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### **Review Article**

## **Novel Drug Delivery System Using Microemulsion**

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### **ABSTRACT**

A layer of surfactant molecules at the boundary stabilises microemulsions, which are homogeneous, transparent, and thermodynamically stable mixtures of two immiscible liquids, such as water and oil. Because of their potential uses in a variety of industries, such as fuel, cosmetics, and pharmaceuticals, they have been the subject of much research in recent decades. Depending on the temperature, oil-to-water ratio, and surfactant concentration, microemulsions are categorised as water-in-oil (W/O), oil-inwater (O/W), or bicontinuous. They have a number of benefits, including long shelf life, enhanced treatment efficacy, and natural stability. stability. However, they also have some disadvantages, including the requirement of a large amount of surfactant and cosurfactant, limited solubilizing capacity for high melting point substances, and potential phase separation. Microemulsions have been successfully applied in parenteral, oral, and ophthalmic drug delivery, as well as in cosmetics and fuel. Light scattering, electron microscopy, NMR spectroscopy, and cytotoxicity tests are some of the methods used to characterise them. They are made by phase titration or phase inversion techniques. A greater range of therapeutic applications can be achieved by using microemulsions, which are extremely adaptable pharmaceutical delivery systems that can overcome the majority of the drawbacks of traditional routes of administration. To fully realise their potential as multipurpose delivery carriers, more research is necessary.

### INTRODUCTION

In pharmaceutical research, the creation and advancement of new drug delivery systems aimed at boosting the efficacy of existing medications is an ongoing endeavor. Numerous drug delivery systems have been developed <sup>[1]</sup>.

A microemulsion is a homogeneous, transparent, and thermodynamically stable mixture of two immiscible liquids (like water and oil). A layer of surfactant molecules at the boundary stabilizes this

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blend. The surfactant molecules possess very unique features since they contain polar and nonpolar groups. They first adsorb on the interface, thus allowing them to complete their dual affinity where the hydrophilic groups are in the aqueous phase and the hydrophobic groups are in the oil or the air. Besides, they minimize solvent incompatibility via micellization. The dispersed phase normally comprises tiny particles or droplets of between 5 and 200 nm, and this makes the interfacial tension of the oil/water very small. Microemulsions, when viewed with the naked eye, appear transparent due to the fact that the droplet size measures much less than 25 percent of the wavelength of visible light. They are mixtures that are easily (and sometimes spontaneously) achieved, often in applications that do not require much energy. A co-surfactant or co-solvent may be added in many cases in addition to the surfactant, oil phase, and water phase [2].

Microemulsions have been thoroughly studied over the last several decades due to their potential and promising prospects in a variety applications. The complex phase behavior and attractive microstructures of microemulsion systems have prompted many researchers to gain insight into their structure. deeper microstructures observed in microemulsion phases have been reviewed in detail. Various potential uses of microemulsions as pharmaceuticals have been investigated, particularly for pulmonary, intravaginal, and intrarectal delivery systems of lipophilic drugs (e.g., microbicides, steroids, formulations hormones) and intramuscular (microbicides, steroids, hormones, peptides, or cell-targeting). Other drugs have been tested as well. A recent review by Garti and Aserin covers, among other things, the most recent developments related to microemulsions and both oral and intravenous administration. Due to space

limitations, we cannot go into detail regarding these applications in this review [3].

Microemulsions include oil phase, surfactant, cosurfactant (e.g., sorbitan monooleate, propylene glycol) and aqueous phase blended to form one uniform phase that facilitates the bioavailability of drugs either topically or systemically [4].

It is observed that microemulsions have diverse structural arrangements that are influenced by factors such as the concentration of surfactants, the oil-water ratio, and temperature (Lawrence et al., 2005). Unlike emulsions, microemulsions are made up of a mixture of oil, water, and surfactant, and usually require another ingredient: cosurfactants, which are typically medium-chain linear alcohols that are miscible in water. A combination of both surfactant and co-surfactant ensures the spontaneous dispersion of oil in water (or water in oil) to produce large interface areas. A mixed film that consists of the molecules of a surfactant and co-surfactant stabilizes these interfaces. This is promoted by the low interfacial tension between oil and water, which is nearly zero. Structurally, it is possible to consider microemulsions as micelles greatly expanded by the addition of large amounts of solubilized oil [5].

The interface of microemulsions is dynamic, and the fluctuations that occur on such an interface are continuous and spontaneous. Structurally, they are grouped into water in oil (W/O), oil in water (O/W), and bicontinuous. In normal circumstances, bicontinuous microemulsions are obtained when the oil and water are in approximately equal proportions. (Figure 1) [6].

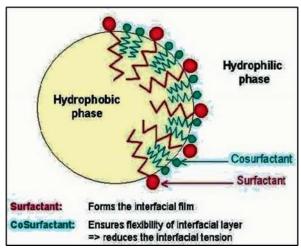


Fig 1: Structure Of Microemulsion

ME exists in two major phases [7]:

- 1. Droplet Phases
- 2. Bicontinuous Phases
- 1. DROPLET PHASES: At higher water concentrations, microemulsions take the form of small oil droplets immersed in an interfacial film of surfactant and co-surfactant molecules, which are distributed throughout a continuous water phase, making up an O/W microemulsion. Conversely, under low water levels, the opposite occurs, and the droplets of water are dispersed in a continuous oil phase, producing a W/O microemulsion.
- **2. BICONTINUOUS PHASES**: The gradual shift from O/W to W/O microemulsions is possible by adjusting the ratio of water to oil. Bicontinuous (or lamellar) structures are most commonly observed in the intermediate region, where water and oil are found in essentially equal quantities. In these systems, the two phases continuously fluctuate, resulting in a net zero overall curvature.

### **ADVANTAGES:**

1. Microemulsions have natural stability, which makes them subject to self-emulsification [8].

- 2. The use of microemulsions as drug delivery mechanisms has the ability to improve the effectiveness of treatment and, in fact, provides a lower total dose exposure and can lessen the threat of adverse reactions<sup>[8]</sup>.
- 3. The microemulsions can be easily prepared without the need to add external energy to form them [9].
- 4. The formation of the microemulsions is reversible <sup>[9]</sup>.
- 5. Compared to emulsions, microemulsions have lower viscosity [1].
- 6. O/W and W/O microemulsions can be used to incorporate a reservoir of either lipophilic or hydrophilic drugs, respectively, in the dispersed phase [1].
- 7. The shelf stability of the microemulsions is long <sup>[6]</sup>.
- 8. Microemulsion-based products can be used in different ways ranging from oral to intravenous administration [6].

### **DISADVANTAGES:**

- 1. A large amount of surfactant and co-surfactant is necessary to stabilize the droplets in a microemulsion [8].
- 2. In pharmaceutical applications, the non-toxicity of a surfactant should be emphasized [8]
- 3. They have a limited capacity for solubilizing substances that have high melting points <sup>[9]</sup>.
- 4. After the formation of an M-3-02 microemulsion, several environmental factors influence its stability e.g. pH and temperature [6]
- 5. There is a possible threat of phase separation [6]

### **APPLICATION:**

In the last two decades, microemulsions have received a lot of research attention because of their



massive potential in a variety of applications. The role of microemulsions in various fields is

- 1. Parentral Delivery
- 2. Oral Delivery
- 3. Microemulsions In Cosmetic
- 4. Microemulsions In Fuel

### 1. PARENTRAL DELIVERY [10]:

A major problem with the use of parenteral delivery, especially through an intravenous route, is that poorly soluble drug delivery faces an insignificant contribution from drug concentration at the target site. Microemulsion formulations afford definite advantages for parenteral application as compared to macroemulsions. Characterized by their small particle size, microemulsions are excreted at a lower rate when compared to coarse emulsions, thereby entailing a longer residence time in the body. O/W and W/O microemulsions may be used for parenteral injection.

### 2. ORAL DELIVERY [8]:

Microemulsion formulas avoid several drawbacks of regular oral dosage forms, such as high levels of drug absorption, improved therapeutic activity, and minimized therapeutic side effects. They have therefore been recognized as an ideal delivery system for drugs such as steroids, hormones, diuretics, and antibiotics.

## 3. MICROEMULSIONS IN COSMETICS [11]:

It is believed that microemulsion formulations enhance faster absorption by the skin. Designing substantial benefits of ultrafine emulsions produced through technologies such as the condensation technique includes excellent stability, safety, and controllable droplet sizes in applications such as the cosmetic and medical fields. Since these ultrafine emulsions are O/W

emulsions with droplets of comparable diameters to microemulsions, the idea behind them is that they are thermodynamically unstable microemulsions. Studies have also been carried out in the production of cosmetic skincare products using commercial nonionic surfactants and oils that are usually used in skincare cosmetic products. There are also patents in the use of the dispersion method to prepare formulations comprising ionic surfactants, and silicone oilbased ultrafine emulsions have been patented as well.

## 4. MICROEMULSIONS IN FUEL [12]:

An added advantage of microemulsion-based fuels is their capability to stably contain water, which can help in limiting soot formation. In combustion, the presence of water increases the cooling depths of the flame and the flicker of the flame. This causes a notable reduction in the emission of gases, including nitrogen oxides (NOx) and carbon monoxide (CO).

### **MICROEMULSIONS IN DRUG DELIVERY:**

Microemulsions have been of great interest over a period of time as potential systems for drug delivery. The strengths of microemulsions are that they are thermodynamically stable, optically transparent, and can be easily produced. Their single-phase structure has microdomains of different polarity and is able to simultaneously solubilize both water-soluble and oil-soluble compounds when necessary. Various methods of drug delivery via microencapsulation are...[13].

- 1. Topical Drug Delivery
- 2. Parentral Drug Delivery
- 3. Oral Drug Delivery
- 4. Opthalmic Drug Delivery

### 1. TOPICAL DRUG DELIVERY [14,15]:



Topical microemulsions perform better penetration of drugs into the skin due to the small diameter of the droplets and the penetration of the lipid bilayer by the use of surfactants. Increased inhibition zones and better retention were demonstrated by Amra K. et al. in the development of a ketoconazole-loaded microemulsion used as an antifungal, in comparison to the conventional cream formulation.

Topical medication administration the following effects are the main ways that microemulsions may improve transdermal drug delivery: Because microemulsions have a high solubility capacity for both hydrophilic and lipophilic drugs, more drugs can be added to them, increasing the concentration gradient across the skin without depleting it.

### 2. PARENTERAL DRUG DELIVERY [14,16]:

Parenteral formulations have relied on sterile microemulsions in order to deliver lipophilic drugs in a safe and controlled manner. Campos et al. produced docetaxel-loaded microemulsion to be administered intravenously and the combination of microemulsion with Brucea javanica oil enhanced the treatment effect. Additional benefits include the internal oil phase's greater resistance to drug leaching and their greater physical stability in plasma compared to liposomes or other vesicles. In parenteral nutrition, microemulsions can also be utilized as intravenous delivery systems for lipids and fat-soluble vitamins.

### 3. ORAL DRUG DELIVERY [17]:

The key goal in formulating a drug has been the creation of an effective drug delivery system that

must be in oral form because the performance of the drug is frequently hampered by either instability or poor solubility in gastrointestinal fluids. Microemulsions may improve the solubilization of poorly soluble medications and solve issues with bioavailability associated with dissolution. This is especially crucial for BCS class II or class IV medications. The effectiveness of the formulated product is crucial to the successful formulation of such medications.

### 4. OPTHALMIC DRUG DELIVERY [18]:

Microemulsions are also a good option for the ocular route of drug delivery. They are inexpensive and simple to make, especially from the perspectives of production and sterilization. Because they have both aqueous and oily layers, they can carry hydrophilic and lipophilic drugs. Moreover, water/oil microemulsions can serve as meaningful carriers for transporting hydrophilic irritating compounds through the eye, as they appear to offer shielding activity.

### CLASSIFICATION OF MICROEMULSIONS

Winsor states that there are four types of equilibrium phases that microemulsions can exist in, normally referred to as Winsor phases. These are:

- 1. O/W Microemulsion Or Winsor I
- 2. W/O Microemulsion Or Winsor II
- 3. Bicontinuousmicroemulsion Or Winsor III
- 4. Single Phase Homogeneous Mixture Or Winsor IV

Fig 2: Classification Of Microemulsion

# 1. O/W MICROEMULSIONS OR WINSOR I

A combination of oil-in-water (O / W) emulsion is created in this type of microemulsion, in which the main part of the surfactant is solubilized in the water phase. The former type is known as a Winsor I microemulsion. It consists of an O/W microemulsion in dynamic equilibrium with excess oil. This microemulsion tends to have a larger interaction volume than W/O microemulsions.

# 2. W/O MICROEMULSIONS OR WINSOR II [19]:

In water-in-oil microemulsions, the oil phase is the continuous phase in which water, as a discontinuous phase, is dispersed. It comprises W/O microemulsions in equilibrium with a surplus water phase, where most of the surfactant is contained in the oil phase, resulting in the establishment of water-in-oil microemulsions. In this type, the region of the continuous surfactant-containing oleic phase constitutes the oil phase, and the water phase is deficient in terms of surfactant; thus, it is assigned the term 'Wins'.

# 3. BI CONTINUOUS MICROEMULSIONS OR WINSOR III [20]:

It contains a microemulsion phase that exists in equilibrium with an oversupply of water and oil. The channels of oil and water interconnect and form a 3-dimensional structure, and the O/W microemulsion can change to a W/O microemulsion by going through this bicontinuous phase. The surfactant concentration in the leaves of water and oil is small in this kind of microemulsion. This is also normally called a Winsor III microemulsion.

# 4. SINGLE PHASE HOMOGENEOUS MIXTURE OR WINSOR IV [20]:

In a one-phase homogeneous system, or Winsor IV, the oil, water, and surfactants are mixed together uniformly. This one-phase (isotropic) micellar solution is obtained through the addition of an adequate amount of amphiphile (a mixture of surfactant and alcohol).

### **COMPONENTS OF MICROEMULSIONS:**

The absorption of drugs at the point of contact is improved since the microemulsions have the property of enhancing penetration, which is primarily related to the oil phase that consists of both saturated and unsaturated fatty acids.

- 1. Oil Phase
- 2. Aqueous Phase
- 3. Primary Surfactant
- 4. Secondary Surfactant (Co-Surfactant)
- 5. Co-Solvent

### 1. OIL PHASE:



Oil is an excellent excipient in formulations because it not only solubilizes the required dose of lipophilic drugs, but it also increases their transportation along the lymphatic intestinal system. This, in turn, enhances gastrointestinal absorption, which depends on the molecular traits of the triglyceride used [21].

### 2. AQUEOUS PHASE:

The water in microemulsion design is purified to a high degree by deionization, double distillation, and the ion exchange process. Hydrophilic drugs, as well as some preservatives, may be included in the aqueous phase, and sometimes even buffer solutions are added. In O/W microemulsions, the droplet structure does not collapse on dilution with biological aqueous fluids, but vice versa in the W/O microemulsion counterpart. In the case of W/O systems, a larger volume of the aqueous phase decreases the ratio of surfactant to water and results in an increased size of the droplet. Further dilution can lead to phase inversion, separation, or of loss the initial microemulsion characteristics, thus at the expense of system stability [22].

### 3. PRIMARY SURFACTANT:

The chosen surfactant must also be able to lower the butanol/water interfacial tension to such a low value that it facilitates dispersion during the preparation of microemulsions and is also capable of forming a compliant film that can readily adjust around the globule, as well as having the appropriate lipophilicity to acquire the required interfacial curvature. Surfactants with low HLB values are generally valuable for W/O mixtures, while those with high HLB values (greater than 12) are more suitable for O/W mixtures. Surfactants with an HLB greater than 20 tend to

require co-surfactants to decrease their effective HLB to a suitable range in order to form a microemulsion [23].

### **4. CO- SURFACTANT:**

One type of surfactant, either ionic or nonionic, typically cannot produce a microemulsion or even attain a maximum microemulsion curve. Any cosurfactant is defined as anything that aids the main surfactant in stabilizing the system. This can consist of either incorporating an extra surfactant or a low molecular weight amphiphilic molecule, e.g., alcohol [24].

### 5. CO-SOLVENT:

The mixture is often required to have quite large surfactant concentrations to form a stable microemulsion of over 30% w/w. The organic solvents in oral formulations, such as ethanol, propylene glycol (PG), and polyethylene glycol (PEG), are suitable since they can enhance the solubility of large quantities of hydrophilic surfactants or drugs in the lipid phase. Additionally, these solvents have the ability to act as co-surfactants in microemulsions [25].

### **METHODS OF FORMULATION:**

Microemulsions offer an attractive drug delivery system for the eye. They are economical and convenient to prepare at the point of production and sterilization. They can hold hydrophilic and lipophilic drugs as they have both an aqueous phase and an oily phase. Moreover, water-in-oil microemulsions can be useful in delivering irritating hydrophilic compounds to the eye since they appear to offer a protective effect [24]. Two methods for the preparation of microencapsulation include:

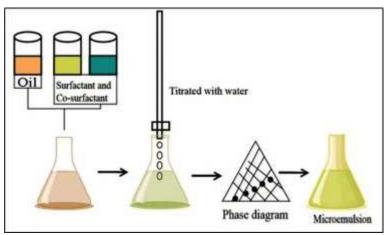


Fig 3: Formation Of Microemulsion

- 1. Phase Titration Method
- 2. Phase Inversion Method

### 1. PHASE TITRATION METHOD [26]:

Microemulsions are generally produced by the spontaneous emulsification (phase titration) method and represented in phase diagrams. Drawing a phase diagram will provide useful information about the complicated relationships that occur when various components are blended. Microemulsions may also be stabilized by other structural forms, depending on the constitution and content of each of the components, which include

emulsions, micelles, lamellar phases, hexagonal and cubic forms, gels, or oleaginous dispersions. However, determining phase equilibria and clearly identifying phase boundaries are important steps involved in their studies. A pseudo ternary phase diagram is frequently created to identify the various zones, including the microemulsion zone, where each corner of the diagram represents 100% of the specific component, By merely taking into account the composition, or whether it is waterrich or oil-rich, the region can be divided into w/o or o/w microemulsions. Careful observations must be made to exclude metastable systems.

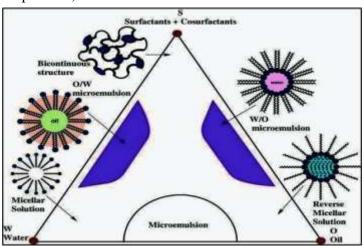


Fig 4: Phase Titration Method

## 2. PHASE INVERSION METHOD [27]:

Microemulsions may be subjected to phase inversion due to an excessive amount of the

dispersed phase introduced or due to changes in temperature. Such inversion carries with it significant physical modifications, such as changes in particle size that may have detrimental



effects on drug release in laboratories and under biological conditions. The mechanism is guided by modifying the inherent curvature of the surfactant. In non-ionic surfactants, this may be accomplished by varying the temperature of a system to obtain an oil-in-water microemulsion at a low temperature and a water-in-oil microemulsion at a higher temperature. This method can also be referred to as the temperature inversion method adopted during the process where phase transition takes place.

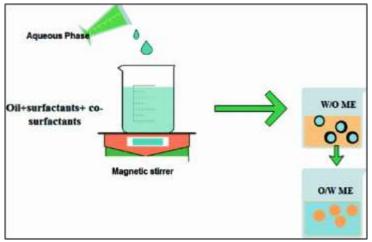


Fig 5: Phase Invesion Method

# THEORIES OF MICROEMULSIONS FORMATION:

Historically, three approaches have been used to explain microemulsion formation and stability. They are as follows:

- 1. Interfacial Or Mixed Film Theory
- 2. Solubilization Theory
- 3. Thermodynamic Theory

# 1. INTERFACIAL OR MIXED FILM THEORY [28]:

The spontaneous generation of microemulsions can be considered a result of the significant entropic benefit of mixing the droplets with the continuous phase. Schulman emphasized the essential importance of the interfacial film, and in the self-formation of microemulsion droplets, he postulated that a complex film is formed at the oilwater interface by surfactants and co-surfactants. This interaction causes a tremendous decrease in

interfacial tension, bringing it to values near zero or even negative, which is expressed as follows.

$$\gamma i = \gamma o/w - \pi i$$

Where,

 $\gamma$ o/w = Oil-water interfacial tension without the film present

 $\pi i = Spreading pressure$ 

 $\gamma i$  = Interfacial tension

## **2. SOLUBILIZATION THEORY** [11]:

The solubilizing capacity of the microemulsions depends on the influences of pressure, temperature, type, and concentration of the components. Therefore, it is of great importance to draw phase stability diagrams (or phase maps) and determine the different structures that will form in a system of water (or salt) with oil, surfactant, and alcohol under various conditions.

### 3. THERMODYNAMIC THEORY [29]:



The free energy of the process of microemulsion formation is affected by the strength of the surfactant in reducing the interfacial tension between water and oil, as well as by entropic changes in the system in a manner that...

### $\Delta Gf = \gamma \Delta A - T \Delta S$

Where.

 $\Delta Gf = Free energy of formulation$ 

 $\gamma$  = Surface tension of the oil-water interface

 $\Delta A$  = Change in surface area on microemulsification

 $\Delta S$  = Change in entropy of the system T = Temperature

### **CONCLUSION:**

Microemulsions are single-phase, isotropic, and thermodynamically stable mixtures of oil, water, and an amphiphile. They contrast with conventional emulsions by being transparent, low in viscosity, and, above all, thermodynamically stable. The application of microemulsions as drug delivery vehicles is a potentially valuable technique for obtaining controlled release, increasing bioavailability, and transporting drugs to a specific location in the body.

Microemulsions are proving to be useful in stabilizing thermolabile drugs, controlling and regulating drug release, as well as in improving drug solubility, increasing bioavailability, and reducing patient variability. They have also been successfully formulated for a wide number of routes of administration. Nevertheless, further investigations are required to elaborate on their physicochemical characteristics in order to attain maximum potential as multi-purpose delivery carriers.

In spite of these gaps, the potential of microemulsions is well worth pursuing, since they

hold no less promise than liposomes. It is interesting to note that one of the microemulsion-based products hit the market long before the first type of liposome-based drug delivery vehicle.

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