PHARMACEUTICS



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PHARMACOPIEA

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- Pharmacopoeia is the official book of standards for drugs prepared by any country or regulatory body to specify the standards of identity, purity and strength for the drugs imported, manufactured or distributed throughout the country or a specific region.
- It is a book containing collection of monographs and published by an authorized body like government or Pharmaceutical society.
- The term Pharmacopoeia comes from the Greek word "Pharmakon" meaning drug and "Poieo" meaning make, and the combination means any formula or standards required to make a drug.

- A monograph is a collection of detailed information on a particular drug, its dosage forms and methods of analysis.
- A monograph contains:
- 1. Chemical name
- 2. Formula
- 3. Solubility
- 4. Identification
- 5. pH

- 7. Specific optical rotation
- 8. Loss on Drying
- 9. Sulphated ash
- 10. Dose

6. Assay

Importance of pharmacopoeia

- 1. To maintain the uniformity and control the standards of the drugs available in market.
- 2. Avoid adulterated drugs.
- Complete information on drugs and their dosage forms.
- 4. Reference for laboratory, industry and academic institutions.

Formulary

- Formularies are the list of drugs or collections of formulas for the compounding of medicinal preparations.
- Formularies contains more comprehensive details on therapeutics.
- Collectively these books are known as drug compendia.

Pharmacopoeias + Formularies = Drug Compendia

Drug compendia

- 1. Official compendia
- Official compendia are the compilation of drugs and other substances recognized as legal standards of purity, quality and strength by government agency of respective countries.
- British Pharmacopoeia (BP)
- British Pharmaceutical Codex (BPC)
- United States Pharmacopoeia (USP)
- Indian Pharmacopoeia (IP)
- Japanese pharmacopoeia (JP)

- 2. Non-official compendia
- The books other than official drug compendia which are used as secondary reference sources for drugs and other related substances are known as non-official drug compendia.
- Merck Index
- Martindale (The extra Pharmacopoeia)

Indian Pharmacopoeia (IP)

- Indian Pharmacopoeia is the official book of standards for drugs to define identity, purity and strength for the drugs imported, manufactured for sale, stocked or distributed in India.
- In 1946 Government of India Published Indian Pharmacopoeial List which served as supplement to BP.
- Indian Pharmacopoeia was prepared by Indian Pharmacopoeia Committee formed in 1948.

Indian Pharmacopoeia	Year of Publication	Contents
1st Edition Supplement to 1 st Edition	1955 1960	986 monographs
2nd Edition Supplement to 2 nd Edition	1966 1975	890 monographs
3 rd Edition	1985	 Consists of 2 Volumes IUPAC system of nomenclature Analytical Techniques were included e.g: Electrophoresis, Fluorimetry Instrumental Analysis were included e.g: UV spectroscopy Dissolution of 6 tablets included Limit tests for microbial contamination
Addendum to 3 rd Edition Addendum to 3 rd Edition	1989 1991	

Indian Pharmacopoeia	Year of Publication	Contents
4th Edition Addendum to 4 th Edition Supplement to 4 th Edition Addendum to 4 th Edition Addendum to 4 th Edition	1996 2000 2000 2002 2005	 Consists of 2 Volumes Included 1149 monographs Included new monographs e.g: cream, gels, eye drops Included method of preparation and analytical methods like HPLC Include In Process Quality control Veterinary Products
5th Edition Addendum to 5 th Edition	2007 2008	Consists of 3 Volumes
6 th Edition Addendum to 6 th Edition	2010 2012	Consists of 3 Volumes
7th Edition Addendum to 7 th Edition Addendum to 7 th Edition	2014 2015 2016	Consists of 4 Volumes with DVD

Indian National Formulary

 It is a reliable reference book on drugs formulations for the practicing physicians/clinicians, pharmacists, clinical pharmacists, nurses and others engaged in healthcare profession.

Indian Pharmaceutical Codex 1953

 It is a book containing detailed information on indigenous drugs of India.

British Pharmacopoeia (BP)

- British Pharmacopoeia is the source of official standards of drugs in UK and other parts of the world.
- It was first published by General Medicine Council and was later done by Pharmaceutical Commission.
- Since then Pharmacopoeial commission is reconstituted from time to time and new editions of British Pharmacopoeia are published.

British Pharmacopoeia	Year of Publication	Contents
First Publication	1864	extracts, crude drugs, galenicals a medicine made of natural rather than synthetic components.
14 th Edition	1988	2100 monographs Contains 2 Volumes Volume I: monographs of medicinal and pharmaceutical substances Volume II: formulations, blood products, appendices

It is now published annually and consists of 6 volumes.

British Pharmaceutical Codex (BPC)

- British Pharmaceutical Codex was prepared as a reference book to physicians and dispensing pharmacists in 1907 as per the Council of Pharmaceutical Society.
- Since then subsequent revisions of these books are published.
- The decision of medicine commission stated that there should be only one book of standards of medicine, so BPC was discontinued.
- Later BPC was published as "The Pharmaceutical Codex" and plans to be encyclopedia.

a book or set of books that gives information about very many subjects, arranged in the order of the alphabet

The BPC differs from BP in:

- BPC contains more drugs and preparations.
- It contains additional information on standard of drugs, surgical dressing, pharmaceutical preparations, etc
- It provides action and uses of drugs.
- It contains formula and preparation methods of some other formulations.

British National Formulary (BNF)

- British National Formulary is a source of essential information on drugs and medicines published by pharmaceutical society of Great Britain and British Medical Association.
- Pharmacological classification of drugs are given.
- It includes preparations as per Pharmaceutical forms.
- It provides information about actions, uses, dosage & adverse reactions.

United States Pharmacopoeia (USP)

- The United States Pharmacopoeia and the National Formulary (USP-NF) are recognized as the official compendia and are used as reference books for determining the strength, quality, purity, packaging and labeling of drugs and other related articles.
- First USP was published in 1820 by US Pharmaceutical Convention in English and Latin. It consists of 272 drugs.
- USP contains over 3400 monographs for drug substances and products, together with over 160 general chapters that describe specific procedures to support monograph tests and other information as well.
- USP also contains 16 monographs and 9 general chapters on nutritional supplements.

National Formulary (NF)

- First National Formulary of US was published in 1888 by American Pharmaceutical Association.
- USP and NF was combined as a single book of drug standards as USP-NF.
- USP-NF represents 25th revision of USP & 20th revision of NF official on 2002. From then USP-NF was published annually.
- NF covers over 3800 monographs for excipients and dietary supplements.

International Pharmacopoeia

- The International Pharmacopoeia is published by the WHO and is practically used in developing countries.
- It was prepared to meet the international uniformity and standardization of drugs.
- International Pharmacopoeia was first published in 1951 in multilanguages (English, French, German, Japanese, etc.).

European Pharmacopoeia (Ph. Eur.)

- The European Pharmacopoeia (Ph. Eur.) is the legal document for the standards of drugs and related substance prepared by the Council of Europe.
- European Pharmacopoeia Volume I was published in 1969 as first European Pharmacopoeia.
- It includes more than 2000 specific and general monographs, including various chemical substances, antibiotics, biologicals, vaccines, immunosera, radiopharmaceuticals, herbal drugs and homeopathic preparations.

Japanese Pharmacopoeia (JP)

- Japanese Pharmacopoeia is established and published to regulate the properties and quality of drugs by Ministry of Health, Labour and Welfare of Japan.
- It consists of general notices, rules for crude drugs, rules for preparations, general tests, processes, apparatus and official monographs.
- First published in 1886, JP has been revised many times.

THANK YOU

SUPPOSITORIES

Suppositories are solid dosage form of medicament for insertion into body cavities other than mouth. They may be inserted into rectum, vagina or nasal cavity. The medicament is incorporated into the suppository base and the product is formulated in such a way that they will either melt or dissolve in the body cavity fluid to release the medicament. Suppositories are available in different shapes, sizes and weights. Suppositories are used to produce local, systemic and mechanical action.

ADVANTAGES

(1) These can be easily administered to children, old persons and to unconscious patients who cannot swallow the drug easily.

(2) These are inserted into body cavity to produce local effect of the medicament incorporated in the base.

- (3) These are inserted into the rectum to exert a direct and rapid action on the rectum.
- (4) These are inserted into the rectum to promote evacuation of the bowel.
- (5) Suppositories are unit dosage form of drugs.

(6) These are convenient mode of administration of drugs which irritate gastro-intestinal tract, cause vomiting and destroyed in the acidic pH of the gastric juice of stomach.

(7) Drugs in suppositories are slowly absorbed giving sustained action.

DISADVANTAGES

(1) The irritant drugs can't be administered by this route.

(2) Suppositories cause embarrassment to the patient, when a drug is administered by inserting a suppository into a body cavity.

- (3) The suppositories are required to be stored at low temperature (10° to 20°C). Hence suppositories are required to be stored in a refrigerator, which is costly for poor patients.
- (4) Suppositories cannot be prepared easily.

TYPES OF SUPPOSITORIES

 Rectal suppositories : These are meant for introduction into the rectum for their systemic effect. These are generally made from theo-broma oil and are available in various sizes to meet the needs of infants children and adults. Rectal suppositories are usually available in weight about 1-2 g. They are either cone or torpedo shaped.

2. Vaginal suppositories : These are meant for introduction into the vagina. These suppositories are also known as pessaries and are larger than rectal suppositories. The vaginal suppositories may be conical, rod-shaped or wedge shaped and are usually available in weight about 4-8 g. Vaginal suppositories are mainly used for their local action on the vagina. Nowadays, vaginal tablets and vaginal capsules are also available which has substituted the vaginal suppositories.

3. Nasal suppositories : These are meant for introduction into the nasal cavity and are also known as nasal bougies. These are similar to urethral suppositories. These are thin and cylindrical in shape and are always prepared with glycero-gelatin base. Nasal suppositories are about 9-10 cm long and weigh about 1.0 g.

4. Urethral suppositories : These are meant for introduction into the urethra and are also known as urethral bougies. These are thin, long and cylindrical forms rounded at one end to facilitate insertion. Their weight varies from 2 to 4 g. These suppositories are very rarely used.

5. Ear cones : These are meant for introduction into the ear and are also known as aurinaria. Nowadays, these are rarely used. These suppositories arc thin, long and cylindrical in shape and weigh about I gram. Ear cones are usually prepared with the obroma oil.

SUPPOSITORY BASES

The various types of suppositories bases are used to prepare suppositories, so that they can retain its shape, and firmness during storage and administration. They should melt or dissolve in body cavity fluids, when inserted into the body cavity. An ideal suppository base should have the following properties:—

- 1. It should melt at body temperature or dissolve or disperse in body fluids.
- 2. It should keep its shape when being handled.
- 3. It should release the medicament readily.
- 4. It should be non-toxic and non-irritant to the mucous membrane.
- 5. It should be stable on storage.
- 6. It should be compatible with large number of drugs.
- 7. It should be stable if heated above its melting point.
- 8. It should be easily molded and it should not adhere to the mould.
- 9. It should be good in appearance.
- 10. It should be easily moldable by pouring or cold compression \setminus

CLASSIFICATION OF SUPPOSITORY BASES

Suppository bases can be broadly classified into three categories:—

- 1. Fatty bases
- 2. Water soluble and water miscible bases
- 3. Emulsifying bases

1. Fatty Bases

(i) **Theobroma oil** : It is a yellowish white solid obtained from crushed and roasted seeds of theobroma cocoa. It is also known as cocoa butter. It has butter like consistency having melting point of 30-35°C. It is a mixture of glyceryl esters of stearic, oleic, palmitic and other fatty acids.

Theobroma oil melts at body temperature and release the medicament for rapid absorption. It is considered a most suitable base for rectal suppositories but not suitable for nasal and urethral because after melting it has a tendency to leak out of the cavities. It is readily liquefy on warming and quickly settle on cooling.

(ii) Emulsified theobroma oil : This may be used as a base when large quantities of aqueous solutions are to be incorporated. The use of 5% glyceryl monostearate, 10% lenette wax, 2-3% cetyl alcohol, 4% beeswax is recommended to prepare emulsified theobroma oil suppositories.

(ii) Hydrogenated oils : These are obtained by hydrogenation of various vegetable oils, such as arachis oil, cotton seed oil, coconut oil, palm oil etc. It is used as a substitute for theobroma oil because it has a number of advantages over theobroma oil.

2. Water Soluble and Water Miscible Bases

(i) Glycero-gelatin base : It is a mixture of glycerin and water which is made stiff by the addition of gelatin. The base may be used for preparing all type of suppositories but it is particularly used for making pessaries.

The suppositories prepared from glycero-gelatin base are translucent, which tend to dissolve or disperse slowly in the body cavity and release the medicament. Glycero-gelatin base is well suited for suppositories containing boric acid, chloral hydrate, bromides, iodides, iodoform, opium etc.

(ii) **Soap-glycerin suppositories :** In glycero-gelatin base, the gelatin is replaced with either curd soap or sodium stearate which makes the base sufficiently hard to prepare good quality of suppositories. Soap also helps in the evacuation action of glycerin.

The main disadvantage of this base is that they are very hygroscopic. Therefore, the suppositories prepared with this base must be protected from atmosphere and wrapped in waxed paper or tin foil.

(iii) **Polyethylene glycols :** Polyethylene glycol polymers are commonly known as carbowaxes or polyglycols or macrogols. The physical character of these carbowaxes varies according to the molecular weight.

The macrogols having molecular weight less than 1000 are liquids and those with molecular weight higher than 1000 are wax like solids.

3. Emulsifying Bases

These are synthetic bases and a number of proprietary synthetic bases are available in the market. Some of these are described as under:—

- (i) Witepsol : The suppositories prepared with witepsol bases should not be cooled rapidly, in order to prevent them from becoming brittle and fracture. The mould should also be properly lubricated to get good qualities of suppositories.
- (ii) Massa estarinum : It is a mixture of mono, di- and triglycerides of saturated fatty acids.
 It is a white, brittle, almost odourless and tasteless solid. It has a m.p. 33.5 to 35.5°C. They are available in various grades but grade B is commonly used in dispensing.
- (iii) Massuppol : It consists of glyceryl esters mainly of lauric acid to which small amount of glyceryl monostearate has been added to improve its water absorbing capacity.

The suppositories arc prepared by any of the following methods:—

- (1) Rolling method
- (2) Hot process or fusion method
- (3) Cold compression method

1. Rolling method

It is an ancient method of preparing the suppositories. The suppository base is rolled and then desired shape is given with the hand. The method is not used nowadays.

2. Hot process or fusion method

This method is commonly used in the preparation of suppositories for dispensing purposes. The suppository base is melted, the medicament is incorporated in it and filled in lubricated mould. On cooling, suppositories are formed which are removed from the suppository mould.

Suppository mould The suppository mould of various types and sizes are available in the market for commercial use. In dispensing, the suppository mould having b-12 cavities, with desired shape and size may be used! These moulds are generally made up of stainless steel, nickel copper alloy. brass, aluminum or plastic.

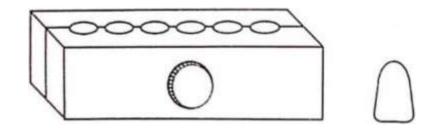


Figure- Dispensing suppository mould

The suppository mould can be opened longitudinally by removing the screw in the centre of the plates. The mould is opened at the lime of cleansing, lubrication and removal of suppositories. The mould is cleaned by removing ihe plates and immersed in hot water containing detergent. After washing with water, the mould is dried thoroughly. Then the lubricant is applied. Every care should be taken, so that the inner surface of the cavities of the mould do not have any scratch, otherwise suppositories with uneven surface will be produced.

Lubrication of mould The lubrication of the suppository mould is essential in case cocoa butter, or glycero-gelatin base is used for the preparation of suppositories. Table shows different types of lubricants used for different types of suppository base.

The lubricant should be applied with the help of a brush or a swab made of gauze. Cotton wool should not he used because the cotton fibers gel detached from it. Excessive lubrication of Ihe mould should be avoided. The excess of lubricant can be drained by closing the mould and put it in the inverted position on a white tile.

3. Cold Compression Method

The method is useful for thermolabile and insoluble drugs because heating and stirring of the base with medicament is not required. The various steps involved in this method are as under:—

(1) Cocoa butter is grated. The ingredients arc mixed with an equal quantity of grated cocoa butter. Add the remaining amount of grated cocoa butter. While calculating the amount of cocoa butter to be incorporated with the medicaments, allowances are made for unavoidable wastage during the preparation.

(2) The compression of the prepared mass is done on hand or power-operated compression machines. The prepared mass is placed in a cylinder 'C' and forced through a narrow opening 'O' by means of a piston 'P' into a mould. The threads of mass passing into mould 'G' are compressed until a homogeneous fused mass is formed. On the removal of retaining stop plate 'S' the suppositories are ejected by further pressure. The operation of the machine is shown diagrammatically in Figure.

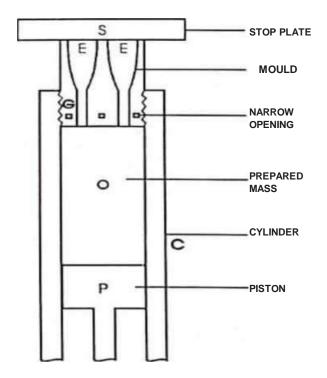


Figure- Cold compression machine for suppositories

"e moulds are of different sizes and contain several cavities. The mass and the compression cylinder of the machine may be chilled to prevent heat of compression from making the mass too fluid.

GENERAL METHOD OF PREPARATION

- (1) Thoroughly clean and lubricate the mould with a suitable lubricant. Keep it on ice in the inverted position to cool and drain an excess of the lubricant. The lubrication of the mould is not required in case the emulsifying base or synthetic base is used.
- (2) Heat the china dish over water bath. To this add the required quantity of cocoa butter or any other base after taking into account the displacement value of the medicament. Allowance is made for unavoidable wastage during preparation by calculating for two extra suppositories.
- (3) Remove the china dish from water bath, when two-third of the base melts and stir thoroughly until whole of the mass melts. The process prevents over heating of the base.
- (4) Place the weighed quantity of powdered medicament to be incorporated with the suppository base on an ointment tile. Pour about half of the melted base over it. Mix it thoroughly with a flexible spatula. Transfer the mixed mass to the china dish and mix thoroughly so that a homogenous mass is formed.

(5) Warm the china dish over water bath for a few seconds with constant stirring, so that mass becomes pourable.

(6) Pour the melted mass into the cavities of the suppository mould, kept over the ice. Fill each cavity to overflowing, in order to prevent the formation of hollows in the tops of the finished suppositories because cocoa butter contracts on cooling and hollows are formed at the lop of the suppositories. The precautions must be taken while pouring the mass into the cavities. It must be continuously stirred to ensure even distribution of the medicament in all the suppositories.

(7) Remove the excess of mass with the help of sharp knife or blade when the mass is properly set.

(8) Keep the mould over ice or in cool place for 10 to 15 minutes.

(9) Open the mould and remove the suppositories.

(10) Wipe off the suppository lightly with a clean cloth or filter paper.

(11) Wrap the individual suppository in a wax paper

BIPHASIC LIQUID DOSAGE FORM SUSPENSIONS

Suspensions are the biphasic liquid dosage form of medicament in which the finely divided solid particles ranging from 0.5 to 5.0 micron are dispersed in a liquid or semisolid vehicle. The solid particles act as disperse phase whereas liquid vehicle acts as the continuous phase. Suspensions are generally taken orally or by parenteral route. They are also used for external applications.

The particle size of the disperse phase is very important in the formulation of suspensions. The suspensions which are meant for external application, should have small particle size to avoid gritty feeling to the skin and to cover a greater area of the application. Moreover, it also helps penetration of solid medicament into the skin because its smaller particle size gives a faster rate of dissolution. The suspensions which are meant for parenteral administration should have a particle size that can pass through the needle. The suspensions which are instilled into the eye, should be free from gritty particles to avoid irritation pain and discomfort. The particle size of the suspended drug particles should not go beyond 10 micron.

QUALITIES OF A GOOD SUSPENSION

- (1) It should settle slowly and should be readily re-dispersed on gentle shaking of the container.
- (2) The suspension should pour readily and evenly from its container.
- (3) It should be chemically inert.
- (4) The suspended particles should not form a cake.
- (5) It should be free from large particles which spoil its appearance.

CLASSIFICATION OF SUSPENSIONS

Suspensions are classified into four main classes according to its pharmaceutical use. These are:— (1) Oral suspensions (2) Parenteral suspensions (3) Ophthalmic suspensions (4)Suspension for external use

1. Oral suspensions : These suspensions are to be consumed by the patient by oral route. Oral suspensions generally contain flavoring agent and sweetening agent to mask the bitter taste of the drug. They are also made palatable by using a suitable derivatives of drugs e.g., chloramphenicol palmitate suspension is prepared to mask the bitter taste of chloramphenicol. Nowadays suspensions are available in the market in dry powder form and these are reconstituted by adding a specified quantity of freshly boiled and cooled water before use e.g., antibiotics in suspension for pediatric use.

2. Parenteral suspensions : The suspensions which are administered by Parenteral route are called parenteral suspensions. These suspensions are required to fulfill the following qualities:—

- (i) The particle size of the drug should be such that it can be easily pass through the needle of the syringe.
- (ii) There should not be any crystal growth in the suspension during its storage.
- (iii) The concentration of solid particles in the suspension should be between 0.5 to 30%.
- (iv) The viscosity of the suspension should not interfere with its flow through the syringe needle.(v)The suspensions should be sterilized.

3. Ophthalmic suspensions : These are not commonly used as compared to eye-drops. These are prepared only in those cases, when the drug is insoluble in the desired solvent or unstable in liquid form. These suspensions must fulfill the following conditions:—

- (i) The particle size of the eye-suspensions should be fine enough so that it should be non-irritating to the eye.
- (ii) The suspensions should be sterilized.
- (iii) These suspension should be isotonic.
- (iv) These should have desired viscosity.
- (v) The suspension should be packed in a suitable container, so that it can be easily instilled into the eye.
- 4. Suspensions for external use : These suspensions are meant for external use. e.g., lotions, ear drops etc. These suspensions contain very small particles to avoid grittiness. Lotion containing suspended particles evaporate when applied to the skin leaving a light deposit of medicament on the surface. Lotions are easier to apply and less messy than many other semi-solid external preparations. Calamine lotion is a suspension type preparation which is applied on the skin to provide protective effect. Lotions which are meant for application on broken or inflamed skin should be free from harmful microorganisms.

FLOCCULATED AND NON-FLOCCULATED SUSPENSIONS

The suspensions are said to be flocculated, when the individual particles are in contact with each other and form a network like structure. Whereas in case of non-flocculated suspensions, the individual particle exists as a separate entity. The following are the differences between flocculated and non-flocculated suspensions as given in Table :—

Sr.No	Flocculated Suspension	Nun-flocculated Suspension
1	Particles form loose aggregates and form a net work like structure.	Particle exist as separate entities
2	The rate of sedimentation is high.	The rate of sedimentation is slow.
3	Sediment is rapidly formed.	Sediment is slowly formed.
4	Sediment is easy to redispersc.	Sediment is difficult to redispersc
5	Sediment is loosely packed and does not form a hard cake.	Sediment is very closely packed and a hard cake is formed.
6	Supernatant liquid is clear.	Supernatant liquid is not clear.
7	The floccules stick to the sides of the bottle.	The floccules do not stick to the sides of the bottle.

Comparison between Flocculated and Non-flocculated Suspensions

FORMULATION OF SUSPENSIONS

Following additives are used in the preparation of suspensions:—

1. Flocculating agents : In suspensions, the solid particles arc well dispersed in dispersion medium i.e., vehicle. The dispersion can be improved by adding a surfactant or protective colloid which acts as flocculating agent. The flocculating agent acts by reducing the surface tension and thereby improving the dispersion of solids and minimize flocculation e.g., sodium lauryl sulphate, tweens, spans and carbowaxes, etc. are commonly used as flocculating agents.

2. Thickening agents : These are hydrophilic colloids which form colloidal dispersions with water and increases the viscosity of the continuous phase, so that the solid particles remain suspended in it for a sufficient long time to measure a uniform accurate dose.

The thickening agents used to stabilise suspensions are classified into three major groups — polysaccharides, inorganic agents and synthetic compounds.

(1) Polysaccharides : Two types of polysaccharides are used nowadays. These are:—

- (a) Natural polysaccharides
- (i) Gum acacia
- (ii) Tragacanth
- (iii) Starch
- (iv) Sodium alginate

(b) Semi synthetic

(i) Methyl cellulose(ii) Sodium carboxy methyl cellulose(iii) Microcrystalline cellulose

(2) Inorganic agents

(i) Clay (ii) Aluminium hydroxide

(3) Synthetic compounds

(i) Carbomer (carboxy vinyl polymer) (ii) Colloidal silicon dioxide

3. Wetting agents : These are the substances which reduce the interfacial tension between the solid particles and liquid medium, thus producing a suspension of required quality. This may be achieved by adding a suitable wetting agent which is adsorbed at the solid/liquid interface in such a way that the affinity of the particles for the surrounding medium is increased and the interparticular forces are decreased. For example, alcohol in tragacanth mucilage, glycerin in sodium alginate or bentonite dispersion and polysorbate in oral and parenteral suspensions.

The excessive use of wetting agent may cause foaming or may give bad taste or odour to the suspension.

4. Preservatives : A suitable preservative is needed to preserve suspensions against bacterial growth. Preservatives selected should be effective against a wide range of microorganism. Benzoic acid, sodium benzoate, methyl paraben and propyl paraben are commonly used as a preservative in suspensions.

5.Organoleptic additives : Colouring agents, sweetening agents and flavouring agents are generally incorporated in oral suspensions. A suitable perfume and colour is incorporated in suspensions which are meant for external use.

STABILITY OF SUSPENSIONS

A stable suspension can be redisperse homogeneously with moderate shaking and can be easily poured throughout its shelf life. The most stable pharmaceutical suspensions are flocculated i.e., the suspended particles are bonded together physically to form a loose, semi-rigid structure. The suspended particles are said to uphold each other while exerting no significant force on the liquid. The sedimented particles of a flocculated suspension can be redispense easily at any time with only moderate shaking.

The non-flocculated suspensions can be made stable by decreasing the particle size of the suspended material or by increasing the density and viscosity of the vehicle.

EVALUATION OF THE STABILITY OF SUSPENSIONS

The following methods are commonly used for evaluating the physical stability of suspension:—

1. Sedimentation method : The measurement of sedimentation volume is the most important parameter in the evaluation of the stability of suspensions. It is determined by keeping a measured volume of the suspension in a graduated cylinder in an undisturbed position for a definite period of time and noted the ultimate height (Hu) of the sediment and initial height of the total suspension. The sedimentation volume F is the ratio of the ultimate height and initial height. (Hu/Ho). The sedimentation volume can be plotted against time. The graph indicates the sedimentation pattern of suspension on storage. A stable suspension shows a horizontal or less steep curve. The evaluation of redispersibility can also be determined by shaking the suspension and again find out the sedimentation volume (Hu/Ho).

2. Micromeritic method : The stability of a suspension depends _{(he} particle size of the dispense phase. The size of the particle in a suspension may grow and may ultimately lead to the formation of lumps or caking. So any change in particle size with reference to time will provide useful information regarding the stability of a suspension. A change in particle size distribution and crystal habit may be studied by microscopy and coulter counter method.

3.Rheological method : The viscosity of the suspension is studied at different time intervals by using a good quality of viscometer. It provides useful information about the stability of suspension.

4. Electrokinetic method : The determination of surface electric charge or zeta potential of suspension is helpful to find out the stability of suspension. (Zeta potential is a physical property which is exhibited by any particle in suspension, macromolecule or material surface)



CAREERS IN PHARMACY

FOR PHARMACIST

Mr.Kishor S.Rathi

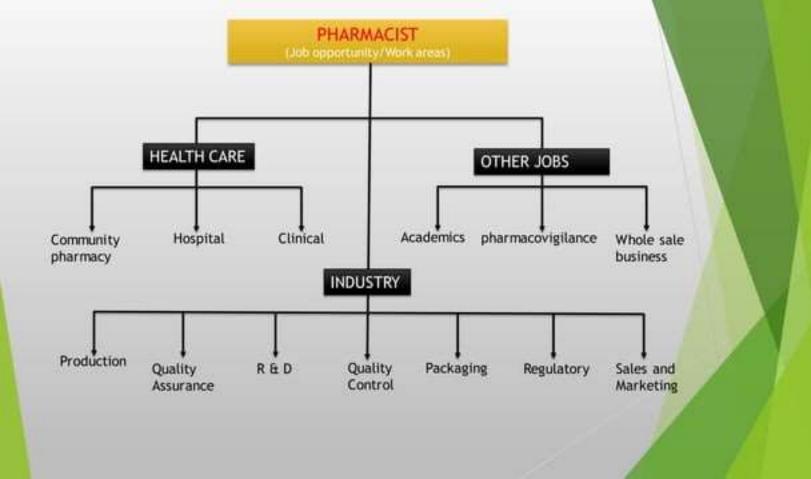
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INTRODUCTION

- Pharmacy is a versatile, dynamic, growing, and increasingly divers profession.
- One which creates an excitement because there are so many opportunities for services. It is an age old profession which has transformed in to hub for "Global healthcare".
- On the other hand unfortunately, in the eyes of the public, the role of pharmacist is
 restricted to merely buying and selling of medicines.







 There are about 5 lakh Pharmacies (Chemist, Druggists and Medical stores) in India in almost every nook and corner of the country. These friendly neighbourhood Pharmacies are doing yeomen service to the nation by providing quick service and medicines to the public through the day and even at hours

Eligibility- B.PHARMA, D.PHARMA both



2. Hospital Pharmacy

Hospital pharmacy is defined as 'practice of pharmacy inside a hospital close to the patient' where nurse and other health care professionals interact with the pharmacists on matters related to medicines, surgical and other patient care items required

Eligibility- B.PHARMA, D.PHARMA both





Clinical pharmacy is the branch of pharmacy in which clinical pharmacists provide direct patient care that optimizes the use of medication and promotes health, wellness, disease prevention.

Eligibility- B.PHARMA, with 3 months additional experience with MBBS doctor.



PHARMACEUTICAL INDUSTRY

1. PRODUCTION

Production/Manufacturing is the process of synthesis of pharmaceutical drug.

Eligibility- B.PHARMA, D.PHARMA both



2. QUALITY ASSURANCE

In this field there are several work for Pharmacist. Such as making BPR, BMR, Data entry and other paper works .

Eligibility- B.PHARMA, D.PHARMA both



3. RESEARCH AND DEVELOPEMENT

In this field we research a new chemical entity or drug for acting against any type of disease.

Eligibility- B.PHARMA, M.PHARMA and PhD.

4. QUALITY CONTROL

In this field Pharmacist perform some chemical test for checking the quality of drugs.

Eligibility- B.PHARMA, D.PHARMA, B.Sc. (chemistry).





5.PACKAGING

We can also do a in packaging area. Here we the process of packaging with product's detail.

Eligibility- B.PHARMA, D.PHARMA both





This the area of pharmaceutical industry where we regulate and maintain all the work industry.

Eligibility- B.PHARMA, M.PHARMA.

7.SALES AND MARKETING

Here pharmacist sales drug directly as well as indirectly through the pharmaceutical industry to the medical and patient.

Eligibility- B.PHARMA, D.PHARMA both



SOME PHARMACEUTICAL COMPANIES

- SUN PHARMACEUTICAL INDUSTRIES LTD (MUMBA!)
- LUPIN MULTINATIONAL PHARMACEUTICAL COMPANY (MUMBAI)
- > Dr. REDDY'S LABs (HYDRABAD)
- > CIPLA MULTINATIONAL COMPANY
- > GLENMARK MULTINATIONAL COMPANY
- > MANKIND MULTINATIONAL COMPANY

OTHER CAREERS

1.ACADEMICS

PHD holder can teach in all pharmacy's courses.
 M. PHARMA holder can teach to B. Pharma and D. Pharma
 B.PHARMA holder can teach to D.Pharma student

2.PHARMACOVIGILANCE

Clinical research and data analysis.
 Eligibility- B.PHARMA, M. PHARMA.





3. WHOLE SALE AND RETAIL SALE BUSINESS

· Medical and whole sale agency of drug

Eligibility- B.PHARMA, D.PHARMA

4. RAILWAY PHARMACIST

· Competitive exam for railway pharmacist

Eligibility- B.PHARMA should be registered.



4. DRUG INSPECTOR

Eligibility- B.PHARMA with 18 month experience in manufacturing or testing of Schedule C or C1 drugs.





INTRODUCTION TO DIFFERENT DOSAGE FORMS





Powered By



(Dept. of Pharmaceutics)

Drug

- Drug may be defined as an agent or substance, intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in human beings or animals.
- Drugs are rarely administered in their original or crude forms. They are administered in different dosage forms by converting them into suitable formulations.



Crude Drugs

Dosage Forms

- Dosage forms are the carrier through which drug molecules are delivered to sites of action within the body.
- Every dosage forms is a combination of the drug and different kinds of non - drug components called as Excipients.
- The Excipients are used to give a particular shape to the formulation, to increase stability, palatability & more elegance to preparations.

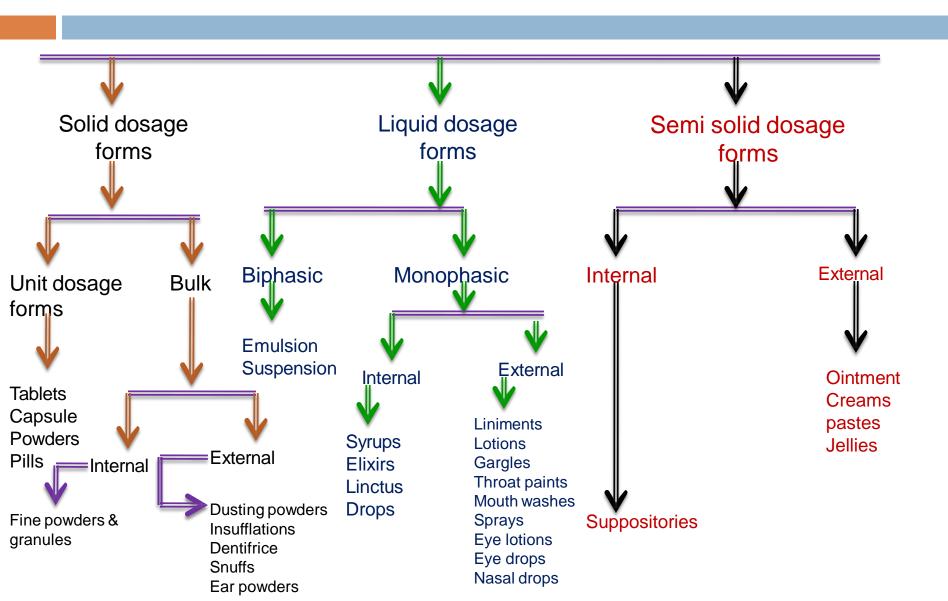
Need For Dosage Forms

Accurate dose.

- Protection e.g. coated tablets, sealed ampules.
- Masking unpleasant taste and odour.
- Provide drugs within body tissues, e.g. injection
- Sustained release medication.
- Insertion of drugs into body cavities (rectal, vaginal)

- Provide optimum drug action through inhalation therapy.
- Provide drug action through topical administration at local area of body. e.g. creams, ointment, emulsion, lotions etc.
- > Use of desired vehicle for insoluble drugs.

Classification



Solid dosage forms

Solid dosage forms



Tablets



Pills



Dusting Powders



Capsules



Granules

- Solid dosage forms one of the oldest dosage forms and most of the solid dosage forms are available in Unit dose.
- Unit dose may be defined as a exact quantity of the drug administered at once. e.g. Tablets, Capsule, pills, powders etc.
- When drugs are to be administered orally in dry state, then tablets, capsules are most convenient dosage forms.
- Some solids are supplied in bulk (Means quantity available in large). Bulk powders can be supplied as Internal (Granules, Fine powders) as well as External (Dusting Powders, Insufflations etc)



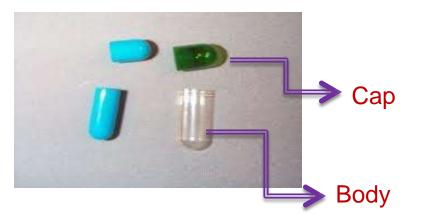
- These are solid dosage forms of medicaments which are prepared by moulding or by compression with or without Excipients.
- The tablets can be prepared by two methods namely as a
 I) Dry granulation, II) Wet Granulation







- Capsules are solid unit dosage forms in which one or more medicaments endosed within a shell.
- Capsules mainly divided in to two parts namely as I) Body (Longest part of capsule shell), II) Cap (Smallest part of capsule shell)
- > The capsule are generally prepared by gelatin.
- Depending on their formulation, two types of gelatin are used namely as - I) Hard gelatin, II) Soft gelatin.









- These are small, rounded solid dosage forms containing medicaments intended for oral use.
- The medicaments are mixed with excipients to forms a firms plastic mass.
- The mass is rolled to uniform pill pipe, which cut into numbers of uniform pills. The pills are spherical in shape & produced by rolling them under wooden pill rounder.
- Sometimes pills are coated to improve finish, unpleasant taste & stability.
- Now a days pills are outdated preparations because of number of disadvantages such as -

Disintegration time of pill is uncertain means freshly prepared pills are disintegrates readily rather than old dried pills.
 It is difficult to prepare pills of uniform size & weight.





Granules

- Granulation is the process in which primary powder particles are made to adhere to form larger multiparticle or large particles entities called granules.
- The bitter, nauseous, unpleasant powders can not be given tablets, capsule due to bulk quantity are required to be taken, as well as they are not given in liquid dosage forms due to their stability such powders are given in the granules forms.
- These powders are mixed with suitable exicipent along with granulating agent, prepare a coherent mass then dried & passed through the sieve to obtained desired size of granules.
- > Eg. Effervescent granules



Effervescent Granules

- > Effervescent granules are meant for internal use.
- They contained medicaments mixed with citric acid, tartaric acid & sodium bi carbonates, sometime saccharin or sucrose may be added for sweetening taste.
- Before, administration desired quantity of granules are dissolved in water, the acid & bicarbonate reacts with each other to produce effervescence.

Dusting Powders

- Dusting powders are applied externally to skin, so they should be applied in very fine state to avoid local irritation. Hence dusting powders should be passed through sieve no 80 to obtained fined powders.
- Dusting powders are prepared by mixing of more than one ingredients in which either starch, kaolin, or talc are used in their formulation. Generally talc or kaolin are used because they are inert in nature.
- Dusting powders are used for antiseptic, astringent, absorbent etc.



Insufflations

- These are medicated dusting powders meant for introduction into body cavities (nose, throat, ear, vagina etc) with the help of an apparatus known as a insufflator.
- It sprays the powders (in a state of fine particles) on site of application.
- Now a days insufflations are also available in pressure aerosols. This pressure aerosols are used for administration of potent drug.
- They are used in the treatment of ear, nose, throat infections with antibiotics to produce local effect of drugs.



- These are finely divided solid dosage forms of medicaments which are inhaled into nostrils.
- They are mainly used for their antiseptic, bronchodilator action.

Liquid dosage forms

Liquid dosage forms











- It may be defined as "A solution is a liquid-preparation that contains one or more soluble chemical substances dissolved in a specified solvent"
- Liquid dosage forms are intended for External, Internal or parenteral use.
- The component of the solution which is present in a large quantity is known as "SOLVENT" where as the component present in small quantity is termed as "SOLUTE"
- They mainly classified in to two category namely as I) Monophasic Liquid dosage forms.
 II) Biphasic liquid dosage forms.
 - II) Biphasic liquid dosage forms.

Advantage

- Immediately available for absorption.
- > Administration convenient, particularly for psychotic patients.
- > Easy to color, flavor & sweeten.
- Liquids are easier to swallow than solids and are therefore particularly acceptable for pediatric patient.
- A solution is an homogeneous system and therefore the drug will be uniformly distributed throughout the preparation.
- Some drugs like aspirin, KCl can irritate gastric mucosa if used orally as a solid dosage forms. But this effect can be reduce by solution system.

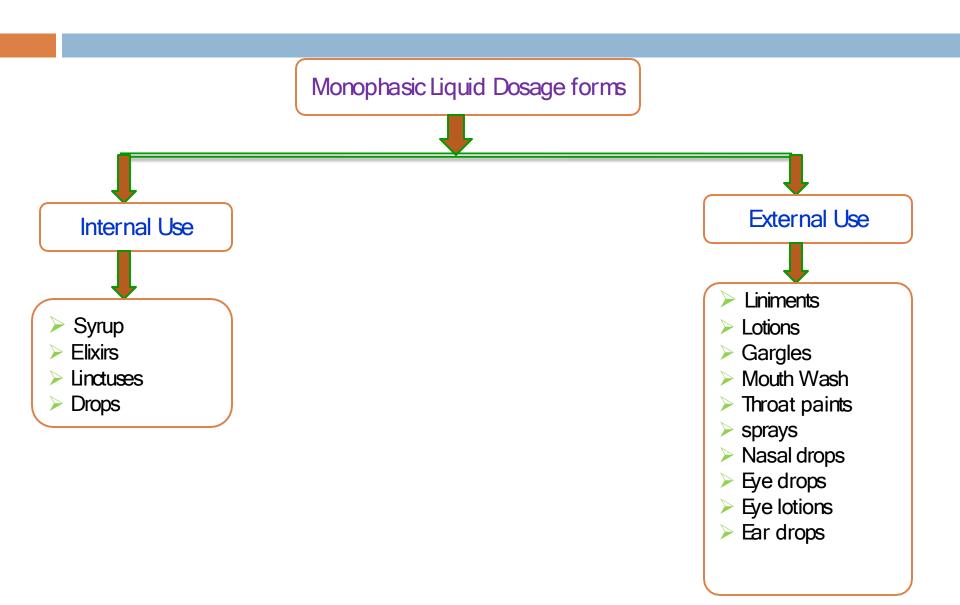
Disadvantage

- > Patients have no accurate measuring device.
- Accident breakage of container results in complete loss.
- Solution often provide suitable media for the growth of micro organisms.
- The taste of a drug, which is often unpleasant, is always more pronounced when in solution than in a solid form.
- > Bulky than tablets or capsule, so difficult to carry transport.

Monophasic liquid dosage forms



- > Monophasic liquid dosage forms are represent by colloidal solution.
- The component of the solution which is present in a large quantity is known as "SOLVENT" where as the component present in small quantity is termed as "SOLUTE".
- In case of colloidal solutions, the solutes are present as aggregates although they cannot be seen by necked eye or ordinary microscope.
- It is sub dassified as -
 - I) Internal Use, II) External use



Monophasic liquid dosage forms for Internal Use





- It is a saturated solutions of sucrose in purified water.
- The concentration of sucrose is 66.7% w/w & due to that it is a viscous preparations.
- The syrup which contains medical substance called as a medicated syrup & those containing aromatic or flavored substance known as a flavored syrup.



- It is clear, sweetened, aromatic, hydroalcholic preparations meant for oral use.
- The medicated elixirs are generally contained potent drug like as antibiotics, antihistamine or sedative, where as non - medicated elixirs contained flavoured.
- The composition of elixirs contained mainly as ethyl alcohol (active ingredients),water, glyœrin or propylene glycol, colouring agent, flavouring agent & preservative.







- These are viscous liquid preparations that's are used for the treatment of cough.
- They contain medicaments which have sedative, expectorant action.
- They are taken in small doses without diluting with water to have prolonged effect of medicines.
- syrup is preferred in certain cases because of its aromatic odour & flavour. Moreover it have a mild expectorant action.





Drops are liquid preparations of drugs, usually in solution, intended to be administered to patients in small doses with the aid of suitable measuring devices (calibrated droppers). Typical drops include eye drops, nose drops and ear drops.



Monophasic liquid dosage forms for External use

Liniments

- Liniments are liquid or semi- liquid preparations meant for external application to the skin.
- They are usually applied to the skin with friction & rubbing of the skin.
- Are usually alcoholic liquid preparations (monophasic)
- Alcoholic liniments are used generally for their counterirritant effects. Such liniments penetrate the skin more readily than do those with an oil base.



Lotions

- Are usually alcoholic or oily liquid preparations.
- They are intended for external application without friction or rubbing to the affected area
- Usually applied with the help of some absorbent material such as cotton wool.
- It is generally used to provide cooling, soothing and protective & antiseptic action.







- Gargles are aqueous solutions used for treating throat infection (pharynx and nasopharynx part)
- Supplied in concentrated forms with directions of dilution with warm water before use
- They are used into intimate contact with the mucous membrane of throat for few seconds, before they are thrown out of the mouth.
- > They are used to relieve soreness in mild throat infection.
- > They are also used for their antiseptics, antibiotics and/or anesthetics



Mouth wash

- These are aqueous solutions with pleasant or acceptable taste & odour
- These are used to make clean & deodorise the buccal cavity or used for oral hygiene and to treat infections of the mouth.
- They mainly contain antibacterial agent, alcohol, glycerin, sweetening agent, flavoring agent & colouring agent.



Throat paints

- Throat paints are viscous liquid preparations used for mouth and throat infections
- Glycerin is commonly used as a base because being viscous it adheres to mucous membrane for long period and it possess a sweet taste.





Nasal drops



- Drugs in solution may be instilled into the nose from a dropper or from a plastic squeeze bottle.
- > The drug may have a local effect, e.g. antihistamine.
- Alternatively the drug may be absorbed through the nasal mucosa to exert a effect.
- The use of oily nasal drops should be avoided because of possible damage to the nasal mucosa & if it is used for long period may reach the lungs & cause pneumonia.



Eye drops

- Sterile, aqueous solutions or suspensions intended for instillation in eye sac.
- Eye drops may contain buffers, stabilizing agents, dispersing agents, solubilising agents, anti-oxidants & agents required for tonicity/ viscosity adjustment
- In case of multi dose container a dropper should be supplied with it for administration. Maximum size of such containers is 10 ml.

Eye lotions

- > These are the aqueous solutions used for washing the eyes.
- These are supplied in concentrated forms & are required to diluted with warm water immediately before use.
- > They should be free from foreign particles to avoids irritation to the eye.
- They are required to prepared fresh & should not be stored for more than two days to avoid microbial contaminations.



Ear drops

- These are the solutions of drugs that are instilled into ear cavity with the help of dropper.
- These are generally used for cleaning the ear & for treating the mild infections.
- The solutions is generally prepared in water, glycerin, propylene glycol & dilute alcohol.





Biphasic liquid dosage forms

Biphasic liquid dosage forms

- The liquid which consist of two phases are known as a biphasic liquid dosage forms.
- > They are sub categorized into two different forms namely as -
 - I) Emulsion
 - II) Suspension
- In emulsion both phases are available in liquid where as in suspension, finely divided solid particles are suspended in liquid medium.



- Emulsion is a biphasic liquid preparations containing two immiscible liquid (Continuous Phase & dispersed phase) made missicible.
- The liquid which is converted into minute globules is called as dispersed phase & the liquid in which the globules are dispersed is called the continuous phase



 An emulsion is a thermodynamically unstable system consisting of at least two immiscible liquid phases one of which is dispersed as globules in the other liquid phase stabilized by a third substance called emulsifying agent.
 The globule size in emulsion varies from 0.25 to 25 µm.

Suspension

- Suspensions are the biphasic liquid dosage forms of medicament in which finely divided solid particles ranging from 0.5 to 5 micron are dispersed in a liquid or semisolid vehicle
- In which solid particles acts as disperse phase where as liquid vehicle acts as continuous phase
- The particle size for non oral suspension is so important to avoid grittiness to skin.





Ideal qualities of good suspension

- It should settle slowly & easily re dispersed on shaking
- > It should readily & evenly pour from container.
- It should be chemically inert.
- It should not forms hard cake.
- > It should prevent degradation of drug or to improve stability of drug.

Semisolid dosage forms

Semisolid dosage forms

- Semisolid dosage forms meant for external application
- Semisolid dosage forms subcategorized are as-
 - I) ointment
 - II) creams
 - III) paste
 - IV) Jellies







Ointment

- Ointment are semisolid preparation meant for application to skin or mucous membrane.
- > The ointments are mainly used for their protective or emollient properties
- It may be defined as a medicament or medicaments dissolved, suspended or emulsified in ointment base.
- There is no single ointment base which possesses all the qualities of ideal ointment base, so it become necessary to use more than one ointment base in the preparation of ointment.



Qualities of ideal ointment base

- It should be inert, odourless & colourless & smooth.
- It should be physically & chemically stable.
- It should be compatible with the skin & with incorporated medicaments.
- It should be of such consistency that it spread & soften when applied to skin with stress.







- These are viscous semisolid emulsions which are meant for external use.
- Cream is divided in to two types namely as

I) Aqueous creams

II) Oily creams



- In case of aqueous creams the emulsions are o/w type & it is relatively non greasy. The emulsifying waxes are used. Generally polysorbate, triethanolamine soap are used as emulsifying agent.
- In case of oily creams w/o type & it is relatively greasy. The emulsifying agent such as wool fat, wool alcohols, beeswax & calcium soap is used.
- The cream should be store in collapsible tube & supplied in well closed container to prevent evaporation & contamination.



- Pastes are semisolid preparations intended for external application to skin.
- > The pastes are generally very thick & stiff.
- They do not melt at ordinary temperature & thus forms a protective coating over the area where they are applied.
- Pastes are differ from ointment as they contain a high proportion of finely powdered medicaments.
- They are mainly used as a antiseptic, protective, soothing dressings.
- Pastes should be stored & supplied in well closed containers







- Jellies are transparent or translucent, non greasy, semi solid preparations mainly used for external application to skin.
- These are also used for lubricating catheters, surgical gloves & rectal thermometer.
- The substance like gelatin, starch, tragacanth, sodium alginate & cellulose derivatives are used for the formulation of jellies.
- Jellies are of three types namely as
- Medicated jellies
- Lubricating jellies





HISTORY OF PHARMACY IN INDIA

0

1947 (Before Independence)

Initially all the drugs were imported from Europe. Later some drugs of this system began to be manufactured in this country.

1901: Establishment of the Bengal Chemical and Pharmaceutical Works, Calcutta by Acharya P.C. Ray.

1903: A small factory at Parel (Bombay) by Prof. T.K. Gujjar.

1907: Alembic Chemical Works at Baroda by Prof. T.K. Gujjar.

Drugs were mostly exported in crude form and imported in finished form. During World War-1 (1914-1920) the imports of drugs were cut-off. Imports of drugs were resumed after the War. In absence of any restrictions on quality of drugs imported. manufacturer abroad took advantage of the situation. The consequences were as follows

(i) foreign manufacturers dumped inferior quality medicines and adulterated drugs.

(ii) Markets were full of all sorts of useless and deleterious drugs were sold by unqualified men.

DRUG INQUIRY COMMITTEE

On 11th August 1930, appointed a committee under the chairmanship of Late Col. R.N.Chopra to see into the problems of Pharmacy in India and recommend the measures to be taken. This committee published its report in 1931. It was reported that there was no recognized specialized profession of Pharmacy. A set of people known as compounders were filling the gap

Just after the publication of the report Prof ML Shroff (Prof Mahadeva Lal Shroff) initiated pharmaceutical education at the university level in the Banaras Hindu University. In 1935 United Province Pharmaceutical Association was established which later converted into Indian Pharmaceutical Association.

The Indian Journal of Pharmacy was started by Prof .M.L. Shroff in 1939. All India Pharmaceutical Congress Association was established in 1940. The Pharmaceutical Conference held its sessions at different places to publicize Pharmacy as a whole

1937: Government of India brought 'Import of Drugs Bill' later it was withdrawn.

1940: Govt. brought 'Drugs Bill to regulate the import manufacture, sale and distribution of drugs in British drug Bill was finally adopted as 'Drugs Act of 1940'

1941: The first Drugs Technical Advisory Board (D.T.A.B.) under this act was constituted. Central Drug Laboratory (CDL) was established in Calcutta. 1945- Drug rule under the Drugs Act 1940 was established.

The Drugs Act has been modified from time to time and at present the provisions of the Act cover Cosmetics and Ayurveda Unani and Homeopathic medicines in some respects

1946: The Indian Pharmacopoeia List was published under the chairmanship of late Col R.N Chopra It contains list of drugs in use in India at that time which were not included in British Pharmacopoeia.

Pharmacy profession after independence section..

In India, formal pharmacy education leading to a degree began with the introduction of a 3-year bachelor of pharmacy (B.Pharm at Banaras Hindu University in 1937)

FATHER OF PHARMACY IN INDIA

The father of Pharmacy in India. Mahadeva Lal Schroff, was born on 6th March 1902 at Darbhanga in Bihar. He was not a trained pharmacist, but he introduced and led pharmaceutical education and pharmaceutical industries towards success in India.

During his time as a professor at Banaras Hindu University Shroff. he struck upon the idea to start a separate branch of pharmaceutical Sciences at BHU for the first time ever in India in 1932. First, he introduced Chemistry as the principal subject in the B.Sc. course. Then, two years later, he proposed an integrated two- year B.Sc course with the subjects Pharma Chemistry, Pharmacy, and Pharmacognosy. It was later turned into a complete three-year B.Pharm course at BHU for the first time in India.

B.pharm course was in 1944 at the Punjab University. The B.pharm course at BHU was industry oriented while that at Punjab University was oriented towards Pharmacy practice.

Though the profession was oriented towards pharmacy practice at the introductory stage but as it grew it became more industry oriented. This bend lead to the development of the modern Indian pharmaceutical industry, which is now the 3" in terms of volume.

Prof Shroff started the M.Pharm education in 1940 at BHU, Slowly pharmacy education started in different places in India. He left BHU in 1943 to join Birla Brothers as the Chief Chemist and Research Officer.

Still, his efforts and interest earned him the position of principal at BITS, Pilani, where he successfully introduced Pharmacy education at a degree level for the next five years.

Before India gained independence in 1947, there were 3 institutions offering pharmacy degree programs (Central University).

1937 -BHU University
1944 – Chandigarh/ Punjab University
1947 - L M College of Pharmacy , Ahmadabad (Private)

After independence, Pharmacy Profession in India

At independence in 1947, India inherited a system for the pharmacy profession from the British rulers that was unorganized and there was no legal restriction on the practice of pharmacy. The concept of pharmacy practice was not realized until after independence was gained. In 1948, the Pharmacy Act 1948 was enacted as the nation's first minimum standard of educational qualification for pharmacy practice to regulate the practice, education, and profession of pharmacy. 1948 - Pharmacy Act 1948 published.

1948: Indian Pharmacopoeia Committee was constituted under the chairmanship of late Dr. B.N. Ghosh.

1949: Pharmacy Council of India (P.C.I.) was established under Pharmacy Act 1948.

1954: Education Regulation have come in force in some states but other states lagged behind.

1954: Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 was passed to stop misleading advertisements (e.g. Cure all pills)

1955: Medicinal and Toilet Preparations (Excise Duties) Act 1955 was introduced to enforce uniform duty for all states for alcohol products.1955: First Edition of Indian Pharmacopoeia was published.

DPCO: The DPCO (DRUGS (PRICES CONTROL) ORDER) was first passed in 1966 and then revised in 1970, 1979, 1987, 1995 & 2013 (Issued under the "Essential Commodities Act, 1955")

1985: Narcotic and Psychotropic Substances Act has been enacted to protect society from the dangers of addictive drug.

Currently, one needs at least a diploma in pharmacy to practice as a pharmacist. Provisions of the Act are implemented through the Pharmacy Council of India. The Act requires individual states to establish state pharmacy councils that are responsible for controlling and registering pharmacists in their respective states.

EDUCATIONAL PROGRAMS/COURSES IN INDIA

A variety of pharmacy degree programs are offered in India: diploma in pharmacy (D Pharm), bachelor of pharmacy (B Pharm). master of pharmacy (M Pharm), master of science in pharmacy [MS(Pharm)] and master of technology in pharmacy [M Tech (Pharm)), doctor of pharmacy (Pharm D), and doctor of philosophy in pharmacy (PhD).

Pharmacy programs/courses are offered in India today:

- 1. Diploma in Pharmacy (D. Pharm.)
- 2. Bachelor of Pharmacy (B. Pharm.)
- 3. Master of Pharmacy (M. Pharm.)
- 4. Master of Science in pharmacy [MS (Pharm)]
- 5. Practice-based Doctor of Pharmacy (Pharm. D.)
- 6. Doctor of Philosophy in Pharmacy (Ph.D)



INDUSTRY AND ORGANIZATION

- It is well-known fact that because of the British rule, pharmaceutical industry could not be developed significantly in India.
- After independence, the government declared its industrial policy in the year 1950.
- The government gave importance to the development of the pharmaceutical industry.
- During 1950, there were 65 domestic pharmaceutical units in India, while foreign units were 28 in number.
- In 1952 about 1,643 licenses were issued under the drug act.
- In 1989, the no. has increased to 12000.
- Of there only 1554 were manufacturing units.

- In the year 2003-04 it had increased to over 24,000 units.
- In 1952, total investment in the pharmaceutical industry was only Rs.24 crores which increased to Rs. 1,175 crores in 1984-85,now in 2000-05, it has reached over Rs. 15000 crores.
- Due to development of the pharmaceutical industry, the overage life expectancy of Indian increased from 32 years to 60 years.
- In fact, India has also made adequate research in this field.
- However, the multinationals have already entered the Indian market.
- These companies are competing with the indian pharmaceutical companies.

INTRODUCTION TO PHARMACY

Mr.K.S.Rathi

M.Pharm (Pharmaceutics)

J.E.S'S College of Pharmacy Nandurbar



"The Right Choice for a Promising future"





Pharmacy

- The word Pharmacy is derived from the Greek word
 'pharmakon', meaning 'drug'
- The word 'Pharmacy' has two meanings:

General sense- it is a place or shop where drugs or medicines are sold

Professional sense- it is the profession, the member of which deal with the drugs.





Pharmacy



Pharmacy is the art and science of preparing and dispensing medications and the provision of drug and related information to the public

Or

Pharmacy is the study of the science of drugs-Where they come from? How they act on the body? How to turn drugs into medicines?

<u>Pharmacist</u>

A Pharmacist is one who is educated and licensed to prepare and dispense drugs and to provide drug and related information to

the public- An expert on drugs.

" I am a Pharmacist I am a specialist in medications I am a companion of physician I am a counselor to the patient I am a guardian of public health This is my calling This is my pride"

Drug & Medicine



- A drug is any substance that acts on the living body to alter the physiological process and are used for the prevention, diagnosis and treatment of diseases
- A medicine is any drug which has definite form & dose and are therapeutically used for the treatment of diseases of living subjects

Why choose Pharmacy?

- ✓ I want a dynamic, people-oriented career in health care.
- ✓ I want diverse employment opportunities.
- ✓ I want comfortable income
- ✓ I want flexible work environment
- \checkmark I want to be part of a respected profession

WELCOME TO PHARMACY PROFESSION

Pharmacy is not only an occupation; it is now a well recognized profession in most of the countries.



Occupation and Profession:

- Occupation: The job by which somebody earns a living.
- Profession: an occupation characterized by-
- Extensive study
- Specialized training
- Specialized knowledge
- Professional organization
- Professional behavior

Some examples of professions are

- Medicine
- Nursing
- Accounting
- Law
- Military
- Engineering
- PHARMACY etc....

Pharmacist are *experts of drugs*

Pharmacist are members of pharmacy profession dealing with all aspects of drugs

- Preparation
- Identification
- Selection
- Preservation
- Analysis
- Standardization
- Analysis
- Use

CAREER OPPORTUNITIES

- **Pharmaceutical Industry-**
- ➢ Production
- ➢ Quality Control (QC)
- ➢ Quality Assurance (QA)
- ➢ Research and development (R&D)

➢ Store

- ≻ Marketing (local, global)
- Product management

Hospital and Clinics-

Hospital Pharmacist
 Community Pharmacist
 Wholesale & Retail Pharmacy
 Government Services-

- Regulatory affairs
- Military services

Pharmacy Education-

(Teaching & Research)

Other Areas-

- Pharmaceutical IT
- Pharmaceutical consultancy
- Pharmaceutical Business (Import-export)



PRODUCTION



in I



SYLLBUS

Course Content:

$\mathbf{UNIT} - \mathbf{I}$

10 Hours

- Historical background and development of profession of pharmacy: History
 of profession of Pharmacy in India in relation to pharmacy education, industry
 and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP,
 USP and Extra Pharmacopoeia.
- Dosage forms: Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- Posology: Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT - II

10 Hours

- Pharmaceutical calculations: Weights and measures Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- Liquid dosage forms: Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III

08 Hours

- Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- Biphasic liquids:
- Suspensions: Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- Emulsions: Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV

08 Hours

- Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V

07 Hours

 Semisolid dosage forms: Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms



LIQUID DOSAGE FORM

0

Mr.Kishor S.Rathi

Assistant Professor M.Pharmacy (Pharmaceutics)

J.E.S'S COLLEGE OF PHARMACY NANDURBAR

LIQUID DOSAGE FORM

Liquid dosage form are meant for either internal or external use. They are prepared by dissolving Active Pharmaceutical Drug' (API) in aqueous or Non- aqueous solvent.

CLASSIFICATION

Liquid dosage form can be further classified into two categories:

- I. Monophasic Liquid dosage form
- 2. Biphasic Liquid dosage form.

MONOPHASIC LIQUID DOSAGE

These liquid dosage form consist only single phase and consist colloidal solution. They consist aqueous or Non-aqueous solvent as a base.

BIPHASIC LIQUID DOSAGE FORM

They are generally represented by emulsion Suspension and consist of two immiscible phases i.e. continuous phase and dispersed phase.



ADVANTAGES

- I. Drugs in the form of liquid dosage are easily and fastly absorbed Compared to solid dosage form.
- 2. Liquids are easier to swallow than tablets / capsules
- 3. Drugs with large doses can be easily administered
- 4. Drugs with bitter and unpleasant taste can be easily masked by adding sweetening and flavoring agents
- 5. These are the most suitable dosage form for patients having difficulty taking tablets or capsules i-e. children and old aged patient



DISADVANTAGES

I. Liquid dosage forms are usually less stable compared to solid dosage form.

- 2. They are bulky and therefore inconvenient to transport and store.
- 3. High chances of microbial contamination specially in aqueous preparations
- 4. Inaccuracy in doses compared to tablet, capsules.

EXCIPIENTS USED IN THE FORMULATION OF LIQUID DOSAGE FORM

Excipients are those substances which included during the formation of dosage form but do not having any therapeutic activity of their own A number of Excipients/ additives are used during the formation of liquid dosage form. These included :-

I.Vehicle / Solvent

2. Co-solvent
3. Preservatives
4. Antioxidants
5. Suspending/ Emulsifying Agents
6. Viscosity Enhancing Agents
7. Buffering Agents/ Buffers
8. Sweetening Agents
9. Flavoring Agents
10. Coloring Agents

I.VEHICLE/SOLVENTS

In liquid dosage form vehicles/ solvents are major components used as a base in •which drugs or other Excipients / ingredients are dissolved Vehicles used in the formulation of liquid preparations may be aqueous or oily. The choice of vehicle used depends on the nature and physiochemical properties of Active Pharmaceutical Ingredient (API).

2. CO-SOLVENTS

Co-solvents are basically liquid components often used to increase the solubility of drugs in the desired solvent i-e, Glycerol, DMF

3. PRESERVATIVES

Preservatives are chemical compounds that are added to formulation to protect them from microbial contamination. Only a limited no. of anti-microbial preservatives are appropriate for oral administration.

4.ANTI-OXIDANTS

These are the substances added to prevent oxidative degradation/ Oxidation of substances used in liquid preparations. The ideal antioxidant should be non-toxic, soluble in vehicle and stable at all temperature.

5. SUSPENDING AND EMULSIFYING AGENTS

These are the Excipients that are mainly used in the formulation of emulsions and suspensions. They are basically used to help the Active Pharmaceutical Ingredient to stay dissolved in the formulation.

6.VISCOSITY ENHANCING AGENTS

They are basically used to increase the viscosity of the solvent. They are mainly used to convert liquids to gels / pastes.

7. BUFFERING AGENTS/BUFFERS

Buffers are used to maintain the stability and pH of liquid preparation as pH of most of the body fluid is 7.4, hence liquid preparations such as injection / eye drops and nasal drops should be be set pH 7.4 to avoid irritation.

8.SWEETENING AGENTS

Sweetening agents are used to mask the unpleasant/ bitter taste of the formulation. Sugar, Glucose, Sucrose, Saccharin and Honey are some commonly used sweetening agents.

9. FLAVOURING AGENTS

Flavoring agents are used to overcome the unpleasant smell / taste of the formulation. Apple, Ginger, clove, rose, orange a commonly used flavoring agent.

10. COLOURING AGENTS

They are generally used in the liquid dosage form to mask the unpleasant appearance of the preparation and to improve the acceptance of consumers.

THANK YOU

PHARMACEUTICAL INCOMPATIBILITY

Introduction

"It is defined as when two or more ingredients of a prescription are mixed together, the undesired changes that may takes place in the physical, chemical or therapeutic properties of the medicament is termed as incompatibility."

Classification of Incompatibility

- 3 classes of drug incompatibility
- Physical incompatibility
- Chemical incompatibility

Therapeutic incompatibility

Physical Incompatibility/ Pharmaceutical Incompatibility

- It is a evidence that failure of the drug combine properly.
- In physical incompatibility involves interaction between two or more substance which leads to change in colour, odour, taste, viscosity & morphology.
- It is a result of insolubility & immiscibility, precipitation, liquefaction, adsorption & complexation of solid materials.

Physical incompatibilities can be corrected by one or more methods viz.

- Order of mixing
- Alteration of solvents
- Changes in the form of ingredients
- Alteration of volume
- Accurate choice of emulgent & suspending agent
- Addition

Examples of physical incompatibilities

Immiscibility

Immiscibility is the result of the mixture of two or more immiscible liquids or an immiscible solids with liquid.

- e.g. oil & water
- Rectifying method ...
- Vigorous shaking

- Choice of emulgent or Solubilizing agents..

Examples of physical incompatibilities

Insolubility

Changes in pH, milling, surfactant, chemical reaction, co-solvent are the factors that affect the solubility.

- e.g. –if mucilage of acacia & alcohol are put together they form precipitation of acacia by the alcohol. For that reason acacia not be used with alcohol for mucilage preparation.
- In the suspension contains diffusible solids in that type of the suspension uses the thickening agents. If thickening agents are not used then particles settle quickly & dose cannot be maintained.

Chemical Incompatibility

- Chemical incompatibility is also called as immediate incompatibility.
- After compounding it shows immediate incompatibility.
- It occurs due to oxidation-reduction, acid base hydrolysis or combination reactions & those noticed by effervescence, decomposition, colour change.
- Chemical interaction occurs between the ingredients & a toxic & inactive product will be formed.

Examples of Chemical Incompatibility

Formation of precipitate

- Most alkaloid salts are soluble in water but alkaloidal bases practically insoluble in water & are freely soluble in organic solvents.
- e.g. strychnine HCl

aromatic spirit of ammonia

purified water to 100ml

- In that case, strychnine HCl is an alkaloid salt & aromatic spirit of ammonia is an alkaline substance.
- Those, two insoluble mixture combine with each other that time forms the precipitate of strychnine.

In this case, strychnine HCl solution should be dissolved in half quty. of water & aromatic spirit of ammonia dissolved in the remaining quty. of water.

- Then mix both the mixture slowly.

Gas formation

- e.g. carbonates or bicarbonates with an acid or acidic drug resulting in the evolution of carbon dioxide.
- So those compounds compounded in open container to avoid explosion.

Colour Changes

- Colour changes due to changes in pH.
- It can be prevented by properly buffering the vehicle.

Ionic Reaction

- Many organic compounds associated with a large cation or anions.
- Interaction of such ions of opposing types may yield compound which may totally lack the useful properties of the interacting molecules.
- e.g. cream prepared using cationic emulgent may crack if mixed with a cream prepared using an anionic emulgent.

Therapeutic Incompatibility

 Therapeutic incompatibility is also called as drug interactions.

- In that modification of the therapeutic effect of one drug by the prior concomitant administration of another.
- It occurs due to when drug or excipients, which are antagonist to one another & are prescribed together.

- Also therapeutic incompatibility occurs due to following reasons viz...
- Overdose
- Wrong dosage form
- Contraindicated drug
- Drug interaction
- Wrong dosage form
- There are some drugs which have similar names.
- E.g. digoxin & digitoxin
- **Digitoxin** is a cardiac glycoside. It is a phytosteroid and is similar in structure and effects to **digoxin**(though the effects are longer-lasting). Unlike **digoxin**(which is eliminated from the body via the kidneys), it is eliminated via the liver, so could be used in patients with poor or erratic kidney function.

Contraindicating Drugs

- Some drugs are not prescribed for lactating mother because it will excrete into milk.
- E.g. Phenytoin, Phenobarbitone, Chloramphenicol etc.

Drug Interaction

- e.g. tetracycline is inactivated by the milk due to the presence of calcium.
- It forms insoluble complex with milk and not show any effect on systemic circulation.

