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## Review Paper

# Nanoemulgel As A Novel Carrier for Topical Drug Delivery System: A Brief Review

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### ABSTRACT

Nanoemulgel is an excellent delivery method for lipophilic medicines. Nanoemulgel refers to an emulsion that has gelled with the help of a gelling agent. Immiscible liquids can be spread as droplets within another liquid to create o/w or w/o variants. Hydrogel-based nanoemulsion systems, also known as nanoemulgels, use a homogeneous hydrogel matrix to enhance skin penetration of nanoemulsion droplets (10-200 nm in size). This alternate delivery method is effective for treating a wide range of disorders due to its high drug loading, enhanced bioavailability, and controllable release. Nanoemulgel formulations have been effective in treating inflammation caused by rheumatoid arthritis, psoriasis, fungal infections, acne, and pimples. Nanoemulgel is anticipated to become the standard for topical delivery of lipophilic medications in the future. Applying nanoemulgels alters the skin's composition, which increases the drug's capacity to pass through the epidermis. Nanoemulgels are characterized by a high water content, bioadhesive qualities, high biocompatibility, biodegradability, and the capacity to form deposits that enable drugs to gradually elute into surrounding tissues while sustaining a high local concentration for a prolonged period of time. This brief review covers the components, formulation methods, characterization, factors affecting drug absorption. Despite a few drawbacks, nanoemulgel formulations are viable and promising options for topical delivery of lipophilic medications in the future.

### INTRODUCTION

Nanoemulgel is being an effective delivery system for lipophilic drugs. It enhances the therapeutic profile of lipophilic drugs. Poor solubility and erratic absorption are characteristics of lipophilic medicines that change their pharmacokinetics. To

improve the solubility of active moieties, certain techniques are employed, such as physical and chemical alterations of API with formulation criteria like particle size reduction<sup>1</sup>.

#### **Nano-Emulsions:**

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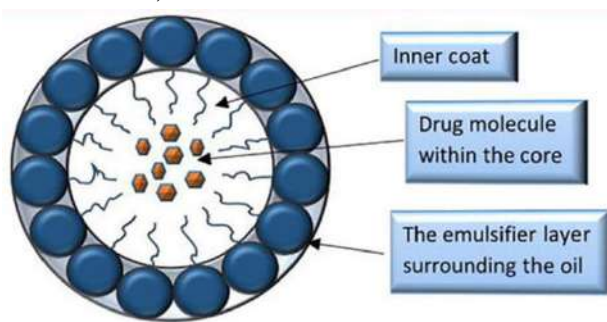
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Nanoemulsions are defined as two immiscible liquids one of which is dispersed in the second but continuous phase. Nanoemulsions can be made into oil in water (O/W) or water in oil (W/O) nanoemulsions are solid in nature, sphere in shape with amorphous surface and lipophilic in nature, having charge nanoemulsions being submicron in size are of great interest for use as a drug carrier and improving therapeutic efficacy of drugs. They are advanced nano-droplet system for systemic, controlled and target drug delivery systems<sup>2</sup>. Nano-emulsions are heterogeneous colloidal systems consisting of oil and water, where one phase is dispersed within the other, and are

stabilized by emulsifying agents that reduce the surface tension between the dispersed and continuous phases. They exhibit high thermodynamic stability, resulting in a longer shelf life compared to standard emulsions and other formulations. Despite these benefits, nano-emulsions face certain drawbacks, such as low viscosity, which affects their retention time and spreadability. These issues can be addressed by transforming nano-emulsions into nano-emulgels using appropriate gelling agents<sup>3</sup>. The structure of nanoemulsion as shown below Fig 1,

### Structure of Nano Emulsion:



**Fig 1: Structure of nanoemulgel**

### Nano-Emulgel:

Nano-emulsions offer numerous benefits, but their low viscosity results in poor spreadability and short retention time, limiting their use in clinical settings. To overcome these issues, nano-emulgels have been developed by incorporating a gelling agent into the nano-emulsion. Gels are typically created by adding large amounts of aqueous or hydroalcoholic bases to a colloidal system. By embedding the nano-emulsion within a hydrogel matrix, a nano-emulgel is formed, which enhances the thermodynamic stability of the nano-emulsion. This formulation provides a controlled release for topical applications, making it particularly beneficial for drugs with short half-lives, as it improves retention time and allows gradual drug release<sup>3</sup>. The enhanced thermodynamic stability results from reduced mobility of the non-aqueous phase, caused by the increased viscosity of the

external medium. This greater retention time, along with improved thermodynamic stability, allows the formulation to release the drug gradually over time, making nano-emulgel a controlled release system for topical use, which is particularly advantageous for drugs with a short half-life<sup>4</sup>. The nanoemulgel system releases drugs by facilitating the transfer of drug molecules from the inner phase to the outer phase. When applied to the skin, the gel releases oil droplets containing the drug, which penetrate into the stratum corneum (SC) of the skin. The drug is then delivered to the targeted site. The nanoemulgel has excellent adhesive properties, and the high solubilization of the drug in the oil phase creates a larger concentration gradient, further enhancing skin penetration and drug delivery<sup>5</sup>.

### Advantages:

- Capable of avoiding first-pass metabolism.

- Proven effectiveness for controlled and sustained drug delivery over time.
  - Compatible with the skin and non-irritating.
  - Suitable for self-administration.
  - Nanoemulsion offers a large surface area and high free energy, enhancing its efficiency as a delivery system.
  - Nanoemulsions do not exhibit common emulsion defects such as creaming, phase separation, flocculation, or coalescence.
  - Nanoemulsions can be formulated into a variety of products, including foams, creams, sprays, and other cosmetic applications<sup>6</sup>.
- Promote drug deposition and skin permeability<sup>7</sup>.
- Disadvantages:**
- Some medications are not easily absorbed through the skin.
  - For individuals with contact dermatitis, the active ingredients or additives in the medication may lead to skin irritation.
  - Medications with larger particles can be harder to absorb through the skin.
  - There is a risk of allergic reactions<sup>8</sup>.
- Components of Nanoemulgel:**

**Table 1: Components of nanoemulgel**

Components	Example
Oil	Clove oil, olive oil, castor oil, coconut oil
surfactants	Tween 80, Span 80, Polyethylene glycol.
Co-surfactants	Lecithin, Propylene glycol, Propanolol, Transcutol P, Polyethylene glycol Butanol
Gelling agents	Carbapol 934, Carbapol 940, and hydroxypropyl methylcellulose
Penetration enhancers	Alcohols., Polyols., Alkanes., Ester., Terpenes., Surface active agent

**Components:**

The main components of nanoemulgel are as follows:

**Oil:** The choice of the oil phase is a crucial factor for stabilizing a nanoemulsion, as it enables the highest possible drug solubilization<sup>9</sup>. Typically, the oil with the greatest solubilizing capacity for the specific drug candidate is chosen as the oily phase in nanoemulsion formulations to maximize drug loading. Additionally, a combination of oils can be used to enhance the solubilization of the drug like Clove oil, olive oil, castor oil, coconut oil<sup>10</sup>.

**Surfactants:** The amphiphilic nature of surfactants allows them to disperse two immiscible phases, lowering interfacial tension and forming a stable film that can deform around droplets with optimal curvature<sup>11</sup>. Surfactants also enhance skin permeation by temporarily binding to keratin

filaments, leading to corneocyte disruption and altering the diffusion coefficient of the stratum corneum<sup>12</sup>. The penetration of various drugs through the skin is influenced by the concentration of the surfactant mixture, with higher surfactant concentrations significantly improving the permeation of hydrophilic drugs. Most frequently used surfactants are Tween 80, Span 80, Polyethylene glycol etc<sup>13</sup>.

**Co-surfactants:** Cosurfactants can work alongside surfactants to aid the emulsification process by breaking up the interfacial film, and they may also assist in oil solubilization<sup>14</sup>. Commonly used cosurfactants in the formulation of nanoemulsions and nanoemulgels include propylene glycol, PEG 400, ethanol, transcutol P, carbitol, among others, based on their physicochemical properties<sup>15</sup>. Research indicates that as the concentration of cosurfactant increases,

the nanoemulsion region in the phase diagram shrinks<sup>16</sup>.

**Aqueous solvents:** Aqueous solvents act as the aqueous phase in emulsion preparation. Worldwide widely used aqueous solvents are ethanol and water.

**Gelling agents:** Carbapol 934, Carbapol 940, and hydroxypropyl methylcellulose (HPMC) are commonly used as gelling agents in nanoemulgel formulations. They enhance the formulation's thickness and may interact with surfactants to adjust its viscosity<sup>17</sup>. These agents are incorporated into nanoemulsions to transform their physical state from liquid to gel, addressing issues such as low spreadability, low viscosity, and poor skin retention associated with nanoemulsions.

**Penetration enhancers:** Using penetration enhancers is one of the most effective ways to increase transport efficiency through the skin and its underlying layers. As a key component of conventional drug delivery systems, penetration enhancers are frequently employed in topical nanoemulgels. They generally work by interacting with skin components, leading to a temporary and progressive increase in skin permeability.<sup>18</sup>

**Preservatives:** Preservatives are chemicals used to prevent microbiological degradation and prolong the shelf life of a product. Commonly used preservatives include methylparaben, propylparaben, benzalkonium chloride, and phenoxylethanol<sup>19</sup>.

## **METHOD OF PREPARATION:**

### **Preparation of Nanoemulsion:**

The medication, cosurfactant, and surfactant are dissolved based on their solubility in the chosen aqueous or oil phase. Both phases are heated separately, and once they cool to room temperature, they are combined by gradually adding one to the other while stirring continuously<sup>20</sup>. Nanoemulsions can be formulated using both low and high-energy methods. Examples of low-energy techniques include self-

emulsification, phase inversion (such as phase inversion temperature (PIT) and phase inversion composition (PIC), emulsification, and solvent diffusion. On the other hand, high-energy techniques include ultrasonication, microfluidization, and high-pressure homogenization. Low-energy methods are preferred over high-energy ones because they are more efficient and do not require complex equipment<sup>21</sup>. The high-energy method decreases the size of both phases by generating intense disruptive forces using mechanical equipment. However, this process may lead to overheating of the formulation's components, making the emulsion thermodynamically unstable and unsuitable for heat-sensitive medications<sup>22</sup>.

### **Preparation of Nanoemulgel:**

The preparation of gelling media requires dissolving gelling agents in an aqueous solution until full swelling occurs. To achieve this, the chosen polymer is dispersed in pure water while being continuously stirred using mechanical methods under controlled conditions for a specific duration and at a constant rate. Once complete swelling is achieved, the gel base is adjusted to the desired pH for effective delivery to the topical system. An o/w nanoemulsion solution forms a gel when a gelling agent is added due to the agent's thixotropic properties, allowing the formulation to shift from gel to liquid under shear force without altering its volume. Any of the previously mentioned methods can be used to create the nanoemulsion, which can then be transformed into a nanoemulgel by incorporating a gel base. To integrate the nanoemulsion into the gel matrix, the gel and nanoemulsion are mixed at a fixed ratio and stirred continuously to ensure uniformity<sup>23</sup>.

### **High-Pressure homogenization method:**

High-pressure homogenizers provide significant energy and create a uniform flow to achieve the smallest particle sizes, making them the most commonly used method for preparing



nanoemulsions. These homogenizers generate highly disruptive forces that produce nanoemulsions with extremely fine particle sizes, as small as 1 nm. The coarse emulsion is forced through a small orifice under high pressure (ranging from 500 to 5,000 psi), during which several forces—such as intense turbulence, hydraulic shear, and cavitation—work together to reduce droplet size. The particle size of nanoemulsions produced by high-pressure homogenizers depends on the sample composition, the type of homogenizer, and operating conditions like energy intensity, duration, and temperature. Increasing homogenization intensity reduces droplet size, but in some cases, such as when biopolymers are used as emulsifiers, excessive homogenization can actually increase particle size. For this reason, small-molecule surfactants are preferred as emulsifiers in high-pressure homogenizers, as they are more effective than biopolymers for producing nanoemulsions. High-pressure homogenization is widely used in the creation of nanoemulsions for food, pharmaceutical, and biotechnological applications<sup>24</sup>.

#### **Microfluidization method:**

Microfluidization is a micro-scale mixing technology that utilizes a device called a microfluidizer. In this process, fluids are forced through microchannels under high pressure (ranging from 500 to 20,000 psi). These microchannels enable mixing at the microscopic level<sup>25</sup>. The aqueous and oil phases of the macroemulsion are combined and then passed through the microfluidizer. As the macroemulsion moves through the microchannels under high pressure, it reaches the interaction chamber, where two streams of the macroemulsion collide at high speed. This collision generates forces such as shearing, cavitation, and impact, which help create stable nanoemulsions<sup>26</sup>.

#### **Ultrasonication method:**

This process produces a nanoemulgel using ultrasonic waves. After combining the hydrophilic matrix with the oil phase, high-frequency ultrasonic waves are applied to the mixture. The ultrasonic energy breaks down the oil phase into nanosized droplets, which are then uniformly dispersed throughout the gel matrix.

#### **Solvent evaporation method:**

This method involves using a water-miscible solvent to dissolve both the oil phase and the hydrophilic matrix. The solvent is then evaporated under reduced pressure, resulting in a nanoemulgel with nanosized oil droplets dispersed within the gel matrix<sup>27</sup>.

#### **Self-emulsification method:**

This method utilizes a self-emulsifying drug delivery system (SEDDS) to produce a Nanoemul gel in situ. SEDDS consists of a blend of oil, surfactants, and co-solvents that can spontaneously emulsify upon contact with water. When combined with a hydrophilic gel matrix, it results in the formation of a Nanoemul gel.

#### **High energy emulsification method:**

This method requires high-energy input to create small droplets of the dispersed phase (oil) within the continuous phase (water). Techniques like sonication, high-pressure homogenization, and microfluidization are commonly used to achieve this. A gelling agent, such as a polymer or surfactant, can then be introduced to the resulting emulsion, transforming it into a gel.

#### **Phase inversion temperature (PIT) method:**

This process utilizes a thermosensitive surfactant that transitions from a water-soluble state to an insoluble one at a specific temperature. By altering the system's temperature, the surfactant can trap the dispersed phase, forming a gel-like structure.

#### **Coacervation method:**

This method involves using two or more polymers that separate into different phases when exposed to an electrolyte or a shift in pH, resulting in a gel-like structure. The dispersed phase can then be

incorporated into the gel through techniques such as high-energy emulsification<sup>28</sup>.

#### **Sol-gel method:**

This method utilizes a sol-gel transition system, where a gel forms through the aggregation of particles or polymers in a solvent. This can be accomplished by introducing a crosslinking agent or a thermosensitive polymer to the emulsion, which induces gel formation under specific conditions or at a certain temperature<sup>6</sup>.

#### **Electrostatic complexation method:**

This approach uses oppositely charged polymers or surfactants to form a stable emulsion, which can later be converted into a gel by adding a crosslinking or gelling agent<sup>6</sup>.

#### **Characterization of Nanoemulgel:**

##### **Droplet size:**

Nanoemulgels, with average droplet sizes of less than 200 nm, provide considerable benefits for improving drug delivery. The formulation's ingredients, especially surfactants and co-surfactants at higher concentrations, are crucial in enhancing drug penetration. The nanoscale droplet size increases the available surface area for drug release, which in turn speeds up the drug release rate. In addition, droplet size is a key factor in determining the stability of nanoemulgel formulations. To support these conclusions, extensive studies on the interactions between active ingredients and the nanoemulgel matrix, along with thorough clinical trials, are necessary<sup>29</sup>.

##### **Zeta potential:**

Nanoemulsions carry an electrical charge due to the presence of various surfactants in their formulation. A higher zeta potential increases the repulsive forces between droplets, thereby improving the stability of the formulation. For example, emulsion droplets are prevented from clustering when the zeta potential is high. The surface charge can be modified with a charge-altering agent, where the zeta potential becomes positive if a positively charged modifier is used,

and negative if a negatively charged one is applied. Thus, anionic or cationic surfactants play a key role in maintaining emulsion stability<sup>30</sup>.

##### **Viscosity:**

The emulgel formulation provides numerous benefits compared to conventional emulsions, mainly due to the incorporation of gelling agents that improve stability by raising the viscosity of the aqueous phase. Viscosity testing is essential for assessing the consistency and thickness of the final emulgel product. The concentration of the gelling agent is a key factor in determining the viscosity, with higher concentrations leading to a direct increase in the formulation's viscosity<sup>31</sup>. Nanoemulgel was specifically created to overcome the low viscosity of nanoemulsions, which restricts their effectiveness in topical uses<sup>32</sup>. Important factors like particle size, surface charge, and viscosity are vital for the efficient delivery of active ingredients through the skin<sup>33</sup>.

##### **Rheological Properties:**

Rheological studies focus on analyzing the flow and deformation of materials when subjected to external stress or force. These analyses help determine how different excipients, like oils, surfactants, and gelling agents, influence the flow behavior of a formulation. Changes in viscosity and flow properties can impact factors such as stability, spreadability, drug release, and other in vivo outcomes. For example, the shear-thinning behavior of a formulation forms a thin layer on the skin, enhancing permeability, while a more viscous formulation limits permeation. Therefore, rheological properties are crucial in the development of NEGs and can be measured using various viscometers, like the Brookfield viscometer or rheometers<sup>34</sup>.

##### **pH:**

The pH indicates the acidity or alkalinity of a formulation. For topical products, an excessively high or low pH can lead to negative effects on the skin, such as irritation or allergic reactions. pH

also influences the drug's stability and its release from the formulation. Ideally, the pH of the formulation should align with the skin's natural pH, typically between 4 and 7. Digital pH meters are commonly used to measure pH levels<sup>35</sup>.

#### **Spreadability:**

Spreadability measures how uniformly the NEG spreads across the skin, ensuring even distribution of the dosage form and avoiding uneven dosing that could affect efficacy. The viscosity of the nanoemulgel significantly influences its spreadability. Currently, there is no standardized procedure for evaluating spreadability, but the parallel plate method (also known as the slide and drag technique) is widely used due to its simplicity and adaptability. In this method, the sample is placed in the center of a marked glass slab, with another slab placed parallel above it. A specific weight is applied and left for a set period. Spreadability is then calculated using the following formula:

$$\text{Spreadability (S)} = M L / T$$

where M is the weight on the upper glass slab, L is the length of the slabs, and T is the time taken to separate them<sup>36</sup>.

#### **In-Vitro Release Test (IVRT):**

The effectiveness and safety of the active pharmaceutical ingredient (API) are linked to its release from the dosage form. In vitro release testing (IVRT) is a method used to evaluate the quality of drug products. According to the FDA, IVRT studies for semi-solid dosage forms are performed using either a vertical diffusion cell or an immersion cell. The vertical diffusion cell consists of donor and receptor chambers separated by a receptor membrane. The dosage sample is placed in the donor chamber, while the receptor chamber holds a buffer or hydro-alcoholic solution, chosen based on the API's solubility, sink conditions, and stability. A receptor membrane, similar to skin, is selected for its appropriate pore size, high permeability, and inertness toward the

API. If needed, the membrane is saturated with release media. For topical products, the temperature of the media is maintained around  $32 \text{ }^{\circ}\text{C} \pm 1 \text{ }^{\circ}\text{C}$ , and for mucosal membrane products, it is kept at  $37 \text{ }^{\circ}\text{C} \pm 1 \text{ }^{\circ}\text{C}$ . A Teflon-coated magnetic stirrer is used to stir the receptor media. The immersion cell model includes a reservoir-like cell body covered with a membrane, sealed with a leakproof cap that prevents dosage form leakage. The cap has an opening at the top and should be positioned so the membrane contacts the dosage form at the bottom and the release media at the top. This setup is used with a USP-2 apparatus, where the immersion cell is placed in a flat-bottomed dissolution vessel with a typical volume of 150–200 mL. A mini spin-paddle is employed to stir or agitate the media<sup>37</sup>.

#### **Bio-Adhesive Property:**

Bio-adhesive strength measures the force needed to detach a drug delivery system from a biological surface, a key factor for topical dosage forms requiring extended contact. This test is commonly conducted using rat or pig skin, with pig skin being preferred due to its similarity to human skin. While various methods exist to assess bio-adhesive strength, none are FDA-approved. One method involves using a texture analyzer, where both the movable upper probe and the stationary lower base plate are covered with skin. The dosage form is placed on the skin-covered base plate, and the upper probe is lowered to contact the lower plate for at least a minute. The probe is then gradually raised until the skin sheets separate, and the instrument measures the force required for separation, represented as the area under the force-distance curve<sup>38</sup>.

#### **Factors Affecting Topical Absorption of Drugs:**

##### **Physiological factors:**

- The lipid content of the skin acts as a barrier to drug absorption, and reducing this barrier enhances drug penetration.



- The thickness of various skin layers affects the penetration rate, with thicker layers resulting in slower penetration. For example, the palms and soles have higher diffusion rates compared to other areas.

- Skin pH.
- Hydration of skin.

#### **Physicochemical factors:**

- Partition coefficient- higher log p value gives rise to absorption.
- Effect of vehicles- hydro alcoholic gel provides the most efficient absorption through skin.
- Degree of ionization<sup>8</sup>.

#### **CONCLUSION:**

Topical nanoemulgels have emerged as a superior option for effective and convenient drug delivery. With their gel-like and non-greasy characteristics, these formulations enhance patient compliance. Unlike traditional formulations with oily bases, nanoemulgels offer improved drug release. By integrating nanoemulsions into a gel matrix, the system achieves controlled dual-release, solving issues like creaming and phase separation found in classical emulsions, while also improving spreadability. Nanoemulsion-loaded gels have demonstrated greater efficacy in treating certain topical conditions. In the future, nanoemulsion-gel formulations could provide a more reliable method for delivering hydrophobic drugs. Many drugs used in treating skin conditions are hydrophobic, and nanoemulgels can effectively deliver these by incorporating the drug into the oil phase of the nanoemulsion, which is then combined with the gel base. Despite a few limitations, nanoemulgels are likely to become a key method for topical delivery of lipophilic drugs.

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