Review Article

Microemulsions: A Comprehensive Review of Drug Delivery Systems

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ABSTRACT

Microemulsions are thermodynamically stable, isotropic systems composed of oil, water, and surfactant, offering a versatile platform for improving the pharmacokinetics of insoluble compounds and creating safe formulations. These systems have garnered significant attention in pharmaceutical applications due to their ability to enhance drug solubilization, bioavailability, and controlled release. Microemulsions can be categorized into three types: water-in-oil, oil-in-water, and bi-continuous, each with distinct properties and applications. The formulation of microemulsions involves the selection of suitable components, including oils, surfactants, co-surfactants, and co-solvents, which play a crucial role in determining their stability and efficacy. This review aims to provide a comprehensive overview of microemulsions, including their definition, types, structure, phase behaviour, theories of formation, preparation methods, and physicochemical principles. Additionally, the advantages, disadvantages, and limitations of microemulsions are discussed, along with their applications in various diseases, such as infectious diseases, cancer, and autoimmune disorders. The effects of temperature, pH, and pressure on microemulsion phase behaviour are also examined, highlighting the importance of understanding these factors in optimizing microemulsion formulation and performance.

Keywords: Microemulsion, Drug delivery, Solubilization, Bioavailability, Controlled release.

INTRODUCTION

An alternate drug delivery method called microemulsion has become a useful tool for improving the pharmacokinetics of insoluble compounds and creating safe formulations for them [1]. Microemulsions, which are transparent systems made up of two immiscible liquids stabilized by proper emulsifiers, are thermodynamically stable and isotropic [2].

For the delivery of medications through a variety of administration routes, such as oral, pulmonary, ocular, and parenteral, microemulsions have been characterized as the perfect carriers [3]. Hoar and Shulman proposed the definition of a microemulsion in 1943. According to these scientists, microemulsions are translucent systems that spontaneously form and are made up of a group of droplets bounded by an interphase film made of a surfactant mixture and, if required, a cosurfactant [4].

1. TYPES OF MICROEMULSIONS:

According to their composition, microemulsions can be divided into three categories: [5]

1) Water-in-oil microemulsions, in which water droplets are distributed throughout the continuous oil phase
2) Oil-in-water microemulsions, in which oil droplets are distributed throughout the continuous aqueous phase
3) Bi-continuous microemulsions, in which water and oil microdomains are scattered throughout the system

As microemulsions are thermodynamically stable systems, they can be made simply by combining oil, water, and surfactant at room temperature without the requirement for additional energy [6]. They exhibit a very narrow globule size distribution (< 100 nm) and can form spontaneously without the need for extra kinetic energy [7]. MEs are made up of transparent liquids because the dispersed phase droplets are smaller, typically smaller than 150 nm [8]. Cosurfactants also increase the effectiveness of drug loading and drug dissolution [9]. The system facilitates the delivery of certain sensitive molecules and is thought to be thermodynamically stable (Gasco, 1997). It's remarkable to think about the benefits that microemulsions may offer in drug solubility [10].

Hydrophobic drugs are typically made more orally bioavailable using microemulsion drug delivery systems. They can dissolve hydrophobic medications and are typically small and globular in shape [11].

One of the best techniques for creating active photocatalysts is microemulsion. To maximize interaction and generate specific external surfaces using hollow, core-shell, and other structures, it can control the morphological and structural parameters of both single-phase and composite materials [12]. The water-in-oil (W/O) microemulsion method is a more recent technique that has gained popularity because it effectively controls the particle's size, shape, monodispersity, and composition [13]. Numerous studies have examined how different microemulsion parameters and constituents affect the ultimate size and shape of these structures [14]. The oil-in-water microemulsion is quickly diluted with considerable amounts of water, which lowers the concentration of the surfactant that keeps the system thermodynamically stable[15].

2. STRUCTURE OF MICROEMULSION:

1) Basic structure of microemulsion

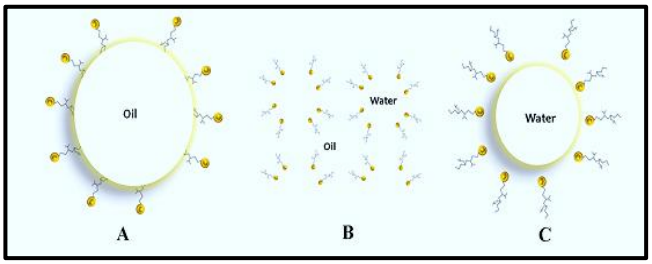

Figure 1: Basic structure of MEs: (A) Oil phase, (B) water and oil phases, (C) water phase [8]

2) Phase behaviour:

Since the first description of microemulsions, which are distinguished by their liquid solutions, optical isotropy, and thermodynamic stability, ternary or pseudoternary surfactant/oil/water systems phase behavior has been studied extensively [16]. Dynamic light scattering (DLS) equipment (Nano ZS ZEN3600 Zetasizer, Malvern Instruments, Malvern, UK) was used to measure the microemulsion droplet size. A Cole-Parmer conductivity meter model 500 was used to test electrical conductivity in three copies on undiluted samples [17].

3. FORMULATION OF MICROEMULSION:

1) Components of microemulsion:

Microemulsion components include the following are the main components of a microemulsion system:[18]

- Phase of oil
- The primary surfactant, or surfactant
- Secondary surfactant, or co-surfactant
- A co-solvent

Table 1: composition of microemulsion [18]

Composition	Example
Oil	1. Saturated fatty acid- lauric acid, carpic acid 2. Unsaturated fatty acid-oleic acid, linolic acid, linolenic acid 3. Fatty acid ester-ethyl or methyl ester of lauric, oleic acid and myristic acid
Surfactant	1. Polyoxyethylene/polysorbate/tween 20,40,60,80 2. Sorbitan monolaurate, eggs lecithin 3. Sodium dodecyl sulphate
Co-Surfactant	1. Ethanol, proranol, butanol, isopropanol, pentanol, hexanol 2. Polyoxyethylene-10-oelyl ether 3. Sodium monohexyl phosphate 4-cinnamic alcohol, cinamic alcohol

2) Winsor phases of formulation:

Winsor categorized the systems based on how solvents and amphiphilic molecules influenced the formation of droplet curvature [19]. However, study of reverse micelle-based microemulsions of the water in oil (Type II) type is currently of interest [20]. Depending on the ratios of water, oil, surfactant, and co-surfactant, three distinct phases may form. Winsor phases I, II, and III are the names given to these phases [21].

When a surfactant biphasic system of oil-in-water (o/w) MEs with excess oil is present in small concentrations, Winsor type I is formed. As an alternative, the ionic liquid-poor aqueous phase (Winsor type II) may coexist with surfactant-rich water-in-oil (w/o) MEs. Winsor type IV is a single phase isotropic solution that forms when a higher amount of surfactant is added, whereas type III is a three-phase system in which a middle phase that is rich in surfactant coexists with both excess water and oil surfactant-poor phases. Winsor III and IV are both microemulsions that are bicontinuous (BC) [22].

The Winsor classification also had an impact on the definition of a microemulsion, which is now fully defined as a colloidal system composed of a mixture of water, oil, and surfactants that permit the spontaneous formation of a system with a single isotropic and translucent aspect, thermodynamically stable, and composed of droplets with a hydrodynamic size of less than 100 nm [19].

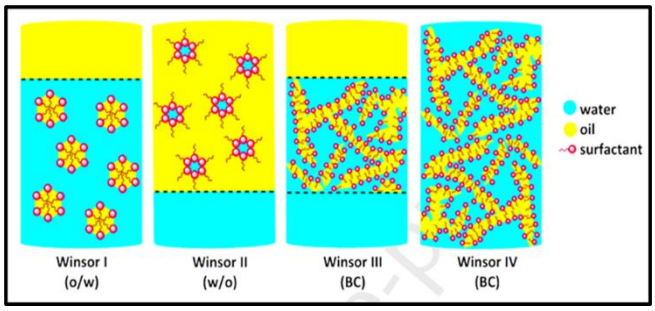

Figure 2: Winsor classification of microemulsion [22]

3) Theories of microemulsion formation:

The formation and stability of microemulsions have traditionally been explained by three different methods. i) Thermodynamic treatments, ii) interfacial or mixed film theories, and iii) solubilization theories [23].

4. PREPARATION TECHNIQUES OF MICROEMULSION: [24]

1) Phase titration method

2) Phase inversion method

1) Phase titration method:

Phase diagrams can be utilized to demonstrate microemulsions, which are created using the spontaneous emulsification method (also known as the phase titration method). Fatty acid and oil are combined with a caustic solution for creating a microemulsion. After that, the resultant microemulsion is titrated using a cosurfactant and an alcohol until the system becomes transparent [25]. From a mechanistic perspective, the rapid diffusion of surfactant, co-surfactant, and/or solvent molecules between the continuous and dispersed phases (interface) causes ME to

form in self-emulsification, also known as spontaneous emulsification. Interfacial tension results from the diffusion and arrangement of those molecules at the interface [26]. In the Phase Inversion Temperature (PIT) method, the oil phase's complete solubilization in the bicontinuous microemulsion results in an o/w nanoemulsion with small droplets [15]. It has been discovered that oils with longer chain lengths can form microemulsions with important transmittances by visible spectrum as the surfactant's chain length increases. Additionally, it is discovered that various alcohols have varied impacts on the development of microemulsions [25].

2) Phase inversion method:

By adding an excessive amount of the dispersed phase, the phase inversion method causes microemulsions to undergo phase inversion. Particle size changes that can impact drug release in vitro and in vivo are among the rapid physical changes that take place during phase inversion [25]. There are two types of phase inversion techniques: (i) Catastrophic Phase Inversion (CPI), which uses the emulsion inversion point (EIP), and (ii) Transitional Phase Inversion (TPI), which includes the phase inversion temperature (PIT) and phase inversion composition (PIC) techniques. It is important to understand that TPI affects spontaneous curvature or surfactant affinity, but CPI does not. A system made up of a fixed amount of non-ionic surfactant, oil phase, aqueous phase, and other components will change from an O/W ME at low temperatures to a W/O ME at higher temperatures by crossing a point of zero-curvature (bi-continuous phase, BC) when the temperature of the system is changed using the PIT method. Once more, the system will create an O/W ME as it cools down [26].

Interfacial tension, bulk viscosity, phase transition region, surfactant structure, and concentration are all variables that contribute to the formation of nanoemulsion. Because it increases the volume fraction of dispersed phase, this technique is also referred to as catastrophic inversion [15].

Rapid physical changes, such as variations in particle size, take place during phase inversion and may affect drug release both in vitro and in vivo. This can be accomplished for non-ionic surfactants by adjusting the temperature, which will force a transitional phase inversion from low-temperature oil-in-water microemulsion to higher-temperature water-in-oil microemulsion [25].

5. PHYSICOCHEMICAL PRINCIPLES OF MICROEMULSIONS: [27,20]

1) **Potential as a Drug Delivery Vehicle:** One of the most promising submicron drug delivery vehicles is microemulsions, particularly for medications that are poorly soluble in water.

2) **Composition of Microemulsions:** The oil phase, aqueous phase, surfactants, and co-surfactants are the four main phases which make up microemulsions.

3) **Ease of Preparation and Stability:** Microemulsions are relatively simple to make, affordable, and thermodynamically stable.

4) **Physical Properties:** The density and viscosity of microemulsions with a higher alcohol content are comparable to those of petrol and diesel.

5) **Factors Affecting Stability:** The concentration of surfactant, temperature, kinematic viscosity, droplet size, and foreign material in the oil feedstock all affect how unstable the microemulsion is.

6) **Variability in Synthesis Products:** The synthesis products varied significantly in terms of crystallinity, textural characteristics, and surface adsorptive qualities towards water, in addition to phase composition [28].

7) **Impact on Physicochemical Characteristics:** It's also crucial to remember that a lipophilic compound's solubilization into an oil may alter its physicochemical characteristics, including its dielectric constant and critical hydrophilic lipophilic balance (cHLB) [19].

6. ADVANTAGES AND DISADVANTAGES:

1) Advantages of Microemulsion: [24-29]

1. Low formation energy requirements and thermodynamic stability.

2. Manufacturing compatibility

3. Better bioavailability and increased drug solubilization.

4. Microemulsions are widely used in colloidal drug delivery systems for controlled release and drug targeting.

5. Because of their superior thermodynamic stability, microemulsions are simple to prepare and require no energy input.

6. Microemulsion formation is reversible.

7. They can become unstable at low or high temperatures, but the microemulsion re-forms when the temperature reaches the stability range.

8. In contrast to emulsions, microemulsions are less viscous.

9. Being able to transport both hydrophilic and lipophilic drugs.

10. By lowering the overall dosage and thereby reducing adverse effects, the use of microemulsions as delivery systems can increase a drug's effectiveness.

2) Disadvantages of Microemulsion [29]

1. Having a limited ability to dissolve substances with high melting points.

2. A lot of surfactants are needed to stabilize the droplets.

3. Environmental factors like pH and temperature have an impact on microemulsion stability.

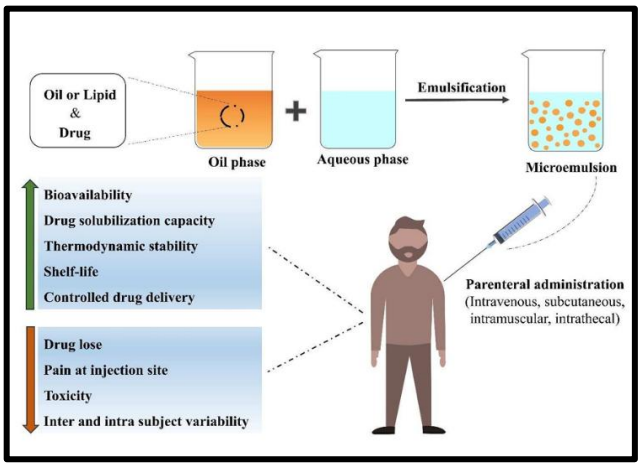

Figure 3: Basic properties of microemulsion concerning biological action [30]

7. APPLICATIONS

1) Pharmaceutical applications: [30]

MEs have become well-known in the pharmaceutical industry as efficient means of delivering drugs with different solubilities, such as hydrophilic and lipophilic substances.

The following diseases are treated with MEs:

1. Infectious disease
2. Cancer
3. autoimmune disorders
4. Diseases that reduce inflammation
5. Cardiovascular diseases
6. A brain disorder
7. The disease Alzheimer's
8. Parkinson's diseases
9. Lateral amyotropic sclerosis
10. HD, or Huntington's disease

2) Other uses: [5]

1) The microemulsions enhance lycopene's skin penetration.
2) Using microemulsion to deliver nimesulide transdermally
3) Microemulsions improve oil recovery, detergency, cosmetics, agrochemicals, and foods.
4) Microemulsions for use as coatings, textile finishing, cutting oils, lubricants, and fuels.
5) Microemulsions in the synthesis of microporous media (microemulsion gel technique) Applications of microemulsions in analysis.
6) New crystalline colloidal arrays as chemical sensor materials using microemulsions as liquids or membranes

8. FACTORS INFLUENCING MICROEMULSION:

Specifically, the theory's simplified geometric assumptions might not adequately represent molecular interactions, and it is insensitive to environmental variables like temperature, pressure, and the oil-to-water ratio [31]. Microemulsification is influenced by several factors, including the nature and concentration of the oil, surfactant, and aqueous phase, the oil/surfactant and surfactant/cosurfactant ratio, the temperature and pH of the environment, and the drug's physicochemical properties (hydrophilicity/lipophilicity, pKa, and polarity). Therefore, these characteristics should be considered while developing microemulsions [32].

1) Temperature:

The phase inversion temperature (PIT) of non-ionic surfactants is reduced by electrolytes, such as sodium chloride. When the PIT is close to the operational conditions, the developing of microemulsions is extremely sensitive to temperature [32]. The microemulsion system undergoes a phase transition from II → III → I and the microemulsion content progressively increases as the temperature of the ionic surfactant system rises from 0℃ to 100℃ [33].

2) pH:

pH of the aqueous phase is a critical factor that also significantly impacts the phase behavior of microemulsions. In the case of microemulsions based on lecithin, it is also important to adjust the initial pH to 7–8 to prevent the hydrolysis of phospholipids and triglycerides to fatty acids. This process can reduce the pH of the microemulsion and potentially impact its stability [32]. The aqueous phase can be composed of water or an aqueous buffer, depending on the desired pH of the system [34].

3) Pressure:

The size of the dispersed droplets within the microemulsion can be influenced by the pressure. Higher pressures can lead to smaller droplet sizes and a more stable system[35]. The traditional approaches to conformance improvement have either shown indications of thermal and chemical degradation, segregation, or irreversible formation damage, among other issues, which has limited the applicability of conformance in the oilfield, especially under different reservoir pressure conditions [36].

9. LIMITATIONS OF MICROEMULSION: [37]

Some factors limit the use of microemulsion in pharmaceutical applications.

1) The selection of microemulsion components (such as cosurfactants) is restricted by the requirement for pharmaceutically acceptable ingredients. causing problems in formulation and with oil and surfactants.
2) For toxicological reasons, the concentration of surfactants and co-surfactants used must be kept low.
3) Phase separation limitations also affect microemulsion.

4) The formulation must meet strict toxicity requirements for intravenous use, and there haven't been many studies published to date.

5) The toxicity of excipients, such as surfactants and co-surfactants, is the main drawback. Research in this area may be expanded with the aid of investigations into safe excipients and assessments of the toxicity parameters of currently available excipients.

CONCLUSION

Microemulsions offer a promising platform for improving the delivery of insoluble compounds and creating safe formulations. Their unique properties, such as thermodynamic stability, isotropicity, and versatility, make them an attractive option for various pharmaceutical applications. The formulation of microemulsions requires careful consideration of component selection, phase behavior, and preparation methods to optimize their stability and efficacy. While microemulsions present several advantages, including enhanced drug solubilization, bioavailability, and controlled release, they also have limitations, such as restricted component selection and potential toxicity concerns. Further research is necessary to overcome these limitations and explore the full potential of microemulsions in pharmaceutical applications. The effects of temperature, pH, and pressure on microemulsion phase behavior highlight the importance of understanding these factors in optimizing microemulsion formulation and performance. By advancing our knowledge of microemulsions and their applications, we can harness their potential to improve the treatment of various diseases and enhance patient outcomes. Ultimately, microemulsions hold promise as a valuable tool in the development of innovative pharmaceutical formulations and delivery systems.

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