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A NOVEL APPROACH AND RECENT TRENDS AND FUTURE DEVELOPMENTS OF MICROEMULSION DRUG DELIVERY

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ABSTRACT

Microemulsions are liquid solutions of water, oil and amphiphile that are thermodynamically stable and optically isotropic. They have become novel drug delivery systems that allow controlled or sustained release of medication for parenteral, ocular, topical, oral, percutaneous and transdermal administration. Microemulsions are among the best choices for novel drug delivery systems due to their enhanced drug solubilization, extended shelf life and ease of preparation and administration. Microemulsions differ from typical emulsions in that they have low viscosity, transparency and more accurately, thermodynamic stability. This review article's goal is to talk about using microemulsions. a succinct summary and explanation, together with details on the composition, nature and effects of additives, pressure and temperature on the phase behaviour of mixtures.

KEYWORDS

Amphiphile, Microemulsion and Controlled release.

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INTRODUCTON

Dispersions of two immiscible liquids, such as water and oil, that are stabilised by an interfacial coating of surfactants and co-surfactants and thermodynamically stable are known as microemulsions. Compared to standard emulsions, suspensions, micellar solutions and the colloidal systems being studied, microemulsions provide advantages. Microemulsions are an alternative medication carrier. The ability to form spontaneously, simplicity of manufacturing and scaling up, thermodynamic stability, improved drug solubilization of hydrophobic medications, and bioavailability are some of the benefits of microemulsions[1-2].

Microemulsions are among the best choices for novel drug delivery systems due to their improved drug solubilization, longer shelf life and ease of preparation and administration. Microemulsions are liquid solutions of oil, water and amphiphile that are thermodynamically stable and optically isotropic. They have become innovative drug delivery systems that allow for controlled or sustained release of medication for parenteral, ocular, percutaneous, topical, oral, and transdermal administration. Microemulsions are easily distinguished from ordinary emulsions due to their low viscosity, transparency, and-more precisely-thermodynamic stability. Microemulsions are used in a wide range of sectors, including pharmaceuticals, agrochemicals, cutting oils, biotechnology, food, cosmetics, analytical applications, environmental detoxification and many more[3]. Other names for these systems that are commonly used are swelling micelle, transparent emulsion, solubilized oil, and micellar solution. The bulk phases of water and oil in microemulsions are separated by an interfacial region that is abundant in surfactants and cosurfactants. Microemulsions are bi-continuous systems. The fact that these systems are liquid systems with thermodynamic stability and spontaneous development gives them advantages over conventional emulsions. Microemulsions are currently the subject of numerous investigations because of their enormous potential and practical applications. Because of their superior ability to carry drugs, microemulsions are a preferred pharmaceutical formulation. For oral administration, these methods also offer improved clinical potency, reduced toxicity, and increased absorption[3].

STRUCTURE OF MICROEMULSION

Micellar emulsions, another name for micro emulsions, are dynamic systems in which the interface is always and erratically changing[4]. Three fundamentally distinct groupings include them: water in oil, oil in water (o/w) and bi-continuous micro emulsions. To make w/o micro emulsions, water droplets are dispersed in the continuous oil phase, while to create o/w micro emulsions, oil droplets are disseminated in the continuous aqueous phase. When the amounts of oil and water in a system are similar, bi-continuous micro emulsions can form. The mixture of oil, water, and surfactants can produce a wide diversity of structures and phases, depending on the component ratios[5].

TYPES OF MICROEMULSION[6-8]

Microemulsions are only present under precisely specified circumstances, yet they are thermodynamically stable. Winsor identified four different types of microemulsion phases that can exist in equilibrium; these phases are also known as Winsor phases. It's them,

Oil- in- water microemulsion or winsor I

Top oil layer coexists in equilibrium with lower (o/w) micro emulsion phase

Water in oil microemulsions or winsor II

The top (w/o) micro emulsion is in equilibrium with the lower surplus water.

Winsor III

Middle bi-continuous phase of o/w and w/o occurs in equilibrium with upper phase oil and bottom phase water.

Single phase homogeneous mixture, or winsor IV

It creates a homogeneous mixture of oil, water, and surfactant.

Oil- in- water microemulsion or winsor I

The continuous phase, or internal phase, is created in oil-in-water microemulsions by the encircling film of surfactant (and occasionally cosurfactant) that disperses the oil droplets within the water. This type of microemulsion frequently has a larger interaction volume than microemulsions without water[9].

Water - in - oil microemulsion or winsor II

In a microemulsion of the water-in-oil kind, water droplets are surrounded by a continuous oil phase. The reason these are called "reverse micelles" is that the fatty acid tails of the surfactant are directed towards the oil phase, while the polar head groups of the surfactant are directed towards the water droplets. Whether given parenterally or orally, the aqueous biological system has the capacity to destabilise a w/o microemulsion[10].

Bi-continuous microemulsion or winsor III

A bi-continuous microemulsion system has similar amounts of both oil and water. In this case, the mixture's two phases are continuous. When water and oil are combined in an unequal channel, a

"sponge-phase" is produced. When switching from wet to dry microemulsions, this bi-continuous state may be overcome. The malleability and non-Newtonian flow of Microemulsions that are bi-continuous are feasible. These properties make them especially beneficial for topical drug delivery or intravenous administration[11].

Single phase homogeneous mixture or winsor IV

Winsor IV is a single phase homogeneous mixture in which the surfactants, water, and oil are well combined[12].

COMPONENTS OF MICROEMULSION

Oil phase
Aqueous phase
Surfactant
Co- surfactant

Oil phase

The body's lipid layer facilitates better absorption of lipophilic medication molecules, making oil phase the second most important transport medium after water. Oil is perfect for delivering lipophilic active medications because of its unique capacity to permeate cell membranes. The tail group area swelling of the surfactant is influenced by the oil phase. Compared to long chain alkanes, short chain alkanes exhibit a higher degree of this penetration[13].

Aqueous phase

Preservatives and hydrophilic active substances are typically found in the aqueous phase. Buffer solutions may occasionally be employed as the aqueous phase[13].

Ex: Ultrapure Water

Surfactants

To aid in the dispersion of all components, the surfactant used in the creation of the microemulsion must be able to lower interfacial tension as close to zero as possible. These surfactants may:

Non-ionic
Anionic
Cationic
Zwitterionic,

The stability of the microemulsion is influenced by the surfactants' nature. Whereas dipole and hydrogen bond interactions sustain non-ionic surfactants, electrical double layers stabilise ionic surfactants. Ionic surfactants are also affected by salt concentration. Ionic surfactants are therefore generally not recommended because of their susceptibility to stability issues and possible toxicity. Non-ionic surfactants, on the other hand, are more frequently utilised due to the possibility of safe dose forms for medications. Surfactants with HLB values between 3 and 6 are useful when making a W/O microemulsion, while those with higher values between 8 and 18 are useful when making an O/W microemulsion. Surfactants with more than 20 HLB values function as co-surfactants to lower surfactant concentrations to an allowable limit and prevent the development of microemulsions[13].

Co-surfactants

It has been found that substantial quantities of single-chain surfactants are required to reduce the O/W interfacial tension to a point where a microemulsion can form spontaneously. To create a stable micro emulsion composition, various interfacial film curvatures can be created with the least amount of surfactant present if cosurfactants are used. Co surfactants alter the HLB value, break down liquid crystalline or gel formations, and increase the fluidity of the interface due to the presence of fluidizing groups like unsaturated bonds, which causes the spontaneous formation of micro emulsions[13].

FORMATION OF MICROEMULSION[14]

The following steps involved in microemulsion

Preparing Water Phase

(Dissloving water soluble components) (Solids dissolve possibly by heating)

(Centrifugation is used to separate undissolved material)

Preparing Oil Phase

(Dissolving oil soluble component)

Emulsifying Water and Oil Phases

(Mixed in appropriate glassware and equilibrate to given time)

(Using emulsification techniques- stirring, use of membranes, applying shear,ultrasound etc.).

PSEUDO TERNARY PHASE DIAGRAM

The three elements of a typical emulsion-oil, water and surfactant-are optimised using a pseudo ternary phase diagram to determine the concentration range

at which they combine to produce a stable emulsion.

Ternary phase diagrams utilised in microemulsion systems are referred to as pseudo-ternary phase diagrams. When there are more than three formulation components, corners frequently signify a binary mixing of two components, such as a surfactant and a co-surfactant, water and a pharmaceutical, or an oil and a medication.

One side of the triangle, divided into 100 equal parts, represents one component (water, surfactant, or oil). A pseudo ternary phase diagram was made in order to identify the area in which microemulsions are found[15].

Phases Involved Water phase

The amount of water in the system will determine whether it forms a water pool or acts as a dispersion medium in a micro-emulsion system

Oil phase

There are two primary considerations that need to be taken into consideration before choosing the right oil phase since it determines the selection of the other ingredients for the micro emulsion[15].

PREPARATION METHODS

Phase titration method

Microemulsions, which are produced by the spontaneous emulsification process (sometimes referred to as the phase titration technique), can be represented using phase diagrams. Phase diagrams are a useful tool for researching the complex network of interactions that may arise from the combination of multiple components. Microemulsions and a range of association structures (emulsion, micelles, lamellar, hexagonal, cubic, and various gels and oily dispersion) are produced according on the chemical composition and concentration of each component[16]. Phase boundary delineation and phase equilibrium identification are the main components of the investigation. Instead of using quaternary phase diagrams (four component systems), which are more time-consuming to create and comprehend, pseudo ternary phase diagrams are commonly used to identify the various zones, including the microemulsion zone, where each corner of the figure represents 100% of the specific component. Only the composition-whether it is rich in water or oil-may be used to categorise the region as w/o or o/w microemulsion. When making observations, caution should be used to rule out metastable systems[17].

Phase inversion temperature method (PIT)

Phase inversion in microemulsions can occur as a result of excessive dispersed phase addition or temperature fluctuations. Phase inversion causes significant physical changes, such as particle size alterations, which may affect medication release in vivo and in vitro. These methods function by changing the natural curvature of the surfactant. For non-ionic surfactants, this can be accomplished by adjusting the system's temperature to produce a transition from an o/w microemulsion at low temperatures to a w/o microemulsion at higher temperatures (transitional phase inversion). As the system cools, it crosses a threshold of zero spontaneous curvature and negligible surface tension, which promotes the production of finely distributed oil droplets[18]. This process is called the phase inversion temperature (PIT) technique. It is possible to consider more than just the temperature, such as the salt content or pH level, in addition to the temperature. Furthermore, a change in the spontaneous radius of curvature can be accomplished by adjusting the water volume percentage[19].

When water is gradually added to oil, water droplets initially form in a continuous oil phase. Initially stabilising a w/o microemulsion, the spontaneous curvature of the surfactant switches to stabilising an o/w microemulsion at the inversion locus. Short-chain surfactants form flexible monolayers at the o/w interface, which at the inversion point produce a bicontinuous microemulsion[20].

ADVANTAGES OF MICROEMULSION SYSTEM[21-26]

As a result of their improved thermodynamic stability, microemulsions are simple to make and require minimal energy input.

Microemulsion creation is reversible. At low or high temperatures, they may become unstable, but when the temperature returns to the stable range, the microemulsion recovers.

Microemulsions are thermodynamically stable systems that enable the system to self-emulsify.

In contrast to emulsions, microemulsions have low viscosities.

Drugs that are hydrophilic and lipophilic as well as those that are insoluble in both aqueous and hydrophobic solvents can be dissolved using microemulsions, which function as super solvents.

Possessing the capacity to transport both hydrophilic and lipophilic medications.

Lipophilic or hydrophilic (O/W, or W/O microemulsions) dispersion phase medications may be stored in the dispersed phase as either a lipophilic or hydrophilic drug reservoir.

The effectiveness of a medicine can be increased by using microemulsion as a delivery mechanism, allowing the overall dose to be decreased and minimising adverse effects.

Make liquid dose forms more palatable to patients.

By removing fluctuations, this approach is excellent for increasing both the rate of absorption and bioavailability.

The development of regulated and sustained drug release systems may be favoured.

First pass metabolism should be minimised using the best method.

DISADVANTAGES OF MICROEMULSION SYSTEM[21-23]

Having a low solubilizing ability for compounds with high melting points.

To stabilise droplets, a lot of surfactants are needed.

Environmental factors like pH and temperature might affect how stable a microemulsion is.

Mucosal toxicity can result from an excess concentration of surfactants.

APPLICATION OF MICROEMULSION

The application of micro-emulsion in delivery system is given as follows

Oral delivery system

Parental delivery system

Topical delivery system

Nasal delivery system

Parenteral Delivery

Formulating lipophilic and hydrophilic drugs in parenteral dosage forms has proven to be difficult. The preparation of w/o microemulsions is beneficial in parenteral drug delivery scenarios when the injection of suspensions is not required. Frequent administration of medication requires high concentration. They have better physical stability in plasma than liposomes or other delivery technologies and the internal oil phase is more resistant to drug leaching. Many poorly soluble drugs have been made into o/w microemulsions for parenteral administration[27].

Oral delivery

Due to the possibility that low solubility or gastrointestinal fluid instability could impair a drug's ability to function, developing effective oral delivery systems has proven challenging. Microemulsions can address the problems with dissolution-related bioavailability by improving the solubilization of drugs that are not easily soluble, particularly BCS class II/class IV medicines. Different amounts of macromolecule solubility are present in the polar, non-polar and interfacial domains that encapsulate hydrophilic medicines. In integrated medications, these systems have been preventing agonist oxidation, enzymatic degradation and enhanced membrane permeability. To prepare oral administration, readily accessible microemulsions from the market

Comprise Norvir® (Ritonavir), Fortovase® (Saquinavir), Sandimmune Neoral® (Cyclosporine A), and so on. Poorly water-soluble medicines can have their oral bioavailability increased by making them more soluble in gastrointestinal fluids, which might be beneficial in the creation of microemulsions[28-30].

Topical Delivery

One of the advantages of topical medicine distribution is the avoidance of the drug's hepatic first-pass metabolism and its negative effects. These offer direct drug administration and drug targetability to the affected areas of the skin and eyes. The subject of medication absorption through the skin has been well researched. To improve drug penetration, these studies include both hydrophilic (5-fluroracil, apomorphine hydrochloride, diphenhydramine hydrochloride, tetracaine hydrochloride, methotrexate) and lipophilic (5-fluroracil, finasteride, ketoprofen, meloxicam, felodipine, triptolide) drugs. Microemulsion creation requires a high concentration of surfactant. Features that cause skin irritation must be especially

considered when they are intended for long-term use[31].

Nasal Delivery

Nowadays, studies are being conducted on microemulsions as a pharmaceutical delivery technique to enhance drug absorption through the nasal mucosa. Adhering polymers help to extend their stay in the mucosa. Lianly *et al*. examined the impact of diazepam on emergency treatment for status epilepticus. At a dosage of 2mg kg-1, they found that diazepam was absorbed by the nose very fast, reaching peak plasma concentration in 2-3 minutes[32].

Other Applications

The microemulsions enhance lycopene skin penetration.

The use of microemulsion as a carrier for nimesulide transdermal permeation.

The microemulsions improve oil recovery, detergency, cosmetics, agrochemicals, andmeals.

The use of microemulsions as lubricants, coatings, cutting fluids, corrosion inhibitors, and textile finishing agents.

Synthesis of microemulsions in microporous medium (microemulsion gel method) Applications of microemulsions in analysis[33].

FACTOR AFFECTING FORMULATION OF MICROEMULSION SYSTEM Property of surfactant

Surfactant has two sets of hydrophilic and lipophilic groups. The hydrophilic single chain surfactant cetylethyl ammonium bromide completely dissociates in diluted solution and tends to form an o/w microemulsion. When the surfactant is administered in large concentrations or is present in salt, the degree of polar group dissociation is greatly reduced and the resulting system may lack type[34,35].

Property of Oil Phase

The capacity of the oil phase to permeate and inflate the surfactant monolayer's tail group area also affects curvature; this enhanced negative curvature compared to the state without a microemulsion is known as tail swelling[36].

Packing Ratio

The kind of microemulsion is determined by the surfactant's HLB through its impact on packing and film curvature. The examination of film curvature for surfactant interactions resulting in microemulsion production[37].

Temperature

When establishing the effective head group size of nonionic surfactants, temperature is crucial. They are hydrophilic at low temperatures and form a typical o/w system. They create w/o systems at higher temperatures because they are lipophilic. Microemulsion coexists with excessive water and oil phases at a medium temperature and develops a bicontinuous structure[38].

EVALUATION OF MICROEMULSION[13]

Visual inspection

After each addition of water, the combination of the oil, surfactant, and co-surfactant was visually inspected. By visual inspection, the samples were classified as microemulsion, emulsion, or gel formation.

Thermodynamic stability

Thermodynamic stability studies were conducted to address the issue of the formulation being metastable.

Centrifugation

For 30 minutes, the formulation was centrifuged at 3500rpm to assure its physical stability.

Stress test

These studies were carried out in an effort to identify the ideal microemulsion formulation for harsh environments. Six cycles of stress were conducted at 4°C, 45°C, and then 25°C and 21°C for 48 hours, which was followed by around three cycles at each of those temperatures. Coalescence, cracking, and phase separation were examined in the samples.

Measurement of pH

Using a calibrated pH metre (Digital Potentiometer Model EQ-601 Equip-Tronics), the pH values of the optimised formulation were determined by submerging the electrode into the dispersion.

Viscosity measurements

Using a Brookfield Viscometer (DV-E Brookfield Viscometer Model-LVDVE), the viscosity of the optimised formulation was assessed without dilution.

Zeta potential determination

The zeta sizer was used to measure the samples' zeta potential. Results were obtained after samples

were put in transparent disposable zeta cells. Before each experiment, cuvettes were cleaned with methanol and rinsed with the sample that would be analysed.

Particle size determination

Using a Horiba SZ-100 nanoparticle analyzer at 28°C, the mean particle size and particle size distribution of the drug-loaded microemulsion were assessed. It gauges the variation in scattered light intensity brought on by particle mobility. In triplicate, each sample wasmeasured.

RECENT TRENDS AND FUTURE DEVELOPMENT

Over the past 20 years, a lot of research has been done on the microemulsion system in an attempt to provide consistent bioavailability and innovative solutions for the low water solubility of highly lipophilic medicinal compounds. Scaling up is easy from an industrial perspective when evaluating the relative costs of commercial manufacturing. Microemulsion is used for cosmetic and medicinal targeted applications.

These days, research efforts are focused on developing safer, more appropriate, and effective microemulsion components that will expand the applicability of this novel delivery mechanism. In order to allow the use of such an extraordinarily powerful drug delivery system for the benefit of humanity while taking significant ethical considerations into account, one hopes that our society will be able to muster the resources and moral fortitude required.

Examples

Table No.1

S.No	Oil	Surfactant	Co- Surfactant
1	Olive oil	Tween 20	1- butanol
2	Castor oil	Tween 40	Ethylene glycol
3	Palm oil	Tween 80	Ethanol
4	Sunflower oil	Span 40	Glycerol
5	Almond oil	Cremophor EL	Isopropyl alcohol

Mineral oil	Cremophor RH40	Propylene glycol
Soyabean oil	Labrafac PG	PEG 400
Captex355	Labrafil M1944CS	PEG 600
Capryol90	Labrasol	Span 20
Isopropyl myristate	Lecithin	Span 80
Isopropyl palmitate		
Octanic acid		

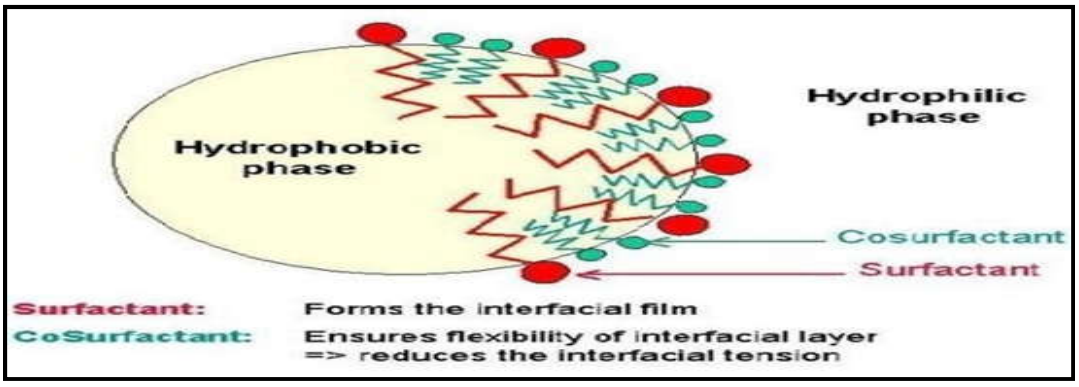

Figure No.1: Structure of Microemulsion

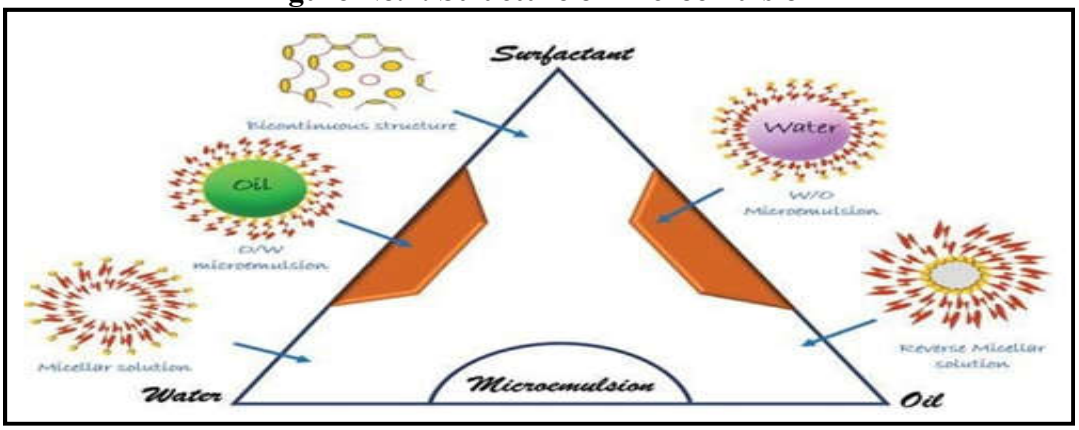

Figure No.2: Ternary phase diagram

CONCLUSION

A microemulsion drug delivery system allows for the simultaneous delivery of many drugs. It is possible to make preparations using microemulsions that work well with most delivery systems, protect labile pharmaceuticals, control drug release, improve solubility and increase bioavailability. The role of microemulsion in providing novel solutions to address the problems of highly lipophilic pharmaceutical compounds' limited water solubility and delivering high, more consistent, repeatable bioavailability. Research on the administration of medications using microemulsions is ongoing and shows potential for both drug targeting to different parts of the body and controlled release with enhanced bioavailability.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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