



An Evaluation of Emulgel for Topical Application.

*Deeksha Dangwal *G. Gananarajana

*Student *Professor

Shri Guru Ram Rai University , Dehradun , India

Abstract

Emulgels are multifunctional pharmaceutical formulations that combine the benefits of emulsions with gels, providing improved stability and extended drug release. The objective of this study was to create an emulgel formulation that is appropriate for delivering active pharmaceutical ingredients (APIs) through topical application. The emulgel was produced by combining an oil-in-water emulsion with a gel base using appropriate gelling chemicals. An assortment of emulsifiers and gelling agents were assessed in order to get the most favourable stability, spreadability, and rheological characteristics.

The emulgel that was created demonstrated exceptional stability, uniformity, and viscosity that is appropriate for use on the skin. The emulgel formulation underwent characterization for pH, viscosity, drug content, spreadability, and in vitro release profile. In addition, stability experiments were performed to evaluate the physical and chemical stability of the formulation under various storage circumstances.

Moreover, the emulgel formulation exhibited prolonged release of the included active pharmaceutical ingredient (API), indicating its potential as a suitable option for delivering hydrophobic medicines by topical application. In summary, this study emphasises the capability of emulgels as efficient methods for delivering drugs through the skin and offers valuable information on how to formulate and analyse them for use in the pharmaceutical industry.

Keywords: emulgel, topical medication administration, prolonged release.

Introduction

Emulgels, a novel category of pharmacological formulations, have gained considerable interest in recent times owing to their distinctive characteristics and adaptability in administering active pharmaceutical ingredients (APIs) via the skin. This introduction is to offer a comprehensive review of emulgels, including their composition, benefits, and uses in the pharmaceutical and cosmetic sectors.

Emulgels are a type of substance that combines the qualities of emulsions and gels. They create a two-phase system that displays the traits of both oil-in-water emulsions and hydrogels. Typically, they comprise three main constituents: an oil phase, a water phase, and a gelling agent. The oil phase consists of lipophilic compounds, whereas the water phase consists of hydrophilic components. Gelling agents are included to impart the desired rheological characteristics and improve stability.

An important benefit of emulgels is their capacity to efficiently distribute medications that are both hydrophobic and hydrophilic. The emulsion component facilitates the dissolution of hydrophobic medicines, while the gel component offers a stable structure for controlled release and enhanced penetration of the active pharmaceutical ingredient (API) into the skin. Emulgels possess a dual nature that makes them well-suited for several therapeutic applications, such as dermatology, cosmeceuticals, and transdermal drug administration.

Furthermore, emulgels possess many additional benefits compared to traditional types of medication. Gels provide superior stability in comparison to emulsions due to the gel matrix, which offers physical safeguarding against phase separation and degradation. Emulgels are favoured for topical formulations because they have an exquisite texture, do not feel greasy, and are easy to apply. This makes them more likely to be used by patients.

The emergence of emulgels has stimulated study and advancement in the field of formulation science, resulting in the investigation of new additives, methods, and uses. Several research have examined how several factors, such as the type of emulsifier, the quantity of gelling agent, and the ratio of oil to water, affect the performance and properties of emulgels.

Emulgels are a promising platform for delivering drugs topically. They offer adaptability, stability, and improved therapeutic effectiveness. This introductory section establishes the context for further investigation into the use of emulgels in pharmaceutical and cosmetic products, which in turn facilitates the advancement of innovative methods for delivering substances via the skin.[1]

Variables influencing the topical delivery of drugs

The administration of drugs topically provides several benefits, such as precise distribution to the desired area, minimised adverse effects on the whole body, and enhanced adherence by patients. Nevertheless, the effectiveness and result of topical drug therapy are impacted by multiple factors that influence the penetration of drugs through the skin. This review is to offer a thorough examination of the parameters that impact the administration of topical drugs and their consequences in the fields of pharmaceutical formulation and clinical practice.

Influences on Topical Drug Administration:

1. **The skin's physiology**, which encompasses its structure and composition, such as the stratum corneum, epidermis, and dermis, is vital in determining the penetration and absorption of drugs. Variables such as the level of moisture in the skin, the thickness of the skin, and the amount of lipids present affect how quickly and deeply a medicine can enter the skin.
2. **The physicochemical properties of medications**, such as their molecular weight, lipophilicity, and solubility, impact their capacity to permeate the epidermal barrier. Lipophilic medicines typically demonstrate superior permeability in comparison to hydrophilic substances.
3. **Formulation Factors:** Different formulation characteristics, including drug concentration, vehicle composition, viscosity, and pH, have an impact on drug release and skin permeation. Optimising the formulation is crucial for improving drug solubility, stability, and skin penetration.
4. **Chemical permeation** enhancers and physical approaches, such as iontophoresis and microneedle technology, can enhance the penetration of drugs by modifying the characteristics of the skin barrier. Nevertheless, it is crucial to thoroughly assess their safety and effectiveness.
5. The **presence of skin illnesses**, such as eczema, psoriasis, and dermatitis, might disrupt the normal functioning of the skin barrier and potentially impact the absorption of drugs. Furthermore, variables such as age, gender, ethnicity, and body site can have an impact on the permeability of the skin and the dispersion of drugs.
6. **Medication delivery and therapeutic effects** are influenced by various factors connected to the application technique, including the dose, frequency, duration, and occlusion of the medication. Optimising therapy efficacy requires the use of proper application technique and providing patients with knowledge.
7. **Environmental factors**, including temperature, humidity, and sunlight exposure, can impact the permeability of the skin and the stability of drugs. Formulations should be engineered to endure environmental difficulties throughout storage and utilisation.

Transdermal drug delivery.

Transdermal drug delivery provides a method of administering drugs to the body without the need for intrusive procedures. This approach avoids the drug being metabolised by the liver before reaching the bloodstream and allows for a controlled and continuous release of the drug. Comprehending the mechanisms and factors that affect the penetration of drugs via the skin is crucial for creating transdermal formulations that are effective. This study offers a comprehensive examination of the mechanisms involved in the penetration of drugs through the skin and emphasises the crucial aspects that influence the delivery of drugs via the skin.

Drug penetration through the skin: mechanisms and processes.

The transcellular route refers to the process by which lipophilic medicines move through the stratum corneum by diffusing across intercellular lipid bilayers. This pathway entails the segregation of medicines into the lipid matrix and their subsequent diffusion across the corneocytes.

The intercellular route involves the penetration of hydrophilic medicines through aqueous channels between corneocytes in the stratum corneum. This pathway depends on the moisture and swelling of the outermost layer of the skin, known as the stratum corneum, which enables the movement of water-soluble molecules through it.

The appendageal route refers to the extra channels for drug penetration provided by hair follicles, sweat glands, and sebaceous glands. Through these appendages, drugs can permeate the deeper layers of the skin, effectively bypassing the stratum corneum. This has been supported by references [3,4,5].

Benefits of emulgel

1. Emulgels provide enhanced stability in comparison to traditional emulsions because they contain a gel network that prevents phase separation and degradation of active pharmaceutical ingredients (APIs) over time.

Controlled Drug Release: The gel matrix of emulgels creates an environment that regulates the release of drugs, resulting in a gradual and extended therapeutic impact. This is especially beneficial for medications that need to be applied topically for an extended period of time.

2. Enhanced Skin Permeation: Emulgels promote the absorption of Active Pharmaceutical Ingredients (APIs) through the outermost layer of the skin, known as the stratum corneum. This improves the availability and effectiveness of the APIs for therapeutic purposes. Emulgels possess a dual-phase characteristic that facilitates effective transportation of both hydrophilic and lipophilic medications.

3. Improved Patient Adherence: Emulgels has a refined consistency, devoid of greasiness, and are easily applied, hence augmenting patient receptiveness and adherence to topical treatment. This is particularly advantageous for treatment regimens that extend over a lengthy period of time.

4. Emulgels provide the ability to incorporate a broad spectrum of Active Pharmaceutical Ingredients (APIs) that have different physical and chemical characteristics. This characteristic makes emulgels well-suited for a variety of therapeutic uses. The ability to customise formulations enables tailoring to meet the specific requirements of individual patients.

Drawbacks of Emulgels:

1. The process of formulating emulgels involves the meticulous selection of emulsifiers, gelling agents, and other excipients in order to attain the necessary qualities. Optimising formulation parameters might require a significant amount of time and resources.

2. Potential for Allergic responses: Certain individuals may develop allergic responses or skin sensitivity to the constituents of emulgels, such as emulsifiers or preservatives. Thoroughly examining and evaluating substances is crucial in order to reduce the likelihood of negative consequences.
3. Emulgels that contain penetration enhancers or other active substances have the potential to cause skin irritation or sensitization, especially in those with sensitive skin or pre-existing dermatological problems.
4. The gel matrix of emulgels may restrict the ability to load high quantities of active pharmaceutical ingredients (APIs), hence restricting their suitability for medications that require high dosages or potent formulations.[6,7,8]

Emulgel preparation method

Emulgels are formulated by combining emulsion and gel production methods. Here is a universal procedure for preparing emulgels:

Required components:

The oil phase consists of lipophilic compounds, such as oils and fatty acids.

Water phase: Substances that have an affinity for water (e.g., water, solutions in water)

An emulsifier is a type of surfactant that is used to stabilise an emulsion.

Gelling agent: Polymers used to create the gel structure

Preservatives, antioxidants, and other excipients (if desired)

Procedure:

Preparation of the Oil Phase: Step a. Measure and apply heat to the lipophilic substances (such as oils) in an appropriate container until they become liquid, if they are in solid form. Secondly. Incorporate any supplementary lipophilic excipients (such as fatty acids or lipophilic active substances) and mix thoroughly until a uniform mixture is achieved.

Preparation of the Water Phase: step a. Measure and warm the hydrophilic substances (such as water) in a distinct vessel until the appropriate temperature is attained. Secondly. Agitate the aqueous phase to incorporate any hydrophilic excipients, such as active substances that are soluble in water.

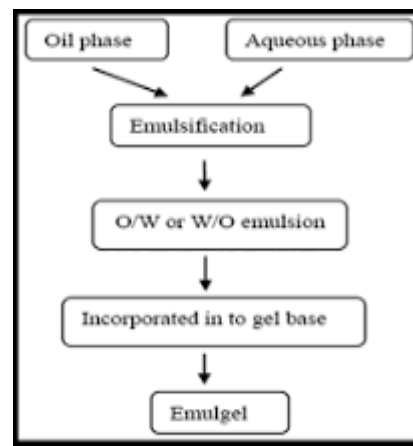
Emulsification: noun. Gradually incorporate the water phase into the oil phase while stirring incessantly. Secondly. To achieve a consistent distribution of the phases in the emulsion, it is necessary to employ an appropriate emulsifier, such as a non-ionic surfactant, which will stabilise the emulsion. The user's text is already straightforward and precise. Keep swirling until a consistent emulsion is created.

Inclusion of Gelling Agent: a. After achieving stability in the emulsion, gradually add the gelling agent to the emulsion while stirring continuously. Secondly. Ensure the even distribution of the gelling ingredient throughout the emulsion. The text is concise. If needed, modify the pH of the emulgel using appropriate pH adjusters.

Cooling and homogenization: a. Allow the emulgel to cool to ambient temperature while gently stirring to prevent phase separation. Secondly. To enhance consistency and texture, employ a homogenizer or high-shear mixer to homogenise the emulgel.

Inclusion of preservatives and other excipients: a. Incorporate preservatives, antioxidants, and any other desirable excipients into the emulgel through comprehensive blending. Secondly. Ensure uniform distribution of all components inside the formulation.

Packaging and Storage: a. Transfer the emulgel that has been made into appropriate containers for the purpose of storage and utilisation. Secondly. To preserve the stability of the emulgel, it should be stored in a cool and dry location, shielded from direct sunlight and heat. [9,10,11]



Emulgel preparation flow chart

Varieties of Commercialised Products

Marketed Product	Active Pharmaceutical Ingredient	Manufacturing Company
Voltaren Emulgel	Diclofenac diethylamine	GlaxoSmithKline
Isofen Emulgel	Ibuprofen	Beit Jala Pharmaceutical Co.
Benzolait Emulgel	Benzoyl peroxide & Biguanide	Roydermal
Miconaz-H Emulgel	Miconazole nitrate & Hydrocortisone	Medical Union Pharmaceuticals
Derma Feet	Urea	Herbitas
Adwiflam Emulgel	Diclofenac diethylamine, Methyl Salicylate & Menthol	Saja Pharmaceuticals
Nucoxia Emulgel	Etoricoxib	Zydus Cadila Healthcare LTD

Evaluation parameters of emulgel

1. The physical appearance of the emulsion formulations was assessed by visually examining their colour, homogeneity, consistency, and pH. The pH of 1% aqueous solutions of the gellified emulsion was determined using a digital pH metre (model 115 ppm) [12].

2. The drug concentration in the Gellified Emulsion was determined using a spectrophotometer. The drug concentration in the Gellified Emulsion was determined by dissolving a known amount of the emulsion in a solvent (methanol) using sonication. After appropriate dilution, absorbance was determined using a UV/VIS spectrophotometer (UV-1700 CE, Shimadzu Corporation, Japan) [13].

3. In Vitro release study : A Franz diffusion cell, with an effective diffusion area of 3.14 cm² and a cell volume of 15.5 ml, was utilised for conducting the drug release tests in vitro. A 200 mg Gellified Emulsion was equally put onto the surface of the egg membrane. The egg membrane was firmly secured between the donor and receptor chambers of the diffusion cell. The receptor compartment was filled with a newly prepared solution of PBS (pH 5.5) in order to dissolve the medication. A magnetic stirrer was used to agitate the receptor chamber. The 1.0 ml aliquots were collected at appropriate time intervals. The drug content of the samples was analysed using a UV visible spectrophotometer, following the necessary dilutions. The total drug release at each time interval was calculated by making cumulative corrections. The amount of medication released across the egg membrane was determined as a function of time. The user's text is "[14]".

4. Viscosity measurement: The viscosity of the emulgel was evaluated using a Brookfield viscometer without any dilution. The 30mL sample was placed in a beaker and left to reach a state of equilibrium for 5 minutes. Afterward, the reading was measured using a spindle rotating at speeds of 20 and 30 revolutions per minute. The reading on the viscometer was recorded for each speed. The user's text is "[15]".

5. Spreadability Test: Approximately 1g of the emulgel being studied was applied onto a glass slide. The emulgel preparation was placed between a slide and a second glass slide of the same size as the fixed ground slide. The second glass slide is equipped with the hook15. A 100 g weight was placed on top of the two slides for 5 minutes to remove air and create a consistent layer of emulgel between them. A predetermined weight of 35 grammes was placed in the pan, which was then fastened to the pulley using a hook. The duration, measured in seconds, it takes for two slides to slide off from emulgel when placed between them under a specific stress. The shorter the period required for the separation of two slides, the greater the spreadability.

The calculation is performed using a specific formula.

The formula $S = m.l / t$ represents the relationship between the variables S , m , l , and t .

Where S represents the measure of how easily a substance may be transferred or distributed,

The variable m represents the weight that is placed on the top slide, l represents the length of the higher slide, and t represents the time taken. The user's text is "[16]".

Conclusion

To summarise, the assessed emulgel formulations demonstrate potential as topical administration systems, providing regulated drug release, desirable texture, and sufficient stability. Additional optimisation may be necessary to rectify minor formulation errors and improve overall performance. Further research should investigate supplementary methods of characterisation and in vivo efficacy evaluations to authenticate these findings and bolster their clinical implications.

In summary, these emulgels provide a significant contribution to the field of pharmaceutical science and have the potential to be used in dermatology, pain treatment, and other areas of therapy that require targeted drug delivery.

Bibliography

1. Singh B, Garg B, Chaturvedi SC, Arora S, Kapil R, Singh B. Emulgel: An In-depth Analysis. The article is published in the International Journal of Pharmaceutical Sciences Research in 2019, volume 10, issue 1, pages 37-47.
2. Barua and Mitragotri conducted a comprehensive study on the challenges related to the penetration of nanoparticles through cell and tissue barriers. The review provides an overview of the current state and potential future advancements in this field. Nano Today. The citation is "2014;9(2):223-243."
3. Prausnitz MR and Langer R authored a publication on the topic of transdermal medication delivery. Nat Biotechnol The reference is from the year 2008, volume 26, issue 11, and the pages are 1261-1268.
4. Paudel KS, Milewski M, Swadley CL, Brogden NK, Ghosh P, Stinchcomb AL. Dermal/transdermal delivery presents both challenges and potential. The delivery. The reference is in the format of a journal article citation, specifically from the year 2010, volume 1, issue 1, and pages 109
5. Williams AC and Barry BW conducted research on substances that improve the penetration of drugs through the skin. The publication is titled "Adv Drug Deliv Rev" and was published in 2004. It is found in volume 56, issue 5, and spans pages 603 to 618.

6. Akhtar N, Verma A, and Pathak K conducted a study on the topical delivery of an anti-psoriatic drug using an ethosomal system. The study involved statistical optimisation, characterisation, and in vivo evaluation. Drug Delivery The reference is from the year 2016, volume 23, issue 7, and spans from page 2454 to 2469.
7. Singh B, Garg B, Chaturvedi SC, Arora S, Kapil R, Singh B. Emulgel: An In-depth Analysis. The article is published in the International Journal of Pharmaceutical Sciences Research in 2019, volume 10, issue 1, pages 37-47.
8. The authors Prajapati ST, Patel CG, and Patel CN developed and assessed a topical emulgel that includes diclofenac diethylamine. Journal of Pharmaceutical and Allied Sciences. The text "2012;4(4)" refers to a specific publication or document.
9. Vora B, Khopade AJ, and Jain NK conducted a study on the transdermal delivery of levonorgestrel using proniosomes for the purpose of contraception. The article is titled "J Control Release." The reference is from the year 1998, volume 54, issue 2, and the page range is from 149 to 165.
10. Choudhury H, Gorain B, Pandey M, Kundu A, Bhattacharjee A, Manna P, et al. An innovative method for delivering substances directly to the skin using nanoparticles made of poly- γ -glutamic acid. Nanomedicine. The reference is from a publication in 2014, volume 10, issue 5, with page numbers 1141-1154.
11. The study conducted by Prajapati ST, Patel CG, and Patel CN focused on the development and assessment of a topical emulgel that contains diclofenac diethylamine. Journal of Pharmaceutical and Allied Sciences. The text "2012;4(4)" refers to a specific publication or document that was published in the year 2012 and is part of the fourth
12. WB Saunders Co. Philadelphia, in the year 1970, had a population between 55 and 60.
13. Chaudhari P, Ajab A, Malpure P, Kolsure P, Sanap D. Development and in-vitro evaluation of thermo-reversible nasal gel formulations containing Rizatriptan benzoate. Indian Journal of Pharmacy. Edu. Reference: Res., 2009; Volume 43, Pages 55-62.
14. There is no text provided. Masmoudi H, Piccerelle P, Le Dréau Y, and Kister J developed a rheological approach to assess the physical stability of medicinal oil-in-water emulsions with high viscosity. The article titled "Pharmaceutical Research" was published in 2006 and can be found in volume 23, issue 8, pages 1937-1947.
15. Zhang LW, Al-Suwayeh S.A., et al. The study titled "Oil components modulate the skin delivery of 5-aminolevulinic acid and its ester prodrug from oil-in-water and water-in-oil nanoemulsions" was published in the International Journal of Nanomedicine in 2011. The study investigated how oil components affect the distribution of 5-aminolevulinic acid and its ester prodrug to the skin using oil-in-water and water-in-oil nanoemulsions. The URL provided is a link to the article with the Digital Object Identifier (DOI) 10.2147/IJN.S17524 in the International Journal.
16. Khullar R, Kumar D, et al. Formulation and evaluation of mefenamic acid emulgel for topical delivery. Saudi Pharm J., 2011; 2. <https://doi.org/10.1016/j.jsps.2011.08.001>