PHARMACEUTICS-I- BP103T

UNIT: 1 (Historical background and development of profession of pharmacy, Dosage forms, Prescription, Posology)

CLASS:4

TOPIC: Pharmacopoeias

PHARMACOPOEIA

The word pharmacopeia is derived from two Greek words 'pharmakon' meaning 'drug' and 'poeia' means to make. It is the book prepared under the authority of government of respective countries which contains list of drugs, crude drugs, formulae for making different preparations, sources of drugs, their descriptions, standards, tests, actions, uses, dosage, storage condition etc. It is revised from time to time to include latest information available. To maintain the size of book in limit the drugs which are less frequently used are omitted from the new edition. In new editions new monographs are added. Pharmacopeia prepared under the authority of government of the respective countries known as national pharmacopoeias. For example IP, BP, USP, etc. International pharmacopoeia is used as a reference book by the law of the respective country to solve the problems arises regarding the drugs. Classification – The Drug compendia classified into two groups. 1.Official compendia – Ex. British Pharmacopoeia (BP), British Pharmacopoeial Codex (BPC), Indian Pharmacopoeia (IP), United States Pharmacopeia (USP), National Formulary (NF), The pharmacopoeia of other countries. 2.Non official compendia – Ex. Merck Index, Extra Pharmacopoeia, (Martindale) United States Dispensatory.

Indian Pharmacopoeia

Indian Pharmacopoeia Commission (IPC) is autonomous establishment of the Ministry of Health and Family Welfare which sets the standards for all drugs that manufacture, sold and consumed in India. History and Publications of IP– The actual process of publishing the first pharmacopoeia was started in the year 1944 under the chairmanship of Colonel R. N. Chopra. In 1946, Government of India issued one list known as the 'Indian Pharmacopoeia list'. The Government of India constituted a permanent Indian Pharmacopoeia Committee in 1948. Tenure of this committee was

five years. Indian Pharmacopoeia Committee under the leadership of Dr. B. N. Ghosh published first edition of IP in 1955.

♣ First edition of IP was written in English and official titles of monographs given in Latin. It covers 986 monographs. Supplement to this edition was published in 1960.

♣ Second edition of IP was published in 1966 under the leadership of Dr. B. Mukkerji. 274 monographs from IP 1955 and there supplement was deleted. 93 new monographs were added. Official titles of monographs given in English. Dose was expressed in metric system. For tablets and injection usual strength has given. Formulation of the drugs given immediately after the monograph of drugs and supplement to this edition was published in 1975. 126 new monographs are added and 250 monographs amended. Cholera vaccine was deleted.

♣ Third edition of IP published in 1985 with two volumes and nine appendices. 261 new monographs are added and 450 monographs were deleted. Addendum I to IP 1985 was published in 1989 in which 46 new monograph were added and 126 where amended. Addendum 2 was published in 1991 where in 62 new monographs where added and 110 were Amended. In 1978, the IPC for 3rd edition of IP was reconstituted by the government of India under the chairmanship of Dr. Nityanand, Director of CDRI Lucknow.

♣ Fourth edition of IP was published in 1966 under the leadership of Dr. Nityanand. It covered 1149 monographs and 123 appendices. It includes 294 new monographs and 110 monographs have been deleted. It was published in two volumes. The Volume I contains Monographs from A to O. The Volume II contains Monographs from P to Z. It included 294 new monographs and 110 monographs were deleted. Addendum I was published in 31st December 2000 while Addendum II was published on 2002. The supplement to 4th edition of IP published in 2002 for veterinary products which contained 208 monographs and 4 appendices.

♣ Fifth edition of IP was published under the chairmanship of Dr. Nityanand in 2007 and presented in user friendly format in 3 volumes. Addendum to this edition was published in 2008. Volume I contents general notices and general chapters. Volume 2 and 3 contains general monographs on drug substances, dosage form and pharmaceutical aids.

♣ Sixth edition of IP was published by IPC (Indian Pharmacopoeia Commission) under chairmanship of Shri K. Chandramauli in 2010 in Ghaziabad. It having three volumes.

Volume 1 contains notices, structure of IPC, acknowledgements, introduction, general chapters.
Volume 2 contains Monographs from A to M.
Volume 3 contents monographs from N to Z.
Addendum to sixth edition of IP was published in 2012 which contains 52 new monographs.

♣ Seventh edition of IP was published in 2014 under the chairmanship of P. K. Pradhan, Secretary Health and Family Welfare Government of India in four volumes. It include 2548 monographs of drugs. First time 19 new radiopharmaceutical monographs are included in this pharmacopeia. The Addendum I was published in 2015, Addendum II was published in 2016. The total number of IP standards was almost 3000 at par with other international pharmacopoeias.

♣ Eighth edition of IP was published in 2018 under the chairmanship of Dr. C. K. Mishra, Secretary Health and Family Welfare Government of India in 4 volumes. It include 220 new monographs and 366 revised monographs and 7 are deleted. Addendum to IP 2018 was published in 2019.

BRITISH PHARMACOPOEIA

The British Pharmacopoeia is the national pharmacopoeia of the United Kingdom. British Pharmacopoeia is published annually and comprises of the standards required for maintaining the quality of medical substances of United Kingdom. BP is normally employed by professionals as well as organizations related to pharmaceutical research, development, manufacturing and testing.

♣ The first edition of BP was published in 1864. The addition was compiled with the help of three old pharmacopeia which were London Pharmacopeia 1618, Edinburgh Pharmacopeia 1699 and Dulbin Pharmacopeia 1807. The second edition of BP was published in 1874. Third edition of BP was published in 1885 with its addendum in 1890. In 1898 fourth edition of BP was published. The fifth edition of BP was published in 1914, which was little delay. As a result the commission was made in 1928 which published the sixth edition in 1932. Recommendation was made by the commission to revise the British Pharmacopoeia once in a decade. In this edition diagnostic materials, standard test for antioxidants and insulin were included. Total 7 addendums are published to this edition of BP. 7th edition was published in 1948, 8th edition was published in 1953, 9th edition was published in 1958, 10th edition of BP was published in 1963. BP 2010 was published by The Stationery Office (TSO), on the behalf of BP.

♣ The standards in the BP 2010 were made legally effective in the UK from 1st January 2010. BP 2010 consists of four volumes and single volume of veterinary product.

♣ BP 2020 is the most comprehensive collection of official standards for UK Pharmaceutical substances and medicinal products. It include around 4000 monographs including the veterinary and all European Pharmacopoeia monograph that makes the BP convenient and fully comprehensive set of standards that can be used across the Europe and worldwide. The new edition of BP 2021 is legally made effective from 1st January 2021. This edition has incorporated with 30 new BP monographs and 20 new European Pharmacopoeia monograph along with significant number of revised monographs. Today BP is published on behalf of the health ministers of the UK. It has been prepared by the BP commission with the collaboration and support of its expert advisory groups and panels of experts. British Pharmacopoeia including BP veterinary and European Pharmacopoeia are the two pharmacopoeias that have legal status in the United Kingdom. BP is published every year in August becomes effective on 1st January of the following year that incorporates all the monographs of the European Pharmacopoeia.

UNITED STATES PHARMACOPOEIA

♣ The United States Pharmacopeia is a compendium of drug information for the United States, which published early by the United States Pharmacopeial Convention (USPC). It is published in a combined volume with the National Formulary as the USP-NF. If ingredients has an applicable as per USP quality standard, it must confirm in order to use the designation USP or NF. Drugs subject to USP standards include both human and animal drugs. USP also sets standards for dietary supplements and food ingredients. ♣ First edition of USP was published on 15th December 1820 in both Latin and English. From 1820 to 1942 it was published at 10 years interval, from 1942 to 2000 it was published at five years intervals and from 2002 it was published annually. The first national formulary of the United States was published in 1888.

National Formulary contains a list of medicines that approved for prescription throughout the country. It is useful for the guidance to the medical students, nurses and pharmacist working in hospitals and in sales department. It includes key information on the composition, description, selection, prescribing, dispensing and administration of medicines. There are various National formularies, ♣ Australian Pharmaceutical Formulary (APF). ♣ TheAustralian national Formulary (ANF). ♣ British National Formulary (BNF) and British National Formulary For Children

(BNFC). ♣ National Formulary of India (NFI) ♣ Sri Lankan National Formulary ♣ United States National Formulary it is merged with United States Pharmacopeia (USP- NF). In preparation of National Formulary of India (NFI) expert opinion of medical practitioners, teachers in medicine, nurses, pharmacist, and pharmaceutical manufacturers was obtained. The selection of drugs for inclusion in the INF was made by taking into consideration the relative advantages and disadvantages of the various drugs used, their extent of use in current medical practice and their availability in the country. The first edition of NFI was published in 1960 by the Government of India Ministry of Health, in 1966 second edition was published and 3rd edition in 1979. Fourth edition was published in 2011 while 5th edition was published in 2016. National Formulary

EXTRAPHARMACOPOEIA

♣ The Extra Pharmacopoeia originally created by William Martindale in 1883 and now published by the Pharmaceutical Society of Great Britain. It contains information on the drugs presently used in Great Britain. It was first published under the title 'Martindale - The Extra Pharmacopoeia'. Martindale contains information on drugs in the clinical use worldwide as well as selected veterinary drugs, Pharmaceutical excipients, radiopharmaceuticals, vitamins and nutritional agents, vaccines, diagnostic agents, medicinal gases, toxic substances, disinfectants and pesticides. Martindale book is arranged into two main parts which having three indexes. ♣ The Merck Index – It is an encyclopedia of chemicals, drugs and biologicals. The first edition was published in 1989 Jersey, USA by Merck and Company, Rahway. ♣ The International Pharmacopoeia - It is published by the World Health Organization and particularly used in developing countries. The first edition was published in 1951 (Volume I) in 1955 (Volume II). The object of this was to provide uniform list which would avoid the confusion caused by different National standard, strengths and names especially for the use of travelers who might need use the same prescription in different countries.

Following are some important distinguishing features of each edition of IP. Salient Features of First edition of IP ♣ The titles of monographs have been given in Latin language. Abbreviated titles for use in prescription have been given immediately below the Latin title. ♣ The English title has also been given below the abbreviation title. ♣ The weights and measures have been given in metric system. ♣ All statements contained in the individual monographs have been considered as constitute standards for the official substances. ♣ Doses are expressed both in the metric system

as well as in the English system. ♣ Alist of preparations has been given at the end of some of the monographs. ♣ The temperature has been expressed in Celsius thermometric scale. ♣ Descriptive terms (very soluble, freely soluble, sparingly soluble, slightly soluble, very slightly soluble, practically insoluble) have been used where the exact solubility of a pharmaceutical substance is not known. Salient features of Indian Pharmacopoeia

Salient Features of Second edition of IP ♣ The titles of monographs have been changed from Latin to English. ♣ The words of the title have been transposed to give the name of the drug first. Eg. Injection of Aminophylline has been changed to Aminophylline Injection. ♣ Doses are expressed in the metric system only. ♣ Solubility is expressed in parts of solvent per unit part of solute. ♣ The preparations of a drug have been given immediately after the monograph of the parent drug. ♣ The test for sterility has been modified for detection of fungi in addition to aerobic and anaerobic bacteria. ♣ New analytical techniques such as non aqueous titration, column chromatography have been included. ♣ In the monographs of "Tablet" and "Injections"a new subheading "Usual Strength" has been given to represent the strength of the tablet or injection in which it should be generally marketed. Salient Features of Third edition of IP ♣ IUPAC system of nomenclature of organic chemical drugs has been used. ♣ Analytical techniques like electrophoresis, fluorometry, flame photometry have been recognize for first time. ♣ Instrumental techniques like UV spectroscopy, gas liquid chromatographyhave been used. ♣ Limit testfor microbialcontamination has been mentioned for new frequently used PharmaceuticalAids. ♣ The pyrogen test has been revised to make the test less time consuming. ♣ Dissolution test has been introduced in the case of certain tablets. ♣ Disintegration test has been amended by modifying the design of the apparatus and method of testing.

Salient Features of Fourth edition of IP ♣ The computer generated structural formulae have been introduced. ♣ Infrared and ultra red absorption spectrophotometric tests for identification of drug substances have been introduced as alternative test to the classical chemical test. ♣ The infrared reference spectra of a number of drugs have been given in appendix. ♣ Number of general monographs like eye drops, eye ointment, creams, nasal preparations, suppositories, pessaries, oral liquids have been included. ♣ Some titles have been changed to include the more commonly accepted names of India for example hyoscine hydrobromide for scopolamine hydrobromide.

Salient Features of Fifth edition of IP ♣ General chemical test for identification have been almost eliminated and most specific infrared and ultraviolet spectrophotometric test have been given. ♣ The test for pyrogens involving the use of animals has been virtually eliminated. Test for bacterial endotoxins has been introduced. ♣ The test for abnormal toxicity is confined (compulsory) to certain vaccines. ♣ The use of chromatographic methods been extended in essays to large number of pharmaceutical products. ♣ Labelling and storage are featured at the end of a monograph. ♣ Limit of bacterial contamination has been introduced for controlling the microbial quality of all medicinal products.

Salient Features of Sixth edition of IP ♣ The no. of monographs of excipients, anticancer drugs, herbal products and antiretroviral drugs has been increased. ♣ Monographs of vaccines and immunosera are upgraded in view of development of latest technology in the field. ♣ A new chapter on liposomal products and monograph of liposomal amphotericin B is added. ♣ Chapter on NMR is incorporated inAppendices. ♣ The chapter on microbial contamination is updated to meet the international requirements. ♣ Standards for new drugs and drugs used under National Health Programs are added and the drugs as well as their formulations not in use nowadays are omitted from this edition. Salient Features of Seventh edition of IP ♣ This edition includes advanced technology and experimental methods widely adopted in India and Abroad. ♣ Drugs and their formulations not in use now a days are omitted. ♣ 19 new Radiopharmaceutical Monographs and one general chapter is first time being included in this edition. ♣ This edition is presented in four volumes. ♣ It incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms, antibiotics monographs, insulin products and herbal products.

Salient Features of Eighth edition of IP ♣ This edition has been brought into four volumes. ♣ Standards for new drugs and drugs used under National Health Programs are included. ♣ 53 new Fixed Dose Combinations (FDCs) have been included, out of which 25 FDC monographs are not available in any Pharmacopoeia. ♣ More emphasis is given on infrared and ultraviolet spectrophotometer and HPLC tests. ♣ The use of chromatographic methods has been greatly increased to identify the nature and extent of impurities in ingredients and products.