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A comprehensive review on nanoemulgel formulations for skin disease management

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Abstract
Skin diseases represent a significant global health concern, often requiring long-term treatment and patient compliance with topical drug delivery systems. Conventional topical formulations, however, are limited by poor drug penetration, instability, and inadequate therapeutic efficacy. Nanoemulgel formulations have emerged as a promising approach to overcome these challenges by combining the advantages of nanoemulsions with the favorable characteristics of hydrogels. These systems enhance drug solubility, stability, skin permeation, and patient acceptability, thereby improving therapeutic outcomes in dermatological disorders. This review comprehensively discusses the fundamental principles of nanoemulgels, their components, methods of preparation, characterization techniques, and mechanisms of skin penetration. Furthermore, it highlights recent advancements in the application of nanoemulgel formulations for the management of various skin diseases, including infections, inflammation, acne, psoriasis, and cancer. Emphasis is also placed on regulatory considerations, challenges, and future perspectives in clinical translation. Overall, nanoemulgel technology offers a versatile and effective platform for the development of advanced topical therapies in skin disease management.

Keywords: Nanoemulgel, topical drug delivery, skin diseases, dermatological therapy, nanoemulsion, hydrogel

Introduction

Skin, the largest organ of the human body, serves as a protective barrier against environmental, chemical, and microbial insults. Despite its critical role, the skin is highly susceptible to a wide spectrum of diseases, including infections, inflammatory conditions, acne, psoriasis, and even malignant disorders. These diseases not only impair physiological function but also significantly affect quality of life, making effective therapeutic strategies a global healthcare priority.

Topical drug delivery remains the preferred route for the treatment of most dermatological disorders due to its ability to provide localized drug action, minimize systemic side effects, and improve patient compliance. However, conventional topical formulations such as creams, ointments, and gels are often associated with limitations, including poor drug solubility, limited skin penetration, instability of active ingredients, and inadequate therapeutic efficacy. These drawbacks necessitate the exploration of advanced drug delivery platforms capable of enhancing drug permeation and sustaining therapeutic action at the site of application.

Nanoemulgels have emerged as a novel and versatile drug delivery system that combines the benefits of nanoemulsions and hydrogels. Nanoemulsions, owing to their ultrafine droplet size, provide enhanced solubility, stability, and bioavailability of poorly water-soluble drugs. When incorporated into a gel matrix, they exhibit improved viscosity, spreadability, and ease of application, making them suitable for topical use. This unique hybrid system not only facilitates efficient drug permeation through the stratum corneum but also ensures patient acceptability.

Recent research has highlighted the significant potential of nanoemulgels in the management of various skin diseases, offering superior therapeutic outcomes compared to conventional dosage forms. The growing interest in this delivery platform underscores the need for a comprehensive understanding of its design, formulation strategies, characterization methods, and clinical applications.

This review aims to provide an in-depth overview of nanoemulgel formulations, focusing on their components, preparation techniques, characterization parameters, and mechanisms of drug penetration. Furthermore, it discusses recent advancements in their application for dermatological therapy, highlights existing challenges, and explores future prospects for their clinical translation in skin disease management.

Advantages

1. The ability to resist first-pass metabolism.
2. The effectiveness of a managed, long-term drug delivery system has been proven.
3. Skin-friendly.
4. Suitable for self-medication.
5. Patients accept it quickly.
6. The unique properties of nanoemulsions, including large surface area and free energy, enable efficient delivery.
7. Emulsion defects like creaming, phase separation, flocculation, and coalescence are not present in nanoemulsion.
8. Nanoemulsion can be prepared in various forms, including foams, creams, sprays, and many other cosmetic products.
9. It is safe for transdermal application due to its non-toxic nature
10. Using a biocompatible surfactant in a nanoemulsion formulation allows for oral administration.
11. It shows better drug penetration because the nano-sized particles can easily enter through the rough skin surface.
12. The process of precipitation and interfacial poly-condensation of the nanoemulsion prepares nanocapsules and nanospheres [3]

Disadvantages

1. Bubbles formed during emulgel formulation.
2. For use in pharmaceutical applications, the surfactant must be non-toxic.
3. Possibility of allergic reactions.
4. Skin irritation from contact dermatitis [3].

Mechanisms of Skin Penetration of Nanoemulgel Formulations

The skin is a complex barrier, mainly due to the stratum corneum, which restricts the penetration of most drugs. Nanoemulgels enhance penetration by combining the properties of nanoemulsions (nanosized droplets) with hydrogels (viscous, spreadable bases). Their mechanisms can be explained as follows:

1. Reduction of Droplet Size (Nano-scale Penetration)

- Nanoemulgels have droplet sizes typically 20–200 nm.
- These ultrafine droplets offer a large surface area, enabling closer contact with the skin surface.
- The reduced droplet size facilitates drug transport through the stratum corneum by both intercellular (between cells) and transcellular (through cells) routes.

2. Disruption of Stratum Corneum Lipids

- Surfactants and co-surfactants in nanoemulsions act as penetration enhancers.
- They temporarily disrupt the lipid bilayers of the stratum corneum, increasing fluidity and reducing resistance to drug passage.

3. Improved Solubilization of Lipophilic Drugs

- Nanoemulsions enhance the solubility of poorly water-soluble drugs, maintaining a high drug concentration gradient at the skin surface.
- A higher concentration gradient drives passive diffusion across the stratum corneum.

4. Hydration Effect of Gel Matrix

- The hydrogel base of nanoemulgel keeps the skin hydrated, which swells the stratum corneum.
- Hydration loosens tight junctions between corneocytes, facilitating deeper penetration of drug-loaded droplets.

5. Sustained and Controlled Release

- Nanoemulgels act as reservoir systems.
- The drug is gradually released from the oil droplets into the skin, providing sustained therapeutic action and reducing dosing frequency.

6. Follicular Penetration Pathway

- Due to their nanosize, droplets can penetrate through hair follicles and sebaceous glands, serving as reservoirs for drug accumulation and prolonged release.

Formulative components

Nano-emulgels consist of two distinct components: the gelling agent and the nano-emulsion, which is an emulsion comprising nano-sized droplets that can be of either oil-in-water or water-in-oil type. Each type of emulsion contains a water phase and an oil phase. The gel matrix is formed from polymers that have the capacity to swell upon absorbing a liquid.

1. Oil phase

In selecting oils or fatty ingredients, care must be taken to guarantee that the oily phase is authentic and protected against impurities like peroxides, free radicals, and degraded lipids. Like sterols and polymers. One important factor in choosing lipids for making nanoemulsions is the length of the hydrocarbon chains.This is essential for proper emulsification. Common oils used in nanoemulsions include mineral oil, cottonseed oil, maize oil, arachis oil, olive oil, coconut oil, eucalyptus oil, rose oil, and clove oil [6].

2. Aqueous phase

The gelling agent is what transforms the emulsion into an emul gel. Typically, we use distilled or ultra-purified water to make the nano emul gel [5].

3. Surfactant

Surfactants are used to make Nano-emulgel, providing stability and emulsification to the final formulation. Non-ionic surfactants are preferred because they have low toxicity. Some common non-ionic surfactants used include esters of sorbitan and polyoxyethylene fatty acids [6].

4. Co-surfactant

Co-surfactants are used to improve the final product's thermodynamic stability while lowering the amount of surfactant needed. Examples of cosurfactants are ethyl alcohol, propylene glycol, Transcutol HP, and polyethylene glycols [6].

5. Penetration enhancers

A highly effective method to enhance drug delivery through the skin and its underlying layers is the use of penetration enhancers, which play a crucial role in conventional drug delivery systems. Often found in topical nano-emulgel. These enhancers usually work by interacting with the skin's components. This interaction causes a temporary and cumulative increase in skin permeability [5].

6. Gelling Agents

Gelling agents are important for nano-emulgel formulations. They create a smooth structure.They act as cross-linking agents. Some of the gelling agents used are tragacanth, HPMC, and Carbopol [6].

7. Preservatives

Preservatives are chemicals that protect substances from microbiological breakdown and help extend the shelf life of products. Common preservatives include methylparaben, Propyl paraben, Benzalkonium chloride, and phenoxyethanol.

8. Antioxidant

Antioxidants are compounds used in formulations to stop the oxidation of different components. For example, ascorbyl palmitate and butylated hydroxytoluene.

9. PH modifiers

The pH value is an important sign of how stable the nanoemulsion is. The ideal pH range should be between 5.4

and 5.9, which is similar to the pH of skin. The most frequently used pH modifier is triethanolamine [5].

Methods of Preparation of Nano Emulgel

Screening of components

Based on the results of the preformulation tests, the final composition of the formulation must be chosen carefully. At this stage, the oily phase is selected based on how effectively it dissolves the drug. The ratios for the surfactant and co-surfactant are determined based on how well they work with the oil, as well as the type of emulsion (o/w or w/o). One way to assess whether the concentration of these components can create a nanoemulsion is by plotting a pseudoternary phase diagram. This diagram helps identify the stable nanoemulsion development point in the nanoemulsification region based on the ratio of these three components.

Preparation of Nano Emulsion

1. Prepare the oil and water phases: Mix the oil and water phases separately. The surfactant dissolved in one of the phases.
2. Combine the phases: Slowly add the water phase to the oil phase, or vice versa, while stirring.
3. Apply high-energy mixing: Use an ultrasonicator or high-pressure homogenizer to reduce the droplets to the nanoscale range.
4. Improve the formulation: Adjust the surfactant concentration, oil-to-water ratio, and mixing conditions to make a stable nanoemulsion.

Preparation of nano emulgel

1. High pressure homogenisation method

Using a high-pressure homogenizer, this method breaks the oil phase down into Nano sized droplets that can be easily spread out in a hydrophilic gel matrix. The homogenization process creates high shear forces that help break up droplets and make a stable Nano-emulgel.

2. Ultra sonication method

This method uses ultrasonic waves to create nano-emulgel gel. High-frequency ultrasonic waves are applied to the mixture following the combination of the oil phase and hydrophilic matrix. The ultrasonic energy breaks down the oil phase into nanosized droplets, which are then uniformly dispersed throughout the gel matrix.

3. Solvent evaporation method

With this method, the oil phase and the hydrophilic matrix must be dissolved using a water-miscible solvent. A nano-emulgel with microscopic oil droplets scattered throughout the gel matrix is the end result of removing the solvent with less pressure.

4. Microfluidization method

By passing the hydrophilic matrix and oil phase through a microfluidizer that generates high shear pressures, this method produces nano-emulgel by breaking the oil phase down into tiny droplets that are distributed throughout the gel matrix.

5. Self emulsifying gel agent

This process uses a self-emulsifying drug delivery system (SEDDS) that can create Nano-emulgel gel in situ. The SEDDS is a blend of co-solvents, surfactants, and oil that can emulsify on its own when it comes into contact with water. A nanoemulgel is created when the SEDDS is combined with a hydrophilic gel matrix.

6. High energy emulsification method

With this technique, small droplets of the dispersed phase (oil) are produced in the continuous phase (water) using a high-energy input. This can be achieved using a variety of methods, such as microfluidization, high-pressure homogenization, and sonication. A gelling agent, such as a polymer or a surfactant, can then be added to the resultant emulsion to turn it into a gel

7. Phase inversion temperature (PIT) method

This procedure uses a thermosensitive surfactant, which phases out of a water-soluble state and becomes insoluble at a specific temperature. By altering the system's temperature, the surfactant can trap the dispersed phase and take on the structure of a gel.

8. Sol- gel transition method

This method makes use of a sol-gel transition system, where a network of particles or polymers forms a gel by aggregating in a solvent. This can be accomplished by adding a thermosensitive polymer or crosslinking agent, which will give the emulsion gel-like properties at a specific temperature or under specific conditions.

9. Electrostatic complexation method

Applying surfactants or oppositely charged polymers creates a stable emulsion that can be gelled or crosslinked later.

10. Coacervation method

This method creates a gel-like structure by using two or more polymers that phase independently when an electrolyte is present or when the pH changes. The gel and the dispersed phase can then be combined using methods like high-energy emulsification.

Evaluation of Nano Emulgel

Determination of homogeneity

The prepared gels were checked for clarity and color. They were also examined for any particles. Smears of the gels were placed on a glass slide and looked at under the microscope to detect any particles or grittiness.

Determination of PH

The pH of the prepared nanoemulgel was measured with a digital pH meter (Micropro Gradmate). The average of three readings was recorded.

Determination of viscosity

The viscosity of gels is dependent on the type and concentration of polymer used. The viscosity of different Nanoemulgels was measured using a Brookfield digital rheometer (DV III+) with spindle #7 at 200 RPM with torque ranging from 10-100%. An average of three determinations was recorded.

Determination of zeta potential

The zeta potential of the nanoemulsion was measured using the Horiba Scientific SZ-100 nano zeta sizer.

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Determination of spreadability

Spreadability of the gels was determined by glass slides and wooden blocks which were provided by a pulley at one end. A ground glass slide was attached to this block. An excess of Gel, about 1 gram, from different formulations was placed on the ground slide. The gel was then pressed between the same shaped slides. Excess of the gels was scrapped off from the edges. The top plate was then subjected to pull 20 gms, less the time taken for separation of two slides better the spreadability.

In vitro drug release study

In-vitro drug release study was done with a Franz diffusion cell, using a dialysis membrane with a molecular weight cut-off of 12000-14000 Da. (Hi-Media, India). This was mounted between both chambers of the Franz diffusion cell. The receiver chamber was filled with

Phosphate buffer pH 6.4 as diffusion medium and the whole assembly was placed on a magnetic stirrer with 50 rpm. 1 gm. of nanoemulgel was placed on the donor chamber equally distributed on the membrane. Samples were taken from the receiver solution at set time intervals of 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 7 hours, 8 hours, and 24 hours later, the cell was refilled to the marked volumes with fresh buffer solution.The samples were filtered and analyzed for the % of drug release.

Stability studies

The stability study of a pharmaceutical product looks at its physical, chemical, microbiological, and pharmacokinetic features over its shelf life after it is made. The shelf life of the product is when the substance decreases to 90% of its original concentration. "Shelf life" refers to the product's stability and is often used the same way as "expiration date." Each medicinal preparation has a unique expiration.

Accelerated stability studies

As noted in the ICH guidelines, the formulations are stored in the oven at 37±2°C, 45±2°C, and 60±2°C for three months. Drug content is checked every two weeks using a suitable analytical method. Stability is determined by watching changes in the pH of the gel or the breakdown of the drug.

Application of nanoemulgel

Topical Drug Delivery

Treatment of skin disorders, such as acne, psoriasis, and eczema.

Transdermal Drug Delivery

Systemic delivery of drugs, including pain management and hormone replacement therapy.

Cosmeceuticals

Products for anti-aging, skin care, and UV protection.

Dermatological Disorders

Treatment of fungal, bacterial, and viral infections.

Pain Management

Delivery of pain relievers and anti-inflammatory agents.

Cancer Treatment

Topical delivery of chemotherapy drugs.

Vaccine Delivery

Transdermal delivery of vaccines.

Summary and conclusions

Nano-emulgels are new drug delivery systems that combine nanoemulsions with gel bases. They address issues found in traditional lipophilic drug formulations, like poor solubility, low bioavailability, and inconsistent absorption. By adding tiny oil droplets to a gel, nano-emulgels improve drug stability. They also allow for controlled and focused release. This leads to better skin penetration and makes it easier for patients to apply. The formulation includes several components, such as oils, water phase, surfactants, co-surfactants, penetration enhancers, gelling agents, preservatives, antioxidants, and pH modifiers.

There are various methods for preparation, such as high-pressure homogenization, ultrasonication, solvent evaporation, microfluidization, and self-emulsifying techniques.

Evaluation parameters include homogeneity, pH, viscosity, spreadability, zeta potential, in-vitro drug release, and stability testing.

Nano-emulgels have many applications in topical and transdermal drug delivery, cosmeceuticals, treatment of skin disorders, cancer therapy, pain management, and vaccine delivery. They provide a promising platform for effectively delivering lipophilic drugs. They offer benefits like high drug loading, a non-greasy texture, better spreadability, and solutions to stability problems common with traditional emulsions. Their ability to improve drug penetration, offer sustained release, and bypass first-pass metabolism makes them very suitable for treating various local and systemic conditions.

With ongoing improvements in formulation techniques and evaluation methods, nano-emulgels are likely to become a favored drug delivery system in pharmaceutical and cosmeceutical fields. Their use will expand beyond topical applications to include ocular, vaginal, dental, and nose-to-brain therapeutic routes.

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