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Review Article

Pharmaceutical Dosage Form "Emulsion"

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ABSTRACT

Pharmaceutical emulsions are liquid dispersed systems in which one liquid is present as very small droplets within another liquid that does not mix with it. The droplets of the dispersed phase usually have a size ranging from approximately 0.1 to 10 μm . Since the two liquids are immiscible, emulsions are considered thermodynamically unstable systems and therefore require the addition of emulsifying agents to maintain stability. In pharmaceutical preparations, emulsions are mainly classified into two types: oil-in-water (O/W) emulsions, where oil droplets are dispersed in water, and water-in-oil (W/O) emulsions, where water droplets are dispersed in oil. For an emulsion to remain stable, certain conditions must be maintained. However, emulsions may show different types of physical or chemical instability, such as creaming, cracking (breaking), phase inversion, and flocculation. Various tests are commonly used to identify the type and stability of emulsions, including the dilution test, conductivity test, dye solubility test, fluorescence test, solubility test, and cobalt chloride test. Emulsions offer several advantages compared with other pharmaceutical dosage forms. Drugs dissolved in emulsions may show improved bioavailability, as the drug is already in a dispersed form. In some cases, emulsions can also reduce gastrointestinal irritation and help minimize the first-pass metabolism effect, thereby improving therapeutic effectiveness.

INTRODUCTION

The word emulsion originates from the Latin term *emulgeo*, which means "to milk." Milk is considered one of the most common natural examples of an emulsion. ⁽¹⁾ In pharmaceutical science, emulsions are defined as liquid dispersed systems in which tiny droplets of one liquid are

distributed throughout another liquid with which it cannot mix. In this system, the liquid that forms droplets is known as the dispersed phase (also called the internal or discontinuous phase), while the liquid that surrounds these droplets is called the continuous phase (or external phase). The size of the dispersed droplets in an emulsion generally ranges from about 0.1 to 10 μm , although in some

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cases it may vary from 0.01 μm to 100 μm . Emulsions are naturally thermodynamically unstable systems, which means the two liquids tend to separate over time. To prevent this separation and maintain stability, emulsifying agents are usually added. ⁽²⁾ An emulsifier is a substance that helps two immiscible liquids, such as oil and water, mix and remain evenly distributed. For example, oil and water normally separate when placed in a container, but the addition of an emulsifier allows them to stay mixed for a longer time. Natural emulsifiers include substances like egg yolk and mustard. Structurally, emulsifiers contain two parts: a hydrophilic (water-loving) head and a hydrophobic (oil-loving) tail. The hydrophilic portion interacts with the aqueous phase, while the hydrophobic portion attaches to the oil phase, helping stabilize the mixture.⁽³⁾ The process of forming an emulsion is known as emulsification. Emulsions are widely used in several industries, including food, pharmaceuticals, agriculture, cosmetics, and petroleum. Although emulsions are commonly described as mixtures of oil and water, they may also contain solid particles or gases in some formulations. Generally, emulsions are unstable because of the natural tendency of oil and water to separate. However, some emulsions can remain relatively stable due to very small droplet sizes and the formation of a protective interfacial film around the droplets, which prevents them from merging together.⁽⁴⁾

Ideal Properties of an Emulsion

1. An ideal emulsion should contain uniformly distributed, very fine droplets of the internal phase. These droplets should remain separate and should not join together to form larger droplets.
2. The droplets of the dispersed phase should not undergo creaming or sedimentation. If slight

creaming occurs, the system should easily redisperse with gentle shaking.

3. The emulsion must retain its original type (oil-in-water or water-in-oil) and should not undergo phase inversion during storage or handling.
4. The formulation should be resistant to microbial contamination, ensuring that microbial growth does not occur during storage.
5. A good emulsion should remain physically stable over a wide range of temperatures without separation or instability.
6. The components of the emulsion should be chemically stable and should not become rancid or degrade due to oxidation during storage.

Types of Emulsions

1. Oil in Water (O/W) Emulsion

In an oil-in-water (O/W) emulsion, small oil droplets are distributed within a continuous water phase. In pharmaceutical preparations, these emulsions are commonly used because they are non-greasy and can be easily washed from the skin with water. O/W emulsions are widely used for oral as well as topical formulations. Oils or fats administered orally, either as active agents or as carriers for oil-soluble drugs, are generally prepared in this form. Such emulsions provide a cooling sensation when applied to the skin and can also help in masking the unpleasant taste of oily drugs. Water-soluble drugs tend to be released more rapidly from O/W emulsions because the external phase is aqueous. Another important characteristic of O/W emulsions is that they show a positive conductivity test, since water is the



continuous phase and conducts electricity efficiently.⁽⁵⁾

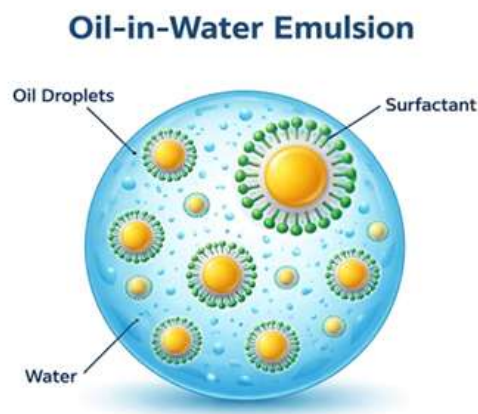


Fig.1 Oil in Water emulsion

2. Water in Oil (W/O) Emulsion

A water-in-oil (W/O) emulsion is a system in which water droplets are dispersed within a continuous oil phase. These emulsions are generally greasy in nature and cannot be easily washed away with water. They are mainly used for topical applications. W/O emulsions form an occlusive layer on the skin that reduces evaporation of moisture and helps hydrate the

stratum corneum. This property can influence drug absorption through the skin. Because of their ability to dissolve oily impurities, they are also useful for removing oil-soluble dirt from the skin. However, their greasy texture may make them cosmetically less acceptable. A typical example is cold cream. These emulsions do not show a positive conductivity test because oil forms the external phase and is a poor conductor of electricity.⁽⁶⁾

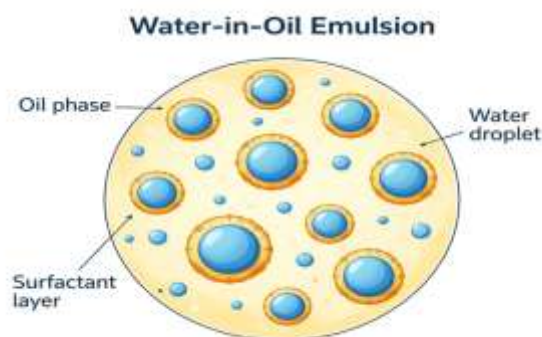


Fig.2 Water in Oil emulsion

3. Multiple Emulsions

Multiple emulsions are complex systems often described as “emulsions within emulsions.” In these systems, small droplets of one emulsion are

dispersed within another continuous phase. The two most common forms are:

- **Oil-in-water-in-oil (O/W/O) emulsion** – oil droplets dispersed in water droplets which are further dispersed in an oil phase.

- **Water-in-oil-in-water (W/O/W) emulsion** – water droplets dispersed in oil droplets that are further dispersed in a continuous water phase.

Multiple emulsions have several pharmaceutical applications, including taste masking, vaccine adjuvants, enzyme immobilization, and controlled drug delivery. They may also enhance drug

penetration through the skin. These systems are sometimes used in cosmetic formulations such as skin moisturizers. Although they provide advantages like protection of entrapped substances and the ability to incorporate different active ingredients in separate compartments, their practical use is limited due to thermodynamic instability and structural complexity.⁽⁷⁾

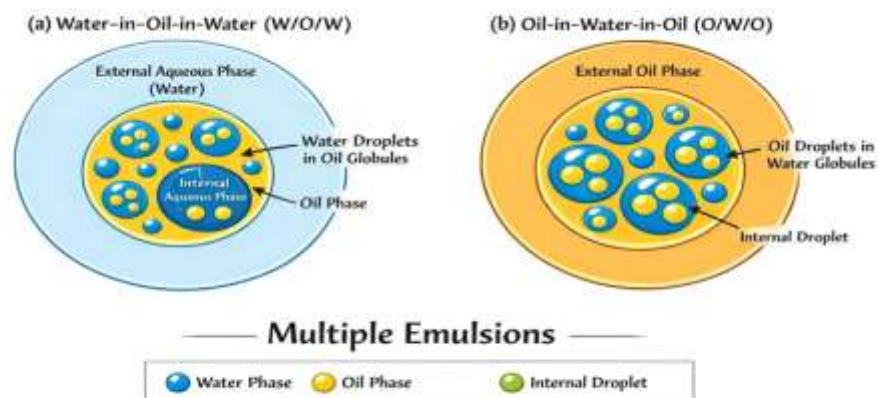


Fig.3 Multiple emulsion

4. Microemulsions

Microemulsions are clear, thermodynamically stable systems composed of oil, water, surfactant, and often a co-surfactant. They appear transparent or slightly translucent because of their extremely small droplet size. Unlike conventional emulsions, microemulsions form spontaneously under appropriate conditions. They can exist as oil-in-water (O/W) or water-in-oil (W/O) systems depending on the surfactant composition and preparation method. Microemulsions are widely studied for drug delivery because they can enhance solubility and bioavailability of poorly soluble drugs. However, one drawback is that they may disturb the lipid structure of the stratum corneum, which can increase drug penetration but may also lead to skin irritation.^(8,9)

5. Macroemulsions

Macroemulsions are traditional emulsions in which the dispersed droplets usually have a size range between 0.1 and 100 μm . Because of the relatively large droplet size, these systems scatter light strongly and therefore appear milky or opaque. Macroemulsions are widely used in pharmaceutical, cosmetic, and food formulations. However, they are thermodynamically unstable and require emulsifying agents to maintain stability.

6. Pickering Emulsions

Pickering emulsions are stabilized by solid particles instead of traditional surfactants. These solid particles adsorb at the interface between oil and water, creating a physical barrier that prevents droplet coalescence. Recently, Pickering

emulsions have gained considerable attention in several fields such as pharmaceutical formulations, cosmetics, food technology, oil recovery, and wastewater treatment due to their improved stability and reduced use of synthetic surfactants.^(10,11)

7. Nanoemulsions

Nanoemulsions are emulsions with extremely small droplet sizes typically ranging from 20 to 200 nm. Because the droplet size is much smaller than the wavelength of visible light, many nanoemulsions appear transparent or slightly translucent. These systems provide several advantages such as improved drug solubility, enhanced bioavailability, and better stability against sedimentation or creaming. When droplet size increases beyond approximately 80 nm, nanoemulsions may become slightly turbid and eventually appear white due to increased light scattering. Unlike microemulsions, nanoemulsions are kinetically stable but not thermodynamically stable.^(12,13)

Theories of Emulsification

Emulsification refers to the process of mixing two immiscible liquids, usually oil and water, with the help of an emulsifying agent to form a stable system. The formation and stability of emulsions can be explained through different scientific theories. The most commonly accepted theories are surface tension theory, oriented-wedge theory, and interfacial film theory.

1. Surface Tension Theory

According to the surface tension theory, emulsification occurs when the interfacial tension between two immiscible liquids is reduced. Emulsifying agents such as surfactants decrease the surface tension at the interface of oil and water.

This reduction in tension allows one liquid to break into very small droplets within the other liquid. As the droplets become smaller, the attractive forces between molecules of the same liquid decrease, which reduces the possibility of droplets joining together again. As a result, a more stable emulsion is formed.

2. Oriented-Wedge Theory

The oriented-wedge theory suggests that emulsifying agents arrange themselves around the droplets of the dispersed phase as a monomolecular layer. These molecules possess both hydrophilic (water-loving) and hydrophobic (oil-loving) parts. Depending on their solubility, they orient themselves at the interface between oil and water. If the hydrophilic portion of the emulsifier is dominant, it tends to form an oil-in-water (O/W) emulsion. On the other hand, if the hydrophobic portion is stronger, a water-in-oil (W/O) emulsion is produced. This orientation helps stabilize the droplets within the continuous phase.

3. Interfacial Film (Plastic Film) Theory

The interfacial film theory states that emulsifying agents form a thin protective film at the boundary between oil and water. This film surrounds the dispersed droplets and acts as a barrier that prevents the droplets from merging with each other. Because of this protective layer, the droplets remain separated and the emulsion remains stable. Emulsifiers that are soluble in water generally favor the formation of oil-in-water emulsions, while oil-soluble emulsifiers tend to produce water-in-oil emulsions.⁽¹⁴⁾

Methods of Preparation of Emulsions

1. Continental Method (Dry Gum Method)

The continental method is commonly known as the dry gum method and is also called the 4:2:1 method. In this technique, the primary emulsion is prepared by mixing 4 parts of oil, 2 parts of water, and 1 part of gum (usually acacia). In this method, the emulsifying agent such as acacia is first mixed thoroughly with the oil in a dry porcelain or Wedgwood mortar. A mortar with a rough internal surface is preferred because it provides better grinding and helps reduce the size of the oil droplets. The gum and oil are triturated until a uniform mixture is obtained. After proper mixing, the required quantity of water is added all at once, and the mixture is triturated rapidly and continuously. During this process, a creamy white emulsion is formed and a characteristic crackling sound can be heard when the pestle moves in the mortar. This sound indicates the formation of a stable primary emulsion. When acacia is properly dispersed in the oil phase, this method generally produces a stable emulsion. However, in certain cases, the quantity of acacia may need to be increased to obtain a satisfactory emulsion. For example, oils such as volatile oils, mineral oil (liquid paraffin), and linseed oil may require modified ratios such as 3:2:1 or 2:2:1 for successful emulsification. ^(15,16)

2. English Method (Wet Gum Method)

The English method, also known as the wet gum method, uses the same basic proportions of oil, water, and gum as the dry gum method, but the order of mixing the ingredients is different. In this technique, the emulsifying agent is first mixed with water to form a mucilage. This is done by triturating acacia with twice its weight of water in a mortar until a smooth and uniform mucilage is formed. After preparing the mucilage, the oil is added gradually in small portions while continuously triturating the mixture. The slow addition of oil along with continuous mixing

allows the oil droplets to disperse evenly in the aqueous phase, leading to the formation of a stable oil-in-water emulsion. The operator may adjust the proportions slightly during the preparation process if necessary to obtain the desired consistency and stability of the emulsion.

3. Bottle Method (Forbes Bottle Method)

The bottle method, also called the Forbes bottle method, is mainly used for the extemporaneous preparation of emulsions containing volatile oils or oils with low viscosity. In this method, powdered acacia is placed in a dry bottle, and the required quantity of oil is added. The bottle is tightly closed and shaken vigorously to mix the oil and gum thoroughly. After this, water is added gradually in small portions, and the bottle is shaken after each addition to facilitate emulsification. Once the entire amount of water has been added, a primary emulsion is formed. Additional water can then be added to adjust the final volume of the preparation. This method is not suitable for highly viscous oils because they cannot be adequately mixed by shaking in a bottle, making proper emulsification difficult. ⁽¹⁷⁾

Tests for Identification of type of Emulsion

Different tests are performed to determine whether an emulsion is oil-in-water (o/w) or water-in-oil (w/o). These tests are based on the properties of the external phase of the emulsion.

1. Dilution Test

The dilution test helps identify the continuous phase of an emulsion. In this method, the emulsion is diluted with either water or oil. An oil-in-water (o/w) emulsion can be easily diluted with water because water is the external phase. However, when oil is added to an o/w emulsion, it may break



because oil is not compatible with the continuous aqueous phase.

Similarly, a water-in-oil (w/o) emulsion can be diluted with oil without separating, since oil is the continuous phase in this type of emulsion.⁽¹⁸⁾

2. Conductivity Test

Water is a good conductor of electricity, whereas oil does not conduct electricity effectively. This property is used in the conductivity test. In this test, two electrodes connected to a small electric bulb are placed into the emulsion. If the bulb glows, it indicates the presence of a continuous aqueous phase, confirming that the emulsion is oil-in-water (o/w). If the bulb does not glow, it suggests that the external phase is oil, indicating a water-in-oil (w/o) emulsion.

3. Dye Solubility Test

This test involves adding a water-soluble dye, such as amaranth, to the emulsion and observing the sample under a microscope. If the continuous phase becomes uniformly coloured, it indicates that water is the external phase, confirming an oil-in-water (o/w) emulsion. In this case, the dispersed oil globules remain colourless while the surrounding phase appears coloured. If an oil-soluble dye, such as Sudan III or Scarlet Red C, is added and the continuous phase becomes red, it suggests that oil is the external phase, indicating a water-in-oil (w/o) emulsion.

4. Cobalt Chloride Test

Filter paper treated with cobalt chloride solution is used in this test. Normally, cobalt chloride paper is blue in colour but turns pink in the presence of water. When a drop of emulsion is placed on the cobalt chloride paper, a change from blue to pink indicates the presence of water as the external phase, confirming an oil-in-water (o/w) emulsion.

If the paper remains blue, it indicates a water-in-oil (w/o) emulsion.

5. Fluorescence Test

This test is performed using ultraviolet (UV) light under a microscope. Oils generally exhibit fluorescence under UV radiation.

If the emulsion shows continuous fluorescence, it indicates that oil is the external phase, suggesting a water-in-oil (w/o) emulsion. On the other hand, spotty or scattered fluorescence indicates that oil is present as dispersed droplets, confirming an oil-in-water (o/w) emulsion.

6. Dye Test

In this test, dyes that are soluble in either oil or water are used to determine the type of emulsion. A water-soluble dye colours the aqueous phase, while an oil-soluble dye colours the oil phase. By observing which phase becomes coloured, the external phase of the emulsion can be identified, thereby determining whether the emulsion is o/w or w/o type.⁽¹⁹⁾

Instability of Emulsions

Emulsions are thermodynamically unstable systems and may undergo several types of physical and chemical instability during storage. The common types of instability observed in emulsions include flocculation, creaming, coalescence, breaking, phase inversion, and chemical degradation.

1. Flocculation

Flocculation occurs when dispersed globules come close to each other and form loose aggregates known as flocs. In this condition, the individual droplets remain separate and do not merge together. Because the droplets maintain their



identity, the system can usually be restored to its original state by gentle shaking. Flocculation can be minimized by providing sufficient electrical charge on the droplets and by maintaining a uniform droplet size distribution. ⁽²⁰⁾

2. Creaming

Creaming is the separation of the dispersed phase due to differences in density between the oil and water phases. The droplets either rise to the top or settle at the bottom depending on the density of the dispersed phase.

- **Upward creaming:** Occurs in oil-in-water (O/W) emulsions when oil droplets rise to the surface.
- **Downward creaming:** Occurs in water-in-oil (W/O) emulsions when water droplets settle at the bottom.

Although creaming does not immediately destroy the emulsion, it can cause uneven distribution of the drug in the formulation. Therefore, emulsions are usually shaken before use to ensure uniform dosing. ⁽²¹⁾

3. Coalescence

Coalescence refers to the merging of smaller droplets into larger ones when the protective film surrounding the droplets becomes weak or damaged. As the droplets combine, the size of the globules increases, which may eventually lead to complete separation of the phases. This phenomenon may occur due to insufficient emulsifying agent, temperature fluctuations, microbial contamination, or prolonged creaming.

4. Breaking (Cracking)

Breaking, also called cracking, is the complete separation of the dispersed and continuous phases of an emulsion. It occurs when the protective film around the droplets is destroyed, causing the droplets to combine irreversibly. In this condition, the oil and water phases separate entirely, and simple shaking cannot restore the original emulsion. ⁽²²⁾

5. Phase Inversion

Phase inversion occurs when an emulsion changes from an oil-in-water (O/W) type to a water-in-oil (W/O) type or vice versa. This transformation may occur due to changes in the volume ratio of the phases, addition of electrolytes, or changes in temperature. For instance, an O/W emulsion stabilized with sodium stearate can convert into a W/O emulsion when calcium chloride is added, as calcium stearate favors the formation of W/O emulsions.

6. Chemical Instability

Apart from physical instability, emulsions may also undergo chemical degradation. The active pharmaceutical ingredient (API) must remain chemically stable throughout the product's shelf life under recommended storage conditions. The formulation should maintain the required potency of the drug while keeping impurities within acceptable limits. In emulsions, the distribution of drug molecules between the oil and aqueous phases can influence reaction rates. In some cases, separating reactive components into different phases may help reduce chemical degradation and improve the stability of the drug. ⁽²³⁾



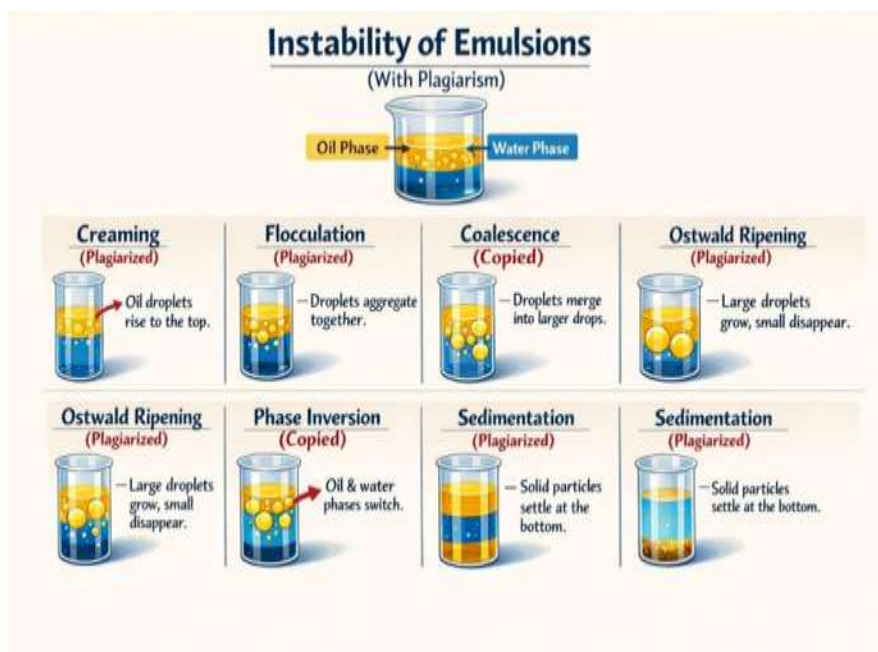


Fig.4 Instability of emulsion

Current Scenario of Emulsions in the Market

Bioemulsifiers

Bioemulsifiers are biologically derived surface-active molecules that act as natural emulsifying agents. These compounds have gained considerable attention in recent years because they offer several advantages over synthetic surfactants, including low toxicity, biodegradability, environmental safety, and excellent biocompatibility. They are capable of stabilizing emulsions even at low concentrations and can function effectively across a wide range of pH values, temperatures, and salinity conditions. Bioemulsifiers are produced naturally by various microorganisms such as bacteria, fungi, and yeast, and they can also be obtained from other biological sources. In comparison with biosurfactants, bioemulsifiers generally possess higher molecular weight structures, which contribute to their strong emulsifying capability. Due to their safety profile and functional properties, bioemulsifiers are increasingly being utilized in the food, pharmaceutical, and biomedical industries. Natural bioemulsifiers are often preferred over

chemically synthesized emulsifying agents because they may provide additional nutritional and health benefits. Therefore, bioemulsifiers derived from microbial sources are considered a promising and sustainable alternative to conventional synthetic emulsifiers when used within acceptable and recommended limits. ⁽²⁴⁾

Applications of Bioemulsifiers

1. Bioemulsifiers have wide industrial applications in sectors such as petroleum processing, food technology, pharmaceuticals, chemical manufacturing, paper and pulp processing, textile production, and cosmetics.
2. They are also regarded as eco-friendly or "green molecules" due to their important role in bioremediation processes, particularly in the treatment and recovery of contaminated soil.
3. In the biological field, bioemulsifiers show promising antiviral, antifungal, and antibacterial properties, which make them

useful in medical and pharmaceutical research.

up operations, including the removal of crude oil spills and polyaromatic hydrocarbons in industrial settings. ^(25,26)

4. These compounds have demonstrated significant potential in environmental clean-

Table 1. Example for bioemulsifier

Microbial Strain	Carbon Source Used	Functional Property	Major Applications
Streptomyces species	Sugarcane vinasse	Production of bioemulsifying compounds	Used in environmental clean up processes such as bioremediation
Streptomyces species	Glucose	Acts as a natural bioemulsifier	Helpful in removing both organic and inorganic contaminants
Streptomyces rimosus	Rapeseed oil	Promotes emulsification activity	Utilized in various industrial as well as non-industrial applications
Streptomyces sp. S22	Sunflower oil	Produces bioemulsifier molecules	Applied in formulation of pesticides, food products, and pharmaceutical preparations
Streptomyces sp. S1	Toluene	Exhibits bioemulsifying ability	Used in preparation of agrochemical, food, and medicinal formulations
Streptomyces spp.	Sunflower oil	Generates both bioemulsifier and biosurfactant	Applied in remediation of hydrocarbon-contaminated environments

Applications of Emulsions

1. Macroemulsions and microemulsions are widely used as drug delivery systems for both hydrophilic and lipophilic therapeutic agents.
2. Pharmaceutical preparations such as creams and ointments are examples of emulsified systems in which liquid phases are dispersed within semi-solid bases for topical application. ⁽²⁷⁾
3. In dermatological and cosmetic formulations, emulsions allow formulation scientists to modify viscosity, texture, appearance, and greasiness of the final product.
 - o Oil-in-water (O/W) emulsions are commonly used as water-washable bases.
 - o Water-in-oil (W/O) emulsions are frequently applied for dry skin treatment and emollient therapy due to their occlusive properties. ⁽²⁸⁾

4. Emulsions also play an important role in medical applications such as radiopaque emulsions, parenteral nutrition emulsions, and blood replacement therapy.
5. Lipid-based emulsions have been explored as ophthalmic drug delivery systems for improved drug absorption and therapeutic effectiveness.
6. The cleansing action of common soaps used for washing clothes and utensils occurs due to the formation of oil-in-water emulsions, which help remove oily dirt.
7. Microemulsions are also being investigated as vaccine delivery systems to enhance the immune response against various microorganisms.
8. In industrial chemistry, emulsions are widely applied in polymer dispersion and polymer synthesis processes. ⁽²⁹⁾

9. Double emulsions (such as W/O/W systems) are particularly useful for the encapsulation of biotechnological compounds, including proteins and peptides.
10. In biological systems, emulsification also plays a crucial role in the digestion and absorption of dietary fats in the gastrointestinal tract.⁽³⁰⁾

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