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Research Article

Preparation And Evaluation Of Herbal Emulgel

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ABSTRACT

The goal of this study is to create and assess an emulgel for the treatment of oral ulcers that contains clove oil, curcumin, and Argemone maxicana latex. Emulgels have emerged as a possibly useful delivery system for hydrophobic drugs. As a penetration booster, menthol was utilised, which also gives ulcers a cooling effect. Clove oil also serves this purpose. Herbal remedies with strong antiulcer properties include menthol, curcumin, and clove oil. While Argemone maxicana exhibits antimicrobial action, clove oil possesses anlgesic and antioxidant properties. While menthol offers cooling properties, curcumin, which is derived from curcuma longa, has anti-inflammatory and antibacterial properties. While menthol soothes mouth sores or ulcers. Diffusion tests, viscosity, spreadability, extrudability, and short-term stability were performed on five formulations. By the conclusion of the following analysis, the optimised formulation revealed that the medicines' respective releases—clove and curcumin—were 79 ± 3.2% and 72.07 ± 4.8%. The results of the investigation indicate that the emulgel has improved penetration properties and can be applied topically.

INTRODUCTION

One of the most prevalent disorders affecting the oral mucosa is oral ulceration. When the An ulcer is the result of damage to the epithelium and lamina propria [1]. Oral ulcers have been found to be a symptom of several systemic disorders, such as inflammatory bowel disease. The kind, location, length, and frequency of systemic sickness have all been linked to the development of oral ulcers [2]. The peroral route is thought to be the most practical method of medicine administration by both patients and medical professionals [3]. The oral cavity's environment, which has a temperature of 37°C and a pH range of 5.75 to 7.05, acts as a buffer. Water makes up 99.5% of the oral fluid, while organic compounds and inorganic elements make up 0.3% and 0.2% of the fluid, respectively

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[4, 5]. There A number of commercially available items, including as vitamin B12 tablets, mouthwash or spray containing benzydamine hydrochloride, steroid lozenges, and local anaesthetics, can be used to treat aphthous ulcers.[6] Commercially available dose forms have certain drawbacks, such as tablets that take longer to start working and mouthwashes that rinse quickly, which reduces the amount of medication that is effective [7]. Compared to emulgel, spray formulation waste occurs, and lozenges take longer to start working [8]. As their name implies, emulgels are a blend of emulsion and gel. Medicines are applied topically as water-in-oil and oil-in-water emulsions. They have a high degree of skin penetration.[9] The BCS classification systems state that emulgel is a better choice for class II medications that have high permeability and poor solubility[10]. In this investigation, emulgel was prepared using herbal medications including curcumin and clove oil. composition. By blocking capsaicin receptors, clove oil derived from Syzygium aromaticum plants has strong analgesic and pain-relieving properties. [11] While menthol comes from the plants mentha piperita, it functions as a cooling agent. Curcumin is derived from Curcuma longa and inhibits the formation of prostaglandin, acting as an antimicrobial and anti-inflammatory to the mouth sores or ulcers [12, 13]. The gel phase was prepared using carbopol 940, a crosslinked polyacrylic acid polymer. It is a very powerful rheology modifier that can result in clear gels with high viscosity or hydro-alcoholic gels and shimmering creams [14, 15]. The goal of this study was to create, refine, and evaluate an emulgel including essential oils and herbal components to treat mouth ulcers while lessening the side effects of commercially available formulations, such as mouthwashes, sprays, and lozenges Many of the enormous variety of flowers are regarded as weeds or wild plants that have no commercial value and are therefore often overlooked. One such weed that proliferates widely throughout practically all of India and Rajasthan is Argemone mexicana L. Argemone mexicana, commonly known by the popular names Mexican poppy,Mexican pricly poppy, blooming thistle, cardo, cardosanto is a species of poppy found in Mexico and now widely naturalized in many regions of the world.

Local name – Mexican poppy.

Botanical name – Argemone maxicana.

Family – Papaveraceae.

Kingdom - Plantae.

Genus – Argemone.

Species – A. Mexicana.

Supplies and techniques

Materials:

propylene glycol, methyl paraben, span 80, tween 80, liquid paraffin, and carbopol 940 propyl paraben and triethanolamine (obtained at RJS College of Pharmacy' Kokamthan).

Honey, distilled water, Argemone maxicana latex (from the stem of Argemone maxicana), clove oil (from Extraction) , and curcumin.

Research on preformulation

Identification by physical means

Clove oil, Argemone maxicana latex, and curcumin were found to be pure based on their physical state, colour, odour, melting point, boiling temperature, and acid value, among other organoleptic and physical characteristics.

Research on solubility

Through solubility experiments, the excipients to be included in the formulation were selected. Whether medications were soluble in liquid paraffin and propylene was evaluated qualitatively. distilled water, span 80, methanol, tween 80, and glycol.

Emulgel formulation

The gel's preparation

Using a mechanical stirrer set at 200 rpm, carbopol 940 was dissolved in purified water to create the gel phase of the emulgel formulation. After that, triethanolamine was used to modify the pH of the gel to a range of 6.0 to 6.8.

Emulsion preparation

The emulsion was prepared by taking the oil phase i.e. liquid paraffin as a solvent for clove oil (8% w/w) curcumin (0.2% w/w), menthol (5% w/w) a, span80 and Argemone maxicana latex in a beaker and in another beaker propylene glycol, methyl paraben and propyl paraben were taken. Then the required amount of water with honey was added in a beaker and tween80 was added in this water. Then both oil phase and aqueous phase were heated at 60- 70°C and mixed together with continuous stirring by mechanical stirrer at 200 rpm at room temperature, till the emulsion was formed.

Preparation of Emulgel

The emulgel was prepared by mixing the emulsion with gel in 1:1 ratio with continuous stirring by a mechanical stirrer at 200 rpm for 60 minutes. pH was adjusted by using triethanolamine.

Table 1. Different emulgel formulation compositions (%w/w)

Ingredients	E1	E2	E3	E4	E5
Liquid paraffin	2.5	2.5	2.5	2.5	2.5
Carbopol	0.25	0.5	0.75	1	1.5
Span80	3	3	3	3	3
Tween 80	1.5	1.5	1.5	1.5	1.5
Propylne glycol	5	5	5	5	5
Methyl glycol	0.3	0.3	0.3	0.3	0.3
Honey	10	10	10	10	10
Propyl paraben	0.2	0.2	0.2	0.2	0.2
Triethanolamine	QS	QS	QS	QS	QS
Purified water	100QS	100QS	100QS	100QS	100QS

Emulgel Formulation Optimization

The amount of the polymer (Carbopol 940) and the ideal processing parameters (stirring speed and stirring time) were determined based on viscosity homogeneity, phase separation, and spreadability , and the resulting emulgels were optimised

Table 2: Optimization of Polymer Concentration based on Viscocity and Spreadability.

Formulation	Carbopol 940 concentration (%w/w)	Viscosity (cps)	Spreadability (cm)
E1	0.25	16830 +30.55-	48.00+0.69-
E2	0.5	19470+20.16-	46.66+1.34-
E3	0.75	27690+25.0-	43.33+0.38 -
E4	1.00	29400+60.33-	40.00+0.33-
E5	1.5	32340+70.00-	36.00+0.19-

For additional research, the formulation with a concentration of 0.75 percent w/w of carbopol 940 was chosen or optimised, as it demonstrates optimal viscosity and good spreadability.

Process variable optimisation

200 rpm of stirring speed for 60 minutes was thought to be the ideal speed for emulgel formulation since formulation E5 displayed optimal viscosity, great homogenicity, and no phase separation.

Table 3. Optimization of stirring speed based on viscosity, phase separation and homogenicity

Formulation	Stirring speed(rpm) for 60 min	Viscosity(cps)	Phase separation	Homogeneity
E1	80	29540+20.66-	Not observed	Poor
E2	100	29020+15.00-	Not observed	Poor
E3	120	28350+25.55-	Observed	Good
E4	150	27700+30.16-	Not observed	Good
E5	200	27000+10.00_	Not observed	Excellent

Table no 4. Optimization of stirring time based on viscosity, phase separation and homogenicity

Formulation	Stirring time (min)at 200rpm	Viscosity (cps)	Phase separation	Homogeneity
E1	30	28270+20.00-	Not observed	Good
E2	60	27500+30.55-	Not observed	Excellent
E3	90	26850+30.00-	Observed	Good
E4	120	26200+25.16-	Observed	Poor
E5	150	25900+10.00-	Observed	Poor

The ideal stirring time for emulgel formulation was determined to be 60 minutes at 200 rpm, as formulation E2 demonstrated optimal viscosity, great homogenicity, and no phase separation.

Evaluation test for Emulgel.

Emulgel's physical characteristics

Using a digital pH meter, the colour, appearance, phase separation, homogeneity, and pH of each created mixture were examined visually.

Viscosity

The viscosity of produced formulations with spindle number 64s was measured at room temperature using a Brookefield digital viscometer running at 20 rpm for 10 minutes.

Spreadability

The spreadability of two glass slides was tested for emulgel compositions. The formulation whose spreadability was to be evaluated was spread across one slide, and the gel was sandwiched between the two by placing the other slide on top of it. The slides were pressed together to eliminate any potential air before the adhering gel was removed. A 20 g weight was fixed firmly to the top slide. It was recorded how long it took the upper slide to fully separate from the lower slide. where T is the time it takes to separate the slide, L is the length of the glass slide, and M is the weight attached to the upper slide.

Formula: S = M x L/T

Index of Swelling

1g of emulgel formulations were placed in a 50 ml beaker with 10 ml of distilled water, then covered with porous aluminium foil.

In order to drain and weigh the external liquid, the samples were taken out of the beaker at different intervals and left undisturbed in a dry environment. The following formula was used to calculate the swelling index:

Swelling Index (SW)% = [(Wt − Wo)/Wo] × 100

Where,

(SW) % = Equilibrium percent swelling,

Wt = Weight of swollen emulgel after time t,

Wo = Original weight of emulgel at zero time.

Extrudability

To determine the extrudability of emulgels, a closed, collapsable tube containing emulgel formulations was forcefully pushed at the crimped end. The mixtures were extruded till the pressure decreased. following the removal of the cap. The weight was computed using grammes. required 10 seconds to extrude a 0.5 cm ribbon of the formulation.

Centrifugation testing for phase separation

Using centrifuge tubes, 6g of the emulgel mixture was placed and spun for 10 minutes at 4000 RPM. After ten minutes, every formulation was checked for the occurrence of phase separation.

Drug content

After dissolving 1g of emulgel in 10 ml of methanol, the mixture was filtered using Whatman filter paper. Next, 1 ml of the filtrate was placed in a volumetric flask containing 10 ml and diluted using up to 10ml of methanol. Following that, the absorbance was measured using UV-Visible Spectroscopy at 277 nm,307 nm to determine the relative contents of curcumin , clove oil.

RESULT AND DISCUSSION

Studies on pre-formulation

Drug identification by physical means

The physio-chemical features of the medications, such as clove oil and curcumin, were the focus of identification research. The liquid form of clove oil was pale yellow, while the scent of basil oil was sweet and spicy. Curcumin was a golden powder with no smell. The melting and boiling points of curcumin powder (180- 182°C) and clove oil (148–250°C) were determined. Clove oil was found to have an acid value of 4.5.

Curcumin's Differential Scanning Calorimetry

Temperatures between 25 and 400 °C were used to measure curcumin's thermal behaviour. The DSC thermogram of curcumin indicated that its melting point was 170 °C. curcumin. As Figure 1 makes evident, curcumin was thermally stable at temperatures below 180 °C.

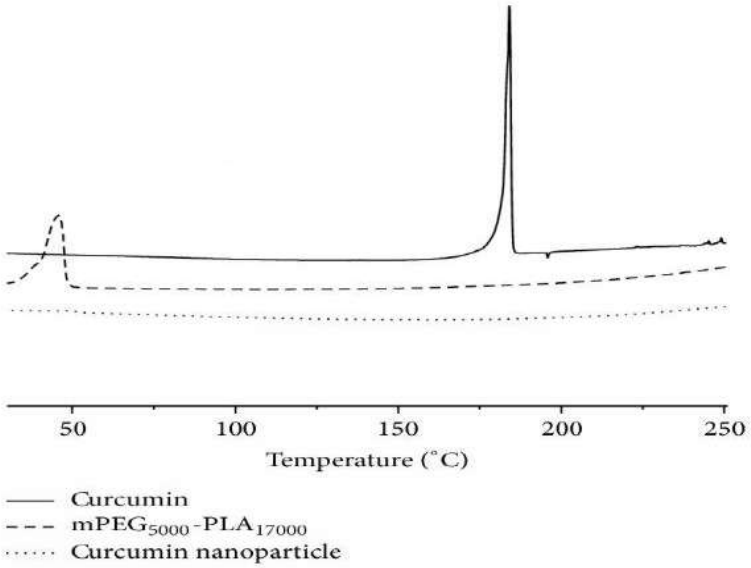

Figure1. Fig. Differential scanning calorimetry of curcumin

Studies on solubility

The oil phase for emulgel production consisted of span80 and liquid paraffin since the medicines were miscible and soluble in these solvents.

Table 5. shows the solubility and miscibility various medications, such as clove oil and curcumin.

Solvent	Curcumin	Clove oil
Liquid paraffin	Soluble	Miscible
Methanol	Soluble	Miscible
Tween 80	Insoluble	Miscible
Span 80	Soluble	Miscible
Propylene glycol	Insoluble	Immiscible
Distilled water	Insoluble	Immiscible

Emulgel evaluation

Emulgel's physical characteristics

The optimised mixtures produced a uniform, highly consistent yellowish emulgel. thick, creamy mixture that isn't gritty.

Acidity

Because the pH of the oral cavity ranges from 6.5 to 6.8, the pH values of the optimised formulation E2 were determined to be 6.7, which is considered adequate to prevent the risk of irritation when applied to the oral mucosa.

Viscosity

The viscosities of formulas E1 through E5 were the lowest and greatest, respectively. The emulgels containing 1.5% w/w Carbopol 940 had the highest viscosity, whilst those with 0.25% w/w Carbopol 940 had the lowest. The viscosity of formulations increases with increasing polymer concentration while all other variables are held constant. The optimised formulation E2's viscosity was found to be 27500 ± 55.67cps.

Spreadability.

Spreadability is the rate at which the emulgel will cover the damaged tissue with the least amount of shear. The optimised formulation E2 was found to have a spreadability of 43.33 ± 0.33 inches.

Index of Swelling

Of all the formulations, the E5 emulgel with 1.5% w/w Carbopol 940 exhibited the highest swelling index. The swelling index value may be impacted by the polymer's chain strength and degree of water absorption. The optimised formulation E2 was found to have a swelling index of 65 ± 0.5%.

Capability to Extrude

The optimised formulations E2 exhibited excellent extrudability, indicating that the emulgel has outstanding flowability.

Centrifugation testing for phase separation

The optimised formulation E2 showed no signs of phase separation, demonstrating the product's stability at high shear rates.

Emulgel's drug content

The optimised formulations E2's medication content was ascertained. Clove oil and curcumin were determined to have a percentage drug concentration of 97.07 ± 2.1%, 95.91 ± 1.9%, and 96.22 ± 2.0%, respectively. It indicates that the medication was dispersed evenly throughout the compounds.

CONCLUSION

The results of this study indicate that an emulgel containing eugenol, clove oil, Argemone maxicana latex, and curcumin can be applied topically for the local treatment of mouth sore. The topical emulgel also showed promising medication release and penetration properties, which is an added bonus. The presence of clove oil, Argemone maxicana latex, and curcumin in the gel dosage form facilitates easier application to the oral mucosa. The primary obstacle to the drug's gel formulation is its hydrophobic nature, which calls for additional research on the drug's therapeutic efficacy.

ADHERENCE TO MORAL PRINCIPLES

RECOGNITIONS.

New Delhi is home to the All India Council of Technical Education (AICTE).

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