

Nanoemulgel Drug Delivery System for Topical Treatment: A Review

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ABSTRACT:

Nanoemulgels have emerged as a promising platform for topical drug delivery by integrating the advantages of Nano emulsions and gels. This review provides an overview of recent advances in nanoemulgel systems, focusing on their formulation strategies, characterization techniques, and therapeutic applications. Nano emulsions, composed of oil, surfactant, co-surfactant, and aqueous phases, offer enhanced drug solubility, improved skin penetration, and controlled release. Incorporation of these Nano emulsions into gel matrices improves viscosity, spreadability, and patient compliance, making them suitable for topical administration.

Recent developments highlight the use of novel excipients, advanced emulsification techniques, and optimization approaches such as Quality by Design (QbD) to improve stability and efficacy. Various evaluation parameters, including droplet size, zeta potential, rheology, drug release, and in vitro/ex vivo permeation studies, are discussed as essential for ensuring formulation performance. Nanoemulgels have demonstrated significant potential in the treatment of dermatological conditions such as acne, psoriasis, fungal infections, and inflammation, as well as in transdermal delivery of drugs with poor oral bioavailability. Furthermore, advancements in targeted delivery, incorporation of natural bioactives, and use of biocompatible polymers have expanded their therapeutic scope. Despite these advantages, challenges such as long-term stability, large-scale production, and regulatory considerations remain. Overall, nanoemulgels represent an innovative and effective approach for topical drug delivery, with ongoing research expected to further enhance their clinical applicability and commercial potential.

Key Words: Nanoemulgels, drug solubility, evaluation, targeted delivery, Advances

I. INTRODUCTION

Topical drug administration offers advantages over oral delivery by avoiding first-pass metabolism and improving patient acceptance due to its non-invasive nature. It also allows immediate withdrawal of treatment and provides continuous drug release, maintaining steady plasma levels, especially for drugs with short biological half-lives.¹ though there are many drug delivery system approaches, lipid-based drug delivery system has gained much interest in lipophilic drug delivery. It includes macroemulsion, nanoemulsion, niosomes, self-emulsifying formulation, liposomes, solid-lipid nanoparticle, etc. Among all these formulation approaches, emulsion-based preparation can be considered an industrially feasible approach to overcome the limitation of poor bioavailability.²

Formulation containing nanoemulsion in gel base are called nanoemulgel. It is the addition of nanoemulsion system integrated into gel matrix which influences a better skin permeation³

The nano-emulgel acts as a colloidal system consisting of a mixture of emulsion and gel. The emulsion part protects the drug from enzymatic degradation, and hydrolysis and improves the permeation like other nano-carriers. Besides enhancing the penetration of the drug through the skin, it is equally important to retain the therapeutic concentrations of the drug for a sufficient period of time. The gel part improves the viscosity and spreadability resulting in improved retention time, and also reduces the surface and interfacial tension, thus improving the thermodynamic stability. Nano-emulgel possesses various advantages having high drug loading capacity, better penetration, diffusion, and low skin irritation compared to other nano-carriers.^{4,5}

Advantages:⁶⁻¹⁰

1. A stable nanoemulsion formulation is enhanced through nanoemulgel, by decreasing surface and interfacial tension, which leads the viscosity of the aqueous phase to be increased.

Emulsifier and thickeners added to hold the gelling capability of hydrogel serves a better stability, permeation and suitable viscosity for the delivery of topical drug-loaded Nano emulsion.

2. In nanoemulgel system, the stability of nanoemulsion is enhanced by the distribution of oily droplets in gel network.
3. Nanoemulgel system is more stable than other transdermal drug delivery system, because it decreases the interfacial as well as the surface tension of the formulation, which make it superior from a conventional transdermal delivery system.
4. Nanoemulgel bypasses the first-pass metabolism, thus solving one of the major problems of drug, that is, the oral side effect. It does not cause skin irritation or any toxicity on the application.
5. Nanoemulgel formulation gives higher t_{max} and peak plasma concentration of lipophilic drugs than the conventional gel as well as oral formulation. Thereby, nanoemulgel preparation improves the bioavailability of lipophilic drug many folds than the other lipophilic drug formulations
6. Nanoemulgel acts as a drug reservoir and has shown prolong residence time leading to sustained release of the drug. Thus, it is beneficial for the drugs having shorter half-life.
7. Improved permeability of nanoemulgel preparation through the skin enables more drugs to penetrate into the site of action. This enhances the pharmacodynamic activity of the drug increasing its therapeutic efficacy.
8. Major issue with the transdermal preparation is the sticky nature and low spreading coefficient which require rubbing mechanism. Nanoemulgel being nonsticky and easily spreadable preparation results in better patient compliance than other transdermal preparations

Disadvantages¹¹

1. Small particle sized formulation yet concerned when delivering drug through the skin, the rheology properties of nanoemulsion is important. The nanoemulsion formulation, it is not convenient to be used due to low viscosity and spreadability is noted.

II. APPLICATIONS OF NANOEMULGEL¹²⁼¹⁵

- 1 Treatment of acne – Used for drugs like Flutamide to reduce sebum production and inflammation.
- 2 Anti-inflammatory applications – Delivers drugs like Diclofenac for localized pain and inflammation.
- 3 Antifungal therapy – Effective in treating fungal infections such as Candidiasis.
- 4 Antibacterial treatment – Used in managing skin infections caused by bacteria.

III. COMPONENTS OF NANOEMULGEL

Oil Phase:

The selection of oil and its quantity depends on the application and utility of the nanoemulgel. The permeability, stability, and viscosity of the prepared nano-emulsion depends on the type and quantity of chosen lipid component, i.e., oil phase. Primarily in case of pharmaceutical and cosmetic applications, the oil phase is made up of either naturally or synthetically originated lipids, unless the oil phase itself is an active ingredient. The consistency of the lipids may vary from liquid to high molecular solids. The hydrophobicity of an oil plays a crucial role in forming a stable emulsion, wherein poor hydrophobicity of the oil is shown to increase the emulsification, concurrently affecting the solubility of lipophilic moieties. Thus, choosing an oil is an essential prerequisite for nano-emulgel development as a novel drug delivery system.

Natural oils exhibit an additional medicinal significance leading to an increase in the researcher's interest to use these additive properties supporting the pharmacological action of the active moiety. For example, oleic acid is frequently used oil in nano-emulgel formulations and is obtained from vegetable and animal sources. It is a biodegradable and biocompatible omega-nine fatty acid and has elevated solubilization characteristics along with improving percutaneous absorption.

Antioxidants present in oleic acid contribute to cellular membrane integrity. It also repairs cell damage and showcases formulation stabilization. It moisturizes the skin and has high amounts of unsaturated fatty acids like oleic acid, thus improving the penetration of the drug. The edible oils considered to be the preferred lipid excipient of choice for the development of emulsions, are not frequently chosen due to their poor ability to dissolve large amounts of lipophilic drugs. Therefore, these oils are chemical

modification or hydrolysed to form an appropriate oil, which upon combining with a suitable surfactant enhances the solubility of hydrophobic compounds for nano-emulgel formulation.

Surfactant:^{19,20}

The surfactant's amphiphilic structure allows for the dispersion of two immiscible phases, reducing interfacial tension and resulting in a sufficiently stable film capable of deforming around the droplets with the optimum curvature.

Surfactants are molecules that can improve permeation across the skin, by reversibly attaching to keratin filaments, causing corneocyte destruction and thereby changing the stratum corneum (SC) diffusion coefficient. The penetration of various drugs through the skin is affected differently depending on the surfactant mixture concentration. The permeation of hydrophilic drugs was greatly improved when the concentration of surfactant increased.

Non-ionic surfactants are commonly preferred because, in comparison to ionic surfactants, they are safer and are widely tolerated also for systemic absorption. The polysorbates Tween 80® and Tween 20®, are the two most commonly used surfactants for the lipid based formulation.

Co-Surfactant:^{21,22}

Co-surfactants were needed to formulate nanoemulsion with minimum concentration of surfactant as it lowered the interfacial tension as well as enhanced the interface fluidity. Different co-surfactants (such as PEG 400, propylene glycol and ethanol) were completely solubilized with selected surfactant (1:1) as single phase system called S_{mix} . The efficiency of this S_{mix} combination for nano-emulsification potential would be assessed by phase diagram construction after the aqueous titration. The S_{mix} were dissolved in oil phase in different ratios for continuous aqueous titration. The nano-emulsification region obtained in phase diagrams study was compared for particular co-surfactant combination.

Variations in surfactant and co-surfactant packing at the oil/water interface affect phase properties, and the surfactant/co-surfactant ratio is a key factor in defining phase properties. As a result, fixed ratios cannot be established because they can vary depending on the surfactant, co-surfactant, and oil phase used. In this case, a formulation study is commonly used to determine the best qualitative-quantitative composition. The pseudo-ternary phase diagram is the most widely used screening method. This technique was used to

determine the accurate concentration range for development of nanoemulsion utilizing water titration method. Different diagrams can be constructed by varying the S_{mix} weight ratio.

Aqueous Phase:²³

Distilled water is commonly utilized as an aqueous phase for the preparation of Nanoemulsion and Hydrogel.

Gelling Agent:^{18,23}

These agents are used to enhance the consistency of any dosage form and can also be used as a thickener. Carbopol 934, Carbopol 940, HPMCK4M, and HPMC are typical gelling polymers used in emulgel formulation. Carbomers are acrylic acid polymers with a high molecular weight that have been crosslinked with allyl sucrose or pentaerythritol ethers. Different grades of carbomer are available based on the degree of cross-linking and manufacturing requirements, including carbopol 934 (lowest cross-linking density), carbopol 981 (intermediate cross-linking density), and carbopol 940 (maximum cross-linking density).

Miscellaneous Components:²⁴

To protect the formulation from microbial attack and increase the shelf life of formulation, preservatives are added in the preparation. Most commonly used preservatives are methyl paraben, benzoic acid, propyl paraben, benzalkonium chloride, etc. Antioxidants like butylated hydroxytoluene, butylated hydroxy anisole, and ascorbyl palmitate are used to prevent oxidative degradation of formulation components and to prevent loss of moisture. Glycerine and propylene glycol are used as humectants. Hence, the stability of the nanoemulsion and nanoemulgel preparation increased.

IV. METHOD OF PREPARATION OF NANOEMULGEL²⁵⁻²⁸

Step 1: Preparation of nanoemulsion

Nanoemulsions may be made spontaneously by blending the compositions and lowering the interfacial tension between the oil/water interfaces, or by introducing high energy into the heterogeneous mixture. Thus, high-energy and low-energy emulsification processes may be used to develop a thermodynamically stable nanoemulsion.

High-energy method

Since nanoemulsion droplet sizes usually range from 5 to 500 nm, achieving this size requires a lot of mechanical energy. High-energy input for fabrication can be accomplished using a variety of techniques, including high-pressure homogenizers, ultrasound generators, microfluidizers, and high-speed homogenizer. The use of low emulsifier concentrations is the most important benefit of a high-energy mediated nanoemulsion formulation. The formation of an emulsion by mechanical stirring, with droplet size in the micron range, is the first step in using high-energy techniques. To turn the emulsion into a nanoemulsion, the second step is breaking huge droplets into small droplets with high-energy equipment's.

Low energy method

The production of nanoemulsions using a low-energy emulsification process uses less energy than high-energy methods. They produce nanoemulsions by utilizing the system's inherent chemical energy and just requiring mild stirring. Low-energy approaches include phase inversion methods and spontaneous emulsification

Step 2: Preparation of nanoemulgel

The gel base is produced by dissolving the polymer in purified water and continually stirring it with a mechanical stirrer. Following the preparation of the nanoemulsion and the gelling agent, the two are continuously stirred until a nanoemulgel is formed. Water in oil (w/o) or oil in water (o/w) nanoemulsion is turned into thick and semisolid nanoemulgels with the aid of different polymeric gelling agents

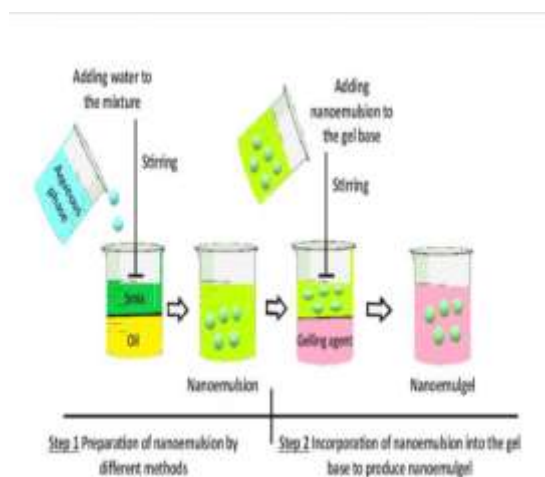


Fig. No. 1: Preparation of Nanoemulgel

V. CHARACTERIZATION OF NANOEMULGEL²⁹⁻³⁴

1. Physical appearance

The produced nanoemulgels may be examined visually to determine their color, appearance, and uniformity.

2. pH measurement

The pH of nanoemulgel changes depending on its intended use, such as on the skin or another form of mucous membrane. According to reports, the pH of human skin ranges between 4.5 and 6. The pH simply indicates the acidity or basicity of a composition. In the case of topical formulations, an excessively high or low pH might induce irritation or allergy on the skin's surface. It also influences the drug's stability and release from the formulation. Digital pH meters can be used for measuring pH.

3. Viscosity

The gel's viscosity is crucial for effective application to the skin. It is important for gel to know the rheological behavior. Viscosity can be defined as the resistance of fluid to flow and higher viscosity means higher resistance to flow. Fluids generally a classified into Newtonian and non-Newtonian systems. In Newtonian flow, the fluid with higher viscosity, requires greater force per unit area (shear stress) to generate a certain shear rate. In Newtonian flow, the viscosity is constant with different shear rate. In contrast to the Newtonian fluid, non-Newtonian flow does not comply with newton law and the viscosity is changed with the differences in shear rate.

4. Spreadability

As Mutimer indicates, it may be measured using the Slip and Drag basis. Two grams of Nanoemulgel are placed on a lower ground slide secured with a wooden block, and another glass slide of comparable size is created and secured with a hook that contains a 500 mg weight. After five minutes, the pan connecting to the second slide received more weight. The time required to span a 5 cm distance on the upper slide was measured, and spreadability was calculated using the following equation:

Spreadability (S) = $M \cdot L / T$, Where,

M = weight linked to the top slide, L = glass slide length, T = distance travelled by the top slide in a single slide.

5. Drug content

Drug content is an essential characteristic that defines the overall quantity of drug included in the prepared formulations; higher drug content is connected with less drug loss throughout the manufacturing process.

6. Droplet size and Zeta potential

Droplet size is typically determined using the dynamic light scattering (DLS) approach. Zeta Potential. Because nanoemulgel is made up of nanoemulsion and a gelling agent, the formulation can acquire an electrical charge as a result of the presence of different surface-active ingredients.

7. In vitro drug release

The Franz diffusion cell apparatus was employed in this study. The 1g drug was placed on the dialysis membrane and finally penetrated when it comes into touch with the phosphate buffered saline (7.4 pH at $37\pm 1^\circ\text{C}$). The experiment was run for 8 hours to determine the percentage of medication release. Every hour, 1 ml of sample was collected and evaluated using ultraviolet visible spectrophotometer.

VI. RECENT ADVANCEMENTS:³⁶

Nanoemulsion-hydrogel hybrid systems are an innovative drug delivery platform that combine the solubilization and bioavailability benefits of nanoemulsions with the biocompatibility and controlled release features of hydrogels. They are used in transdermal, ocular, oral, and injectable delivery, as well as in tissue engineering, wound healing, and cancer therapy. With nanoscale droplets for improved penetration, tunable properties, and the capacity to carry both hydrophilic and lipophilic drugs, these systems provide enhanced stability, sustained or stimuli-responsive release, prolonged therapeutic effects, reduced side effects, and better patient compliance, making them a promising technology for advanced pharmaceutical and biomedical applications. Nanoemulgels can be reckoned as a potential candidate of choice in place of traditional drug delivery systems because they have the potential to integrate the advantages of nanoemulsions and hydrogels. They are especially ideal for drugs that are poorly soluble, localized therapy (dermatology, ophthalmology), and in non-invasive administration to facilitate better patient compliance. Incorporation of nanoemulgel-based systems into pharmaceutical pipelines can lead to better therapeutic efficacy, bioavailability, and

lower side effects than traditional formulations. Extended use in human and veterinary medicine, and cosmetic applications, is suggested for better therapeutic and patient results.

VII. FUTURE PROSPECTIVE:³⁷

Nanoemulgel has emerged as a highly promising option for topical medication delivery, supported by multiple reviewed studies. Its prominence as a leading drug delivery method arises from the necessity to enhance the pharmacokinetics and pharmacodynamics of drugs with limited bioavailability and patient usability. Nanoemulgel formulations demonstrate the ability to effectively administer a broad spectrum of lipophilic drugs from diverse therapeutic categories, leading to improved therapeutic outcomes. These formulations are actively used in healthcare for managing both acute and chronic conditions such as fungal infections, inflammation, cardiovascular issues, psoriasis, and alopecia. Furthermore, the utilization of nanoemulgel presents significant potential for financial gain and could breathe new life into drug categories previously abandoned due to challenges like low bioavailability and clinical ineffectiveness. As a result, the future prospects of nanoemulgel as a drug delivery system appear promising, especially for addressing drug categories struggling with efficient delivery.

VIII. CONCLUSION

Transdermal drug delivery system is a good alternative to many conventional drug delivery systems, however it suffers from many limitations. Nanoemulgel is a nanoemulsion-based system prepared by incorporating a gelling agent that provides the system its three dimensional structure. Nanoemulgel has the advantages of nano-size range that allow facilitated deep entry. In addition, it can be used for applying lipophilic drug in the interior structure with the acceptable aqueous exterior structure. Moreover, nanoemulgel has the advantages of easy application and non-greasy characteristics that impart aesthetic appearance. It can be concluded that nanoemulgel is considered as effective and practical drug delivery system that impart prolong contact when applied to the tissue.

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