International Pharmacopoeia

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The International Pharmacopoeia (Ph. Int.) constitutes a collection of recommended procedures for
analysis and specifications for the determination of pharmaceutical substances and dosage forms that
is intended to serve as source material for reference or adaptation by any WHO Member State wishing
to establish pharmaceutical requirements. The pharmacopoeia, or any part of it, shall have legal
status, whenever a national or regional authority expressly introduces it into appropriate legislation.
Further explanation or the role of The International Pharmacopoeia is provided in the paragraphs
entitled "Scope and function" at the end of the Preface of this edition.

The history of *The International Pharmacopoeia* dates back to 1874 when the need to standard terminology and to specify dosages and composition of medicines led to this internation pharmacopoeial compendium. The first World Health Assembly in 1948 established with the resolute WHA1.27 the Secretariat of *The International Pharmacopoeia* and the "Expert Committee on Unification of Pharmacopoeias of the World Health Organization", which later became the "Exp Committee on Specifications for Pharmaceutical Preparations".

Compared to other pharmacopoeias, priority is given to medicines included in the WHO Model List of Essential Medicines and to medicines which are important for WHO health programmes and for which other pharmacopoeias do not offer any test specifications. The quality control specifications published in *The International Pharmacopoeia* are developed independently via an international consultative procedure. The needs of developing countries are taken into account. The ultimate goal of *The International Pharmacopoeia* is to provide quality control specifications so as to help enabling access to quality medicines worldwide.

About this Library

This Library contains the Sixth Edition of The International Pharmacopoeia.

This Library was produced by WHO Department of Essential Medicines and Health Products with the help of Human Info NGO/WIT and its logistic partner HumanityCD Ltd, and the University of Waikato, New Zealand, using the Greenstone software of the New Zealand Digital Library. It also includes Mozilla Firefox, distributed by Human Info NGO/WIT.

Logo



The International Pharmacopoeia Sixth Edition, 2016

URL http://apps.who.int/phint/en/p/about/

Subject Pharmacopoeias;

Pharmaceutical Preparations – standards;

Dosage Forms – standards;

Pharmaceutical Preparations – analysis-standards.

Accessibility Free

English, Latin Language

Publisher World Health Organization

Brief History The International Pharmacopoeia (Pharmacopoeia Internationalis, Ph. Int.) is

> a pharmacopoeia issued by the World Health Organization as a recommendation, with the aim to achieve a wide global uniformity of quality specifications for selected pharmaceutical drugs, excipients, and dosage forms. The history of *The* International Pharmacopoeia dates back to 1874 when the need to standardize terminology and to specify dosages and composition of medicines led to this

international pharmacopoeial compendium. The first World Health Assembly in 1948 established with the resolution WHA1.27 the Secretariat of *The International Pharmacopoeia* and the "Expert Committee on the Unification of Pharmacopoeias of the World Health Organization", which later became the "Expert Committee on Specifications for Pharmaceutical Preparations". The first edition of International Pharmacopoeia was published in 1951 with in volume and in 1955 with five volumes. In 2006, the fourth edition was published with CD-ROM. From 2015 it can be access online.

Scope and Coverage

Compared to other pharmacopoeias, priority is given to medicines included in the WHO Model List of Essential Medicines and to medicines which are important for WHO health programmes and for which other pharmacopoeias do not offer any test specifications. The quality control specifications published in *The International Pharmacopoeia* are developed independently via an international consultative procedure. The needs of developing countries are taken into account. The ultimate goal of *The International Pharmacopoeia* is to provide quality control specifications so as to help enabling access to quality medicines worldwide.

The Pharmacopoeia provides monographs for pharmaceutical substances, like Acetic acid, Acetylsalicylic acid, Aciclovir, Cytarabine, Dacarbazine etc., Monographs for dosage forms and Radiopharmaceuticals (unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy), Physical and Physicochemical, Chemical, Biological Methods for analysis, and Pharmaceutical technical procedures, Infrared reference spectra, like Abacavir sulfate, Acetazolamide, Allopurinol, Amidotrizoic acid, Amiloride hydrochloride etc. International pharmacopeia also includes the reagents, test solutions and volumetric solutions and explanatory and other supplementary information like recommendations on Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products, dissolution testing of tablets and capsules, related substances in dosage form monographs, microbiological quality of non-sterile products: recommended acceptance criteria for pharmaceutical preparations, test methods used during development or manufacture, test methods used for investigative testing of suspicious samples etc.

Kind of Information

The information published in the International Pharmacopoeia is collated via a consultative procedure and is based on international experience, the monographs being established in an independent manner. Under the category namely monographs on Pharmaceutical substances, it give information like Molecular formula, Relative molecular mass, Graphic formula, Chemical name and Description of that substance, Solubility, Category, Storage, Labelling and Additional information. Under the heading "Requirements" it provides information like Definition, Identity tests, name of related substances (sometimes) etc. In this standard priority is given to those medicines that are widely used throughout the world. High priority is accorded to medicines that are important to WHO health programs, and which may not appear in any other pharmacopoeias, e.g., new antimalarial drugs etc. The dosage form of General monograph like Capsules includes definition, manufacture, visual inspection, uniformity of mass, uniformity

of content, dissolution/disintegration, Labelling, storage, requirements for specific types of capsules like hard capsules, soft capsules, modified-release capsules etc.

Special Features

- ➤ Under the heading "Help" the International Pharmacopeia provides detailed guidelines which help its users to navigate the tool. It gives also 8 useful tips to access quickly its contents. Also it provides tips for browse preferences, search preferences, finding the needed information and searching for particular words;
- ➤ WHO Library provides Cataloguing-in-Publication Data for this standard and also provides NLM classification number of this tool;
- ➤ Users can type words in the search box, and then click on the "Search" button for a full-text search. Searching for some words displays the titles by nearest hits. Searching for all words displays the exact hits alphabetically by titles. One can use Boolean operators (AND, OR and NOT) and the proximity operator (NEAR) to specify additional search information. One must have to click on a document icon to view a full-text version of the document:
- ➤ The Ph. Int. is guided by the Expert Committee on Specifications for Pharmaceutical Preparations;
- ➤ Collaboration with standard-setting organizations and parties, including regional and national pharmacopoeias;
- Networking and close collaboration with WHO Member States, Drug Regulatory Authorities;
- > Links with other WHO activities;
- > Free for use by all Member States.

Arrangement Pattern

The content of this standard is divided into categories like General Notices, Appendices to the General Notices, Monographs, Methods of Analysis, Infrared reference spectra, Reagents, test solutions and volumetric solutions and Supplementary information. Under each category there are further subdivision into sub categories and then monographs. The arrangement of categories and subcategories are topic wise. The monographs under those categories and sub categories are arranged alphabetically.

Remarks

The International Pharmacopeia which is provided by the WHO becomes an exceptionally good reference source for the pharmaceutical specification for the world and due to the WHO participations it becomes trust worthy in this field. This standard is a collection of monographs and requirements for drug substances, excipients, dosage forms, dissolution testing and many more. The navigating of this tool is easy for the guidelines provided by the WHO library and they make such a

	well organized easy to use pharmaceutical specification tool for the world. Its aim is to promote quality assurance and quality control of pharmaceuticals.
Comparable Tools	 European Pharmacopoeia (https://www.edqm.eu/) Indian Pharmacopoeia Commission (http://ipc.nic.in/) Chinese Pharmacopoeia (http://wp.chp.org.cn/en/index.html) United States Pharmacopeia (http://www.usp.org/) British Pharmacopoeia (https://www.pharmacopoeia.com/)
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