**INTRODUCTION TO DOSAGE FORMS**

Sandhya Jaiswal1, Ghanshyam Das Gupta2, Anjoo Kambooj3, Kiran Yadav4, Nisha Yadav5

1, 4, 5 Department of Pharmaceutics, Chandigarh College of Pharmacy, CGC, Landran, Mohali, India

2 Department of Pharmaceutics, ISF College of Pharmacy, Moga, Punjab, India

3 Department of Pharmaceutical Chemistry, Chandigarh College of Pharmacy, CGC, Landran, Mohali, India

**ABSTRACT**

Dosage form design is a multidiverse field which involves pathways from selection of drug and excipients to designing the formulation, manufacturing procedures, and quality assurance for the drug product. Prior to the development of any dosage form, it is important to understand the physical description of both the drug and excipients individually and in blend. Compatibility studies will results into stable dosage form throughout the shelf life. Thus before formulating a dosage form, a pharmacist should create the framework for product development by keeping in mind various factors like disease, the manner by which disease is treated (locally or through systemic), age and physiological conditions of the patient which could be helpful in pilot plant scale-up studies leading to desired drug release profile with improved bioavailability, and clinical effectiveness.

Keywords—Dosage form design; Drug; Excipients; Bioavailability

1. **INTRODUCTION**

A pharmaceutical drug, also known as medicine is a chemical substance which is generally used to treat, cure, prevent or diagnose a specific disease was previously obtained from the extraction of medicinal plants but now it has been obtained from organic synthesis [1]. The need for designing a dosage form is to protect the drug from external environment, improve its therapeutic activity and patient compliance. The dosage form is the physical form of the medication, where an active pharmaceutical ingredient (drug) and excipients (non-drug) are converted into suitable forms for administration [1]. Active pharmaceutical ingredients, API) are chemical compounds with pharmacological activity intended for use in diagnosis, treatment or prophylaxis of diseases. Excipients or additives are inactive pharmaceutical ingredients including diluents/fillers, binders, lubricants, coatings, preservatives, colorants, flavouring agents and disintegrants. The pharmaceutical ingredients solubilise, suspend, thicken, dilute, emulsify, stabilize, preserve, colour, flavour, and fashion medicinal agents into efficacious and appealing dosage forms. Each type of dosage form is unique in its physical and pharmaceutical characteristics. The medication is effective only when the drug in its desired form reach its site of action irrespective of its different routes of drug administration used according to the treatment. The proper formulation and designing of any dosage forms are important consideration focused by the product manufacturers. The nature of the disease or illness for which the drug substance is intended is essential in deciding which dosage forms of that drug should be prepared and marketed. Commercially, a variety of different dosage forms available, according to the mode of treatment and depending on the characteristics and advantages [2].

 **Ideal characteristics of a dosage form**

1. It should be safe and simple to administer
2. It should be economical for the patient
3. It should be physically and chemically stable in environmental conditions
4. It should be easy to reproduce and formulate
5. It should maintain its therapeutic activity throughout the shelf life
6. It should provide high patient compliance
7. It should be easy to handle for all kind of patients
8. It should be biocompatible

**Figure 1: Ideal requirements of Dosage forms [3]**

The drug and excipients must be compatible with each other besides providing a dosage form that is stable, efficacious, easy to administer, and convenient delivery of accurate dosage. The potent nature and low dosage of most of the drugs in use today precludes any expectation that the general public could safely obtain the appropriate dose of a drug from the bulk material. Pharmaceutical dosage forms are needed for the following additional reasons [3]:

* 1. To provide drug products like injections, topical dosage forms etc. that could bypass the first-pass metabolism.
	2. To protect the drug substance from the adverse influence of atmospheric oxygen or humidity e.g., coated tablets.
	3. To protect the active pharmaceutical ingredients (APIs) from the influence of gastric acid pH following oral administration of the dosage form e.g., enteric-coated tablets.
	4. To mask the bitter and undesirable taste or noxious odor of drug substances e.g., capsules, coated tablets, taste-masked suspensions, and flavored syrup.
	5. To provide useful dosage form for administering substances that are either insoluble or unstable in the desired vehicle e.g., suspensions.
	6. To provide rate-controlled drug action e.g., various controlled-release tablets, capsules, and suspensions.
	7. To provide drug products that are stable, effective, and safe for consumption under specified suitable storage conditions e.g., powders for reconstitution.
	8. To provide optimal drug action from topical administration sites g., creams, transdermal patches, ointments, and ophthalmic, ear, and nasal preparations.
	9. To provide sterile, clear, and particulate-free liquid dosage forms of substances e.g., injections and eye drops.
	10. To provide site-specific and local drug delivery e.g., rectal and vaginal suppositories.
	11. To target the drug at the desired site of action e.g., nanoparticulate systems, liposomes, etc.
	12. To achieve rapid onset of action through inhalation therapy e.g., inhalants and inhalation aerosols.

 Broadly, dosage form design is a multidiverse field which involves selection of drug and excipients to designing the formulation, manufacturing procedures, and finally assuring the quality for the dosage form and drug. It is important to understand the physical description of a drug substance prior to the development of any dosage form. Today, most of the drug substances appear in solid materials, either having crystalline or amorphous nature. Therapeutically, drugs can be used as solids, liquids, and gases. Liquid drugs are used to a lesser extent than solid drugs whereas gases even less frequently. In the designing of dosage forms liquid drugs pose more problem than solid drugs. Many liquids are volatile, therefore must be sealed to prevent evaporation loss to the atmosphere. Another problem associated with liquid drugs is that those intended for oral administration cannot generally be formulated into tablet form without chemical modification. An exception to this is nitroglycerin, which is formulated into sublingual tablets that disintegrate within seconds after placement under the tongue. However, because the drug is volatile, it has a tendency to escape from the tablets during storage therefore it is critical that the tablets be stored in a tightly sealed glass container. In most part, when a liquid drug is to be administered orally and a solid dosage form is desired, one of two approaches is utilized. First, the liquid substance must be packed in a soft gelatin capsule like vitamins A, D, and E, cyclosporin (Neoral, Sandimmune), and ergoloid mesylates (Hydergine LC) etc are some of the liquids commercially available in capsule form. Secondly, the liquid drug may be developed into a solid ester or salt form that will be suitable for tablets or drug capsules. For certain liquid drugs, especially those taken orally in large doses or applied topically, their liquid nature may have some advantage in drug therapy. For example, 15-mL doses of mineral oil may be administered conveniently as such. Also, the liquid nature of undecylenic acid certainly does not hinder but rather enhances its use topically in the treatment of fungus infections of the skin. However, in most of the instances pharmacists prefer solid drugs in formulation development because they can easily transformed them into tablets and capsules dosage form. Formulation and stability difficulties arise less frequently with solid dosage forms than with liquid preparations, and for this reason many new drugs first reach the commercial market as tablets or dry filled capsules [2, 3].

 Before formulating a dosage form, a pharmacist should create the framework for product development and consider factors like nature of the disease, the manner by which disease is treated (locally or through systemic), age and physiological conditions of the patient. Pilot plant scale-up studies of the dosage forms are developed and examined for its desired features e.g., drug release profile, bioavailability, and clinical effectiveness. On the basis of results obtained from pilot plant studies, formulation that best meets the goals for the product is selected and considered to be its master formula. Each batch of product subsequently prepared must meet the specifications established in the master formula record. If the medication is intended to be delivered for systemic use, oral/solid dosage form such as tablets and/or capsules are prepared because they are easily handled by the patient and are most convenient in the self-administration of medication. If a drug substance has application in an emergency usage in which the patient is unable to take oral medication, an injectable/parenteral dosage form of the medication may be prepared. For children’s below 5 years of age, pharmaceutical liquids dosage forms rather than solid forms are preferred choice of administration. These formulations commercially are available as flavored aqueous solutions, syrups, or suspensions, and are administered directly into the child’s mouth by dropper, spoon, or oral dispenser [3].

1. **CLASSIFICATION OF DOSAGE FORMS**

Oral dosage forms can be divided into two main groups based on the physical state of the dosage form, that is, solid oral dosage forms (tablets, capsules, or powders) and liquid oral dosage forms (solutions, syrups, emulsions, and powders for suspensions) [4].



**Figure 2: Classification of Dosage Forms**

**A. Solid oral dosage forms**

The solid dosage forms are solid by nature and contain excipients like binders, sweeteners, colouring agents, etc. as well as one or more medicines for therapeutic effects [4]. These dosage forms are taken by patients orally and intended to deliver the drug to the site of action without any time delay for example Cachets, Capsules, Powders, Insufflations, Dentifrices, Effervescent, Granules, Lozenges, and Tablets. Out of the mentioned solid dosage forms, tablets and capsules are the preferred first choice of medication that a doctor prescribed Because of its ease of availability and patient compliance. It is estimated that tablets and capsules constitute the dosage form dispensed 70% of the time by community pharmacists, with tablets dispensed twice as frequently as capsules **[4]**.

**Tablets**: - A tablet is a solid dosage form that contains one or more medications in a specific quantity, with or without appropriate excipients. To enable flexibility in dosing, manufacturers commonly make available various tablet or capsule strengths of a given medication. Tablets can be chewed or consumed whole. Before administration, some are dissolved or distributed in water. Some are placed in the mouth, where the active substance releases at a set rate. Tablets are typically solid, right-angled cylinders with flat or convex end surfaces and bevelled edges. [5] Most tablets are manufactured on the industrial scale by compression, using highly sophisticated machinery. The content uniformity, low cost, product identification makes compressed tablets ideal formulations [5, 6]. Types of Tablets dispensed by pharmacist:-

**Multiple Compressed Tablets**

These tablets are prepared by subjecting the tablet powder to more than one compression cycle. The result may be a multilayered tablet or a tablet-within-a-tablet. Multilayer tablets are mainly used for incompatible substances, for example, phenylephedrine hydrochloride and ascorbic acid in admixture with paracetamol. Paracetamol and phenylephedrine hydrochloride are contained in one layer, and paracetamol and ascorbic acid in the other.

**Sugar coated Tablets**

These compressed tablets are coated with a sugar layer that is colored or uncolored. Sugar coats are water soluble. These coats protect the drug from the environment and provide a barrier for bad tasting or smelling drugs.

**Film Coated Tablets**

Film coated tablets are a type of compressed tablets coated with a thin layer of a polymer capable of forming a skin-like film over the tablet. These coats rupture in the gastrointestinal tract, exposing the drug.

**Gelatin Coated Tablets**

The innovator product gelcaps, is a capsule shaped compressed tablet coated with a gelatin layer. It allows the product to be smaller than an equivalent capsule filled with an equivalent amount of powder.

**Enteric Coated Tablets**

These tablets are intended to pass unchanged through the stomach to the intestines, where the tablets disintegrate and drug dissolution occurs. This helps protect drug molecules that are susceptible to degradation in gastric acid and drugs that can irritate the gastric mucosa. It can also be used to control the delivery of certain drugs to the intestines to enhance absorption.

**Buccal or Sublingual Tablets**

Buccal tablets are inserted in the buccal pouch, and sublingual tablets are inserted beneath the tongue. Where rapid drug availability is required such as in the case of nitroglycerin tablets these tablets are administered sublingually. They are sometimes also referred to as instant disintegrating or dissolving tablets. Examples are isoprenaline sulphate (bronchodilator) and glyceryl trinitrate tablets (vasodilator). These tablets are usually small and flat. Sometimes sweeteners are added.

**Chewable Tablets**

Chewable tablets, when chewed, produce a pleasant tasting residue in the mouth that when swallowed does not leave a bitter or unpleasant aftertaste. These tablets have been used for children, especially multivitamin formulations, and for the administration of antacids and selected antibiotics. Chewable tablets are prepared by direct compression method and contain mannitol, sorbitol, or sucrose as binders and fillers and colors and flavors to enhance their appearance and taste. Mannitol is sometimes preferred as a chewable base diluent, since it has a pleasant, cooling sensation in the mouth and can mask the taste of some objectionable medicaments.

**Effervescent Tablets**

These tablets are also known as compressed effervescent powders. They are usually dissolved in a glass of water before administration. The resultant solution is usually a flavored, bubbling drink. This type of tablet offers quick dissolution of the active ingredient in water if the tablet is broken apart by the internal liberation of carbon dioxide. This also increases palatability.

**Immediate Release Tablets**

These tablets are designed to disintegrate and release the drug absent of any rate-controlling features such as special coatings or other formulation techniques.

**Extended Release Tablets**

Extended release tablets, sometimes called sustained release tablets, are designed to control the release of a drug in a predetermined manner over an extended time [7].

**Powders**: - Powders represent one of the oldest solid dosage forms. However, with the use of highly potent compounds, powders as a dosage form have largely been substitute by capsules and tablets. Powder is a mixture of finely divided drugs/chemicals in dry form. Although tablets and capsules have overtaken powders as a dose form in contemporary medicine, however in certain situations, powders still hold advantages and thus still represent a small portion of the solid dosage forms currently being employed. For example, because of their greater specific surface area, powders can disperse and dissolve more readily than compacted dosage forms. Similarly, children and adults who have find trouble in swallowing tablets or capsules may consider powders more acceptable. Immediately before use, oral powders are mixed with a beverage or applesauce [5, 6, 7]

**Types of powder dosage forms:-**

**Oral powders**: - Oral powders generally can be supplied as finely divided powders or effervescent granules. The finely divided powders are suspended or dissolved in water or mixed with soft foods such as applesauce before administration. Antacids and laxative powders frequently are administered in this form. Powdered antibiotic unit dose sachets intended to be supplied for children are reconstituted before administration. Powders for reconstitution into an oral solution or suspension are commonly dispensed to the patient in multidose bottles. Herbal medicines, such as laxatives, are commonly dispensed in bulk powder containers for dose dispensing and administration by the patient. Dentifrices are prepared in the form of a bulk powder, generally contains a soap or detergent, mild abrasive, and anticariogenic agent

**Dusting powders**:-Dusting powders are intended to be applied to the skin in a very fine state of subdivision, for external application to avoid local irritation. Dusting powders are generally prepared by mixing 2 or more ingredients one of which must be starch, kaolin or talc as one of the ingredients of the formulation. To enhance their effectiveness, dusting powder should always be passed through an 80 no. sieve. They are of two types: - (1) Medical dusting powders (2) Surgical dusting powders. Medical dusting powders are used for superficial skin infections whereas surgical dusting powders are used in body cavities and burns. It must be sterilized before use.

**Effervescent granules**: - Effervescent granules are bulk powders intended for dispensing of a unit dose and reconstitution with water to form a solution by the patient immediately before administration. These contain sodium bicarbonate and either citric acid, tartaric acid, or sodium biphosphate as effervescent substance in addition to the active ingredients. On solution in water, carbon dioxide is released because of the acid-base reaction. The release of the water of crystallization makes the powder coherent and helps form the granules. The effervescence from the release of the carbon dioxide masks the taste of salty or bitter medications.

**Insufflations**: - Insufflations are finely divided medicated powders introduced into body cavities such as nose, throat, ears and vagina with the help of an apparatus called ‘Insufflator’. An insufflator (powder blower) is usually employed to administer these products. It sprays the powder into a stream of finely divided particles all over the site of application. Nowadays, the insuffalations are available in the form of pressure aerosols. The Norisodrine Sulfate Aerohaler Cartridge (Abbott) is an example. In the use of this aerohaler, inhalation by the patient causes a small ball to strike a cartridge containing the drug. The force of the ball shakes the proper amount of the powder free, permitting its inhalation. Another device, the Spinhaler turboinhaler (Fisons), is a propeller-driven device designed to deposit a mixture of lactose and micronized cromolyn sodium into the lung as an aid in the management of bronchial asthma. Insufflations are used to produce a local effect and to produce a systemic effect. However, the difficulty in obtaining a uniform dose has restricted its general use.

**Dry powder inhalers**: - Dry powder inhalers (DPIs) are devices that deliver medication to the lungs using an inhalation device in the form of a dry powder. These devices are commonly used for drug delivery for local action.

**Cachets**: - Cachets are unit solid dosage forms of medicaments meant for administering nauseous or disagreeable powders in tasteless form and a large dose. e.g. Sodium amino salicylate cachets and Sodium amino salicylate and isoniazid cachets. They are moulded from rice paper, a material made by pouring a mixture of rice flour and water between two, hot, polished, revolving cylinders; the water evaporates and sheet of wafer is formed. Two types of Cachets (1) Wet seal cachet:-Upper half (moisten with water) which is pressed over Lower half (contains drug). (2) Dry seal cachets: - Upper half is pressed over Lower half which contains the drug material. It’s just like a capsule [5, 6, 7].

**Dentrifices**: - Since ancient times, dentifrices (toothpastes) have been used, but recently, formulations that provide active ingredients intended to cure and/or prevent oral disorders have been produced. Depending on the claims made and the concentration of specific ingredients, toothpaste may fall under the cosmetic or medicinal categories. The main purpose of toothpaste is to clean teeth, which is seen as an aesthetic advantage. Cosmetic claims include the use of terms like "protects," "cleans," "freshens breath," "fights microorganisms that may cause gum issues," "whitens," or "fights tartar" [8].

**Lozenges**: - Lozenges are flavoured medication dose forms that are meant to be retained in the mouth or throat while being sucked. They typically include one or more medications in a sweetened foundation. Lozenges are used to treat oropharyngeal symptoms, which are frequently brought on by local infections. If the medication is adequately absorbed via the buccal linings or when it is eaten, they may also have a systemic impact. Lozenges are classified as (1) According to site of action: local effect and systemic effect. (2) According to texture and composition: Chewy or caramel based medicated lozenges; compressed tablet lozenges; soft lozenges and hard lozenges [9].

**Capsules**: - The word capsule is derived from the Latin word Capsula, meaning “a small box or packet.” Capsules are characterised as a unit solid dose form of medications and inert substances that come in the shape of tiny gelatin capsules (shells) containing precisely calculated drugs. Depending on their formulation, the gelation capsule shell may be hard or soft. Hard shell capsules can be regarded as containers for delivery of formulated drug substances that are generally designed for oral administration, although non-oral products for rectal or vaginal administration are available. Capsules as a platform for delayed or controlled-release delivery offer numerous advantages and adaptabilities over tablets. Because of their production procedure compared to other dosage forms, they are considered main oral dosage form as they can readily accommodate a range of special excipients, formulations, and pre-fabricated systems to target specific regions of the GI tract. Hard shell capsule sizes range from number 5, the smallest, to number 000, which is the largest, except for veterinary sizes. However, size number 00 generally is the largest size acceptable to patients. Hard gelatine capsules are used for enclosing solid medicaments while soft gelatine capsules are used for liquid and semi solid medicaments [10, 11].

**B. Liquid oral dosage forms [12-16]**

Liquids are homogenous liquid solutions that typically include one or more active agents suspended or emulsified in a suitable liquid foundation. They are either produced this way or after dilution for oral delivery. In addition, they could include antibacterial compounds for preservation as well as appropriate dispersing, solubilizing, wetting, emulsifying, stabilising, suspending, and thickening agents. They may also contain legal colouring additives, flavourings, and appropriate sweeteners. If potassium or sodium saccharin is used to sweeten foods for children, the content in those foods shouldn't exceed 5 mg per kg of body weight. They include:- Syrups; Oral suspension; Oral solution; oral drop; oral emulsions; Mixtures; Elixirs; Linctus. During manufacturing, packaging, storage and distribution process of oral liquids, microbial quality should be maintained and microbial count should be within the acceptance criteria. Oral Liquids should not be diluted and stored after dilution unless the individual monograph directs for dilution. Diluted oral liquids may not be stable for long period physically and chemically so it should be diluted freshly or should be used within the period as stated on the label.

**Syrups**: - The syrup is a saturated sugar solution. It is a vicious oral liquid that contains one or more active ingredients in solution. The base generally contains large amounts of saturation concentration of 67% weight per weight of sucrose to inhibit crystallization or to modify solubilization, taste and other base properties. In exceptional cases, other sugars (such glucose/dextrose) or non-sugars may be used to replace it completely or in part (e.g., sorbitol, glycerin, and propylene glycol). Nonmedicated syrups are those that contain flavouring ingredients but no medicines. Sugarless syrups may contain other sweetening agents as saccharin and thickening agents. Syrups may contain ethanol (95%) as a preservative or as a solvent for flavors. Antimicrobial agents may also be added to syrups to maintain the microbial quality of preparation. Drugs that dissolve in water should be taken as syrups. The most popular types of medicinal syrups are those used to treat colds and coughs. In addition to purified water and drug(s), most syrups also include the following ingredients: (a) Sugar, often sucrose or other sugar substitutes, (b) antimicrobial preservatives, (c) flavorants, and (d) colourants are employed to produce sweetness and viscosity. Additionally, thickeners, stabilisers, and solubilizing chemicals may be present in syrups.

**Oral Suspension**: - Because of their intrinsic structural instability, issues with manufacturing and packing, and importance as a class of pharmaceutical formulation, suspensions pose several difficulties for those responsible for formula development. Suspensions may be intended for parenteral usage, external application, or oral delivery. They typically consist of a finely split solid suspended in a liquid or semi-solid medium that makes up the continuous phase, with individual particles ranging in size from 0.5 to 5.0. Nowadays, a lot of suspensions are sold as dry powders that must be "constituted" before usage by adding a certain quantity of a vehicle. Such "suspensions" are created mostly due to stability issues.

Types of suspension

1. According to the route of administration:- oral, topical, parentral and ophthalmic.
2. According to the nature of dispersed phase and method of preparation:- diffusible solid and indiffusible solids etc.
3. According to nature of sediment:-Flocullating and Deflocullatingsuspemsion.

**Oral Solution**: - Oral Solution is an oral liquid that contains one or more active ingredients dissolved in a suitable base.

**Oral Drop**: - Oral Drop is an oral liquid that is prepared to take in small quantity with the help of a suitable measuring device such as a dropper.

**Oral Emulsions**: - A biphasic system with two immiscible liquids, of which one (the dispersed phase) is finely and evenly scattered as globules throughout the second phase, is known as an emulsion (the continuous phase). Emulsifier, a third agent, is introduced to stabilise the system since emulsions are a thermodynamically unstable system.

Types of emulsions are

1. Oil in water emulsion in which oil behaves as a dispersed phase white water is the continuous phase
2. Water in oil emulsion in which water is the dispersed phase and oil is continuous phase.
3. Multiple emulsion also known as emulsion in emulsion e.g., O/W/O (oil in water in oil emulsion) and W/O/W (water in oil in water emulsion).
4. Microemulsion consisting of water, oil and surfactant, which constitute a single optically isotropic and thermodynamically stable liquid solution.

**Mixtures**: - An appropriate base is used to suspend or distribute one or more active components in the combination, which is an oral liquid. When kept for a while, suspended solids may separate, but shaking quickly brings them back to suspension.

**Elixirs**: - This is a transparent, flavoured oral liquid with a high concentration of sucrose that may also contain ethanol (95 percent) or a diluted form of ethanol, one or more active agents, and an appropriate base.

**Linctus**: - One or more active chemicals are dissolved in a base that is acceptable and typically has a greater concentration of sucrose or other sweets in linctus, a violent oral liquid. Typically, linctuses are produced to cure a cough, and these are taken without the use of water.

 Drug and excipients solubility in pharmaceutical solvent are essentially required to be present in solution over the shelf-life of the formulated product. One of the major challenges faced by the pharmaceutical scientist is the attainment of homogeneity in the formulation, due to the limited aqueous solubility of the drug. The difference between the aqueous solubility of the drug and the required concentration is bridged by the use of co-solvents or surfactants. Commonly used co-solvents are glycerol, propylene glycol, ethanol and poly (ethylene glycol). Prediction of the solubility of drug in mixed solvent systems (the vehicle, water and the chosen co-solvent) is difficult, due to the effects of many variables on the solubility. In practice the pharmaceutical scientist used to measure the solubility of the chosen drug in a series of mixed solvents in order to determine the most suitable solvent system for the given purpose. The final choice of the co-solvent system for a particular formulation involves consideration of the solubility of the therapeutic agent in the vehicle, the toxicity of the vehicle and the cost of the formulation. Indeed, it should be noted that the range of concentrations of each co-solvent used in oral formulations is primarily limited by concerns regarding toxicity. Excipients used in pharmaceutical solutions for oral administration should be physiologically inert, physically and chemically stable, so as to enhance the solubility of the therapeutic agent.

A wide range of excipients can be utilized in liquid dosage forms.

**The vehicle:** The preferred and most commonly used vehicle in solutions for oral administration is Purified Water USP, due to the low cost and low toxicity of this ingredient. Under normal circumstances tap (drinking) water should not be used due to the possibility of chemical imcompatibities within the formulation. The main features of Purified Water USP are as follows:

1. It is prepared by distillation, ion exchange methods or by reverse osmosis.
2. The solid residue (obtained after evaporation) is less than 1 mg per 100 ml of evaporated sample.
3. It must not be used for the preparation of parenteral formulations. In the case of parenteral formulations Water for Injections BP must be used.

**Cosolvents:** are mostly employed to increase the solubility of the therapeutic agent within the formulation. The main co-solvents that are used in the formulation of oral solutions are detailed below. Glycerol (also termed glycerin) is an odorless, sweet liquid that is miscible with water and whose cosolvency properties are due to the presence of three hydroxyl groups (termed a triol. It has similar cosolvency properties to ethanol. Alcohol USP (CH3CH2OH) Alcohol USP contains between 94.9 and 96.0% v/v ethyl alcohol (ethanol) and is commonly used as a co-solvent, both as a single co-solvent and with other co-solvents, e.g. glycerol. The known pharmacological and toxicological effects of this co-solvent have compromised the use of alcohol in pharmaceutical preparations. As a result there are both labelling requirements for preparations that contain alcohol and upper limits with respect to the concentration of alcohol that may be used in formulations. Propylene Glycol USP is an odourless, colourless, viscous liquid diol that contains two hydroxyl groups. It is used in pharmaceutical preparations as a co-solvent, generally as a replacement for glycerin. Poly (ethylene glycol) (PEG) PEG is a polymer composed of repeating units of the monomer ethylene oxide (in parenthesis). The physical state of the polymer is dependent on the number of repeat units (n) and hence on the molecular weight. Lower-molecular-weight grades (PEG 200, PEG 400) are preferred as co-solvents in pharmaceutical solutions. Miscellaneous agents used to enhance the solubility of therapeutic agents In addition to the use of co-solvents, other pharmaceutical strategies are available to the pharmaceutical scientist to increase the solubility of therapeutic agents in the chosen vehicle.

**Surface-active agents**:- are chemicals that possess both hydrophilic (water-liking) and hydrophobic (water-disliking) regions. At dilute concentrations surface-active agents will orient at the interface between two phases (e.g. water/oil, water/air), with the hydrophilic and hydrophobic regions of the molecule being positioned to the hydrophilic and hydrophobic phases, respectively. As the concentration is increased, the interface will become saturated with surface-active agent and the molecules that are present in the bulk aqueous phase will orient themselves in an attempt to shield the hydrophobic regions of the surface-active agent. This orientation is referred to as a micelle and the concentration of surface-active agent is termed the critical micelle concentration (CMC). The use of surface-active agents for the solubilisation of poorly soluble drugs occurs exclusively in the presence of micelles and hence at concentrations of surface-active agents in excess of the CMC. In this the core of the micelle represents a hydrophobic region into which the poorly water-soluble drugs may partition. The location in the micelle is related to the chemical structure of the drug. For example, if the therapeutic agent is poorly soluble the molecule will locate exclusively within the micelle, whereas if the drug is water-insoluble but contains polar groups, the molecule will orient within the micelle, with the polar groups at the surface of the micelle and the hydrophobic region of the molecule located within the hydrophobic core of the micelle. In so doing the drug is solubilised within the colloidal micelles; due to their small size, the resulting solution appears homogeneous to the naked eye.

**Complexation**:- Complexation refers to the interaction of a poorly soluble therapeutic agent with an organic molecule, e.g. surface-active agents, hydrophilic polymers to generate a soluble intermolecular complex. Drug–polymer complex would prevent drug absorption across biological membranes. There are several excipients that are commonly employed in the formulation of pharmaceutical solutions. These include: (1) buffers; (2) sweetening agents; and (3) viscosity-enhancing agents.

Buffers are employed within pharmaceutical solutions to control the pH of the formulated product and, in so doing, optimise the physicochemical performance of the product.

Typically pH control is performed:

1. To maintain the solubility of the therapeutic agent in the formulated product. The solubility of the vast number of currently available drugs is pH-dependent and, therefore, the solubility of the therapeutic agent in the formulation may be compromised by small changes in pH.
2. To enhance the stability of products in which the chemical stability of the active agent is pH dependent. The concentration (and hence buffer capacity) of buffer salts employed in the formulation of oral solutions should be selected to offer sufficient control of the pH of the formulation but yet should be overcome by biological fluids following administration. This latter property is particularly appropriate for parenteral formulations to ensure that there is no irritation or damage following injection. Examples of buffer salts used in pharmaceutical solutions are acetates (acetic acid and sodium acetate), citrates (citric acid and sodium citrate), and phosphates (sodium phosphate and disodium phosphate). It must be remembered that the buffer system used in solution formulations should not adversely affect the solubility of the therapeutic agent, e.g. the solubility of drugs may be affected in the presence of phosphate salts.

**Sweetening agents**: - Sweetening agents are employed in liquid formulations designed for oral administration specifically to increase the palatability of the therapeutic agent. The main sweetening agents employed in oral preparations are sucrose, liquid glucose, glycerol, sorbitol, saccharin sodium and aspartame. Saccharin sodium is used either as the sole sweetening agent or in combination with sugars or sorbitol to reduce the sugar concentration in the formulation. The use of sugars in oral formulations for children and patients with diabetes mellitus is to be avoided.

**Viscosity-enhancing agents: -** The administration of oral solutions to patients is usually performed using a syringe, a small-metered cup or a traditional 5-ml spoon. The viscosity of the formulation must be sufficiently controlled in order to ensure the accurate measurement of the volume to be dispensed. Furthermore, increasing the viscosity of some formulations may increase the palatability. Accordingly there is a viscosity range that the formulation should exhibit to facilitate this operation. Certain liquid formulations do not require the specific addition of viscosity-enhancing agents, e.g. syrups, due to their inherent viscosity. The viscosity of pharmaceutical solutions may be easily increased (and controlled) by the addition of non-ionic or ionic hydrophilic polymers. Examples include non-ionic (neutral) polymers – cellulose derivatives, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, polyvinylpyrrolidone, ionic polymers – sodium carboxymethylcellulose (anionic) – sodium alginate (anionic).

**Antioxidants**: - Antioxidants are included to enhance the stability of therapeutic agents that are susceptible to chemical degradation by oxidation. Typically antioxidants are molecules that are redox systems that exhibit higher oxidative potential than the therapeutic agent or, alternatively, are compounds that inhibit free radical-induced drug decomposition. Typically in aqueous solution antioxidants are oxidised (and hence degraded) in preference to the therapeutic agent, thereby protecting the drug from decomposition. Both water-soluble and water-insoluble antioxidants are commercially available, the choice of these being performed according to the nature of the formulation, sodium sulphite, sodium meta bisulphite, sodium formaldehyde sulphoxylate and ascorbic acid. Examples of antioxidants that may be used in oil-based solutions include: butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA) and propyl gallate. Typically antioxidants are employed in low concentrations (0.2% w/w) and it is usual for the concentration of antioxidant in the finished product to be markedly less than the initial concentration, due to oxidative degradation during manufacture of the dosage form. Antioxidants may also be employed in conjunction with chelating agents, e.g. ethylenediamine tetraacetic acid, citric acid, that act to form complexes with heavy-metal ions, ions that are normally involved in oxidative degradation of therapeutic agents.

**Preservatives**: - are included in pharmaceutical solutions to control the microbial bioburden of the formulation. Ideally, preservatives should exhibit the following properties like broad spectrum of antimicrobial activity against Gram-positive and Gram-negative bacteria and fungi, should be chemically and physically stable throughout the shelf-life of the product, and must possess low toxicity. A wide range of preservatives are available for use in pharmaceutical solutions for oral use, including benzoic acid and salts (0.1–0.3%), sorbic acid and its salts (0.05–0.2%), alkyl esters of parahydroxybenzoic acid (0.001–0.2%). Usually a combination of two members of this series is employed in pharmaceutical solutions, typically methyl and propyl parahydroxybenzoates (in a ratio of 9:1). The combination of these two preservatives enhances the antimicrobial spectrum. Unfortunately, in many solution formulations, the concentration of preservative within the formulation may be affected by the presence of other excipients and by formulation pH.. In some aqueous formulations the use of acidic preservatives, e.g. benzoic acid, sorbic acid, may be problematic.

**Flavours**: - These are employed whenever the unpalatable taste of a therapeutic agent is apparent, even in the presence of the sweetening agents. The flavours may be of natural origin (e.g. peppermint, lemon, herbs and spices) and are available as oils, extracts, spirits or aqueous solutions. Alternatively, a wide range of synthetic flavours are available that offer advantages over their natural counterparts in terms of purity, availability, stability and solubility. Certain flavours are also associated with a (mild) therapeutic activity. For example, many antacids contain mint due to the carminative properties of this ingredient. Alternatively other flavours offer a taste-masking effect by eliciting a mild local anaesthetic effect on the taste receptors. Examples of flavours in this category include peppermint oil, chloroform and menthol. The concentration of flavour in oral syrups is that which is required to provide the required degree of taste-masking effectively.

 **Colours**: - These are generally natural or synthetic water soluble, photo-stable ingredients that are selected according to the flavour of the preparation. For example, mint-flavoured formulations are commonly a green colour, whereas in banana-flavoured solutions a yellow colour is commonly employed. Such ingredients must not chemically or physically interact with the other components of the formulation.

**C. Semi-solid dosage forms [17-21]**

Pharmaceutical semisolid preparations may be defined as topical products intended for application on the skin or accessible mucous membranes to provide localized and sometimes systemic effects at the site of application. In general, semisolid dosage forms are complex formulations having complex structural elements. They are often composed of two phases (oil and water), one of which is a continuous (external) phase and the other a dispersed (internal) phase. The active ingredient is often dissolved in one or both phases, thus creating a three-phase system. Semisolids are characterized by a three-dimensional structure that is sufficient to impart solid-like character to the undisturbed system but that is easily broken down and realigned under an applied force. Suppositories are also a part of this class although these are unit dosage forms. It include: - Ointments, Creams, Pastes, Jellies and Suppositories.

**Ointments**: - When shear force is applied, ointments, which are semisolid systems, often act like viscoelastic materials. They often contain medications and are designed for external application to the skin or mucous membranes. Non-medicated ointments, also known as ointment bases, are used to make medicated ointments or can be used directly for lubricating or emollient properties.

**Creams**: - The topical products that may be applied to the skin are called creams. In terms of dosage forms, creams are "viscous liquid or semi-solid emulsions of either the oil-in-water or water-in-oil type," whose consistency changes depending on the amount of oil and water present. Creams are used for therapeutic or cosmetic functions such as washing, beautifying, enhancing looks, protecting, etc. These topical formulations are intended to distribute drugs to specific areas of the skin or mucous membrane for localised effects. These items are made to be used topically for more effective site-specific medicine delivery into the skin for skin conditions.

They are divided into two types:

1. Oil-in-Water (O/W) creams which are composed of small droplets of oil dispersed in a continuous phase, and an emulsion in which the oil is dispersed as droplets throughout the aqueous phase is termed an oil-in-water (O/W) emulsion.
2. Water-in-Oil (W/O) creams which are composed of small droplets of water dispersed in a continuous oily phase. When water is the dispersed phase and oil is the dispersion medium, the emulsion is of the water-in-oil (W/O) type.

**Pastes**: - Pastes are essentially ointments with a significant amount of insoluble solids added. By adsorbing the liquid hydrocarbon component of the vehicle on the particle surface and by directly interacting with the scattered particles, the system is stiffened by the unusual amount of particulate matter. Pastes are often made by adding solids directly into a congealed system and allowing them to leech with some of the base material to create a paste-like mass. Once the solids are evenly distributed throughout the vehicle, the base's remaining components are applied. There are two types of paste, a) Fatty pastes and b) Non greasy pastes.

**Jellies**: - Gels are semisolid systems in which a liquid phase is restrained by a 3-D polymeric matrix (made of gum, either natural or synthetic) that has a high level of physical or chemical cross-linking. Gels are aqueous colloidal suspensions of the hydrated forms of insoluble medicament. They are employed as carriers for spermicidal drugs to be used intra vaginally with diaphragms as an additional method of contraception, as well as for medicine, lubrication, and other purposes. [

**Suppositories**: - An active substance is often inserted into an inert base, which can be either stiff or semi-rigid, to create a standard suppository. For patients in comas or who are unable to take oral medications owing to recurrent bouts of nausea and vomiting or pathological disorders of the gastrointestinal tract, it provides an alternative form of oral drug for systemic action. Depending on the nature of the suppository base, the suppository's function after administration is to liberate the active ingredient so that it can either move to the mucosal barriers into the systemic circulation to produce a pharmacological effect or melt at body temperature and dissolve in the local mucosal fluids.

**Pessaries**: - Devices called pessaries, which are often made of silicone or rubber, support the uterus, vagina, bladder, and rectum structurally. The market currently offers a variety of models and sorts, increasing popular acceptability. Vaginal touch is used to choose the model. The perineal body supports the pessary, which is positioned beneath the pubic symphysis. There are several types of devices (ring, donut, gelhorn, and cube) that are divided into two categories: support and occlusive.

**Excipients used in the formulation of semisolids dosage forms includes Bases, Antimicrobial preservative, Chelating agents, Humectants, fragrances**

**Bases**: - A large number of drugs for external use are presented as semi-solid formulations. Ointment and suppository bases do not merely act as the carriers of the medicaments, but they also control the extent of absorption of medicaments incorporated in them. An ointment base should be compatible with skin, stable, smooth and applicable, non irritating, non-sensitizing, inert, capable of absorbing water or other liquid preparations, and of releasing the incorporated medicament, readily. The criteria for selection of ointment base depends on

1. Desired release rate of the drug substance from the ointment base
2. Rate and extent of percutaneous drug absorption.
3. Desirability of occlusion of moisture from skin.
4. Stability of the drug in the ointment base
5. Easy removal of base on washing
6. Characteristic of the surface to which it is applied.

**Ointment bases may be classified in several ways**

**Oleaginous bases**: - These generally consist of a combination of more than one oleaginous material such as water-insoluble hydrophobic oils and fats. Earlier ointment bases used to be exclusively oleaginous in nature but nowadays the materials obtained from plant, animal, mineral as well as synthetic origin is employed as oleaginous ointment bases. Combinations of these materials can produce a wide range of melting points and viscosities.

**Absorption Bases**: - These are essentially anhydrous systems composed of hydrophobic ingredients. They are called as emulsifiable bases because they initially contain no water but are capable of taking it up to yield W/O and O/W emulsions. Absorption bases are W/O type emulsions and have capacity to absorb considerable quantities of water or aqueous solution without marked changes in consistency. Absorption bases are mostly mixtures of animal sterols with petrolatum. Combinations of cholesterol and/or other suitable lanolin fractions with white petrolatum are available under different commercial names e.g. Eucerin and Aquaphor.

**Emulsion Bases**: - These bases are classified as W/O or O/W. All W/O emulsions are not water-washable as the oil is in the external phase and O/W emulsions are used in dermatological preparations and cosmetic creams. Some of the popular creams include cold creams, vanishing creams. Skin creams, emollient creams, foundation creams, hand creams etc. Fundamentally creams can be divided into cold and vanishing types.

**Water Soluble Bases**: - These include both anhydrous and hydrous dermatological non-emulsion bases which are water soluble and contain no oil phase. These are generally based on either polyethylene glycols or one or more of the other hydrocolloids. Polyethylene glycols (Carbowaxes) are water soluble, non-volatile, unctuous compounds.¬ They do not hydrolyse or deteriorate and do not support mold growth. They have low irritancy and dermal/oral toxicities. Carbowaxes allow easy diffusion of medicaments to the body tissues but the degree of their absorption is low. Different grade of cabowaxes are available which are designated by a number roughly representing their average molecular weights e.g.- 200, 300, 400, 600, 1000, 1540, 4000 and 6000. At room temperature, carbowaxes 200 to 400 are clear liquids whereas carbowaxes 1000 to 60000 are white, waxy solids. A variety of water washable ointment bases with consistencies ranging from semi-solid to solid can be obtained by blending different polyethylene glycols. Polyethylene Glycol Ointment USP is a blend of Carbowaxes 4000 and 400. Medicaments containing acidic hydrogen may interact with high molecular weight polyethylene glycols forming molecular complexes.

**Water Removable Bases**: - Popular example of this includes vanishing cream.

**Antimicrobial Preservatives: -** Some base, although, resist microbial attack but because of their high water content, it require an antimicrobial preservative. Commonly used preservatives include Methyl hydroxyl benzoate, Propyl- hydroxybenzoate, Chlorocresol, Benzoic acid, Phenyl mercuric nitrate, Benzalkonium chloride, Chlorhexidine acetate, Benzyl alcohol and Mercurial.

**Antioxidants**: - Example of commonly used antioxidants includes Butylated hydroxy anisole, Butylated hydroxy toluene.

**Chelating Agents**: - Example of commonly used chelating agents includes Citric acid, Maleic acid.

**Humectants**: - Example of commonly used humectants includes Poly Ethylene Glycol, Glycerol or Sorbitol.

**Fragrances**: - Examples of widely use fragrances are Lavender oil, Rose oil, Lemon oil, Almond oil.

**Emulsifier**: - Alkyl sulphates, Soaps, Dodecyl benzene, sulfonate Lactylates, Sulfosuccinates, Monoglyceride, sulfonates Phosphate ester, Silicones, Taurates, Quaternary, ammonium compounds Alkoxyalkylamines, Polyoxyethylene, alkyl-aryl ethers Polyoxyethylene fatty, acid ester Polyoxyethylene, sorbitan esters Sorbitan fatty acid, esters Glyceryl fatty acid, esters Sucrose fatty acid, esters Polyoxyethylene polyoxypropylene

**Permeation Enhancers**: - Skin can act as a barrier and prevent deep penetration of drug molecules. With the introduction of various penetration enhancers systemic drug delivery through the transdermal route has gained major footing.

**D. Gaseous dosage forms [22]**

These include: - Inhalers; Nebulisers; Aerosols.

**Inhalers**: - Inhalers are collections, suspensions, or emulsions of drugs kept under pressure in an airborne distributor by a combination of latent forces. Gases, vapours, solutions, and suspensions designed for oral or nasal inhalation are also considered to be forms of inhalation. The medication is delivered from the holder through a spring-stacked valve fusing a metering device in the form of beads that are 50 um wide or fewer. The drug is subsequently inhaled by the patient via a mouthpiece. In certain types, the finger weight propels the valve, whereas in others, the patient breathes through the mouthpiece to activate the valve. It is frequently utilised to treat respiratory related problems including asthma.

**Nebulisers**: - A nebulizer is a medicine delivery system used to inhale medication into the lungs in the form of a mist. Nebulizers are frequently used to treat conditions including cystic fibrosis, asthma, Coronary obstructive diseases, and other respiratory illnesses. Another form of nebulizer is an analytical one, and they are typically utilised in lab settings. It turns a liquid drug into a vapour by pumping air or oxygen through it, which the patient then inhales.

**Aerosols**: - A pressurised dosage form containing one or more therapeutic active substances is called an aerosol. When activated, an aerosol releases a fine dispersion of liquid and solid components in a gaseous medium with a particle size less than 50um. Pressurized packages, pressure packages, or pressurised dosage forms are other names for aerosol. Most of the aerosols are use topically.

The component of an aerosol includes:

* 1. Propellent
	2. Container
	3. Valve and actuator
	4. Product concentrates

**E. Novel dosage forms [23]**

Novel dosage forms have been established and documented to be useful for controlled and targeted drug delivery. They are designed with an aim to minimize drug degradation, prevent harmful side effects and to improve drug bioavailability at the site of administration.

**Liposomes**: - Liposomes were discovered in the early 1960s by Bingham and co-workers. Initially, through they were used to study in vitro simulated – biomembrane behaviour, subsequently, they enraged as strong therapeutic tools in drug delivery and drug targeting. Structurally, liposomes are phospholipid -based colloidal vesicular structures in which hydrophilic core is entirely enclosed by membranous lipid bilayer’s.

**Nanosomes**: - Non – ionic surfactants vesicles or niosomes are now widely studied as an alter - native to liposomes. Through the terminology suggests that distinctions exist between niosomes and liposomes of which the former is having chemical differences in the monomers units, niosomes posses physical properties, which are similar to liposomes, which are formed from phospholipids. As the name indicated, generally non- ionic surfactants vesicles are prepared by the incorporation of components containing non- ionic surfactants. The vesicles forming non-ionic compounds are mainly alkyl ether lipids. These can be broadly divided into two classes based on nature of their hydrophilic head groups, i.e. Alkyl ethers in which the hydrophilic head group consists of repeat glycerol subunits, related isomers or larger sugar molecules, and those in which the hydrophilic head group consists of repeat ethylene oxide subunits. In addition, alkyl esters, amides and fatty acids, and amino acids compounds also from vesicles. Although, niosomes formulations commercially yet to be exploited but they have been proven to be useful in the delivery of anti-infective agents, anti- cancer agents, anti-inflammatory agents, and as a vaccine adjuvants. These systems have been proven to target certain areas of the mammalian anatomy and may be exploited as diagnostic imaging agents.

**Microparticles**: - These are defined as spherical particles with size varying from 50 nm to 2nm, containing a core substance. However, the term microcapsules & microspheres are often used interchangeably. Sphere and spherical particles are also used for particles of large size & rigid morphology. The solid bio degradable microspheres bearing a drug dispensed or dissolved throughout particles matrix have potential in controlled- release of drugs. These carriers received much attention not only prolonged- release formulations but also for the carrier potential in drug targeting particularly anti- cancer drug the tumour. Pre-requisites for ideal micro particulate carriers includes: Longer duration of action, control of drug release, Increase of therapeutic efficiency, Protection of drug, Biocompatibility, Relative stability and water solubility and targetability. Microspheres can be prepared by using any of appropriately selected method including in situ polymerization, solvent evaporation, coacervation phase separation, spray drying and spray congealing, etc., but the choice of techniques depends on the nature of the polymer used, the drug, the intended use and duration of therapy. A number of different substances biodegradable as well as non- biodegradable had been investigated for the preparation of microspheres. These materials include the polymer of natural synthetic origin and also modified natural substances. Synthetic polymers employed as carriers materials are methyl methacrylate, acrolein, lactide, Glycolide and their co-polymers, ethylene vinyl acetate copolymer, polyanhydrides etc. The natural polymers used for the purpose include albumin gelatin, starch, collagen & carrageenan, etc.

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