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A Comprehensive Review On Microemulsion:- Novel Drug Delivery System

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ABSTRACT

Microemulsions are clear, stable, transparent, and isotropic systems composed of oil, water, surfactant, and co-surfactant. They have gained significant attention in pharmaceutical research due to their ability to enhance the solubility, stability, and bioavailability of poorly water-soluble drugs. They possess unique characteristics such as low interfacial tension, high solubilization capacity, and large interfacial surface area, making them suitable for delivering hydrophobic drugs. Due to their ability to enhance bioavailability and penetration, they have gained significant attention for oral, topical, and parenteral drug delivery. This review focuses on their structure, types, advantages, disadvantages, composition, preparation methods, pharmaceutical applications, current and future development. They significantly improve solubility, absorption, and stability of lipophilic as well as hydrophilic drugs. This study concludes that microemulsions can be effectively used for oral, topical, and parenteral drug delivery with promising future aspects in targeted therapy.

KEYWORDS: Microemulsion, Drug Delivery, Surfactant, co-surfactants, Novel System, Thermodynamically stable, Targeted Delivery, phase inversion, phase titration ,current and future development.

I. INTRODUCTION

The concept of microemulsion was first introduced by Hoar and Schulman in the 1940s, when they titrated a milky emulsion with hexanol to obtain a clear single-phase solution [1]. They successfully formed a microemulsion by dispersing oil in an aqueous surfactant solution and adding alcohol as a co-surfactant, which resulted in a transparent and stable formulation. Later, the term “microemulsion” was first officially used by Schulman and colleagues in 1959 [2], and since then, several definitions have been proposed. Danielsson and Lindman (1981) described microemulsion as “a system of water, oil, and amphiphile that forms a single optically isotropic and thermodynamically stable liquid solution” [3].Microemulsions differ significantly from conventional emulsions. While emulsions are kinetically stable but thermodynamically unstable, microemulsions are thermodynamically stable and do not phase separate over time [4]. In contrast to emulsions, microemulsions exhibit spontaneous formation, small droplet size, and fluctuating structures that can break and reform dynamically [5]. Their droplet size typically ranges between 10–140 nm, and they may exhibit either water-continuous, oil-continuous or bicontinuous structures [6,7]. Surfactants in microemulsions act at the interface between the oil and water phases. Traditional surfactant molecules possess a polar head and a non-polar tail, which help reduce interfacial tension and stabilize the system. Microemulsions can have asymmetrical shapes such as prolate or oblate ellipsoids, depending on the formulation and environmental conditions [8]. Due to their ability to enhance solubilization and thermodynamic activity, microemulsions are considered promising candidates for the oral delivery of poorly water-soluble drugs [9,10]. The absorption rate of drugs also increases as the thermodynamic activity of the vehicle improves [11].

STRUCTURE OF MICROEMULSION:-

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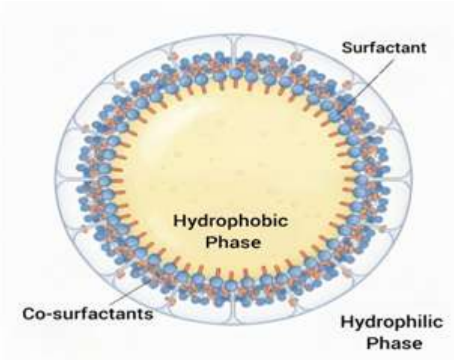
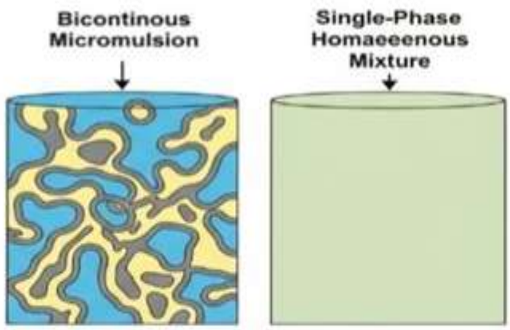


Microemulsions also known as micellar emulsions, are dynamic systems in which the interfacial layer undergoes continuous and spontaneous fluctuations[11]. Structurally, they can be categorized as oil-in-water (o/w), water-in-oil (w/o), or bicontinuous types. In w/o systems, water droplets are dispersed within a continuous oil phase, whereas in o/w systems, oil droplets are distributed throughout the continuous aqueous phase. When water and oil are present in nearly equal proportion, bicontinuous microemulsions may be formed[12]. Depending on the relative amounts of oil, water, and surfactants, these mixtures can generate diverse structural arrangements and phases.

TYPES OF MICROEMULSIONS[13-16]Microemulsions are thermodynamically stable, but are only found under carefully defined conditions. According to Winsor, there are four types of microemulsion phases exists in equilibria, these phases are also referred as Winsor phases.
They are as following:-

1. Oil- in- water microemulsion or winsor I
2. Water – in oil microemulsion or winsor II
3. Bicontinuousmicroemulsion or winsor III
4. Single phase homogeneous mixture or winsor IV

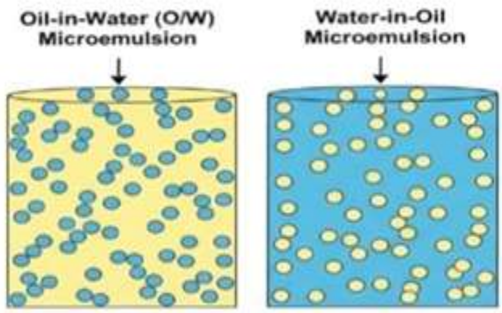


1.Oil-in-Water Microemulsion (Winsor I):-In an oil-in-water (o/w) Microemulsion, oil droplets are encapsulated by a surfactant film (often with the aid of a co surfactant) and dispersed within water, which acts as the continuous phase. This system typically provides a greater interaction volume compared to water-in-oil (w/o) microemulsions.

2.Water-in-Oil Microemulsion (Winsor II):-In a water-in-oil (w/o) microemulsion, water droplets are dispersed within a continuous oil phase. These systems are also referred to as reverse micelles, where the polar heads of the surfactant molecules face inward toward the water droplets, while the hydrophobic tails extend into the oil phase. However, w/o microemulsions administered orally or parenterally can become unstable when exposed to the aqueous biological environment.

3. Bi-continuous Microemulsion (Winsor III):-A bi-continuous microemulsion arises when oil and water are present in nearly equal proportions, resulting in both phases being continuous. In this “sponge-like” structure, irregular channels of oil and water interconnect. During transitions between o/w and w/o systems, the formulation may pass through this intermediate state. They often exhibit non-Newtonian flow and plasticity,characteristics that make them advantageous for drug delivery through topical or intravenous routes.

4.Single-Phase Homogeneous Mixture (Winsor IV):-In a Winsor IV system, oil, water, and surfactant molecules form a single, homogeneous phase without distinct separation between oil and water domains.



ADVANTAGES:-[17-19]

1) Microemulsions are thermodynamically stable and require very little energy to form.
2) They can solubilize poorly water-soluble or oil-soluble drugs.
3) Enhance drug solubilization and improve bioavailability.
4) Useful for controlled and targeted drug delivery through oral, injectable, and topical routes.

5) It Can mask the unpleasant taste of drugs.
6) Help improve the palatability of nutrient oils.

DISADVANTAGES:-[20-22]
1) Limited ability to dissolve substances with high melting points.
2) Require large amounts of surfactants and co-surfactants to stabilize droplets.
3) Their stability is easily affected by environmental factors like temperature and pH.

LIMITATIONS OF MICROEMULSION SYSTEMS:-[23-25]
1) Risk of phase separation during storage or use.
2) Due to potential toxicity, the concentration of surfactants and co-surfactants must be kept low.
3) Not very suitable for intravenous administration because of toxicity issues; only limited studies are available.
4) To ensure safety, surfactants used must belong to the "Generally Recognized as Safe (GRAS)" category.

COMPOSITION
The major components of micro emulsion system are
1) Oil phase
2) Surfactant (Primary surfactant)
3) Co-surfactant (Secondary surfactant)

1) Oil Phase:-
The oil phase is considered the second most important vehicle after water because it helps dissolve lipophilic drug molecules and enhances their absorption through the body's lipid layers.[26] Oils have the special ability to penetrate cell membranes, making them highly effective for delivering lipophilic drugs. The oil phase also affects the swelling of the surfactant's tail group region. Short-chain alkanes penetrate more effectively compared to long-chain alkanes.[27]

2) Surfactant:-
In microemulsion formulation, surfactants play a key role by lowering interfacial tension nearly to zero, which allows proper dispersion of all components. The types of surfactants include non-ionic, anionic, cationic, and zwitterionic. The nature of the surfactant determines the stability of the microemulsion. Non-ionic surfactants gain stability through dipole and hydrogen bonding interactions, while ionic surfactants are stabilized by the formation of an electrical double layer. However, the performance of ionic surfactants can be influenced by salt concentration.

3) Co-surfactant:-
Studies show that a high concentration of single-chain surfactants is needed to lower the oil–water interfacial tension enough for spontaneous microemulsion formation. However, the addition of co-surfactants allows stable microemulsions to form with much lower surfactant concentrations by creating different interfacial film curvatures.[28]Co-surfactants enhance the fluidity of the interface through fluidizing groups such as unsaturated bonds, disrupt liquid crystalline or gel-like structures, and modify the HLB value in a way that promotes spontaneous microemulsion formation.

Composition	Examples
1.Oil Phase	**Saturated fatty acids:** lauric, myristic and capric acid **Unsaturated fatty acids:** oleic acid, linoleic acid and linolenic acid **Fatty acid esters:** ethyl or methyl esters of lauric,myristic and oleic acid
2.Surfactant	Polyoxyl 35 castor oil (Cremophor EL) Polyoxyl 40 hydrogenated castor oil (Cremophor RH 40) Polysorbate20(Tween20) Polysorbate80(Tween80)
3.Co-surfactants	Short chain alcohols like ethanol to butanol Short chain glycols like propylene glycol Medium chain alcohols like amines or acids**.**

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COMPARISON BETWEEN EMULSION AND MICROEMULSION :-

Emulsion	Microemulsion
1.Emulsion is Biphasic	1.Micro-emulsion is Monophasic
2.Stability is Thermodynamically unstable but Kinetically stable	2.Stability is Thermodynamically stable but Kinetically unstable
3.Droplet size about 1-20nm	3.Droplet size about 10-100 nm
4.Interfacial tension is High	4.Interfacial tension is low
5.Appearance of emulsion is cloudy	5.Appearance of emulsion is transparent
6.They are lyophobic	6.They are on the borderline between lyophobic and lyophilic colloids.

Methods of preparation

Two common methods are widely used for the preparation of microemulsions:-
1)Phase Titration Method
2)Phase Inversion Method

1) Phase Titration Method:-

This technique is also known as the spontaneous emulsification method. In this method, a phase diagram is constructed to understand how different components behave when mixed together. The phase diagram helps to study various interactions between oil, water, surfactant, and co-surfactant.Depending on the composition and concentration of these components, different structures may form such as: Micelles,Emulsions,Lamellar phases, Hexagonal or cubic phases, Gels and oily dispersions. The microemulsion region can be easily identified by checking whether the system is oil-rich or water-rich, which helps to distinguish between: o/w (oil-in-water) microemulsion& w/o (water-in-oil) microemulsion (29).

2) Phase Inversion Method:-

In this method, physical changes in particle size and phase occur during preparation, which may affect drug release in both in-vitro and in-vivo conditions.For non-ionic surfactants, phase inversion can be achieved by altering the temperature of the system:At low temperature: o/w (oil-in-water) microemulsion forms**&**At higher temperature: it converts into w/o (water-in-oil) microemulsion.This process is known as the transitional phase inversion method (30). During cooling, the system passes through a point where the surface tension is minimal, allowing the formation of finely dispersed oil droplets.Additionally, changing the water volume fraction can also cause phase inversion. As water content increases, surfactants shift from stabilizing a w/o microemulsion to forming an o/w microemulsion

APPLICATION OF MICROEMULSION IN DRUG DELIVERY:-

Pharmaceutical Applications

During the last two decades, microemulsions have been promisingly used as drug delivery system for its advantages include their thermodynamic stability, optical clarity and ease of penetration. The role of microemulsion as drug delivery system shall be discussed herein.

1)Oral delivery[31]

Designing effective oral drug delivery systems has always been a challenge because drug activity is often limited by instability or poor solubility in gastrointestinal fluids. Microemulsions can improve the solubilization of poorly soluble drugs, especially those belonging to BCS class II and IV, thereby overcoming dissolution-related bioavailability issues. Owing to their polar, nonpolar, and interfacial domains, they can encapsulate hydrophilic drugs and even macromolecules with different solubility profiles. These systems also protect incorporated drugs from oxidation and enzymatic degradation while improving membrane permeability. Currently, marketed microemulsion formulations include SandimmuneNeoral® (Cyclosporine A), Fortovase® (Saquinavir), and Norvir® (Ritonavir). Overall, microemulsions hold great potential for enhancing the oral bioavailability of poorly water-soluble drugs by improving their solubility in gastrointestinal fluids.

2)Parenteral Delivery [32]

Formulating parenteral dosage forms for both lipophilic and hydrophilic drugs is often challenging. Oil-in-water (O/W) microemulsions are advantageous for parenteral delivery of poorly soluble drugs, eliminating the need to administer suspensions. They allow relatively high drug concentrations, reducing the frequency of administration. Compared to liposomes and other carriers, O/W microemulsions provide greater physical stability in plasma, and the oil phase is more resistant to drug leakage. Several poorly soluble drugs have already been formulated using this system. An alternative approach, reported by Von Corsewant and Thoren, replaced C3–C4 alcohols with safer, parenterally acceptable co-surfactants such as polyethylene glycol (PEG 400/660), 12-hydroxystearate, and ethanol. This maintained a flexible surfactant film with near-zero spontaneous curvature, enabling the formation of a balanced middle-phase microemulsion.

3)Topical Delivery [33]

Topical drug delivery offers several advantages, including bypassing hepatic first-pass metabolism, avoiding drug degradation in the stomach and saliva, and reducing related toxic effects. It also allows direct and targeted delivery to affected sites such as the skin or eyes. Recent studies have explored drug penetration through the skin using microemulsions, which can effectively incorporate both hydrophilic drugs (e.g., 5-fluorouracil, apomorphine hydrochloride, diphenhydramine hydrochloride, tetracaine hydrochloride, methotrexate) and lipophilic drugs (e.g., estradiol, finasteride, ketoprofen, meloxicam, felodipine, triptolide), thereby improving their permeation. However, since microemulsion formation requires high surfactant concentrations, the possibility of skin irritation must be considered, especially for long-term applications.

4)Ophthalmic Delivery[34,35]

In conventional ophthalmic formulations, water-soluble drugs are usually prepared as aqueous solutions, while poorly soluble drugs are delivered in suspensions or ointments. However, such systems often face challenges like low corneal bioavailability and limited effectiveness in targeting the posterior ocular tissues. To address these limitations, recent studies have focused on designing novel and more efficient drug delivery systems. Among them, microemulsions have gained attention as promising carriers for ocular application.For instance, chloramphenicol, an antibiotic commonly used to treat trachoma and keratitis, undergoes rapid hydrolysis in traditional eye drop formulations. Lv and colleagues developed an alcohol-free oil-in-water microemulsion system using Span 20, Tween 20, isopropyl myristate, and water, where chloramphenicol was successfully encapsulated. Their findings showed that this microemulsion produced significantly less glycol—the main hydrolysis by-product—compared to marketed eye drops during accelerated stability testing. As a result, chloramphenicol stability was greatly improved.Similarly, Fialho et al. formulated dexamethasone microemulsion eye drops, which demonstrated better ocular tolerability and enhanced bioavailability. The improved penetration into ocular tissues reduced the required dosing frequency, thereby increasing patient compliance.

5)Nasal Delivery [36[

Recently, microemulsions have been explored as potential carriers to improve drug absorption through the nasal mucosa. When combined with mucoadhesive polymers, they can further extend the residence time of the formulation at the absorption site. Lianly et al. studied diazepam microemulsion for the emergency management of status epilepticus and reported that intranasal administration at a dose of 2 mg/kg resulted in rapid absorption, with peak plasma concentrations achieved within 2–3 minutes.

6)Drug Targeting [37]

Targeting drugs to specific tissues is now considered one of the most important objectives in drug delivery. By modifying pharmacokinetics and drug distribution, and confining drug action to the diseased site, both therapeutic effectiveness can be enhanced and toxicity reduced. Shiokawa and co-workers designed a microemulsion system aimed at tumor-targeted delivery of the lipophilic anticancer antibiotic aclacinomycin A (ACM). Their findings indicated that folate-conjugated microemulsions provide a promising approach for delivering ACM to tumor cells. They further observed that attaching folate through a sufficiently long PEG chain improves the targeting efficiency of the emulsion toward tumor tissues.

OTHER APPLICATIONS:-[38]

- Microemulsions as coatings and textile finishing.
- Microemulsions in detergency.
- Microemulsions in cosmetics.
- Microemulsions in agrochemicals.
- Microemulsions in food.

- Microporous media synthesis (microemulsion gel technique).
- Microemulsions in analytical applications.
- Microemulsions as liquid membranes.

CURRENT AND FUTURE DEVELOPMENT:-

Drug Name	Path	Purpose	Ref.no.
Piroxicam	Oral	Increased the solubility	39
Acyclovir	Oral	Increased Bioavailability	40
Diclofenac	Transde-rmal	Permeability enhancement	41
Ibuprofen	Topical	Enhanced the solubility	42
Chloramphenicol	Ocular	Enhancement of permeability	43
Dexamethasone	Topical-Ocular	Improved the Bioavailability	44
Carbamazepine	Intra-nasal	Improved bioavailability	45
Timolol	Ophthal-mic	Enhanced the solubility	46

Over the past two decades, extensive research has been conducted on microemulsion systems to address the challenges associated with the poor aqueous solubility of highly lipophilic drugs and to achieve consistent bioavailability. From an industrial perspective, these systems offer the advantage of easy scale-up while maintaining cost-effectiveness in commercial production. Beyond pharmaceuticals, microemulsions also find applications in cosmetics and drug targeting. Current research is increasingly focused on developing safer, more efficient, and biocompatible components, which will further broaden the potential of this novel delivery platform.

In recent years, microemulsion-based drug delivery systems have gained a lot of attention because they can improve the solubility, stability, and bioavailability of drugs that are poorly soluble in water. Researchers are now developing advanced formulations such as microemulsion-loaded hydrogels, nanoemulsion combinations, and vesicular carriers to achieve better control and targeted delivery of drugs. The use of safe, biodegradable, and biocompatible ingredients has also made these systems more suitable for pharmaceutical applications.

Microemulsions are being studied for various routes of administration including oral, nasal, transdermal, and parenteral delivery. They are especially useful for drugs belonging to BCS Class II and IV, which normally have low solubility. Recent Studies are also investigating their role in treating cancer, neurological disorders, eye diseases, and even in vaccine delivery.Looking ahead, the use of nanotechnology, green formulation methods, artificial intelligence for formulation optimization, and personalized medicine is expected to further improve the efficiency of microemulsions. Scientists are also working on surfactant-free and stimuli-responsive microemulsions that can react to changes in pH, temperature, or enzymes inside the body. With continuous advancements and regulatory support, microemulsions have strong potential to become a reliable and effective platform for future drug delivery and targeted therapies.

II. CONCLUSION

Microemulsions are versatile drug delivery systems capable of carrying multiple therapeutic agents simultaneously. They offer several advantages, including protection of labile drugs, controlled release, improved solubility, enhanced bioavailability, and reduced inter-patient variability. Moreover, microemulsions can be formulated for administration through various routes. Their ability to address the challenges of poor aqueous solubility in highly lipophilic drugs and to provide consistent, reproducible bioavailability highlights their significance. Drug delivery via microemulsions remains a promising research field, with ongoing efforts focused on achieving controlled release, improved bioavailability, and targeted delivery to specific sites within the body.

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