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Emulgel Formulation And Evaluation Utilizing Natural Polymer For Antifungal Activity

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ABSTRACT

Emulgel is a brand-new, innovative topical medication delivery technology that combines the benefits of hydrophilic gel and emulsions.Emulgel comprises both emulsions entrapped in polymer gel phase. To comprehend the drug and its behavior, preformulation research is carried out. Preformulation research included drug identification via DSC, FTIR, melting point, and solubility. To facilitate further drug calculations, a calibration curve for fluconazole in ethanol and pH 5.5 phosphate buffer is developed. Two approaches were used in the drug excipient compatibility investigation. Drug and drug excipient physical stability tests are conducted at room temperature and run for 14 and 28 days, respectively. The FTIR technique was used to verify the medication and polymer compatibility. The carbomer polymer and fluconazole are compatible.

For the creation of emulgel, carbomer homopolymer type C and aloevera are utilized. Aloevera demonstrated exceptional gelling qualities. Physical characteristics, rheological investigations, pH of the formulations, texture analyzer spreadability, bioadhesive strength assessment, extendability, drug content determination, and invitro drug release tests are all considered when evaluating formulations. The chosen formulation is stable for one month and was charged for the stability research at rapid, intermediate, and room temperature storage settings.

Keywords: *Emulgel, Emulsion, Fluconazole, Aloevera*

1. INTRODUCTION

1. Emulgel- Emulgel is the combination of the words "emulsion" and "gel." It describes a kind of topical formulation that combines the qualities of a gel (semisolid consistency) and an emulsion (combination of water and oil). Because they have benefits such ease of application, the capacity to deliver both hydrophilic (loving water) and lipophilic (loving fat) compounds, and improved skin penetration of active chemicals, emulgels are commonly utilized in pharmaceutical and cosmetic applications. They are frequently used in skincare formulas, anti-inflammatory lotions, and pain-relief gels.

1.2. Emulsions- Emulsions are composed of two or more generally immiscible liquids (unblendable or unmixable).Emulsifying agents, also known as surfactants, are used to lower the surface tension between the two liquids and keep the droplets from coalescing or separating over time, therefore achieving the stability of emulsions.and are transformed into gel by mixing with the appropriate polymers. Emulgel is an extremely promising tool for the transport of medicinesthat are hydrophobic. Stated differently, the Emulgel is an amalgam of the terms emulsion and gel.

Types of Emulsions:

- Macro emulsions or Coarse emulsions
- Micro emulsions
- Nano emulsions
- Double/ Multiple emulsion

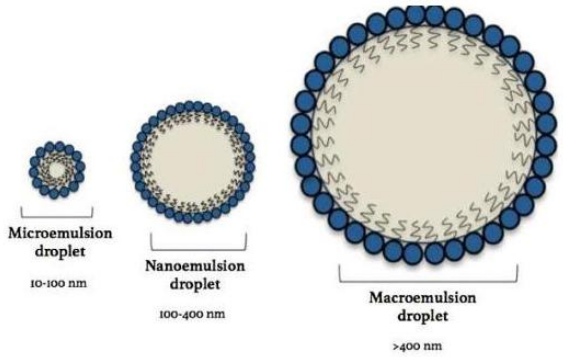

Fig-Types of emulsion

1.3. Gel -Gel is a semisolid formulation with a viscosity ranging from high to low. It is composed of a dispersion that can contain small inorganic particles or big organic molecules, or it can be encased and penetrated by liquid phase. When the gels reach a steady state, they show no flow because diluted polymer system with crosslinking. One system that is abundant in liquids is the gel. The qualities of a solid are provided by the continuous structure.Following gel application, the liquid phase evaporates and leaves a gel film on the skin that contains the medication. Gels provide superior medication release as compared to creams and other ointments. They are very biocompatible.Gels are frequently applied topically to act as occlusive dressings, emollients, protective agents for both local and systemic medications.

1.4. Emulgel-- Formulation in which an oil-and-aqueous phase emulsion is confined in an emulgel gel phase A suitable mixture of oil and aqueous phase is used to generate the main emulsion, which is Fluconazole emulgel subsequently mixed into the thick gel phase.In order to make an emulsion, An aqueous form oily substances, gel-forming agents, penetration enhancers, and emulsifiers make up an emulgel formulation. An emulsion found in emulgel serves as a means of medication dissolution. There are several drawbacks to the majority of commonly used topical formulations, including lotions, emulsions, suspensions, ointments, and creams. When applied topically, conventional topical formulations are oily and uncomfortable for the patient.

Emulgel is a mixture of gel and emulsion. When a gelling ingredient is present, the water phase in emulgel transforms into the classical emulsion. Hydrophilic medications are in the W/O system, while lipophilic pharmaceuticals are stuck in the O/W system. It is a reliableand efficient way to administer hydrophobic medications. Because emulgel has a deeper drug penetration, it exhibits a more effective mechanism than a gel.The emulsion is easier to wash, has a higher propensity to permeate the skin, and has a certain level of elegance. Emulgel is translucent, thixotropic, emollient, biocompatible, water soluble, easily removed, greaseless, nonstaining, and has a prolonged shelf life.

Technique for Making Emulgel

Step 1: Prepare the emulsion (W/O or O/W).

Step 2: Aqueous phase formulation

Step 3: Gel Base Preparation

Step 4: Homogenization with emulsification

Step 5: Emulsion incorporation into gel basis, either continuously stirred or homogenized.

2. METHOD OF PREPARATION

The emulgel formulation process consists of three steps:

Step 1: Emulsion formulation (o/w or w/o).

Step 2: Gel formulation. Q.s

Step 3: Emulsion is added to the gel base while being constantly stirred. q.s

Drug Phase: Transcutol P was used to dissolve fluconazole while stirring until a clear solution formed.

Oil Phase: After dissolving BHT in clove oil, Span 80 was added and well combined while stirring slowly. After adding the drug phase and stirring for ten minutes, the oil phase was combined.

Aqueous Phase: Tween 20 and filtered water were combined, then Carbopol 980 and Aloevera gel were distributed while being stirred continuously at a moderate pace. PH changed from 6 to 6.5

Emulsification: After the oil and aqueous phases were combined, the homogenization process lasted 30 minutes at a speed of 3000–4000 RPM. Sodium Benzoate Addition: Purified water was used to dissolve sodium benzoate. As the After homogenizing the resultant solution, the emulsified bulk was homogenized for 30 minutes at a speed of 3000–4000 RPM.

Mixing: The final mass was stirred for 30 minutes to obtain emulgel.

Aloe Vera Gel Extraction: • Fresh leaves of the plant were harvested in order to extract aloe vera gel. After then, it was rinsed with a light chlorine solution and distilled water after being cleaned for around 15 to 20 minutes under running tap water.Following a sectional removal of the thick epidermis, the leaves were cut, and a sterile knife was used to scrape away the colorless parenchymatous tissue (aloe gel). After being spoon-separated, the pulpy gel was diced and homogenized in a mixer grinder.

Flow chart of Emulgel Formulation

3. ADVANTAGES

- The emulgel manufacturing process consists of short, easy phases that make production more feasible on a commercial scale.
- The cost of production is reduced by the lack of expensive and difficult-to-find tools required for manufacture, as well as the materials themselves.
- It is a simple way to administer drugs to specific parts of the body and can be used for self-medication.
- It aids in the acceptability of in patients.
- A medication with a shorter half-life can have its effects prolonged with emulgel.
- Their lack of greasiness makes them acceptable for application on hair.

Evaluation of Emulgel

1. Physical Characteristics - Every formulation was assessed visually for homogeneity, color, and appearance. and regularity.

2. Study of Rheology- A digital viscometer made by Brookfield (Model 2000+, Cone and Plate) The viscosities of the formulations were measured using a 25 cm3 volume sample holder (Breakfield Engineering Laboratories Incorporated, United States of America). Using spindle number 62, were evaluated for one minute at 100 RPM using a hundred mg bulk sample. On the mentioned digital reader, the readings were visible.

3.Measurement of pH - Both the direct approach and the dilution method used for the measurement of formulation's pH. In the direct approach, a glass vial containing 10g of the samples was used; a pH electrode was immersed in a specimen. Once it steadied, the reading was recorded. 10% of the formulation made in purified water was dispensed in the dilution procedure. 10% dispersion was achieved by diluting 1g of the sample formulation to 10g with purified water and stirring frequently. The produced dispersion was applied to the pH electrode. The reading was noted as soon as it studied.

4.Spreading via Texture Analyzer- Under external load, a product's spreadability is its deformation. The degree to which Product evaluation is done using the words adhesive force (negative force) and firmness. In order to deform a cream, gel, or lotion to the desired depth, the greatest force needed is called firmness. The sample is less spreadable when the peak load (Firmness) value is larger. A more spreadable sample, is indicated by a lower peak load (Firmness). The sample adhesive force by measuring the maximum negative force; the higher negative force, the more "sticky" the sample.

5.The ability to extrude(extrubility)- With the aid of a laminated tube sealing machine, the emulgel formulation was loaded into laminated aluminum tubes and sealed. Each tube has the measured amount of mass filled in it.aluminum tube with laminations. The filled tube was clamped together after being pressed b/w two glass slides. After a predetermined amount of fixed weight (500g) was placed on glass slides, the tube's cap was opened. Weighing and collecting the emulgel formulation's quantity. Grades are assigned based on the percentage of the emulgel formulation that was extruded (+ average, ++ good, and +++ Fluconazole emulgel excellent). Effort was noted needed to extract 5g of samples from the laminated tube.

6..Determining the Drug Content- 1000 mg of the formulation were taken in a 100 ml vol.flask. Methanol was added to the volumetric flask and well mixed while being shaken frequently. Amount adjusted with methanol to 100 ml. To get a clear solution, this sample was filtered. From the solution above, 1 milliliter was pipetted out and put into a 10 milliliter volumetric flask. Using methanol, the volumetric flask's capacity was brought down to 10 ml. The Ultraviolet spectrophotometer was utilized to quantify the absorbance of the solution. By using the calibration curve and a reverse calculation of absorbance to the drug concentration, one can estimate the quantity of active that is present in 1000 mg of formulation.

9.Analysis of Stability - Completed emulgel formulations were placed in 15 g aluminum laminated tubes and charged for stability tests at room temperature (25°C +/- 2°C) for 60% of the formulation. RH± 5% RH, 30°C± 2°C/65% RH± 5% RH, and 40°C± 2°C/75% RH± 5% RH for an accelerated temperature storage condition for a duration of three months. The samples were examined for homogeneity, pH, spreadability (g/s), extrudability, viscosity (cPs), drug content (%), in vitro release (%), color and appearance, and tube uniformity.

Current and Future Prospects of Emulgel

Recent Uses

- Improved Drug Delivery: Emulgels enable the delivery of hydrophobic antifungal medications by embedding them in an emulsion within a gel structure. This approach boosts the drug's solubility and stability, thereby enhancing its effectiveness.
- Better Skin Absorption: The gel structure allows for a gradual release of the drug, ensuring extended contact with the skin and improving its absorption into deeper layers.
- Increased Patient Adherence: Emulgels provide a non-greasy, clear, and visually appealing formulation, which can enhance patient compliance with treatment plans.

Prospects for the Future

- Nanotechnology Integration: Drug delivery can be further improved by including nanocarriers such solid lipid nanoparticles (SLNs) and nanostructured lipid carriers (NLCs) into emulgels. More effective therapies may result from these nanocarriers' potential to increase the stability and solubility of antifungal medications.
- Use of Natural Polymers: In line with the growing trend towards natural and sustainable pharmaceutical goods, the use of natural polymers such as gelatin and chitosan in emulgel formulations might improve biocompatibility and minimize potential side effects.
- Targeted Drug Delivery: To reduce systemic exposure and possible adverse effects, future emulgel formulations may include targeting ligands to guide the antifungal drugs precisely to infected regions.

Marketed Formulations

Product Name	Active Ingredient(s)	Manufacturer	Therapeutic Use
Miconaz-H Emulgel	Miconazole nitrate, Hydrocortisone	Medical Union Pharmaceuticals	Antifungal, anti-inflammatory
Cloben Gel	Clotrimazole, Beclomethasone dipropionate, Neomycin	Indoco Remedies	Antifungal, corticosteroid, antibiotic

4. CONCLUSION

The goal of this work was to create an Emulgel formulation of anti-fungal drug for topical administration using ALOEVERA, a naturally occurring polymer with antifungal properties. The Emulgel formulations satisfy the requirements for evaluation parameters, including physical characteristics, spreadability, extrudability, rheological characteristics, measurement of bioadhesive strength, drug content, and drug release kinetics.

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