| | |
|---|---|
| NAME OF TEACHER | Km Uma |
| MOB. NO. | 6396132349 |
| EMAIL ID | umamahur@gmail.com |
| DESIGNATION | Assistant Professor |
| UNIVERSITY NAME | Monad University |
| COLLEGE NAME | School of Pharmacy Monad University Hapur. |
| STREAM NAME | Pharmacy |
| FACULTY NAME | Km Uma |
| DEPARTMENT NAME | School of Pharmacy |
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| SUB TOPIC NAME | Errors and Pharmacopoeia |
| CONTENT TYPE | Notes |
| SEARCH KEY WORD | Errors And Pharmacopoeia, |

**(CONTENTCREATER/TEACHER)**

**Course Content:**

| UNIT | CONTENTS |
|---|---|
| **UNIT-1** | Error:- Introduction, sources,types,methods of minimizing error,accuracy,precision And Pharmacopoeia:-I.P,B.P |

# UNIT 1st

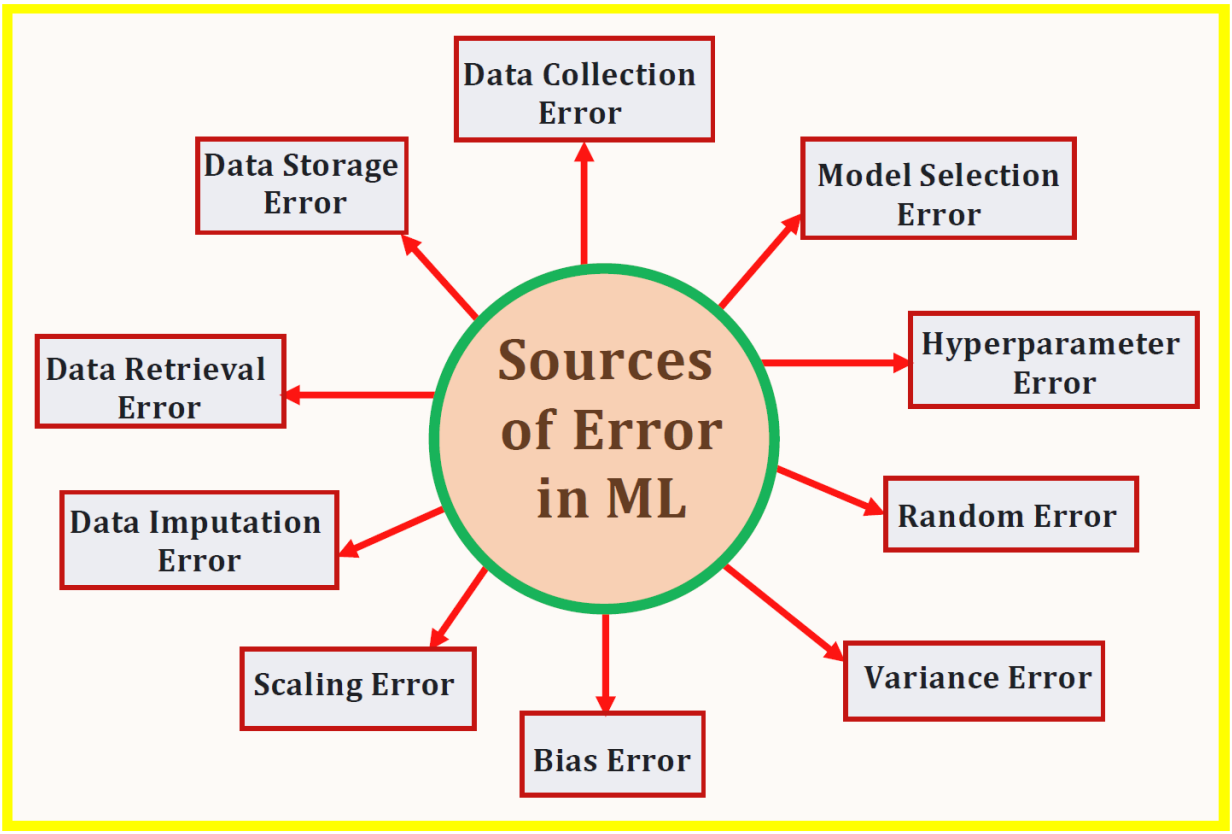
## Errors:-

Error is the difference between the true result (or accepted true result) and the measured result. If the error in an analysis is large, serious consequences may result. As reliability, reproducibility and accuracy are the basis of analytical chemistry. A patient may undergo expensive & even dangerous medical treatment based on an incorrect laboratory result because of an analytical error.

**Error = measured mean value – true value/ true value**

And the difference between the experimental value and true value is termed as absolute error. Absolute error may be negative or positive.

**Source of error:-**



**1.)** Contaminated or decomposed reagents can cause determinate errors. Prepared reagents may also be improperly labeled.

**2.)** Faulty construction of balances,Incorrect instrument alignment, Incorrect wavelength settings, Use of uncalibrated or improperly calibrated weights.

**3.)** These problems can be eliminated by a systematic procedure to check the instrument settings and operation before use. Such procedures are called std. operating (SOPs) in the many labs. There should be a written SOP for each instrument and each analytical method used in the laboratory.

**4.)** Incorrect sampling incomplete reaction for chemical methods, Unexpected interferences from the sample itself or reagents used. Loss of analyte during sample preparation by volatilization or precipitation

**5.)** Failure of reactions to proceed to completion.Occurrence of induced and side reactions.

**6.)** Decomposition co-precipitation and post–precipitation.Precipitation of constituents other than the desired ones.

**7.)** Contamination of sample by external sources can be a serious source of error and may be extremely variable. Aluminum levels in the dust in the normal laboratory are so high that dust prohibits the determination of low ppb levels of aluminum in samples.

**Types of errors:-**

There are two principle types of error in analysis:-

**1.)** Determinate or systematic error

**2.)** Indeterminate or random error

## 1.) Determinate error

They are caused by faults in the analytical procedure or the instruments used in the analysis. Determinate errors are systemic errors i.e. they are not random. As the name indicates that the cause of this type of error may be found out & then either avoided or corrected.

A particular determinate error may cause the analytical results produced by the method to be always too high. Another determinate error may render all results too low. Sometimes the error remains constant ;All results are too high or too low by the same amount.

Determinate error can be additive or they can be multiplicative. It depends on the error & how it enters into the calculation of the final result. This determinate error could be the result of an incorrectly calibrated balance.

If the balance is set so that the zero point is actually 0.5 mg too high, all masses determined with this balance will be 0.5mg too high. If this balance was used to weigh any std. sol. Used in the laboratory, the std. concentration will be erroneously high, and all of the results obtained using this std. will be erroneously high

The error is reported as the absolute error, the absolute value is the difference between the true and measured value.

**Measured mean value – True value = Absolute error.**

Determinate errors may arise from some faulty step in the analytical process. The faulty step is repeated every time the determination is performed. Whether a sample is analyzed 5 times or 50 times, the results may agree with each other but differ widely from the true answer.

Determinate error can arise from uncalibrated balances, improperly calibrated volumetric flasks or pipettes, malfunctioning instruments, impure chemicals, incorrect analytical procedures or techniques and analyst error.

**Analyst error :-**

They may be the result of inexperience, insufficient training. An analyst may use the instrument incorrectly, Perhaps by placing the sample in the instrument incorrectly each time. Setting the instrument to the wrong conditions for analysis. Misreading a meniscus in a volumetric flask as high( or low)

**Operational and Personal errors :-**

These are due to factors for which the individual analyst is responsible and are not connected with the method or procedure they form part of the personal equation of an observer.

## 2. Indeterminate errors:-

Indeterminate errors can not be pin- pointed to any specific well defined reasons. They are random in nature & take place in several successive measurements performed by the same analyst under the same conditions and identical experimental parameters.

Sources of random error include the limitations of reading balances, electrical noise in instruments and vibrations caused to the building by heavy vehicular trafficking , which are beyond anyone's control. For eg. A balance that is capable of measuring only to 0.001 g can not distinguish between two samples with masses of 1.0151 & 1.0149 g. In one case the measured mass is low, in the other case it is high.

## Minimizing systematic errors

**Analyst has no control on random errors but systemic errors can be reduced by following:-**

**1)Calibration of instruments, apparatus and applying necessary corrections:-** Instruments commonly used in lab, such as spectrophotometer, electrical balance etc must be calibrated before use. Pipettes, burettes, volumetric flasks, thermometers must be calibrated.

The response of most of the instruments changes with time because of wear corrosion or mishandling, etc. The determinate personal errors may be eliminated .

**2)Calibration of apparatus:-** By calibrating all the instruments, errors can be

minimized and appropriate corrections are applied to the original measurements.

**3)Control determination:**-standard substance is used in experiment in identical experimental condition to minimize the errors.

**4) Blank determination:-** By omitting sample, a determination is carried out in identical condition to minimize the errors occurs due to impurities present in reagent.

**5) Independent method of analysis:-** It is carried out to maintain accuracy of the result e. g. Iron (III) is first determined gravimetrically by precipitation method as iron (III) hydroxide and then determined titrimetrically by reduction to the iron (II) state.

**6) Parallel determination:-** Instead of single determination, duplicate or triplicate determination is carried out to minimize the possibilities of accidental errors.

**7) Standard edition:-** This method is generally applied to physico-chemical procedures such as polarography and spectrophotometry.

**8) Internal standards:-** It is used in spectroscopic and chromatographic determination.

**9) Amplification methods:-** It is used when a very small amount of material is to be measured which is beyond the limit of the apparatus.

**10) Isotopic dilution:-** It is used for the compound containing radio-active isotope.

## ACCURACY:-

An accurate result is the one which matches very nearly with true value of a measured amount. Accuracy is inversely proportional to the error i.e. the greater the accuracy, smaller is the error.

Accuracy is the closeness of a measurement (or set of observations) to the true value. The higher the accuracy the lower the error.

How close you are to the actual value • Depends on the person measuring • Calculated by the formula:

**% Error = (YV – AV) x 100 ÷ AV**

Where: YV is YOUR measured Value & AV is the Accepted Value

## PRECISION:-

Agreement among a cluster of experimental results however it does not imply anything with respect to their relation to the true value. Precision designates reproducibility of a measurement, whereas accuracy the correctness of a measurement.

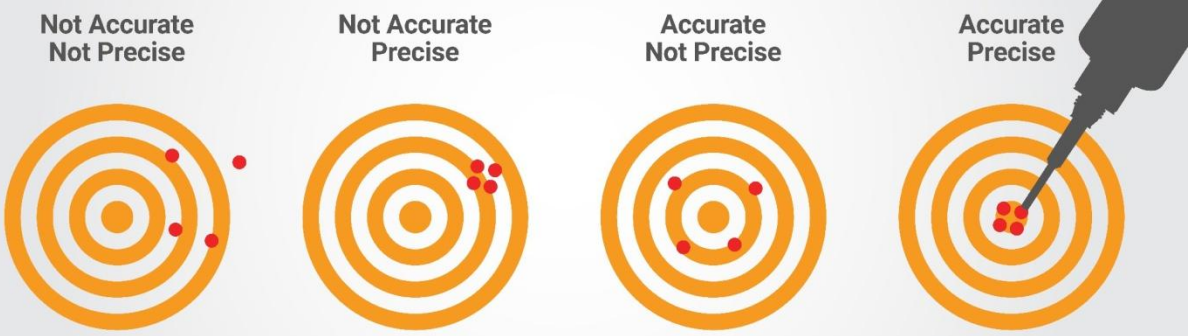
Precision is the closeness of multiple observations to one another, or the repeatability of a measurement.

How finely tuned your measurements are or how close they can be to each other . Depends on the measuring tool .Determined by the number of significant digits

## Accuracy & Precision:-

Accuracy & Precision may be demonstrated by shooting at a target.Accuracy is represented by hitting the bulls eye (the accepted value) . Precision is represented by a tight grouping of shots (they are finely tuned)

# Accuracy versus Precision/Repeatability

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# PHARMACOPOEIA

## INTRODUCTION TO PHARMACOPOEIA:

The term pharmacopoeia comes from Greek word ***"Pharma-kon"*** meaning 'drug' and *"Poein"* meaning 'make', and the combination means any recipe or formula or other standard required to make or prepare a drug.

*"Pharmacopoeia (literally, the art of the drug compounder),* in its modern technical sense, 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. The name has also been applied to similar compendiums issued by private individuals".

## HISTORY OF PHARMACOPOEIA:

Some of the earliest pharmacopoeia books were written by Muslim physicians. These included *The Canon of Medicine* of Avicenna in the 1020s' and other pharmacopoeia books by Abu-Rayhan Biruni in the 11th century, Ibn Zuhr (Avenzoar) in the 12th century (and printed in 1491), and Ibn Baytar in the 14th century. The first work of the kind published under government authority appears to have been that of **Nuremberg in 1542;** a passing student named Valerius Cordus showed a collection of medical receipts, which he had selected from the writings of the most eminent medical authorities, to the physicians of the town. An earlier work, known as the *Antidotarium Florentinum*, had been published under the authority of the college of medicine of Florence. The term pharmacopoeia was first given **by Dr A. Foes** in 1561 in a work published at Basel.

The term 'Pharmacopoeia' was first used in 1580 in a book on drug standards printed in Bergamo, Italy. After that a number of national pharmacopoeia were published by various European Pharmacopoeias the London, the Edinburgh and the

Dublin. Until 1617 such drugs and medicines as were in common use were sold in England by the apothecaries and grocers. The apothecaries obtained a separate charter and it was enacted that no grocer should keep an apothecary's shop. The preparation of physicians' prescriptions was thus confined to the apothecaries, this was than their responsibility to make and dispense medicines accurately, by the issue of a pharmacopoeia in May 1618 by the College of Physicians, and by the power which the wardens of the apothecaries received in common with the censors of the College of Physicians of examining the shops of apothecaries within 7 m of London and destroying all the compounds which they found unfaithfully prepared. Then, the first authorized London Pharmacopoeia, was selected chiefly from the works of Mezue and Nicolaus de Salerno, but it was full of errors that the whole edition was cancelled, and a fresh edition was published in the following December. At this period the compounds employed in medicine were often heterogeneous mixtures, some of which contained from 20 to 70, or more ingredients, while a large number of samples were used in consequence of the same substance being supposed to possess different qualities according to the source from which it was derived. Although other editions of the London Pharmacopoeia were issued in 1621, 1632, 1639 and 1677, it was not until the edition of 1721, published under the guidance of Sir Hans Sloane, when all important alterations were made. In the edition published in 1788 the tendency to simplify was carried out to a much greater extent, and the extremely compound medicines which had formed the principal remedies of physicians for 2000 years were discarded, while a few powerful drugs which had been considered too dangerous to be included in the Pharmacopoeia of 1765 were restored to their previous position. In 1809 the French chemical nomenclature was adopted, and in 1815 a corrected impression of the same was issued. Subsequent editions were published in 1824, 1836 and 1851.

Pharmacopoeias were official throughout the United Kingdom. Each pharmacopoeia described different strength and method of preparation for same preparation. Hence there was a lot of confusion. To overcome this difficulty, the first British Pharmacopoeia came into existence in 1864. In the United States, the first pharmacopoeia was published in December 1820 both in English and Latin. Later on a national formulary was also published in addition to USP (United States Pharmacopoeia). The object of first USP was to select from substances the ones which posses medicinal power, converted them into preparations of suitable composition in order to enhance their power to the maximum advantage. The first International pharmacopoeia was published by the World Health Organization in 1951 (Vol. 1) and in 1955 (Vol. 2).

These books are revised from time to time so as to introduce the latest information available as early as possible after they become established in order to introduce new products and to keep the size of book within reasonable limits; it becomes necessary to omit certain less frequently used drugs and pharmaceutical adjuvant from each new edition of the book. Therefore in each new edition of these books certain new monographs are added while the older once are deleted.

For the preparation of these books the expert opinion of medical practitioners, teachers and pharmaceutical manufacturers is obtained.

The drug compendia are classified as:

1. Official compendia
2. Nonofficial compendia.

**1. Official Compendia**

Official compendia are the compilations of drugs and others related substances which are recognized as legal standards of purity, quality and strength by a

government agency of respective countries of their origin. An official compendium includes British Pharmacopoeia, British Pharmaceutical Codex, Indian Pharmacopoeia, United States Pharmacopoeia, National formulary, the State Pharmacopoeia of USSR and Pharmacopoeia of other countries.

**2. Nonofficial Compendia**

The books other then official drug compendia which are used as secondary reference source for drugs and other related substances are known as nonofficial drug compendia. For instance, Merck index, Remington's pharmaceutical sciences, etc.

## INDIAN PHARMACOPOEIA (IP)

The Government of India through its letter No. 2338H(C)/43 dated 26 January, 1944, directed the Drugs Technical Advisory Board to list the drugs in use in India, which are not mentioned in British Pharmacopoeia and also recommend the standards to be prescribed to maintain uniformity and the chemical tests to be used to establish identity and purity. The Government of India published the Indian Pharmacopoeial List in 1946, as a supplement to the British Pharmacopoeia. The term "list" in the title was "misleading" in that, the book not only contained a list of drugs which were of substantial medicinal value but also laid down standards. The Indian Pharmacopoeial list contained about 180 monographs and a number of appendices prepared on the lines of the British Pharmacopoeia.

Approximately 100 monographs were on vegetable drug growing in India and on their galenicals, for example berberis, cannabis, ispaghula, rauwalfia, vasaka, digitalis etc. were included. Similarly several oils such as chaulmoogra, neem, and pudina, were included in it. The Pharmaceuticals and Drug Research Committee of the Council of Scientists and Industrial Research decided in February 1947 to compile a "Brochure" to highlight the information and clinical uses of the important indigenous drugs of India, in the form of a "codex". The first Indian Pharmaceutical codex was published in 1953. The codex consist of two parts, the first part carried about 190 general monographs on natural products and drugs of vegetable and animal origin , and a few chemicals . The second part consisted of formulary of galenicals and other preparations.

After the publication of Indian Pharmacopoeial list, the government of India constituted an eleven-member Indian Pharmacopoeial Committee in 1948, in their notification no. F.1-1/48-DS dated 23rd November, 1948, for preparing the Pharmacopoeia of India. The tenure of the office of the members of committee was five years. It was extended by one year vide Government notification No. F.6-10/53-DS dated the 21st November, 1953. In compiling the monographs of the first Pharmacopoeia of India, help was taken from all available established scientific data in modern Pharmacopoeia, such as British Pharmacopoeia, United States Pharmacopoeia, International Pharmacopoeia, and from scientific institutions interested in drugs and pharmaceutical products. The first edition of Pharmacopoeia of India was compiled and then published in 1955.

**Main Features of First Edition of Indian Pharmacopoeia (1955)**

1. The title of monograph was given in Latin language and Abbreviated titles for use of prescription were given immediately below the Latin line.
2. The English title were also given below the abbreviation title..
3. The weights and measures were given in metric system.
4. All statements given in the individual monographs were considered as constitute standards for official substances.
5. Doses were expressed both in the metric system as well as in the English system.
6. A list of preparation was given at the end of some of the monographs.
7. The temperature was expressed in Celsius.
8. The descriptive terms (very soluble, freely soluble, sparingly soluble, slightly soluble, very slightly soluble, and practically insoluble) have been used where the exact solubility of a pharmacopoeial substance is not known.

The tenure of the Indian Pharmacopoeial Committee expired in 1954, and the Committee was reconstituted under the chairmanship of **Dr BN Ghosh**, Professor of Pharmacology, **RG Kar** Medical College, Calcutta. The Committee compiled a supplement to the first edition of the Indian Pharmacopoeia. The supplement was published in 1960. The composition of the committee was as follows:

1. Chairman 1
2. Members 11
3. Member-Secretary 1
4. Assistant-Secretary 1

A Subcommitte was appointed by the committee to help in the compilation work, the following subcommittees were made.

1. Pharmacology and Bioassay Subcommittee.

2. Biological Product Subcommittee.
3. Antibodies, Vitamins and Hormones Subcommittee.
4. Pharmacognosy Subcommittee.
5. Pharmacy Subcommittee.
6. Pharmaceutical Subcommittee.
7. General Chemistry Subcommittee.
8. Analytical Subcommittee.
9. Physical Standards, Weights, Measures and Nomenclature Subcommittee.
10. Indian Medical Plants Subcommittee.

A coordination subcommittee consisting of the chairman and secretary of the Indian pharmacopoeia committee and the chairman of the various subcommittees was also constituted to coordinate the work of various subcommittees. The second edition of the pharmacopoeia of India was published in 1966 and later on its supplement was published in1975.

**Main Features of the Second Edition of Indian Pharmacopoeia (1975)**

1. The titles of monographs were changed from Latin to English.
2. The name of the drug was given first, e.g. injection of Ranitidine has been changed to Ranitidine injection
3. Doses were expressed in the metric system only.
4. Solubility is expressed in parts of solvent per unit part of solute.
5. The preparations of a drug have been given immediately after the monographs on the parent drug.
6. For the detection of fungi apart from aerobic and anaerobic bacteria The test for sterility was included.
7. New analytical techniques such as non-aqueous titrimetry, column chromatography, HPLC were added

8. In the monographs of "tablets" and "injection", a new subheading "usual strength" has been given to represent the strength of the tablet or injection.
9. Some drugs were renamed in this edition e.g. 'Acetylsalicylic Acid 'has been changed to 'Aspirin'.

The Government of India, Ministry of Health and Family Welfare, vide their resolution No. X 19014/1/77-D and MS, dated 30th june1979, reconstituted the Indian Pharmacopoeia committee for a period of five years for the preparation of the edition of Pharmacopoeia of India. The composition of the committee was as follows:

| | | |
|---|---|---|
| I. | Chairman | 1 |
| II. | Members | 13 from academic, research and industry. |
| III. | Member Secretary | 1 |
| IV. | Assistant Secretary | 1 |

The committee appointed the following subcommittees:

1. Clinical Medicines and Pharmacology Subcommittee.
2. Biological Products and Bioassay Subcommittee.
3. Antibiotics Subcommittee.
4. Synthetic Drugs Subcommittee.
5. Medicinal Plants, Galenicals and Surgical-Dressing Subcommittee.
6. Chemicals & Sterile Products Subcommittee.
7. Parenteral & Sterile products Subcommittee.
8. Nonparenteral Products Subcommittee.
9. Analytical Methods, Reagents, Diagnostic Aids and Containers Subcommittee.
10. Nomenclature & Formulae Subcommittee.

The Indian Pharmacopoeia Committee also constituted a "Working Group" for the purpose of preparing draft monographs and appendices, to examine the comments received on these from various sources and then make suitable recommendations to the committee.

The monographs, appendices and General notices are prepared by the "working Group" and finalized by the committee were then published in the form of third edition of Pharmacopoeia of India in 1985 by the Government of India.

**Main Features of Third edition of Indian Pharmacopoeia (1985)**

1. The newer analytical techniques like Flame Photometry, Flurimetry, Electrophoresis were introduced for certain analytical methods
2. For certain tablets, dissolution test was introduced.
3. Disintegration Test was modified regarding the design of the apparatus and method of testing.
4. Microbial limit test was prescribed for various pharma-ceutical aids and oral liquid dosage form.
5. In spite of Shivering response for rabbit the Pyrogen Test was introduced.
6. GLC (gas liquid chromatography) was introduced for analytical purposes of alcohol concentration detection.
7. Ostwald Viscometer was used to determine the viscosity.
8. The new appendix on "Water for Pharmaceutical Use" has been introduced for purified water, water for injection and sterile water for injection.
9. Drugs were renamed e.g. 'Acetylsalicylic Acid' has been changed to 'Aspirin'.
10. New drugs were added and some drugs were omitted from the third edition.

The Government of India, Ministry of Health and Family Welfare vide their resolution No. X19020/1/89-DMS and PFA dated 12th August 1991, reconstituted the Indian Pharmacopoeia Committee for a period of five years for the preparation of the fourth edition of pharmacopoeia of India. The composition of the committee was as follows:

1. Chairman 1
2. Member's 18 in number representing arcade- mic, research and industry.
3. Member secretary 1
4. Assistant secretary 1

The Committee appointed the subcommittees and working groups in order to expedite the preparation of the new edition of the Indian Pharmacopoeia.

The Monographs, Appendices and General Notes as prepared by the "Working Group" and finalized by the Committee were then published in the form of fourth edition of the pharmacopoeia of India in 1996 by the Government of India

**Main Features of the Fourth Edition of Indian Pharmacopoeia (1996):**

1. It contains 1149 monographs and 123 appendices in two volumes.
2. It contains computer-generated structural formulae
3. Some titles were changed to include the more commonly accepted names, e.g. Hyoscine Hydro bromide for Scopolamine Hydro bromide.
4. Infrared and ultra red adsorption spectrophotometrically tests for identification of drug substance was added. The infrared reference spectra of a number of drug substances were also included in an appendix.
5. The high performance liquid chromatography (HPLC) has been widely used as a method to analyze many formulations which can otherwise be analyzed

only by more difficult and less accurate method e.g. biological assay of insulin has been replaced by HPLC.

6. Bacterial end toxins test for pyrogens has been introduced.
7. A number of general monographs e.g. eye drops; eye ointments, nasal preparation, oral liquids, pessaries, suppositories etc. have been included.
8. A quantitative method for determining particulate matter in injectable preparations has been replaced by the qualitative test.
9. The specific biological assays and tests provided for vaccines; hormones, blood products and enzymes have been transferred to the individual monograph.
10. In the monograph of oral rehydration salts (ORS), ORS -bicarbonate formula was omitted due to its stability problem, whereas ORS- citrate formula recommended by WHO is added.

## BRITISH PHARMACOPOEIA (BP)

The British Pharmacopoeia (BP) is a collection of quality standards for UK medicinal substances. It is used by individuals and organizations involved in pharmaceutical research, development, manufacturing and testing. The British Pharmacopoeia is an important statutory component in the control of medicines which complements and assists the licensing and inspection processes of the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom. It is published every year.

The British Pharmacopoeia is published by the Health Ministers of the United Kingdom on the recommendation of the Commission on Human Medicines in accordance with section 99(6) of the Medicines Act 1968 and notified in draft to the European Commission in accordance with Directive 98/34/EEC.

In 1907 the British Pharmacopoeia was supplemented by the British Pharmaceutical Codex, which gave information on drugs and other pharmaceutical substances not included in the BP, and provided standards for these.

The first publication of British Pharmacopoeia was in 1864 and has grown throughout the world. It is now used in over 100 countries. Australia and Canada are two of the countries that have adopted the BP as their national standard alongside the UK, and in other countries (e.g. Korea) it is recognized as an internationally acceptable standard. The BP is prepared by the Pharmacopoeial Secretariat working in collaboration with the BP Laboratory, the British Pharmacopoeia Commission (BPC) and its Expert Advisory Groups (EAG) and Advisory Panels. The development of pharmacopoeia) a standard receives input from relevant industries, hospitals, academia, professional bodies and governmental sources, both within and outside the UK. The BP Laboratory provides analytical and technical support to the British Pharmacopoeia

The current edition of the British Pharmacopoeia 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 comprehensively indexed and cross-referenced for easy reference.

*BP Volumes I and II contains*

- Medicinal Substances

*BP Volume III contains*

- Formulated Preparations

- Blood related Preparations,
- Immunological Products,
- Radiopharmaceutical Preparations
- Surgical Materials
- Homeopathic Preparations

*BP Volume IV contains*

- Appendices
- Infrared Reference Spectra
- Index

*BP Volume V contains*

- British Pharmacopoeia (Veterinary)

*BP Volume VI (CD-ROM version) contains*

- British Pharmacopoeia
- British Pharmacopoeia (Veterinary)
- British Approved Names

The BP 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 130,000+ hypertext links within the text.

The major functions of BP are:

1. Development of new pharmacopoeial monographs

2. Development and validation of qualitative and quantitative test methods for new BP monograph specifications
3. Refining and revalidating test methods for existing BP monographs.

**British Pharmaceutical Codex (BPC):**

It was in 1903 that the council of the Pharmaceutical society of Great Britain decided to prepare a reference book for the use of medical practitioners and dispensing pharmacists. The first edition of the British Pharmaceutical Codex was published in 1907. The subsequent revisions of this codex were published in 1911, 1923, 1934, 1949, 1954, 1959, 1963, 1968, and 1973.

On the request of British Pharmacopoeia Commission, the Council of the pharmaceutical society agreed in 1959 for the publication of Codex to coincide with that of the British Pharmacopoeia, so that these two books i.e. British pharmaceutical codex and British pharmacopoeia should come into effect on the same dates.

The British pharmaceutical codex differs from British pharmacopoeia in that:

1. It contains many new drugs and preparations; some were included in advance, which were in the pipeline of clinical trials or synthesis.
2. It provides standards for drugs, surgical dressings and pharmaceutical preparations not included in the British pharmacopoeia.
3. It provides information on the actions and uses of drugs, their undesirable effects, precautions and the treatment of poisoning.
4. It contains formulae, method of preparation, dose, container and storage conditions of majority of pharmaceutical preparations for eg.mixtures,

powders, eye drops, ear drops, liniments, lotions, ointments, creams, pastes, suppositories etc.

## UNITED STATES PHARMACOPEIA (USP)

The United States Pharmacopeia is an official public standards-setting authority for all prescription and over-the-counter medicines and other health care products manufactured or sold in the United States. USP also sets recognized standards for food ingredients and dietary supplements. These standards help to ensure the quality, purity, strength, and consistency of products made for public consumption. USP's standards are recognized and used in more than 130 countries around the globe.

The United States pharmacopoeia and the National Formulary (USP-NF) are recognized as official compendia and are used as reference books for determining the strength, quality, purity, packaging and labeling of drugs and other related articles. The United States Pharmacopoeia was originally published in 1820 under the authority of the United States Pharmacopoeial convention and the National Formulary was published in 1888 under the guidance of the American pharmaceutical association. In 1974 the National Formulary was purchased by the United States Pharmacopoeial convention and from 1980 onwards only one official book of drug standards was published under the heading, the United States Pharmacopoeia and the National formulary (USP-NF).

USP is a non-governmental, not-for-profit public health organization whose independent, volunteer experts work under strict conflict-of-interest rules to set its scientific standards. USP's work is aided by the participation and oversight of volunteers representing pharmacy, medicine, and other health care professions as

well as academia, government, the pharmaceutical and food industries, health plans, and consumer organizations.

**Main Features of USP**

***1. Product Quality—Standards and Verification***

USP establishes documentary and reference standards to ensure quality medicines, food ingredients, and other health care products. Prescription and over-the-counter medicines available in the United States must, by federal law, meet USP's public standards, where such standards exist. Many other countries require the use of high-quality standards such as USP's to assure the quality of medicines and related products.USP also conducts verification programs for dietary supplement ingredients. Much like food ingredients, USP's standards for dietary supplements have no legal recognition in the United States, but involve independent testing and review to verify ingredient and product integrity, purity, and potency for manufacturers who choose to participate.

**2.** ***Healthcare Information***

USP develops information relating to various aspects of drug use and disseminates this information to practitioners, pharmacists, and others who make decisions about health care around the world. Significant among USP's health care information initiatives is the development of a drug classifications system that Medicare Prescription Drug Benefit plans may use to develop their formularies. USP also partners with the U.S. Agency for International Development, the World Health Organization and others in worldwide projects that help to assure drug quality and proper drug use in many developing countries.

### *3. Patient Safety*

USP operates two programs to promote safer care of patients who take medications and stay in hospitals. The Medication Errors Reporting Program allows healthcare professionals to directly report medication errors to USP. MEDMARX®, an Internet-based medication error and adverse drug reaction reporting program, is designed for use in hospitals and health systems. USP also uses its knowledge base to provide information that supports the healthcare community in the research and development of patient safety initiatives.

### 4. Drug Quality and Information

USP's Drug Quality and Information (USP DQI) Program is a cooperative agreement with the United States Agency for International Development (USAID). The USP DQI program has established a presence in USAID-priority countries on four continents advancing strategies to improve drug quality and the appropriate use of drugs.

The four main programs that USP promotes:

a. Ensuring drug quality by working with local governments, USAID missions, the World Health Organization (WHO), and other partners to evaluate a country's readiness and capacity to provide necessary drug quality assurance
b. Providing continuing education for physicians, pharmacists and nurses in drug information and pharmacovigilance to help improve drug dispensing and ensure competence and accountability

c. Developing and disseminating evidence-based drug and therapeutic information through targeted drug and therapeutic information materials for health care providers based on specific needs
d. Establishing regional and international cooperation through USP's system of open conferences, Internet-based communications, and regular publications.
e. USP's Global Presence

Activities at USP are focused on promoting the public health by disseminating authoritative standards and information for over-the-counter medicines, dietary supplements, food ingredients and other health care technologies, and related practices used to maintain and improve health and promote optimal health care delivery around the world.

**THE INTERNATIONAL PHARMACOPOEIA:**

The International Pharmacopoeia (Phlnt) is issued by the World Health Organization. The aim is to achieve a wide global uniformity of quality specifications for selected pharmaceutical products, excipients, and dosage forms.

High priority is given to medicines that are important to WHO health programs, and which may not appear in any other pharmacopoeias, e.g. new antimalarial drugs.

The International Pharmacopoeia (Ph. Int.) comprises a collection of quality specifications for pharmaceutical substances (active ingredients and excipients) and dosage forms together with supporting general methods of analysis that is

intended to serve as source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements.

The activities related to the International Pharmacopoeia are an essential element in the overall quality control and assurance of pharmaceuticals contributing to the safety and efficacy of medicines. The International Pharmacopoeia recognizes the needs of specific disease programmes and the essential medicines nominated under these programmes; it is based primarily on those substances included in the current WHO Model List of Essential Medicines. The work on The International Pharmacopoeia is carried out in collaboration with members of the WHO expert advisory panel on the International Pharmacopoeia and Pharmaceutical Preparations and with other specialists. The process involves consultation of and input from WHO member states and drug regulatory authorities.

**References:**


1. Agrawal G. Pharmaceutics 1 Theory and practical CBS Publishers and distributor's Pvt.Ltd. 2018; 5-11.
2. https://www.web-formulas.com/Formulas_of_Chemistry/Minimization_of_Errors.aspx#:~:text=Calibration%20of%20apparatus%3A%20By%20calibrating,condition%20to%20minimize%20the%20errors.