SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES
Sathy Main Road, SNS Kalvi Nagar,
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PHARMACEUTICAL INORGANIC CHEMISTRY

UNIT I

Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, the principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

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HISTORY OF PHARMACOPOEIA

The word "pharmacopoeia" is derived from the Greek words 'pharmacon' meaning 'drug' and 'poiein' means 'make'. A pharmacopoeia is a legally binding collection, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region.

The books containing the standards for drugs and other related substances are known as pharmacopoeia. The pharmacopoeia contain a list of drugs and other related substances regarding their source, descriptions, standards, tests, formulae for preparing the same, action and uses, doses, storage conditions etc. These books are prepared under the authority of the Government of the respective countries.

These books are revised from time to time so as to introduce the latest information available as early as possible after they become established. In order to keep the size of book within reasonable limit it becomes necessary to omit certain less frequently used drugs and pharmaceutical adjuvants from each new edition of the book. Therefore, in each new edition of these books certain new monographs are added while the older ones are deleted. For the preparation of these books the expert opinion of medical practitioners, teachers and pharmaceutical manufacturers are obtained.

History of IP

The historical developments of Pharmacopoeia in India traces back to 1563 and the credit goes to Garcia da Orta a Portugese physician-cum-teacher. The idea of indigeneous Indian Pharmacopoeia was concieved in 1837 which bore fruits in 1841 in the shape of **Bengal Pharmacopoeia** and **Conspectus of Drugs.**

The hindustani version in Bengali and Hindi of London Pharmacopoeia was made available in India from 1901 onwards. The Indian Pharmacopoeial List, published in 1946 formed the seeding for the true **Official Indian Pharmacopoeia** published in **1955.**

The first edition of Indian Pharmacopoeia was published in 1955, but actually the process was started as early as 1944. In 1944 Government of India asked the Drugs Technical Advisory Board to prepare the list of drugs used, in India, having sufficient medicinal value to justify their inclusion in official pharmacopoeia.

The Indian Pharmacopoeial List, 1946.

The list of drugs both included and not included in the British Pharmacopoeia along with standards to secure their usefulness, tests for identity and purity was prepared by the committee and was published by the Government of India under the name 'The Indian Pharmacopoeial List 1946'.

The committee constituted under the chairmanship of Col. Sir R.N.Chopra along with other nine members, prepared the list of drugs with the following details:

- Substances included in the British Pharmacopoeia for crude drugs, chemicals and their preparations.
- Substances not included in the British pharmacopoeia
    a) Drugs of plant origin
    b) Drugs of animal origin
    c) Biological products
    d) Insecticides
    e) Colouring agents
    f) Synthetics
    g) Miscellaneous
    h) Drugs for veterinary use.

The Indian Pharmacopoeial List 1946 was prepared by Department of Health, Govt. of India in 1946. In 1948, the Govt. of India constituted a permanent Indian Pharmacopoeia Committee. This committee was assigned the task of preparing Indian Pharmacopoeia and to keep it up-to-date. Tenure of this committee was 05 years. In 1978, the Indian Pharmacopoeia Committee was reconstituted by the Govt. of India, Ministry of Health and Family Welfare, under the chairmanship of Dr. Nitya Nand, Director, Central Drug Research Institute, Lucknow.

EDITION	**YEAR OF PUBLICATION**	**YEAR OF ADDENEDUM RELEASED**	**FEATURES OF EDITION**
First	1955	1960	Indian Pharmacopeia committee under chairmanship of Dr. B. N. Ghosh Published first edition of IP. It contains both western and traditional system drugs commonly used in India. First edition of IP is written in English & official titles of monographs given in Latin. It covers 986 monographs.
Second	1966	1975	It was published under the chairmanship of Dr. B. Mukherjee. It contains both western and traditional system drugs commonly used in India. 274 monographs from IP 55 & their supplement were deleted. 93 new monographs were added. Official titles of monographs given in English. Dose were expressed in Metric system. For Tablets and Injections "USUAL STRENGTH" have been given. Formulations of the drugs were given immediately after the monograph of drugs. Cholera vaccine has been deleted.
Third	1985	1989(1st) 1991(2nd)	261 new monographs have been added. 450 monographs were deleted.

Fourth	1996	2000(1st) 2002(2nd) 2005(3rd)	which included a large number of antiretroviral drugs and raw plants commonly used in making medicinal products not covered by any other pharmacopoeias and attracted much global attention. The indian Pharmacopeia Committee decide to delete the less used product monographs and added monographs based on their therapeutic merit and medicinal need. It covered 1149 monographs and 123 appendices. It includes 294 new monographs & 110 monographs have been deleted.
Fivth	2007	2008	It is presented in 03 Volumes. Volume 1: contains general notices & general chapters. Volume 2 & 3: Contains general monographs on drug substances, dosage forms & Pharmaceutical aids.
Sixth	2010	2012	It is presented in 03 volumes. Volume I: contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction and the General Chapters. Volume II: contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids (A to M). Volume III: contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z). Monographs on vaccines and immunosera for human use, herbs and herbal products, blood and blood-related products, biotechnology products and veterinary products. Products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, fixed-dose combinations.
Seventh	2014	2015	It contains 313 New monographs on drug substances, dosage forms & pharmaceutical aids (A to Z) 43 New drugs substances monographs, 10 Antibiotic monographs, 31 Herbal monographs, 05 Vaccines & immunosera for human use 06 Insulin products, 07 biotechnology products etc. along with the 19 new general chapters 19 New radiopharmaceutical monographs & 1 general chapter is first time being included in this edition
Eighth	2018	2019	04 Volumes, 170 Chemical Monographs, 15 herbal monograph, 10 monograph on blood and related products, 06 monographs on biotechnology derived products, 02 monographs on vaccine and immune sera.
Nineth	2022		It contains a total of 92 new monographs including 60 Chemical, 21 Vitamins, Minerals, Amino acids, Fatty acids etc., 3 Biotechnology-derived Therapeutic Products, 4 Human Vaccines, 2 Blood and Blood Related Products, 2 Herbs and Herbal Related Products, and 7

			Phytopharmaceutical Ingredient Category monographs. This has led to the total number of 3152 monographs in the current edition of IP. In additions, 12 new general chapters have also been introduced. Several monographs and general chapters have also been revised to update them as per current global requirements and to harmonize with other pharmacopoeias like USP, BP, EP, etc.