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Original Article

Formulation and Evaluation of Antiacne Topical Emulgel: A Comprehensive Review

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ABSTRACT

The latest developments in emulgel formulations for cosmeceutical applications are examined in this thorough analysis. Emulgels provide improved stability, bioavailability, and targeted administration of active chemicals in skincare products by fusing the advantages of emulgel systems and nanotechnology. The review focuses on the essential elements of emulgels, such as the selection of oils, gelling agents, and surfactants, and how these affect the formulation's characteristics. There is discussion of developments in characterisation techniques, preparation procedures, and the use of new active components. The assessment also discusses the possible drawbacks and opportunities for emulgels in the cosmeceutical sector, highlighting how they might enhance the effectiveness and allure of skincare products for consumers. Researchers and experts in the business can better grasp the technological advancements propelling the creation of next-generation cosmeceuticals by reading this review.

Keywords: Emulgels, techniques, characterization, cosmeceuticals

INTRODUCTION

Acne vulgaris is one of the most prevalent dermatological conditions affecting a significant portion of the adolescent and adult population worldwide. Characterized by the formation of comedones, papules, pustules, nodules, and cysts, acne arises primarily due to the obstruction and inflammation of the pilosebaceous units. [1] Factors contributing to its pathogenesis include excessive sebum production, follicular hyperkeratinization, colonization by *Cutibacterium acnes* (formerly *Propionibacterium acnes*), and inflammatory immune responses. Although acne is not life-threatening, it can lead to considerable physical and psychological distress, including permanent scarring, social withdrawal, anxiety, and reduced self-esteem. The global burden of acne and its associated complications have led to an increasing demand for safe, effective, and patient-compliant therapeutic interventions. [2] Conventional therapies for acne include topical and systemic agents such as antibiotics (e.g., clindamycin, erythromycin), retinoids (e.g., tretinoin, adapalene), benzoyl peroxide, and hormonal treatments. While systemic therapy is often effective for severe cases, it is associated with systemic side effects and poor patient adherence. In contrast, topical therapy offers a targeted approach with fewer systemic effects, better patient compliance, and ease of application. However, traditional topical formulations like creams, gels, and ointments often suffer from limitations such as poor skin penetration, greasiness, stickiness, or instability of active ingredients. [3] In this context, emulgel**,** a novel hybrid topical drug delivery system combining the properties of both emulsions and gels, has emerged as a promising alternative. Emulgels possess the ability to incorporate both hydrophilic and lipophilic drugs, improve the spreadability and absorption of the drug across the skin barrier, and offer enhanced patient compliance due to their non-greasy texture. They also facilitate controlled and sustained drug release, improving therapeutic efficacy and minimizing dosing frequency. The formulation of an effective antiacne emulgel involves careful selection of both the active pharmaceutical ingredient (API) and excipients such as emulsifiers, gelling agents, penetration enhancers, and stabilizers. The evaluation of these formulations through various physicochemical, microbiological, and performance-based parameters is critical to ensure safety, stability, and efficacy. [4] This review aims to provide a

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comprehensive overview of the formulation and evaluation of antiacne topical emulgels. It discusses the pathophysiology of acne, the rationale behind using emulgel systems, types of antiacne agents (both synthetic and herbal), formulation components, preparation methods, and standard evaluation protocols. The review also highlights recent advances, challenges, and future perspectives in this evolving domain of dermatological therapeutics.

Emulgel

Emulgel is an emulsion that is gelled by mixing it with a gelling agent. It can be either water-in-oil or oil-in-water. Additionally, the emulsion serves as a controlled release medication delivery mechanism, allowing drug particles trapped in the internal phase to pass through the external phase and gradually soak into the skin. Through the interior phases of the skin, which serve as a drug reservoir, the medication is carefully delivered to the external phase of the skin. Gel's cross-linked network allows it to trap tiny drug particles and release them in a regulated way. Because of its mucoadhesive qualities, it extends the time that medication is in contact with the skin. Emulgel functions as a dual control release mechanism since it has the qualities of both gel and emulsions. While oil-in-water emulsions are most effective in general cosmetic applications and as water-washable medication bases, water-in-oil emulsions are more commonly used for emollient activities, dry skin therapy, and emollient applications. [5]

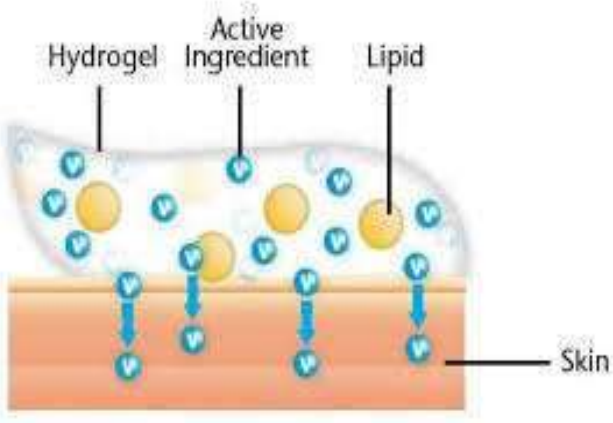

Figure 1: Structure of Emulgel

The emulgel have many advantages like thixotropic, greaseless, easily spreadable, easily removable, emollient, non-staining, bio-friendly, pleasing appearance, transparent and cosmetically acceptable, which also have a good skin penetration and long shelf- life. Two types of topical delivery products are available. They are external and internal products. As their name indicates, the external products are applied by spreading or spraying, and the internal products are applied orally, vaginally or rectally. [6]

Types of Emulgel Based on Emulsions:

1. Macroemulgel
2. Microemulgel
3. Emulgel

Formulation of Emulgel:

For the preparation of emulgel some constituents are used including drug, which are:

• Vehicle

Vehicle should follow the ideal characters given in the Pharmacopeias.

• Aqueous material

This forms aqueous phase of the emulsion. Generally, water and alcohol is used.

• Oil

Emulsion preparation involves the use of oils. Pharmacopeias use paraffin and mineral oils separately or together. They are in charge of the emulsion's oily phase. When creating an emulsion, microemulsion, or nanoemulsion, the oil phase is

crucial. since the physicochemical characteristics of oil, such as its molecular volume, polarity, and viscosity, greatly influence the drug's solubility, the droplet size of the corresponding emulsion, and the spontaneity of the emulsification, micro-, and nano-emulsification processes. When creating an emulsion, microemulsion, or nanoemulsion, the oil with the highest solubilizing potential for the chosen drug candidate is often used as the oily phase. This aids in achieving the highest possible medication loading.

• Emulsifiers

Emulsifiers used for preparation of emulsion. Some examples are span 80, tween 80, stearic acid, sodium stearate.

• Gelling agents

Gelling agents are used for prepare gels, which enhance consistency of preparation.

• Penetration enhancers

Penetration enhancers help to absorb drug to the skin.

• pH adjusting agent [7,8]

PREPARATION OF EMULGEL:

Gel and emulsion are combined to create emulgel. The gel and emulsion are made independently and combined. The aqueous and oil phases are separated and combined to create the emulsion. The gelling ingredient is then used to prepare the gel. Gel and emulsion are prepared and then combined while being gently stirred. Castor oil, clove oil, liquid paraffin, and other substances are utilized as oil phases. Alcohol and water are employed as aqueous phases. Tween 80 and water are combined to create the aqueous phase, and paraben and propylene glycol are combined to create the oil phase. Ethanol is used to dissolve the medication, and the two mixtures are continuously stirred. After that, the polymers are dissolved in water that has a pH between 6.0 and 6.5. Emulgel is created by combining the separately prepared emulsion and gel. [9-11]

Materials Required for Emulgel Fabrication:

Fabrication of emulgel for the purpose of drug delivery through topical route requires a variety of materials suitable and compatible with the skin along with consideration of some important factors such as the amount of drug to be loaded, amount of water to be used and route of permeation of the drug through the skin.

1.Aqueous Phase

For the formulation of emulgel, most commonly distilled water or ultra-purified water is used as the aqueous phase and this phase is responsible for the conversion of emulsion form into the emulgel in the presence of a gelling agent.

2.Oils and lipids

In emulgel formulation, selection of oils and lipids is the most crucial parameter and responsible for the selection of the other components such as surfactants and co-surfactants. In the oil which has maximum solubilizing potential for a selected drug candidate is selected as an oily phase for the formulation of emulgel. This helps to achieve maximum drug loading in the Nanoemulges. Pharmaceutically approved long-chain triglycerides (LCTs), medium-chain triglycerides (MCTs) and shortchain triglycerides are mainly used for emulgel formulation. As most of the recently approved active pharmaceutical ingredients have solubility and permeability limitation, MCTs are more attractive than LCTs for the emulsification purpose because of their more solubilizing capacity as compared to LCTs.

2.1. Vegetable Oils

Plants are the source of these oils that are found in the form of fatty acid glycerides. Many plant derivative oils are approved for the topical delivery of drugs such as soybean oil, olive oil, coconut oil, almond oil and castor oil through various drug delivery systems. Many of these oils like sesame oil and soybean oil are also used for the preparation of emulgel. These oils are fixed in nature and comparatively less preferred in many nanolipoidal formulations due to the low solubility of drugs.

2.2. Fatty Acids and Alcohols

Many fatty acids are widely distributed in plant oils. Fatty acids are mainly carboxylic acids along with a long aliphatic chain which are either saturated or unsaturated in nature. for topical drug delivery, US FDA has approved many oils belonging to the category of fatty acids and alcohols such as Oleic acid, Undecylenic acid, acetyl alcohol Stearyl alcohol and Oleyl alcohol etc.

2.3. Fatty Acid Ester and Glycerol

These categories of lipids are the most commonly used oil phase for the preparation of emulgel and microemulsions. In case of topical preparation also, these oils are most preferred because of their comparatively better solubility in recently approved APIs. These oils exhibit some of the properties of the surfactants. This category of lipids can be re-categorized as monoglycerides, diglycerides and triglycerides and are mainly medium-chain triglyceride. [12]

3.Surfactant and Co-Surfactant:

Surfactants are used both to give emulsification at the time of formulation and control day to day stability during shelf life of prepared Emulgel. General selection of surfactant depends on the type of emulsion. (O/W or W/O) E.g. Span 80 (Sorbitanmonooleate), Acrysol K 140, Polyethyleneglycol-40-stearate, Acrysol, Labrasol, Stearic acid, PlurolOleique, Tween 80 (Polyoxyethylene- sorbitanmonooleate), Labrafil, Sodium stearate, Where agents like, Transcutol ,Captex, Cammul, Migyol, etc. can be use as cosurfactant or co-solvents.

4. Gelling Agents

Polymers essential to give the structural network for the preparation of gels are known as gelling agents. The gelling agent is one of the major components of emulgel and it gives texture to the formulation. These are actually cross-linking agents. - Agar, Tragacanth, Guar gum, Xanthan Gum, Semisynthetic and Synthetic Carbapol, Poloxamer, HPMC etc. are some of the gelling agents used in emulgel preparation.

5. Preservatives

These are the chemical agents used to protect the formulation by the microbial attack and hence increase the shelf life. Phenoxyethanol, Benzalkonium chloride, Benzoic acid, Methyl paraben and Propyl paraben are generally used preservatives in the formulation of emulgel. [12,13]

6. Permeation Enhancers:

They interact with different skin constituents to produce a reversible temporary increase in permeability. They can act by one or more mechanisms like

i. Disrupting the highly compact structure of SC.

ii. Improving partition of drug or solvent or co-enhancer into the SC.

iii. Interacting intercellular protein. Causing conformational changes in protein or solvent swelling is the key for alternating polar path. Some enhancers improve the fluidity of protein in SC, where some act on both pathways by disrupting multilaminate pathway. They can increase the diffusion of drug through skin proteins. Type of enhancer has a significant impact product designing E.g. Eucalyptus oil, Linoleic acid, Lecithin, Oleic acid, Chenopodium oil, Isopropyl myristate, Urea.

7. Antioxidants

These are the chemical agents used in the formulation to protect the various components from oxidation. Butylated hydroxyl toluene, Ascorbylpalmitate, and Butylated hydroxyl anisole are most preferred antioxidants in topical nanolipoidal preparation. [14]

Method of Preparation for Emulgel:

1. High-pressure homogenization method:

This method involves the use of a high-pressure homogenizer to break down the oil phase into nanosized droplets that can be easily dispersed in a hydrophilic gel matrix. The homogenization process generates high shear forces that help to reduce the droplet size and create a stable Emulgel.

2. Ultrasonication method:

In this method, ultrasonic waves are used to create Emulgel. The oil phase and the hydrophilic matrix are mixed together, and the mixture is subjected to high-frequency ultrasound waves. The ultrasonic energy breaks down the oil phase into nanosized droplets, which are dispersed uniformly in the gel matrix.

3. Solvent evaporation method:

This method involves the use of a water-miscible solvent to dissolve the oil phase and the hydrophilic matrix. The solvent is then evaporated under reduced pressure, leaving behind a Emulgel with nanosized droplets of oil dispersed throughout the gel matrix.

4. Microfluidization method:

In this method, the oil phase and the hydrophilic matrix are passed through a microfluidizer to create Emulgel. The microfluidizer generates high shear forces that break down the oil phase into nanosized droplets, which are dispersed in the gel matrix.

5. Self-emulsifying gel method:

This method involves the use of a self-emulsifying drug delivery system (SEDDS)that can create Emulgel in situ. The SEDDS is a mixture of oil, surfactants, and co-solvents that can spontaneously emulsify when in contact with water. When the SEDDS is mixed with a hydrophilic gel matrix, a emulgel is formed.

6. High-energy emulsification method:

This method involves the use of high-energy input to create small droplets of the dispersed phase (oil) in the continuous phase (water). This can be achieved through various methods such as sonication, high-pressure homogenization, or micro fluidization. The resulting emulsion can then be transformed into a gel by adding a gelling agent such as a polymer or a surfactant.

7. Phase inversion temperature (PIT) method:

This method involves the use of a thermosensitive surfactant that undergoes a phase transition from a water-soluble to a water-insoluble state at a certain temperature. By adjusting the temperature of the system, the surfactant can be induced to form a gel-like structure that entraps the dispersed phase.

8. Sol-gel transition method:

This method involves the use of a sol-gel transition system, where a gel is formed by the aggregation of a network of particles or polymers in a solvent. This can be achieved by adding a crosslinking agent or a thermosensitive polymer to the emulsion, which triggers the formation of a gel-like structure at a certain temperature or under certain conditions.

9. Electrostatic complexation method:

This method involves the use of oppositely charged polymers or surfactants to create a stable emulsion, which can then be transformed into a gel by adding a crosslinking agent or a gelling agent.

10. Coacervation method:

This method involves the use of two or more polymers that undergo phase separation in the presence of an electrolyte or a pH change, resulting in the formation of a gel-like structure. The dispersed phase can then be incorporated into the gel by high-energy emulsification or other methods. [15]

Method of Formulation of Emulgel:

a. Screening of components
b. Preparation of Nanoemulsion
c. Preparation of Nano emulgel
d. Preparation of Gelling Agent
e. Incorporation of Gelling Agent

a. Screening of compound: Drug solubility was determined in different oils by adding more than drugs in different ingredients, then stirring continuously for 72 h to reach equilibrium. Then, samples were centrifuged and the supernatant was collected and the solubility was determined using appropriate analytical methods. Thereafter, excipients from each class with the highest drug solubility were selected for additional studies.

b. Preparation of Nanoemulsion: The drug is then solubilized in oil and oil is added to Nmix, this mixture is diluted with water to form of Nanoemulsion of the given drug.

c. Preparation of Emulgel: Gel base is ready mistreatment 1g of the Carbopol in a very needed amount of water. When the Carbopol solution has fully swelled and dispersed over a twenty-four-hour period, the ready nanoemulsion is progressively added to the mixture while stirring continues. The addition of Triethanolamine offers homogenized gel dispersion. Finally needed remaining half is adjusted with H2O. [16]

d. Preparation of Gelling Agent: In fabrication of a emulgel, the purpose of using a gelling agent is to change the physical form from liquid to semi-solid which has many advantages in terms of patient compliances. Various categories of the gel base for the purpose of gelling can be prepared by adding the polymer in purified water and stirred continuously with a glass rod or any other suitable mechanical device until desired texture achieved and then pH should be adjusted. In various experimental works, the preparation of the gelling agent is carried out by adding the polymer in purified water by a cold method. In cold method, the components are added in purified water at 20o C followed by the addition of gelling polymer and cooling the water up to 4o C.

e. Incorporation of Gelling Agent: After the preparation of nanoemulsion as well as the gelling agent, both are mixed and a emulgel is prepared. Here a liquefied form of water in oil (w/o) or oil in water (o/w) nanoemulsion is converted into a thick and semisolid emulgel with the help of various polymeric gelling agents. This gel form can change again into a solution form after applying a mechanical force such as rubbing. This property of the material is known as thixotropy where gel to sol and sol to gel transformation occurs on the application of shear stress and reversal of the same respectively without a change in volume. Innumerable polymers have been used as gelling agents such as Carbomer 940, Carbopol 943, Chitosan, Carbopol 934, Carbopol 940, Poloxamer 407, Methyl cellulose etc. for the preparation of emulgel of desired characteristics for various applications. [17]

Characterization of Emulgel

1. Appearance:

The prepared emulgel formulations were inspected visually for their color, homogeneity, consistency and pH. The pH values of 1% aqueous solutions of the prepared gellified emulsion are measured by a pH meter (Digital pH meter DPH 115 pm).

2. Spreadability Testing:

Desirable spreadability is one of the important criteria for the selection of a topical delivery system. In emulgel dosage form, spreadability can be determined by some special apparatus made up of a wooden block or glass having a pulley on the opposite end. With the help of this apparatus, spreadability is measured which comes under ‘Slip’ and ‘Drag’ method.

A shorter interval indicates better Spreadability. Spreadability is calculated by using the formula:

$S = M.L/T$

Where,

S = spreadability,
M = Weight tied to upper slide,
L = Length of glass slides
T = Time taken to separate the slides from each.

3. Globule size and Its distribution in emulgel

Globule size and distribution was determined by Malvern zetasizer. A 1.0 gm sample was dissolved in purified water and agitated to get homogeneous dispersion. Sample was injected to photocell of zetasizer. Mean globule diameter and distribution was obtained.

4. Drug released study:

To analyze the mechanism of drug release from the topical emulgel, the release date is fitted to the following equations:

Zero-order equation:

$Q=K0t$

Where Q is the amount of drug released at time t, and K0 is the zero-order release rate.

First-order equation:

$\ln (100-Q) = \ln 100 – K1t$

Where Q is the percentage of drug release at time t, and K1 is the first-order release rate constant.

Higuchi's equation**:**

$Q=K2\sqrt{t}$

Where Q is the percentage of drug release at time t, and K2 is the diffusion rate constant.

5. Accelerated stability studies of gellified emulgel:

Stability studies were performed according to ICH guidelines. The formulations were stored in a hot air oven at 37±2°, 45±2° and 60±2° for 3 months [19]. The samples are analyzed for drug content every two weeks by UV-Visible spectrophotometer. A stability study was carried out by measuring the change in pH of the formulation at a regular interval of time. [18]

6. Skin irritation test:

0.25 gm Emulgel is applied to each different site (two sites/rabbit). After 24 hr. of application rabbit skin site are wiped and cleaned, change in color of skin or undesirable change in morphology is noted and checked.

7. In-vitro Diffusion studies

Franz diffusion cell is used to perform diffusion study of prepared nanomeulgel. A cellophane membrane is used for study and 0.5g of sample applied on membrane and diffusion is carried out for 8 hr at 37±1°C using phosphate buffer (pH 7.4). At time interval of 1 hr, 1 ml sample is collected and replaced with new buffer solution. Collected samples are analyzed by using suitable analytical method.

8. Rheological Characterizations

It has been discussed that a emulgel contains oil, surfactants and a gelling agent as fabricating components. A minute change in the physicochemical properties of formulation components can greatly affect the rheological properties of a dosage form such as viscosity and flowability. The change in viscosity can further affect the stability factors as well as drug release and other biological functions. Taking these factors into consideration, it is very essential to understand the rheological properties of emulgel. Viscosity measurement can be carried out with different kinds of viscometers.

9. Measurement of Bioadhesive strength:

On each arm of the apparatus, one glass slide was separated from two additional glassed plates. A single plate is used to add weight. Between slides containing rate skin fragments, 1 gram of emulgel is inserted precisely. By putting weight on a single glass slide, you can detach the sandwich of two slides. The extra weight is added at a rate of 200 mg/min until the skin surface detaches. It is calculated by using the following equation: Bioadhesive Strength = W / A Where W denotes the desired weight (in gm) and A denotes the area (cm2). [19]

10. Swelling Index:

1 gm of prepared topical emulgel is taken on porous aluminum foil which is then placed on 10ml of 0.1 N NaOH solutions. The sample is removed from time to time and weight is noted till no further change in weight: Swelling Index (SW) % = [[Wt-Wo]/Wo]*100 Where, (SW) % = Percentage swelling, Wo = Original weight of emulgelWt = Weight of swollen emulgel at time.

11. Skin irritation test

0.25 gm Emulgel is applied to each different site (two sites/rabbit). After 24 hr of application rabbit skin site are wiped and cleaned, change in colour of skin or undesirable change in morphology is noted and checked.

12. In- vitro release study

Franz diffusion cell (with effective diffusion area 3.14 cm2 and 15.5 ml cell volume) was used for the drug release studies. Emulgel (200 mg) was applied onto the surface of egg membrane evenly. The egg membrane was clamped between the donor and the receptor chamber of diffusion cell. The receptor chamber was filled with freshly prepared PBS (pH 5.5) solution to solubilize the drug. The receptor chamber was stirred by magnetic stirrer. The samples (1.0 ml aliquots) were collected at suitable time interval. Samples were analysed for drug content by UV visible spectrophotometer at 226 nm after appropriate dilutions. Cumulative corrections were made to obtain the total amount of drug release at each time interval. The cumulative amount of drug released across the egg membrane was determined as a function of time.

13. Measurement of Bioadhesive strength:

On each arm of the apparatus, one glass slide was separated from two additional glassed plates. A single plate is used to add weight. Between slides containing rate skin fragments, 1 gram of emulgel is inserted precisely. By putting weight on a single glass slide, you can detach the sandwich of two slides. The extra weight is added at a rate of 200 mg/min until the skin surface detaches. It is calculated by using the following equation: Bioadhesive Strength = W / A Where W denotes the desired weight (in gm) and A denotes the area (cm2). [20]

ADVANTAGES OF EMULGEL:

a. Stability of Nanoemulsion is enhanced due to distribution of oil droplets in Gel base; where affinity of the drug toward oil determines stability.
b. Also good adhesion on the skin with high solubilising power leads to high concentration gradient that increase penetration of drug as it moves down.
c. Moreover, these types of formulation give support to delivery of lipophilic and poorly water-soluble drugs and also improve patient compliance.
d. Emulgel also helps in controlled release of drugs having the shorter half-life.
e. Provide higher Spread-ability of the formulation than creams.
f. Emulgel are Non-toxic and non-irritant.
g. Better loading of drug compare to other formulation.
h. Increase skin permeability and drug deposition.

DISADVANTAGES:

1.Bubbles formed during emulgel formulation.
2.For utilization in pharmaceutical application, surfactant used ought to be non-poisonous.
3.Possibility of allergenic reactions.
4.Skin irritation on contact dermatitis. [21-24]

CONCLUSION

Acne vulgaris continues to be a common yet challenging dermatological condition that affects individuals across various age groups, significantly impacting quality of life. Despite the availability of numerous conventional topical and systemic treatment options, limitations such as poor patient compliance, systemic side effects, and suboptimal skin penetration necessitate the development of more effective and user-friendly formulations. Emulgels, as a novel and versatile topical drug delivery system, offer a promising solution by combining the therapeutic advantages of both emulsions and gels. Their unique biphasic structure allows for the incorporation of a wide range of active agents both hydrophilic and lipophilic while ensuring improved stability, enhanced permeation, better aesthetic appeal, and controlled drug release. This makes emulgels particularly suitable for the treatment of acne, where targeted and sustained delivery of drugs to the pilosebaceous unit is crucial for therapeutic success. The formulation of antiacne emulgels requires a strategic selection of active ingredients ranging from synthetic drugs such as clindamycin and tretinoin to herbal agents like tea tree oil and neem and functional excipients including gelling agents, emulsifiers, and permeation enhancers. A thorough understanding of formulation principles, coupled with standardized evaluation protocols (such as drug content, spreadability, in-vitro release, antimicrobial activity, and skin irritation studies), ensures the development of safe, stable, and efficacious products. Recent advancements such as the incorporation of nanotechnology, herbal extracts, and bioenhancers into emulgel formulations have further expanded the scope of this delivery system, offering opportunities for innovation and personalized dermatological care. However, challenges related to long-term stability, large-scale manufacturing, and regulatory compliance still need to be addressed through ongoing research and clinical validation. In conclusion, antiacne emulgels represent a scientifically sound, patient-friendly, and therapeutically effective approach in acne management. With continued advancements in formulation science and dermatological research, emulgel-based therapies have the potential to redefine the landscape of topical antiacne treatment and significantly improve patient outcomes.

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