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MICROEMULSIONS -AS AN EXCELLENT CARRIER FOR ADVANCED DRUG DELIVERY SYSTEM

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ABSTRACT

The microemulsion is the best candidate as a novel drug delivery system because of its long-life span and improves drug solubilization with ease of preparation and administration. Microemulsions are transparent, long-lasting, an isotropic fusion of oil, water, and surfactant, regularly mixed with a cosurfactant. Microemulsions are thermodynamically secure and optically isotropic liquid solutions of oil, water, and amphiphile. They have risen as novel vehicles for drug delivery that allow controlled or sustained release for ocular, percutaneous, topical, transdermal, and parenteral management of medicaments. After finding microemulsions, they have increased importance in basic research and industry due to their unique properties, ultralow interfacial tension, large interfacial area, thermodynamic security, and the capacity to solubilize the insoluble drugs. Microemulsions are readily differentiated from typical emulsions by their lucidity, low viscosity, and, more basically, their thermodynamic secureness. This review paper gives knowledge about microemulsions' preparation, composition, advantages, and applications.

KEYWORDS

Microemulsions, Advantages, Composition, Preparation and Evaluation.

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INTRODUCTION

The design and development of a new drug delivery system to increase the efficacy of the existing drug is an ongoing process in pharmaceutical research. Since there are many types of drug delivery systems that have been developed, one in particular, the colloidal drugs delivery system, has the capability for achieving the goal in drug targeting[1]. Hoar and Schulman introduced the microemulsion idea was introduced in the 1940s by Hoar and Schulman,

who brought about a clear single-phase solution by triturating a milky emulsion with hexanol. They prepared the first microemulsion by dispersing oil in an aqueous surfactants solution and adding alcohol as a co-surfactant, leading to a clear, stable formulation[2]. Microemulsions are thermodynamically secure, isotopically clear dispersion of two immiscible liquids, such as oil and water, stabilized by an interfacial film of surfactants along with co-surfactants. Microemulsions provide possible drug carriers. Microemulsions offer the advantages of spontaneous formation, peaceful manufacturing and scale-up, thermodynamic stability, improved drug solubilization of hydrophobic drugs, and bioavailability[3]. The existence of surfactant and cosurfactant in the system makes the interfacial tension very low. Therefore, microemulsions form spontaneously, with a 10 to 140nm mean droplet diameter. The main difference between macroemulsions and microemulsions lies in the size and shape of the particles dispersed in the continuous phase: these are at least an order of magnitude smaller in the case of microemulsions (10-200nm) than those of standard emulsions (1-20μm). Macroemulsions consist of approximately spherical droplets of one phase dispersed into the other, whereas microemulsions continuously evolve between various structures ranging from droplet-like swollen micelles to continuous structures[4] (Table No.1).

Advantages of microemulsion[3,5,6]

- Microemulsions are thermodynamically stable and allow the self-emulsification of the system.
- Microemulsions behave like super solvents for drugs and can dissolute both hydrophilic and lipophilic drugs, inclusive of fairly indissoluble drugs in both aqueous and hydrophobic solvents.
- The drug moiety should be quick and effective penetration.
- Enlarge the patient compliance in liquid dosage forms.
- Drug targeting and controlled drug release behave as a bioavailability enhancer for poorly water-soluble drugs.
- It is used as a carrier for topical, oral, nasal, and transdermal applications.
- Microemulsions are minimized toxic side effects and depletion in the volume of carrying vehicles.
- They give protection from hydrolysis and oxidation.

Disadvantages of microemulsion[7,8]

- It has a limited capacity for topical application due to its destructive and irritant properties.
- The surfactant should be non-poisonous for use in pharmaceutical applications.
- Microemulsion stability is affected by environmental parameters such as temperature and pH. These parameters change as microemulsion is delivered to patients.
- The use of a massive concentration of surfactant and co-surfactant is necessary for stabilizing the droplets of a microemulsion.

Structure of microemulsion[1]

Structurally, they are split into oil in water (o/w), water in oil (w/o), and bi-continuous microemulsions. In w/o microemulsions, water droplets are dispersed in the continuous oil phase, while o/w microemulsions are found when oil droplets are distributed in the continuous aqueous phase. In a system where water and oil are similar, the bi-continuous microemulsions may arise (Figure No.1).

TYPES OF MICROEMULSIONS[9]

According to Winsor, four types of microemulsion phases exist in equilibrium. These phases are mentioned as Winsor phases (Figure No.2). They are:

Winsor I (two-phase system)

Upper oil layer exists in balance with the lower (o/w) microemulsion phase.

Winsor II (two-phase system)

The upper (w/o) microemulsion is balanced with lower excess water.

Winsor III (three-phase system)

Middle bi-continuous phase is in equilibrium with upper phase oil and lower phase water.

Winsor IV (single-phase system)

Appears as a homogenous mixture of oil, water, and surfactant.

Composition of microemulsions[10] **(Table No.2)**

An oil phase.

An aqueous phase.

A primary surfactant (anionic, nonionic or amphoteric).

A secondary surfactant or Co surfactant.

An oil phase[11]

The oil phase must be selected appropriately since it controls the selection of the other ingredients for the microemulsion. Two main factors need to be considered before selecting the suitable oil phase. The first factor is to notice the oil's solubilizing capacity for the selected substance. The second factor is determined the microemulsion forming region must enhance the oil phase. Oils with tiny hydrocarbon chains are more accessible to micro-emulsify than oils with long hydrocarbon chains. An oil's capacity to dissoluble lipophilic groups is directly proportional to the chain length of the oil. Thus, the chosen oil should be solubilizing the API and ease the formation of microemulsions with desired characteristics.

An aqueous phase[12,13]

The aqueous phase comprises preservatives and hydrophilic active components. Sometimes Buffer solutions are used as an aqueous phase. Most frequently, water is used as the aqueous phase. The pH of the aqueous phase always needs to be adjusted due to its significant impact on the phase behaviour of microemulsions.

Surfactants[14]

Non-ionic surfactants are known to be slighter toxic than ionic surfactants. The surfactant chosen must decrease the interfacial tension to a minimal value, which eases the dispersion process during the microemulsion preparation and provides a flexible film that can gladly deform around the droplets and be of the relevant lipophilic character to give the correct curvature at the interfacial region. The typical surfactant concentration in the microemulsion formulation ranges between 30-60% w/w. Surfactants with high HLB (>12) values assist the immediate formation of o/w droplet and quickly spread the appearance in aqueous media.

Example: Sodium lauryl sulphate, sodium glycolate.

Co-surfactants[15]

In most instances, single-chain surfactants exclusively are impotent to decrease the o/w interfacial tension adequately to enable a microemulsion to form. The presence of cosurfactants allows the interfacial film sufficient flexibility to take up distinct curvatures required to develop microemulsion over a wide range of compositions. Short- to medium-chain-length alcohols (C3-C8) are regularly added as cosurfactants which decrease the interfacial tension and enlarge the fluidity of the interface.

Construction of phase diagram[8]

Pseudo-ternary phase diagrams of oil, water, and co-surfactant/surfactants mixtures are constructed at established cosurfactant/ surfactant weight ratios. Phase diagrams exist by mixing the ingredients pre-arranged into glass vials, titrated with water, and stirred effectively at room temperature. The formation of the Monophasic/Biphasic system is confirmed by seeing only. If turbidity appears followed by phase separation, the samples are examined as a biphasic system. Single-phase, limpid and transparent mixtures are visualized after stirring, and the samples are marked as points in the phase diagram. The region covered by these points is considered the microemulsion region of existence.

METHODS OF PREPARATION

Phase Titration Method

Phase inversion method

Phase titration method[16]

Microemulsions are produced by the spontaneous emulsification method (phase titration method) and can be illustrated with the help of phase diagrams.

The construction of a phase diagram is a convenient approach to study the complex series of interactions that can occur when different components are mixed. Microemulsions are formed along with various interrelation structures (emulsion, micelles, lamellar, hexagonal, cubic, multiple gels, and oily dispersion) depending on each component's chemical composition and concentration. Understanding their phase equilibria and separation of the phase boundaries are essential aspects of the study. The quaternary phase diagram is time-consuming and hard to interpret. A pseudo ternary phase diagram is often constructed to find the different zones, including the microemulsion zone. Each corner of the diagram represents 100% of the specific component (Figure No.3). The region can be separated into w/o or o/w microemulsion by simply considering the composition, whether it is oil-rich or water-rich. Observations should be made delicately so that the metastable systems are not included.

Phase inversion method[17]

Phase inversion of microemulsion occurs upon incorporating excess of the dispersed phase or in response to temperature. During phase inversion, severe physical changes occur, including changes in particle size that can alter the drug release both *in-vivo* and *in-vitro*. These methods make use of changing spontaneous curvature of the surfactant. For non-ionic surfactants, these can be achieved by changing the system's temperature, forcing a transition from an o/w microemulsion at low temperatures to a w/o microemulsion at elevated temperatures (transitional phase inversion). During cooling, the system crosses a point of zero unconstrained curvature and minimal surface tension, encouraging the formation of finely dispersed oil droplets. This technique is referred to as the phase inversion temperature (PIT) method. Instead of the temperature, it may consider other variables such as salt concentration or Ph value instead of the temperature alone. Also, it can receive a transition in the unconstrained radius of curvature via changing the water amount fraction. By successively including water into the oil, in the beginning, water droplets are fashioned in a non-stop oil phase. Enlarge the water amount fraction adjustments, the unconstrained curvature of the surfactant from at first stabilizing a w/o microemulsion to an o/w microemulsion at the inversion locus. Short-chain surfactants structure pliable monolayer at the o/w interface arises in a discontinuous microemulsion at the inversion.

EVALUATION PARAMETERS OF MICROEMULSION SYSTEM

Physical appearance[18]

For a Physical look, the micro emulsion can be explored visually for homogeneity, fluidity, and optical clarity.

Limpidity test (percent transmittance)

The limpidity of the systems was measured spectrophotometrically make use of spectrophotometer (Shimadzu, UV-160, Japan).

Determination of the specific gravity

The specific gravity of the systems was determined, at environment conditions, using a specific gravity bottle of 25ml Capacity.

Determination of the globule size[19]

The droplet size of the microemulsion formulation was determined by JDS Quasi Elastic Light Scattering, Uniphase, US Instruments. The size determination is much easier than the photomicroscope technique through the light scattering method.

Determination of thermal stability

To stored twenty milliliters of drug-loaded microemulsions in a 25ml translucent borosil volumetric container at three different temperatures, i.e., 4°, 25° and 40°C, 1°C in BOD for 1 month. Samples were periodically withdrawn for visual inspection to observe any physical changes like loss of clarity, coalescence, turbidity, etc. Also, the samples were observed to determine the loss of the aqueous phase that is an essential part of the microemulsion stability.

pH of the microemulsions

The microemulsion samples were taken into the sample tubes and used a μ pH meter to determine the pH of the distinct samples as the pH of the

formulation are not the only factor and that the stability of the microemulsions also imparts a role to changes the bioavailability of the drug through microemulsion at the site of permeation.

Measurement of electrical conductivity[20]

The conductivity measurements help determine whether the microemulsion system formed is oil-continuous or water-continuous. The solubilization of the water phase in the chosen oily mixture was monitored quantitatively by measuring the electrical conductivity (σ). The conductivity (σ) of the formulated samples was measured using a conductivity meter (Digital Conductivity meter Model–ME-976 C from Max Electronics).

Viscosity measurements

The viscosity of the optimized formulation was determined as such without dilution using Brookfield Viscometer (DV-E Brookfield Viscometer Model-LVDVE). Brookfield Viscometer contains a cup, which is stationary, and a spindle that is rotating. Different sized rotating spindles are used and immersed in the test material. Large-sized spindles (large diameter and surface area) are used for liquids with low viscosity, while for higher viscosity liquids, small spindles (small diameter and surface area) are used. Rotate the spindle in the microemulsion till we get a constant dial reading on the display of the viscometer. This procedure is repeated three times for reproducible results.

***In-vitro* drug release**[2]

The diffusion study is assigned on a changed Franz diffusion cell at intervals of 20mL. To fill the receptor compartment with buffer. The donor compartment was mounted with a plastic wrap membrane containing the microemulsion formulation and the plain drug resolution.

At present intervals, samples were withdrawn from the receptor compartment and analyzed for drug content, employing an ultraviolet light photometer at a specific wavelength.

APPLICATIONS OF MICROEMULSIONS[21]

Microemulsions have broad area of applications some of the pharmaceutical applications are as fallows;

Oral drug delivery
Topical drug delivery
Ocular and pulmonary delivery
Parenteral administration
Microemulsions in biotechnology
Perfluoro microemulsions.

Table No.1: Basic differences between macroemulsion and microemulsion[22]

S.No	Macroemulsion	Microemulsion
1	They are lyophobic in nature.	They are the border between lyophilic and Lyophobic.
2	Droplet diameter 1 to 20μm.	Droplet diameter 10 to 100nm.
3	Macroemulsion droplets exist as individual entities.	Microemulsion droplets disappear within fraction of seconds.
4	Emulsion droplets are roughly spherical droplets of one phase dispersed into the other phase.	Microemulsions are the structures of various droplets like bi-continuous to swollen micelles.
5	Macroemulsions requires quick agitation for their formation.	Microemulsions are obtained by gentle mixing of ingredients.
6	Most of the emulsions are opaque (white) in appearance.	Microemulsions are transparent or translucent in nature.
7	Thermodynamically unstable.	Thermodynamically stable.

Table No.2: Components of microemulsion

S.No	Components	Examples
1	Oil	Glyceryl caprate, corn oil, olive oil, soybean oil, oleic acid, Propylene glycol monolaurate etc.,
2	Surfactant	Tween-20, tween-80, Cremophore, Labrafil M 2125, Labrasol (PEG-8 caprylic/capric glycerides) Span-40, Span-80. etc.,
3	Co-surfactant	Propylene glycol, polyethylene glycol, Ethanol, isopropyl alcohol, Isopropyl myristate, propanol, isopropanol, etc.,

Table No.3: List of recent research work reported on microemulsions

S.No	Author name	Method of preparation	Drug	Components	Report
1	Shah *et al*,[23] (2021)	Water Titration method	Quetiapine	Oil: Capmul MCM. Surfactants: Tween80, labrasol. Co-surfactants: Transcutol-p	They concluded; the prepared micro emulsions easily overcome the BBB and improve brain targeting.
2	Kaur *et al*,[24] (2021)	Water titration method	Nebivolol Hydrochloride	Oil: Capmul Pg-12 Surfactants: Tween-80 Co-surfactants: Propylene glycol	They concluded that the ME formulation could improve the bioavailability of a poorly soluble drug like Nebivolol using a suitable and compatible medium.
3	Ebrahimi *et al*[25], (2021)	Titration method	squalene	Oil: pumpkin seed oil. Surfactants: Tween 80 and Span 80	Their results of that clinical trial suggested that SQ microemulsion administration is a novel medicine in SARS-CoV-2 infected patients. Can improve several clinical outcomes.
4	Cinteza *et al*[26]. (2021)	Titration method	Curcumin	Oil: Grape seed oil, Surfactants: Tween80 Co-surfactants: Plurol® Diisostearique CG	They reported the prepared gel microemulsions to have high encapsulation Capacity and the improvement of the penetration degree of the curcumin and suitable to be used as colloidal vectors for topical application.
5	V.Agrawal *et al*[27], (2021)	Water titration method	Efinaconazole	Oil: Capmul MCM Surfactant: Labrasol Co-surfactants: transcutol P	They concluded, the microemulsion formulations showed better antifungal activity against *trichophyton rubrum*, *Trichophyton mentagrophytes,* and *Candida albicans.*
6	Tlijani M *et al*[28] (2021)	Water titration	Fenofibrate	Oil: Miglyol 812, Surfactants;	They reported the formulated microemulsion

		method		Tween80, Co-surfactants: Transcutol P	showed good stability and improved the permeability of the drug
7	Chakraborty R *et al*[29] (2021)	Water titration method	Metronidazole	Oil: Isopropyl myristate Surfactant: Tween 80 Co-surfactant: PEG400	They concluded, the formulated microemulsion showed better thermodynamic stability, *in-vitro* release and bioavailability compared to the marketed product.
8	Sarika G Z *et al*[30]. (2021)	Water titration method	Terbinafine hydrochloride	Oil: Oleic acid Surfactant: tween20 Co-surfactant: propylene glycol	They concluded, the formulated micro -emulgel Showed good drug release and permeability of drug through the skin.
9	Payyal *et al*[31]. (2020)	water titration method	Sulconazole nitrate	Oil: Olive oil, Surfactant: Tween 20, Co-surfactant: PEG 400	They concluded the formulated microemulsion based gel of Sulconazole nitrate is promising for topical delivery against fungal infections.

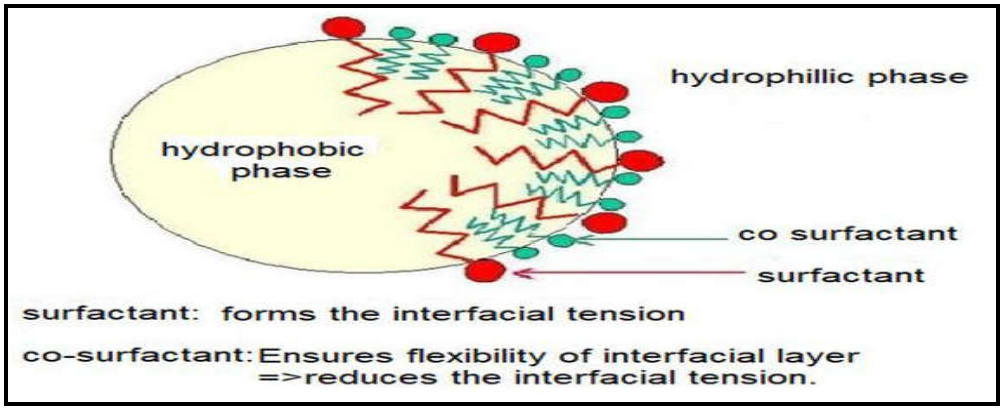

Figure No.1: Structure of microemulsion

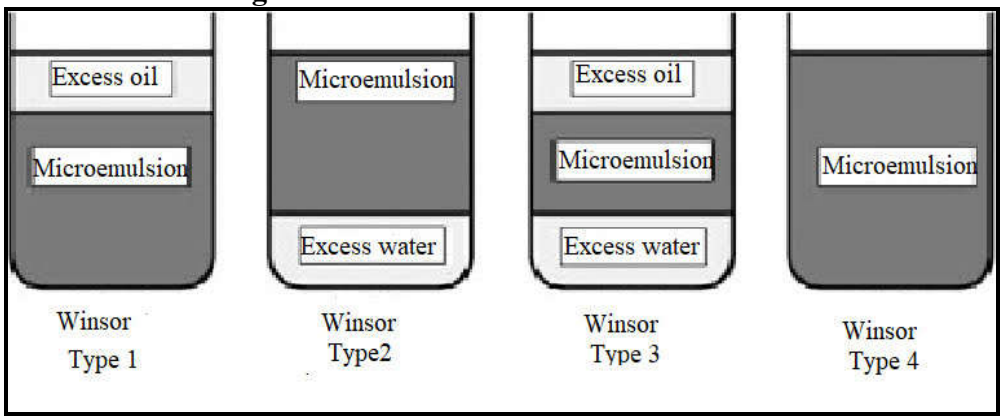

Figure No.2: Winsor types of microemulsion

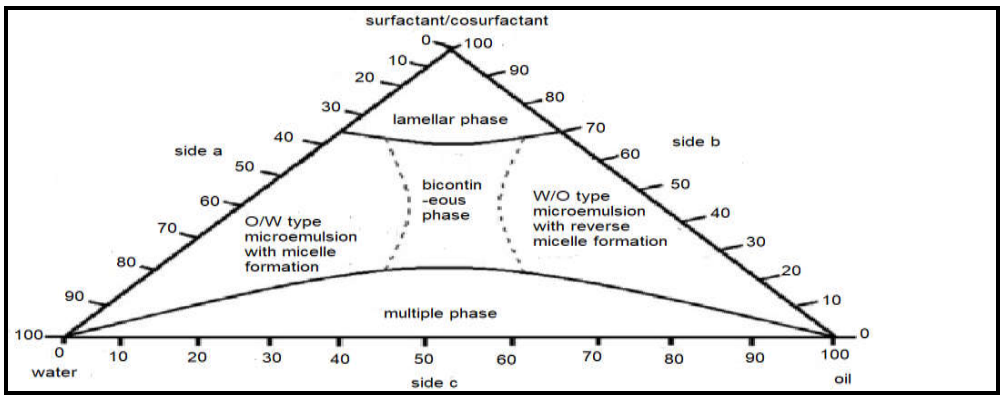

Figure No.3: Pseudo ternary phase diagram of oil, water and surfactant showing microemulsion region

CONCLUSION

Microemulsions are commercially feasible, convenient, and straightforward novel vehicles for delivering medicaments that can enhance drug absorption with reduced systemic side effects. Nowadays, micro-emulsions are shown to be ready to defend the liable drug, control drug release, increase drug solubility, increase bioavailability, reduce patient variability, increase the rate of absorption, help to solubilize the lipophilic drugs. Furthermore, it has proven possible to formulate preparations suitable for most routes of administration. A microemulsion is accepted as full of potential for novel drug delivery systems in today's world. Current review focuses on the preparation of safe, efficient, and more compatible microemulsion constituents, which will further enhance the utility of these novel vehicles.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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