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NANOEMULGEL: A NOVEL APPROACH IN TOPICAL DRUG DELIVERY SYSTEMS

Avani T. C.[1]*, Deekshitha[2] and A. R. Shabaraya[3]

Srinivas College of Pharmacy, Valachil, Farangipete Post, Mangalore, Karnataka, India-574143.

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***Corresponding Author**
Avani T. C.
Srinivas College of Pharmacy, Valachil, Farangipete Post, Mangalore, Karnataka, India-574143.

ABSTRACT
Nanoemulgels are advanced topical drug delivery systems that enhance drug penetration, stability, and therapeutic efficacy by combining the benefits of nanoemulsions and gels. They effectively overcome the skin's stratum corneum barrier, improving the solubility, permeability, and bioavailability of hydrophobic drugs. These formulations are composed of oils, surfactants, co-surfactants, penetration enhancers, gelling agents, and stabilizers, ensuring optimal drug delivery. Nanoemulgels are prepared using high-energy techniques such as ultrasonication and microfluidization, as well as low-energy methods like spontaneous emulsification and phase inversion. They are widely used for treating various skin conditions, including infections, psoriasis, alopecia, acne, and melanoma, offering enhanced absorption, prolonged drug release, and reduced systemic side effects. Their non-greasy nature, easy application, and ability to bypass first-pass metabolism contribute to improved therapeutic outcomes. Comprehensive evaluation parameters, such as pH, viscosity, spreadability, drug content, in-vitro drug release, and stability studies, ensure their effectiveness and reliability in dermatological applications.

KEYWORDS: Nanoemulgel, Transdermal Drug Delivery, Skin Permeability, Topical Formulation.

INTRODUCTION

Human skin plays a vital and multifaceted role, with one of its primary functions being to serve as a barrier that prevents the loss of internal substances like water and blocks the entry of external agents such as chemicals and drugs. The outermost layer of the skin, known as the stratum corneum (SC), is the final product of a differentiation process initiated in the basal layer of the epidermis, where keratinocytes are formed through mitotic division. The SC consists of dead cells (corneocytes) embedded within a lipid-rich matrix. Its "brick-and-mortar" structure and lipophilic nature are key to the skin's barrier function. The SC demonstrates selective permeability, allowing only relatively lipophilic substances to diffuse into deeper layers. Due to its non-living composition, solute transport across the SC occurs mainly via passive diffusion, as no active transport mechanisms have been identified. Various delivery systems can be employed for transdermal or dermal drug delivery, with the former involving the passage of drugs through the skin. The SC is also known to have selective permeability, meaning that only substances that are somewhat lipophilic can permeate into the lower layers. Solutes are mostly transported across this layer by passive diffusion because the SC is dead, and no active transport mechanisms have been found. Both dermal and transdermal drug delivery can be accomplished with standard delivery methods. The former includes administering medication via the skin.[1]

In traditional medicine, the human skin has been widely utilised as the primary organ to distribute different medications and achieve the intended therapeutic effect. The purpose of this action was to achieve the desired therapeutic effect. In a similar vein, the Transdermal Drug Delivery System (TDDS), which has been a part of contemporary medicine for many years, has significantly improved health care by offering a compelling substitute for the oral route of drug administration. Another way to give patients their medication is through a Transdermal Drug Delivery System (TDDS). Over the years, there have been three generations of advancements in transdermal drug delivery systems (TDDS).[2]

Emulgels, transdermal patches, and gels are examples of transdermal medication delivery methods. Emulgel is a gel and emulsion combination, with the emulsion being either type W/O or O/W and being employed as a vehicle to deliver a specific medicine to the skin. The gelling ingredient in the water phase transforms a traditional emulsion into emulgel. Emulgel works well for dermatology since it is easy to spread, greaseless, thixotropic, water soluble, easy to remove, has a longer shelf life, is non-staining, and is bio-friendly. Nanoemulgel, a new method for topical distribution of hydrophobic medications, has recently been shown to offer a number of advantageous qualities, such as increased physical stability, non-toxicity, and non-irritability. In addition to these features, it incorporates hydrogel and nanoemulsion dual release control systems

and nanoparticles that enable quick penetration and administration of active medicinal components. When compared to other conventional formulations, the nanoemulgel's previously listed properties offer better drug efficacy in treating bacterial and fungal infections as well as a variety of skin conditions.[3,4]

In the topical drug delivery system, nanoemulgel is crucial. Because of its enhanced pharmacokinetic profile, greater therapeutic efficacy, and more robust absorption capabilities, topical nanoemulsion gel is a superior choice over traditional lipophilic drug formulations. Compared to alternative topical administration methods, patients prefer the nanoemulgel formulation because of its better spreading qualities and decreased stickiness. When compared to other formulations, the non-greasy properties enhance patient compliance, and the absence of an oily foundation results in increased medicine release. By adding Nanoemulsion to the gel matrix, problems with creaming and phase separation that arise with traditional emulsions are resolved and increased spreadability is achieved. In some topical situations, a gel containing nanoemulsion is more beneficial. Hydrophobic qualities are present in several drugs used to treat skin infections. By incorporating the medication into the oil phase of the nanoemulsion before it merges with the gel foundation, these drugs can be delivered efficiently as nanoemulgels.[5,6]

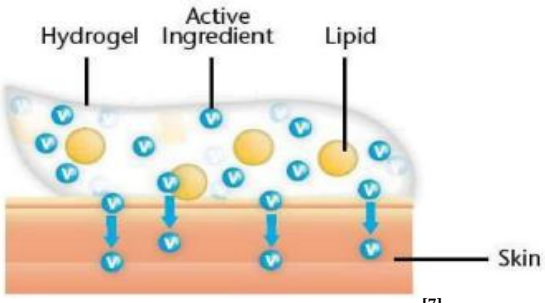

Fig. 1: Structure of Emulgel.[7]

COMPOSITION OF NANOEMULGEL

A nano-emulgel is a formulation comprising two primary systems: a nanoemulsion and a gelling agent. The nanoemulsion consists of nanoparticles or droplets, which can be either oil-in-water (O/W) or water-in-oil (W/O). The gelling agents, also referred to as gel bases, are composed of polymers that absorb liquids, swell, and form a gel-like structure. The formulation of a nano-emulgel involves various components, including oils, surfactants, cosurfactants, polymers.[8,9]

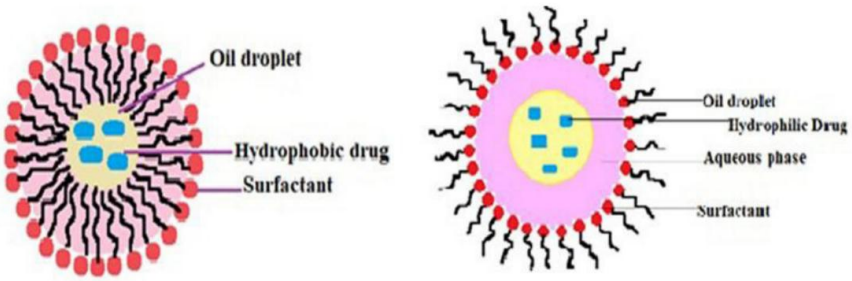

Fig. 2: Represent O/W nanoemulsion and W/O nanoemulsion.[10]

1. **Oil phase:** It is important to make sure that the oily phase is genuine and protected against contaminants such as peroxides, free radicals, and other fatty acids like sterols and polymers when selecting oil or other lipid components. The bulk of hydrocarbon chains is a major consideration when using lipids for the production of nano emulates; this is justified by the homogeneity and fundamentals of emulsification. Among the oils commonly used in nanoemulsions are mineral oil as a medication vehicle, cottonseed oil, maize oil, Arachis oil, olive oil, coconut oil, eucalyptus oil, rose oil, clove oil, etc.
2. **Aqueous phase:** In the case of the gelling agent, this component is responsible for converting the emulsion into an emulgel. Water that has been distilled or ultra-purified is typically utilized to make the nanoemulgel.
3. **Surfactant:** When creating nanoemulgel, surfactants are used to provide stability and emulsification to the finished mixture. Because of their low toxicity, non-ionic surfactants are used to create nanoemulgel. Sorbitan and polyoxyethylene fatty acid esters are two examples of commonly used nonionic surfactants.
4. **Co-surfactant;** Co-surfactants are usually used to lower the surfactant concentration while increasing the thermodynamic stability of the finished product. Examples of co-surfactants include PEGs, PGs, ethyl alcohol, and Transcutol HP.[11]
5. **Penetration enhancers**: Using penetration enhancers has proven to be one of the best ways to increase the effectiveness of transportation through the skin and associated layers. The penetration enhancer, commonly used in topical nanoemulgel, is one of the key elements of the conventional drug delivery method. These penetration enhancers typically work by reacting with the skin's constituents, which causes a temporary and gradual increase in skin permeability.
6. **Gelling agent**: The gelling agent, one of the main ingredients of nanoemulgel, provides the formulation with an impeccable structure. As cross-

linking agents, these make sense. Several gelling agents are used, including Tragacanth, HPMC, Carbopol, and others.

7. **Preservatives**: Preservatives are chemicals used to prolong the shelf life of products and shield them against microbial deterioration. Commonly used preservatives include methylparaben, propyl paraben, benzalkonium chloride, and phenoxyethanol.
8. **Antioxidant**: Chemical substances called antioxidants stop certain parts of a composition from oxidizing. As an illustration, consider butylated hydroxytoluene and ascorbyl palmitate.
9. **pH modifiers**: The nanoemulsion's stability was also determined by the pH value. The pH of the skin should be between 5.4 and 5.9 on average. Triethanolamine is the pH modifier that is most frequently employed.[12]

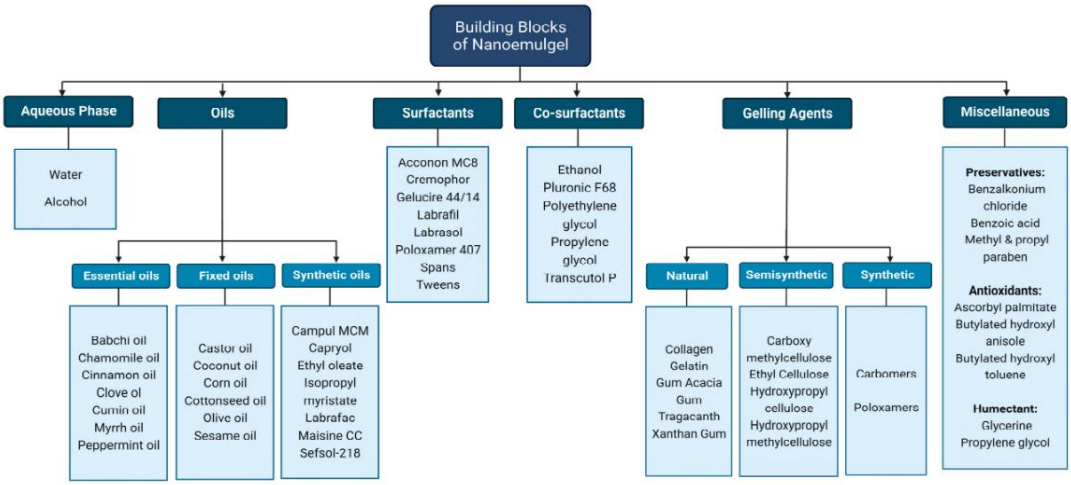

Fig. 3: Building blocks of Nanoemulgel.[13]

METHOD OF PREPARATION

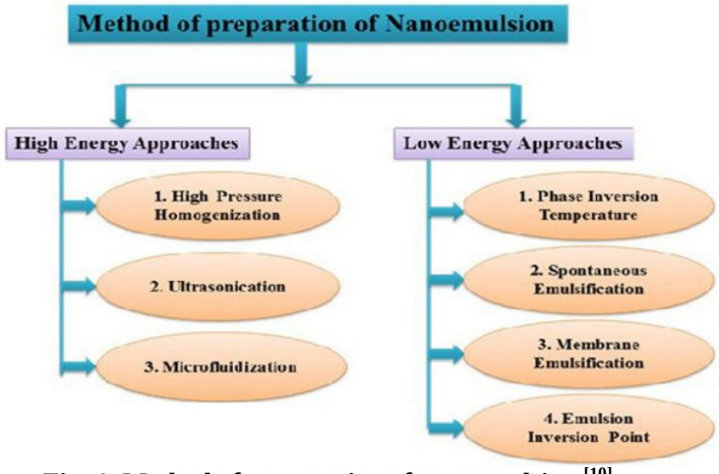

Fig. 4: Method of preparation of nanoemulsion.[10]

1. High energy method

Since a nanoemulsion droplet's normal size is between 5 and 500 nm, achieving this size requires a substantial amount of mechanical energy. Using low emulsifier concentrations is the primary benefit of using a high-energy mediated nanoemulsion formulation. Applying high-energy techniques begins with mechanical stirring, which produces an emulsion with droplet sizes in the micron range. Using low emulsifier concentrations is the primary benefit of using a high-energy mediated nanoemulsion formulation. In order to turn the emulsion into a nanoemulsion, the second step is splitting big droplets into tiny droplets using high-energy equipment.

a) Ultrasonication

A sonicator probe can be used to turn the rough emulsion into the desired nano-sized emulsion droplets. At frequencies higher than 20 kHz, the sonicator probe produces high-intensity sound waves that have the potential to break up the hard emulsion into nanometer-sized (5–500 nm) droplets. These are different kinds of probes with varying diameters that can be reduced to predetermined proportions. The duration, kind of probe, and strength of the sonication input all affect the droplet scale.

b) Microfludisation

This method uses a microfluidizer device that uses a high-pressure positive displacement pump (500–20,000 psi) to force the product through an interaction chamber with stainless steel microchannels on the contact region, producing extremely tiny sub-micron particles. Until the required particle size is reached, the resultant mixture is constantly run through the microfluidizer. The final product is filtered to separate the bigger and smaller droplets, creating a uniform nanoemulsion**.**

c) High-pressure homogenization technique

When creating nanoemulsions, a range of forces are frequently used, most notably cavitation, severe turbulence, and hydraulic shear. In order to create nanoemulsions, surfactants and cosurfactants are pushed through a small hole in a piston homogeniser at high pressures (500–5000 psi). High-pressure homogenisation is a low-cost, high-yield method that may be used on both small and large scales to produce nanoemulsions with particles as small as 1 nm. Adding more surfactants to the mixture is the way to address the potential coalescence problem. The droplet size is influenced by the homogenisation cycles and the dispersed and continuous phase viscosities.

2. Low energy methods

Low-energy emulsification procedures were developed after studying the cumulative behaviour of the oil, surfactants, co-surfactants, drug, watery component, hydrophilic lipophilic balance of the utilised oil surfactant blend, and operation temperature.

Emulsification that happens on its own is one low-energy technique. These methods produce tiny droplets by using the system's stored energy. Low energy methods might not always be feasible, depending on the kind of oil and emulsifier that are available.

a. Spontaneous emulsification

The method of nanoprecipitation, which is employed to produce polymeric nanoparticles, is comparable to spontaneous emulsification. Instead of using polymer, oil is used. The technique involves the production of two phases: an oil-soluble surfactant termed Span, an organic solvent like acetone or ethyl acetate that is partially water miscible, and an oil-based or organic phase like mygliol that contains a drug. The organic phase is added dropwise to the aqueous stirring phase to produce small nanoscale emulsions (although the converse, i.e., adding water to oil, is equally plausible in the case of W/O emulsions).

b. Phase Inversion Temperature

This approach produces a fine dispersion because of the chemical energy originating from phase transitions created by the emulsification pathway. Phase inversion in an emulsion can occur in two ways: either by changing the emulsion's composition while maintaining a constant temperature, or vice versa.

- Transitional Inversion: This is caused by shifting variables that impact the system's HLB. For instance, the electrolyte concentration and/or temperature.
- Catastrophic inversion: caused by utilising surfactant combinations to alter the surfactant's HLB number at a constant temperature.

c. Membrane Emulsification:

One low energy method for creating nanoemulsions is membrane emulsification. This approach requires very little surfactant and produces an emulsion with a restricted size distribution range. This approach involves a dispersed phase forming into a continuous phase through a membrane. One drawback of this approach is its poor distributed phase flux, during scale-up, this being a problem through the membrane.

d. **Emulsion Inversion Point:**

This method involves changing the system's composition while maintaining a steady temperature. To produce kinetically stable nanoemulsions, structures are created by gradually diluting the material with water or oil.

Preparation of Nanoemulgel

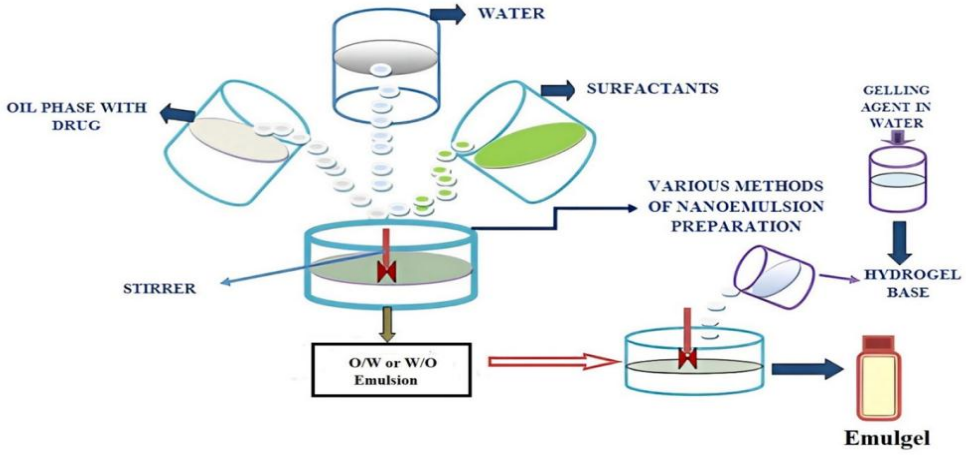

Fig. 5: Diagram of nanoemulgel preparation.[2]

Step 1: Preparation of O/W or W/O Emulsions
The process begins by dissolving water-soluble ingredients in the aqueous phase and oil-soluble ingredients in the oil phase. These two phases are then mixed vigorously to break them into fine droplets, ensuring uniform dispersion. While industrial emulsification typically involves equipment like ultrasonicators, homogenizers, or colloid mills, a mechanical stirrer can be used effectively for this purpose.

Step 2: Preparation of Gel Base
In a mixing vessel, water-soluble components or excipients are stirred mechanically until fully dissolved in the aqueous phase. The hydrophilic polymer is then gradually added while stirring continuously to ensure complete dissolution. Care is taken to maintain an appropriate pH throughout the process. Excessive stirring should be avoided to prevent air entrapment, which could affect the gel's quality.

Step 3: Combining Emulsion with Gel Base
The emulsion and gel base are blended in a 1:1 ratio with consistent mixing to produce the nanoemulgel.

Preparation of Gel Phase
The polymer is dispersed in purified water using a mechanical shaker and agitated at a moderate speed to form the gel phase for the formulation. Triethanolamine (TEA) is then added to adjust the pH to a range of 6–6.5.

Preparation of Oil Phase for Emulsion
Emulsifiers, such as Span 20, are dissolved in the oil phase to create a light liquid paraffin mixture.

Preparation of Aqueous Phase
An emulsifier, such as Tween 20, is dissolved in purified water to form the aqueous phase.

Preparation of Drug Solution
The drug is dissolved in ethanol to create a uniform solution.[14,15]

Benefits of Nanoemulgel:
- Nanoemulgel has the advantage of bypassing first-pass metabolism, ensuring better bioavailability of the drug.
- It has demonstrated effectiveness as a controlled, long-duration drug delivery system, offering sustained release of the active ingredient.
- Nanoemulgel is highly convenient, making it an ideal option for self-administration by patients.
- The ease of application makes it well-accepted and comfortable for patients to use regularly.
- Due to the large surface area and the increased free energy provided by nanoemulgel, it serves as an efficient delivery system for active compounds.
- Unlike traditional emulsions, nanoemulgel does not suffer from common defects such as creaming, phase separation, flocculation, or coalescence, ensuring its stability.
- The small size of the particles in nanoemulgel allows them to penetrate the skin more effectively, enhancing drug absorption through the skin's surface.

Drawbacks of Nanoemulgel
- The surfactants employed in nanoemulgel formulations must be non-toxic to ensure safety in pharmaceutical applications.
- There is a risk of allergic reactions to certain components in the formulation, which could affect patient safety.
- Prolonged contact with the skin may lead to dermatitis, causing discomfort and irritation for some users.[16]

Evaluation of nanoemulgel
Determination of pH
A digital pH meter was used to measure the formulation's pH. In order to test pH, the pH meter electrode was cleaned with distilled water and then dipped into the mixture three times.

Measurement of viscosity
A Brookfield viscometer (RVDV-I Prime, Brookfield Engineering Laboratories, USA) equipped with spindle 63 was used to measure the viscosity of the prepared batches. Before the measurement was made, the formulation whose viscosity was to be ascertained was put into the beaker and let to settle for 30 minutes at the assay temperature (25±1ºC). The spindle was revolved for 10 minutes at 50 rpm after being lowered perpendicularly into the centre of the emulgel, being careful not to contact the jar's bottom. The measurement of viscosity was recorded.

Spreadability
The spreadability of the gel compositions was assessed using two standard-sized glass slides. The gel was sandwiched between the two slides after the formulation whose spreadability was to be ascertained was spread over one slide and the other slide was placed over its top. After pressing the slides against one another to remove any remaining air, the sticky gel was removed. The two slides were positioned on a pedestal such that the weight attached to the higher slide could remove it freely, while the clamp's opposing fangs held the lower slide firmly in place. A 20-gram weight was securely fastened to the upper slide. It was recorded how long it took for the top slide to fully separate from the bottom slide. The following formula was used to determine the spreadability.

$S = M. L/T$
Where M is the weight attached to the top slide.
L is the glass slide length.
T is the amount of time needed to split the slides.

Drug content study

To find out how much of the drug was in a specific amount of the formulation, a drug content analysis was conducted. Methanol was poured to a 10 ml volumetric flask containing 1 g of the formulation. The flask was shaken thoroughly, and the volume was adjusted using methanol. To ensure appropriate mixing, the volumetric flask was shaken vigorously in a shaker for two hours. After passing the solution through the filter paper and filtering the mixer, the absorbance was measured at 261 nm using a spectrophotometer.

In-vitro Drug release study

Emulgel's in vitro drug release experiments were conducted on diffusion cells using egg membranes. Carefully, this was clamped to one end of the dialysis cell's hollow glass tube. The dialysis membrane's egg membrane was coated with 1g of emulgel. PBS (pH 7.4) solution was newly made and put into the receptor chamber. The total amount of gel that was put into the tube to dissolve the medication. A magnetic stirrer agitated the receptor chamber. The samples (1 ml aliquots) were taken at the necessary intervals and, following the proper dilutions, were examined for drug content using a UV visible spectrophotometer set at 261 nm. For each time interval, the total amount of drug release was calculated using cumulative adjustments.

Parameters in Diffusion study

Reference apparatus for test:	Franz Diffusion Cell
Mode of Agitation	Magnetic Stirrer (50 rpm)
Mode of Temperature control	Thermostat (37± 0.50C)
Donor Compartment	One side open ended tube, 24 mm diameter
Receptor Compartment	250 ml, beaker containing 100 ml phosphate buffer solution pH 7.4
Semi-permeable membrane	Egg membrane.

Release kinetics of selected formulation

The cumulative release data was fitted to models that represented Zero order (cumulative percentage of drug release v/s. time), First order (log cumulative percentage of drug retained v/s. time), and Higuchi model (cumulative percentage of drug retained v/s. square root of time) in order to investigate the drug release kinetics and mechanism.

Accelerated stability studies of Emulgel:

According to guidelines, stability studies are conducted. The prepared emulgels were filled into aluminium collapsable tubes weighing 5 g, and they were put through strength tests at 5°C, 25°C/60% RH, 30°C/65% RH, 40°C/75% RH, and 60 ± 2° for three months. Tests were taken out and examined for physical characteristics, pH, rheological characteristics, and medicinal component at intervals of 15 days.[17]

Application

Anticancer activity

The application of chrysin-loaded nanoemulgel presents a transformative approach in localized drug delivery, particularly for melanoma treatment, due to its ability to overcome the challenges of poor solubility and low transcutaneous permeation. The nanoemulgel system enhances drug stability, penetration, and retention within the skin layers, ensuring targeted delivery while minimizing systemic side effects. Its thermodynamic stability, optimized droplet size, and gel viscosity contribute to effective percutaneous absorption and controlled release. Moreover, its cytotoxic efficacy against melanoma cell lines, coupled with biocompatibility on normal skin cells, underscores its therapeutic potential. This formulation reduces the required dose frequency and overall drug quantity, which can improve patient compliance and therapeutic outcomes. Additionally, its mechanical properties, such as hardness and adhesiveness, ensure ease of application and sustained contact with the skin, further augmenting its utility. Thus, chrysin nanoemulgel represents a promising candidate for advancing melanoma treatment while addressing current limitations in topical cancer therapies.[18]

Antifungal activity

Nanoemulgel (NEG) is emerging as an effective topical formulation for the treatment of fungal infections. It combines the benefits of nanoemulsions and gels to improve the delivery of antifungal agents to the site of infection. The nanoemulsion component enhances skin permeability and drug solubility, while the gel base offers a controlled, sustained release of the active ingredient.

NEG formulations typically incorporate essential oils or antifungal agents that, when encapsulated in the nanoemulsion droplets, show enhanced diffusion and deeper skin penetration. This results in increased therapeutic efficacy compared to traditional topical antifungal treatments. Additionally, the gel matrix provides a non-greasy, easy-to-apply formulation that improves patient compliance.

Studies have shown that nanoemulgel formulations exhibit superior antifungal activity, higher skin retention, and reduced systemic exposure. This makes them a promising alternative for localized treatment of fungal infections, offering both efficacy and safety.[19]

Anti-inflammatory activity

Nanoemulgels are gaining popularity in inflammation treatment due to their enhanced delivery and stability of bioactive compounds. These formulations combine nanoemulsions (tiny droplets of oil in water) with a gel base, improving skin penetration and providing controlled release of active ingredients.

In inflammation therapy, nanoemulgels offer better anti-inflammatory effects compared to traditional formulations. The nanoemulsion helps active compounds reach deeper layers of the skin, while the gel base ensures a non-greasy and easy-to-apply texture. Studies have shown that nanoemulgel formulations significantly reduce inflammation and swelling, making them an effective solution for conditions like arthritis or skin inflammation.

Overall, nanoemulgels represent a promising approach for topical anti-inflammatory treatments, offering improved efficacy, stability, and patient compliance.[20]

Anti- Psoriatic activity

Psoriasis, a chronic and often debilitating skin condition, is challenging to manage with traditional treatments due to their limited effectiveness and potential side effects. Nanoemulgels present a promising alternative by enhancing the delivery of active ingredients directly to the skin. These formulations are designed to improve the penetration of therapeutic agents, ensuring better absorption and more targeted treatment of affected areas. Nanoemulgels offer several advantages, including controlled release of active ingredients, which reduces the need for frequent applications and prolongs the therapeutic effect. Additionally, the non-greasy, lightweight nature of nanoemulgels improves patient adherence, making them easier and more comfortable to use. Research has shown that nanoemulgels can significantly reduce inflammation, redness, and scaling, common symptoms of psoriasis. Furthermore, they are well-suited for sensitive skin, reducing the risk of irritation and side effects compared to conventional topical treatments. Overall, nanoemulgels provide an innovative and effective approach to psoriasis management, offering better outcomes, improved patient compliance, and reduced side effects.[21]

Alopecia

The small size of the nanoemulsion droplets allows for deeper skin penetration, ensuring that active ingredients are delivered to the targeted layers of the skin where psoriasis occurs. This leads to more effective reduction in inflammation, redness, and scaling, which are common symptoms of psoriasis. Additionally, nanoemulgels provide controlled release of the active compounds, offering prolonged therapeutic effects and reducing the need for frequent applications.

The gel base of nanoemulgels provides a non-greasy, lightweight texture, which enhances patient comfort and encourages better adherence to the treatment regimen. They are also less likely to cause irritation compared to traditional topical treatments, making them suitable for sensitive skin. Research shows that nanoemulgels can improve the bioavailability of active ingredients, increasing their effectiveness and providing faster relief from psoriasis symptoms. Furthermore, the combination of improved drug delivery, enhanced stability, and reduced side effects makes nanoemulgels a superior treatment alternative, offering patients a more effective, convenient, and safer option for managing psoriasis.[22]

CONCLUSION

Nanoemulgels represent a promising and versatile pharmaceutical formulation that integrates the advantages of both nanoemulsions and gel-based systems. By utilizing nanoparticles or droplets, these formulations enhance the delivery of active compounds, ensuring deeper skin penetration, controlled release, and improved bioavailability. This makes them an ideal solution for a wide range of therapeutic applications, including anticancer, antifungal, anti-inflammatory, and psoriasis treatments, as well as for conditions like alopecia.

The major benefits of nanoemulgels include better stability, higher efficacy, reduced systemic side effects, and increased patient compliance due to their easy-to-apply and non-greasy nature. The incorporation of penetration enhancers and controlled release mechanisms further improves the therapeutic outcomes of these formulations.

However, challenges such as the potential risk of allergic reactions, skin irritation, and the need for non-toxic surfactants must be carefully managed during formulation development. The continued research and optimization of nanoemulgel formulations will likely overcome these hurdles, making them a more effective and widely adopted approach in modern medicine.

In conclusion, nanoemulgels offer a novel and effective drug delivery system with numerous therapeutic benefits. Their ability to deliver drugs more efficiently to target areas, enhance stability, and reduce side effects positions them as a valuable tool in both clinical practice and pharmaceutical research.

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