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A COMPREHENSIVE REVIEW ON LIQUID ORAL DOSAGE FORM

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ABSTRACT

The oral route is preferred for drug administration due to its convenience and patient compliance. Oral dosing is convenience, patient preference, cost-effectiveness and ease of use. Large-scale production of oral dosage forms. Despite their challenges, oral liquid drug delivery systems remain the dosage form of choice for pharmaceutical scientists. Oral liquid dosage forms are mainly divided into biphasic liquid dosage forms and monophasic liquid dosage forms. Biphasic oral dosage forms also include suspensions and emulsions. Syrups, elixirs, and many other liquids are examples of monophasic dosage forms.

KEYWORDS: Liquid oral, Elixir, Syrup, Emulsion, Suspension.

INTRODUCTION

Liquid dosage forms are pharmaceutical preparations where an active drug is combined with non-active components such as solvents and additives to create a liquid medication.[1] While liquid oral dosage forms offer advantages such as dose flexibility and ease of swallowing for children, they may indeed require ingredients that are not child-friendly. Some compounds or excipients commonly used in liquid formulations, such as alcohol, artificial sweeteners, or certain preservatives, may not be suitable for young children due to safety concerns or potential adverse effects.[2]

They are often classified into monophasic and biphasic formulations, and there are several dosage forms within each of these two major groups. In monophasic liquids, it contains only one phase (eg. syrups, elixir, linctuses etc). On the other hand, biphasic liquids are

characterized by the presence of two distinct phases within the formulation. (eg. suspension, emulsion).[3]

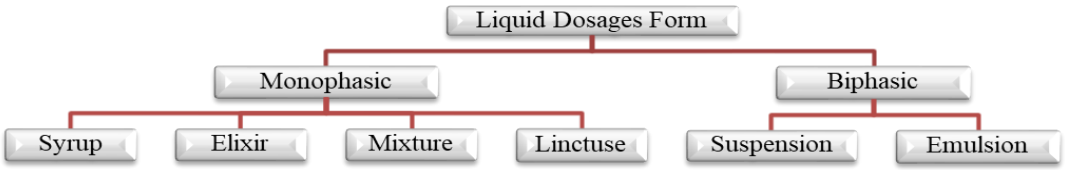


Fig. 1 Classification of liquid oral dosage form.

ADVANTAGES OF LIQUID ORALS[4]

1. Ease of administration: Oral medications are relatively simple to administer compared to other routes. They do not require any specialized equipment or professional assistance, making them convenient for self-administration at home or in outpatient settings.
2. Accurate dosage: Oral dosage forms allow for precise and accurate dosing. Medications can be prepared in specific strengths and easily measured using calibrated devices such as syringes, measuring cups, or droppers, ensuring accurate dosing.
3. Self-medication: Oral medications are well-suited for self-medication, where patients can take prescribed medications independently without the need for healthcare professional assistance. This empowers patients to manage their health and treatment to some extent.
4. Pain avoidance: Some routes of drug administration, such as injections or intravenous infusions, can cause discomfort or pain. Oral medicine, on the other hand, has a painless and non-invasive drug delivery method preferred by many patients.
5. Patient compliance: The ease and convenience of oral dosage forms contribute to higher levels of patient compliance. Patients are more likely to adhere to their prescribed medication regimens when the administration is straightforward and does not involve complex procedures or discomfort.
6. Cost-effective: Oral medications are generally more cost-effective compared to other routes of administration. They are often available in generic forms, which tend to be less expensive than branded or specialized formulations. Additionally, the manufacturing and packaging of oral dosage forms are usually less complex and costly.

DISADVANTAGES OF LIQUID ORALS[5]

1. Medications may lack the structural integrity of solid forms, making them more susceptible to damage and degradation.

2. Patient compliance and developing controlled-release formulations can be challenging with liquid medications.
3. The unpleasant taste of certain medications in liquid form can be challenging, particularly for pediatric and geriatric patients.
4. Liquid medications may require excipients (inactive ingredients) with unknown safety profiles, which could raise concerns.
5. The bioavailability of liquid medications can be influenced by the time the medication spends in the mouth before swallowing.
6. Packaging and storage play an important role in maintaining the safety and efficacy of liquid medicine.

MONOPHASIC LIQUID ORALS

A liquid preparation with two or more compounds in a single-phase system represented by the real solution is referred to as a single-phase equilibrium form. Actual solutions are made by dissolving the solute in an appropriate solvent to create transparent, single-compound solutions.[6] Syrup, elixir, and many other liquids are examples of monophasic dose forms.[7]

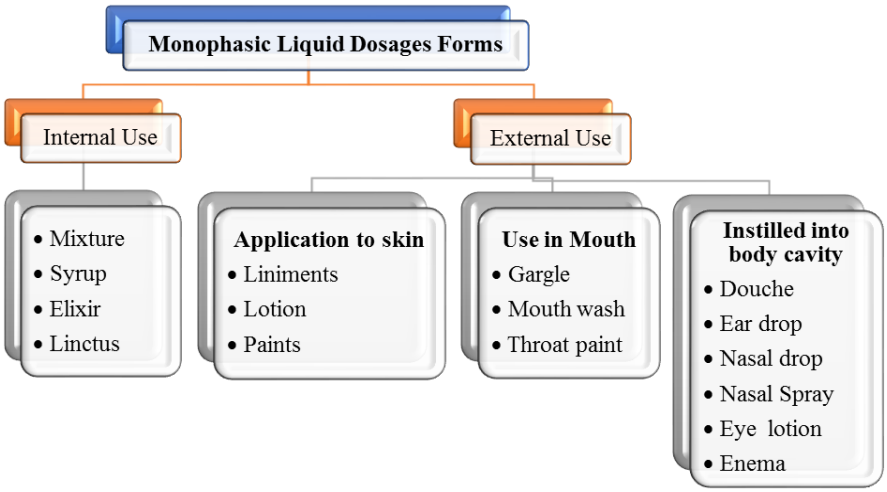


Fig.2-Monophasic Liquid Dosages Forms.

SYRUP

Syrups are aqueous preparations containing sucrose, in concentrations of sugar 66.7% (w/w), and also contain flavoring agents, and medicinal substances.[8] The simplest type of pharmaceutical preparation that exhibits high absorption of medicinal drugs and rapid onset is a solution. In a solution, two components are combined: the solute and the solvent.[9] In a

suspension, the particle diameter is typically greater than 0.5 µm (micrometers). Suspensions are a type of pharmaceutical preparation in which solid particles are dispersed in a liquid medium, such as water or a suitable solvent.[10]

Fig.3

Types of syrup[3]

1. Simple syrups: Simple syrups are non-medicated liquid preparations that are primarily used as a medium or vehicle for other liquid medications, providing sweetness and flavor to enhance palatability and facilitate drug administration.

2. Medicated syrups: Medicinal syrups are commonly used for oral administration and may contain various types of medications, including antitussives, expectorants, antihistamines, analgesics, and more.

3. Flavoured syrups: Flavoured syrups are commonly used in the culinary industry to enhance the taste of beverages, desserts, baked goods, and other food items. They come in a wide range of flavors, including popular options like vanilla, chocolate, caramel, strawberry, mint, and more. These syrups can be added to drinks like coffee, tea, and cocktails, or used as toppings for ice cream, pancakes, waffles, and other treats.

Preparation[11]

Add the sucrose to clean water

↓

Heat to dissolve sucrose, stirring occasionally

↓

Solution is cooled

↓

Add more purified water to get the desired weight

↓

Transfer to a vial, label and dispense

Advantage[12,13]

1. Ease of swallowing: Liquid medications are generally easier to swallow than solid tablets or capsules, making them more suitable for children and elderly individuals who may have difficulty swallowing.
2. Faster absorption: Liquid dosage forms are already in a dissolved or dispersed state, which allows for faster absorption of the drug into the bloodstream compared to solid dosage forms. This can result in a quicker onset of action and more rapid therapeutic effects.
3. Uniform dose: Liquid formulations are homogenous, meaning the drug is evenly distributed throughout the solution. This ensures that each dose provides a consistent amount of the active ingredient, unlike suspensions or emulsions which may require shaking to distribute the drug before administration.
4. Simplified formulation: Developing liquid dosage forms can be simpler and faster compared to solid dosage forms. The drug can be dissolved or dispersed in a suitable liquid vehicle, and additional excipients or flavorings can be easily incorporated to enhance taste, stability, or other characteristics.
5. Various routes of administration: Liquid formulations offer versatility in terms of administration routes. They can be taken orally (by mouth), administered via injections (parenteral route), used as enemas for rectal use, or applied as otic preparations (ear drops), nasal sprays, or ophthalmic (eye) preparations. This allows for flexibility in choosing the most appropriate route based on the specific needs of the patient or the nature of the condition being treated.

Disadvantages[12,13]

1. Bulky and difficult to transport and store: This refers to liquid dosage forms, such as syrups or suspensions, which can take up more space and may require special handling during transportation and storage.
2. Water is commonly used as a vehicle, which is prone to microbial growth: Liquid medications often contain water as a solvent or vehicle. Water provides a good environment for bacteria to grow, so antibiotics are often added to prevent microbial infections.
3. Susceptibility to hydrolysis in direct sunlight: Some medications, particularly those in liquid form, may undergo hydrolysis when exposed to direct sunlight. Hydrolysis could be a chemical response including the breakdown of a compound by water. To maintain

stability, liquid medications should be stored in cool and dark places to minimize exposure to light.

4. Shorter expiry dates compared to solid dosage forms: Liquid medications, due to their susceptibility to degradation processes like hydrolysis and oxidation, may have shorter expiration dates compared to solid dosage forms (such as tablets or capsules) that are less prone to these degradation reactions.
5. Signs of drug instability: Various indicators can suggest drug instability, including changes in colors, precipitation (formation of solid particles or crystals), and microbial growth. These signs may indicate a loss of potency or potential safety risks, highlighting the importance of proper storage and handling.

ELIXIR

British Pharmacopoeia (2013) defines elixirs as pure aromatic preparations for oral administration, containing one or more active ingredients dissolved in a solvent usually consisting mainly of sucrose or polyol derivatives or alcohol containing ethanol (96%). or diluted.[14] Elixirs are transparent and flavored oral liquids that encompass one or more active pharmaceutical ingredients (API) dissolved in a solution, which typically consists of a substantial concentration of sucrose or suitable polyhydric alcohol.[15]

Fig. 4

Elixirs are mainly of two types[3]

1. Medicinal elixirs: These are used as solvents or carriers in the manufacture of medicinal elixirs. Dissolve the active ingredient in a 15–50% by-volume ethanol solution:

a. Elixir (NF)

b. Compound Benzaldehyde Elixir (NF)

2. Medicated Elixir

These include:

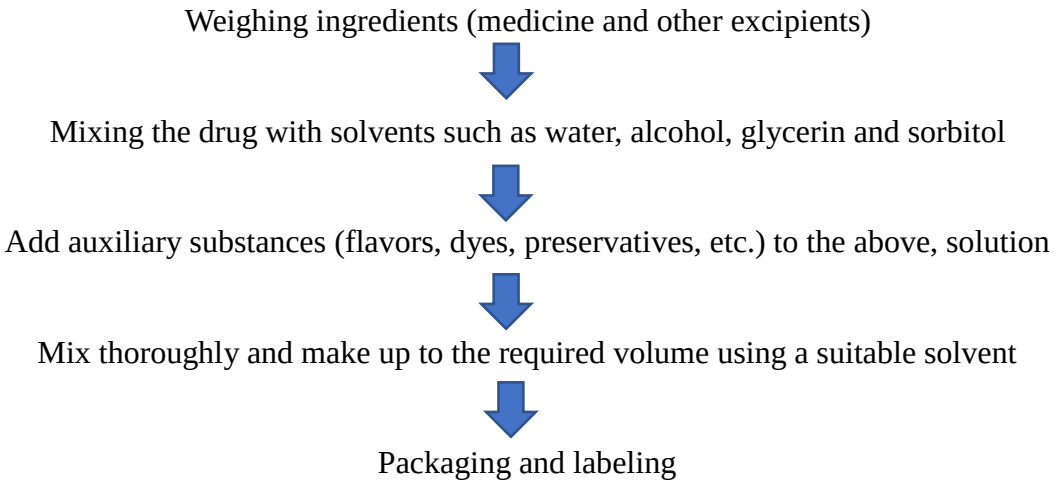
a. Antihistamine elixirs for allergies, such as chlorpheniramine maleate (USP) or diphenhydramine hydrochloride

b. Tranquilizers and hypnotics, the former believed to induce drowsiness and the latter to induce drowsiness

c. Pediatric elixirs, such as chloral hydrate

d. Expectorant elixirs, such as pine oil hydrate, for the relief of coughing up phlegm (that is, coughing up phlegm)

Preparation(11.1)



Advantages[16]

1. Maintenance of Water and Alcohol-Soluble Components: Elixirs, due to their hydroalcoholic nature, are effective in maintaining both water-soluble and alcohol-soluble components in the solution. This makes them suitable for medications that contain both types of components, ensuring better solubility and stability of the active ingredients.
2. Enhanced Stability: Elixirs are often more stable compared to aqueous syrups. The presence of alcohol in elixirs can contribute to the preservation of the formulation, preventing the growth of microorganisms and extending the shelf life of the product. This increased stability is particularly advantageous for medications that require longer-term storage.
3. Ease of Preparation: Elixirs are relatively simple to prepare. They typically involve the dissolution of the therapeutic agent in the appropriate solvent, which can be a

combination of water and alcohol. The straightforward preparation process contributes to the ease and efficiency of compounding these formulations in the pharmacy setting.

4. Pleasant Flavor: Elixirs can be formulated with flavoring agents to provide a pleasant taste. This is especially important for medications with naturally bitter or unpleasant tastes. By incorporating flavors into the elixir formulation, the medication becomes more palatable, improving patient compliance and acceptability.

Disadvantages[17]

1. Inappropriate for Alcohol-Avoidance: Elixirs, by their nature, contain alcohol as a component of the formulation. This can be a disadvantage for individuals who need to avoid alcohol due to personal, cultural, or religious reasons. In such cases, alternative dosage forms that do not contain alcohol, such as syrups or non-alcoholic suspensions, may be more appropriate.
2. Precipitation of Water-Soluble Substances: Alcohol can cause the precipitation of certain water-soluble substances, such as tragacanth, acacia, agar, and many inorganic salts, from aqueous solutions. This can result in the formation of solid particles or a cloudy appearance in the elixir, which may affect the uniformity and consistency of the formulation.
3. Potential Precipitation with Aqueous Solutions: If an aqueous solution is added to an elixir, the reduced alcoholic content in the final preparation may lead to partial precipitation of ingredients. This can occur due to the interaction between the water-soluble components and the remaining alcohol in the elixir, causing the separation or precipitation of certain ingredients.

BIPHASIC LIQUID ORALS

Pharmaceutical suspensions are a specific kind of solid-liquid dispersion that are described as heterogeneous biphasic liquid dosage forms of drugs in which the internal or dispersed phase is composed of particulate matter that is insoluble in the continuous phase but dispersed through it.[18] An emulsion is a type of biphasic dosage form consisting of two immiscible liquids: one being dispersed as droplets within the other, which acts as the continuous phase. The dispersed phase is typically composed of small droplets that are uniformly distributed throughout the continuous phase, resulting in a stable mixture.[19]

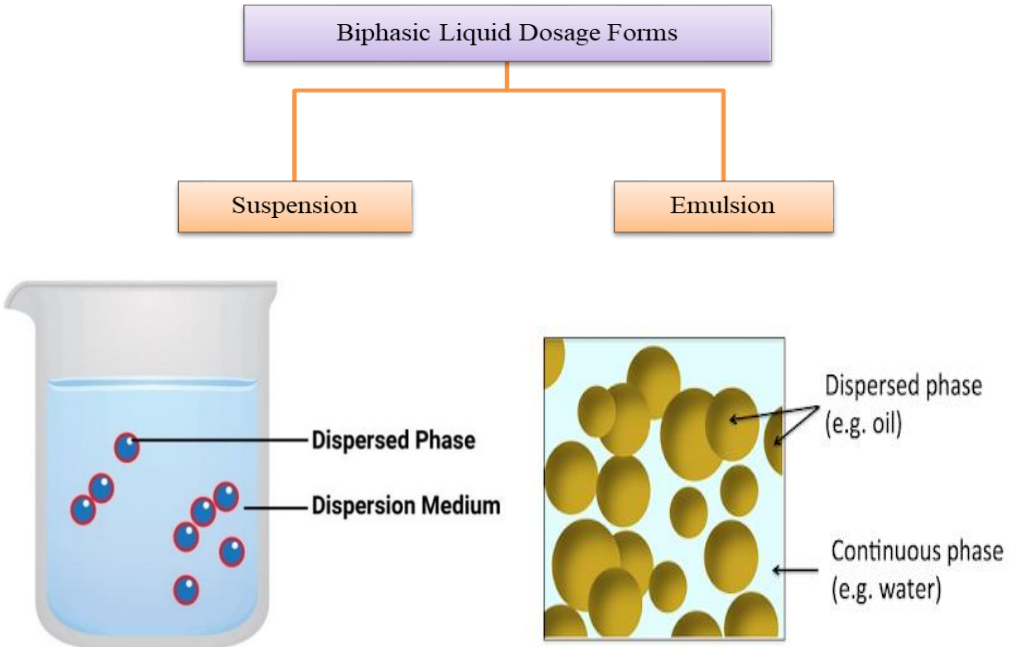


Fig.5

SUSPENSION

A suspension is a biphasic liquid dosage form composed of undissolved drug particles dispersed throughout a liquid vehicle. The dispersed phase consists of the insoluble or poorly soluble drug particles for uniform distribution and accurate dosing, while the continuous phase is the liquid vehicle that maintains the stability of the suspension and prevents the setting or aggregation of drug particles.[20] Pharmaceutical suspensions are thermodynamically unstable due to the tendency of solid particles to settle over time. To prevent this, stabilizers or suspending agents are added to the composition.[21]

Fig.6

Types of Suspensions[22,23,24]

1. According to the Route of Administration

a. Oral Suspensions: Oral suspensions are intended to be taken by the oral route. To enhance patient acceptability and palatability, suitable flavoring and sweetening agents are commonly added to oral suspensions. These additives help mask the unpleasant taste of the action and make the suspension more enjoyable to consume.

b. Topical Suspensions: Topical suspensions are designed for external application, typically on the skin. These suspensions need to be free from gritty particles to ensure a smooth and comfortable application. Gritty particles can cause discomfort, irritation, or potential damage to the skin. The suspension should have a homogeneous texture to ensure uniform and easy application.

c. Suspensions: Parenteral suspensions are administered through injection, typically into the muscle or bloodstream. These suspensions needed to be sterile to prevent the introduction of microorganisms into the body. Additionally, parenteral suspensions should possess the property of drinkability, meaning they can be easily drawn into a syringe and administered smoothly without clogging or causing blockages.

d. Ophthalmic Suspensions: Ophthalmic suspensions are intended for use in the eyes. They must be sterile to avoid any risk of infection or damage to the delicate ocular tissues. Moreover, ophthalmic suspensions require very fine particles to ensure they can be properly distributed and deliver the active ingredients evenly across the eye surface. Large particles can cause discomfort or interfere with vision.

2. According to the Nature of the Dispersed Phase and Methods of Preparation

These classifications based on the type and concentration of solids help in understanding and formulating different types of suspensions for various applications

a. Dilute Suspensions: Dilute suspensions contain a relatively low concentration of solid particles, typically ranging from 2-10% weight/volume (W/V). These suspensions are often used for medications where a lower concentration of active ingredient is desired. Examples you provided, such as cortisone acetate and prednisolone acetate, fall into this category.

b. Concentrated Suspensions: Concentrated suspensions have a higher concentration of solid particles, usually ranging from 10-50% W/V. These suspensions are used when a higher concentration of active ingredient is needed. An example you mentioned is zinc oxide suspension, which is a concentrated suspension.

It's worth noting that highly concentrated suspensions are sometimes referred to as "slurries." Slurries typically have an even higher solid concentration compared to concentrated suspensions.

3. According to the nature of sediment

a. Flocculated suspension: In this type, the solid particles of dispersed phase aggregate leading to a network-like structure of solid particles in a dispersion medium. The aggregates form no hard cake.

b. Non-flocculated suspension**:** Non-flocculated suspensions have solid particles that settle slowly and exist separately in the dispersion medium, forming a hard cake. Although they have a more uniform appearance, redispersing the particles may be difficult.

Preparation[11]

Finely grind all ingredients that are not a fine powder

⬇

Mix the insoluble powders in a mortar

⬇

Add the ingredient that is smallest in volume first and dilute it with the others in ascending order

⬇

Add enough vehicles to create a smooth stage

⬇

Dilute with vehicle until liquid

⬇

Top up with the vehicle and shake thoroughly

⬇

Transfer the suspension to a suitable container, label it and dose.

Advantages[23,25]

1. Duration and onset of drug can be controlled: Suspensions offer flexibility in controlling the duration and onset of drug action. This can be achieved by formulating the suspension with specific excipients or utilizing sustained-release technologies.

2. Mask's bitter taste: Suspensions can be used to mask the bitter taste of certain drugs, such as chloramphenicol. By suspending the drug in a palatable vehicle, it becomes easier for patients to consume the medication.
3. Higher bioavailability: When compared to other dosage forms, suspensions can exhibit a higher rate of bioavailability. Generally, the order of bioavailability from highest to lowest is as follows: solution > suspension > capsule > compressed tablets > coated tablets. This means that suspensions can potentially offer better drug absorption and availability in the body.
4. Improved chemical stability: The chemical stability of some drugs can be enhanced by formulating them as suspensions. An example provided is penicillin G, which may have improved stability when prepared as a suspension.
5. Efficient in intramuscular depot therapy: Suspensions can be suitable for intramuscular depot therapy, where the medication is injected into the muscle and forms a depot or reservoir for slow and sustained drug release over an extended period.
6. Avoidance of co-solvents: Some medications require co-solvents to enhance solubility in other dosage forms. Suspensions can eliminate the need for co-solvents, which can simplify the formulation process and potentially reduce any associated risks or side effects
7. Easy to swallow for elderly patients: Suspensions are often easier to swallow compared to solid dosage forms such as tablets or capsules. This characteristic is particularly beneficial for elderly patients who may have difficulty swallowing or have reduced gag reflexes.

Disadvantages[25]

1. Difficulties in the formulation: Formulating a stable suspension can be challenging. It requires careful selection and optimization of ingredients, including the choice of suspending agents, stabilizers, and preservatives. Achieving a homogenous and uniform distribution of drug particles throughout the suspension can be technically demanding.
2. Handling and transportation challenges: Suspensions may require special handling and storage considerations. Due to their liquid nature and the presence of suspended particles, they can be more prone to settling or sedimentation. Proper care is needed during transportation to prevent the settling of particles and ensure uniform distribution before administration.

3. Sedimentation and stability issues: Over time, the solid particles in a suspension can settle at the bottom of the container, leading to sedimentation. This can result in non-uniform dosing, as the concentration of the active ingredient may vary depending on the portion of the suspension that is administered. Sedimentation can also affect the stability of the suspension, leading to changes in drug potency and effectiveness.
4. Non-uniformity and non-accuracy of dosing: Suspension formulations can be more challenging to achieve precise and accurate dosing compared to other dosage forms. Variations in the dispersion of solid particles and settling can lead to uneven distribution and inconsistent dosing. This can potentially impact the efficacy and safety of the medication, especially in cases where precise dosing is critical.
5. Need for shaking or reconstitution: Before administration, suspensions often require shaking or reconstitution to ensure uniform distribution of the drug particles throughout the vehicle. This additional step can be inconvenient for patients and may introduce errors in dosing if not performed correctly.

EMULSION

The term emulsion is derived from the word emulate meaning "to milk". An emulsion is a type of biphasic liquid preparation consisting of two immiscible liquids that are dispersed and stabilized with the help of an emulsifying agent.[26] Emulsions are colloidal dispersions composed of two immiscible liquid phases that are intricately combined through the application of mechanical shear and surfactant.[27] Indeed, in the realm of pharmaceuticals, emulsions hold great significance as efficacious vehicles for the delivery of drugs through various routes such as parenteral, oral, and topical (skin and eye) administrations.[28]

Fig.7

Types of emulsion[29,30,31]

1**. Simple Emulsion**: Simple emulsions, also known as primary emulsions, are emulsions that consist of two immiscible fluids: a dispersed phase and a continuous phase. The dispersed phase is usually present as droplets suspended within the continuous phase. Simple emulsions can further be categorized based on the nature of the dispersed phase:

a. Oil-in-Water (O/W) Emulsion: In an oil-in-water emulsion, oil droplets are dispersed within a continuous aqueous phase. The oil acts as a dispersed phase, and the water acts as a continuous phase. Examples of oil-in-water emulsions include milk and most topical lotions.

b. Water-in-Oil (W/O) Emulsion: In a water-in-oil emulsion, water droplets are dispersed within a continuous oil phase. Water acts as the dispersed phase, and oil acts as the continuous phase. Examples of water-in-oil emulsions include butter and mayonnaise.

2. Multiple Emulsions: Multiple emulsions, also known as complex emulsions, are emulsions that contain two or more levels of emulsification. They consist of droplets within droplets. Multiple emulsions are designated using a numerical nomenclature (e.g., W/O/W or O/W/O), which indicates the order of the dispersed phases.

a. Water-in-Oil-in-Water (W/O/W) Emulsion: In a water-in-oil-in-water emulsion, water droplets are dispersed within oil droplets, which are further dispersed within a continuous aqueous phase. This type of emulsion is used to encapsulate water-soluble compounds within oil droplets. It finds applications in pharmaceuticals, cosmetics, and food products.

b. Oil-in-Water-in-Oil (O/W/O) Emulsion: In an oil-in-water-in-oil emulsion, oil droplets are dispersed within water droplets, which are further dispersed within a continuous oil phase. This type is used to encapsulate oil-soluble compounds within water droplets. It has applications in controlled release systems and encapsulation technologies.

Preparation[11]

Measure the required amount of oil, water, rubber

Crush the acacia gum in a mortar

Add water and rub it with a rubber band to make slime

Add the required amount of oil in small batches with a rapid spread to form a primary emulsion

Add the remaining water to obtain the desired volume; mix thoroughly to form a uniform emulsion

Transfer the emulsion to a suitable container, label and dispense

Advantages[31]

1. More Consistent Drug Absorption: Drug delivery systems can enhance the consistency of drug absorption by controlling the release of the drug at a desired rate and location.
2. Control of Delivery Profile: Drug delivery systems allow for precise control over the release profile of the drug, enabling sustained or controlled release over an extended period.
3. High Drug Loading Efficiency: Drug delivery systems can achieve high drug loading efficiency by incorporating the drug into a carrier or matrix system.
4. Ease of Manufacture & Scale-up: Many drug delivery systems can be manufactured using well-established processes and technologies, making them easier to produce on a large scale.
5. Enhancement of absorption: Emulsions can be formulated to enhance the absorption of drugs through different routes, such as enteric or dermal absorption. Formulating the drug as an emulsion can improve its solubility and bioavailability, leading to better absorption and therapeutic efficacy.

Disadvantages[30,32]

1. Short Shelf-Life: Emulsions generally have a shorter shelf-life compared to solid dosage forms. This is because emulsions are prone to physical and chemical changes over time, leading to a decrease in their stability and efficacy.
2. Creaming: Creaming refers to the separation of the dispersed phase (oil droplets) from the continuous phase (water) in an emulsion. This separation occurs due to differences in density or particle size distribution. Creaming can result in the formation of a distinct layer of oil on top of the emulsion, leading to changes in appearance and potential loss of active ingredients.
3. Cracking (Breaking): Cracking or breaking occurs when an emulsion loses its homogeneity and separates into two or more distinct phases, usually oil, and water. This

can be caused by factors such as improper formulation, inadequate emulsifier concentration, or external stresses such as temperature changes or agitation.

4. Flocculation: Flocculation is the aggregation of emulsion droplets, leading to the formation of visible clusters or flocs. This can occur due to attractive forces between the droplets, destabilizing the emulsion and resulting in poor physical stability.
5. Phase Inversion: Phase inversion happens when the dispersed and continuous phases in an emulsion switch their roles. For example, an oil-in-water (O/W) emulsion can undergo phase inversion to become water-in-oil (W/O) emulsion. This can occur due to changes in the emulsion's composition, temperature, or other environmental factors.

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