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Review Paper

Microemulsion Based Hydrogel for Topical Drug Delivery: A Review

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ABSTRACT

Microemulsion-based hydrogels (MBH) have emerged as an advanced and promising approach for enhancing topical drug delivery, particularly for drugs with poor solubility and limited skin permeation. Oil, water, surfactants, and co-surfactants make up microemulsions, which are thermodynamically stable, isotropic systems that can enhance drug solubilisation and enable effective transport through the stratum corneum. Their low viscosity, however, prevents them from being applied directly to the skin. In order to get over this restriction, inclusion into hydrogel systems offers longer residence times, better uniformity, and increased patient acceptability. The basic principles, formulation, kinds, and skin penetration mechanisms of microemulsion-based hydrogels are all covered in detail in this review. It talks about how different elements including the aqueous phase, oil phase, co-surfactants, and surfactants affect the stability and production of microemulsions. Various preparation techniques, including phase titration and phase inversion methods, are elaborated along with formulation strategies for developing stable MBH systems using polymers like Carbopol, HPMC, and xanthan gum. Important characterisation factors that are essential for assessing formulation performance are also highlighted in the paper, including viscosity, pH, globule size, zeta potential, spreadability, drug content, and in vitro diffusion tests. To comprehend the mechanism of drug release from MBH systems, drug release kinetics models are also studied. Recent developments show that MBH systems improve therapeutic efficacy and patient compliance by greatly increasing drug penetration, offering regulated drug release, and lowering dose frequency. Notwithstanding these benefits, issues including scalability, high surfactant concentration, and formulation stability still exist. Prospects for the future centre on improving formulation design and developing MBH systems for use in clinical settings. Overall, microemulsion-based hydrogels represent an effective and versatile platform for topical drug delivery, offering improved drug solubilization, enhanced skin penetration, and sustained therapeutic action.

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INTRODUCTION

Topical dosage forms are a broad class of medicinal preparations intended for use on the skin, mucous membranes, eyes, and bodily cavities. These formulations have two functions: they administer therapeutic agents for local action and, in certain situations, they facilitate systemic medication delivery^{1,2}. Due to the rising incidence of dermatological disorders, ageing populations, and advancements in formulation technologies, the global topical medication delivery market has grown significantly, reaching \$102.3 billion in 2024 and expected to surpass \$135 billion by

2029³. Dermal, nasal, ophthalmic, vaginal, and rectal are the five categories that make up the topical medication delivery market. These figures demonstrate how skin disorders affect healthcare, necessitating the development of drug delivery systems for ailments including acne, psoriasis, and eczema. This demand is advantageous to the dermal medication delivery market. The necessity for efficient skin condition treatments is driving the medication delivery industry. One way to address this demand is by dermal medication delivery⁴. The skin, the largest organ of the human body, serves as the primary interface for topical drug administration.^{5,6}

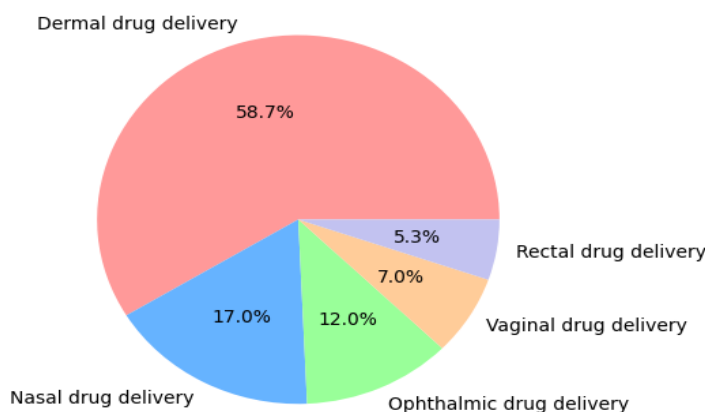


Fig 01 Topical medication drug delivery market

MICROEMULSION

Microemulsions are a clear, stable, isotropic liquid mixture of oil, water and surfactant, often in combination with a surfactant. In pharmaceutical research, creating new drug delivery systems with the goal of increasing efficacy is a continuous process. Numerous medication delivery systems have been created since then. They created a transparent, stable formulation by first dispersing oil in an aqueous surfactant solution and then adding alcohol as a co-surfactant to the microemulsion⁷. Microemulsions have attracted considerable interest over the years as potential drug delivery systems. Microemulsion-based formulations provide several advantages, including improved drug solubilization, strong thermodynamic stability, and simplicity of

production. Drugs can be delivered using microemulsions in a number of ways since they are flexible systems. The topical administration of these systems has been well investigated. Microemulsions as a topical carrier can improve medication delivery locally or systemically via an alternative mechanism⁸. In addition to oral and intravenous delivery, they are amenable for sustained and targeted delivery through ophthalmic, dental, pulmonary, vaginal and topical routes. Microemulsions are experiencing a very active development as reflected by the numerous publications and patents being granted on these systems⁹.

TYPES OF MICROEMULSION¹⁰



According to Winsor, there are four types of microemulsion phases exists in equilibria, these phases are also referred as Winsor phases. They are,

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

Composition11:-

The major components of micro emulsion system are:

1) Oil Phase

Oil phase is second most important vehicle after water due to its properties to solubilize lipophilic drug molecules and improve absorption through lipid layer present in body. Oil has unique property of penetrating cell wall and hence very useful for lipophilic active drug delivery. Swelling of tail group region of the surfactant is influence by oil phase. Such penetration is to greater extent in case of short chain alkanes as compared to long chain alkanes. Example: -Lauric, Myristic acid, Capric acid, Oleic acid, Linolenic acid.

2) Surfactant (Primary surfactant)

During preparation of the microemulsion, the surfactant must be able to reduce the interfacial tension as close to zero as possible to facilitate the dispersion of all components. These surfactants can be:

- Non-ionic
- Anionic
- Cationic
- Zwitterionic

Example:- Polyoxyl 35 castor oil (Cremophor EL)
Polyoxyl 40 hydrogenated castor oil (Cremophor RH)

3) Co-surfactant (Secondary surfactant)

In most cases, single-chain surfactants alone are unable to reduce surface tension sufficiently to form a microemulsion. Due to its amphiphilic

nature, the cosurfactant accumulates significantly at the interface layer, which increase the fluidity of the interfacial film by penetrating into the surfactant layer. Short to medium chain alcohols often added as a co-surfactant to increase fluidity of the interface. Among the short-chain alkanols, ethanol is widely used as permeation enhancer. The ratio of surfactant and co-surfactant is key factor for phase properties.

4) Aqueous Phase

The aqueous phase may contain hydrophilic active ingredients and preservatives. Water is most used as the aqueous phase. Due to its significant effect on the microemulsion's phase behaviour, the pH of the aqueous phase must always be adjusted. Commonly used agents are alcohol, water etc.

Advantages of microemulsion12:-

- 1) Microemulsions are easily prepared and require no energy contribution during preparation this is due to better thermodynamic stability.
- 2) The formation of microemulsion is reversible.
- 3) They may become unstable at low or high temperature, but when the temperature returns to the stability range, the microemulsion reforms.
- 4) Microemulsions are thermodynamically stable system and allows self-emulsification of the system.
- 5) Microemulsions have low viscosity compared to emulsions.
- 6) Microemulsions act as super solvents for drug, can solubilize both hydrophilic and lipophilic drugs including drugs that are insoluble in both aqueous and hydrophobic solvents.
- 7) Having the ability to carry both lipophilic and hydrophilic drugs.
- 8) The dispersed phase, lipophilic or hydrophilic (O/W, or W/O microemulsions) can act as a



potential reservoir of lipophilic or hydrophilic drugs, respectively.

- 9) The use of microemulsion as delivery systems can improve the efficacy of a drug, allowing the total dose to be reduced and thus minimizing side effects.

Disadvantages of Microemulsion12:-

- 1) Microemulsions are thermodynamically stable system and allow emulsification of the system.
- 2) Require large amount of Surfactants for stabilizing droplets.
- 3) Micro-emulsion stability is influenced by environmental parameters such as temperature and pH.
- 4) Require large amount of S/Cs for stabilizing droplets.
- 5) The surfactant should be nontoxic for use in pharmaceutical applications.
- 6) Having limited solubilizing capacity for high melting substances.

HYDROGEL

Hydrogels are polymeric material that exhibits the ability to swell and retain a significant fraction of water within its structure but will not dissolve in water. Hydrogels have received considerable attention in the past 50 years, due to their exceptional promise in wide range of applications. The ability of hydrogels to absorb water arises from hydrophilic functional groups attached to the polymeric backbone, while their resistance to dissolution arises from cross-links between network chains¹³.

Classification of Hydrogel¹⁴-

Hydrogels can be classified into two groups based on their natural or synthetic origins. Classification according to polymeric composition, the method of preparation leads to formations of some important classes of hydrogels:

(a) Homopolymeric hydrogels are referred to polymer networks derived from a single species of monomer, which is a basic structural unit comprising of any polymer network. Homopolymers may have crosslinked skeletal structure depending on the nature of the monomer and polymerization technique.

(b) Copolymeric hydrogels are comprised of two or more different monomer species with at least one hydrophilic component, arranged in a random, block or alternating configuration along the chain of the polymer network.

(c) Multipolymer interpenetrating polymeric hydrogel (IPN) an important class of hydrogels, is made of two independent cross-linked synthetic and/or natural polymer component, contained in a network form. In semiIPN hydrogel, one component is a cross-linked polymer, and other component is a non-cross-linked polymer.

Advantages ^[15,16]:-

- 1) Hydrogel is more elastic and stronger.
- 2) Due to their significant water content, they possess a degree of flexibility very similar to natural tissue.
- 3) Hydrogels possess good transparent properties and easy to modification.
- 4) They are biocompatible, biodegradable and can be injected.
- 5) Release of Medicines or nutrients timely.
- 6) Hydrogels have ability to sense change pH, temperature, or the concentration of metabolite and release their load as result of such a change.
- 7) They can be injected.
- 8) More resistance to protein deposits.
- 9) Soothing effect promotes patient acceptance.

Disadvantages ^[15, 16]

- 1) High cost.
- 2) Low mechanical strength
- 3) Difficult to sterilize
- 4) In contact lens less deposition hypoxia, dehydration and red eye reactions.



5) Non-adherent

PREPARATION OF MICROEMULSION BASED HYDROGEL

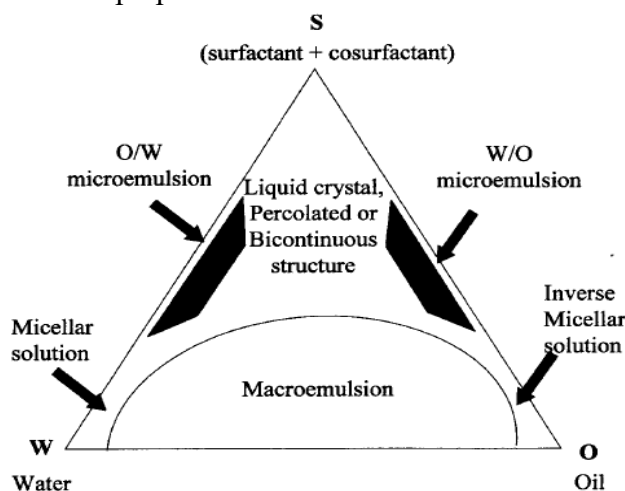
Methods of preparation of microemulsion

Microemulsion can be prepared by two different methods, they are Phase titration method and phase inversion method.

Phase Titration Method [17, 18]

Phase titration, also known as the spontaneous emulsification method, can be used to create the microemulsion. Phase diagrams can be used to illustrate microemulsions. The process of creating a quaternary phase diagram is time-consuming and challenging. Therefore, we prepare the

microemulsion using a pseudo ternary phase diagram. These display 100% of the specific component and feature many zones, including microemulsion zones. This phase titration method uses a set weight ratio of oil, water, surfactant, and cosurfactant blend. This phase diagram oversees the ingredient mixing. The monophasic/biphasic phase system will be verified by visual inspection after all these mixes were agitated at room temperature. In the separation phase, the sample which shows turbidity should be considered as two phases because one phase is clearly displayed and the mixture is transparent after constant stirring. The obtained points must be marked in the phase diagram.



Phase Inversion Method [19,20]

The phase inversion of the microemulsion is carried out on addition of excess dispersed phase or in response to temperature. In vitro and in vivo drug release may be impacted by potential physical and particle size changes that take place during the phase reversal procedure. This can be accomplished for non-ionic surfactants by driving the system's temperature to change from an o/w microemulsion at low temperatures to a w/o microemulsion at higher temperatures (transitional phase inversion). The system experiences negligible surface tension, zero spontaneous curvature, and a rise in the creation of finely

dispersed oil droplets during the cooling process. Phase inversion temperature method (PIT) is another name for this technique. Other factors, such pH or salt concentration, can be taken into consideration more successfully than temperature. Additionally, a transition in the spontaneous radius of curvature can be obtained by changing the water volume fraction. By successively adding water into oil, initially water droplets are formed in a continuous oil phase. The spontaneous curvature of the surfactant is changed from originally stabilizing a w/o microemulsion to an o/w microemulsion at the inversion point by raising the water volume percentage.

PREPARATION OF MICROEMULSION

A predetermined amount of the drug is accurately weighed and dissolved in oil by stirring on a magnetic stirrer. Surfactant and co-surfactant are mixed in fixed ratio, and this mixture is added into oily solution of the drug. Finally, an appropriate amount of water is added to the solution mixture drop by drop to get microemulsion. The clear solution shows the formation of microemulsion.

Preparation of Hydrogel and Microemulsion based hydrogel (MBH) [21,22,23]

Hydrogel can be prepared by using various polymers such as Carbopol 934p, HPMC K15M and Xanthan gum. Polymer is hydrated in fixed amount of water for at least 4h to swell for the formation of hydrogel. The previously formulated microemulsion is gradually added to the above solution with continuous stirring until a clear viscous solution is obtained. Finally, the fixed amount of triethanolamine is added to obtain microemulsion based hydrogel (MBH).

Characterization of Microemulsion [24-27]

Viscosity

The viscosity of Microemulsion based hydrogel (MBH) is determined by using Brookfield viscometer. For this hydrogel is filled in a beaker and the viscosity is measured by using suitable spindle number.

pH

pH can be determined by using digital pH meter. 1g of formulation is mixed in 10 ml distilled water. Electrodes are then immersed in the developed gel solution and readings are recorded.

Zeta potential and globule size analysis

Zeta potential and globule size analysis can be detected by using Malvern zeta sizer.

Centrifugation

This metric is assessed in order to gauge the physical endurance of the microemulsion. The produced microemulsion is centrifuged at room temperature for 10 minutes at 5000 rpm. to evaluate the formulation's stability (phase separation or cream formation). The microemulsion's appearance is thoroughly evaluated.

% Transmittance

% Transmittance of microemulsion can be measured by UV spectrophotometer.

In vitro drug release studies

The in vitro drug release studies are performed by using Franz diffusion cell with cellophane membrane. The membrane is clamped between the donor and the receptor chamber. The receptor compartment contains buffer that is maintained at $37 \pm 10^\circ\text{C}$ and the microemulsion formulation is placed in the donor compartment. At predetermined time interval samples are periodically withdrawn from the receptor compartment, replacing with the same amount of fresh buffer solution and analysed for drug content, using a UV spectrophotometer at specific wavelength.

Characterization of Microemulsion Based Hydrogel (MBH) [28-32]

Physical parameter

Gel formulations are tested for visual color, uniformity, consistency, texture and feel on application such as graininess, stickiness and softness.

Viscosity

A Brookfield viscometer can be used to determine the viscosity of MBH.

pH

The pH of microemulsion based hydrogel is determined using digital pH meter.

Spreadability

The spreadability of the gel formulation is determined by taking two glass slides of equal length. A weighed quantity of gel is taken on one glass slide. To another glass slide, weights (125g) are added and the time in seconds require to separate the slides is taken as a measure of spreadability. The spreadability is calculated by using the following formula: $S = (M \times L)/T$ Where S = Spreadability; M=weight kept on upper slides; L= length of glass slide and; T = time taken in seconds to separate the slides.

Drug content

One gram of gel is dissolved in a 100 ml of suitable solvent, stirred constantly for 10 min. From this 1 ml of solution is diluted to 10ml with solvent. The resultant solution is filtered and analysed by U.V spectrophotometer. Drug content can be calculated by using following formula: Amount of drug = [Concentration/1000] × Dilution factor.

In vitro diffusion studies

The in vitro drug release studies are performed by using Franz diffusion cell with cellophane paper. The membrane is clamped between the donor and the receptor chamber of Franz diffusion cell. Then, formulation is placed in the donor compartment. The receptor chamber is filled with buffer. The receptor medium is set at 37 ± 0.5 °C and stirred at 600 rpm throughout the experiment. Samples are periodically withdrawn from the receptor compartment, replacing with the same amount of fresh buffer solution, and assayed by a UV spectrophotometer.

Drug release kinetics

By using a variety of kinetic model equations, the drug release kinetic study can be carried out to identify pattern of drug release process. Hixon

Crowell's zero-order, first-order, Higuchi plot and Korsmeyer Peppas are tested.

CONCLUSION

Microemulsion-based hydrogels (MBH) can improve how well a drug dissolves and passes through the skin. They can be created with appropriate gelling agents, which thicken the mixture and prolong the drug's duration of action by extending its duration on the skin. These compositions have the potential to greatly improve medication absorption when administered topically. By altering the formulation or the way the skin permits the medicine to pass through, drug penetration can be further enhanced. All things considered, MBH formulations are safe and efficient, assisting in improving medication absorption, lowering the frequency of application, and offering regulated release over a chosen duration.

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