CHAPTER 1

INTRODUCTION TO PHARMACEUTICAL INORGANIC CHEMISTRY

1.1 PHARMACEUTICAL CHEMISTRY

Pharmaceutical Chemistry is a branch of chemistry that deals with the chemical, biochemical and pharmacological aspects of drugs. It includes synthesis/isolation, identification, structural elucidation, structural modification, Structural Activity Relationship (SAR) studies, study of the chemical characteristics, biochemical changes after drug administration and their pharmacological effects.

1.1.1 Inorganic Chemistry

Inorganic chemistry is the study of all the elements and their compounds except carbon and its compounds (which is studied under organic chemistry). Inorganic chemistry describes the characteristics of substances such as nonliving matter and minerals which are found in the earth except the class of organic compounds. Branches of inorganic chemistry include coordination chemistry, bioinorganic chemistry, organometallic compounds and synthetic inorganic chemistry. The distinction between the organic and inorganic are not absolute, and there is much overlap, especially in the organometallic chemistry, which has applications in every aspect of the pharmacy, chemical industry–including catalysis in drug synthesis, pigments, surfactants and agriculture. In short, Inorganic chemistry is the branch of chemistry that deals with inorganic compounds. In other words, it is the chemistry of compounds that do not contain hydrocarbon radicals.

1.1.2 Inorganic Compounds

These are traditionally viewed as compounds being synthesized by the geological systems and lack hydrocarbon (carbon-hydrogen). In contrast, organic compounds are those found in biological systems. In general organic chemists say any molecule containing carbon as an organic compound and hence this means that inorganic chemistry deals with the compounds or molecules which lack carbon atom. Berzelius, the 19th century chemist, described inorganic compounds as inanimate. The first important synthetic inorganic compound was

ammonium nitrate for soil fertilization. Inorganic compounds are found in nature as minerals. Soil contain iron sulfide as pyrite or calcium sulfate as gypsum. They are also found multitasking as biomolecules: As electrolytes (sodium chloride), in energy storage (ATP) or in construction (the polyphosphate backbone in DNA). Inorganic compounds are synthesized for use as drugs such as cisplatin, magnesium hydroxide, catalysts such as vanadium (V) oxide and titanium (III) chloride, or as reagents in organic chemistry such as lithium aluminium hydride.

Medicinally useful substances are derived from either organic or inorganic sources. Naturally obtained compounds attracted the attention of humans always, in which inorganic chemicals contributing significantly in some of the ailments, even after the development of many drugs from synthetic and plant sources. Many of the inorganic salts (antimony, arsenic and mercury) are known to be poison, still they are used in medicine cautiously. Some of them are replaced by the organic medicines.

Study of pharmaceutical applications of the inorganic compounds led to the establishment of a new avenue called Pharmaceutical inorganic chemistry, which deals with the study of both non-essential and essential elements about their preparation, standards of purity, test for identification, limit tests to be performed for determining the quality and extent of purity, storage, different formulations and their storage conditions and therapeutic uses.

The term 'Pharmaceutical' is used for any chemical substance useful in preventive or therapeutic or which finds use in the preparation of medicament. Some find use only in the laboratory during the preparation but may not be present in the final product, these are also incorporated under pharmaceuticals. Quality of all these pharmaceuticals must be carefully controlled. For this reason specifications of quality are mentioned for each pharmaceutical. These descriptions are reported in the pharmacopoeia.

1.1.3 Importance of Inorganic Pharmaceuticals

Inorganic pharmaceuticals are useful in any of the following ways.

1. Useful medicinally for their therapeutic purpose. Example: Astringents and antimicrobials etc.
2. Useful as pharmaceutical aids. Example: Bentonite, talc etc.
3. To change the reaction of body fluid. To acidify or alkalise. Example: Antacids, alkalis, mineral acids.
4. Replacing or replenishing the normal content of body fluids. Example: Sodium, potassium, calcium, chloride, phosphate etc.
5. Useful as reagents to carry out the reactions. Example: Catalysts (platinum, nickel) oxidizing and reducing agents (lithium aluminium hydride).
6. Useful in Pharmaceutical analysis. Example: Titrants such as potassium permanganate etc.

Various uses of inorganic pharmaceuticals in pharmacy are presented herein

Abrasives: Drugs which are used for the cleaning and whitening of teeth. Example: Dibasic calcium phosphate.

Absorbents: Drugs which are used to absorb the toxins and bacteria in the GIT. Example**:** Calcium carbonate.

Acidifiers: Drugs which are used to enhance the acidity temporarily in GIT. Example: Dilute hydrochloric acid.

Adsorbents: Drugs which are used in the treatment of mild dysentery or diarrhoea or other disturbances of GIT due to their ability to adsorb gases, toxins, and bacteria. Example: Bismuth subcarbonate, Bismuth subnitrate.

Alkalizers: Drugs which are used to induce the alkaline condition or used in acidic condition of body. Example: Sodium citrate.

Anaesthetics: Drugs which are used to produce reversible loss of sensation. Example**:** Nitrous oxide.

Analgesic: Drugs which are used to relieve pain. Example**:** Nitrous oxide.

Antacids: These are drugs which are usually alkaline substances, used for neutralizing excess acid in the stomach. Example: Aluminium hydroxide gel, Calcium carbonate, Magnesium carbonate.

Anthelmintics: Compounds used for the treatment of worm infestations or schistosomiasis. Example: Ammoniated mercury, Sodium antimony tartarate.

Antibacterial: Drugs which are used in the treatment of bacterial infections. Example: Yellow mercuric oxide (ophthalmic).

Anticonvulsants: Drugs which are used for the treatment of epilepsy. Example: Potassium bromide.

Anti coagulants: Drugs which are used to prevent blood clotting. Example: Sodium citrate.

Anti depressants: Drugs which are used in the treatment of depression. Example: Lithium carbonate.

Antidotes: Drugs which are used in the treatment of poison. Example: Sodium nitrite, Sodium thiosulphate.

Antifebriles: Drugs which are used to relieve pain or reduce fever. Example: Ammonium acetate.

Antifungal agents: Drugs which are used in the treatment of fungal infections. Example: Zinc undecylenate (topical use), Potassium iodide.

Antihypercalcemic agents: Drugs which are used in the treatment of abnormal calcium concentration in the body. Example: Sodium acid phosphate.

Anti infectives: Drugs which are used in the treatment of local infections. Example: Potassium permanganate, Silver nitrate, Hydrogen peroxide, Boric acid.

Anti inflammatory agents: Drugs which are used in the treatment of inflammatory pain (Rheumatoid arthritis). Example: Sodium aurothiomalate.

Anti irritant agents: Drugs which are used to prevent irritation or allergic reactions. Example: Aluminium metal powder.

Antiseptics: Drugs which are used to inhibit the growth and development of micro organism without killing. Example: Strong iodine solution.

Antiperspirants: Drugs which are used to remove the bad odour in body. Example: Aluminium sulphate.

Anti-protozoals: Drugs which are used in the treatment of protozoal infections or Leishmaniasis. Example: Sodium antimony gluconate.

Anti pruritics (topical): Drugs which are used in the production of soothing effect in the skin. Example: Calamine.

Anti rheumatics: Drugs which are used in the treatment of rheumatism. Example**:** Sodium aurothiomalate.

Anti thyroids: Drugs which are used in the treatment of thyrotoxicosis. Example**:** Potassium perchlorate.

Anti tumor agents: Drugs which are used in the treatment of cancer. Example: Cisplatin (Testicular and ovarian cancer).

Anti schistosomal agents: Drugs which are used in the treatment of schistosomiasis. Example: Sodium antimony tartrate.

Antioxidants: Substances that prevents or delays oxidation. Some formulations, vegetable oils and prepared foods contain antioxidants. Example: Sodium bisulphate, sodium metabisulphite, sodium sulphite.

Astringents: These are the substances which bring about protein precipitation. Astringent action is evidenced by contraction and wrinkling of tissue and by blanching. Example: Calamine, Aluminium citrate.

Bactericides: Drugs which are used to kill bacteria. Example: Potassium permanganate.

Bacteriostatics: Drugs which are used to prevent the growth of bacteria. Example: Alum, borax (local bacteriostatic).

Bleaching agents: Drugs which are used in the cleansing of wounds or bleaching. Example: Hydrogen peroxide.

Buffers: Substance which prevents the change in pH upon addition of acid or base. Example: Acetate buffer (pH – 3.9), Sodium citrate buffer.

Calcium supplements: Drugs which are used as a calcium source. Example: Calcium lactate, Calcium gluconate.

Cathartics: Drugs which are used to enhance defecation, removes constipation and expulsion of intestinal parasites. Example: Calomel, Magnesium sulphate.

Chlorine source: Substance which liberates chlorine. Example: Chlorinated lime, Chlorinated soda.

Dentifrices: Drugs which are used in cleaning the surface of the teeth. Example: Calcium carbonate, Magnesium peroxide.

Depilatory agents: Drugs which are used to remove hair. Example: Barium sulphide.

Diagnostic agents: Drugs which are used in diagnose the diseased conditions of the organs. Example: Barium sulphate.

Diaphoretics: Drugs which are used to promote sweating. Example: Potassium citrate.

Disinfectants: Drugs which are used to kill the microbes in nonliving things. Example: Ammonium acetate.

Diuretics: Drugs which are used to increase the urine output. Example: Ammonium chloride, Ammonium iodide.

Dressing material: Substances which are used for the dressing of burns. Example: Aluminum metal foil.

Dusting powders: Substance which are used to have soothing effect on the skin. Example: Talc, Zinc stearate, Light kaolin.

Electrolyte replenishers: Compounds used to treat acid base imbalance conditions in the body. Example: Sodium chloride, Ringer lactate solution, Potassium chloride.

Emetics: Drugs which are used to induce vomiting. Example: Zinc sulphate, Copper sulphate.

Expectorants: Drugs which are used in the treatment of cough. They promotes the ejection of mucus (sputum) from the lungs, bronchi and trachea by increasing its fluidity (reducing viscosity). Example: Potassium iodide (sedative expectorant), Eucalyptus, Lemon (stimulant expectorant), Ammonium chloride, Potassium iodide.

Fillers: Drugs which are used to fill the dental cavities. Example: Gold and Silver metals.

General anaesthetics: Drugs which are used to produce reversible loss of sensation**.** Example: Nitrous oxide.

Germicides: Drugs which are used to kill the germs. Example: Chlorinated lime.

Haematinics: Drugs which are used in the treatment of anaemia. Example: Ferrous sulphate, Ferric ammonium citrate and other iron compounds.

Haemostatic: Drugs which are used to arrest the flow of blood. Example: Alum.

Inhalants: Inhalants are the drugs or chemicals which in the vapour form are inhaled or administered through the respiratory system in the body. Example: Oxygen, CO_2, Ammonium carbonate, Nitrous oxide, Helium.

Iodine supplements: Drugs which are used in the treatment of iodine deficiency. Example: Potassium iodide.

Laxatives: Drugs which are used to promote the evacuation of bowel. Example: Magnesium Sulphate, Sodium phosphate.

Protectives: Substance which tend to form a coating and protect the exposed skin or mucus membrane from harmful stimuli. Example: Zinc stearate, Zinc oxide.

Purgatives: Drugs which are used to defecate. These agents relieve constipation and helps in the expulsion of intestinal parasites. Example: Magnesium sulphate.

Radiation shields: Compounds which are used to prevent the entry of radiations. Example: Lead sheets, Wall lining.

Radio isotope tracers: Radioactive element or compound added to material to monitor the material's distribution as it progresses through a system. Example: Carbon-14, Tritium.

Radiotherapeutic agents: Radioisotopes used for the treatment of diseases. Example: Iodine-121, Cr- 52 and Gold- 198.

Rubifacients: Substances which causes reddening of skin by dilating blood vessels and increasing blood circulation in the applied area. Example: Ammonia.

Scabicides: Drugs which are used in the treatment of scabies. Example: Sulphur.

Sedatives: Substance which causes CNS depression and produces sedation. At higher dose they produce sleep. Example: Potassium bromide, Lithium carbonate.

1.2 PHARMACOPOEIA

The word Pharmacopoeia is derived from Greek words ‘pharmakon’ means a drug (both remedy and poison) and ‘poiein’ means to make or create. Pharmacopoeia is a book containing directions for the identification of samples and the preparation of compound medicines, and published by the authority of a government or a medical or pharmaceutical society. For this reason Pharmacopoeia is a legislation of a nation which sets standards and mandatory quality indices for drugs, raw materials used to prepare them and various pharmaceutical preparations.

1.2.1 Monograph

In simple way monographs are descriptions of pharmaceutical preparations. In broader way it is a reference work for pharmaceutical drug specifications. It is a complete description of a specific pharmaceutical, which includes chemical formulae, atomic and molecular weight, definition, statement of content, category, dose, usual strength, description, solubility, identification tests, assay, other test, limits of impurities, quantities, and conditions for storage. The appendices include standards for apparatus, reagents and solutions, indicators, reference substances, test animals, calculation of results, other chemicals techniques, processes etc. of the concerned pharmaceuticals.

By the direction of the council of the pharmaceutical society of the certain nations, the world’s most comprehensive source of drug information in a single volume is published periodically in the society’s department of pharmaceutical sciences.

It is the traditional activity, to help the practicing pharmacists and physicians aiming to provide unbiased concise reports on the actions and uses of most of the world’s drugs and medicines. By reflecting clinical practice, every publication of Pharmacopoeia monographs are accurately organized based on the updated needs of today’s pharmacist. In the form of

new monographs the details are provided for new compounds and some of the previous monographs which are not in continued use are deleted. The overall effect is to provide an increase in the average of drugs with typographically improvements to assist the reader in locating sections of a monograph.

With the search for an effective treatment of diseases a few of the developing therapeutics are revised continuously in Pharmacopoeia. Example: Anti HIV agents. In Pharmacopoeia the drug's distinguished features are updated, renewed and discussed for the treatment of infections and development of antiviral, antiprotozoal and antibacterial therapy. Along with novel approaches in the treatment advances in the cardiovascular group of drugs are included. The other areas like anti-malarial drugs, anti-neoplastic agents, anti-parkinsonism drugs etc. are also included in Pharmacopoeia.

Based on the published information, Pharmacopoeia is divided in to three different major parts. Each part is comprised of several chapters.

Part I: Generally the drugs that have similar use or actions are bringing together by part I of Pharmacopoeia. In related chapters to guide reader the cross references is used to find out the drug that may be of interest. The common actions of the groups of drugs are provided as background information in many of the chapters.

Part II: Monographs of new drugs, drugs under investigation, drugs which are not easily classified and obsolescent drugs still of interest are presented in part II of Pharmacopoeia. It also provides details regarding effects of required drug therapy.

Part III: Composition of the proprietary medicines that are advertised to the public in different countries are documented with omission of herbal medicine in part III of Pharmacopoeia.

Only the pharmaceuticals which are commonly and currently in use are included in the Pharmacopoeia; whereas the substances which are found to be undesirable and are not currently in use are excluded. Moreover part of Pharmacopoeia may also comprise the pharmaceuticals which are used for application or internal consumption by human beings.

In the Pharmacopoeia only minimum standards are prescribed for pharmaceuticals, but with more stringent standards the manufacturer may supply these substances. Hence a drug has to obey strictly the standards prescribed by any one of the Pharmacopoeias. The medication may be considered as substandard if it does not obey these standards and usually it is not prescribed by medical practitioners.

1.2.2 History of Pharmacopoeia

Each country has legislation on pharmaceutical preparations which sets a standards and required quality indices for medicament, raw materials and preparations employed in the manufacture of drugs. These regulations are presented in separate articles. General and specific matters relating to individual drugs are published in the form of a book called a Pharmacopoeia.

On 15th December 1820, the first United State Pharmacopoeia (U.S.P) was released. In 1864, the first British Pharmacopoeia (B.P) was published with inclusion of monographs on benzoic acid, gallic acid, tartaric acid, tannic acid, camphor, lactose, sucrose and seven alkaloids along with their salts.

1.3 INDIAN PHARMACOPOEIA

British Pharmacopoeia was utilized as the official book of standards in India before independence. The actual process of publishing the first Indian Pharmacopoeia started in the year 1944 under the chairmanship of Col. R. N. Chopra. The Indian Pharmacopoeia list was first published in the year 1946 and was put forth for approval. The government of India constituted a permanent Indian Pharmacopoeia Committee in 1948 for the preparation of the Indian Pharmacopoeia and established a central Indian Pharmacopoeia Laboratory at Ghaziabad, Uttar Pradesh to keep it up to date. The Indian Pharmacopoeia is published in fulfillment of the requirements of the Drugs and Cosmetics act, 1940 and rules there under.

The drugs and cosmetics act 1940 stated that the Indian Pharmacopoeia is the book of standards for drugs included therein and the standards as included in the Indian Pharmacopoeia would be official. If considered necessary, these standards can be amended and the secretary of the Indian Pharmacopoeia committee is authorized to issue such amendments.

Government of India, Ministry of Health and Family welfare publishes Indian Pharmacopoeia based on the recommendation of Indian Pharmacopoeia committee (in accordance with Drugs and Cosmetics Acts 1940, Dangerous Drugs Act 1930, and Poisons Act 1919 and the rules framed there under). In general, the general notices and appendices included in the Indian Pharmacopoeia and as amended in addendum apply both to the matter contained in the Indian Pharmacopoeia and to the matter contained in this Addendum.

After independence, the first edition of the Indian Pharmacopoeia (I.P) was published in the year 1955 under the chairmanship of Dr. B. N. Ghosh. Supplement for first edition of Indian Pharmacopoeia was published in the year 1960. This Pharmacopoeia contained both western and traditional system drugs commonly used in India. The same policy was continued while preparing the Indian Pharmacopoeia 1966. After eleven years, under the chairmanship of Dr. B. Mukherji the second edition of Indian Pharmacopoeia was released in 1966 with some modification. The supplement to the second edition of Indian Pharmacopoeia was published in 1975.

There had been a phenomenal growth and development of Indian pharma industry especially from early 1970 both in the range of active pharmaceutical ingredients (APIs) and the dosage forms produced. In view of these rapid advances, it was decided to publish a new edition of the Pharmacopoeia and its addenda at regular and shorter intervals for which the Indian Pharmacopoeia Committee was reconstituted in 1978. The third edition of the Indian Pharmacopoeia got published in 1985 under the chairmanship of Dr. Nityanand. Addendum/supplement I and II to third edition has been published in 1989 and 1991 respectively. In this Pharmacopoeia inclusion of traditional system of drugs was limited. However, most of the new drugs manufactured and/or marketed were included while only those herbal drugs which had definite quality control standards had got place in it.

In view of the continuing rapid increase in the range of drugs produced in India eleven year later the fourth edition of the Indian Pharmacopoeia was published under the chairmanship Dr. Nityanand in 1996. Addendum to fourth edition has been published initially in 2000 followed by in 2002 and 2005. In addition, supplement 2000 for veterinary products are also released. The addendum 2005 was published by the Indian Pharmacopoeia

Committee 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 Pharmacopoeia Committee decide to delete the obsolete or less used product monographs and added monographs based on the therapeutic merit, medicinal need and extent of use of such articles in the country.

The Indian Pharmacopoeia Commission (IPC) has been established in the year 2005. The IPC provided systematic approach and practices for publication of Indian Pharmacopoeia 2007 with focus on those drugs and formulations that cover the National health care programs and the national essential medicines. It contained monographs on antiretroviral, anticancer, anti- tubercular and herbal drugs. It further emphasized on biological monographs such as vaccines, immunosera for human use, blood products, biotechnological and veterinary (biological and non biological) preparations. Addendum 2008 to the Indian Pharmacopoeia 2007 was published which had taken care of the amendments to Indian Pharmacopoeia 2007 and also incorporated 72 new monographs.

The sixth edition of Indian Pharmacopoeia published in accordance with the principles and designed plan decided by the scientific body of the IPC. To establish transparency in setting standards for this edition, the contents of new monographs, revised appendices and other information have been published on the website of IPC, besides following conventional approach of obtaining comments. The feedback and inputs were reviewed by the relevant expert committee to ensure the feasibility and practicability of the standards and methods revised. The principle of openness, justice and fairness is kept in mind during compiling and editing the contents of this edition.

The IPC secretariat and Indian Pharmacopoeia laboratory staff, with the support of different advisory expert committee, and expert members of the scientific body have examined the suitability of the standards. In order to make Indian Pharmacopoeia 2010 user friendly, the existing formatting pattern has been suitably revised. The standards prescribed in this edition are encouraged to adhere with the concept of harmonization, keeping in view the technological status for manufacture and analysis of drugs and pharmaceuticals in the country without compromising with the quality of the products. It strives to update the existing monographs as well as incorporating the new monographs of drug substances based on clinical use of medicines in India and improving their test protocols.

The Indian Pharmacopoeia 2010 has been considerably revised and improved in respect of the requirements of monographs, appendices and testing protocols by introducing advanced technology. The contents of appendices are by and large revised in consonance with those adopted internationally. The monographs of special relevance disease of this region have been given special attention.

In addition emphasis has been put to bring out harmonization in appendices to establish a sound connection between individual monographs and the relevant appendices, so as to make this edition precise and well structured. Number of monographs and appendices are expanded further to incorporate the latest technological advancement and regulatory compliance. Constant efforts have been made to unify the national drug standards and to bring them in line with the international standards progressively, by addition of monographs of new drugs and adopting current methodology.

1.3.1 Features of various Editions of Indian Pharmacopoeia

S. No. of Edition	Year of publication	Year of addendum released	Features of edition
First	1955	1960	Contains both western and traditional system drugs commonly used in India.
Second	1966	1975	Contains both western and traditional system drugs commonly used in India.
Third	1985	1989 (1^{st}) 1991 (2^{nd})	In this Pharmacopoeia inclusion of traditional system of drugs was limited. However, most of the new drugs manufactured and/or marketed were included while only those herbal drugs which had definite quality control standards had got place in it.
Fourth	1996	2000 (1^{st}) 2002 (2^{nd}) 2005 (3^{rd})	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 Pharmacopoeia Committee decide to delete the obsolete or less used product monographs and added monographs based on the therapeutic merit, medicinal need and extent of use of such articles in the country.
Fifth	2007	2008	It focuses on those drugs and formulations that cover the National health care programmes and the national essential medicines. It contained monographs on antiretroviral, anticancer, anti-tubercular and herbal drugs. It further emphasized on biological monographs such as vaccines, immunosera for human use, blood products, biotechnological and veterinary (biological and non biological) preparations.
Sixth	2010	2012	It comprises of three volumes. Each volume has got different features. Volume I comprises notices, preface, about Indian Pharmacopoeia Commission, acknowledgements, introduction, general chapters and reference data. Volume II contains general notices, dosage forms (general monographs), drug substances, dosage forms and pharmaceutical aids (A to M). Volume III includes general notices, drug substances, dosage forms and pharmaceutical aids (N to Z), vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products, veterinary products and index.
Seventh	2014	-	It is presented in four volumes. Included 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 which are not in use now a days are deleted from this edition. The IP 2014 incorporates 2548 monographs of drugs among this 577 are new monographs consisting of APIs, excipients, dosage forms, antibiotic monographs, insulin products and herbal products etc. 19 New Radiopharmaceutical Monographs and 1 General chapter is first time being included in this edition.

1.3.2 Indian Pharmacopoeia 2010

This new edition of Indian Pharmacopoeia entitled sixth edition (Indian Pharmacopoeia 2010) was published by the IPC. It supersedes the fifth edition but any monograph of the earlier edition that does not figure in this edition continues to be official as stipulated in the second schedule of Drugs and cosmetics act, 1940.

Presentation

The Indian Pharmacopoeia 2010 comprises of three volumes. Each one volume has got different features. Volume I comprises notices, preface, about Indian Pharmacopoeia Commission, acknowledgements, introduction, general chapters and reference data. Volume II contains general notices, dosage forms (general monographs), drug substances, dosage forms and pharmaceutical aids (A to M). Volume III includes general notices, drug substances, dosage forms and pharmaceutical aids (N to Z), vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products, veterinary products and index.

The scope of 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 programs are added and the drugs as well as their formulations not in use nowadays 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 the development of latest technology in the field. A new chapter on liposomal products and a monograph of liposomal Amphotericin B injection is added advantage in view of latest technology adopted for drug delivery. A chapter on NMR is incorporated in appendices. The chapter on microbial contamination is also updated to a great extend to harmonize with prevailing international requirements.

1.3.3 Format

In an effort to make the Indian Pharmacopoeia more user's friendly, design of the texts of the monographs and of the test methods are kept same like Indian Pharmacopoeia 2007. Cross referencing has been avoided to make each monograph complete in itself thus making it convenient to the analyst.

Basis of pharmaceutical requirements

As in the past, this compendium provides a publicly available statement concerning the quality of a product that can be expected and demonstrated at any time throughout the accepted shelf life of the article. The standards laid down represent the minimum with which the article must comply and it is inculcate on the manufactured in accordance with the GMPs. It is essential that sufficiently stringent limits are applied at the time of release of a batch of a drug substance or drug product so that the pharmacopoeial standards are met until its expiry date when stored under the storage conditions specified.

It must be noted that a valid interpretation of any requirement of Indian Pharmacopoeia should be done in the context of the monographs as a whole, the relevant general monograph, where appropriate, the specified tests and methods of analysis including any reference to relevant general notices. Familiarity with the general notices will facilitate the correct application of the requirements.

1.3.4 Changes

Keeping in view the essential requirement under the Drugs and Cosmetics Act, 1940 and rules there under in the information on category of a drug, dosage and usual available strengths of dosage forms have been kept in this edition.

General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued.

The use of chromatographic methods has been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extend of impurities in drug substances and drug products. Most of the existing assays and related substances tests are upgraded by liquid chromatography method in view to have more specificity and to harmonize with other international Pharmacopoeias.

The test for pyrogens involving the use of animals has been virtually eliminated. The test for bacterial endotoxins introduced in the previous edition is now applicable to more items. The test for abnormal toxicity is now confined to certain vaccines.

1.3.5 General Chapters

Volume I is devoted mainly to test methods that are applicable to all the articles of the Indian Pharmacopoeia and general information pertaining to the quality requirements of medical substances. It also includes reference data such as reference spectra, typical chromatograms etc. The test methods reflect the sophistication of analytical methodology and instrumentation.

Analytical methods are, in general, in harmony with those adopted internationally for monitoring the quality of drugs. The steps taken for harmonization have been initiated by the need to cope with the increasing demand for drugs manufactured in the country to meet globally accepted standards.

The trend towards controlling the microbial quality of all medicinal products have been recognized and the requirement regarding limits of bacterial contamination even of products for oral administration and topical application so that adequate controls are exercised by manufactures by the adoption of Good Manufacturing Practices (GMPs) has been continued.

The chapter on vaccines: General requirements has been updated. Minor corrections have been made in the appendices entitled tests on chicken flocks free from specified pathogens for the production and quality control of vaccines and general provisions. Avian viral vaccines – tests for extraneous agents in seed lot. The peptide mapping test for inactivated

Hepatitis B vaccine has been deleted. Wherever appropriate, other corrections has also been incorporated and over all presentation improved.

In view of considering the microbiological quality, the whole microbiological general chapter comprising of effectiveness of antimicrobial preservatives, microbial contamination in non sterile products and microbiological quality of raw material, dosage forms, herbs, processed herbs and herbal products have been extensively revised. For the first time in this chapter the analysis of certain *Shigella boydii* (strain of tropical region of our country) is made essential as it causes acute dysentery.

The chapter on biotechnology derived therapeutic products has been fully revised. Special emphasis given on monoclonal antibodies and antisera.

The standards prescribed in the Indian Pharmacopoeia are to establish the compliance with regulatory requirements on article. The criteria to be adhered are; a) The interpretation of a monograph must be in accordance with all the general requirements, testing methods, texts and notices pertaining to it, in the Indian Pharmacopoeia. b) A product is not of standard quality unless it complies with all the requirements of the monograph.

This edition of Indian Pharmacopoeia 2010 supersedes the Indian Pharmacopoeia 2007 edition. The Indian Pharmacopoeia 2010 incorporated 287 new monographs consisting of APIs, excipients, dosage forms and herbal products, etc. This Indian Pharmacopoeia edition plays a significant role in improving the quality of medicines which in turn promote public health and accelerate the growth and development of pharma sector.

In Pharmacopoeia under a monograph each pharmaceutical agent has been described. In appendices of the Pharmacopoeia the various standards for chemical apparatus, technique processes etc. are described. Appendices are considered as important as the main body monographs for a pharmaceutical chemist and an analyst. In the Pharmacopoeia those pharmaceuticals which are commonly used in the recent past have been included. Substances which have proved to be undesirable from past experience are removed from Pharmacopoeia. In general due to idleness, substances which are commercially available in excellent purity and are commonly used for other purposes are also not included. In case, if such substances find use internally then they are included in the monographs. The standards prescribed for a chemical are the minimum. It does not prevent a manufacturer from supplying these with more stringent standards. In the Pharmacopoeia if a substance has not been included it does not imply that it cannot be used or marketed. Such non official substances must correspond to standards prescribed either in the earlier editions of the Indian Pharmacopoeia or in other recognized pharmacopoeia (of other countries).

Generally in India products corresponding to the British Pharmacopoeia (BP) and United States Pharmacopoeia (USP) are marketed. Other better known Pharmacopoeias are International Pharmacopoeia (IP), European Pharmacopoeia (EP) and Union of Soviet Socialist Republics Pharmacopoeia (USSRP). To avoid confusion with International Pharmacopoeia, Indian Pharmacopoeia sometimes abbreviated as IND.P. or PI Generally IP will be understood as Indian Pharmacopoeia unless otherwise specified in our country. The various other compendia prescribing standards for pharmaceuticals are British

Pharmaceutical Codex (BPC) and National Formulary (NF). In the interest of proper health any substance which fails to correspond to any official standard should not be used.

Official substances: In the latest edition of the Pharmacopoeia those drugs and pharmaceuticals are termed as official substances in that country of Pharmacopoeia. It is very important to understand the difference between an official substance and chemical individual with same name. The individual chemical can be pure to any specified purity. The official substance is a commercial product which is required to comply with standards specified in the Pharmacopoeia and may often have some other substances added for specific reasons. For example, to prevent the formation and to inactivate any poisonous phosgene (carbonyl chloride) gas that may be formed in contact with the air during storage of chloroform of the Pharmacopoeia contains 1-2 % of added ethyl alcohol.

1.3.6 Pharmacopoeial Description/Presentation

Most of the Pharmacopoeias including Indian Pharmacopoeia consist of the three major sections namely

(a) Introduction including general notices

(b) Monographs of the official drugs

(c) Appendices.

(a) ***Introduction:*** It is a useful pointer to pharmaceutical progress since last edition. It summarizes the different changes including additions/deletions in the current edition compared to last edition. To avoid misinterpretation and misunderstanding of later parts of the text, attention should be paid to general notices at the outset.

(b) ***Monographs:*** The general monographs for dosage forms of active pharmaceutical ingredients (APIs) are grouped together at the beginning of volume II of Indian Pharmacopeia 2010. They are followed by the monographs for the APIs, pharmaceutical aids and individual dosage forms all in alphabetical order. Monographs for other articles of a special nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products, veterinary products are given in separate sections in volume III of Indian Pharmacopeia 2010.

The written study of a subject was implied by the word “monograph”. These are considered as very important because medicinal substances are used for the cure and/or prevention of diseases. Therefore their written studies appear as monographs in the Pharmacopoeia. These monographs are arranged in the alphabetical order of their names and are somewhat stereotyped in style. The following information about the drugs and pharmaceutical aids are described in Pharmacopoeial monographs.

1.3.7 General Monographs

General monographs on dosage forms include requirements of general application and apply to all preparations within the scope of the introduction section of the general monograph, except where a preamble limits the application. The requirements are not necessarily comprehensive for a given specific preparation, additional requirements may sometimes be given in the individual monograph for it.

1.3.8 Production

Statements given under the heading production relate to particular aspects of the manufacturing process and are not necessarily comprehensive. However, they are mandatory instructions to manufacturers. For example, they may relate to source materials, to the manufacturing process and its validation and control, to any process testing that is to be carried out by the manufacturer on the final product either on selected batches or on each batch prior to release. All this cannot be verified on a sample of the final product by an independent analyst. It is for the licensing authority to verify that the instructions have been followed.

The absence of a section on production does not imply that attention to features such as those given above is not required. An article described in a monograph of the Pharmacopeia is to be manufactured in accordance with the principles of good manufacturing practice and in accordance with the requirements of the Drugs and Cosmetic Rules, 1945. The general principles applicable to the manufacture and quality assurance of drugs and preparations meant for human use equally to veterinary products as well.

1.3.9 Manufacture of Drug Products

The opening definitive statement in certain monographs for drug product is given in terms of the active ingredient(s) only. Any ingredient(s) other than those included in the statement, must comply with the general notice on excipients and the product must conform to the Pharmacopoeial requirements.

Official preparations are prepared only from ingredients that comply with the requirements of the Pharmacopoeial monographs for those individual ingredients for which monographs are provided.

1.3.10 Excipients

Any substance added in preparing an official preparation shall be innocuous, shall have no adverse influence in the therapeutic efficacy of the active ingredients and shall not interfere with the tests and assays of Pharmacopoeia. Care should be taken to ensure that such substances are free from harmful organisms.

1.3.11 Individual Monographs

Drug products that are the subject of an individual monograph are also required to comply with the tests given in the general monographs.

1. ***Title:*** The main title for a drug substance is the International Non-proprietary Name (INN) approved by World Health Organization (WHO). The official name of the compound in English is stated in the title. In place of the main title, sometimes sub titles are given which are synonyms/subsidiary names; where included, they have the same significance as the main title. For example, calcium carbonate can also be called precipitated chalk; iron and ammonium citrate can also be called ferric ammonium citrate and milk of magnesia can also be called magnesium hydroxide mixture.

When a product contains one or the other different salts of an active molecule, the main title is based on the full name of the active ingredient. For example, chloroquine phosphate tablet and chloroquine sulphate tablets.

2. ***Chemical formulae:*** When the chemical structure of an official substance is known or generally accepted, the graphic and molecular formulae are normally given at the beginning of the monograph for information. To specify the absolute stereo chemical configuration International Union of Pure and Applied Chemists (IUPAC) systems have been used. If the substance is enantiomer, the sign of optical rotation has been attached to the systematic name.
3. ***Atomic and molecular weight:*** The atomic and molecular weight is shown, as and when appropriate at the top right hand corner of the monograph. For example, magnesium chloride (Molecular weight: 202.30) and potassium permanganate (Molecular weight: 158.03). In general if the correct chemistry is not known or the compound is of indefinite composition these two items are not provided. For example chemical formula and molecular weight for iron ammonium citrate are not provided.
4. ***Definition:*** The opening statement of a monograph is one that constitutes an official definition of the substance, preparation or other article that is the subject of the monograph. In some monographs of pharmaceutical preparations the statement is given in terms of principle ingredient(s). In monographs on vegetable drugs, the definition indicates whether the subject of the monograph is, for example, the whole drug or the drug in powdered form. Certain pharmaceutical substance and other articles are defined by reference to a particular method of manufacture.
5. ***Statement of content:*** The limits of content stated are those determined by the method described under assay.
6. ***Category:*** This part of monograph expresses the pharmacological or therapeutic or pharmaceutical application of the compound. Although the compound may have other applications usually this part describes the main application. Analgesics, antibiotic, antacid, laxative etc. are some of the main categories for inorganic pharmaceuticals in the Pharmacopoeia.
7. ***Dose:*** Dose mentioned in the Pharmacopeia is intended merely for general guidance and represent, unless otherwise stated, the average range of quantities which are generally regarded as suitable for adults when administered by mouth. It provides the quantity guidance to the prescriber or the physician to achieve the desired therapeutic effects in adults. The dose can be altered as and when required. For example the dose of calcium carbonate is 1 – 5 gm.

   This is omitted for substances not used for internal administration. Usual strength may be given for pharmaceutical dosage forms like injection etc. which is the most commonly marketed dosage strength.

8. ***Usual strength:*** It indicates the strength(s) usually marketed for information of the pharmacist and the medical practitioner.
9. ***Description:*** This part of monograph is not to be interpreted in a strict sense and is not to be regarded as official requirements. It illustrates a physical description of the substance such as amorphous nature or crystalline, odor, color and taste etc. In the preliminary evaluation of the integrity of an article these properties help and not themselves the standards or tests or purity. For example, Calcium carbonate is a fine white microcrystalline powder, odorless and tasteless.
10. ***Solubility:*** The solubility mentioned in Indian Pharmacopeia is the approximate solubility at a temperature between 15 °C and 30 °C, unless otherwise stated, and are not to be considered as official requirements. In the Pharmacopoeia under general notices solubility is described. The solubility of a substance in water, hot or boiling water, alcohol, glycerol, other organic solvent, acid and alkali were given.
11. ***Test methods:*** References to general methods of testing are indicated by test method numbers in brackets immediately after the heading of the test or at the end of the text.
12. ***Identification:*** These identification tests are not a proof of identity. This usually involves specific chemical test or tests for identifying the substance. It provides a means of verifying that the identity of the material under examination is in accordance with the label on the container. In certain monographs alternative series of tests are given; compliance with either one or the other set of tests is adequate to verify the identity of the article. In general for inorganic pharmaceuticals color reactions, precipitation reactions and gas evolving reactions are used. For example, Phenol gives violet color with ferric chloride.
13. ***Tests and assay:*** These are the official methods upon which the standards of Pharmacopoeia depend. The requirements are not framed to take into account all possible impurities. Tests and assay are prescribed for the minimum sample available on which the attributes of the article should be measured. Assurance of quality must be ensured by the manufacture by the use of statistically valid sampling and testing programs.
14. ***Tests:*** In general the assays and test are carried out at a temperature between 20 °C and 30 °C unless otherwise stated. Precaution should be taken to avoid exposure to direct sunlight or other strong light where it is directed that an analytical operation is to be carried out “in subdued light”. Similarly precaution should be taken to exclude actinic light by the use of low actinic glassware, working in a dark room or similar procedures where a procedure is directed to be performed “protected from light”. For preparations other than those of fixed strength, the quantity to be taken for a test or an assay is usually expressed in terms of the active ingredient. It means that the quantity of the

active ingredient expected to be present and the quantity of the preparation to be taken are calculated from the strength stated on the label.

15. ***Other tests:*** In the monographs on dosage forms and certain preparations, under the sub heading "other tests" it is stated that an article complies with the tests stated under the general monograph of the relevant dosage form or preparation. Details of such tests are illustrated in the general monographs.
16. ***Limits:*** The limits given are based on data obtained in normal analytical practice. They take into account normal analytical errors, of acceptable variations in manufacture and of deterioration to an extent that is acceptable. No further tolerances are to be applied to the limits for determining whether or not the article under examination complies with the requirements of the monograph.
17. ***Quantities:*** Unless otherwise stated, in tests with numerical limits and assays, the quantity stated to be taken for testing is approximate. Volumes stated in microliters (μl) are measured using a micropipette or micro syringe. The term "transfer" is used generally to indicate a quantitative operation.
18. ***Apparatus:*** Measuring and weighing devices and other apparatus are described in the chapter entitled "apparatus for tests and assays". Unless otherwise stated, comparative tests are carried out using identical Nessler cylinders.
19. ***Reagents and solutions:*** The reagents required for the tests and assays of the drugs in the Pharmacopoeia are defined in the various chapters showing their nature, degree of purity and the strengths of the solutions to be made from them.
20. ***Indicators:*** Where the use of an indicator solution is mentioned in an assay or test, approximately 0.1 ml of the solution shall be added, unless otherwise directed.
21. ***Reference substances:*** These are the authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the Pharmacopoeia and not necessarily suitable in other circumstances.
22. ***Test animals:*** Unless otherwise directed, animals used in test or assay shall be healthy and are drawn from a uniform stock, and have not been previously treated with any material that will interfere with the test or the assay.
23. ***Calculation of results:*** The results should be calculated to one decimal place more than the significant figures stated and then rounded up or down as follows; if the last figure calculated is 5 – 9, the preceding figure is increased by 1; if it is 4 or less, the preceding figure is left unchanged.
24. ***Storage:*** These directions are useful in preserving the activity of the chemical. Specific directions are given in some monographs with respect to the temperatures at which Pharmacopoeial article should be stored, where it is considered that usage at a lower or higher temperature may produce undesirable results. The storage conditions are defined

by the following terms; a) Store in a dry, well ventilated place at a temperature not exceeding 30 °C, b) Store in a refrigerator (2 °C to 8 °C) and do not freeze, c) store in a freezer and d) Store in a deep freezer (below -18 °C). The storage conditions not related to temperature are indicated in the following terms; a) Store protected from light and b) Store protected from light and moisture. Where no specific storage directions or limitations mentioned, it is to be understood that the storage conditions include protection from moisture, freezing and excessive heat (any temperature above 40 °C). For example insulin injection store in multiple dose containers at a temperature between 2 °C to 8 °C. It should not be allowed to freeze.

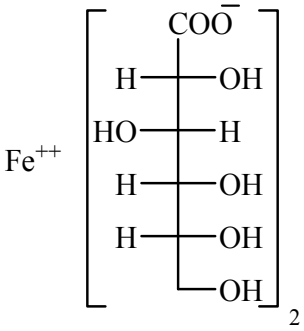
25. ***Storage containers:*** The storage containers in the Pharmacopoeia are indicated in the following terms; a) Well closed containers: This implies the substance is stable and gets protected from dust, dirt, insects etc, getting into the container, b) Tightly closed container: The substances in such cases get affected by atmospheric oxygen or moisture or carbon dioxide. For example, reducing agents, hygroscopic substances, strong bases etc. must be stored in tightly closed containers. It may also include such compounds are volatile or contain dissolved gases etc. c) Light resistant container: Substances which are affected by light are stored in amber or dark colored containers, d) Single dose containers: This is generally prescribed for some injectables which once opened should not be used again. For example, Ferrous fumarate (Store in a light resistant container).

26. ***Labeling:*** The labeling of drugs and pharmaceuticals is governed by the Drugs and Cosmetics Rule, 1945. The statements that are given in the monographs under the side heading “labeling” are not comprehensive. Only those that are necessary to demonstrate compliance or otherwise with the monograph have been given and they are mandatory. For example, in the monograph on betamethasone sodium tablets the labeling statement is “The label states the strength in terms of the equivalent amount of betamethasone”. Any other statements may also include as recommendations.

(c) ***Appendices:*** A comprehensive section of appendices are presented followed by the general notices and monographs. The apparatus that are needed for various Pharmacopoeial tests and assays are described in the appendix 1. Biological tests and assays are described in appendix 2. The details of various chemical tests and assays are included in appendix 3. The details of microbiological tests and assays are included in appendix 4. In the appendix 5, some physical tests and determinations like loss on drying, determination of pH, melting range etc are described. Appendix 6 includes the useful directions on cleaning glassware. Appendix 7 describes the reagents and solutions needed for the various tests and assays, their method of preparation, standards etc. Appendix 8 describes reference substances. Appendix 9 have been described fully the names, symbols used in the Pharmacopoeia for weights and measures and of elements and their atomic weights have been described.

1.3.12 Representative example of a Monograph of Indian Pharmacopoeia 2010

Ferrous Gluconate



Mol. Formula $C_{12}H_{22}FeO_{14}.xH_2O$ Mol. Wt: 446.1 (anhydrous)

Ferrous Gluconate is ferrous di (D-gluconate).

Ferrous Gluconate contains not less than 95.0 percent and not more than 102.0 percent of $C_{12}H_{22}FeO_{14}$, calculated on the dried basis.

***Category**:* Haematinic.

Dose: Prophylactic, 600 mg daily; therapeutic, 1.2 to 1.8 g daily, in divided doses.

(300 mg of ferrous gluconate is approximately equivalent to 35 mg of ferrous iron).

Description: A yellowish grey or pale greenish–yellow, fine powder or granules, odour, slight, resembling that of burnt sugar.

Identification

(a) Dissolve 5 gm in *carbon dioxide –free water* at 60 °C, cool and dilute to 50 ml with water. 1 ml of the resulting solution gives reaction A of ferrous salts.

(b) Determine by thin layer chromatography, coating the plate with *silica gel G*.

*Mobile phase.*A mixture of 10 volumes of *concentrated ammonia*, 10 volumes of *ethyl acetate*, 30 volumes of *water* and 50 volumes of *ethanol (95 percent).*

Test solution. Dissolve 20 mg of the substance under examination in 2 ml of *water* heating if necessary in a water-bath at 60 °C.

Reference solution. Dissolve 20 mg of *ferrous gluconate RS* in 2 ml of *water*, heating if necessary in water-bath at 60 °C.

Apply to the plate 5 µl of each solution. After development dry the plate at 105 °C for 20 minutes and spray with 5 percent w/v solution of *potassium dichromate* in a 40 percent w/v solution of *sulphuric acid*. The principle spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.

Tests

Appearance of solution: Dissolve 5.0 gm in *carbon dioxide- free water* at 60 °C, cool and dilute to 50 ml with the same solvent (solution A). Dilute 2 ml of solution A to 10 ml with *water*. When examined against the light, the resulting solution is clear.

pH: 4.0 to 5.5, determined in solution A, 3 to 4 hours after preparation.

Arsenic: To 5.0 gm add 15 ml of *water* and 15 ml of *stannated hydrochloric acid*, distil 22 ml and add to the distillate 40 ml of *water* and 0.2 ml of *stannous chloride solution AsT*. The resulting solution complies with the limit test for arsenic (2 ppm).

Heavy metals: Warm 2.0 gm gently with 10 ml of *nitric acid* until reaction begins and allow to stand until the evolution of nitrous fumes subsides. Boil gently to complete oxidation, adding a further 5 ml of *nitric acid*, if necessary, and continue boiling until the volume is reduced to about 5 ml. Add 20 ml of *hydrochloric acid*, boil gently for 1 minute, cool and extract with three quantities, each of 20 ml, of *ether*. If the acid solution is still more than faintly yellow, extract with a fourth quantity of 20 ml of *ether* and discard the ether extracts. Transfer the acid solution to a narrow - necked flask, rinse the separator with 5 ml of *water*, and add the rinsing to the flask. Heat to remove the dissolved *ether* and part of the *hydrochloric acid*. Cool and dilute to 50 ml with *water.* 25 ml of the resulting solution complies with the limit test for heavy metals, method A (20 ppm).

Chlorides: 0.4 gm complies with the limit test for chlorides (625 ppm).

Sulphates: 0.3 gm complies with the limit test for sulphates (500 ppm).

Barium: Dissolve 0.1 gm in 50 ml of *distilled water*, and 5 ml of *dilute sulphuric acid*, and allow to stand for 5 minutes. The solution is not more opalescent than a mixture of 10 ml of solution A and 45 ml of *distilled water*, when examined against the light.

Ferric iron: Not more than 1.0 percent, determined by the following method. Weigh accurately about 5.0 gm, transfer to a glass-stoppered flask and dissolve in a mixture of 100 ml of freshly boiled and cooled *water,*10 ml of *hydrochloric acid*. Add 3 gm of *potassium iodide*, shake well and allow to stand in the dark for 5 minutes. Titrate the liberated iodine with *0.1M sodium thiosulphate* using *starch solution*, added towards the end of the titration as indicator. Repeat the operation without the substance under examination. The difference between the titrations represents the amount of iodine liberated by the ferric iron.

1 ml of *0.1M sodium thiosulphate* is equivalent to 0.005585 gm of ferric iron.

Oxalic acid: Dissolve 1 gm in 5 ml of *water*, add 2 ml of *hydrochloric acid* and transfer to a separator. Extract with two quantities, each of 20 ml, of *ether*. Evaporate the combined ether extracts to dryness on a water-bath and dissolve the residue in 5 ml of *water*. Add 0.05 ml of *acetic acid* and 3 ml of *calcium chloride solution*; no turbidity is produced.

Reducing sugar: Dissolve 0.5 gm in 10 ml of *water* and make alkaline with *dilute ammonia solution*. Pass *hydrogen sulphide* into the solution and allow to stand for 30 minutes. Filter and wash the precipitate with two quantities, each of 5 ml of *water*. Combine the filtrate and the washings and acidify with *dilute hydrochloric acid*. Add 2 ml of *dilute hydrochloric acid*

in excess. Boil the solution until the vapors no longer darken *lead acetate paper* and, if necessary, boil further to concentrate the solution to about 10 ml. Cool and add 10 ml of *sodium carbonate solution*, set aside for 5 minutes, filter and dilute the filtrate to 100 ml with *water.* To 5 ml of the filtrate add 2 ml of *potassium cupric-tartrate solution* and boil for 1 minute; no red precipitate is formed.

Loss on drying*:* 5.0 per cent to 10.0 per cent determined on 1.0 gm by drying in an oven at 105 °C.

Microbial Contamination: Total viable aerobic count, not more than 1000 micro- organisms per gm, determined by plate count.

Assay: Dissolve 0.5 gm of *sodium bicarbonate* in a mixture of 70 ml of water 30 ml of *1M sulphuric acid*. When effervescence ceases, add about 1.0 gm, of accurately weighed substances under examination, shake gently to dissolve and titrate with *0.1M ceric ammonium nitrate*, using 0.1 ml of *ferroin solution* as indicator, until the red colour disappears.

1 ml of *0.1M ceric ammonium nitrate* is equivalent to 0.04461gm of $C_{12}H_{22}FeO_{14}$.

Storage: Store protected from light.

1.3.13 Indian Pharmacopoeia 2014

Highlights

- It is effective from 1st January, 2014
- Presented in 4 hard bound volumes with DVD
- Total monographs 2548, 577 new Monographs included.
- For the first time in this edition 19 new Radiopharmaceutical monographs and 1 general chapter is included.
- Presented in user friendly format and cross referencing has been avoided
- Veterinary products monographs are the integral part of this edition
- Use of chromatographic methods has been greatly extended
- More specific IP and UV Spectrophotometer tests have been introduced and classical chemicals tests for identification of an article have been almost eliminated.
- Test for pyrogen almost eliminated
- Obsolete monographs have been omitted
- More herbal drugs monographs has been added
- Included several new monographs not included in any other major pharmacopoeias of the world.

1.4 EXTRA PHARMACOPOEIA (MARTINDALE)

Pharmacopoeia possesses wealth of information with no explanation. The person must familiarize himself with the general notices and the various appendices of Pharmacopoeia to

consult the Pharmacopoeia. From the extra Pharmacopoeia (Martindale), one can obtain most complete information on every type of pharmaceutical or drug. This book was rich especially with therapeutic and clinical information of the drugs. For inorganic pharmaceuticals there are several other useful literature references are included.

A practicing pharmacist William Martindale in the year 1883 published the extra Pharmacopoeia. To provide practical and up to date information concerning drugs and galenicals included in the British Pharmacopoeia was its main aim. In the span of three years four editions of Martindale were published.

Due to the accumulation of information up to the year 1910 the subject matter to be divided into two volumes in the initial editions of Martindale. The first double volume edition was published in 1912. In December 1933, the pharmaceutical society of Great Britain acquired the copy right of the Extra Pharmacopoeia upon the death of Dr W.H Martindale son of William Martindale. Thereafter the society is continuing to issue it under the editorship of the director of pharmaceutical sciences department. 23rd edition of volume II was published in 1955 and the 24th edition of volume I was published in 1958. Supplement for 24th edition was published in 1961. In February 1967 the 25th edition was published by the pharmaceutical society of Great Britain. While the 26th edition was released in July 1972.

The 30th edition of Martindale contains up to date authoritative information on drugs and medicine which are used throughout the world was published in 1993. It is written for all those involve in use of drugs and medicines including practicing pharmacists and physicians.

In order to meet the requirements of today's reader the latest edition of Martindale has been markedly changed. It includes a significant shift to a more clinical emphasis an increase in the number of referenced reviews and a massive increase information on proprietary medicines. In addition usual period between editions was shorten to meet the need for up to date information.

1.5 BRITISH PHARMACOPOEIA

The section 54 of Medical Act of 1858 stressed the need of publication of a book having a list of medicines and compounds, and the manner of preparing them together with true weights and measures by which they are to be prepared and mixed. Hence the British Pharmacopoeia was decided to publish. In the year 1864 the first British Pharmacopoeia was published by combining the three old and reputed Pharmacopoeias namely Pharmacopoeia Londinensis (1618) Edinburgh Pharmacopoeia (1699) and Dublin Pharmacopoeia (1807). New editions and addendum was released quickly. The 2nd edition was released in 1867. The 3rd and 4th edition was published in the year 1885 and 1898 respectively. Addendum to 2nd and 3rd edition was released in the year 1874 and 1890 respectively.

Separate parts such as preparation of compounds are included in the 1864 British Pharmacopoeia. As per practice of several other Pharmacopoeias in this edition of British Pharmacopoeia the contents had been arranged alphabetically. A gap in revision belated the next edition of British Pharmacopoeia until 1914.

In Britain it was realized that technical complexity of the drug specifications was increasing and a different kind of set up was needed to prepare the Pharmacopoeias after publication of the British Pharmacopoeia 1914. Hence the further edition was published in 1928 and 1932. There after the commission was recommended to revise the British Pharmacopoeia every ten years once.

A range of diagnostic materials was included in 1932 revision. An important addition was inclusion of standards and tests for antitoxins and insulin. Seven addenda covered the interim between 1932 and next edition of 1948. In this 1948 edition (7^{th}), for substances newly introduced into medicine, generic names were provided. Methods of analysis such as disintegration tests for tablets and sterilization methods were expanded. Many new monographs related to sex hormones and penicillin's were included. Due to the rapid development of pharmaceutical and pharmacological progress at this time it was decided that the normal interval between new editions should be five instead of ten years.

The next edition was released in the year 1953. In this edition of British Pharmacopoeia, the titles of drugs and preparations were given in English instead of Latin. Abbreviated Latin title was retained as a synonym. Capsules, constituted as new group of formulation and the implant methods for sex hormones and their standards were also described in this edition. The 9^{th} edition (1958) contains 160 new monographs. Spectrophotometric analysis and inclusion of tranquillizing drugs are the other features of this edition. The next i.e., tenth edition was published in 1963.

The duties of the British Pharmacopoeia commission were defined clearly in medicines order 1970. The first edition of British Pharmacopoeia that was prepared strictly under the provisions of Medicines Act was the thirteenth edition which was published in the year 1980. Due to an expansion of drug information latter the British Pharmacopoeia was decided to publish in two volumes.

Authoritative standard for the quality of many substances preparation and articles used in medicine and pharmacy for some 130 years was provided in 1993 edition of British Pharmacopoeia. For the convenience of user this edition consolidates and extends the 1988 edition with its 1989, 1991, and 1992 addenda. Moreover monographs of the European Pharmacopoeia were also included in this particular edition.

The last year edition of the British Pharmacopoeia i.e., British Pharmacopoeia 2013 comprises six volumes which contain nearly 3,000 monographs for drug substances, excipients and formulated preparation, together with supporting general notices, appendices (test methods, reagents etc.) and reference spectra used in the practice of medicine. All are comprehensively indexed and cross-referenced for easy reference. Items used exclusively in veterinary medicine in the UK are included in the BP (Veterinary).

The volume I and II deals with medicinal substances, whereas volume III describes about formulated preparations, blood related preparations, immunological products, radiopharmaceutical preparations, surgical materials and homeopathic preparations. The volume IV contains appendices, infrared reference spectra and index. The volume V is for

veterinary purpose i.e., British Pharmacopoeia (Veterinary). The volume VI is the CD-ROM version of British Pharmacopoeia, British Pharmacopoeia (Veterinary) and British approved names.

The 2013 edition of British Pharmacopoeia is available as a printed volume and electronically in both on line and CD-ROM versions, the electronic products use sophisticated search techniques to locate information quickly. For example, pharmacists referring to a monograph can immediately link to other related substances and appendices referenced in the content by using 1,30,000 plus hypertext links within the text.

The British Pharmacopoeia 2013 package comprises five volumes of the British Pharmacopoeia 2013 and a single volume of the British Pharmacopoeia (Veterinary) 2013, along with a fully searchable CD-ROM and online access which provided flexible resources.

The British Pharmacopoeia 2013 was legally effective from 1 January 2013 and contains 41 new British Pharmacopoeia monographs, 40 new European Pharmacopoeia monographs, 619 amended monographs, 6 new and 1 amended infrared reference spectra and European Pharmacopoeia 7th edition material up to and including Supplement 7.5. In addition updates in January, April and July to harmonise with the European Pharmacopoeia was also provided.

The current edition of the British Pharmacopoeia i.e., British Pharmacopoeia 2014 comprises five volumes and a single volume of the British Pharmacopoeia (Veterinary) 2014, along with a fully searchable CD-ROM and online access to provide with flexible resources.

1.5.1 Highlights of British Pharmacopoeia 2014

- Legally effective from 1 January 2014
- 40 new BP monographs are included
- 272 amended monographs
- Three new Supplementary Chapters are included
- Four new BP (Vet) monographs are included
- One new BP (Vet) Supplementary Chapter is included
- Free in-year updates in April and July to harmonise with the European Pharmacopoeia

1.6 EUROPEAN PHARMACOPOEIA

An official book of standards adopted by Germany, France, Italy, Netherlands, Switzerland and Belgium is European Pharmacopoeia. In July 1964, the council of Europe issued an order, to frame out European Pharmacopoeia. 1969 onwards in the respective member countries it was appeared as official standard book for medicinal substances and other drugs. Later on it was revised continuously to keep the information up to date.

1.7 PHARMACOPOEIA INTERNATIONALS (INTERNATIONAL PHARMACOPOEIA)

In various countries there are no uniformity in terminology and strengths of pharmaceutical preparations used. In the year 1874, a view had been expressed that some world uniformity in the standards for potent drugs must necessary to overcome various problems. These views got further support in second international conference held in 1925 where an international agreement on the Unification of formulae for seventy seven potent drugs and preparations got reached. In 1936 the Health Organization of the League of Nations established a technical commission of Pharmacopoeial experts. The work was undertaken by the WHO after the World War II which was ended in 1946. Finally volume I of the long awaited International Pharmacopoeia was published in 1951 by Latin with translation into English and French. This International Pharmacopoeia contains monographs for over two hundred drugs and chemicals, with appendices on reagents tests and biological assays. Latter in the year 1955 the second volume was published which contains formulae for preparations having various drugs and substances already present in volume I. In 1959 the supplement for first edition was released with incorporation of some newer drugs and substances with its method of preparations and the appropriate tests. In 1967 the second edition of International Pharmacopoeia got published, followed by a supplement in 1971. Third edition of International Pharmacopoeia was published in the form of several volumes, in which volume I appeared in 1979.

The Pharmacopoeial authorities of all countries are expected to give due considerations to its standards so as for achieving uniformity of standards as far as practicable even though the International Pharmacopoeia cannot be imposed legally on any country.

1.8 UNITED STATES PHARMACOPOEIA (USP)

In 1817, Dr. Lyman spalding proposed a plan to publish a National Pharmacopoeia to the medical society of the country at New York. 15th December 1820 the first edition of United States Pharmacopoeia was published with 217 drugs in about 272 pages. After the gap of ten years further editions of USP appeared. The 19th edition of USP was published in the year 1905. However, it was given the title of USP VIII as to show that it was 8th revision. Pharmacopoeia must be revised every 5 years was suggested in the 1940 convention.

On July 5 of 1974, unification of the USP and NF (National Formulary) was announced. Afterwards in the subsequent editions consolidated USP and NF into a single volume was published. USP covers all drug substances and drug products; whereas NF covers only pharmaceutical ingredients.

In January 1990, the 22nd edition of USP combined with 17th edition of NF was published.

The current version of USP–NF standards deemed official by USP are enforceable by the United States Food and Drug Administration (US-FDA) for medicines manufactured and marketed in the United States. The latest edition, USP 36–NF 31, published on November 1, 2012 in English, and became official from May 1, 2013. The highlights and features are it contains more than 4,600 monographs with specifications for identity, strength, quality,

purity, packaging, and labeling for substances and dosage forms. It also comprise more than 260 general chapters providing clear, step-by-step guidance for assays, tests, and procedures. More over it also focus, specific charts and a combined index which help us to find the information.

1.9 PHARMACEUTICAL INDEX

Its 12th edition has been completely revised and incorporated updated material as well as entirely fresh subject areas. The new codex provides a reference source on all aspects of pharmaceutical science and technology.

Part I covers the multidisciplinary nature of pharmaceutics and demonstrates how quality is built into medicines from conception ideas and to develop and for production and use. The chapters broadly encompass the pharmaceutics content of the syllabus for pharmacy undergraduates and also provide direction and support for the continuing education of graduates with special emphasis on the product development and the innovation. Part II includes an extensive collection of pharmaceutical data arranged in monograph form. It is edited by staff of the Royal pharmaceutical society by inviting known experts to write individual chapters.

1.10 THE DRUGS AND COSMETICS ACT 1940

1.10.1 Scope

The Drugs and Cosmetics Act 1940 has been enacted for the purpose of proper enforcement and the purpose is that no substandard drugs be sold in the market and no one will sell even genuine drug without license.

This Act mainly concerned with the standard and quality of drugs manufactured in this country and therefore controls the manufacture, sale and distribution of drugs. This act is not related to excise duty or impositions on narcotic drugs.

1.10.2 Objectives

In view of the commitment undertaken by the Government of India the objects of Drugs and Cosmetics Act 1940 are as follows.

I. Regulation of international traffic in all the drugs covered by the convention.
II. Regulations of manufacture and internal traffic of certain specified drugs such as cocaine and morphine.

1.10.3 Features of Drugs and Cosmetics Act 1940

Definitions: As per Drugs and Cosmetics Act 1940 the drugs and cosmetics are defined as follows,

Drugs (Ayurvedic Unani or siddha): It include all medicines intended for internal or external use for or in the diagnosis treatment, mitigation or prevention of disease of disorder in human beings or animals and manufactured exclusively in accordance with the formulae

described in the authoritative book, Ayurvedic siddha and unani, tibb system of medicine specified in the first schedule.

Cosmetics: It means any article intended to be rubbed, poured, sprinkled or sprayed in on or introduced into or otherwise applied to the human body or any part for cleansing, beautifying, promoting attractiveness or alternating the appearance. It also includes any articles intended for use as a component of cosmetics.

1.10.4 Standard of Quality

In relation to a drug that the drug complies with the standard set out. Cosmetics also complies with standard as recommended.

Misbranded drugs

A drug shall be termed to be misbranded:

(a) If it so colored, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) If it is not labeled in the prescribed manner; or

(c) If its label or container or anything accompanying the drug bears any statement design or

(d) If its label or container or anything accompanying the drug bears any statement design or device which makes any false claim for the drug or which is false or misleading in any particular manner.

Adulterated drugs: The drug shall be termed to be adulterated.

(a) If it consists in whole or in part of any filthy putrid or decomposed substance; or

(b) If it has been prepared packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health, or

(c) If it contains any harmful or toxic substance which may render injurious to health; or

(d) If it bears or it contains for the purposes of coloring only, a color other than one which is prescribed or

(e) If any substance has been mixed therewith so as to reduce its quality or strength.

Spurious drugs*:* A drug shall be termed to be spurious:

(a) If it is imported under a name which belongs to another drug; or

(b) If it is an imitation of or is a substitute for another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug or

(c) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) If it has been substituted wholly or in part by another drug or substance or

(e) If it purports to be the product of a manufacturer of whom it is not truly a product.

1.10.5 License to Sell, Stock, Exhibit or Offer for Sale or Distribute Drugs by Retail other than those Specified in (Schedules c, c (1) and (x))

License form 20 is to be filled by the official drug distributor in the following proforma:

1. Is hereby licensed to sell, stock or exhibit for sale or distribute by retail drugs other than those specified in of the Drugs and Cosmetics Rules 1945 and to operate a pharmacy on the premises situated at subject to the conditions specified below and to the provisions of the Drugs and Cosmetics Act 1940 and the rules there under.
2. The license shall be in force from to
3. Names of qualified person in charge
4. Categories of drugs

1.10.6 Conditions for License

1. This license shall be displayed in a prominent place in a part of the premises open to the public.
2. The license shall comply with the provisions of the Drugs and Cosmetics Act 1940 and the rules there under for the time being in force.
3. No drug shall be sold unless such drugs are purchased under cash or credit memo from a duly licensed dealer or a duly licensed manufacturer.
4. No sale of any drug shall be made to a person not holding the requisite license to sell stock or exhibit for sale or distribute the drug provided that this condition shall not apply to the sale of any drug.
5. An officer or authority purchasing on behalf of government or
6. A hospital medical, educational or research institution or a registered medical practitioner for the purpose of supply to his patient or
7. A manufacturer of beverages confectional biscuits and other non medical products where such drugs are required for processing those products.

The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under license. Where any change in the constitution of firm takes place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless a fresh license has been taken from the licensing authority in the name of firm with the changed constitution.

1.11 CLASSIFICATION OF INORGANIC PHARMACEUTICALS

Inorganic Pharmaceuticals can be classified in two ways

1. Based on their uses,
2. Based on their application in therapy.

Classification based on their uses is described already.

Classification based on their applications (therapeutic classification) is described below.

Acidosis: Acidosis is a pathologic condition resulting from accumulation of acid and hydrogen ions. Inorganic drugs used in this condition are all electrolyte replenishers like sodium chloride, potassium chloride and others.

Acne: Acne is a very common chronic inflammatory dermatosis in adolescent in both sexes. The lesions are seen on face, upper chest and upper back. Inorganic drugs used in this condition are sulphur and its compounds

Alkalosis: Alkalosis is a pathologic condition resulting from accumulation of base and characterized by decrease in hydrogen ion concentration. Inorganic drugs used in this condition are all acidic electrolyte replenishers like sodium chloride, potassium chloride.

Allergic diseases: Allergic disease is a state of hypersensitivity induced by exposure to a particular antigen (allergen) resulting from immunologic reaction. An inorganic drug used in this condition is magnesium thiosulphate.

Anaemia: Anaemia is defined as decreased hemoglobin concentration in blood below the lower limit of the normal range of individual. Inorganic drugs used in this condition are, all iron compounds (Haematinics: Ferrous Sulphate, Ferrous gluconate, Ferric ammonium citrate etc.).

Anoxia: It is a condition characterized by an absence of oxygen supply to an organ or a tissue. Oxygen is used in this condition.

Arthritis: It is a chronic systemic disease manifested as inflammation of peripheral joints and hematological, pulmonary, cardiovascular and neurological abnormalities. Inorganic drug used in this condition is sodium aurothiomalate.

Asphyxia: A condition in which extreme decrease in the concentration of oxygen in the body accompanied with increase in the concentration of carbon dioxide level leads to unconscious or death. Oxygen is used in this condition.

Asthma: Asthma is characterized by hyper responsiveness of bronchial smooth muscle to a variety of stimuli, resulting in narrowing of air tubes accompanied by increased secretions; symptoms include wheezing, cough, and dyspnoea. Organic drugs like salbutamol is used in this condition.

Athlete's foot (Tinea pedis): It is a superficial fungal infection of stratum corneum of skin, located in the web spaces between toes. Inorganic drugs used in this condition are sodium pyrophosphate.

Boils: Bacterial infection of hair follicles and surroundings. An inorganic drug used in this condition is magnesium sulphate.

Burns: Injuries to the tissues caused by frictions, heat, radiation, electricity or chemicals. Inorganic drugs used in this condition are silver nitrate, oxygen, zinc peroxide.

Carbuncles: Carbuncle is a bacterial infection spread under the skin and subcutaneous tissue with oozing of pus. Inorganic drug used in this condition is magnesium sulphate.

Cholecystitis: It is an inflammation of gall bladder, which begins with obstruction, followed by infection of gall bladder. It is of acute and chronic.

Cleaning aids (surgical scrub)*:* An Inorganic drug used in the cleaning of wounds and ulcers or affected area. Example chlorinated soda.

Conjunctivitis: It is characterized by inflammation of conjunctiva (Conjunctiva is a delicate membrane that lines the eyelids and covers the exposed surface of sclera). Inorganic drug used in this condition is silver protein.

Corns (Korn): Corn is a horny thickening of stratum corneum of skin of toes, caused by friction and pressure from poorly fitting shoes. Inorganic drugs used in this condition are silver nitrate, copper oleate.

Dandruff: Dandruff is a dry scaly material desquamated from scalp. Inorganic drugs used in this condition are selenium sulphide, antimony sulphide, cadmium sulphide.

Dental Caries: Dental caries is a disease of teeth caused by acids produced by action of microorganisms on carbohydrates. It is characterized by decalcification of tooth accompanied by foul mouth odour. Inorganic drugs used in this condition are sodium fluoride, strontium and other fluorides.

Dermatitis: Dermatitis is an inflammatory response to a variety of agents acting on skin from outside or within the body such as chemicals, drugs, hypersensitivity to various agents and haptens etc. Inorganic drug used in this condition is cadmium sulphide.

Diarrhoea: Increased frequency or decreased consistency of bowel movement. Inorganic drugs used in this condition are oral rehydration salts, bismuth subcarbonate, calcium carbonate, electrolyte replenishers.

Dysentery: It means diarrhoea with abdominal cramps, tenesmus and passage of mucous in the stools. It is of bacillary and amoebic types. Inorganic drugs used in this condition are all bismuth compounds (Bismuth subcarbonate and Bismuth subgallate)

Eclampsia: It is a serious condition related to high blood pressure caused by pregnancy leads to convulsions, coma, before or during or shortly after child birth. An inorganic drug used in this condition is magnesium sulphate.

Eczema: It is an inflammatory response to a variety of agents acting on skin from outside or within the body such as chemicals and drugs, hypersensitivity to various antigens and haptens. Inorganic drugs used in this condition are iodine (All solutions), fuller's earth and calamine.

Eye infections: Infection of sebaceous gland of the eye lid hordeolum. Inorganic drugs used in this condition are boric acid, silver nitrate, borax, silver protein, yellow mercuric oxide, zinc sulphate.

Flatulence: It is the process of release excess amount of gases like hydrogen, methane, carbon dioxide from the intestine to the anus during final stage of digestion. An inorganic drug used in this condition is activated charcoal, magnesium silicate etc.

Gangrene (Tissue necrosis): It is a form of necrosis of tissue super added putrefaction, caused due to ischemia. An inorganic drug used in this condition is zinc peroxide.

Gingivitis: Inflammation of gums (Gums are red and puffy). An inorganic drug used in this condition is zinc iodide

Hemodialysis: Removal of certain elements from the blood by diffusion phenomena and to retain the normal constituents in it. Inorganic drugs used in this condition are all electrolyte replenishers.

Hyperacidity: Excessive acid secretion in stomach. Inorganic drugs used in this condition are antacids (aluminium hydroxide and magnesium hydroxide).

Hypercalcemia: It is the excess of calcium in blood with the symptoms like muscle weakness, fatigue, depression, nausea, anorexia and constipation. Inorganic drugs used in this condition are sodium phosphate, sodium sulphate.

Hyperhidrosis: It is a disorder caused by excessive sweating. An inorganic drug used in this condition is sodium pyrophosphate.

Hyperthyroidism: Also called as Thyrotoxicosis. It is a hypermetabolic, clinical and biochemical state caused by excess production of thyroid gland in cases of graves' disease, a toxic adenoma and toxic multinodular goiter. An inorganic drug used in this condition is potassium perchlorate.

Hypomagnesemia: It is abnormally low magnesium content of blood plasma as a result of malabsorption, dehydration, alcoholism or renal disease with the symptoms like neuromuscular activity. An inorganic drug used in this condition is magnesium chloride.

Intracranial pressure: Pressure inside the skull and thus in the brain and CSF. An inorganic drug used in this condition is hypertonic saline.

Iron deficiency: It occurs due to increased metabolism of iron, malabsorption from diet or high excretion of iron from the body resulting in hypochromic anemia. Inorganic drugs used in this condition are all iron compounds (ferric ammonium citrate, ferrous Sulphate and ferrous fumarate)

Leishmaniasis: Several different illness caused by an organism protozoan. An inorganic drug used in this condition is sodium antimony gluconate.

Malignant wounds: These are the result of cancerous cells infiltrating the skin and its supporting blood. Oxygen is used in this condition.

Manic Depression: Cyclic alteration of manic and depressive phases bipolar disorder. An inorganic drug used in this condition is lithium carbonate.

Muscular excitability: The ability of a muscle fiber to respond rapidly to stimulating agent. An inorganic drug used in this condition is calcium gluconate.

Osteoporosis: Reduction in the amount bone mass due to loss of bone proteins and calcium, lead into fractures after trauma. Inorganic drugs used in this condition are all calcium compounds and fluorides.

Peritoneal dialysis: It is a technique performed across the membrane of peritoneal cavity and is used to remove toxic chemicals from the body. Inorganic drugs used in this condition are sodium and potassium acetate, electrolyte replenishers.

Pharyngitis: Inflammation of the mucous of the pharynx. Inorganic drugs used in this condition are iodine and its solutions (Aqueous iodine solution, strong iodine solution, weak iodine solution).

Poisoning: A drug substance, when ingested or inhaled or absorbed or applied or injected into or developed within the body, has chemical action that causes damage to the structure or disturbance of function, producing symptoms, illness or death. Inorganic drugs used in this condition are (antidotes are used in this case)

Cyanide poisoning	-	Sodium thiosulphate.
		Sodium nitrite
Digitalis poisoning	-	Potassium chloride injection
Gaseous poisoning	-	Oxygen
Insecticide poisoning	-	Fuller's earth

Pruritis: An unpleasant cutaneous sensation that desire to stretch the skin to obtain relief. Inorganic drugs used in this condition are calomel, ammoniated mercury.

Psoriasis: It is a chronic inflammatory dermatitis with lesions characterized by brownish red papules and plaques which are covered with fine, silvery, white scales. Inorganic drugs used in this condition are calomel, ammoniated mercury.

Ring worm infection: Common fungal infection of the skin. Inorganic drugs used in this condition are sulphur, iodine solution.

Scabies: A contagious dermatitis of humans and various wild and domestic animals caused by a mild "*sarcoptes scabiei*". An inorganic drug used in this condition is sulphur.

Shock: A life threatening clinical syndrome of cardiovascular collapse characterized by an acute reduction of effective circulating blood volume (hypotension) and an inadequate perfusion of cells and tissues (hypoperfusion). Organic drug like adrenaline is used in this condition.

Skin infection: Any infection or allergy due to pathogens. Inorganic drug used in this condition is zinc undecylenate.

Sore throat: Bacterial or viral infection in the throat, such as common cold. Inorganic drugs used in this condition are iodine.

Sun burns: Allergic reactions affecting living tissue skin (rashes). Inorganic drugs used in this condition are calamine, titanium dioxide.

Thyroid deficiency/Hypothyroidism: It is a hypometbolic clinical state resulting from inadequate production of thyroid hormones for prolonged periods or rarely from resistance from peripheral tissues to the effect of thyroid hormones. Inorganic drugs used in this condition are hydroiodic acid, potassium iodide.

Thyrotoxicosis: It is a hyper metabolic and biochemical state caused by excess production of thyroid hormones. Inorganic drugs used in this condition are iodine solutions.

Tonsillitis: It is caused by bacteria called *staphylococci* or *streptococci,* may be acute or chronic, characterized by redness, enlargement and inflammation of the tonsil glands.

Inflammation of throat is due to bacterial or viral infection. Inorganic drug used in this condition is iodine.

Tumors: A new growth of tissue in which multiplication of the cells is uncontrolled and progressive and also called as "neoplasm". An inorganic drugs used in this condition is cisplatin.

Ulcers: It is an exudation of surface of an organ or tissue, which is produced by sloughing of inflammatory necrotic tissue.

Duodenal ulcer: Ulcers formed due to excessive secretion of hydrochloric acid with symptoms like steady or burning pain in upper abdomen that can be relieved by ingestion of food, antacid or cold milk. This may be an infection caused by bacteria (*H. Pylori*). An inorganic drugs used in this condition is aluminium hydroxide gel.

Gastric or peptic ulcer: These are the areas of degeneration and necrosis of gastrointestinal mucosa exposed to acid-peptic secretions; symptoms are vomiting, sepsis and burning pain in upper abdomen. Inorganic drugs used in this condition are bismuth compounds, magnesium trisilicate.

Skin or topical ulcer: An inorganic drug used in this condition is zinc oxide.

Uremia: Excess of urea, creatinine and other nitrogenous end products of proteins and amino acid metabolism in the blood. Drugs used in this condition are haemodialysis fluid (or) peritonical dialysis fluid.

Urethritis: Inflammation of urethra (painful or difficult for urination). An inorganic drug used in this condition is zinc permanganate.

Urticaria: Urticaria or hives is the presence of transient, recurrent, pruritic wheals (raised erythematous areas of edema) on skin and oral, laryngeal and gastrointestinal mucosa. An inorganic drug used in this condition is calamine.

Varicose veins (Varicocele): It is the dilation, elongation, tortuosity of veins of pampiniferous plexus in the spermatic cord. Inorganic drug used in this condition is lead-oleate.

Warts: Common viral lesions of the skin caused by *Human papillomavirus* (HPV) a small, rough growth typically on a human's hand or feet. An inorganic drug used in this condition is silver nitrate.

Wounds: Injury or damage to the skin. Inorganic drugs used in this condition are hydrogen peroxide, zinc peroxide.

1.12 PHARMACEUTICAL AIDS

The following agents which are not used in therapy but they play important role in the manufacture or storage of pharmaceuticals are called as pharmaceutical aids.

Absorbents: Substances used to absorb gases. Inorganic substances used for this purpose are activated charcoal, soda lime.

Adsorbents: Substances used to adsorb gases, coloring matters etc. Inorganic substances used for this purpose are aluminium phosphate, fuller's earth.

Acidifiers: Substances used to make acidic condition. Inorganic substance used for this purpose is dilute hydrochloric acid.

Alkalisers: Substances used to make alkaline condition. Inorganic substances used for this purpose are sodium carbonate, ammonia solutions.

Antioxidants: Substances used to prevent the oxidation of pharmaceuticals. Inorganic substances used for this purpose are sodium bisulphite, hypophosphorous acid.

Buffers: Substances used to maintain pH. Inorganic substances used for this purpose are phosphate buffer, borate buffer.

Chelating agent: Substances used to make complexation. Inorganic substance used for this purpose is EDTA.

Decolorizing agent: Substances used to remove colors. Inorganic substances used for this purpose are fuller's earth, activated charcoal.

Desiccants: Substances used to absorbs moisture and provide dry micro atmosphere in containers of pharmaceuticals. Inorganic substances used for this purpose are calcium chloride, silica gel.

Excipients: Substances used to increase the bulk of a solid mass, which carries a drug. Inorganic substances used for this purpose are di and tri basic calcium phosphate.

Filter aids: Substances used for clarification purpose. Inorganic substances used for this purpose are kieselguhr, fuller's earth.

Opacity agent: Substances used for making high reflectance of capsules. Inorganic substance used for this purpose is titanium dioxide.

Solvents or vehicles: Substances used as a vehicle for liquid dosage forms and injectables. Inorganic substances used for this purpose are purified water and water for injection.

Tonicity adjusting agents: Substances used to adjust the tonicity of injectables. Inorganic substance used for this purpose is sodium chloride.

Thickening agents or suspending agents: Substances used to stabilizes suspensions. Inorganic substances used for this purpose are silica gel, colloidal silica.

Water softeners: Substances used to soften water. Inorganic substance used for this purpose is sodium carbonate.

PROBABLE QUESTIONS

1. Define pharmaceutical chemistry?
2. Explain the various aspects of pharmaceutical chemistry.
3. Explain the importance of inorganic chemistry in pharmacy.
4. Define pharmaceuticals and explain about their uses.

5. Explain about various pharmacopoeias.
6. Write the salient features of recent edition of Indian Pharmacopoeia.
7. Define the following terms:
   (i) Misbranded drug (ii) Adulterated drug
   (iii) Standard of quality (iv) Spurious drug.
8. Define the term monograph and explain with any one official drug.
9. Briefly explain about the storage conditions of drugs.
10. Describe the development of Pharmacopoeias.
11. Briefly explain about Drugs and Cosmetics Act 1940.
12. Classify pharmaceutical inorganic compounds based on their applications with examples.
13. Classify pharmaceutical inorganic compounds based on their therapeutic uses with examples.
14. Explain about pharmaceutical index.
15. Briefly explain the history of Indian Pharmacopoeia.