

WHAT IS PHARMACEUTICAL CHEMISTRY?

Pharmaceutical chemistry is a science that makes use of the general laws of chemistry to study drugs, *i.e.*, their preparation, chemical nature, composition, structure, influence on an organism and studies, the physical and chemical properties of drugs, the methods of quality control and the conditions of their usage. In other words, it is the chemistry of drugs. Drugs mainly exert action depending upon the biochemical pathways.

Pharmaceutical chemistry is a specialized science which depends on other chemical disciplines such as inorganic, organic, analytical; physical and colloid chemistry and also on medico-biological disciplines such as pharmacology, physiology, biological chemistry, etc.

Pharmaceutical chemistry occupies the most important place among the related sciences such as drug technology, toxicological chemistry, pharmacognosy, the economy and organization of pharmacy.

IMPORTANT ASPECTS OF PHARMACEUTICAL CHEMISTRY

- (1) It includes the various methods for isolation, purification and characterization of medically active agents and materials from natural sources (mineral, vegetable, microbiological or animal) which find various uses in the treatment of diseases and in compounding prescriptions.
- (2) It includes the various syntheses of medicinal agents that could not be obtained from natural sources or the synthetic duplication due to reasons of economy, purity or adequate supply of substances obtained from natural sources.
- (3) It includes the various synthetic methods by which natural substances are converted into products with more favorable therapeutic or pharmaceutical properties.
- (4) It includes the determination of the derivatives or forms of a medicinal agent which shows optimum medicinal activity and at the same time results in the stable formulation and elegant dispensing.

(5) It includes the determination of chemical and biological incompatibilities among the various ingredients of a prescription.

(6) It helps in the establishment of safe and practical standards with respect to both dosage and quality in order to maintain uniform and therapeutical standards for all forms of medication.

(7) It helps in the improvement and promotion of the use of chemical agents for prevention of illness, alleviation of pain, cure of diseases and search for new therapeutical agents especially when there exists no satisfactory remedy.

INORGANIC PHARMACEUTICAL CHEMISTRY

Inorganic pharmaceutical chemistry is a science that makes use of the laws of chemistry to study inorganic substances as drugs, *i.e.*, their preparation, chemical nature, composition, structure, influence on an organism, etc.

The main source of inorganic drugs happens to be the natural source such as minerals. There are many reports on the use of minerals in medicine. Some interesting examples of these include mineral waters, salts, partially purified inorganic chemicals, calcined inorganics and chemically transformed inorganics. At a later stage, many of these were found to be poisonous substances but are being still used cautiously by some doctors in sufficiently small quantities. Thus, the ancient physicians were quite familiar with the use of antimony, arsenic and mercury.

In ancient Indian medicine system mercury was supposed to occupy a dominant position for sometime and whole treatises were written giving its therapeutic and other properties. Many noble metals like gold and copper were also used in medicine. The use of minerals as medicinal agents was not restricted to any single country but all ancient cultures were quite familiar with their medicinal uses.

Although many inorganic chemicals are rarely employed today, yet few inorganic chemicals are being still used in modern medicine. Synthetic organic chemicals are able to replace the more toxic inorganic pharmaceuticals.

Most of these belong to one or other of the following categories:

- (1) Those that find use for replacing or *replenishing* the normal content of the body. These are required for normal physiological processes and are required in diet. But disease conditions are able to deplete their amounts in the body. Hence they have to be replenished or replaced. Calcium, sodium, potassium, magnesium, iron, chloride, phosphate, bicarbonate, oxygen, etc.
- (2) Those that are used for changing *reactions* of body fluids, *i.e.*, acidify or alkalise. Mineral acids, antacids, alkalis etc.
- (3) Those that find use as *medicinal and therapeutic* agents in disease conditions. These may be able to change physical (*e.g.*, topical agents, protectants), physiological and/or biochemical processes (*e.g.*, astringents, respiratory stimulants, hypnotics, expectorants). Some may be used as correctives or in infections (*e.g.*, dental products, antidotes, antimicrobials etc.).
- (4) Those that find use as *pharmaceutical aids*. Bentonite, talc, antioxidants, pigments etc. are examples of this category.

(5) Those that find use in *analytical and quality control* processes. Most of inorganic chemicals included in the Pharmacopoeia belong to this category. Titrants such as permanganate, dichromate, iodine, bromate etc., buffers like phosphoric acid salts, boric acid salts, ammonium salts etc. are useful examples of this group.

(6) Those that are used as *reagents* for carrying out other reactions. Some inorganic substances find use as catalysts (platinum, nickel, charcoal etc.), some as oxidizing or reducing agents (chromic the acid, lithium aluminium hydride etc.), some as adsorbents in chromatography (alumina, silica gel etc.) and in other several ways.

The term '*pharmaceuticals*', is used for any chemical that finds use in the preparation of medicament for internal administration of the human body. 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. All pharmaceuticals must be carefully controlled for their quality. For this purpose, specifications of quality have been listed for each pharmaceutical. A collection of such descriptions has been reported in a *Pharmacopoeia*.

PHARMACOPOEIA

Pharmacopoeia:

(Gr. Pharmakon — a drug, and poiein — to make) is a book of directions and requirement for the preparation of medicine; it is generally published by an authority. Thus pharmacopoeia is a legislation of a country which sets standards and obligatory quality indices for drugs, raw materials used to prepare them and various pharmaceutical preparations. These regulations are presented separately in general and specific articles.

Monograph:

is a complete description of a specific pharmaceutical, which includes nomenclature, classification, physical characteristics, dosage, purity, limits for impurities, identification, assay and conditions for storage. The appendices may also include standards for apparatus, other chemicals, techniques, processes etc. related to the said pharmaceutical.

HISTORY OF PHARMACOPOEIA

Every country has legislation on pharmaceutical preparations that sets standards and obligatory quality indices for medicaments, raw materials, and preparations employed in the manufacture of drugs. These regulations are presented in separate articles — general and specific — relating to individual drugs, and are published in the form of a book called a Pharmacopoeia.

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

INDIAN PHARMACOPOEIA

In India, in the pre-independence days, B.P. was employed as the official book of standards. The first edition of the Indian Pharmacopoeia (I.P.) was published in 1955. It was having a large number of crude drugs and their preparations. The third edition of the I.P. got published in 1985, Addendum I to third edition has been published in 1989.

The Addendum I to the Pharmacopoeia of India 1985 amends the Indian Pharmacopoeia 1985 and constitutes a part of Indian Pharmacopoeia, third edition.

The General Notices and Appendices included in the Indian Pharmacopoeia 1985 and as amended in this Addendum apply both to the matter contained in the Indian Pharmacopoeia 1985 and to the matter contained in this Addendum.

Indian Pharmacopoeia, 1996, 2 volumes.

The edition of the Indian Pharmacopoeia was published in 1996. Under the Drugs and Cosmetics Act, 1940, the Indian Pharmacopoeia is the legally recognized book of standards for the quality of drug substances and their preparations included therein.

Contents: Volume I: Notices, Preface, Acknowledgements, Introduction, General notices, Monographs (A-O).

Volume II: Monographs (P-Z), Infra-red reference spectra, Appendices, Index.

The Indian Pharmacopoeia is the legally recognized book of standards for the quality of drug substances and preparations included therein. This new edition, which supersedes the 1985 edition and its addenda, includes many new drugs and their dosage forms and omits others as also amends the specifications and updates standards of others keeping in view the advances in pharmaceutical sciences.

Pharmacopoeial monographs have been organized as described below:

- (1) **Title:** The title is stated in English and refers to the official name of the compound. Sometimes sub-titles are given. These are synonyms and could be used in place of the main title e.g., calcium carbonate can also be called *precipitated chalk*, iron and ammonium citrate can also be called *ferric ammonium citrate*; milk of magnesia can also be called *magnesium hydroxide mixture*.
- (2) **Formula weight and molecular weight:** Following the title has been the chemical formula of the pure compound, with its molecular weight, e.g., $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$ Mol. wt. 202.30. These two items are not given, provided the correct chemistry is not known or the compound is of indefinite composition. For example, for iron ammonium citrate, formula and mol.wt. are not given.
- (3) **Category:** This describes the therapeutic or pharmacologic or pharmaceutical application of the compound. Usually this is the main application, although the compound may be having other applications. Some main categories for inorganic pharmaceuticals mentioned in the Pharmacopoeia include haematinic; antacid; laxative; pharmaceutical aid; astringent, etc.

(4) Dose: are the quantities for the guidance of the prescriber or the physician to achieve the desired therapeutic effects in adults. It can be altered as and when required, e.g., CaCO₃ dose 1 to 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.

(5) Description: This gives a physical description of the substance like crystalline or amorphous nature, colour, odour, taste, etc. These properties help in the preliminary evaluation of the integrity of an article and not themselves the standards or tests of purity, e.g., CaCO₃, fine, white macrocrystalline powder, odourless, tasteless.

(6) Solubility: Solubility is described in popular terms, which are defined in the Pharmacopoeia under general notices. This is usually given in water, sometimes in hot or boiling water, in alcohol, in glycerol, in solvent ether and sometimes in other organic solvents, acids or alkalis.

Solubility for an article given in the monograph may be considered primarily as information, but if it is given under the quantitative solubility test, then it is a standard. If the exact solubility of the article is not known, a descriptive term is used to indicate its solubility. The following table reveals the meaning of such term.

Descriptive term	Approximate volume of solvent in milliliters per gm of solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Insoluble or practically insoluble	More than 10,000

(7) Standard: It is an important part of monograph, which specifies the quantitative purity of the title compound, where the compound is of definite composition, *e.g.*, (1) Potassium bromide is having not less than 98.0 per cent of KBr, calculated with reference to the dried substance, *e.g.*, (2) Hydrogen peroxide solution is an aqueous solution of hydrogen peroxide. It contains not less than 5.0 per cent *w/v* and not more than 7.0 per cent *w/v* of H₂O₂ corresponding to about 20 times its volume of available oxygen. It is having not more than 0.025 per cent *w/v* of a suitable stabilizing agent.

If the composition has been not definite, the standards are vaguely defined, *e.g.*, (1) Bentonite is a natural, colloidal, hydrated aluminium silicate, *e.g.*, (2) Dried aluminium hydroxide gel consists largely of hydrated aluminium oxide and varying small quantities of basic aluminium carbonate and bicarbonate. It contains not less than 47.0 per cent of Al₂O₃

Standards stated in the monograph of the Pharmacopoeia apply only to articles which are intended for medicinal use and not to articles sold for other purposes, *e.g.*, starch.

(8) Identification: This usually involves specific chemical test or tests for identifying the substance. Colour reactions, precipitating tests, and gas evolving reactions are commonly used for inorganic pharmaceuticals.

Identification tests are not absolute proof of identity. It provides a means of verification only, *e.g.*, phenol.

Phenol + FeCl₃ solution gives violet colour.

(9) pH: The pH values given in the monograph are for the guidance of manufacturing pharmacist to develop various dosage forms and to avoid physiological complications, *e.g.*, calcium amino salicylate. 2 percent w/v solution gives pH 6.0-8.0.

(10) Limits for impurities: For different chemicals different limit tests have been included, as also different amounts of such impurities permissible for that chemical. The various tests that are included could be any of these: *acidity or alkalinity, pH, specific impurities* (like phosphates, sulphides, magnesium, barium etc.), arsenic, heavy metals, chloride, sulphate etc. These will be dealt with in another chapter on, Quality control and Tests of purity.

Limit tests for impurities are generally represented in parts per million by weight (ppm) or as a percentage. These are approximate values.

(11) Assay: It is a step-by-step description of a chemical analytical method for the active substance. If the assay method described in the Pharmacopoeia is applied to the chemical, the standards prescribed in the monograph earlier should be realised. For most inorganic pharmaceuticals, *titrimetric* or *gravimetric* methods are used.

(12) Storage: This is the last item under the monograph. These directions are helpful in preserving the activity of the chemical. These are usually brief and general, intended more as guidance than as a condition. The conditions are defined by the following terms.

Cold- Any temp. not exceeding 80 and usually between 20 and 80

Cool- Any temp. between 80 and 250

Room temperature- The temperature prevailing in a working area.

Warm- Any temp. between 300 to 400

Excessive heat- Any temp. above 400

The container is the device that holds the article. The immediate container is that which is in direct contact with the article at all times. The closure is a part of the container.

- (a) *well-dosed* containers; this implies the substance is stable and gets protected from dust, dirt, insects etc. getting into the container,
- (b) *tightly-closed* containers; the substance in such cases gets affected by atmospheric oxygen or moisture or carbon dioxide (e.g., reducing agents, hygroscopic substances, strong bases etc.); it may also include such compounds as are volatile or contain dissolved gases etc. it may also include such compounds as are volatile or contain dissolved gases etc.
- (c) *light-resistant containers*; substances which are affected by light are stored in amber or dark-coloured containers
- (d) *cool place*; this is applicable to substances which are affected by warm climate (e.g., thermolabile substances); for some solutions, freezing is to be avoided

(e) *single-dose* containers; this is generally prescribed for some injectables, which once opened, should not be used again.

Precautions to be taken where there is a possibility of effect of atmosphere, moisture, heat and light are indicated where appropriate in the monograph. In certain specified instances when additional protection against light is necessary, the bottle must further be covered with a black paper.

e.g., Ferrous fumarate — Store in a light resistant container.

e.g., Insulin injection — Store in multiple dose containers at a temperature between 2 to 8 C. It should not be allowed to freeze.

The general notice and monograph are followed by comprehensive section of appendices.

The **appendix 1** describes the apparatus that are required for various Pharamcopeial test and assays in particular standard and tolerance e.g. Bessemer's cylinders, sieves, thermometer, Ultra-violet lamps, volumetric glassware, weights and balances are laid down in this appendix.

The **appendix 2** describes the biological tests and determinations. It involves design and analysis of results of biological tests and assays. It involves tests for abnormal toxicity, bacterial endotoxins, depressor substances, haemolysins, pyrogens, and urinary excretion of dextrans. It also describes the determination of ABO group, Rh group, the limes of flocculations (Lf) of Diphtheria toxin, Diphtheria toxoid, diphtheria vaccine and tetanus vaccine and determination of haemoglobin.

The **appendix 3** lays down the details of various chemical test and assays. It involves identification tests, limit tests, analysis of fixed oils, analysis of vegetable drugs, general titration and assay procedures etc.

The **appendix 4** describes in detail the chromatographic and electrophoresis techniques.

The **appendix 5** describes the spectrophotometric methods.

The **appendix 6** involves the clarity and color of the solutions

Disintegration and dissolution are the part of the **appendix 7**.

Appendix 8 describes the determination of boiling or distilling range, congealing range, ethanol, freezing point, jelly strength, loss on drying, loss on ignition, melting range, optical rotation, osmolarity, pH value, powder fineness, refractive index, viscosity, wt/ml.

Microbiological assays and tests are described in the **appendix 9**.

Appendix 10 describes the limit test for particulate matter.

Other tests for container and closures are given in **appendix 11**.

Appendix 12 describes the general information regarding the cleaning of glassware, dimensions of capsule shells, sterilization, biological indicators, water for pharmaceutical use.

Appendix 13 gives the preparation of reagent and solutions like buffer solutions, general reagent, indicators and indicators test papers, standard solutions and volumetric reagent solutions.

Appendix 14 describes the reference substances.

Tables of names, symbols, atomic weights of elements, weights and measures and abbreviations are included in **appendix 15**.

Indian Pharmacopoeia, 2007, 3 volumes.

The latest edition of the Indian Pharmacopoeia was published in 2007. It was published by the Indian pharmacopoeia commission, Ghaziabad on behalf of Govt. of India, Ministry of health and family welfare.

Contents: Volume I:

1) Notices: legal notices

2) Preface: history

3) IPC: governing body

4) Acknowledgements:

5) Introduction & General chapters:

A) General notices: monograph

B) Test methods:

a) Apparatus: cylinder, pipette etc.

b) Biological methods: endotoxins.

c) Chemical methods: limit tests.

d) Physical & physico-chemical methods: viscosity, refractive index etc.

e) Pharmaceutical methods: dissolution, friability etc.

f) Test on herbal products: ethanol, water extract etc.

g) Tests on vaccines:

h) Tests on blood & blood related products: blood gp, Rh gp etc.

C) Reference data: IR, TLC, HPLC.

D) Reagents & solutions: preparation of buffers, indicators etc.

E) General tests: cleaning of glassware, sterilization, impurity, biological indicator etc.

F) Containers: parenteral, blood products etc.

G) tables: symbols, weights and measures abbreviations.

Volume II:

1) **General notices:** monograph

2) **General monographs on dosage forms:** capsules, creams, drops, gels

Monographs on drug substances, dosage forms and pharmaceutical aids (A-M):

Volume III:

1) **General notices:** monograph

2) **Monographs on drug substances, dosage forms and**

pharmaceutical aids (N-Z):

- 3) **Monograph on vaccines & immunosera for human use:** orange colour
- 4) **Monograph on herbs and herbal products:** green colour
- 5) **Monograph on blood and blood-related products:** red colour
- 6) **Monograph on biotechnology product:** blue colour
- 7) **Monograph on veterinary product:** yellow colour
- 8) **Index.**

EXTRA PHARMACOPOEIA (MARTINDALE)

Although no explanations have been included in the Pharmacopoeia, it is having wealth of information. Anyone who consults the Pharmacopoeia often, should familiarise himself with the general notices and the various appendices. Most comprehensive information on every type of pharmaceutical or drug can be obtained from the *Extra pharmacopoeia* (Martindale, 29th Edn.). This excellent work has been especially rich in therapeutic and clinical information on the drugs. There are several other useful literature references for inorganic pharmaceuticals. Some of these have been included at the end of this book.

The Extra Pharmacopoeia was first edited, compiled and published in 1883 by William Martindale (1840-1902), a practising pharmacist. Its main aim was to provide physicians and pharmacists with practical and up-to-date information concerning drugs and geleniums to supplement that was included in the British Pharmacopoeia. Four editions of "Martindale" were published in the span of three years.

This new edition of Martindale has been markedly changed in order to meet the requirement of today's reader. These changes include a massive increase in information on proprietary medicines a significant shift to a more clinical emphasis, an increase in the number of referenced reviews and shortening of the usual period between editions to meet the need for up-to-date information.

BRITISH PHARMACOPOEIA

The reason for the appearance of a British Pharmacopoeia is ascribed to the Medical Act 1858, Section 54 which 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 if which they are to be prepared and mixed. The First British Pharmacopoeia, 1864 was an outcome of the combination of three old and reputed Pharmacopoeias namely Pharmacopoeia Londinensi (1618), Edinburgh Pharmacopoeia (1699) and Dublin Pharmacopoeia (1807). New editions and addenda followed in quick succession, the 2nd in 1867, an addendum in 1874, a 3rd edition in 1885, a further addendum in 1890 and a 4th edition in 1898. The British Pharmacopoeia 1864 included separate parts: Materia Medica and Preparation and Compounds. In the 1867 edition the contents had been arranged alphabetically as per practice of several other Pharmacopoeias.

A gap in revision delayed the next edition until 1914.

In Britain after publication of the British Pharmacopoeia 1914 it was realised that the technical complexity of the drug specifications was increasing and a different kind of set up was needed to prepare the Pharmacopoeias. As such in 1928, the British Pharmacopoeia from 1932 edition and onwards became responsibility of the Commission. It was then recommended that the B must be revised every ten years.

In 1932 revision, a range of diagnostic materials was included. An important addition was made to include standards and tests for antitoxins and insulin. The interim between 1932 and next 7th edition of 1948, was covered by seven addenda. In 7th edition of 1948, generic names were provided for substances newly introduced into medicine. Methods of analysis, disintegrate tests for tablets and sterilization methods were expanded. Many new monographs related to penicillins and sex hormones were included. At this time, it was decided that the normal interval between new editions should be five instead of 10 years, due the rapid pharmaceutical and pharmacological progress that had been made.

The next edition appeared in 1953. 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. The implant methods for sex hormones and their standards were described. The 9th edition (1958) was having 160 new monographs. Tranquilising drugs and spectrophotometric analysis were added. The tenth edition appeared in 1963.

In Medicines Order 1970, the duties of the British Pharmacopoeia Commission were defined. The thirteenth edition of British Pharmacopoeia (1980) was the first edition of Pharmacopoeia that was prepared strictly under the provisions of Medicines Act. Currently the British Pharmacopoeia starts publishing in two volumes due to an expansion of drug information.

The British Pharmacopoeia (1993) has provided authoritative standard for the quality of many substances, preparations and articles used in medicine and pharmacy for some 130 years. This new edition consolidates and extends the 1988 edition with its 1989, 1990, 1991 and 1992 addenda, and for the convenience for the user also incorporates the monographs of the European Pharmacopoeia.

Volume I deals with medicinal and pharmaceutical substances. It also includes the infrared reference spectra needed for the identification of many of the materials.

Volume II contains sections on formulated preparations, blood products, immunological products, radio-pharmaceutical preparations and surgical materials.

The first addendum to the British Pharmacopoeia 1993 includes monographs for a substantial number of substances and preparations for the first time. Also included are the following:

Several new European Pharmacopoeia monographs, revisions to monographs, edited texts relevant to the human medicine that have been published fascicule 17 of the second edition of the European Pharmacopoeia, replaces the limit test for particulars matter. An indication of the approximate levels of impurities controlled by chromatographic tests wherever appropriate. A new supplementary section containing auxiliary material of relevance to users of the Pharmacopoeia.

EUROPEAN PHARMACOPOEIA

European Pharmacopoeia is regarded to be an official book of standards adopted by Germany, France, Italy, Netherlands, Switzerland and Belgium. Council of Europe issued an order in July, 1964 to frame out European Pharmacopoeial Commission for compiling European Pharmacopoeia. The first edition of European Pharmacopoeia appeared in 1969 and its official standards become applicable within the respective member countries. The second edition is being published in a series of volumes.

PHARMACOPOEIA INTERNATIONAL (INTERNATIONAL PHARMACOPOEIA)

There appears to be no uniformity in terminology and strengths of pharmaceutical preparations used in various countries. As early as 1874 view had been expressed that some world uniformity in the standards for potent drugs must prevail. These views got further support at an international conference in 1902 and an agreement was framed. No progress was achieved until a second international conference got held in 1925 where an International Agreement on the Unification of Formulae for seventy-seven potent drugs and preparations got reached. The Health Organisation of the League of Nations established in 1936, a Technical Commission of pharmacopoeia! experts. After the World War II over in 1946, the work was undertaken by the World Health Organisation.

Volume I of the long-awaited Pharmacopoeia was finally published in 1951, in Latin, with translations into English and French. It was having monographs for over two hundred drugs and chemicals; with appendices on reagents, tests and biological assays. The Volume II, published in 1955 included formulae for preparations having various drugs and substances already present in Volume I. The supplement of 1959 incorporated some newer drugs and substances with the method of preparations and the appropriate tests. The second edition got published in 1967, followed by a supplement in 1971, The third edition got published in the form of several volumes, Volume I appeared in 1979.

UNITED STATES PHARMACOPOEIA (USP)

In 1817, Dr. Lyman Spaulding of New York proposed a plan to the Medical Society of the Country at New York for publishing a National Pharmacopoeia. The first edition of United States Pharmacopoeia was compiled, edited and published on 15th December, 1820 which was having 217 drugs in about 272 pages. Subsequent editions of USP appeared after the gap of ten years. In 1905, the ninth edition of USP was published. However, it was given the title of USP VIII, as to show that it was eighth revision. USP considers 25°C as the standard temperature, for specific gravity and solubility statements. The 1940 Convention directed that the Pharmacopoeia must be revised every 5 years.

The XXII edition of USP combined with XVII edition of NF was published in January, 1990.

PHARMACEUTICAL INDEX

Us 12th edition has been completely revised and incorporates updated material as well as entirely fresh subject areas. The new Codex provides a reference source on all aspects of pharmaceutical science and technology that are relevant to the development and provision of medicine. Part I covers the multidisciplinary nature of pharmaceuticals and demonstrate how quality is built into medicines from conception and development to production and use. The chapters broadly encompass the pharmaceuticals content of the syllabus for pharmacy undergraduates and also provide direction and support for the continuing education of graduates, with special emphasis on the requirements of those associated with product development and innovation. Part U includes an extensive collection of pharmaceutical data, arranged in monograph form. The Codex is edited by staff of the Royal Pharmaceutical Society, using known experts to write individual chapters.