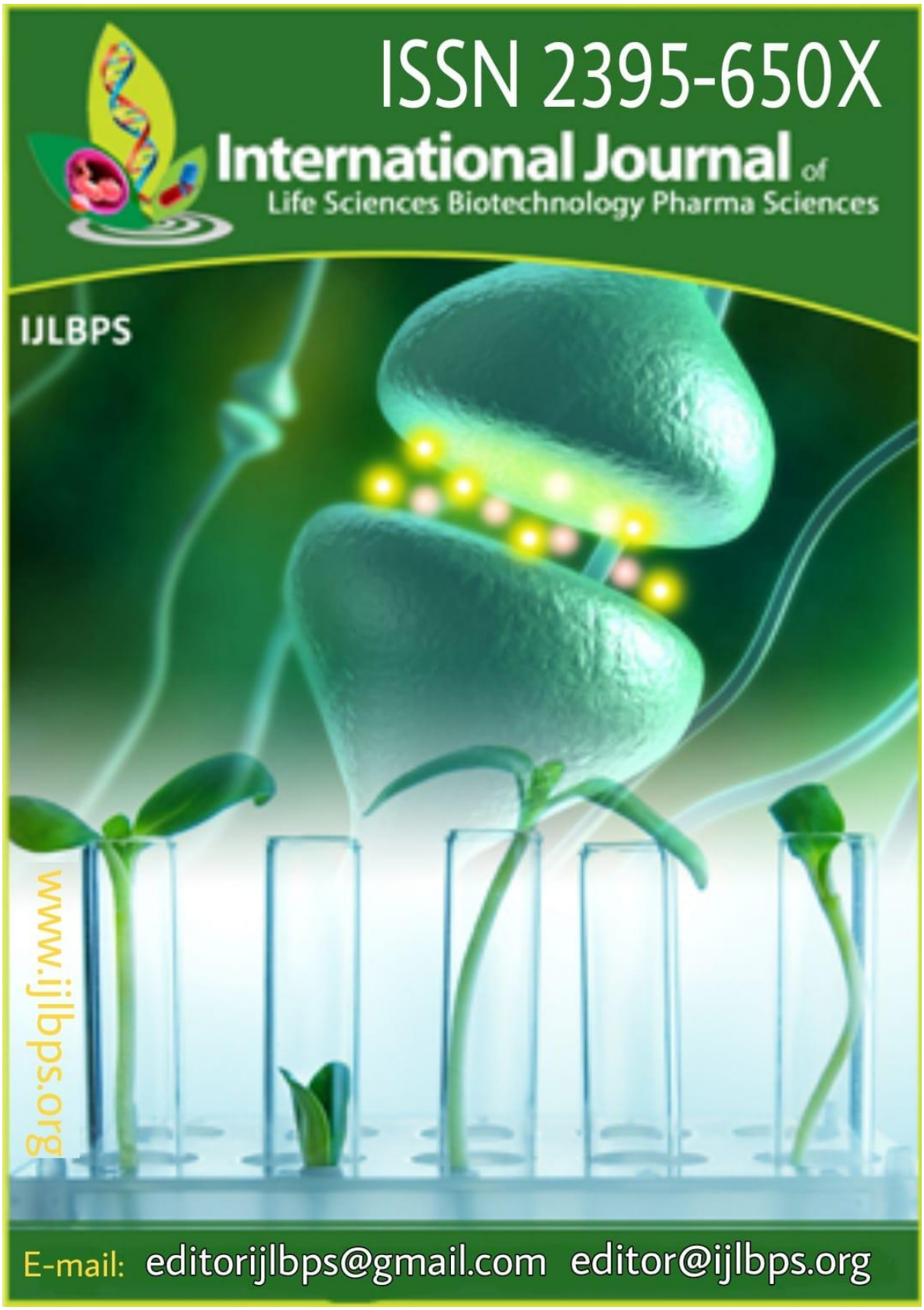

ISSN 2395-650X
International Journal of
Life Sciences Biotechnology Pharma Sciences
IJLBPS
www.ijlbps.org
E-mail: editorijlbps@gmail.com editor@ijlbps.org

International Journal of Life Sciences Biotechnology Pharma Sciences

Volume 12 Issue2, 2024

# PHARMACOPOEIA

Main author : B. Akhila
Co- author : S. Tharun Kumar

## INTRODUCTION

Derived from Greek word ‘ Pharmakon ’ means drug and ‘ Poiea ’ means to make.it is a legal and official book issued by recognized authorities usually appointed by Government of each country. it comprises list of pharmaceutical substances, formula along with their description and stand.

List of Pharmacopeias:

a) Argentine b) Austrian c) Belgian d) Brazilian e)British f) Chinese g) Egyptian h) European i) French j) German k) Hungarian l) Indian m) International n) Italian o) Japanese. p)Yugoslavian q)Mexican r) Netherlands s) Nordic t)Polish u) Portuguese v) Rumana Indian Pharmacopoeia.

## *INDIAN PHARMACOPOEIA*

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India. IP prescribes standards for identity, purity and strength of drugs essentially required from health care perspective of human beings and animals. IPC also provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP.

. First official Pharmacopeia of India appeared in 1868 which was edited by edward John Waring.Inpreindependence days, British Pharmacopeia was used in India. The colonial addendum of BP 1898 was published in 1900.appeared as Government of

India edition in 1901. In 1946

Government of India issued one list known as ,,The Indian Pharmacopeia list"Committee under chairmanship of Sir R. N. Chopra along with other② nine members prepared ,,The Indian Pharmacopoeial list" It was prepared by Dept. of

Health, Govt. of India, Delhi in 1946. In 1948 Government of India appointed an Indian Pharmacopeia committee for preparing „Pharmacopeia of India"

Tenure of this committee was five years.Indian Pharmacopeia committee under chairmanship of Dr. B. N. Ghosh Published first edition of IP in 1955.It is written in English& official titles of monographs given inLatin.It covers 986 monographs. Supplement to this edition was published in 1960.Second edition of IP was published in 1966 under the chairmanship of Dr. B. Mukerji. 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. 274 monographs from IP 55 & their supplement were deleted.93 new monographs were added Supplement to this edition was published in 1975.

126 new monographs have been included & 250 monographs have been amended. Third edition of IP was published in 1985 with two volumes & nine appendices. 261 new monographs have been added. 450 monographs were deleted. Addendum I to IP was published in 1989 were 46 new monographs added and 126 amended.

Addendum II was published in 1991 were 62 new monographs added and 110 amended.

Fourth edition of IP was published in 1996 under the chairmanship of Dr. Nityanand.

It has been made effective from 1st December 1996. It covered 1149 monographs and

123 appendices.It includes 294 new monographs & 110 monographs have been deleted.Addendum I has been made effective from 31st December 2000.were 42 new

monographs have been

added.Addendum II has been made

effective from 30th June 2003 were19

new monographs have been added.

The veterinary supplement to IP 1996 contains 208 monographs &four appendices Fifth edition of IP was published in 2007 & addendum to this edition was published in 2008.

IP 2007 is presented in Three

Volumes. Volume One contains general notices &③ general chapters. Volume Two & Three contains general monographs on drug substances , dosage forms & Pharmaceutical aids.Indian Pharmacopoeia 2010 . 6th edition of IP is published in 2010.The 6th edition of the Indian Pharmacopoeia 2010 is published by the Indian Pharmacopoeia Commission (IPC) Ghaziabad in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.It supersedes the 2007 edition but any monograph of the earlier edition that does not figure in this edition.This edition would be effective from 1st September, 2010.The Indian Pharmacopoeia 2010 is presented in three volumes.Volume I contains the Notices, Preface, the Structure of the IPC, Ac knowledgements, Introduction, and the General Chapters.

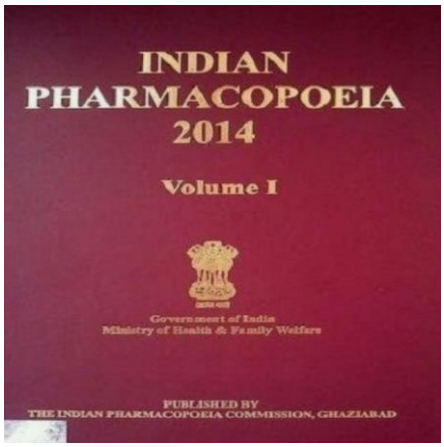
Volume II contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids (A to M).Volume III contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z). Followed by Monographs on Vaccine and Immunosera for human use, Herbs and Herbal products, Blood and blood related products, Biotechnology products and Veterinary products.

The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed- dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a

day are omitted from this edition. The number of monographs of Excipients, Anticancer drugs, Herbal products and antiretroviral drugs has been increased in this edition.

Monographs of Vaccines and immunosera are also upgraded in view of development of latest technology in the field.

A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.




figer:1 Indian Pharmacopeia

.

Achapter on NMR is incorporated in Appendices.

The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing internatioal requirements.

.

Seventh Edition of Indian Pharmacopoeia

The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on be half of the Government of India, Ministry of Health & Family Welfare.

The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of bioh ology, indigenous herbs and herbal products, veterinary vaccines.

The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of Apish, excipients, dosage forms and herbal products etc. A list of 577 New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing 313 New Monographs on drug substances, Dosage for

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. This edition of Indian Pharmacopoeia-2014 is now under printing and will be available to stakeholders probably in Sept.2013, before three

months of its effective date, i.e. 1st Jan 2024.first edition of BP was published in 1864. it

consist of two sections Part I:-Materia Medical& Part II:- Preparation & compounds. Second edition of BP was published in 1867.Fourth edition of BP was published in 1898.
Fifth edition of BP was published in 1914. eighth edition of BP was published in 1953.

In this edition titles of drugs & preparations were in Englishinstead of Latin and metric system. it has been published annually In BP 2007 monographs has been introduced for material specifically used in preparation of Traditional Chinese medicines.Term „Prolonged release“ has been replaced the term „Slow“ and the term „Gastro- resistant“ has been replaced with „Enteric coated“ in number of

monograph.

BP 2008 contains approximately 3100 monographs for substances, preparations and articles used in practice. it has been made effective from 1st January 2008.BP 2007 -2009 were given in Six Volumes i.e. Volume I to Volume VI.

Volume I & II contains medicinal substances.

Volume III contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations,surgical materials & homeopathic preparations. Volume IV contains supplementary chapters, IR spectra etc.

Volume V contains veterinary.Volume VI contains CD ROM version.

Current edition of BP 2010 is in process.TSO (The Stationery Office), on behalf of the British Pharmacopoeia Secretariat, part of the Medicines and Healthcare products Regulatory Agency (MHRA), has recently published the British Pharmacopoeia (BP) 2010.

The British Pharmacopoeia (BP) is the official collection of standards for UK medicinal products and pharmaceutical substances. published annually, the BP contains monographs for pharmaceutical substances, formulated preparations and other articles used in the practice of medicine. the standards in the BP 2010 are legally effective in the UK from 1 January 2010.The BP has been providing authoritative, official standards for pharmaceutical substances and medicinal products since 1864.

Today, it is used in almost 100 countries world wide and remains an essential reference for any individual or organisation working within pharmaceutical research and development, manufacturing and testing across the globe.New to the BP 2010 are 40 monographs for formulated preparations, including veterinary medicines and additional standards for widely used unlicensed formulations. All European Pharmacopoeia 6th edition material up to and including Supplement 6.5 disintegrated into the text of the BP 2010. In addition to the expanding number of monographs for licensed formulated products, the BP supports the regulatory work in the fields of herbal and complementary medicines by providing additional new and revised monographs for herbal medicinal products and for homeopathic stocks and mother tinctures.The print edition of the BP 2010 comprises four volumes of the BP 2010 and a single volume of the BP (Veterinary) 2010.

The BP 2013 package includes:Six volume printed edition including the BP (Veterinary)

2013.new for 2013:41 not even a single person were there in the class don't know where you were dreaming new BP monographs40 new european Pharmacopoeia monographs
619 amended monographs 6

new and 1 amended Infrared

Reference Spectra. THE

BRITISH

PHARMACOPOEIA2014

The only official source of British pharmaceutical standards produced by the British Pharmacopoeia Commission Secretariat of the medicines and healthcare Products

Regulatory agency, and updated annually, the British Pharmacopoeia (BP) is the official,

authoritative collection of standards for UK medicinal substances for human and veterinary use.The 2014 edition includes almost 3500 monographs which are legally enforced by the Human Medicines Regulations 2012.Global standards now used in over 100 countries, the BP remains an essential reference for all individuals and organisation's working within pharmaceutical research and development, manufacture and testing around the globe.flexible access options.


Figer:2 British pharmacopoeia

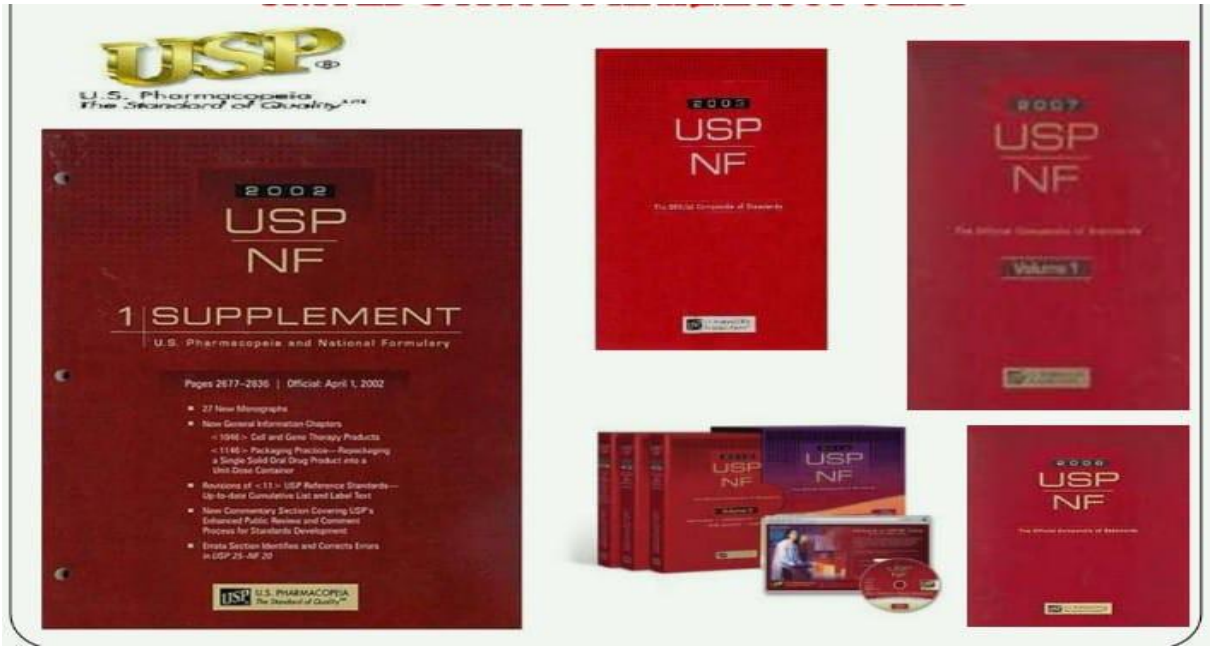
The BP 2014 package comprises five volumes of the British Pharmacopoeia .2014 and a single volume of the British Pharmacopoeia (Veterinary) 2014, along with a fully search CD-ROM and online access to provide you with flexible resources. New for 2014 Legally effective from 1 January 2014 40 new BP monographs 272 amended monographs. three new Supplementary Chapters.four new BP (Vet) monographs One new BP (Vet) Supplementary Chapter.

## UNITED STATE Pharmacopoeia

First edition of United state Pharmacopeia was published on 15thDecember 1820 in both Latin &English.from 1820 to 1942 it was published at Ten years intervals.from 1942 to 2000 it was published at Five years intervals. from 2002 it was published annually. first National Formulary of the united state appeared in 1888. USP21-NF16 have eight supplements.first appeared in January 1985 & last in November 1988.USP22-NF17, 1990

is the third revision that consolidates USP& NF into a single volume.electronic version of USP-NF on floppy disks was introduced in1992. USP23-NF18, was published in Mumbai
as an Asian edition at the end of 1994.USP23 has ten supplements.

First supplement was published in January 1995 & Last in May 1999. USP24-NF19, appeared from first January 2000. USP30-NF25, appeared from May 2007.




Figer:3 United States Pharmacopoeia

contains Scientific standards for drugs, dietary substances, biological products & Excipients used in dosage forms.it contains 4,100 monographs and 200 general chapters. It has been printed in three volume set.volume I contains general chapters & Volume II & III contains monographs.first supplement to USP30-NF25, appeared from August 2007 & second supplement from November 2007 which will be considered official

from May 2008. from 2006, Spanish edition of USP is also being published. Current edition of USP 2014 is in process.

## UNITED STATES PHARMACOPOEIA 30 – NATIONAL FORMULARY 25

Highlights include: New heavier paper stock Complete table of contents and index in each volume. Special 'Using the New USP-NF Print' tutorial CD Convenient slipcase for easy access and storage (English edition only).

.

## UNITED STATES PHARMACOPOEIA 31 - NATIONAL FORMULARY 26

The USP-NF is a single-volume combination of two official compendia, the United

States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP. Excipient monographs are included in the NF.

## UNITED STATES PHARMACOPOEIA 32 - NATIONAL FORMULARY 27

The USP 32-NF 27 Contains:more than 4,200 monographs Includes over 200 general chapters, covering general tests and assays Displays helpful guides and charts that make it easy to find focus-specific information Includes information on emerging areas of science and medicine helps ensure compliance with official standards enables validation of test results against proven benchmarks Creates in-house standards for operating procedures and specifications expedites new product development and approvals.

## UNITED STATESPHARMACOPOEIA 33 – NATIONAL FORMULARY 28:

The USP 33-NF 28 Contains:More than 4,400 monographs

Over 200 general chapters covering general tests and assays A new, easy-to-read format and monograph layout Helpful guides and charts that make it easy to find focus- specific information

Ensures compliance with official standards Establishes in-house standard operating procedures and specifications. Facilitates new product development and approval.

## UNITED STATES PHARMACOPEIA 34 – NATIONALFORMULARY 29:

USP 34-NF 29 features more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics. USP 34-NF 29 also

offers harmonized material and more than

230 General Chapters with current

guidelines for the full range of laboratory

tests and established processes for validating methods.

## UNITED STATES PHARMACOPEIA 35 – NATIONAL FORMULARY 30:

The 'United States Pharmacopeia 35 – National Formulary 30' (USP-NF) is a combination of two official compendia: the 'United States Pharmacopeia (USP)' and the 'National Formulary (NF)' and is officially applicable from 1 May, 2012 to 30 April,2013.European Pharmacopeia. European pharmacopeia commission started working since 1964 to prepare EP editions.

1st edition: published 1961. 2nd

edition: published 1980, 3rd

edition: published 1997.

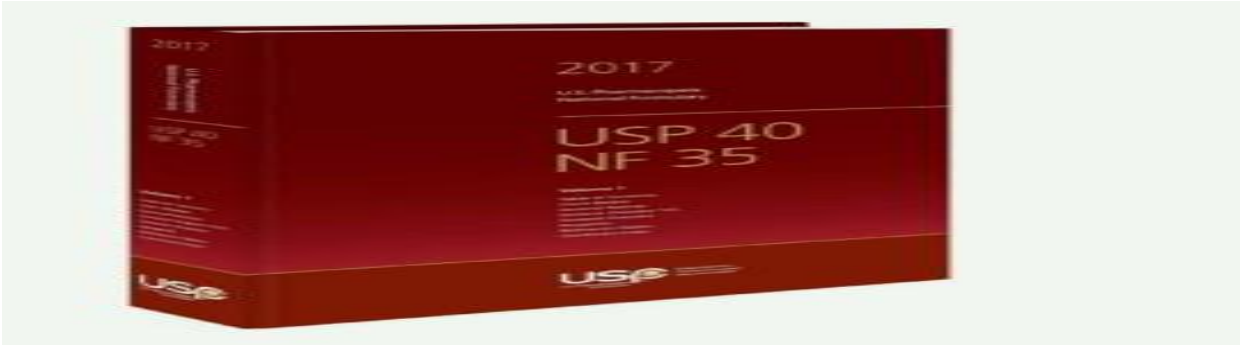
4th edition: published 2001, valid from 1 January 2002.

5th edition: published 15 June 2004, valid from 1 January 2005.

6th edition: published 16 July 2007, valid from1January2008. .

7th edition: published June 2010, valid from 1 January 2011.

8th edition: published June 2013, valid from 1 January 2014.Since its 5th edition, the pharmacopoeia is published in 2 volumes. Volume 1 contains general chapters and monographs (e.g. on dosage forms, methods of analysis, reagents), volume 2 contains all substance monographs. During runtime of current edition several supplements are published. electronics versions are also available (CD-ROM, USB stick and online version.




.

Figer:4. United States Pharmacopoeia

## EUROPEAN PHARMACOPOEIA 8TH EDITIONPUBLISHED ON JUNE 2013

The European Pharmacopoeia (Ph. Eur.) defines requirements for the qualitative and quantitative composition of medicines, the tests to be carried out on medicines and on substances and materials used in their production.

It covers active substances, excipients and preparations of chemical, animal, human or herbal origin, homeopathic preparations and homeopathic stocks, antibiotics, as well as dosage forms and containers. It also includes texts on biologicals, blood and plasma derivatives, vaccines and radiopharmaceutical preparations.

The European Pharmacopoeia and its requirements are legally binding in the member states of the European Pharmacopoeia Convention and the European Union.


Figer:5 European Pharmacopoeia

## PHARMACOPOEIA/FORMULARIES/COMPENDIA

The books containing the standards for drugs and other related substances are known

as pharmacopoeia and formularies - collectively these books are known as the drug compendia. the pharmacopoeias or formularies 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. The word"pharmacopoeia"

is derived from the Greek words ‹ pharmacon › meaning ‹ drug › and ‹ poieo › means ‹ make › . Literally it means that it is a list of medicinal substances, crude drugs and formulae for making preparations from them.

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 adjuvant s 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.

## CLASSIFICATION

The drug-compendia are classified as:
Official compendia (ii)Non-official compendia

Official compendia are the compilations of

### A. OFFICIAL COMPENDIA

drugs and other related substances which

are recognized as legal standards of purity, quality and strength by a government agency of respective countries of their origin.e.g.British Pharmacopoeia (BP)
British Pharmaceutical Codex (BPC) Indian Pharmacopoeia (IP)
United States Pharmacopoeia (USP) National Formulary (NF)
The State Pharmacopoeia of USSR and Pharmacopoeias of other countries.

### B. NON-OFFICIAL COMPENDIA

The book other than official drug compendia which are used as secondary reference sources for drugs and other related substances are known as non-official drug compendia. e.g.Merck Index extra Pharmacopoeia (Martindale) United States Dispensatory etc.

## HISTORY

The historical developments of Pharmacopoeia in India traces back to 1563 and the credit goes to Garcia daorta a Portuguese physician-cum-teacher.
The idea of indigenous Indian Pharmacopoeia was conceived 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 944 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
Drugs of plant origin.
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.
The history of development of Indian Pharmacopoeia:

The Govt. of India published the Indian Pharmacopoeial List.

The Govt. of India constituted a permanent Indian Pharmacopoeia Committee.

This committee was assigned the task of preparing Indian Pharmacopoeia and to keep up
-to-date.

The first edition of Indian Pharmacopoeia (IP) was published.
Supplement of IP 1955 was published.

N.B. The work of revision of the Indian Pharmacopoeia as well as compilation of new edition was taken up simultaneously

under the chairmanship of Dr. B.N.Ghosh, who died in 1958. After Dr. B.N.Ghosh, Dr. B.Mukherjee, the Director of Central Drug Research Institute was appointed as the chairman of Indian Pharmacopoeia committee.
The second edition of IP was published1975 1991,1996*A supplement of IP 1966 was published.
The Indian Pharmacopoeia Committee was reconstituted by the Govt. of India,

Ministry of Health and Family Welfare, under the chairmanship of Dr. Nityananda, Director, Central Drug Research Institute, Lucknow.
The third edition of IP was published in two volumes, Volume-I and VolumeII by the Controller of Publications, on behalf of Govt. of India, Ministry of health and Family Welfare.
Volume-I contains:Legal Notices, Preface, Acknowledgments, Introduction, General Notices, and monographs from A to P.
Volume-II contains:Monographs from Q to Z, Appendices, Contents of Appendices and Index.Addendum (I) to IP 1985 was published.Addendum (II) to IP 1985 was published.
The fourth edition of IP was published.for the preparation of Pharmacopoeia of India, the pharmacopoeias of other countries, like British, Europe, United States, USSR, Japan, the National Formulary (USA) and Merck index were consulted. The persons working in pharmaceutical industry, drug control laboratories, research and teaching institutions also actively participated.under the Drugs and Cosmetics Act 1940, the Indian Pharmacopoeia is an official book

3.

which contains the standards for drugs and

## THE BRITISH PHARMACOPOEIA (BP)

other related substances included in the pharmacopoeia. The drugs and other related substances prepared by pharmaceutical manufacturers must comply with these standards.

## NATIONAL FORMULARY OF INDIA

For the guidance of medical practitioners, medical students and pharmacists in hospitals and in sales departments National Formulary of India has been formulated. 1960 First edition was published by Govt. of India, Ministry of Health.
1966 Second edition was published.1979 Third edition was published.It contains information about drug interaction, resistance, cumulative effects, drug dependence, prescription writing etc.

## THE INDIAN PHARMACOPOEIA

Under the Drugs and Cosmetics Act 1940, the Indian Pharmacopoeia is an official

book which contains the standards for drugs and other related substances included in the Pharmacopoeia. The drugs and other related substances prepared by pharmaceutical manufacturers must comply with these standards.1946 Indian Pharmacopoeial List was published by Govt. of India.1955 First edition of Indian Pharmacopoeia was published.
1960 Supplement of IP 1955 was published.1966 Second edition of IP was published. 1975 Supplement of IP 1966 was published.1985 Third edition of IP was published.
1989 Addendum-I to IP 1985 was published.1991 Addendum-II to IP 1985 was published

1996 Fourth edition of IP was published.Under each monograph chemical structures, molecular weight, physical description, solubility, identification tests, standards, assay method, storage etc. are given. Indian Pharmacopoeia is published by the Controller of Publications, Delhi on behalf of Govt. of India, Ministry of Health and Family Welfare.

Under the Medical Act 1858 the General Council of Medical Education and Registration was empowered to alter, amend and republish the British

Pharmacopoeia (BP) as often as necessary. The first BP was published in 1964.1864 The first BP was published.
1926 Committee of Civil Research recommended that a Pharmacopoeia Commission be formed and it should be entrusted the work of new editions of
BP and also recommended that BP be revised and reissued at an interval of ten years. 1932 New edition of BP was published according to the above recommendation.
1968 Medicines Act 1968 gave the responsibility of preparing the BP to the Medicines Commission. Medicines Commission reconstituted the British Pharmacopoeia Commission and gave the responsibility to British pharmacopoeia Committee.1980 The thirteenth edition of BP was [published.1988 The 14th edition of BP was published.1993 The 15th edition of BP was published.
BP 1988 contains two volumes with 2100 monographs:

Vol-I contains monographs on medicinal and pharmaceutical substances along with Infrared (IR) reference spectra,Vol-II contains formulated preparations, blood products, immunological products, radiopharmaceutical preparations, surgical materials and
appendices.BP is the source of standards of drugs in United Kingdom and other parts of Common Wealth Countries.

## 4. BRITISH PHARMACEUTICAL CODEX (BPC)

It was in 1903 that the council of Pharmaceutical Society of Great Britain decided to prepare a reference book for the use of medical practitioners and dispensing pharmacists.
The first edition of BPC was published in 1907.On the request of British Pharmacopoeia Commission, the Council of the Pharmaceutical Society agreed in 1959 for the publication of Codex to coincide with that of the BP, so that BP and BPC should come into effect on the same date.
The BPC differs from BP in that :

It contains many more drugs and preparations some may be included in advance to the pharmacopoeia while other drugs may have been included in the former editions of
pharmacopoeia but now they are retained in the Codex because they are still commonly used.
It provides information on the actions and uses of drugs, their undesirable effects, precautions and the treatment of poisoning.
It contains formulae, method of preparation, container and storage conditions of most of the preparations which are still extemporaneously prepared in the pharmacy.

## 5. THE UNITED STATES PHARMACOPOEIA (USP)

The USP was originally published in 1820 under the authority of United States

Pharmacopoeial Convention. The National Formulary (NF) was published in 1888 under the guidance of American Pharmaceutical Association.In 1974 the NF was purchased by the United States Pharmacopoeial Convention and from 1980 onwards only one official book of drug standards was published under the heading the United States Pharmacopoeia and The National Formulary (USP-NF).

## 6. EXTRA PHARMACOPOEIA

The Extra Pharmacopoeia was first produced in 1883 by William Martindale and is still known as "Martindale". This is an authorized reference book on drugs and is used
throughout the world. It provides all sorts of latest information on drugs and medicines. Itis published by the direction of the Council of the Royal Pharmaceutical Society of Great Britain and prepared in the Society's Department of Pharmaceutical Sciences.
It is an encyclopaedias of chemicals, drugs and biologicals. The first edition

## 7. THE MERCK INDEX

was published
in 1989 and the eleventh edition was published in 1989 by Merck & Co., Inc. Rahway, New Jersey, USA.

## 8. THE INTERNATIONAL PHARMACOPOEIA

The International Pharmacopoeia is published by the World Health Organization and

is particularly used in developing countries. The first edition was published in 1951 (Volume I) and in 1955 (Volume-II). the object of this was to provide a uniform list which would avoid the confusion caused by different national standards, strengths and names especially for the use of travelers who might need to use the same prescription in different countries.Indian Pharmacopoeial Laboratory.
ISO Guide 34 : 2009 for "Reference Material Producer"

WHO Pre-qualified for Quality Control Laboratory.

ISO/IEC 17025:2005 Accredited for Chemical and biological Analysis.20 international Cooperation.
World Health Organization (WHO)

European Directorate for the Quality of Medicines (EDQM)

Japanese Pharmacopoeia (JP)

United States Pharmacopeia (USP)

Chinese Pharmacopoeia (CHP)International meeting of World Pharmacopoeias.

Active participation in World Pharmacopoeias meetings for WHO Good Pharmacopoeia Practices(Gphp).
Strengthening Global Pharmacopoeia Cooperation.

- GPhP will enable transparency on development of Pharmacopoeial Standards

The history of The International Pharmacopoeia dates back to 1874 when the need to standardize terminology and to specify dosages and composition of drugsled to attempts to produce an international Pharmacopoeial compendium. The first conference, called by the Belgian Government and held in Brussels in 1902,resulted in the Agreement for the Unification of the Formulae of Potent Drugs, which was ratified in 1906 by 19 countries. The outcome considerably influenced the subsequent publication of national pharmacopoeias. asecond agreement, the Brussels Agreement, was drawn up in 1925
and ratified in 1929. This 41-article agreement stipulated that the League of Nations would be responsible for the administrative work to produce a unified pharmacopoeia,
and a permanent secretariat of an international organization would coordinate the work of national pharmacopoeial commissions. General principles for the preparation of galenicals, maximal doses, nomenclature, and biological testing of arseno benzones were included in the articles of this agreement, as was a table of dosage strengths and descriptions for 77 drug substances and preparations.
In response to repeated calls from pharmaceutical experts in various countries that the Brussels Agreement be revised and extended to cover an international pharmacopoeia, the Health Organization of the League of Nations set up a Technical Commission of Pharmacopoeial Experts in 1937.
This first committee comprised seven experts from Belgium, Denmark, France, Netherlands, Switzerland, the United Kingdom (Chairman), and the United States of America. in 1947 the Interim Commission of WHO took over the work on pharmacopoeias previously under taken by the Health Organization of the League of nations, and set up an Expert Committee on the Unification of Pharmacopoeias to continue the work of the League ⁻ s Technical Commission. The aim of the
Expert Committee was to produce a draft international agreement for the uni-fication of pharmacopoeias, modifying and extending the existing Agreement for the Unification of the Formulae of Potent Drugs.
in 1948 the First World Health Assembly approved the establishment of the expert

## SECOND EDITION:

Committee by the Interim Commission. In 1951 this became the Expert Committee on the International Pharmacopoeia; and subsequently, in 1959, the Expert Committee on Specifications for Pharmaceutical Preparations. The panel has always been named the WHO Expert Advisory Article 2 of the WHO Constitution states that one of the functions of the Organization is "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products". The International Pharmacopoeia falls clearly into this category. In this context also the Third World Health Assembly in 1950 adopted a resolution to create the International Non proprietary Names (INN) Programme in order to identify pharmaceutical substances unambiguously on a worldwide basis and to provide a single nonproprietary name to be used in monographs.

## First edition:

The Third World Health Assembly, held in May 1950, formally approved the publication of the Pharmacopoeia Internationalisation and recommended, in accordance with Article 23 of the WHO Constitution, "the eventual inclusion of its provisions by the authorities responsible for the pharmacopoeias".It was thus recommended that the Pharmacopoeia Internationalis was not intended to be a legal pharmacopoeia in any country unless adopted by the pharmacopoeia authority of that country. From that moment the World Health Organization constituted the Permanent International Pharmacopoeia Secretariat.

The first edition, published with the aim of creating a worldwide, unified pharmacopoeia, relied on collaboration with national pharmacopoeia commissions for its preparation. It was published in two volumes (1951 and 1955) anda supplement (1959) in English, French and Spanish, and was also translated into German and Japanese. Altogether, it included 344 monographs on drug substances, 183 monographs on dosage forms (capsules, injections, tablets and tinctures) and 84 tests, methods, and general requirements.

A large number of national pharmacopoeias and official lists were cond edition of The InternationalPharmacopoeia.Owing to the development of new analytical techniques such as infrared spectroscopy, chromatography (column, paper and thin-layer), non-aqueous titration, and radioactivity, the second edition incorporated numerous alterations and constituted a revision of the first edition.

The selection of monographs and appendices was based largely on the availability, at the time of preparation, of specifications intended for publication Third edition

In 1975 the purpose of The International Pharmacopoeia was reconsidered. It was decided that the publication should focus more on the needs of developing countries and recommend only simple, classical chemical techniques that had been shown to be sound.

Priority would be given to drugs that were widely used throughout the world, with emphasis on the therapeutic value of these drugs. High priority would be accorded to drugs important to WHO health programmes, and to those likely to contain impurities arising from degradation or due to difficulties in their manufacture. Wherever possible, classical procedures.

would be used in the analytical methods so that the pharmacopoeia could be applied without the need for expensive equipment. Where a sophisticated analytical method was suggested, an alternative, less complex method would also be proposed.Since 1979, the drugs appearing in The International Pharmacopoeia have been selected from the list of essential drugs based on the first report of the WHO expert Committee on the Selection of Essential Drugs. Specifications are provided in the monographs for the identification, purity, and content of the essential drugs appearing in the WHO Model List of Essential Drugs, and theirupdates.the International Pharmacopoeia currently

stands at five volumes:
Volume 1 contains general methods of analysis; Volumes 2 and 3, quality specifications for the majority of essential drug substances in the WHO Model List of Essential Drugs; and Volume 4, information on tests, methods, and general requirements and quality specifications for pharmaceutical substances, excipients, and dosage forms. Volume 5, the present volume, contains tests and general requirements for dosage forms and quality specifications for pharmaceutical substances and tablets, which will practically complete the list of monographs for active pharmaceutical substances, and a section on
antimalarial drug substances and their most widely used dosage forms.

## REFERENCES:

1. Niles, E. H.: The Massachusetts Pharmacopoeia of 1808. J. Am. Pharm. Assoc. 25:542- 43, 1936. See also Burrage,W. L.: A History (of the Massachusetts,Medical Society, With Brief Biographiesof 'the Founlders an(d Chief Ojficers, 1781-1822. Norwood, Mass., 1923: Kremers,E. and Urdang, G.: History of Phartmacy,v a Guidle and a Surveyv. Philadelphia, Lippincott, 1951, chap. 16.
2. For survey of Spalding's life and worksee Spalding, J. A.: Dr. Lyminan Spalling, the Originator of the Unitedl States pharmnacolpoeia, Co-Laborer wvithDr.Nathan Sinith in the Foundling of'the Dartmouth Medlical School, (11l1 ItsFirst Chemical Lecturer, Presidlent (111(1profeissor of A natomnv at Sumrgerv of theCollege of Phy-sicialls (111(1 Surgeons of the Western District. Boston, Leonard,1916.
3. (By the Authority of the Medical Societies and Colleges.) The Pharmacopoeia of.the United States of'Anerica.Boston, 1820. A similarly respect able work in the English language, The Pharmacopeia of the New Yomk Hospital(18 16) had not enjoyed wide circulation and did not therefore carry much influence in the ultimate content of the U.S.P.
4. Oldberg, O.: On national pharmacopoeias. Medl. Press Western N.Y.2: 130-35:174-79, 1887.
5. The rivalry between the New York and Philadelphia schools is implicit in the introductory remarks of the two pharmacopoeias. See (By the Authority of the General Convention for the Formation of the American Pharmacopoeia) The Pharmacopoeia of the United Stutes America, New York, 1830, and (By the authority of the National Medical Convention) The Pharmacopoeia of the United States of Amneri-ca. Philadelphia, 183 1.
6. Rice, C.: Pharmacopoeia. In: Woodl's Reference Handlbook of the Medilical Sciences. New York, Wood, 1887, pp.638-39.
7. Moore, J. B.: Suggestions as to a New plan by which the next revision of the pharmacopoeia may be rendered more complete and thorough. Amn. J. Phatrmi.47:18- 24, 1875.
8. Squibb,E.R.: Remarks on the pharmacopoeia of the future. Pr-oc. Med. Soc.Brooklvmn 1:215-19, 1876.
9. Squibb, E. R.: Quoted in Baynton, W.N.: The pharmacopoeia and the dispensatory. Med.
⑳ Rec. /2.:316-18, 1877.Professors Alfred Stille and JohnMaisch issued in 1879 a new dispensatory entitled The National Dispensatory,-which sought to replace the Wood
andBache Dispensatory during its troubled years, from the 12th (1865) through the 15th (1883) editions. Its emphasis on the physiological action of medicines offered.a new and practical value to the book,which obviously catered to the physician more than to the pharmacist. This difference, while giving it a longer shelflife, was unable to match the vigor of the revised U.S.D. under Horatio C. Wood,Joseph P. Remington, and Samuel PS adtler, who served as editors from 1883 to 1907.
10. Squibb, E. R., op. cit., pp. 217-18. See also National College of Pharmacy:Review of Dr. Squibb's Proposedl Plan from the

Future Revision of the United States Pharmacopoeia, Being a Special Report Upon this Subject by the Connnittee of the National College of Pharmnacvon the United States Pharmnacopoeia. (a11d1 Resolutions Adopted by N- the Natiomial College of Pharmacy-v, Washington D.C. ait Special Meeting Hell Maxv28. 1877. Washington, D.C..George Washington University 1877; Philadelphia County Medical Society: Proceedings in Reference to the Proposed Plan.the Management 91 of the United States Pharmacopoeia as Presented by Dr.Squibb to the Amnerican Medical Association for Their Action in 1877. Philadelphia. Eagle, 1877.

11. Squibb, E. R.:On the approaching revision of the United State .pharmacopoeia.J.A.M.A. /4:485-93, 1890. See also Squibb, E. R.: The Amnerican Medical Association and the Pharmacopoeia of'the United States (9 Anlerica. Brooklyn,1877; Squibb, E. R.: The Amierican medical Association and the UnitedStates Pharmnacopoeia. A Reprint of the PamphletsoI Dr. H. C. Wood, Alfired B.Taylor, the Philadelphia College of 'Pharmacy, Wit/i a Rejoinder Addressed to the Professions of Medicine and Pharmacy N of the United States. Brooklyn, Eagle, 1877.

12. Oldberg, op. cit., 176.

13. American Pharmaceutical Association Committee on the Revision of the United States Pharmacopoeia: Report on the Revisionoj the United States Pharmnacopoeia Preliminary 'N to the Convention of 1880. Beimng a Rough Drafto J the General Primnciples, Titles, and Working Formnulae Proposed for the Next Pharmacopoeia. New York, Amer. Pharm. Assoc., 1880, iii-iv. See also Taylor,A. B.: The Pharmnacopoeia. of the United States and the American Medical Association. A Review of a Plan of Revision Proposed by Edwvard R. Squibb. Philadelphia, Merrihew, 1877.

14. Oldberg, O.: The pharmaceutical nomenclature. Proc. Am. Pharm'mm. Assoc. 28:383-420, 1880.

15. Dunglison, R. J.: Report of Committee of Revision of the United States Pharmacopoeia, of the Philadelphia County medical Society. Trans. Medl. Soc. 21 Pennsylvania 2.:226-35, 1878.lbid., pp. 228-32.

16.

17. (By the Authority of the National Convention for Revising the Pharmacopoeia.) The Pharmacopoeia of the United States of America.New York, 1882.xvxvii. See also Prentiss, D. W.: On the Rev-ision of the United States PharinacoIpoeia . Washington. D.C., 1880., pp.1-14.

18. Prentiss, D. W.: Review of the Sixth Decennial Revision of the Pharmacopoeia of the United States of America. New Remnedlies/1:364-66,1882.

19. Oldberg,O.: Answersto objection surged against the new pharmacopoeia.St. Louis Courier Medl. 9:385-405,1883. 399; Anonymous: The Sixth Decennial Revision of the Pharmacopoeia of the United States and the Pharmacopoeia Germanica, Editi on Alteration. Br.Med. J. 1:477-78; 531-33, 1883.33:684-85: 979-81: Another United States Pharmacopoeia. Is it needed'? Boston Medi. Suog. J. / /0:161-62.1884. Leech, D. J.: A comparison of some of the national pharmacopoeias.Br. Med. J. /:317-19, 1895.

20. Wilbert, M. 1.: The evolution of the United States Pharmacopoeia. A in.J.Phalrm. 44:261-71, 1902.

21. Committee of Revision and Publication of the Pharmacopoeia of the United States of America, 1880- 1890: Digest of Criticisms on the United States Pharmacy, Sixth Decennial Revision. New York, 1889, part 1, iii; Squibb, E. R.:On the approaching revision of the United States Pharmacopoeia. J.A. M.A./4:485-93, 1890.

22. Report of the proceedings of the Convention of 1890 for the Seventh Revision of the United States Pharmacopoeia.Drug. Bull. 4:141-44, 1890.

23. Greene, C. L.: The relation of druggist and physician. J.A. M.A. /9:718-21,1892; Dumbeck, V. H.: Pharmacists vs.physicians. Peoria Med. Month. 3:25 1-

54, 1881; Swayze, G. B. H.: The professional relations between physician and druggist. Phil. 290-95, 1881.

Med. Times/ /: