

Advancement and Future Window of Emulgel for Intensifying Transdermal Delivery in the Treatment of Skin Diseases

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ABSTRACT

Emulgel is a blend of gel and emulsion that improves drug penetration across the epidermal barrier and facilitates efficient skin diffusion, particularly for drugs that are poorly soluble in water. It is a potent, thermodynamically robust technique that integrates co-surfactants and surfactants. The properties that emulgel includes are easily spreadable, thixotropic, transparent, greaseless, extended shelf life, detachable, emollient, and bio-friendly. These are utilized in analgesics, anti-inflammatory agents, antifungals, anti-acne products, and cosmetic compositions. This article emphasizes preparation, advancements, applications, clinical studies, and current and future aspects of emulgel for improving transdermal delivery with its regulatory challenges.

Keywords: Emulgel, Potent, Advancements, Clinical studies, Future aspects, Regulatory challenges.

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INTRODUCTION

Transdermal Drug Delivery System (TDDS) is used when local effects on severe skin disorders cannot be achieved via oral, sublingual, rectal, or parenteral drug delivery techniques. For TDDS, the skin absorbs the drug and delivers it to the site of action, resulting in a more effective therapeutic effect. The skin is one of the most accessible organs for administering drugs, and it can be utilized for both local and systemic treatment. The skin, the largest organ in the body, consists of three main layers: epidermis, dermis, and hypodermis (Figure 1). The epidermis is the outermost layer, consisting of stratified squamous epithelial cells. The dermis, a thick layer of loose connective tissue, is visible to the naked eye and contains important blood vessels. The hypodermis, or subcutaneous tissue, lies underneath the dermis and contains the vascular plexus, lymphatic veins, and a large amount of adipose tissue (Lopez-Ojeda *et al.*, 2021). By removing first-pass metabolism by topical administration, intravenous therapy's hazards and issues are avoided. Gel formulations are less effective in delivering hydrophobic drugs, but they release active ingredients faster. Because of their high permeability

and poor solubility, class II drugs are more difficult to absorb and move through the body than their membrane-passing counterparts. Research has shown that emulgel, a combination of gel and emulsion, may be a preferable alternative for the topical delivery of weakly water-soluble pharmaceuticals (Prusty *et al.*, 2024; Khamkat *et al.*, 2022). Emulgel is a combination of oil-in-water (o/w) or water-in-oil (w/o) emulsions with a gelling agent incorporated. The smooth texture of emulgel ensures better patient compliance due to its ease of spreading on the skin (Olayemi and David, 2023). It has many beneficial qualities for dermatological applications, including thixotropy, non-greasiness, and spreadability. It has a higher loading capacity than other transdermal preparations and is affordable (Figure 2) (Talat *et al.*, 2021). Emulgels are classified into three types based on particle size: macroemulsion gel, microemulsion gel, and nanoemulsion gel. Macroemulsions are invisible but visible under a microscope due to larger droplets. Microemulsions are isotropic mixtures of water, surfactant, oil, and co-surfactant with droplets ranging from 10 to 100 nm. Nanoemulsions are transparent oil-water dispersions with globule diameters between 1 and 100 nm, providing improved delivery and transdermal penetration (Charyulu *et al.*, 2021; Ganju *et al.*, 2024).

Mechanism of drug absorption of emulgel

Emulgel improves topical medication absorption through follicular, intercellular, and transcellular pathways (Figure 3). Its



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dual-control release method uses both emulsion and gel qualities. Blood vessels are dispersed throughout the subcutaneous layer, under the dermis and epidermis. The most popular route is the pilosebaceous route, where penetration occurs through the intercellular matrix. Organic solvents like propylene glycol, DMSO, and surfactants can improve drug penetration. Permeation enhancers improve solubility, partitioning, and fluidization of the crystalline structure. Factors influencing drug absorption include lipid content, skin thickness, sweat gland density, hair follicle density, skin pH, skin temperature, hydration, inflammation, and blood flow. Low lipid content increases percutaneous penetration, while thicker skin layers may result in faster absorption. Increased blood flow promotes faster drug diffusion and systemic uptake (Patel *et al.*, 2021; Khamkat *et al.*, 2024).

MATERIALS FOR EMULGEL

Various components used to prepare emulgel are described below. Except for drugs, excipients are used to modify the formulations. The ideal properties of excipients must include the significance of stable chemical and physical substances that are nontoxic, readily available, reasonably priced, and not contraindicated.

Vehicles

A vehicle delivers medication uniformly over the skin, ensuring it reaches the intended location, maintaining therapeutic concentration. Its properties determine absorption, with active components like water, mineral oils, castor oils, fish liver oils, and plant fatty oils.

Emulsifiers

These are utilized to enhance the emulsification process during formulation and maintain product stability throughout its shelf life. Emulsifiers like sodium stearate, span 80, stearic acid, and tween 80 are utilized for preparing emulsions.

Gelling agents

To improve the consistency of gel preparation, gelling chemicals are used. These are made from various types of polymers, including natural ones like guar gum, synthetic polymers like carbomer, poloxamers, alkyl acrylates, and polyvinyl alcohol, and semi-synthetic polymers like cellulose derivatives like Hydroxypropyl Methylcellulose (HPMC), MC, and hydroxyethyl cellulose (Kumbhar *et al.*, 2025).

Penetration enhancers

These are compounds that facilitate the skin's ability to absorb medications. Penetration enhancers, such as surfactants, unsaturated fatty acids, organic solvents, essential oils, propylene glycol derivatives, and urea, are used in various formulations. These agents must be inert, non-allergenic, and compatible with agents.

pH adjusting agents

pH level is crucial for emulsion stability, drug solubility, and patient comfort. It prevents phase separation, skin irritation, and allergic reactions. Emulgels use pH adjustment agents like acids to lower pH and bases to increase it, and to prevent skin irritation (Charyulu *et al.*, 2021).

PREPARATION PROCEDURE OF EMULGELS

The simple method used to prepare emulgel has three main steps. The emulgel is created by combining an emulsion into the gel base after the first two phases of preparing the emulsion and gel base independently (Figure 4). Hydrophilic emulsifying agent is first dissolved in distilled water to create the aqueous phase. Similarly, lipophilic emulsifying agent is dissolved in liquid paraffin to create the oil phase. After being heated independently to 70° to 80°, the oil and aqueous phases are combined while being constantly stirred to create an emulsion. Gelling agent is dissolved at room temperature in distilled water to create the gel phase. Ultimately, an emulgel is created by gently swirling the gel and emulsion phases together in a 1:1 ratio (Figure 5).

APPLICATIONS OF EMULGEL

Emulgels are exploited in the treatment of skin diseases. Table 1 represents marketed emulgel products with different skin applications.

Treatment of Inflammation

The potential of emulgels to treat inflammation has been well investigated. According to Using oleic acid, Mahajan *et al.*, made dexbiprofen emulgel and discovered that its anti-inflammatory properties were comparable with those of commercially available diclofenac gel (Mahajan and Basarkar, 2019). Burki *et al.*, discovered that rabbit skin containing different concentrations of capsaicin was penetrated by dexibuprofen-capsaicin emulgel; the maximum amount penetrated after 6.5 hr. He discovered that after 6.5 hr, the total quantity of capsaicin that penetrated oil across rabbit skin was 9.83 µg/cm² when 100 mL of menthol was present, 7.23 µg/cm² when 75 mL of menthol was present, and 2.23 µg/cm² when menthol was absent (Burki *et al.*, 2020). Using carpool 940 and arachis oil as gelling agents, Sri and Arjun made naproxen emulgel. The formulation containing arachis oil (10% w/w), and carbopol 940 (0.5% w/w) was thought to be the best one because it had a greater enhancement ratio than the commercial gel (Sri and Arjun, 2019). For individuals 18 years of age and up, the directly acting drug tapentadol is authorized to treat moderate to severe pain. To create a pseudo ternary phase diagram, Ambhore *et al.*, chose tween 20, light liquid paraffin, and PEG 400 as the surfactant, oil and cosurfactant, respectively (Ambhore *et al.*, 2017). Ambala *et al.*, used span 80 and tween 20, liquid paraffin, hydroxypropyl methylcellulose, and carbopol 934 to generate ketoprofen emulgels. Compared to HPMC, carbopol

performed better as a gelling agent. In 8 hr, the F3 formulation demonstrated a $98.46 \pm 2.05\%$ of drug release with good physical appearance and clarity (Ambala *et al.*, 2015). Mefenamic acid emulgel was created by Khullar *et al.*, using mentha oil and clove oil as penetration enhancers and carbapol 940. The best release of 56% in 240 min and the highest release of 56.23% in 240 min were both demonstrated by the optimised formulation. The hot plate and carrageenan-induced paw oedema tests indicated anti-inflammatory and analgesic properties (Khullar *et al.*, 2012).

Treatment of Acne

Using propylene glycol, light liquid paraffin, span-20 and tween-20, and carbopol 941, Ranjan *et al.*, created clindamycin phosphate emulgel. They found that their anti-acne activity and drug release were higher than those of the commercially available clindamycin gel (Ranjan *et al.*, 2019).

Treatment of bacterial infections

Srivastava *et al.*, created a fusidic acid emulgel by combining propylene glycol, span 20, light liquid paraffin, carbopol 934, and peppermint oil. The formulation is appropriate for topical medication delivery because it demonstrated a maximum release of 95.25% in 8 hr (Srivastava *et al.*, 2020). Metronidazole was made as a topical emulgel by Daood *et al.*, using liquid paraffin, span 20, tween 20, and carbopol 940, and the formulation showed 9% release within 5 hr (Daood *et al.*, 2019). When Manaswitha *et al.*, analysed ofloxacin emulgels made with oleic acid, they discovered that the oleic acid-formulated emulgels had higher flux than other formulations (Manaswitha *et al.*, 2019). Oseni *et al.*, assessed the antibacterial efficacy of *Markhamia tomentosa* leaf extract against skin isolates, this study developed an emulgel formulation. The extracts were evaluated against *Bacillus subtilis*, *Staphylococcus aureus*, and *Staphylococcus epidermidis* after being extracted in five different solvents. It was discovered that the extract from distilled water was the most effective against these microbes. The emulgel was smooth, brown, and applied to the skin with ease. The extract was better suited for skin application since it was more viscous (Oseni *et al.*, 2024).

Treatment of wound healing

Khan *et al.*, assessed the effects of topical application of an emulgel based on *Ocimum basilicum* (OB) on wound healing in an animal model. The prepared OB emulgel released $81.71 \pm 1.7\%$ of the medication in 250 min, exhibiting strong physical characteristics and a satisfactory release profile. In *in vivo* wound healing experiments, OB emulgel demonstrated the highest percentage of wound contraction, exactly like the commercial product. Histopathological analysis showed a discernible improvement in the skin's histological pattern after 16 days of OB emulgel treatment. The data suggests that 5% OB emulgel could be a new approach to wound healing (Khan *et al.*, 2020).

Treatment of Psoriasis

In a study, Ganarajan and his coworkers contrasted xanthan gum, a gelling agent, with carbopol 934, a synthetic compound. They discovered that xanthan gum outperforms carbopol 934 as a gelling agent. Carbopol, polyethylene glycol, Kollicream3C, and KolliphorCS20 were used as emulsifiers to create the calcipotriol emulgel. PEG, isopropyl alcohol, and penetration enhancers were found to promote medication penetration into the epidermis. Excipient ratios and 3^2 response surface design were used to optimise the tretinoin emulgel. The optimised emulgel's anti-acne properties *in vitro* were comparable to those of the commercially available Sotret® gel (Ganarajan *et al.*, 2018).

Treatment of fungal infections

Luliconazole emulgel with carbopol 934 was selected by Shankar *et al.*, because it had the maximum drug release and antifungal activity (Shankar *et al.*, 2018). Tioconazole-loaded emulgels were made by Sah *et al.*, using span 80, tween 80, light liquid paraffin, and carbopol 934. The findings demonstrated viscosity, extensibility, and spreadability, suggesting that tioconazole emulgels provided a superior platform for topical delivery of hydrophobic medications and improved patient compliance (Sah *et al.*, 2017). As per Yadav *et al.*, Transcutol and eucalyptus oil were combined in various quantities to generate tolnaftate, an antifungal agent with low permeability and poor solubility. Compared to a pure medication emulgel without eucalyptus oil, the formulation's zone of inhibition showed a considerable improvement in antifungal activity. This was attributed to the emulgel's greater penetration in fungal cells when eucalyptus oil was present, which produced effective antifungal activity (Yadav *et al.*, 2017). Sawant and Mohite focused on how emulgel might enhance the topical administration of itraconazole. Using Carbopol 934 and Carbopol 940, two gelling agents, emulgel formulations were made. Physical characteristics, globule size, viscosity, drug release, transmission electron microscopy, antifungal activity, skin irritation, and stability were all assessed for the emulgels. When compared to the commercially available

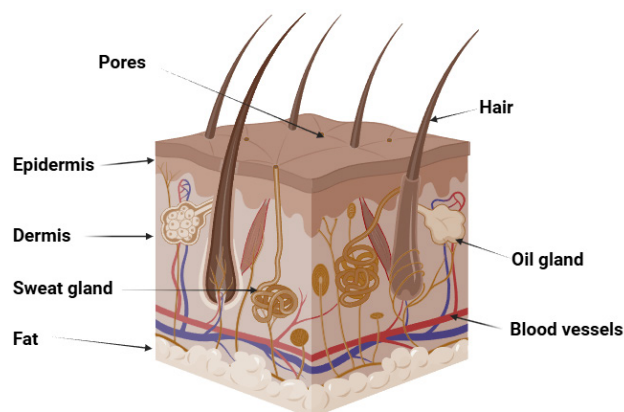


Figure 1: Structure of human skin.

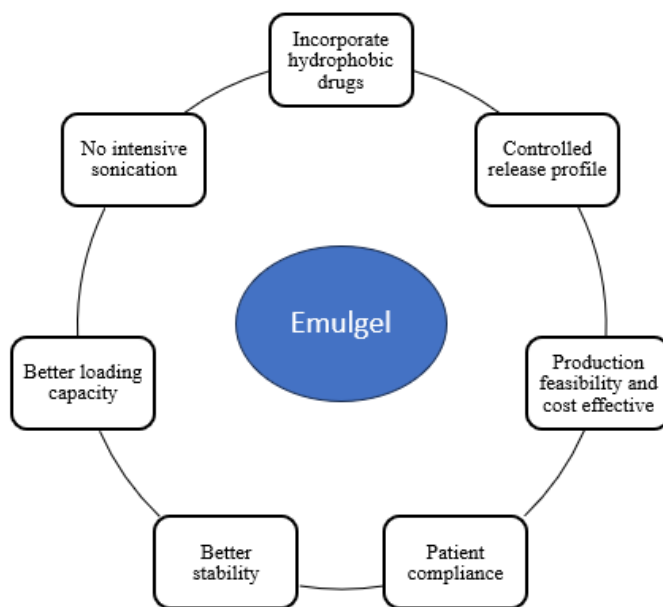


Figure 2: Advantages of emulgel over other transdermal preparations.

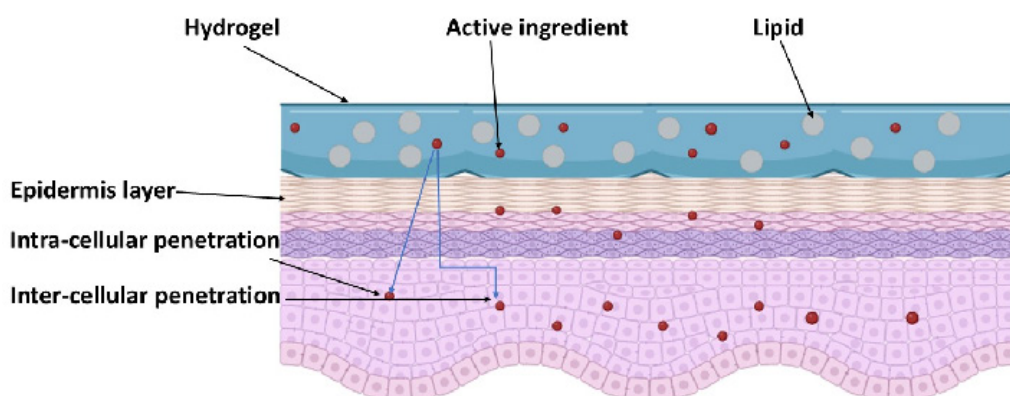


Figure 3: Mechanism of drug absorption of emulgel.

cream, the optimised formulation demonstrated greater antifungal effectiveness and drug release. After three months of storage, the emulgel formulation's stability did not change, and it did not exhibit any oedema or discomfort (Sawant and Mohite, 2015).

CLINICAL STUDIES ON EMULGEL

Gómez-Farto *et al.*, performed a clinical trial between January, 2023 and April, 2024 with 67 patients for the concurrent treatment of Atopic Dermatitis (AD) patients with a formulation that contains Hyaluronic Acid (HA), *Calendula officinalis*, glycerol, polyphenols and aloe vera. Following their recruitment, they were split into two groups at random, as thirty were placed in the left arm group and thirty in the right arm group. Only eight

participants freely decided not to continue the trial, with one patient withdrawing due to annoyance. Therefore, 59 patients in the population were evaluated. 55.9% of the patients with baseline information were female. 64.4% were phototype II patients. One to three times a week, 78% of the patients used creams. For testing on the left arm, 45.8% of patients utilized emulgel. Just 10% of the patients needed no additional care; the others continued receiving their usual course of care. Comorbid conditions such as prurigo nodularis, conjunctivitis, rhinitis, asthma, contact dermatitis, allergies were absent in 21% of the patients. 69% of the patients were exposed to the sun on occasion. Transepidermal Water Loss (TEWL), AD inflammation, epidermal thickness, and allergen-specific Immunoglobulin E (IgE) are all reduced by Epidermal Growth Factor (EGF). Inhibiting the change

of intercellular lamellar lipids from a liquid to a solid phase, glycerol speeds up the skin barrier's repair after disruption, the study revealed. HA is very important for the stratum corneum's structure and the epidermal barrier. Aloe vera decreases the TEWL and increases the SCH, which enhances the skin's physiological function. After 10 days of emulgel use, the study likewise

discovered alterations in the healthy area but no discernible change in the eczematous area's temperature. The emulgel not only reduces swelling and redness but also stops them from getting worse. The outcomes fall within the typical range for the function of the skin barrier (Gómez-Farto *et al.*, 2024). Using four vegetable oils, Thakur *et al.*, created a benzoyl peroxide emulgel

Table 1: List of marketed Products of Emulgel with different applications on skin.

Sl. No.	Brand Name	Manufacturer	Active Ingredients	Uses	References
1.	Diclobar emulgel	Barakat Pharma	Diclofenac diethyl amine	Anti-inflammatory, analgesic	(Patel <i>et al.</i> , 2021)
2.	Diclomax Emulgel	Torrent Pharma	Diclofenac sodium	Anti-inflammatory	(Patel <i>et al.</i> , 2021)
3.	Levorag emulgel	THD Ltd.,	Hibiscus, licorice	Emollient	(Patel <i>et al.</i> , 2021)
4.	Voltarol 1.16% emulgel	Haleon Consumer Healthcare	Diclofenac sodium	Anti-inflammatory	(Kumar D, 2016)
5.	Cataflam emulgel	Novartis India Ltd.,	Diclofenac diethyl ammonium	NSAIDs	(Malavi <i>et al.</i> , 2022)
6.	Accent gel	Zee Laboratories	Aceclofenac	Anti-inflammatory	(Tanaji, 2018)
7.	Avindo gel	Cosme Pharma Lab	Azithromycin	NSAIDs	(Tanaji, 2018)
8.	Cloben gel	Indoco Remedies	Clotrimazole, betamethasone	Antifungal	(Tanaji, 2018)
9.	Nadacin cream	Psycho Remedies	Nadifloxacin	Fluroquinolone antibiotics	(Tanaji, 2018)
10.	Clinagel	Glaxosmithkline Pharmaceuticals Ltd.,	Clindamycin phosphate, allantoin	Antibiotics	(Tanaji, 2018)
11	Voltaren emulgel	GlaxoSmithKline Consumer Healthcare	Diclofenac-diethyl-ammonium	Anti-inflammatory	(Tanaji, 2018)
12	Miconaz-H-Emulge, Miconazole nitrate, hydrocortisone, Medical union pharmaceuticals	Medical Union Pharmaceuticals	Miconazole nitrate, hydrocortisone	Anti-fungal	(Malavi <i>et al.</i> , 2022)
13	Excex gel	Zee Laboratories	Clindamycin, adapalene	Antibiotic	(Malavi <i>et al.</i> , 2022)
14	Pernox gel	Eris Oaknet Healthcare Pvt. Ltd.,	Benzoyl peroxide	Antimicrobial	(Malavi <i>et al.</i> , 2022)
15	Lupigyl gel	Lupin Pharma	Metronidazole, clindamycin	Antibiotic	(Tanaji, 2018)
16	Topinate gel	Systopic Lab	Clobetasol propionate	Inflammatory and allergic	(Tanaji, 2018)
17	Kojivit gel	Micro Labs Ltd.,	Kojic acid, dipalmitate arbuti	Skin pigmentation concerns	(Tanaji, 2018)
18	Zorotene gel	Glenmark Pharmaceuticals Ltd.,	Tazarotene	Treat acne, Sun damage.	(Tanaji, 2018)

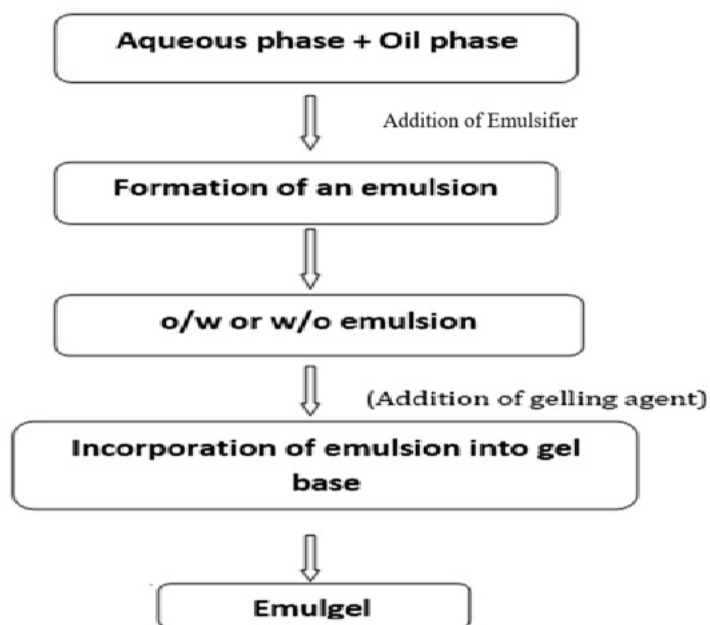


Figure 4: Fundamental steps for preparing emulgel.

to treat dryness and irritation of the skin. Span 60 and tween 20 were used as emulsifiers together with sesame oil in the optimised composition. The effectiveness of the 2.5% *Thymus vulgaris* L. emulgel (TF) was assessed through a single-blind, randomised, split-face, placebo-controlled research. For ninety days, emulgel and a placebo were administered to twenty-five patients with mild to moderate cases of face acne vulgaris. The TF formulation was found to significantly lessen the severity of acne. For mild to moderate acne, the 2.5% *Thymus vulgaris* L. formulation proved to be both effective and well-tolerated. Using non-invasive skin bioengineering methods, another emulgel with 5% avocado oil and 20% green tea extract was made and tested on twelve female participants. The emulgel was discovered to be stable, effective, and aesthetically pleasing, with good moisturising qualities for acne (Thakur *et al.*, 2012).

CHALLENGES OF EMULGEL

Emulgels are a complicated product that can develop stability problems over time, such as layer separation or the formation of cream-like structures. Because it depends on how they blend with water and oil components and fit with their intended usage, the choice of emulsifier is essential for producing stable emulsions within emulgels. For formulations to be effective, active ingredient compatibility is crucial, particularly when dealing with drugs that are fragile or readily degradable. Selecting a preservative is also a difficult issue because it must stop the growth of microorganisms while making sure the product doesn't interfere with other ingredients. Additionally, important are rheological characteristics like texture, spreadability, and ease of application. Scalability and regulatory compliance are two more major issues facing the pharmaceutical industry.

FUTURE PROSPECTIVE

Hydrophobic drugs have been difficult to deliver to the biological system. Emulgel can be utilized as a way to transport the hydrophobic drugs into the body (Sreevidya, 2019). To target certain body zones, research is concentrating on creating emulgels that can effectively transport a variety of drugs, including drugs with low and high solubility. The controlled release and targeted administration of medicinal substances may be improved by combining nanotechnology and emulgels. Emulgels made for certain skin types and conditions could offer personalised skincare solutions. The creation of emulgels may be influenced by the movement towards natural and eco-friendly ingredients. To address certain skin issues, advanced active ingredients, including peptides, growth factors, and stem cell extracts, could be included. Traditional oral or injectable medicine delivery methods may be replaced with transdermal distribution.

REGULATORY CHALLENGES

The formulation, stability, biocompatibility, reproducibility, bubble formation, and management of any skin irritation are the regulatory issues faced by emulgels. It can be difficult for the skin to absorb drugs with large particle sizes since some drugs have limited skin permeability. While repeatability guarantees consistent properties, stability is essential for the long-term stability of the emulsion and gel matrix. Choosing the right excipients is essential to guaranteeing both safety and effectiveness. Because emulgels can irritate the skin or trigger allergic reactions, safety and effectiveness are also very important. Preservatives, drug loading capacity, and biocompatibility are other crucial factors. To overcome these obstacles, quality control

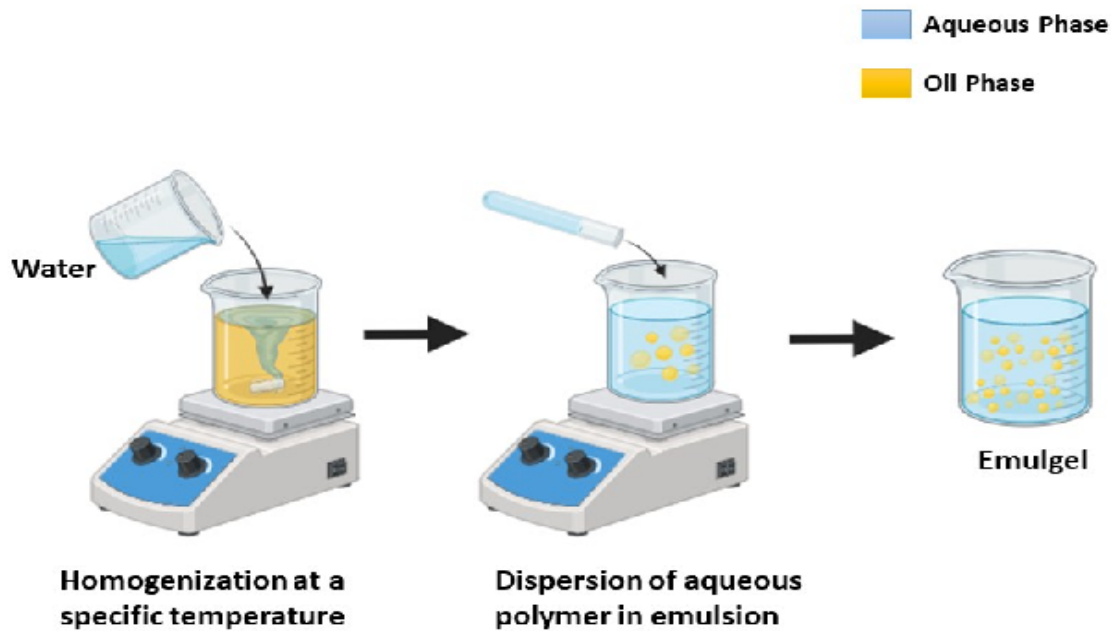


Figure 5: Schematic representation of emulgel preparation.

methods and reverse engineering techniques may be required (Shinde *et al.*, 2022, Bansal, 2023).

CONCLUSION

Emulgels-a combination of emulsion and gel-have enormous potential for use in pharmaceutical formulations because they provide flexibility and adaptability in a range of therapeutic domains. These are helpful in practical healthcare settings due to their ease of use and improved patient adherence. According to various studies, emulgels are a more effective and efficient way to administer drugs than other topical techniques. Emulgels are a common option for delivering hydrophilic and hydrophobic medications because of their exceptional extrusion, spreadability, viscosity, adhesion qualities. They are ideal for loading of hydrophobic medicines onto water-soluble gel bases, making them a viable choice for drug delivery in the future. To administer drugs precisely, future research will focus on improving formulations, finding new emulsifying agents, and using nanotechnology. They might improve treatment results, increase patient adherence, and transform medication delivery systems.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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