PHARMACOPOEIA

PHARMACOPOEIA

- Derived from Greek word **'Pharmakon'** means **drug** and **'Poiea'** means **to make**.
- It is a legal and official book issued by recognized authorities usually appointed by **Government of each country**.
- It comprises list of pharmaceutical substances, formulae along with their description and standards.

- **List of Pharmacopeias:**

a) Argentine b) Austrian c) Belgian d) Brazilian e) **British** f) Chinese g) Egyptian h) **European** i) French j) German k) Hungarian l) **Indian** m) **International** n) Italian o) Japanese p) Yugoslavian q) Mexican r) Netherlands s) Nordic t) Polish u) Portuguese v) Rumanian w) Russian x) Spanish y) Turkish z) **United state.**

INDIAN PHARMACOPOEIA

- First official Pharmacopeia of India appeared in **1868** which was edited by **Edward John Waring.**
- In preindependence days, British Pharmacopeia was used in India.
- The colonial addendum of **BP 1898** was published in **1900** appeared as Government of India edition in **1901.**
- In **1946** Government of India issued one list known as **„The Indian Pharmacopeial list"**
- Committee under chairmanship of **Sir R. N. Chopra** alongwith other nine members prepared **„The Indian Pharmacopeial list"**
- It was prepared by **Dept. of Health, Govt. of India, Delhi** in **1946.**
- In **1948** Government of India appointed an Indian Pharmacopeia committee for preparing **„Pharmacopeia of India"**
- Tenure of this committee was **five years.**
- Indian Pharmacopeia committee under chairmanship of **Dr. B. N. Ghosh** Published **first edition of IP** in **1955.**

INDIAN PHARMACOPOEIA

- It is written in **English** & official titles of monographs given in **Latin**.
- It covers **986** monographs.
- Supplement to this edition was published in **1960**.
- Second edition of **IP** was published in **1966** under the chairmanship of **Dr. B. Mukkerji**.
- Official titles of monographs given in **English**.
- Dose were expressed in **Metric system**.
- For **Tablets and Injections** **"USUAL STRENGTH"** have been given.
- Formulations of the drugs were given immediately after the monograph of drugs.
- **274** monographs from IP 55 & their supplement were deleted.
- **93** new monographs were added.
- Supplement to this edition was published in **1975.**
- **126** new monographs have been included & **250** monographs have been amended.
- **Cholera vaccine** has been deleted.

INDIAN PHARMACOPOEIA

- Third edition of **IP** was published in **1985** with two volumes & nine appendices.
- **261** new monographs have been added.
- **450** monographs were deleted.
- Addendum I to IP was published in **1989** were **46** new monographs added and **126** amended.
- Addendum II was published in **1991** were **62** new monographs added and **110** amended.
- Fourth edition of **IP** was published in **1996** under the chairmanship of **Dr. Nityanand**.
- It has been made effective from **1st December 1996.**
- It covered **1149** monographs and **123** appendices.
- It includes **294** new monographs & **110** monographs have been deleted.
- Addendum I has been made effective from **31st December 2000** were **42** new monographs have been added.
- Addendum II has been made effective from **30th June 2003** were **19** new monographs have been added.
- The veterinary supplement to **IP 1996** contains **208** monographs & **four** appendices.

INDIAN PHARMACOPOEIA

- Fifth edition of **IP** was published in **2007** & addendum to this edition was published in **2008.**
- **IP 2007** is presented in **Three Volumes**.
- Volume **One** contains general notices & general chapters.
- Volume **Two & Three** contains general monographs on drug substances , dosage forms & Pharmaceutical aids.

INDIAN PHARMACOPOEIA 2010

- **6th edition**of **IP** is published in **2010**.
- The **6th edition** of the Indian Pharmacopoeia 2010 is published by the **Indian Pharmacopoeia Commission (IPC) Ghaziabad** in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.
- It supersedes the **2007** edition but any monograph of the earlier edition that does not figure in this edition.
- This edition would be effective from **1st September, 2010.**
- The Indian Pharmacopoeia **2010** is presented in **three volumes.**
- **Volume I** contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters.
- **Volume II** contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids **(A to M).**

INDIAN PHARMACOPOEIA 2010

- **Volume III** contains Monographs on drug substances, dosage forms and pharmaceutical aids **(N to Z).**
- Followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products.
- The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for new drugs and drugs used under National Health Programmes are added and the drugs as well as their formulations not in use now a day are omitted from this edition.

INDIAN PHARMACOPOEIA 2010

- The number of monographs of Excipients, Anticancer drugs, Herbal products and antiretroviral drugs has been increased in this edition.
- Monographs of Vaccines and Immunosera are also upgraded in view of development of latest technology in the field.
- A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.
- A chapter on NMR is incorporated in Appendices.
- The chapter on microbial contamination is also updated to a great extent to harmonise with prevailing international requirements.

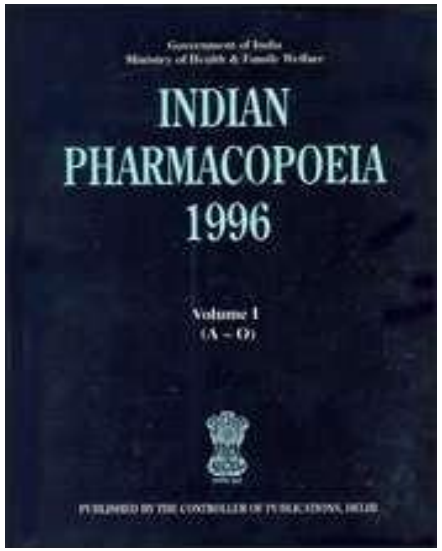
Seventh Edition of Indian Pharmacopoeia

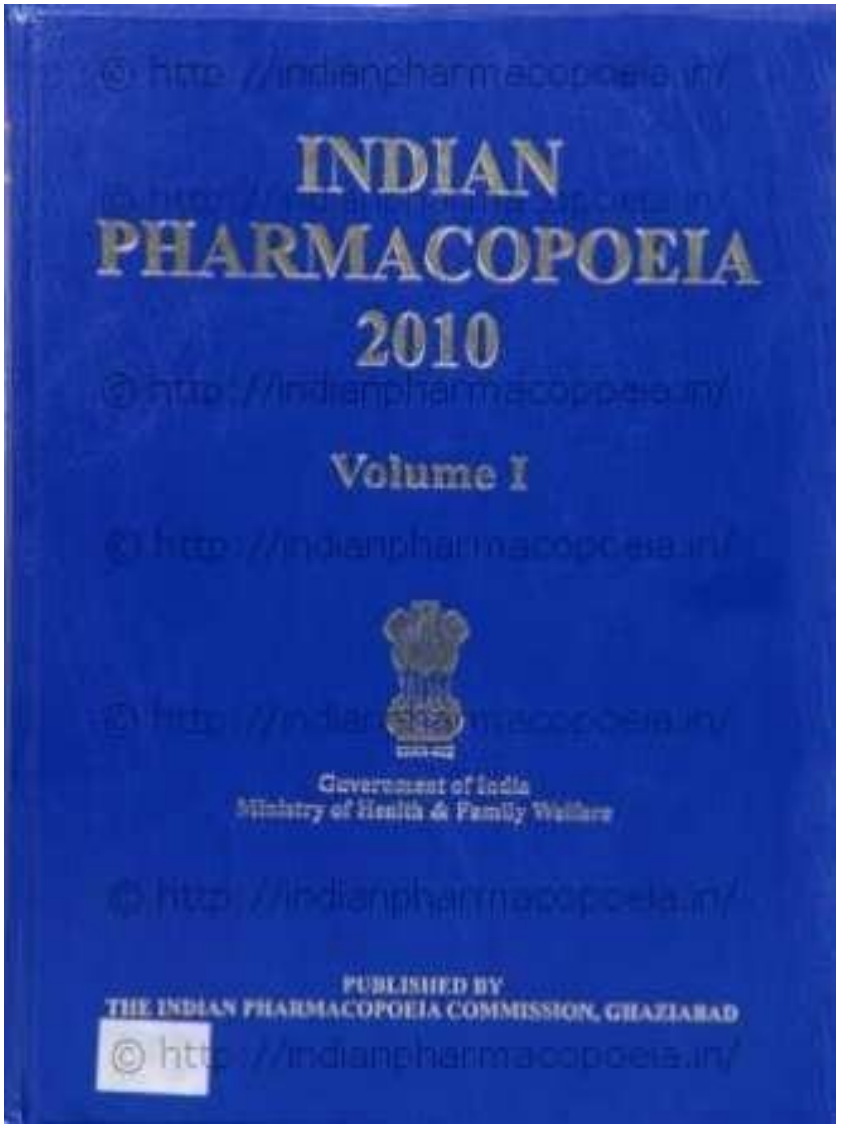
- The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
- The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.

Seventh Edition of Indian Pharmacopoeia

- A list of 577 New Monographs not included in IP-2010 and its Addendum-2012 but added in this edition containing 313 New Monographs on drug substances, Dosage forms & Pharmaceutical aids (A to Z), 43 New Drugs Substances Monographs, 10 Antibiotic Monographs, 31 Herbal Monographs, 05 Vaccines & immunosera for human use, 06 Insulin Products, 07 Biotechnology Products etc. along with the 19 new General Chapters.
- 19 New Radiopharmaceutical Monographs & 1 General chapter is first time being included in this edition.
- This edition of Indian Pharmacopoeia-2014 is now under printing and will be available to stakeholders probably in Sept.2013, before three months of its effective date, i.e. 1st Jan. 2014.

INDIAN PHARMACOPOEIA





BRITISH PHARMACOPOEIA

- First edition of **BP** was published in **1864**.
- It consist of two sections
- Part I:- **Materia Medica** & Part II:- **Preparation & compounds.**
- Second edition of **BP** was published in **1867**.
- Fourth edition of **BP** was published in **1898**.
- Fifth edition of **BP** was published in **1914**.
- Eighth edition of **BP** was published in **1953**.
- In this edition titles of drugs & preparations were in **English** instead of **Latin** and **metric system**.
- It has been published **annually.**
- In **BP 2007** monographs has been introduced for material specifically used in preparation of Traditional Chinese medicines.
- Term **„Prolonged release"** has been replaced the term **„Slow"** and the term **„Gastro-resistant"** has been replaced with **„Enteric coated"** in number of monographs.

BRITISH PHARMACOPOEIA

- BP **2008** contains approximately **3100** monographs for substances, preparations and articles used in practice.
- It has been made effective from **1st January 2008**.
- **BP 2007 -2009** were given in Six Volumes i.e. **Volume I to Volume VI.**
- **Volume I & II** contains medicinal substances.
- **Volume III** contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homoeopathic preparations.
- **Volume IV** contains supplementary chapters, IR spectra etc.
- **Volume V** contains veterinary.
- **Volume VI** contains CD ROM version.
- Current edition of **BP 2010** is in process.

THE BRITISH PHARMACOPOEIA 2010

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

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

The BP has been providing authoritative, official standards for pharmaceutical substances and medicinal products since 1864. Today, it is used in almost 100 countries worldwide and remains an essential reference for any individual or organisation working within pharmaceutical research and development, manufacturing and testing across the globe.

New to the BP 2010 are 40 monographs for formulated preparations, including veterinary medicines and additional standards for widely used unlicensed formulations. All European Pharmacopoeia 6th edition material up to and including Supplement 6.5 is integrated into the text of the BP 2010. In addition to the expanding number of monographs for licensed formulated products, the BP supports the regulatory work in the fields of herbal and complementary medicines by providing additional new and revised monographs for herbal medicinal products and for homeopathic stocks and mother tinctures.

The print edition of the BP 2010 comprises four volumes of the BP 2010 and a single volume of the BP (Veterinary) 2010.

THE BRITISH PHARMACOPOEIA (BP) 2013

The BP 2013 package includes:

Six volume printed edition including the BP (Veterinary) 2013

New for 2013:

41 new BP monographs

40 new European Pharmacopoeia monographs

619 amended monographs

6 new and 1 amended Infrared Reference Spectra

THE BRITISH PHARMACOPOEIA 2014

The only official source of British pharmaceutical standards

Produced by the British Pharmacopoeia Commission Secretariat of the Medicines and Healthcare Products Regulatory Agency, and updated annually, the British Pharmacopoeia (BP) is the official, authoritative collection of standards for UK medicinal substances for human and veterinary use.

The 2014 edition includes almost 3500 monographs which are legally enforced by the Human Medicines Regulations 2012.

Global standards

Now used in over 100 countries, the BP remains an essential reference for all individuals and organisations working within pharmaceutical research and development, manufacture and testing around the globe.

Flexible access options

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

New for 2014

Legally effective from 1 January 2014

40 new BP monographs

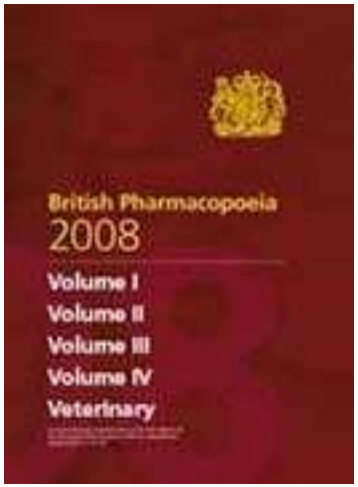
272 amended monographs

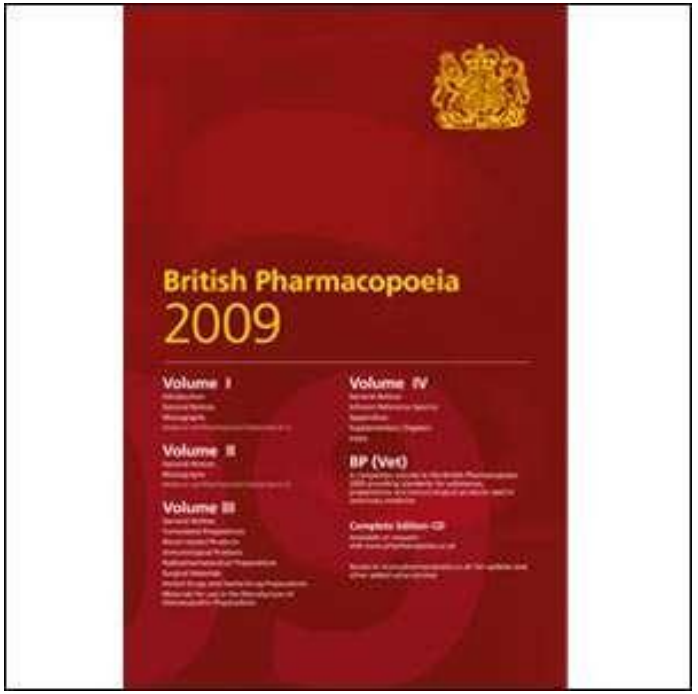
Three new Supplementary Chapters

Four new BP (Vet) monographs

One new BP (Vet) Supplementary Chapter

BRITISH PHARMACOPOEIA





BRITISH PHARMACOPOEIA

UNITED STATE PHARMACOPOEIA

- **First edition** of United state Pharmacopeia was published on 15th **December 1820** in both ***Latin & English***.
- From 1820 to 1942 it was published at **Ten years** intervals.
- From 1942 to 2000 it was published at **Five years** intervals.
- From 2002 it was published **annually**.
- First ***National Formulary*** of the united state appeared in **1888**.
- **USP21-NF16** have eight supplements.
- First appeared in **January 1985** & last in **November 1988**.
- **USP22-NF17**, **1990** is the third revision that consolidates USP & NF into a single volume.
- Electronic version of ***USP-NF*** on floppy disks was introduced in **1992**.
- **USP23-NF18**, was published in Mumbai as an Asian edition at the end of **1994**.

UNITED STATE PHARMACOPOEIA

- ***USP23*** has ten supplements.
- First supplement was published in **January 1995** & Last in **May 1999**.
- ***USP24-NF19***, appeared from first **January 2000**.
- ***USP30-NF25***, appeared from **May 2007**.
- It contains Scientific standards for drugs, dietary substances, biological products & Excipients used in dosage forms.
- It contains **4,100** monographs and **200** general chapters.
- It has been printed in **three volume** set.
- **Volume I** contains general chapters & **Volume II & III** contains monographs.
- First supplement to ***USP30-NF25***, appeared from **August 2007** & second supplement from **November 2007** which will be considered official from **May 2008**.
- From 2006, Spanish edition of USP is also being published.
- Current edition of **USP 2014** is in process.

- **UNITED STATES PHARMACOPOEIA 30 – NATIONAL FORMULARY 25**

Highlights include:

- New heavier paper stock
- Complete table of contents and index in each volume
- Special 'Using the New USP-NF Print' tutorial CD
- Convenient slipcase for easy access and storage (English edition only).
- **UNITED STATES PHARMACOPOEIA 31 - NATIONAL FORMULARY 26**
- The USP-NF is a single-volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP. Excipient monographs are included in the NF.

- **UNITED STATES PHARMACOPOEIA 32 - NATIONAL FORMULARY 27**

The USP 32-NF 27 Contains :

- More than 4,200 monographs
- Includes over 200 general chapters, covering general tests and assays
- Displays helpful guides and charts that make it easy to find focus-specific information
- Includes information on emerging areas of science and medicine
- Helps ensure compliance with official standards
- Enables validation of test results against proven benchmarks
- Creates in-house standards for operating procedures and specifications
- Expedites new product development and approvals.

- **UNITED STATES PHARMACOPOEIA 33 - NATIONAL FORMULARY 28:**

The USP 33-NF 28 Contains:

- More than 4,400 monographs
- Over 200 general chapters covering general tests and assays
- A new, easy-to-read format and monograph layout
- Helpful guides and charts that make it easy to find focus-specific information
- Ensures compliance with official standards
- Establishes in-house standard operating procedures and specifications
- Facilitates new product development and approval.

- **UNITED STATES PHARMACOPEIA 34 - NATIONAL FORMULARY 29:**

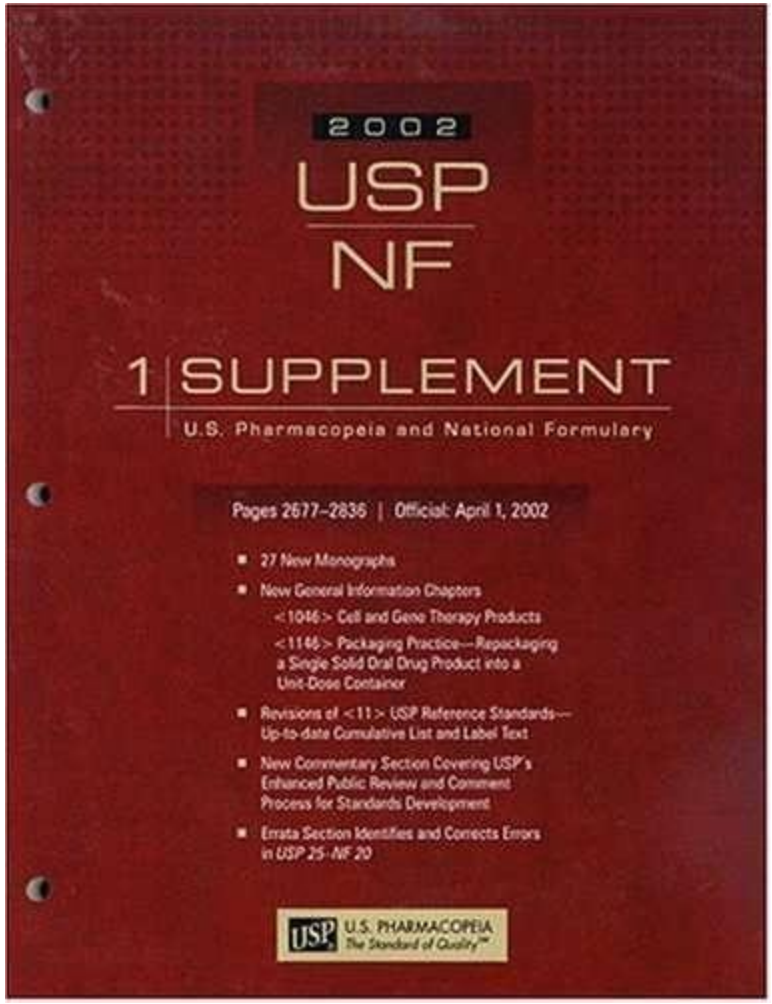
  USP 34-NF 29 features more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics. USP 34-NF 29 also offers harmonized material and more than 230 General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.

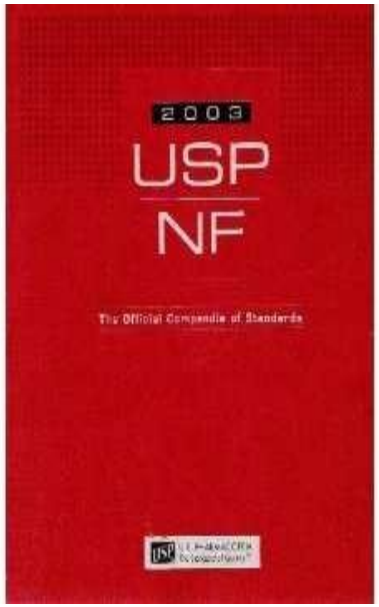
- **UNITED STATES PHARMACOPEIA 35 - NATIONAL FORMULARY 30:**

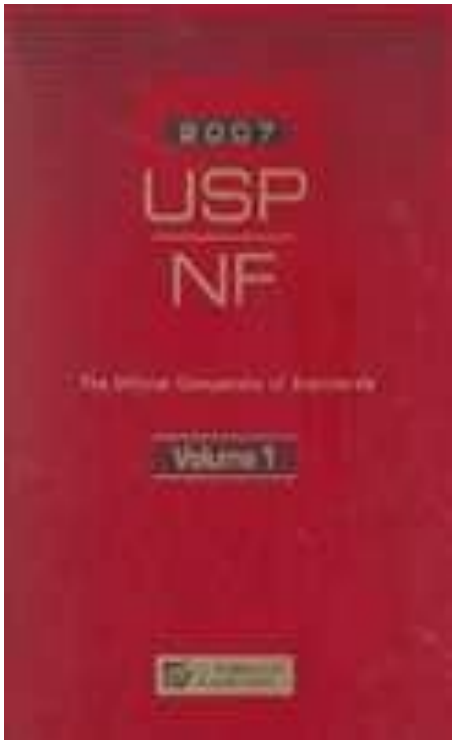
  The 'United States Pharmacopeia 35 - National Formulary 30' (USP-NF) is a combination of two official compendia: the 'United States Pharmacopeia (USP)' and the 'National Formulary (NF)' and is officially applicable from **1 May, 2012 to 30 April, 2013.**

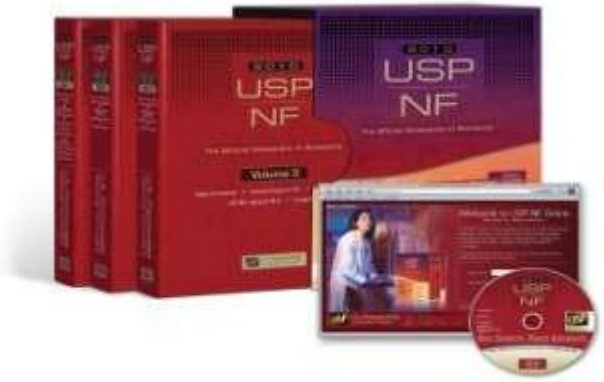
UNITED STATE PHARMACOPOEIA

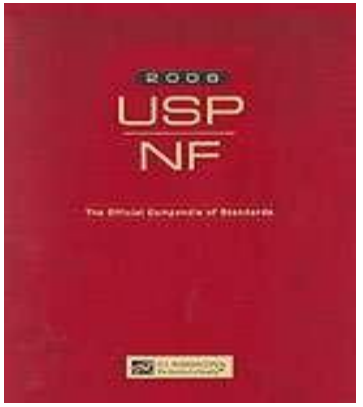
U.S. Pharmacopeia
The Standard of Quality℠











EUROPEAN PHARMACOPEIA

- European pharmacopeia commission started working since 1964 to prepare EP

Editions

- 1st edition: published 1967
- 2nd edition: published 1980
- 3rd edition: published 1997
- 4th edition: published 2001, valid from 1 January 2002
- 5th edition: published 15 June 2004, valid from 1 January 2005
- 6th edition: published 16 July 2007, valid from 1 January 2008
- 7th edition: published June 2010, valid from 1 January 2011
- 8th edition: published June 2013, valid from 1 January 2014

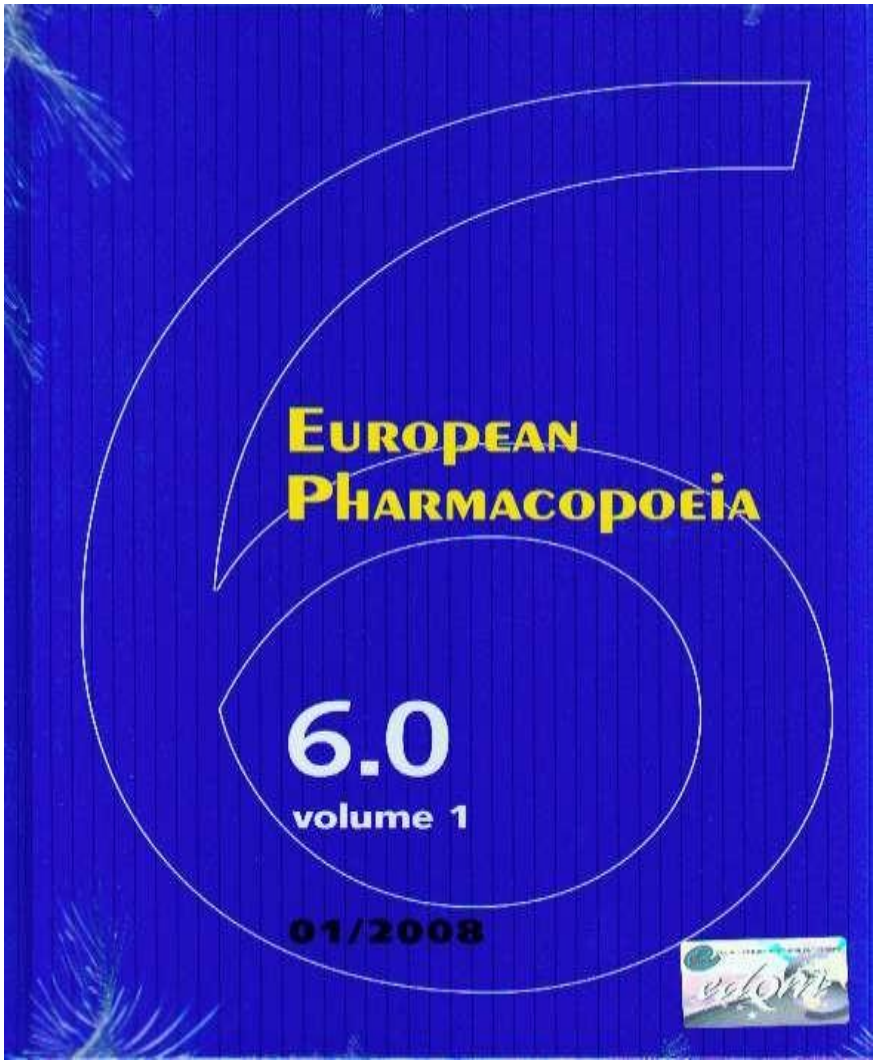
Since its 5th edition, the pharmacopoeia is published in 2 volumes. Volume 1 contains general chapters and monographs (e.g. on dosage forms, methods of analysis, reagents), volume 2 contains all substance monographs. During runtime of current edition several supplements are published. Electronic versions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

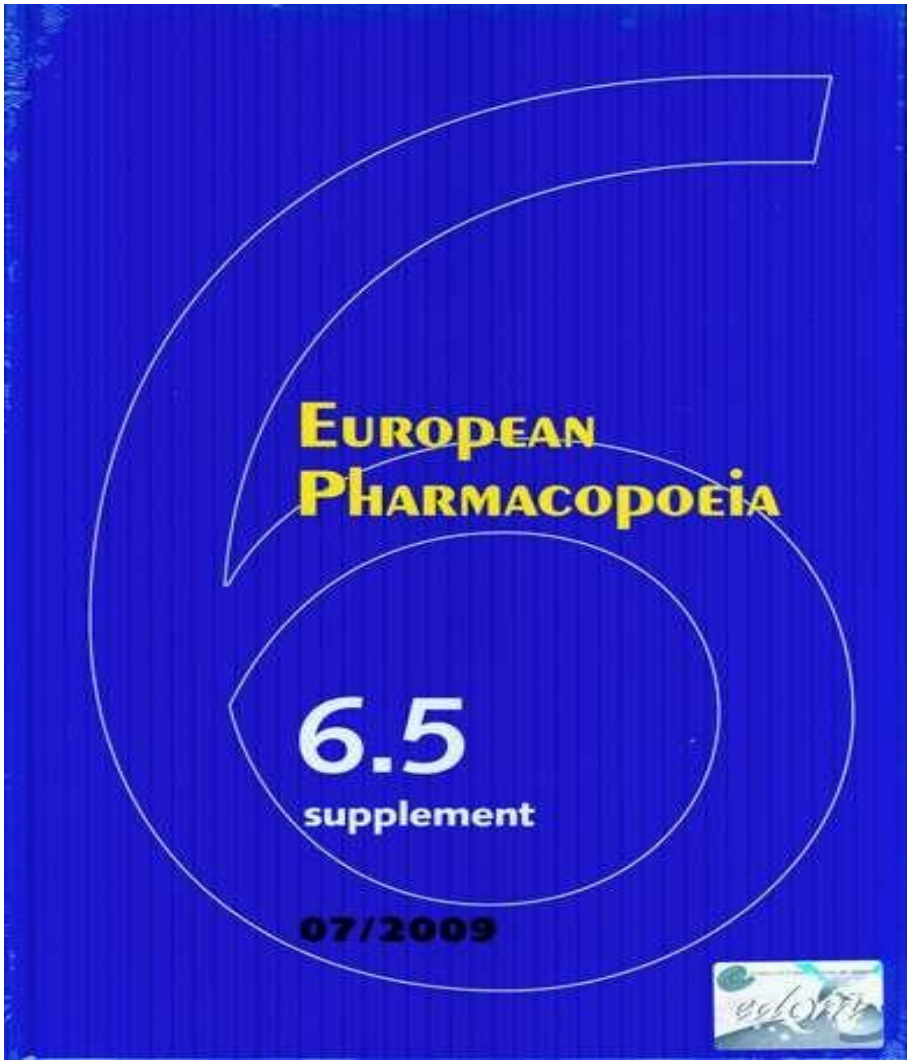
EUROPEAN PHARMACOPOEIA 8TH EDITION

PUBLISHED ON JUNE 2013

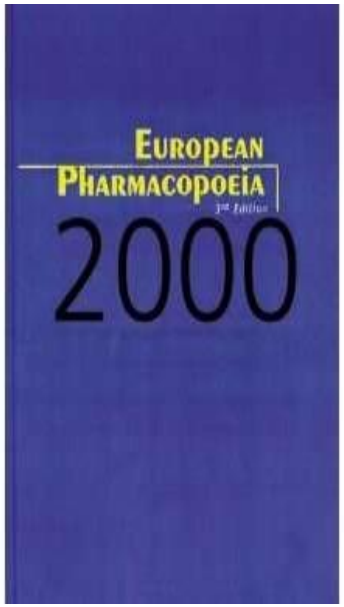
- The European Pharmacopoeia (Ph. Eur.) defines requirements for the qualitative and quantitative composition of medicines, the tests to be carried out on medicines and on substances and materials used in their production.
- It covers active substances, excipients and preparations of chemical, animal, human or herbal origin, homoeopathic preparations and homoeopathic stocks, antibiotics, as well as dosage forms and containers. It also includes texts on biologicals, blood and plasma derivatives, vaccines and radiopharmaceutical preparations. The European Pharmacopoeia and its requirements are legally binding in the member states of the European Pharmacopoeia Convention and the European Union.

EUROPEAN PHARMACOPEIA



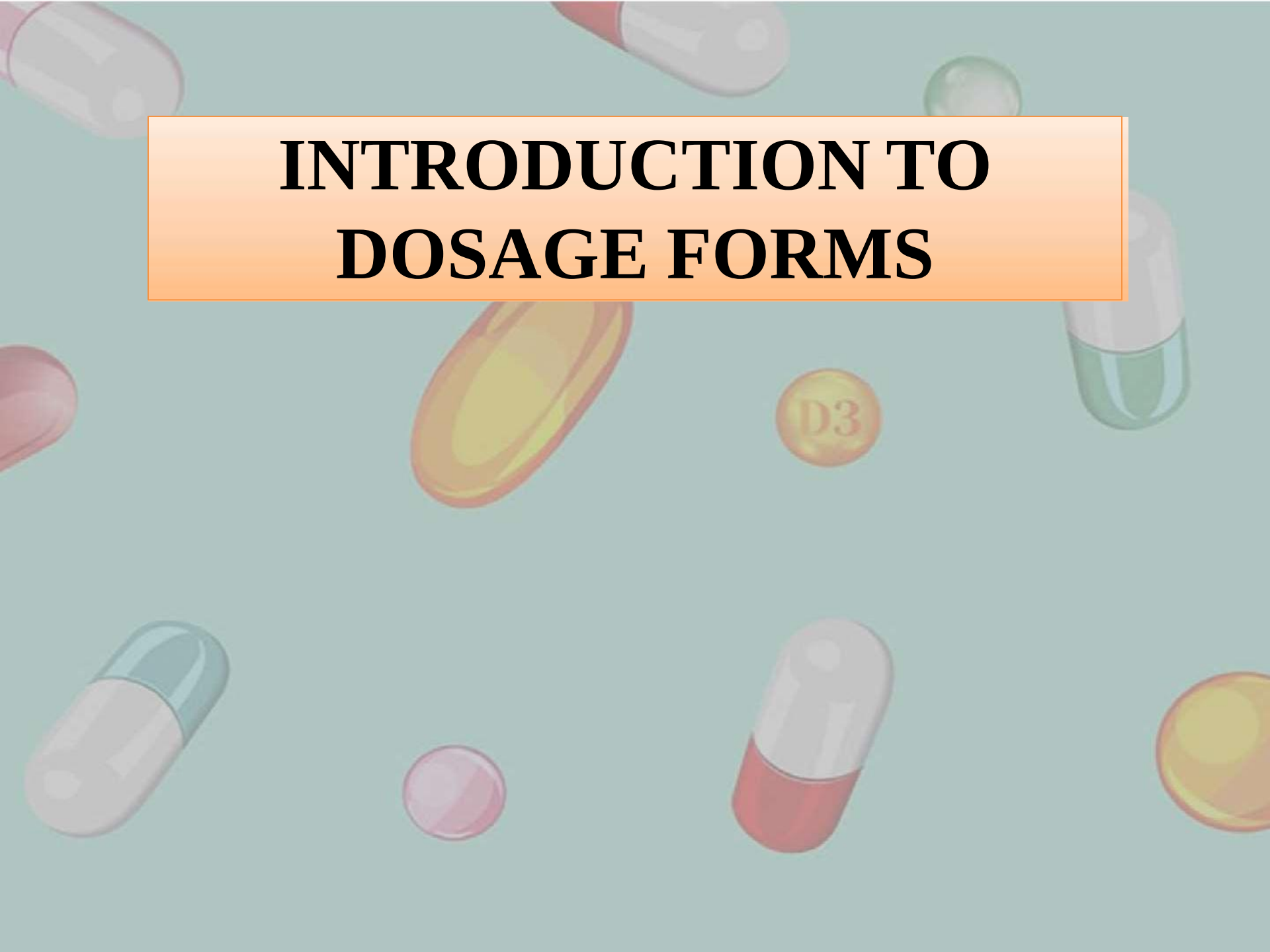


EUROPEAN PHARMACOPEIA



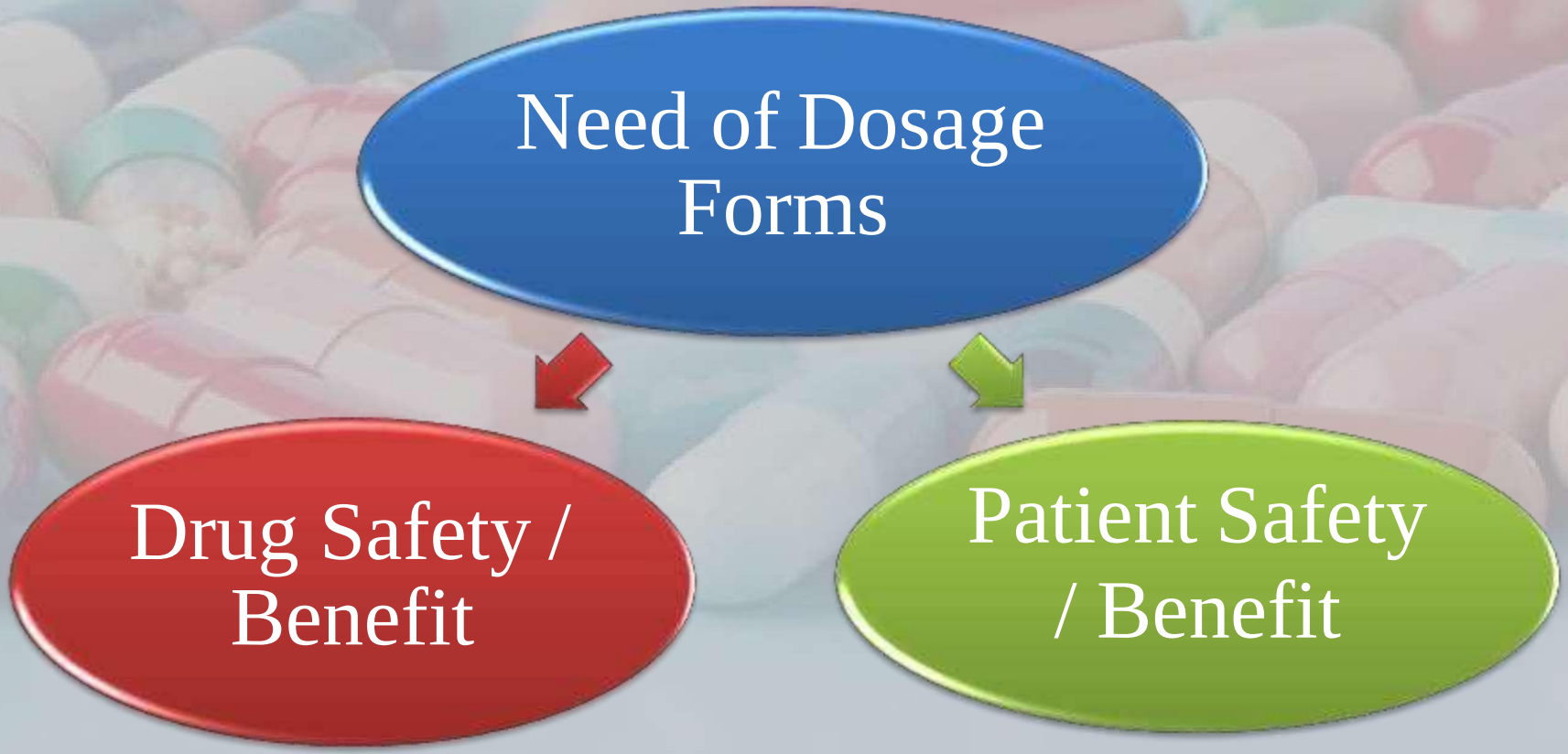
THANK YOU

INTRODUCTION TO DOSAGE FORMS



DOSAGE FORM OF DRUGS

Dosage forms are the means by which drug molecules / APIs are delivered to sites of action within the body to produce optimum desired effects and minimum adverse effect.



NEED OF DOSAGE FORMS

- Provide safe and convenient delivery of accurate dosage.

  Example – Tablets, capsules, syrups

- Protection of a drug substances from atmospheric oxygen or moisture.

  Example – Coated capsules, sealed ampules

- Protection of a drug substances from gastric acid after oral administration.

  Example – Enteric coated tablets

- Conceal bitter taste, or odor of a drug substances.

  Example – Capsules, coated tablets, flavored syrups

- Provide liquid preparation of drug that insoluble or unstable in the desired vehicle. **Example – Suspension**

- Provide liquid dosage forms of substances soluble in desired vehicle.

  Example – Solution

- Provide optional drug action from topical administration sites.

  Example – Ointment, cream, ear and nasal preparations
- Provide for insertion of a drug into one of the body's orifices.

  Example – Rectal and vaginal suppositories
- Provide extended drug action through controlled release mechanisms.

  Example – Controlled release tablets, capsules, suspensions
- Provide for the placement of drugs within body tissues.

  Example – Implants
- Provide for the optimal drug action through inhalation therapy.

  Example – Inhalants

CLASSIFICATION OF DOSAGE FORMS

Based on Route of Administration

- Oral
- Parenteral
- Topical
- Transdermal
- Respiratory/Inhaled
- Ophthalmic
- Rectal
- Veginal
- Otic

Based on Physical Form

- Solid
- Semi-solid
- Liquid
- Gases

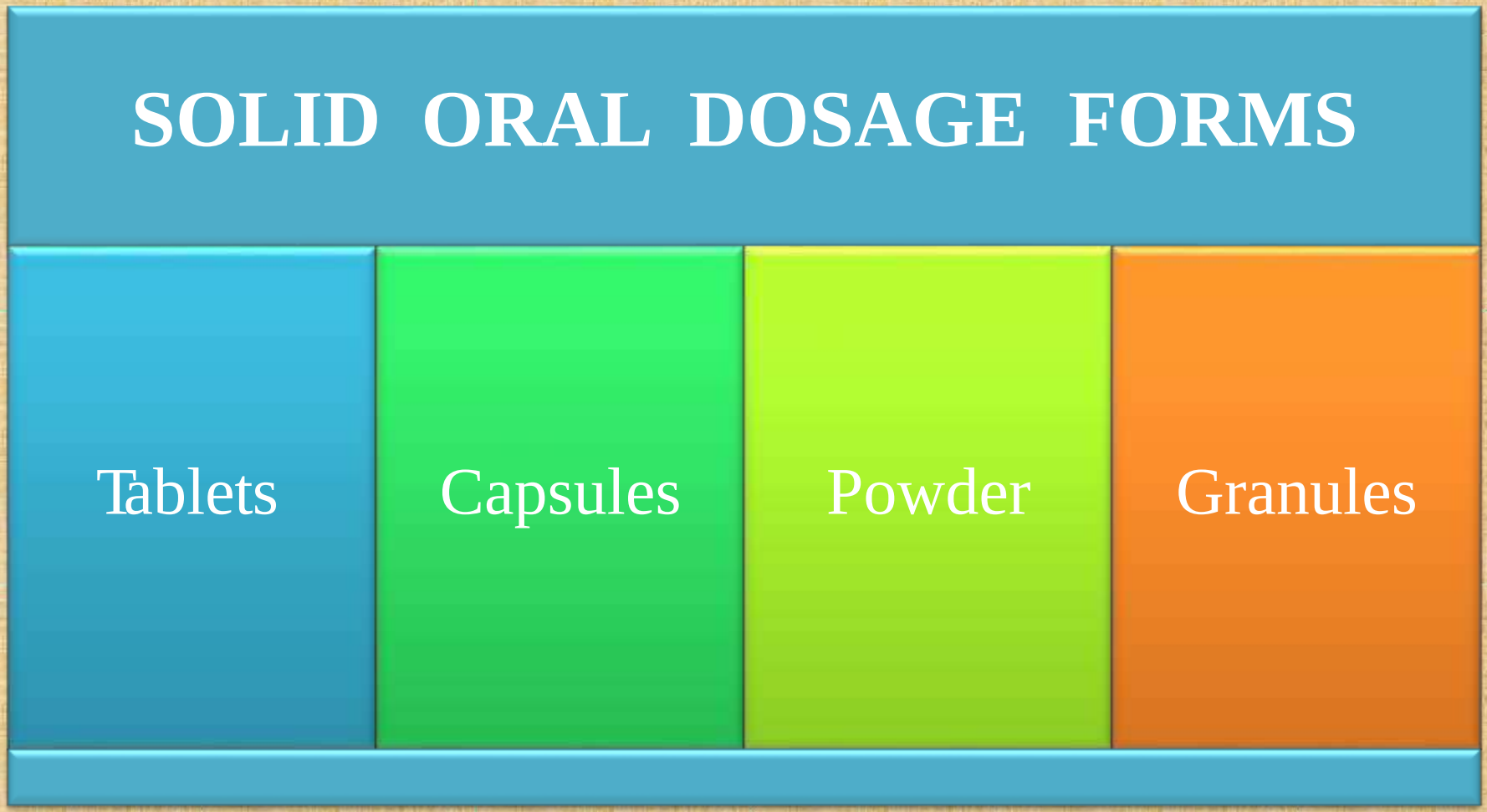
Based on Route of Administration

Enteral Route	
Oral	Tablets, Capsules, Syrups, Suspension, Emulsion etc. Dry Powder Inhaler (DPI), pressurized Metered Dose Inhaler (pMDI) – Nebulizer, Vaporizer
Sub-lingual & Buccal	Orally Disintegrating Tablet (ODT), Lozenges , Chewing tablets, Mouthwash, Toothpaste, Ointment, Oral spray
Rectal & Vaginal	Ointment, Suppository, Enema, Nutrient enema
Parenteral (injections & infusions)	
Intravenous, Intramuscular, Intracardiac, Intraosseous, Intraperitoneal, Intracerebral, Intrathecal, Intradermal, Subcutaneous	
Topical Route	
Dermal	Ointment, Liniment, Paste, Cream, Lotion, Lip balm, Medicated shampoo, Dermal patch
Mucosal	Ear drops, Eye drops, Nasal spray, Ointment, Hydrogel, Nanosphere suspension, Mucoadhesive microdisc (microsphere tablet)
Percutaneous	Transdermal patch etc

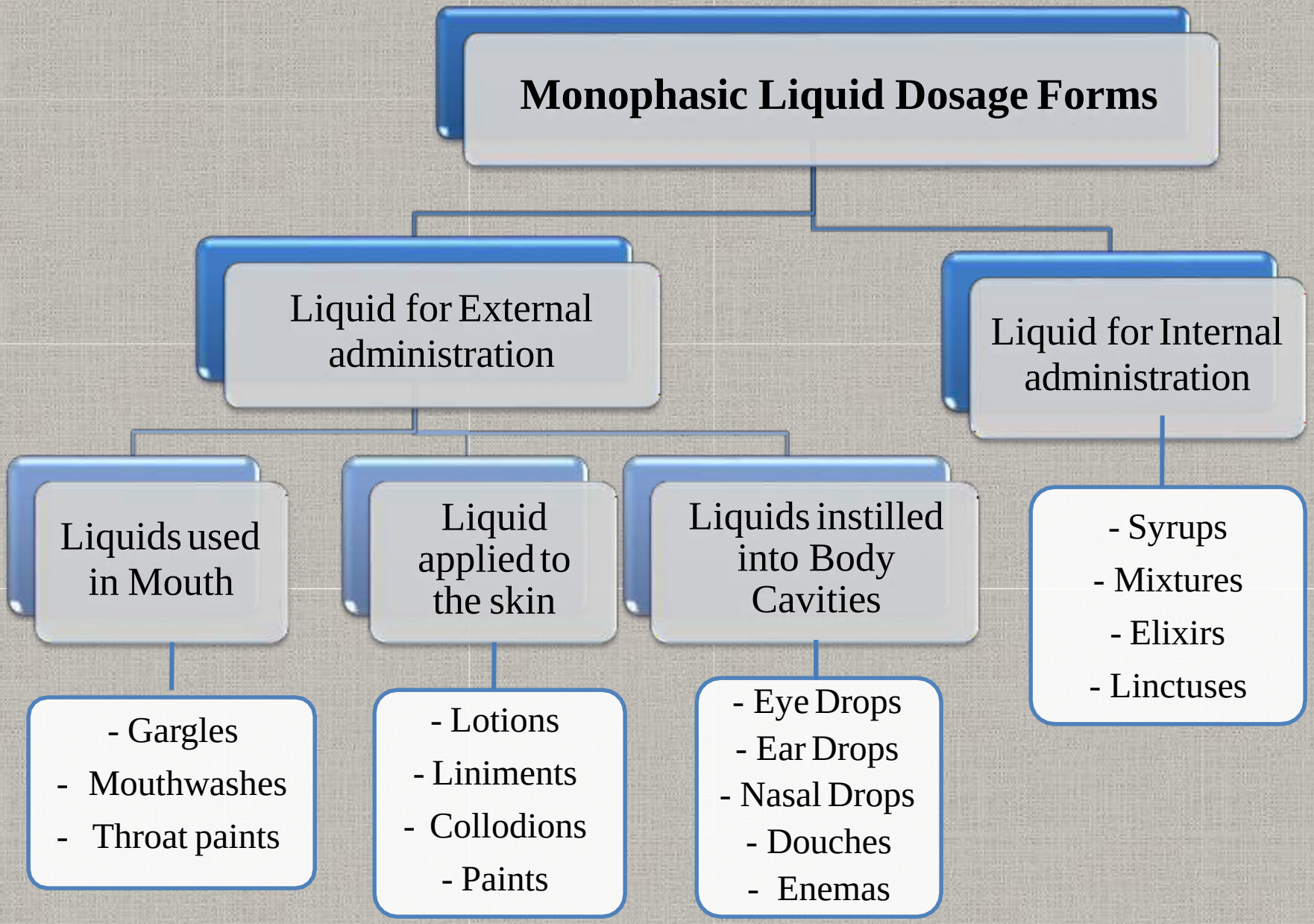
Based on Physical Form

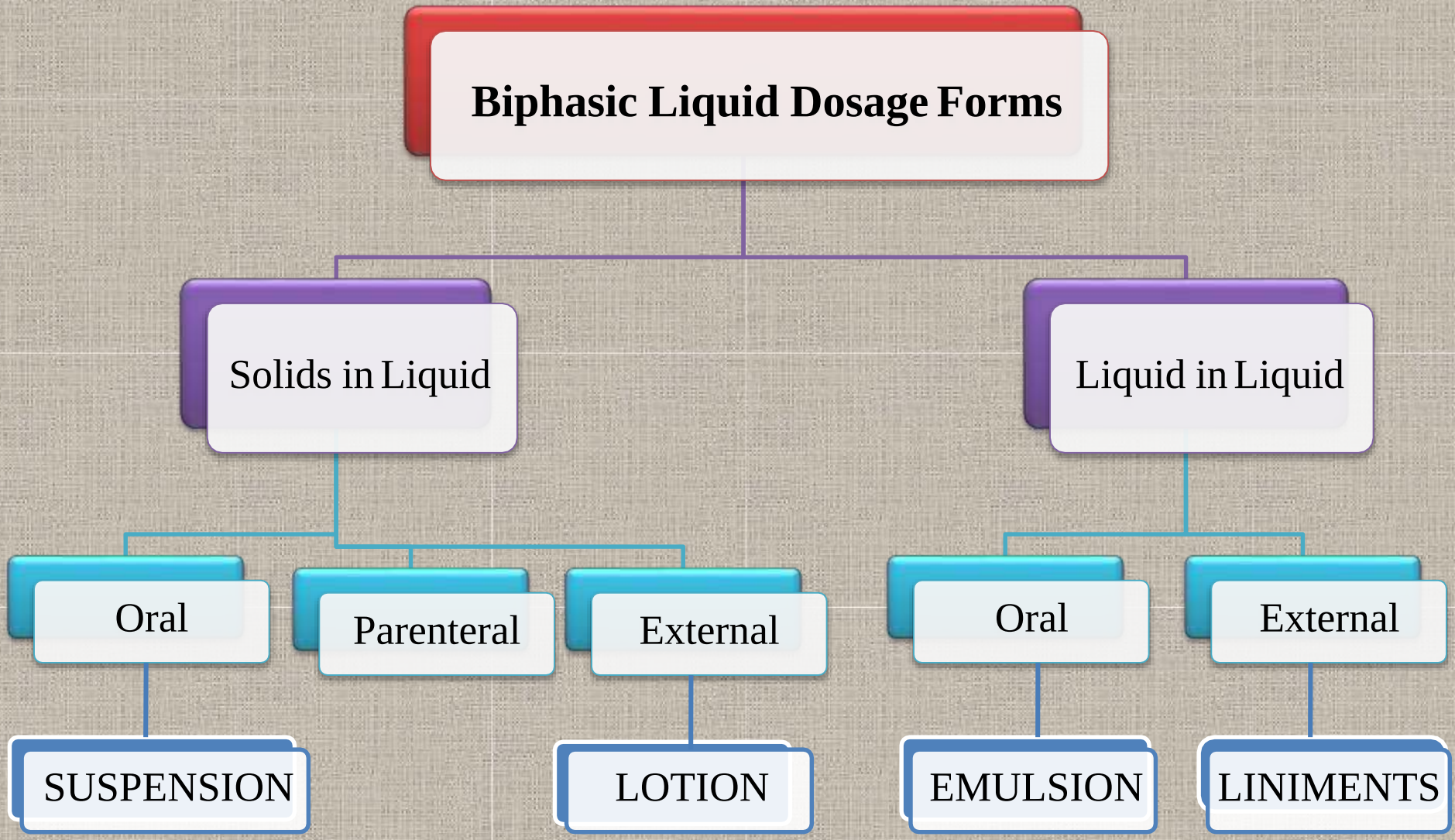
Solid Dosage Forms	
Shaped	Tablets, Capsules, Implants, Transdermal patches
Unshaped	Powders for external/internal use
Semi-solid Dosage Forms	
Shaped	Suppositories (for rectal administration) Pessaries (vaginal suppositories)
Unshaped	Gels, Creams, Ointments, Pastes
Liquid Dosage Forms	
Monophasic	Solutions (syrups, spirits, elixirs, tinctures)
Biphasic	Emulsions, Suspension
External Solutions	Lotions, Liniments, Collodions etc
Gaseous Dosage Forms	
Medicinal Gases	Aerosols: Inhalation/volatile anesthetics
Aerodispersions	Antiasthmatics sprays

CLASSIFICATION OF SOLIDS

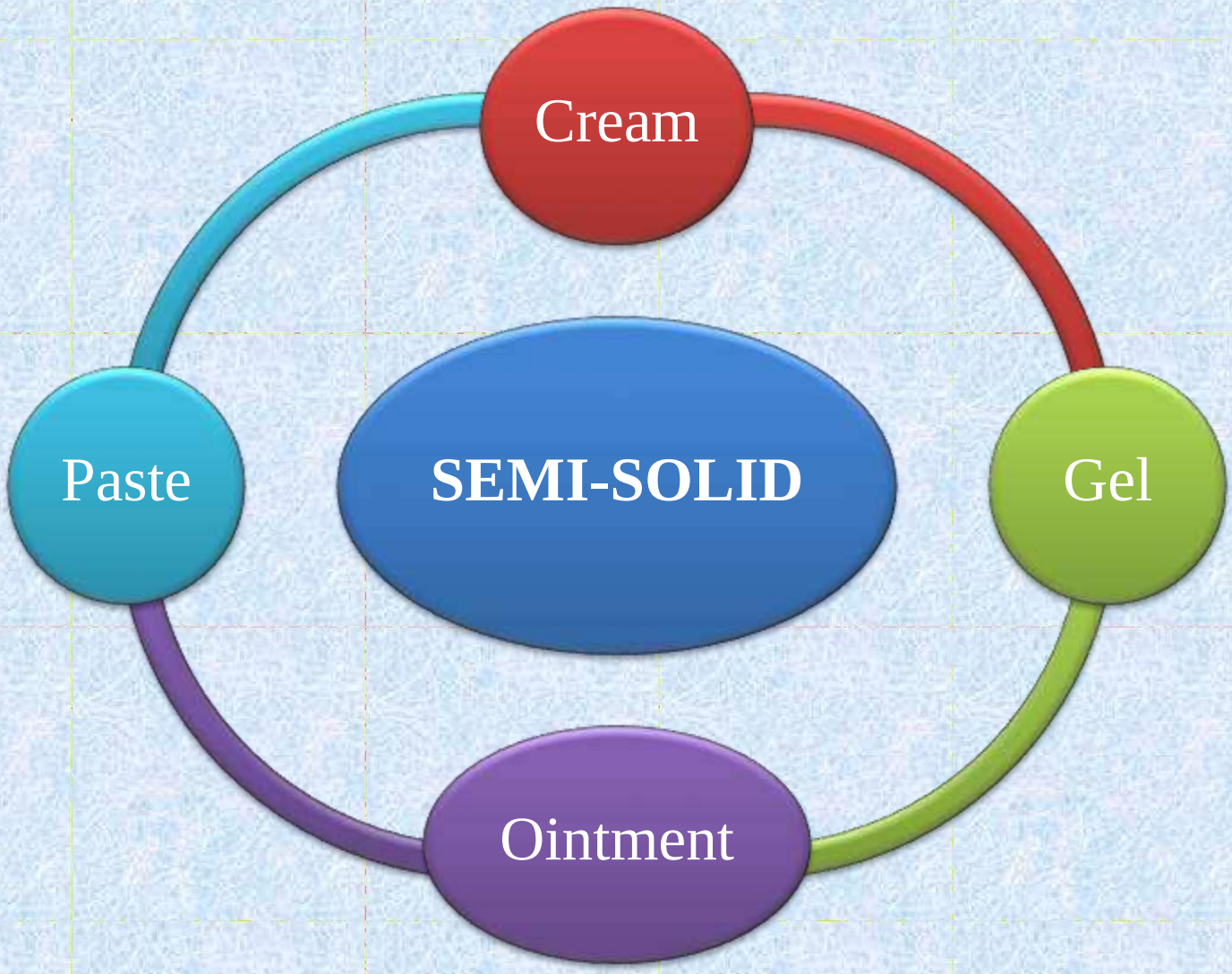


CLASSIFICATION OF LIQUIDS

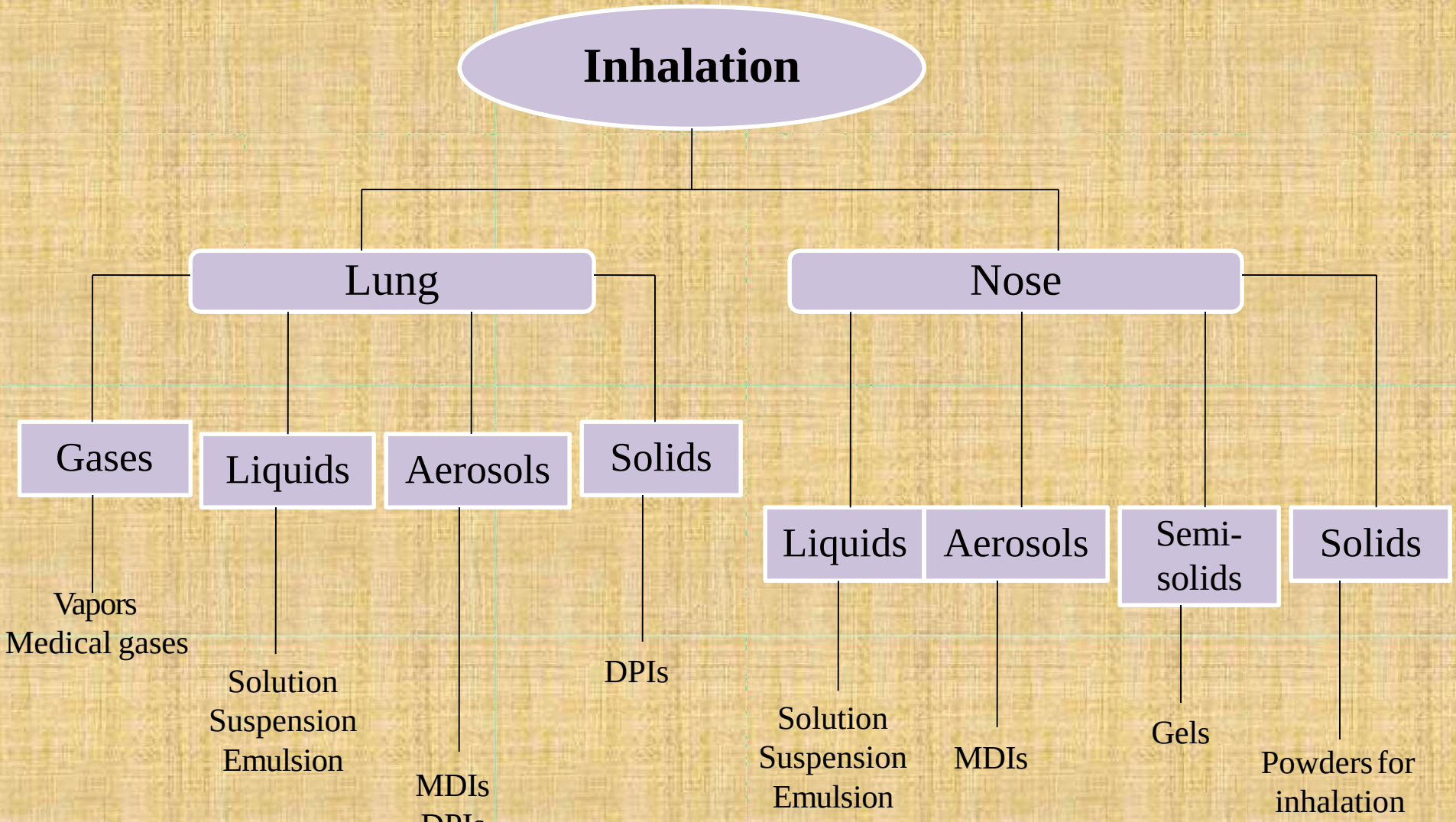



Biphasic Liquid Dosage Forms
Solids in Liquid
Liquid in Liquid
Oral
Parenteral
External
Oral
External
SUSPENSION
LOTION
EMULSION
LINIMENTS

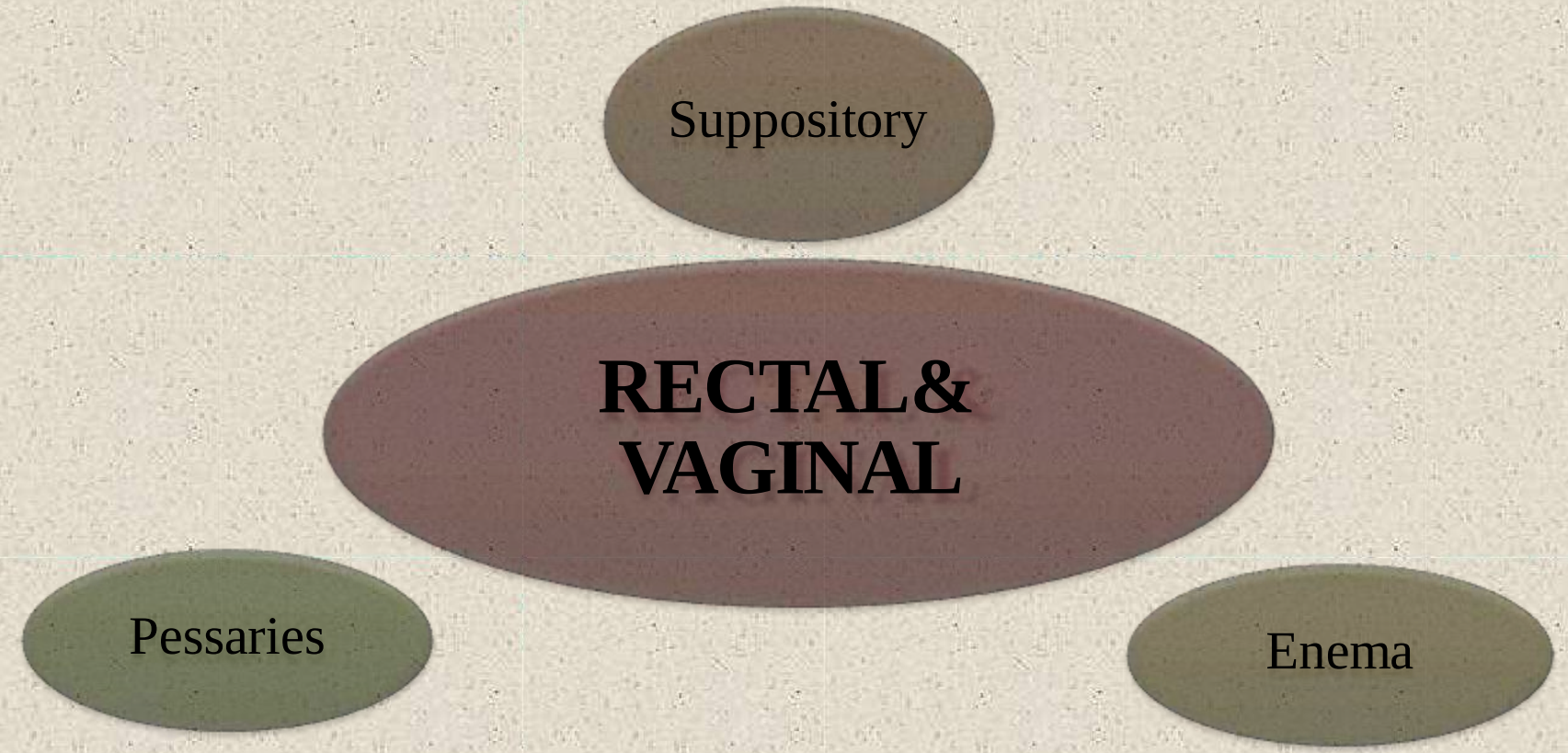
SEMI-SOLID DOSAGE FORMS



INHALED DOSAGE FORMS



RECTAL & VAGINAL DOSAGE FORMS



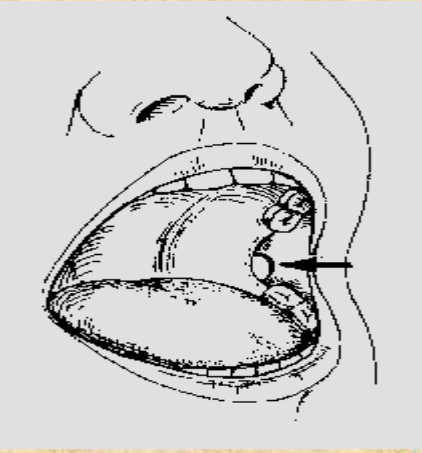
SOLID DOSAGE FORMS

1 -TABLET

- A tablet is unit dose of one or more medicament. Prepare by compression or mould method.
- Common excipients used in tablet are :
  - ✓ **Diluents –** Provide bulkiness of tablet.
  - ✓ **Disintegrants –** To ensure that the tablet breaks up in the digestive tract.
  - ✓ **Binder –** Important for granulation of powder.
  - ✓ **Glidants and Lubricants –** Provide good flow and ensure efficient tabletting.
  - ✓ **Sweeteners and Flavors –** To mask the taste of APIs.
  - ✓ **Pigments –** To mask uncoated tablets visually attractive.
- A coating may be applied to mask taste, smooth tablet for easy swallow, expending shelf life, and prevent gastric degradation of drug.

2 - BUCCAL AND SUBLINGUAL TABLET

- **Buccal tablets** placing between the gum and the cheek.
- **Sublingual tablets** placing under the tongue.
- Medicaments of both systems rapidly dissolve in mouth and absorbed through the mucous membrane of mouth.
- Drug reaches in systemic circulation without affecting by gastric juices and metabolizing enzymes of the liver.
- Examples – **Vasodilators, Steroidal hormones.**



3 - EFFERVESCENT TABLET

- **Effervescent tablets** are uncoated and generally contain acid substances (citric and tartaric acids) and carbonates or bicarbonates , which react rapidly in presence of water and release carbon dioxide.
- They are intended to be dissolved or dispersed in water before use, it provide :
- ✓ Tablet immediately dissolve or dispersed
- ✓ Pleasant taste of carbonated drink

4 - CHEWABLE TABLET

- They are tablets that chewed prior to swallowing.
- They are designed for administration to children e.g. vitamin products.

5 - CAPSULES

- Solid unit dosage form that contain a solid, semi-solid, and liquid fill and a gelatin shell.
- Common excipients used in capsules are :

✓ **Gelatin –** Commonly used as gelling agent.

✓ **Plasticizers –** To ensure elasticity or mechanical stability.

✓ **Additional Additives –** Preservative, coloring and opacifying agents .

- They are mainly two types are :

✓ **Hard gelatin capsules** used for dry powder ingredients.

✓ **Soft gelatin capsules** used for semi-solid and for active ingredients that are dissolved or suspended in oil.

6 - LOZENGE

- It is a solid preparation that used to medicate the mouth and throat for the slow administration of indigestion or cough remedies.
- It consisting of sugar and gum, the latter giving strength and cohesiveness to the lozenge and facilitating slow release of the medicament.

7 - PASTILLES

- It is a solid medicated pill or candy preparation that design to dissolve slowly in the mouth.
- They are softer than lozenge and their base are glycerol, gelatin, acacia and sugar.

8 - DENTAL CONES

- A tablet from intended to be placed in the empty socket following a tooth extraction, for preventing the local multiplication of pathogenic bacteria associated with tooth extractions.
- These tablets contain an excipients like – lactose, sodium bicarbonate, and sodium chloride etc.
- Cones may contain an antibiotic or antiseptic.

9 - PILLS

- It is a solid oral dosage form which consists of spherical masses prepared from one or more APIs with inert excipients.
- Pills are now rarely used.

10 – ORAL GRANULES

- They are consisting of solid, dry aggregates of powder particles with irregular shape often supplied in single-dose sachets.
- Some granules are placed under the tongue and swallowed with water and other are intended to be dissolved in water before taking.
- Effervescent granules evolve carbon dioxide when added to water.

11 – ORAL POWDER

- Bulk Powders are multi dose preparations consisting of solid, loose, dry particles of varying degrees of fineness.
- Contain one or more active ingredients, with or without excipients and, if necessary, coloring matter and flavoring substances.
- Usually contain non-potent medicaments such as antacids since the patient measures a dose by volume using a 5 ml medicine spoon.

LIQUID DOSAGE FORMS

1 – ORAL SOLUTION

- Oral solutions are clear Liquid preparations for oral use containing one or more active ingredients dissolved in a suitable vehicle.

2 – ORAL EMULSION

- Oral emulsions are stabilized oil-in-water dispersions, either or both phases of which may contain dissolved solids either oil is dispersed in finely divided form in water or vice versa.

3 – ORAL SUSPENSION

- Biphasic liquid preparations for oral use containing one or more active ingredients suspended in a suitable vehicle. It sediment which is readily dispersed on shaking to give a uniform suspension which remains sufficiently stable to enable the correct dose to be delivered.

4 – SYRUP

- It is a concentrated aqueous solution of a sugar, usually sucrose to which medicaments are added.
- Flavored syrups are a convenient form of masking disagreeable tastes.

5 – ELIXIR

- It is pleasantly flavored clear liquid oral preparation of potent or nauseous drugs.
- The vehicle may contain a high proportion of ethanol or sucrose together with antimicrobial preservatives which confers the stability of the preparation.

6 – MOUTHWASHES

- These are similar to gargles but are used for oral hygiene and to treat infections of the mouth.

7 – LINCTUSES

- It is viscous, liquid oral preparations that are usually prescribed for the relief of cough. It contain high proportion of syrup and glycerol which have a demulcent effect on the membranes of the throat.
- The dose volume is small (5ml) and, to prolong the demulcent action, they should be taken undiluted.

8 – ORAL DROPS

- Oral drops are liquid preparations for oral use that are intended to be administered in small volumes with the aid of a suitable measuring device.
- They may be solutions, suspensions or emulsions.

9 – GARGLES

- They are prepared in a concentrated solution with directions for the patient to dilute with warm water before use.
- They are aqueous solutions used in the prevention or treatment of throat infections.

10 – LOTIONS

- It is mono-phasic liquid preparations (aqueous) for external application without friction either dabbed on the skin or applied on a suitable dressing and covered with a water proof dressing to reduce evaporation.

11 – NASAL DROPS & SPRAYS

- Drugs in aqueous solution may be instilled into the nose from a dropper or from a plastic squeeze bottle.
- Used for local effect, e.g. antihistamine, decongestant.

11 – COLLODION

- Collodion is a solution of nitro cellulose in ether or acetone, some times with the addition of alcohols.
- As the solvent evaporates, it dries to a celluloid-like film.
- It is highly flammable.
- **Compound Wart Remover** consists of acetic acid and salicylic acid in an acetone collodion base used in treatment of warts by Keratolysis.

12 – PAINTS

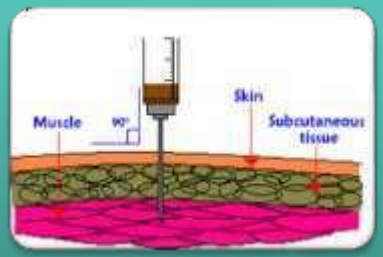
- Paints are mono-phasic liquids for application to the skin or mucous membranes.
- **Skin paints** contain volatile solvent that evaporates quickly to leave a dry resinous film of medicament.
- **Throat paints** are more viscous due to a high content of glycerol that designed to prolong contact of the medicament with the affected site.

PARENTERAL DOSAGE FORMS

An injection is an infusion method of putting liquid in to the body, usually with a hollow needle and a syringe which is pierced through the skin.

Intravenous Injection

- It is a liquid administered directly into the bloodstream via a vein.
- It is advantages when a rapid onset of action is needed.



Intramuscular Injection

- It is the injection of aAPIs directly into a muscle.
- Intramuscular injections are often given in the deltoid, vastus lateralis, ventrogluteal and dorsogluteal muscles.

Subcutaneous Injection

- It is injecting into the subcutis, the layer of skin directly below the dermis and epidermis.
- It is highly effective in administering vaccines and insulin.

SEMI-SOLID DOSAGE FORMS

1 – OINTMENTS

- Ointments are semi-solid, greasy preparations for application to the skin, rectum or nasal mucosa.
- Base is usually anhydrous and immiscible with skin secretions.
- Ointments may be used as emollients or dissolved medicaments to the skin.

2 – GELS

- In gel a liquid phase is constrained with in a 3-D polymeric matrix (consisting of natural or synthetic gum) having a high degree of physical or chemical cross-linking.
- It is used for medication, lubrication and some miscellaneous applications like carrier for spermicidal agents to be used intra vaginally.

3 – CREAMS

Oil-in-water (O/W)

- It composed of small droplets of oil dispersed in a continuous aqueous phase.
- Less greasy and more easily washed off using water.

Water-in-oil (W/O)

- It composed of small droplets of water dispersed in a continuous oily phase.
- More difficult to handle but used for hydrophobic drug preparation.
- Reduces water loss from the stratum corneum maintain moisture of skin.

4 – PASTES

- Pastes are basically ointments into which a high percentage of insoluble solid has been added.
- The extra ordinary amount of particulate matter stiffens the system.
- It provide less heating and penetration than ointment.
- It make good protective barrier when placed on the skin, the solid they contain can absorb and thereby neutralize certain noxious chemicals before they ever reach the skin.

Greasy Pastes	Non-greasy Paste
• Leaser's paste	• Bassorin paste

INHALED DOSAGE FORMS

1 – INHALER

- Inhalers are solutions, suspensions or emulsion of drugs in a mixture of inert propellants.
- Release of a dose of the medicament under pressure in an aerosol dispenser in the form of droplets of 50 um diameter or less from the container through a spring loaded valve incorporating a metering device.
- It is commonly used in the treatment of asthma and other respiratory problems.

2 – NEBULIZER OR ATOMIZER

- It is commonly used in treating asthma, and other respiratory diseases.
- It is a device used to administer medication in forms of a liquid mist to the air ways.
- It pumps air or oxygen through a liquid medicine to turn it into a vapor, which is then inhaled by the patient.
- Generally prefer to inhalers for patients, due to advantages such as:

1- Cheaper

2 More portable

3 Less risk of side effects.

- For that reason, are usually reserved only for serious cases of respiratory disease or severe attacks.

RECTAL & VAGINAL DOSAGE FORMS

1 – SUPPOSITORY

- It is a semi solid medicated mass, usually cone shaped, that is inserted either into the rectum, vagina where it melts at body temperature.

2 – ENEMA

- An enema is the procedure of introducing liquids into the rectum and colon via the anus.

Evacuant Enema	Retention Enema
• Used as a bowel stimulant to treat constipation. • Their volume up to 2 liters. • Warmed to body temperature. • Example - soft soap enema & Magnesium sulphate enema	• Their volume does not exceed 100 ml. • No warming needed. • Example – barium enema & nutrient enema.

3 – PESSARY

- Pessaries are solid medicated preparations designed for insertion into the vagina where they melt or dissolve.

Moulded Pessaries

- Cone shape and prepared by molded method.

Compressed Pessaries

- Prepare by compression as similar manner to oral tablets.
- Available in different shape.

Vaginal Capsules

- Prepare same as soft gelatin capsules and various size and shape.

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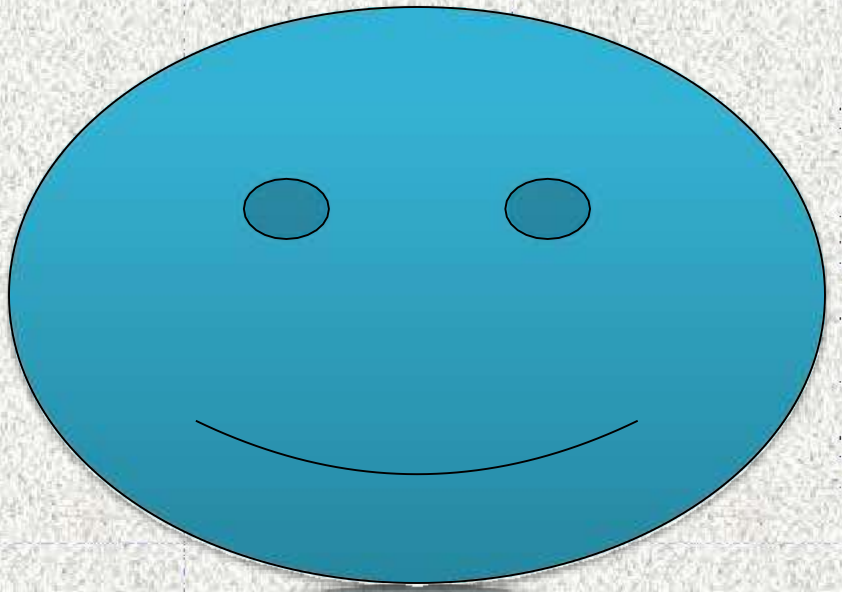
THANK YOU



UNIT I

Historical background and development of profession of pharmacy:

Definition: Pharmacy Greek word of Pharmacy is called (PHARMAKON) Pharmakon means drug or medicine. Pharmacy is defined as the profession which is concerned with the art and science of Identification, Selection, Preparation, Preservation & Standardization of suitable drug substances from natural and synthetic sources and their formulations which are meant for administration for Diagnosis, Prevention, and Treatment of diseases. Therefore, a pharmacist is a "medicine or drug man". While the classes of professionals legally permitted to prescribe medications are physicians, dentists, veterinary doctors and senior registered nurses, pharmacists are required by law to be experts in the preparation, preservation, distribution, and handling of drugs. A health profession that links the health sciences with the chemical sciences, and it is charged with responsibility which ensures the safe and effective use of medication. Hence forth a pharmacist is the right person to look all these aspects because he is educated and trained for this job. They are experts on medication. Prehistoric Medicine links to Spirit World The history of pharmacy is a recognized part of medical practice dating as far back as Sumer times, around 2,000 to 1,500 BC.(It mine BC Befour Christ) In which had list of animal, vegetable and mineral origin that were used in the management of diseases and prescriptions with details of the ingredients used in their compounding. Chinese (2000 BC) – The Chinese believed that diseases resulted from the imbalance in forces acting on humans and animals, thus produced herbal drugs with "spiritual" effects. They were credited to be first users of podophyllum, rhubarb, ginseng,

cinnamon etc. The text Huangdi Neijing listed the basic principles of pharmaceutical drugs in the third century BC. Indian (800 BC) - the Indians art of healing is almost as old as the religion of hindiuism itself. Aurveda attained a state of reverence and is classified as one of the Upa-Vedas- a subsectionattached to the Atharva Veda, it also deals with the diseases, injuries, fertility, sanity and health. The main principle behind life or essence of all life forms was five elements of creation the pancha-maha-bhuta namely the earth, water, fire, air and ether form the basis. Out of these arise the three doshas namely Vata, pitta and kahpa. These three doshas unfortunately have been crudely translated as air, bile and phlegm. The Ayurveda incorporates all forms of lifestyle in therapy. Thus yoga, aroma, mediation, gems, amulets, herbs, diets, astrology, color and surgery etc are used in a comprehensive manner in treating patients. The important contribution was by was Charaka Samhita, Sushruta Samhita, Vaghbata. Separation of pharmacy and medicine: Pharmacy always existed, but not so for pharmacist. A person uses to made diagnosis also provide medicines and he hired assistants to collect herbs for him and make preparation under his supervision known as pharmacopolae but they are not pharmacists. Arabs were of thought that those who prepare medicines could do as independent profession. The first pharmacy scope was opened in a Baghad in 770 under Calip Al- Mansoer. Pharmacists don't have much that time knowledge of drug this situation was changed by Al Mamoen who ruled Baghad from 813 to 833 and pharmacist started acquiring professional education. The profession of pharmacy was honourable called as Sayadilah (Arabic) and Sandaliin (Latin). They also pharmacy as pharmaceutical terms' (the collection of equipment and methods used in the practice of medicine), for the exchange of ideas as well as of goods between people from India, China and Spain that introduced many new drugs in the field of medicine. Arabs develop number of new drug

delivery forms such as syrups, pellets, preserves, confections, marmalades. History of pharmacy profession in India: Pharmacy practice includes traditional practice of compounding and dispensing of medications. History of pharmacy profession in India can be divided in to three parts

1. Ancient history

2. Pre-independence

3. Post –independence

Ancient Pharmacy Profession: In India the source of drugs were of vegetables, animal and mineral origin. They were prepared empirically by few experienced persons. Knowledge of that medical system was usually kept secret within a family. There were no scientific metods of standardization of drugs. The Ayurveda work on internal medicine whereas Sushrute-Samhita deals with surgical medicine. Charaka and Sushruta were physicians and pharmacists who studied more than 1000 herbs. In Tamil Nadu during 900 AD (AD mins Anno Domini/ Common Era) discovered organized practice of hospital activity for the treatment of patients with diseases. India, being rich in flora and fauna, wide variety of herb was mainly used to treat disease like jaundice, haemorrhage etc. British traders brought the practice of allopathic system to India in 15th century. The Indian system of medicine declined during the Muslim rule while the Arabic or the Unani-Tibbi system flourished. Pre-independence Pharmacy Profession: The first chemist shop was opened by Scotch Bathgate at Calcutta in 1811. The pharmacy activities were performed according to London Pharmacopoeia. This situation forced back traditional practice in IndiA and compelled to import drugs from European countries.

¬ 1840- Goa medical college was started at Panjim

¬ 1841- Bengal Dispensatory and Pharmacopoeia was published ¬ 1870- The Madras Medical College were first to train the students to gain skills in pharmacy practice

¬ 1878- The Opium Act was implemented the dealt with cultivation of poppy and the manufacture, transport, export, import and sale of opium

¬ 1889- Indian Merchandise Act was implemented to avoid misbranding of goods in general

¬ 1894- Indian Traiff Act passed for levy of customs duty on goods including foods, drinks, drugs, chemicals and medicines import to India or export

¬ 1909- Bengal Excise Act was implemented Pharmaceutical Education: Pharmacy education in India traditionally has been industry and product oriented.

In contrast to the situation in developed nations, graduate pharmacists prefer placements in the pharmaceutical industry. To practice as a pharmacist in India, one needs at least a diploma in pharmacy, which is awarded after only 2 years and 3 months of pharmacy studies. These diploma-trained pharmacists are the mainstay of pharmacy practice. The pharmacy practice curriculum has not received much attention. In India, there have been number of institutions offering pharmacy degrees at various levels and a practice-based doctor of pharmacy (Pharm D) degree program was started in some private institutions in 2008. However, relatively little information has been published describing the current status of complex pharmacy education of India. D Pharm Program: In India, higher secondary study is concluded by a terminal examination, the higher secondary examination, at the end of 12 years. Admission to the first year D Pharm program in any government college is based on performance on the higher

secondary examination. However, private colleges have their own admission procedures that comply with the education regulations of the PCI. Students generally may choose to undertake the D Pharm program as their second or third choice, having been unable to obtain a place at the college in another degree program that was their first choice. The D Pharm curriculum is framed through the education regulations of the Pharmacy Act. The present education regulations framed way back in 1991 (ER91). The curriculum is the same throughout the country. In the 1990s, the efforts of the pharmacy council of India for upgrading the minimum qualification for registration from D Pharm to B Pharm failed due to lack of consensus.12 B Pharm Program: Admission to the first-year B Pharm program is made directly from higher secondary school on the basis of marks obtained in the higher secondary examination or on the basis of a merit list rank prepared based on scores on an entrance examination administered by a state or individual institution. Administering an entrance examination as an admissions requirement is used mainly by public institutions. For example, admission to the first-year B Pharm of Banaras Hindu University (BHU) is made through the joint entrance examination (JEE) conducted by Indian Institutions of Technology (IITs), a group of 13 autonomous engineering and technology oriented public institutes of higher education established and declared as institutes of national importance by the government of India. M Pharm Program: The criterion for entry to an M Pharm program is academic performance in the B Pharm or an entrance test or both. Currently, there is more demand for the M Pharm program than the availability of places in the country. An important criterion, a high Graduate Aptitude Test for Engineering (GATE) score, qualifies a student to receive government scholarship during the period of their M Pharm study. This criterion is optional for admission to the first-year M Pharm program. However, many

public institutions require both past academic performance and GATE score for application to the M Pharm program. Pharm D Program: Admission to a Pharm D degree program is on the basis of successful completion of the higher secondary examination or the D Pharm program. Passing the higher secondary examination with physics, chemistry, and biology or mathematics entitles a student to enter the Pharm D program. B Pharm degree holders can join the Pharm D program in the fourth year.

Pharmacy education in India is regulated by 2 organizations: the Pharmacy Council of India (PCI), under the Pharmacy Act of 1948, and the All India Council for Technical Education (AICTE), which was established under the AICTE Act of 1987. As mentioned previously, the PCI makes regulations regarding the minimum standard of education required for qualification as a pharmacist. It is responsible for registration of persons fulfilling the prescribed eligibility criteria (minimum D Pharm) and issuing a license permitting them to practice in an Indian state. Registration activity is decentralized and the state pharmacy councils are responsible for registering pharmacists in their respective states. Thus, the PCI regulates the D Pharm program and the recently introduced Pharm D program. The B Pharm program needs to be recognized by the PCI for the qualifications to be accepted for registration purpose only. The PCI has no jurisdiction over M Pharm and other higher-level degree programs. Indian Pharmaceutical Industry: In 1930, in Calcutta the first pharmaceutical company called Bengal Chemicals and Pharmaceutical Works, which still is today as one of 5 government-owned drug manufacturers was started The history of Indian pharmaceutical market in 1970s was almost non- existent. Today, India has gained immense importance and carved a niche for itself in the pharmaceutical domain. In fact, it has emerged as a big mart for the pharmaceutical industry. Formulations, bulk drugs, generics, Novel Drug

Delivery Systems, New Chemical Entities, or Biotechnology, etc. Indian companies are dominating in the marketplace which was traditionally manned by MNC.

INTRODUCTION TO DOSAGE FORMS

Dosage forms are the means by which drug molecules / APIs are delivered to sites of action within the body to produce optimum desired effects and minimum adverse effect.

NEED OF DOSAGE FORMS

- Provide safe and convenient delivery of accurate dosage. **Example – Tablets, capsules, syrups**
- Protection of a drug substances from atmospheric oxygen or moisture. **Example – Coated capsules, sealed ampules**
- Protection of a drug substances from gastric acid after oral administration. **Example – Enteric coated tablets**
- Conceal bitter taste, or odor of a drug substances. **Example – Capsules, coated tablets, flavored syrups**
- Provide liquid preparation of drug that insoluble or unstable in the desired vehicle. **Example – Suspension**
- Provide liquid dosage forms of substances soluble in desired vehicle. **Example – Solution**
- Provide optional drug action from topical administration sites. **Example – Ointment, cream, ear and nasal preparations**
- Provide for insertion of a drug into one of the body's orifices. **Example – Rectal and vaginal suppositories**

- Provide extended drug action through controlled release mechanisms. **Example – Controlled release tablets, capsules, suspensions**
- Provide for the placement of drugs within body tissues. **Example – Implants**
- Provide for the optimal drug action through inhalation therapy. **Example – Inhalants**

CLASSIFICATION OF DOSAGE FORMS

Based on Route of Administration

- Oral
- Parenteral
- Topical
- Transdermal
- Respiratory/Inhaled
- Ophthalmic
- Rectal
- Vaginal
- Otic

Based on physical form

- Solid
- Semisolid
- Liquid
- Gases

Based on Route of Administration

Enteral Route	
Oral	Tablets, Capsules, Syrups, Suspension, Emulsion etc. Dry Powder Inhaler (DPI), pressurized Metered Dose Inhaler (pMDI) – Nebulizer, Vaporizer
Sub-lingual & Buccal	Orally Disintegrating Tablet (ODT), Lozenges , Chewing tablets, Mouthwash, Toothpaste, Ointment, Oral spray
Rectal & Vaginal	Ointment, Suppository, Enema, Nutrient enema
Parenteral (injections & infusions)	
Intravenous, Intramuscular, Intracardiac, Intraosseous, Intraperitoneal, Intracerebral, Intrathecal, Intradermal, Subcutaneous	
Topical Route	
Dermal	Ointment, Liniment, Paste, Cream, Lotion, Lip balm, Medicated shampoo, Dermal patch
Mucosal	Ear drops, Eye drops, Nasal spray, Ointment, Hydrogel, Nanosphere suspension, Mucoadhesive microdisc (microsphere tablet)
Percutaneous	Transdermal patch etc

Based on Physical Form

Solid Dosage Forms	
Shaped	Tablets, Capsules, Implants, Transdermal patches
Unshaped	Powders for external/internal use
Semi-solid Dosage Forms	
Shaped	Suppositories (for rectal administration) Pessaries (vaginal suppositories)
Unshaped	Gels, Creams, Ointments, Pastes
Liquid Dosage Forms	
Monophasic	Solutions (syrups, spirits, elixirs, tinctures)
Biphasic	Emulsions, Suspension
External Solutions	Lotions, Liniments, Collodions etc
Gaseous Dosage Forms	
Medicinal Gases	Aerosols: Inhalation/volatile anesthetics
Aerodispersions	Antiasthmatics sprays

Classification of solids

- Tablet
- Capsules
- Powder
- Granules

Classification of liquids

Monophasic liquid dosage forms:

- Gargles
- Mouthwashes
- Lotions
- Liniments
- Collodions
- Paints
- Throat paints
- Eye Drops
- Ear Drops

- Nasal Drops
- Douches
- Enemas
- Syrups
- Mixtures
- Elixirs
- Linctuses

Biphasic liquid dosage forms

- Suspension
- Lotion
- Emulsion
- Liniment

Semisolid dosage form

- Cream
- Paste
- Gel
- Ointment

Inhaled dosage form

- MDI
- DPI
- MEDICAL GASES
- Powders for inhalation
- Solution, suspension, emulsion

Rectal, vaginal dosage form

- Pessaries
- Suppositories
- Enema

POSOLOGY

Introduction

- Posology: (Derived from the greek words Posos- how much, and logos means science).
- Posology is a branch of medical science which deals with dose or quantity of drugs which can be administered to a patient to get the desired pharmacological action.
- The dose of a drug cannot be fixed rigidly bec. Various factors are responsible i.e age, sex, severity of the disease etc.
- The official doses in pharmacopoeia represent the average range of quty. Suitable for adults which is administered orally within 24 hrs.
- When other routes of administration are followed the relevant appropriate dose is given.

Factors Influencing Dose

1. Age
2. Sex
3. Body weight
4. Route of administration
5. Time of administration
6. Enviourmental factor
7. Emotinal factor
8. Presence of disease
9. Accumulation
10. Additive effect
11. Synergism
12. Antagonism
13. Idiosyncrasy
14. Tolerance
15. Tachyphylaxis
16. Metabolic disturbance

Factors Influencing Dose

- **Age:**

- The pharmacokinetics of many drugs changes with age.
- Newborn infants (pediatric) are abnormally sensitive to certain drugs because of the immature state of their hepatic and renal function by which drugs are inactivated and eliminated from the body. Failure to detoxify and eliminate drugs results in their accumulation in the tissues to a toxic level.
- Whereas, elderly patients are more sensitive to some drug effect e.g. hypnotics which may produce confusion state in them.

Factors Influencing Dose

- **Sex**:

- Women do not always respond to the action of drug in the same manner as it done in men.
- Special care should be taken when drugs are administered during menstruation, pregnancy & lactation.
- The strong purgative eg. Aloes should be avoided during menstruation.
- Similarly the drugs which may stimulate the uterine smooth muscles e.g. drastic purgative, antimalarial drugs, ergot alkaloids are contra indicated during pregnancy.
- Alcohol, barbiturate, narcotic drugs acts on foetus through placenta.
- During lactation, morphine, tetracycline avoided because its affect on babies.

Factors Influencing Dose

- **Body weight:**

- The average dose is mentioned either in terms of mg per kg body weight.

- Another technique used as a total single for an adult weighing between 50-100kg.

- However, the dose expressed in this fashion may not apply in case of obese patients, children & malnourished patients. It should be calculated according to body weight.

Factors Influencing Dose

- **Route of administration:**

- I.V doses of drug are usually smaller than the oral doses, bec…

- Intravenous route this might enhance the chances of drug toxicity.

- The effectiveness of drug formulation is generally controlled by the route of administration.

Factors Influencing Dose

- **Time of administration:**

- The presence of food in the stomach delay the absorption of drug & rapidly absorbed from the empty stomach.

- But it does not mean that much effective when taken during or after meal.

- Iron, arsenic & cod-liver oil should be given after meal & antacid drugs taken before meal.

Factors Influencing Dose

- **Environmental factors:**

- The personality & behavior of a physician may influence the effect of drug especially the drugs which are intended for use in a psychosomatic disorders.
- The females are more emotional than male & required less dose of certain drugs.
- Inert dosage forms called placebos which resemble the actual medicament in the physical properties are known to produce therapeutic benefit in disease like angina pectoris & bronchial asthma.

Factors Influencing Dose

- **Presence of disease:**

- Drugs like barbiturates & chlorpromazine may produce unusually prolonged effect in patient having liver cirrhosis.

- Such as, streptomycin produce toxic effect on these patient their kidney function is not working properly because streptomycin excreted through kidney.

Factors Influencing Dose

- **Accumulation**:

- Some drugs produces the toxic effect if it is repeatedly administered for long time e.g. digitalis, emetine, heavy metals because these drugs excreted slowly.

- This occurs due to accumulative effect of the drug.

Factors Influencing Dose

- **Additive effect:**
  - When two or more drugs administered together is equivalent to sum of their individual pharmacological action, the phenomenon is called as additive effect.
  - E.g ephedrine & aminophylline in the treatment of bronchial ashtma.
- **Synergism:**
  - When desired therapeutic result needed is difficult to achieve with single drug at that time two or more drugs are used in the combination form for increasing their action this phenomenon is called synergism.
  - E.g. procaine & adrenaline combination, increase the duration of action of procaine.

Factors Influencing Dose

- **Antagonism:**

- When the action of one drug is opposed by the other drug on the same physiological system is known as drug antagonism.

- The use of antagonistic response to drugs is valuable in the treatment of poisoning.

- E.g. milk of magnesia is given in acid poisoning where alkaline effect of milk of magnesia neutralise the effect of acid poisoning.

- When adrenaline & acetylcholine are given together, they neutralise the effect of each other due to antagonism because adrenaline is vasoconstrictor & acetylcholine is vasodilator.

Factors Influencing Dose

- **Idiosyncrasy:**
- Idiosyncrasy is also called as allergy.

- An extraordinary response to a drug which is different from its characteristic pharmacological action is called idiosyncrasy.

- E.g. small quty. of aspirin may cause gastric hemorrhage.

- E.g some persons are sensitive to penicillin & sulphonamide because they produce severe toxic effect.

Factors Influencing Dose

- **Tolerance:**

- When an unusually large dose of a drug is required to elicit an affect ordinarily produced by the normal therapeutic dose of the drug, the phenomenon is called as drug tolerance.
- E.g. smokers can tolerate nicotine, alcoholic can tolerate large quantity of alcohol.
- The drug tolerance is of two types:
- True tolerance, which is produced by oral & parenteral administration of the drug.
- Pseudo tolerance, which is produced only to the oral route of administration.

Factors Influencing Dose

- **Tachyphylaxis:**

- When some drugs administered repeatedly at short intervals, the cell receptors get blocked up & pharmacological response to that drug decreased.

- The decreased response cannot be reversed by increasing the dose this phenomenon is called tachyphylaxis or acute tolerance.

- E.g. ephedrine given repeated dose at short intervals in the treatment of bronchial asthma may produce very less response due to tachyphylaxis.

Factors Influencing Dose

- **Metabolic disturbance:**

- Changes in water electrolyte balance & acid base balance, body temperature & other physiological factor may modify the effect of drug.

- E.g. salicylates reduce body temperature in only in case an individual has rise in body temperature. They have no antipyretic effect if the body temperature is normal.

Calculation of Doses

- The dose of a drug given in the pharmacopoeia represents the average max.quty of drugs which can be administered to an adult orally within 24 hrs.

- The doses are also calculated in proportionate to age, body weight & surface area of the patient.

Cont..

- **Dose proportionate to age**: There are number of methods by which the dose for a child can be calculated from the adult dose

1. Young's formula
2. Dilling's Formula
3. Fried's formula
4. Cowling's formula

1. **Young's formula** : This formula used for calculating the dose for children's under 12 years of age.

$$\text{Dose for the child} = \frac{\text{Age in years}}{\text{Age in years} + 12} \times \text{Adult dose}$$

Cont..

2. **Dilling's formula:** This formula is used for calculating the doses for children in between 4 to 20 years. This formula is considered better because it is easier & quick to calculate the dose.

$$\text{Dose for the child} = \frac{\text{Age in years}}{20} \times \text{Adult dose}$$

3. **Fried's Formula** : This formula is used for calculating of dose for infants up to 2 years.

$$\text{Dose for infant's} = \frac{\text{Age in months}}{150} \times \text{Adult dose}$$

Cont..

4. Cowling's formula:

$$\text{Dose for child} = \frac{\text{Age at next birthday (in years)}}{24} \times \text{Adult dose}$$

- **Dose proportionate to body weight:** Clark's formula used to calculate the dose on body weight.

$$\text{Dose for the child} = \frac{\text{Childs weight in Kg}}{70} \times \text{Adult dose}$$

Cont..

- **Dose proportionate to surface area :** In this method dose is calculated accordingly to surface area it's the more satisfactory & appropriate method than based on age method.

$$\text{Percentage of adult dose} = \frac{\text{Surface area of child}}{\text{Surface area of adult}} \times 100$$

or

- **Catzel's formula:**

$$\text{Dose for patient} = \frac{\text{Surface area of patient in } M^2}{1.73\ M^2} \times \text{Adult dose}$$

where, $1.73\ M^2$ = Average adult surface area

Thank you