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REVIEW ON NANOEMULGEL DRUG DELIVERY SYSTEM

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ABSTRACT

Nanoemulgels, hybrid topical delivery systems that integrate nanoemulsions into gel matrices, offer a promising strategy to enhance drug permeation, stability, and therapeutic performance. This review summarizes current formulation strategies, constituent selection, manufacturing techniques, characterization methods, and pharmaceutical applications of nanoemulgel systems. Nanoemulsionssubmicron oil-in-water or water-in-oil dispersions stabilized by surfactants and co-surfactantsimprove solubility and bioavailability of poorly water-soluble actives but often suffer from low viscosity and limited topical handling. Incorporation into polymeric gel bases overcomes these limitations, yielding preparations with superior spreadability and patient acceptability. Critical formulation variables, including the choice of oil phase, surfactant/co-surfactant combination, and gelling agent, govern thermodynamic stability, skin permeation, and drug-release kinetics. Commonly applied production methods encompass high-pressure homogenization, ultrasonication, spontaneous and self-nanoemulsification, and phase-inversion techniques. Preclinical and formulation studies indicate that nanoemulgels can provide enhanced dermal and transdermal penetration, sustained release, prolonged local retention, and improved therapeutic outcomes relative to conventional topical dosage forms. Reported applications span transdermal, ocular, vaginal, dental, wound-healing, antimicrobial, anti-inflammatory, and anticancer therapies. Collectively, the evidence supports nanoemulgels as a versatile and effective platform for delivering both lipophilic and hydrophilic drugs with improved clinical performance and patient compliance.

KEYWORDS: Nanoemulgel, Nanoemulsion, Topical drug delivery, Skin permeation, Controlled drug release, Bioavailability enhancement.

INTRODUCTION

Numerous scientific domains have been impacted by nanotechnology in recent years. Nanotechnology is the application of science to produce incredibly small structures using a variety of techniques and procedures; the name "nano" alludes to miniscule size or extremely small structure.[1] In 1959, American scientist and Nobel Prize winner Richard Feynman introduced the concept of nanotechnology.[2] Both bulk and nanodoses of pharmaceuticals are available, and each has distinct physiochemical and biological properties.[1] Transdermal distribution based on nanotechnology has attracted a lot of interest from the pharmaceutical industry because it has a number of advantages over oral delivery systems, such as the ability to avoid the first-pass effect, enhance patient compliance, increase drug solubility, and achieve higher bioavailability.[3] To administer the created contemporary dosage forms, researchers in this field have introduced a number of modes of administration. The dose forms are mostly determined by the active ingredient's physicochemical characteristics. A recent discovery in synthetic drug development or high throughput screening is the synthesis of lipophilic active pharmacological molecules.[4] Recent data indicate that 70% of novel chemical entities (NCE) have low aqueous solubility[5], which is higher than the previous estimate of 40%.[6–11] The lipophilic characteristics of newly developed pharmaceutical substances lead to problems such as low oral bioavailability, variable absorption, intra- and inter-subject pharmacokinetic variations, and lack of dosage proportionality.[12] To solve those problems and concentrate on improving solubility, the

formulation technique is an ongoing development process. A number of methods, such as formulation development, chemical modification, and physical modification, can be used to increase the solubility of poorly soluble drugs. A number of formulation strategies, such as crystal engineering, amorphous formulation[13–17], decreasing the particle size to distribute through a nanocarrier system, different lipid formulation techniques[18], and more, have been employed to increase the solubility of weakly water soluble drugs. to deal with these lipophilic problems. characteristics of compounds, more recent methods of lipid formulation—such as adding a lipophilic component to an inert lipid vehicle[19,20], making microemulsions or nanoemulsions[21], self-emulsifying formulations, liposomes, solid lipid nanoparticles, or lipid nanocarriers[22,24] are gaining Basedon the formulations unique benefits and drawbacks at the target site, the severity of the disease, the age and condition of the patients, the available dosage form, and, lastly, user compliance, a number of routes of administration have been investigated.

Although oral administration is more likely to cause hepatic first pass metabolism, which necessitates a greater dose, it is the most favored route based on patient compliance.[25,26] Furthermore, gastrointestinal discomfort limits the use of surfactants in lipid-based formulations[27], and the drug's distribution throughout the body may cause inevitable side effects. Consequently, topical formulation distribution that is non-invasive, non-painful, and non-irritating is an alternate approach to prevent such intolerable problems. Increasing the drug's release rate from the formulation to improve percutaneous absorption, avoiding first pass metabolism and gastric irritation, delivering the drug to the precise site of action with less systemic toxicity, and occasionally increasing bioavailability with a sustained release profile through topical application are some of its many advantages.[28, 29]

In addition to the aforementioned advantages, traditional transdermal formulations, such as ointments, creams, and lotions, have a number of disadvantages, such as sticky qualities, poor spreadibility, stability problems, and more, which can ultimately lead to patient noncompliance. Clear gel and emulgel with improved efficacy and patient compliance were shown by the formulation's modernization of transdermal distribution. As a result, these formulations are gaining popularity in the cosmetics and pharmaceutical industries. Despite the many advantages of gel and emulgel formulations, administering hydrophobic medications remains a major obstacle. Additionally, in order to evaluate the systemic activity of transdermal administration, researchers are very worried about skin penetration through the stratum corneum. According to current research, topical formulations that are nanosized may increase the drug's retention at the site of action[31,32] and improve the permeability of the active moiety by disrupting the lipid bilayer, as evidenced by the obvious void and empty spaces in skin samples treated with nanoemulsion.[30] Because one phase is dispersed throughout the other and stabilized by an interfacial layer of surfactant molecules, nanoemulsion, an isotropic, transparent (or translucent) heterogeneous mixture of two media (oil and water), has enormous potential.[33] Studies show that nanoemulsions are more successful than basic micellar solutions at solubilizing medications. Additionally, because they can be made with less energy (heat or mixing) and have a longer shelf life, their thermodynamic stability gives them an advantage over unstable dispersions like emulsions and suspensions.[20]

Despite the many advantages of nanoemulsion, its topical use is limited by its low viscosity and spreadibility.[21] Researchers have solved the problems associated with nanoemulsion for transdermal distribution by simply converting nanoemulsion to nanoemulgel. Water-in-oil (w/o) or oil-in-water (o/w) nanoemulsions can be further converted into nanoemulgels using a gelling agent.[22] Nanoemulgel possesses gel properties and improved nanoemulsion properties for transdermal application. Additionally, nanoemulgel has greater permeability, reduced skin irritation, and a high drug-loading capacity for topical delivery when compared to alternative carriers as microemulsions, liposomes, or solid lipid nanoparticles.[23–25] Therapeutic compounds can be introduced utilizing this colloidal delivery method to increase bioavailability, elevate stability plateaus, and reduce side effects.[26] Nanoemulsion ensures appropriate localization and dispersion of the medicine by guaranteeing adequate percutaneous absorption within the skin to enhance local efficacy and/or via the skin to the circulation to refine its systemic effect. In order to offer further advantages in CNS function, it can even pass across the rigid blood-brain barrier.[27]

The goal of nanoemulgel research is to create a variety of delivery methods for treating different local and systemic conditions, such as transdermal, dental, vaginal, ophthalmic, and nasal to brain nanoemulgel. Intriguing study findings in the realm of pharmaceutical formulation development, patient acceptance, and the researcher's interest serve as the foundation for this.[28–34] The formulation overview and penetration aspects of emulgel[35], nanoemulgel characterization[36], current market products on nanoemulgels and their advantages[37], and the delivery of antifungal agents via nanoemulgel delivery[29] are the main topics of few review articles in the literature.

Nanoemulsion

Nanoemulsions (NEs), a transparent colloidal dispersion, are composed of a mixture of immiscible liquid phases that are kinetically stable and stabilized by the use of the appropriate ratio of surfactant, with a mean droplet size of less than 500 nm.[38] In contrast to the normal emulsion's milky or white color, the nanoemulsions'

small droplet size permits a greater drug loading capacity and makes them clear and translucent.[39] Although submicron emulsion and nanoemulsion are often used interchangeably, they are not the same as microemulsion (ME). Nanoemulsions have different structural characteristics and long-term thermodynamic stability even if they have the same droplet size.[40] It has been demonstrated that nanoemulsion is a creative transdermal delivery technique that can distribute both hydrophilic and water-in-oil (w/o) and oil-in-water (o/w) preparations.[41] Numerous strategies have been put forth to enhance the delivery of nanoemulsions. These include the application of fatty acid-containing surfactants or penetration enhancers, which can break down the stratum corneum and make the lipid bilayer more fluid, lowering the medicines' diffusional resistance. Furthermore, by enabling the passage of medications between their lipophilic and hydrophilic domains into the stratum corneum, nanoemulsions can enhance skin absorption and produce a steady supply of medications in the external phase. Drugs can occasionally enter the body through skin appendages such sweat glands, sebaceous glands, and hair follicles. Sebum in sweat ducts and hair follicles may help the nanoemulsion be delivered transfollicularly.[42]

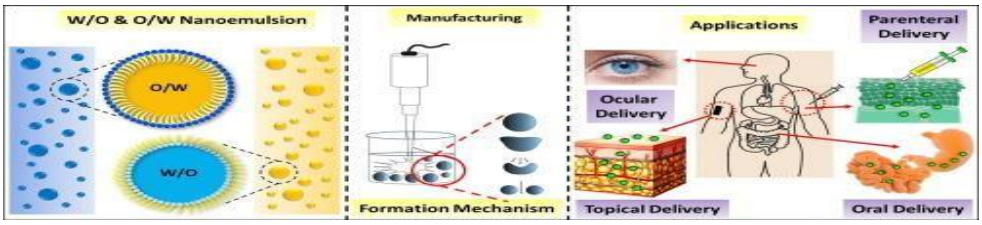

Fig 1: Thevariouscomponentsofastablenanoemulsions.

Nano-Emulgel Drug Delivery System

Although nano-emulsions have several advantages, their lack of viscosity makes it challenging to spread and hold the formulation on the skin.[43] This limitation prevents the use of nano-emulsions in therapeutic settings.[44] This issue was resolved by including a gelling agent into the nano-emulsion to produce a nanoemulgel.[45] Gels are made using a lot of aqueous or hydroalcoholic bases in a colloidal particle system.[46] The thermodynamic instability of the emulsion is reduced and a nano-emulgel is produced by mixing the nano-emulsion with a hydrogel matrix. Thermodynamic stability has improved since the non-aqueous phase's mobility has decreased as a result of the external medium's increased consistency. Nano-emulgel is a controlled release dosage form for topical administration that benefits medications with a short half-life because of its improved retention time and thermodynamic stability, which allow the formulation to release the drug over time.[47,48]

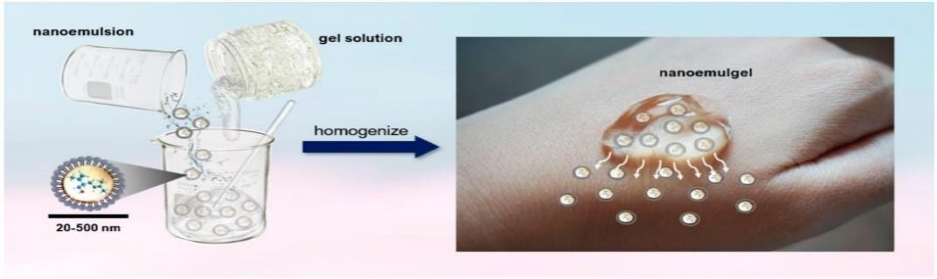

Fig 2: Representationofentryofnano-emulgelintoskin.

Formulation Components

The two separate systems that make up nano-emulgels are the gelling agent and the nanoemulsion, or emulsioncomposed ofo/wor w/o type nanodroplets. Bothforms of emulsions have an oily and an aqueous phase. Polymers that can swell upon the absorption of a liquid make up the gel base.[49]

Oil Phase

Which oil to use and in what quantity depends on how the nanoemulgel is applied and used. The type and amount of permeability, stability, and viscosity of the final nano-emulsion depend on the selected lipid component, or oil phase. In pharmaceutical and cosmetic applications, lipids obtained from natural or synthetic sources typically make up the oil phase, unless it is an active ingredient itself. The fluidity of the fats might range from liquid to a high molecular solid state. An oil must be hydrophobic in order to produce a stable emulsion. Research has shown that low hydrophobicity of an oil promotes emulsification, which influences lipophilic moieties' solubility.[50] As a result, choosing an oil is an essential initial step in creating nano-emulgel as a state-of-the-art drug delivery method.[51]

The additive properties of natural oils, which are of growing interest to researchers because of their additional therapeutic significance, support the pharmacological activity of the active moiety. For example, oleic acid, which is derived from both

vegetable and animal sources, is frequently utilized in nano-emulgel compositions. It is a biodegradable and biocompatible omega-9 fatty acid with enhanced solubilization properties in addition to having better percutaneous absorption.[52]

Surfactant System

Surfactants are a crucialcomponent ofnano-emulsions, which are used to stabilize the unstable mixture of two immiscible phases. This is accomplished through changing the dispersion entropy and reducing the in terfacial tension between the two phases. Atthe liquid-liquid interface, the surfactant should exhibit rapid adsorption. In the end, the individual nano-sized droplets' coalescence is inhibited and interfacial tension is reduced.[53]

When choosingtherightsurfactant, the surfactant'sHL Bvalueisacrucial factor. Either w/o type (HLB of3-8) oro/wtype (HLB of8–16) surfactants are present. Less than 8 low HLB value surfactants are used in w/o emulsions. Since their HLB value is more than 8, spans and tweens are an alternative for o/w emulsion. When compared to formulations containing only Span or Tween, a blend of Span and Tween offers an emulsion system greater stability. Therefore, creating the perfect nano-emulsion requires combining the right combination of surface-activeagents. The surfactantsfall into four primary types based on charge: cationic, non-ionic, anionic, andzwitterionic. Cationic surfactants include quinary ammonium compounds, hexadecyl trimethyl ammonium bromide, acetyl trimethyl ammonium bromide, and dodecyl dimethyl ammonium bromide.[54,55] Caproyl 90, Tween 20, Poloxamer 124, and 188 are a few examples of non-ionic surfactants.[56,57] Anionic surfactants include sodium dodecyl sulfate and sodium bis-2-ethylhexylsulfosuccinate.[58] Phospholipids such as phosphatidylcholine are zwitterion surfactants.[59] Toxicity should be considered when selecting a surfactant because it may irritate the skin or gastrointestinal tract depending on how it is administered. Ionic surfactants are usually not advised due to their toxicity and lack of biocompatibility. Because they are nontoxic, biocompatible, and unaffected by pH or ionic strength changes, non-ionic surfactants are a good choice.[60]

Co-SurfactantSystem

By supporting surfactants, co-surfactants facilitate the emulsification of oil in the aqueous phase. Co-surfactants are required to decrease interfacial tension and enhance emulsification.[61] The co-surfactants cause the interfacial film to become more flexible and experience a temporary drop in interfacial tension. The drug's partitioning into immiscible phases and the co-surfactant's interaction with the surfactant determine the drug release from the nano-emulgel. As a result, selecting a co-surfactant is equally as important as selecting a surfactant. PEG-400, transcutol® HP, absolute ethyl alcohol, and carbitol are often used co-surfactants.[62] Because they can partition between the water and oil phases, improving their miscibility, alcohol-based co-surfactants are the most preferred.[49] The emulsification process by surfactant may be impacted by the co-surfactant concentration, thus it must be selected carefully. Furthermore, unlike non-ionic surfactants with distinct HLB values, acombination of surfactant and co-surfactant with closer HLB values does not result in a stable emulsion. One possible explanation for this could be the solubilization of surfactants with higher HLB values in the aqueous phase. Lower HLB value surfactants, onthe other hand, solubilize inthe non-aqueous phaseandallow for astronger bondwiththesurfactant andco-surfactant mixture.[63]

Gelling Agents

One of the most important components of nanoemulgel is the gelling ingredient, which gives the mixture texture. When a gelling agent is added to the formulations, the result is a gelled structure. There are two kinds of gelling agents available: natural and synthetic.[64] The effect of a gelling agent on the rate of drug release from emulgel has been investigated. It has been discovered that the concentration of the gelling agent and the amount of medication released are inversely correlated. The produced emulgel exhibited a non-Newtonian shear thinning behavior with little to no thixotropy and a variable viscosity that changed depending on the type and concentration of gelling agent. A combination of two gelling agents or a low amount of carbopol in a formulation has been shown to have more stability than other formulations under a variety of stability tests, including centrifugation, temperature cycles, and one-year storage.[65]

Methodofpreparationofnanoemulgel

Apreparednanoemulsionismixedwithanappropriategelbas easpartofthemultistep process known as nanoemulgel development.

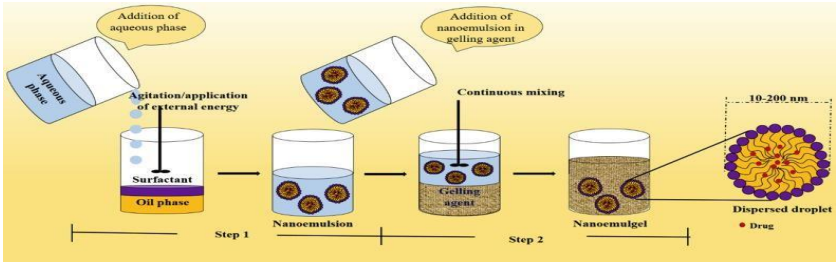

Fig 3: Schematicrepresentationofnanoemulgelspreparation.

1. Aqueous titration method: Aqueous titration approach is frequently used in nanoemulgel development. This approach involves progressively incorporating water while continually stirring different ratios of oil and surfactant/co-surfactant mixture (Smix). Pseudo-ternary phase diagrams are used to further analyse the systems in order to identify locations that can generate transparent and thermodynamically stable nanoemulsions. A clear nanoemulsion zone indicates effective emulsification and improved stability, which makes it easier to choose optimal compositions for sophisticated and reliable nanoemulgel delivery systems.[66] In this Aqueous titration method using particular oils, surfactants, and co-surfactants that demonstrated exceptional solubilisation and emulsification performance, optimised oil-in-water nanoemulsions were created. To create stable nanoemulgels for topical administration, the nanoemulsions were added to a Carbopol gel matrix. Ex vivo permeation tests showed improved local retention, regulated drug release, and increased skin penetration, highlighting their potential as cutting-edge topical and transdermal administration methods.[67]

2. High-pressure homogenization technique: High-pressure homogenisation is a commonly used method for creating nanoemulsions. Intense shear, turbulence, and cavitation forces are created when the formulation is run through a small homogenisation chamber at high pressure, reducing droplet size to the nanometric range. This technique works well for both large-scale and laboratory manufacturing. Droplet properties are significantly influenced by processing parameters such as phase viscosity and homogenisation cycles. However, the stability of thermolabile ingredients may be jeopardised by excessive energy input and temperature generation.[68] nanoemulgel formulations were created by first creating nanoemulsions with appropriate oils, surfactants, and homogenization methods, and then incorporating them into a gel system based on carbopol. The formulations were refined to improve topical retention and medication penetration through the skin. Drug release, skin penetration, and therapeutic efficacy were evaluated using ex vivo and in vivo experiments, while formulation qualities were assessed through characterization tests such DSC, X-ray diffraction, and confocal microscopy. The developed nanoemulgels demonstrated improved permeation, sustained drug release, and enhanced topical delivery compared to conventional formulations.[69]

3. Low energy emulsification method: To create nanoemulsions with little energy input, the low-energy emulsification technique is frequently used. In contrast to high-energy methods, this approach creates nano-sized droplets by using the system's inherent physicochemical characteristics and gentle stirring. It is considered a simple, cost-effective, and suitable approach for thermosensitive compounds due to the low heat generated during the process.[70] nanoemulsions were first created utilizing low-energy emulsification methods with appropriate oils, surfactants, and aqueous phases in order to create nanoemulgel formulations. To enhance topical administration and skin retention, the optimized nanoemulsions were further integrated into hydrogel bases. To assess drug release, stability, and transdermal penetration, a number of characterisation and permeation tests were carried out. The developed nanoemulgels demonstrated enhanced skin permeation, improved stability, prolonged drug release, and better therapeutic effectiveness compared to conventional topical formulations.[71]

4. High speed homogenization technique: The pharmaceutical and industrial industries frequently use the high-speed homogenization technique for emulsification and dispersion procedures. This technique, which frequently uses rotor-stator systems to create nano-sized droplets, is favored because of its affordability, simplicity of installation, and effective emulsification capacity. However, successful formulation requires careful optimization of process and formulation parameters.[72] A chitosan-coated omeprazole nanoemulgel was created in this study employing high-speed homogenization with appropriate oils, surfactants, and Carbopol 940. Particle size, zeta potential, drug content, and antibacterial activity were assessed for the created nanoemulgel. The optimized formulation showed enhanced skin permeation and improved antibacterial effectiveness due to the presence of the chitosan coating.[73]

5. The self-nanoemulsifying drug delivery system: A key strategy in the creation of nanoemulgels for improving drug solubility and stability is the self-nanoemulsifying drug delivery system (SNEDDS). This method involves the spontaneous formation of nanoemulsions when a mixture of oils, surfactants, and co-surfactants comes into contact with an aqueous phase. Optimization of the formulation is commonly carried out using phase diagrams to achieve the desired droplet size and stability.[74] appropriate oils, surfactants, and co-surfactants were used to produce nanoemulgels utilizing self-nanoemulsifying and nanoemulsion methods, which were then included into a Carbopol gel base. Particle size, stability, and skin penetration characteristics of the produced formulations were assessed. Additional assessments of topical administration, antibacterial, anti-acne, and anticancer efficacy were conducted. The developed nanoemulgels demonstrated enhanced skin penetration, improved retention, and superior biological activity compared to conventional formulations due to their nanosized droplet distribution and stable gel system.[75-76]

6. Spontaneous emulsification method: The spontaneous emulsification method is frequently employed to prepare nanoemulsions. This method involves mixing the aqueous phase with the organic phase, which contains oil, surfactant, and water-miscible

solvents. This causes fast diffusion at the interface and the spontaneous production of tiny, nanoscale droplets. The method is considered suitable for producing stable nanoemulsions with minimal energy input.[77] order to enhance topical and targeted drug administration, improved nanoemulsions were incorporated into Carbopol-based gel systems to create nanoemulgels. To obtain the right viscosity, stability, and prolonged drug release properties, the formulations were created utilizing the right oils, surfactants, and gelling agents. To evaluate the performance of the formulation, a number of in vitro tests were carried out, such as drug release and viscosity investigations. The developed nanoemulgels demonstrated enhanced drug diffusion, prolonged release behavior, and improved suitability for wound healing and periodontal therapy applications.[78]

7. Ultrasonication techniques: Using high-frequency sound waves to reduce coarse emulsion droplets into nano-sized particles, the ultrasonication process is frequently used to prepare nanoemulsions. This technique creates nanometer-sized droplets by creating ultrasonic waves above 20 kHz using a sonicator probe. The final droplet size is mainly influenced by the probe type, sonication time, and intensity applied during the process.[79] to promote skin penetration and wound healing activity, a curcumin-loaded nanoemulgel was created in this work employing the ultrasonication approach. After being integrated into a hydrogel system, the improved nanoemulgel was assessed in vitro, ex vivo, and in vivo. The formulation exhibited thixotropic behavior, improved skin permeation, and enhanced wound healing potential compared to conventional hydrogel formulations.[80]

8. Phase Inversion composition technique: Nanoemulsions can be prepared using the low-energy phase inversion composition (PIC) process, which eliminates the requirement for high-energy equipment. This method involves mixing oil and surfactant, then gradually adding water while stirring constantly. At the inversion point, the phase shift from water-in-oil to oil-in-water nanoemulsion occurs. This method is widely preferred due to its simplicity and ability to produce stable nanoemulsions at room temperature. A low-cost and efficient platform for treating methicillin-resistant Staphylococcus aureus infections was created in this work using a lysostaphin-loaded nanoemulgel. The nanoemulgel formulation was created to offer better topical distribution and prolonged medication release. Improved antibacterial and biofilm inhibition effectiveness was shown by additional testing utilizing a mouse skin infection model. The developed formulation showed promising potential for the treatment of resistant skin infections.[81]

CONCLUSION

A promising and cutting-edge medication delivery method for topical and transdermal applications is nanoemulgel. Compared to traditional dosage forms, nanoemulsion and gel technology offer superior drug solubility, improved skin penetration, better spreadability, longer drug release, and increased stability. For nanoemulgel formulations to be stable and effective, a variety of excipients and formulation methods are essential. The reviewed research showed that despite lowering systemic side effects, nanoemulgels greatly increase therapeutic efficacy, bioavailability, and patient compliance. Nanoemulgels have several uses in antibacterial, anti-inflammatory, wound healing, anticancer, and transdermal therapies because of their adaptability and efficacy. Therefore, nanoemulgel might be regarded as a promising and sophisticated carrier technology for next pharmaceutical and cosmetic formulations.

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