochloride for peak identification
- levofloxacin for system suitability

***

Points to consider on the different approaches – including HBEL – to establish carryover limits in cleaning validation for identification of contamination risks when manufacturing in shared facilities

DRAFT FOR COMMENTS

Please send your comments to **Dr Valeria Gigante**, Technical Officer, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (gigantev@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) before **30 June 2020**.

Our working documents are sent out electronically and they will also be placed on the WHO Medicines website
http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/
for comments under the "*Current projects*" link.

If you wish to receive all our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.