Research Article

Formulation and Development of Emulgel Infused with Calendula Oil for Treating the Exfoliative Cheilitis

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ABSTRACT

When gel and emulsion are mixed to make a dose, it is referred to as an Emulgel. Emulgel is one of the most exciting topical administration systems owing to its dual type of release control mechanism. The fundamental aim of this formulation is to transfer hydrophobic medication to the systemic circulation through the skin. Emulgel are essentially just water-based emulsions that have gone through a gelling process. The dermatological Emulgel is non-staining, water-soluble, emulsifying, thixotropic, simple to spread, easy to remove, thixotropic and environmentally friendly. Penetration enhancers may be used to increase the efficacy of a product. Consequently, it might be a more effective method of delivering topical medications than the current methods in use. It has become clear that Emulgel is an excellent delivery mechanism for hydrophobic compounds. Carbopol 934, a gelling chemical, was used in this study to create calendula oil Emulgel. Essential oils like clove and mentha were utilised to increase penetration. Afterward, the gel formulation was poured over the emulsion and allowed to harden. Rheological tests, spreading coefficient testing, and in vitro release investigations were conducted on Calendula oil topical Emulgel to determine their sun protection factor. Exfoliative cheilitis may be treated with calendula oil Emulgel applied to the skin.

Keywords: Exfoliative cheilitis, Emulgel, calendula oil, sun protective factor.

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INTRODUCTION

Exfoliative cheilitis is rare and has no known cause. Exfoliative cheilitis is a persistent superficial inflammatory condition characterized by keratin peeling. Exfoliative cheilitis patients may avoid social events, seek isolation, and suffer from depression due to their appearance[1]. Stress and psychological issues may cause the condition[2]. The literature documents the problems associated with exfoliative cheilitis therapy; however, the authors highlight these issues by emphasizing the limited outcomes obtained in their patients who were treated with corticosteroids, keratolytic drugs, antibiotics, and sunscreen. Due to long term hazards in steroids and persistent symptom, topical *Calendula officinalis* is selected for extensive use and low cost, including daily home administration. *Calendula officinalis* cured exfoliative cheilitis[3]. Topical administration avoids first-pass metabolism[4]. Cosmetics and pharmaceuticals increasingly employ semisolid transparent gels. Despite gels numerous benefits, administering hydrophobic medications is tricky. To counteract this, emulgel were formulated, and even hydrophobic medicine can benefit from them[5]. Emulgel are combine gels with emulsions. Adding a gelling chemical to the water phase produce an emulgel. They penetrate the skin well. Dermatology emulgel are Thixotropy, greaseless, easy to distribute, emollient, soluble in water, bio-friendly, and transparent[6,7]. Combining emulsions with gel makes them popular. Chemical augmentation, physical appearance, biochemistry, and supersaturation may promote medication absorption and penetration[8,9]. Drug incorporation, better loading capacity, stability, controlled release, no intense sonication, avoiding first pass metabolism, gastrointestinal incompatibility, more selective, enhanced patient compliance, simple and fast to give[10,11].

Components of Emulgel

A. Aqueous material:

It is required to make the emulsion's aqueous phase. Water and alcohol may be used as a aqueous material for the formulation of emulgel. [12].

B. Oils:

They produce the emulsion's oily phase. Mineral oil, alone or in combination with soft and hard paraffin, is used as a drug carrier and for occlusive and sensory qualities in topically given emulsions (e.g., Arachis, cottonseed, and maize oils)[13,14]. Polyethylene glycol 40 stearate, Span80, Tween80, stearic acid, and sodium stearate are examples[15].

C. Gelling agent:

Carbopol-934 and 940, HPMC 2910, Hydroxypropyl methylcellulose, and sodium thickened dosage forms are used as a gelling agent for the preparation of emulgel.[16,17]

D. Permeation Enhancers:

These compounds interact with the skin to make it more permeable. Clove Oil, Mentha Oil, Isopropyl Myristate, Linoleic acid are some examples. [18, 19].

MATERIALS AND METHODS

Material

Calendula oil purchased from Zenobia chemicals, carbapol 940, light liquid paraffin, mentha oil, clove oil, Triethanolamine all are purchased from Pallav chemicals pvt ltd, ethanol from CSS chemicals, methyl paraben and ethyl paraben from Spectrum chemicals.

Methods

Preformulation Studies

In terms of testing for identification, the preformulation studies are carried out which are physical appearance, odour, physical state, moisture content, refractive index, relative density, acid value, auto ignition, heavy metal, solubility.

Figure 1: Gel phase, Oil Phase & Aqueous Phase

Preparation of Emugel

Many different formulations were created by varying the amount of penetration enhancers used in the procedure. The technique of creating gel in a range of formulations was the key distinction in the operation. The processes for producing the emulsion were the same in each of the numerous formulations. The gel phase was manufactured by adding Carbopol934 to distilled water and then, by using a mechanical shaker at constant speed, the gel phase was produced. After that, triethanolamine was added to bring the pH to between 6 and 6.5. The water phase of the emulsion is created by dissolving Tween 20 in water. After that, methyl and propyl paraben are dissolved in propylene glycol and calendula oil is dissolved in ethanol. After that, these two-solutions are added to the aqueous phase. Span20 was dissolved in light liquid paraffin to create the oily phase of the emulsion. After that, clove oil and mentha oil are both added to the oily phase. After the oil and aqueous phases are independently heated to temperatures between 70 and 80 degrees Celsius, the oil phase is progressively introduced to the aqueous phase while it is constantly agitated until it reaches room temperature. And the emulsion is produced. The emulsion is added to gel phase in equal ratio to get Emulgel of calendula oil[21]

Figure 2: Gel Phase

Figure 3: Emulgel

Composition of different formulations is as in Table 1.

Table 1: Compositions of different formulations (in % w/w)

Ingredients	F1	F2	F3	F4
Calendula oil	10	10	10	10
Carbopol 934	1	1	1	1
Liquid paraffin	7.5	7.5	7.5	7.5
Tween20	0.5	0.5	0.5	0.5
Span20	1	1	1	1
Propylene glycol	5	5	5	5
Ethanol	2.5	2.5	2.5	2.5
Methyl paraben	0.03	0.03	0.03	0.03
Ethyl paraben	0.01	0.01	0.01	0.01
Clove oil	-	-	8	10
Mentha oil	4	6	-	-
Distilled water	Upto 100 ml	Upto 100 ml	Upto 100 ml	Upto 100 ml

Evaluation of Emulgel

1) Physical Examination:

Visual inspection was used to assess the Emulgel compositions, colour, appearance, and consistency after they had been created.

2) Washability test:

Approximately, 1 gm of the Emulgel is applied to the skin and the washabilty using water is checked manually by visual observation and the results are noted.

3) Extrudability study:

The Emulgel were poured into collapsible metal tubes and the material was extruded through tube and the results are noted.

4) Spreadability test:

A 0.5 gm Emulgel of each formula was placed between two different slides and left it for 5 minutes with no expectation of further spreadings. The sizes of spread circles, measured in centimetres, used to estimate spreadability. The results obtained are the sum of three different assessments.

5) pH determination:

Emulgel pH is determined using pH metre. 1gram of Emulgel was dissolves in 25 mili litre distilled water, and the electrode submerged to the gel formulation for 30 min to get a consistent reading. The pH of each formulation was measured twice[22].

6) Rheological investigation:

A Brookfield viscometer spindle L3 was used to test viscosity of generated batch (Visco Lead Adv, Brand Fungi lab). The system is linked to a thermostatically regulated flowing water bath at a constant temperature of 25 degrees Celsius. The viscosity of the formulation to be determined was measured in a thermostatic jacket with beakers. The measurements were taken while the emulgel's spindle was allowed to rotate [23].

7) Sun protection factor determination in vitro:

The UV spectrophotometric technique was used to analyse the SPF of an emulgel formulation containing calendula oil in vitro. Mansur et.al. (1986) devised the following equation as technique to calculate SPF in vitro using UV Spectrophotometry. It is fast, simple, and inexpensive[24].

$$SPF = CF \times \sum_{290}^{320} EE(\lambda) \times I(\lambda) \times Abs(\lambda)$$

The sunlight intensity spectrum is I and Erythermal effects spectrum is denoted as EE, sunscreen absorbance is denoted as Abs, and the correction factor is CF (=10). Sayre et. al. (1986) determined the value of the [EE x I], as indicated in Table 2[25]

Table 2: SPF calculation using the normalised product function

Wavelength [λ nm]	EE [I normalized]
290	0.150
295	0.817
300	0.02874
305	0.3278
310	0.1864
315	0.839
320	0.0180
Total	**1**

[EE - Erythermal Effect Spectrum; I - Solar Intensity Spectrum]

Fill a 100 mililitre volumetric flask halfway with ethanol and add 1 g of produced Emulgel Furthermore, it is ultrasonically treated for five minutes before filtering through a cotton filter, with the first 10 ml is removed out and volume was adjusted with ethanol after transferring a five mL aliquot to a twenty five (25) mL of volumetric flask[26].

The total absorbance spectrum of the solution-form materials was calculated at 5 nm intervals, with three measurements taken at each location before applying the Mansur equation

RESULTS AND DISCUSSION

Preformulation Studies

The recorded results of tests of identification of calendula oil are given in the Table No 3

Table 3: Test of Identification of calendula oil

Sr No	Test of Identification	Result
1	Appearance	Clear - yellow transparent liquid
2	Odour	Characteristic
3	Physical Test	Liquid
4	Moisture Content	0.01%
5	Refractive Index	1.459
6	Relative Density	0.886gm/ml
7	Acid Value	0.04%
8	Auto Ignition	No
9	Heavy Metal	Passed test
10	Solubility	Soluble in alcohol & most fixed oil

Physical examination

Calendula oil emulgel compositions were thick, creamy yellowish-white emulgels that were smooth and consistent in appearance.

Evaluation of Emulgel

The recorded results of washability, extrubility, spedability, pH, viscosity and % dug content are given in Table 4.

Table 4: Evaluation Test of Emulgel

Batch	Washability	Extrubility	Spredability [gcm /sec]	pH	Viscocity [cps]
F1	+ + +	+ + +	9.5	5.4	4066
F2	+ + +	+ + +	9.2	5.5	4294
F3	+ + +	+ +	8.4	5.7	4437
F4	+ + +	+ +	8.2	5.3	4304

SPF: *in-vitro* Sun Protectative Factor

Table 5: Summarises the results of the SPF of calendula oil.

Sr No	Test of Identification	Result
1	Appearance	Clear - yellow transparent liquid
2	Odour	Characteristic
3	Physical Test	Liquid
4	Moisture Content	0.01%
5	Refractive Index	1.459

The batch F2 is showing a good sun protection factor, which are 29.42.

CONCLUSION

The use of topical medicine administration will become more common in the years to come in order to boost patient adherence. This novel approach to the administration of drugs is becoming more common as a result of the emulgel's potential to improve spreadability, adhesion, viscosity, and extrusion. In addition to this, they will develop a mechanism for loading drugs that are hydrophobic onto water-soluble gel bases in order to ensure their stability over the long term. On calendula oil topical emulgels, physicochemical study was carried out, consisting of rheological studies and spreading coefficient tests, among other things. Applying the calendula oil emulgel directly to the affected area of the skin is the most effective method for treating exfoliative cheities as well as it also protects the skin from damage.

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