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Original Article

Development and Characterization of Mupirocin Emulgel for the Treatment of Primary and Secondary Infections in Dry Skin Conditions

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ABSTRACT

Background: Dry skin conditions' primary and secondary infections can be treated by using mupirocin topically. By overcoming the disadvantages of ointments, creams, and lotions, the goal of the formulation of mupirocin emulgel was to improve the occlusive properties of gels and topical delivery of hydrophobic drugs with favorable properties for dry skin conditions, as well as to investigate the impact of the concentration of different gelling agents (carbopol 940, carbopol 934, xanthum gum) on viscosity and the drug release of prepared. **Materials and Methods:** Oil, an emulsifier, a co surfactant, and three different types of gelling agents, such as Carbopol 940, Carbopol 934, and xanthum gum, were used to make the emulgel. The physical characteristics, pH measurement, spreadability, drug content, rheological study, and *in vitro* drug release of each prepared emulgel were evaluated. Researchers also looked at skin sensitivity, *ex vivo* penetration and skin retention, antibacterial effectiveness, and stability of the mupirocin emulgel formulation. **Results:** Excellent homogeneity, an acceptable pH, spreadability, and medication consistency were all features of newly developed emugels. The mupirocin formulation made with carbopol 934 (0.8 percent w/w), which is F4 batch, demonstrated greatest drug release at 82.54±0.39 percent and optimal viscosity at 4117.0± 0.59 among all emulgel formulations. The improved formulation had good antibacterial activity, was stable, didn't irritate the skin, and exhibited improved retention in the skin. **Conclusion:** The results show that the designed mupirocin emulgel was successfully integrated into various gelling agents and that the drug release was inversely related to viscosity.

Keywords: Mupirocin, Topical delivery, Emulgel, Carbopol 940, Xanthum gum.

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INTRODUCTION

The general public frequently has dry skin. Erythema, edoema, exudation, and crusting are signs of an inflammatory reaction when dry skin is present together with chapping or underlying dermatoses. The most common skin conditions where dry skin may be a symptom include ichthyosis, psoriasis, and dermatitis/eczema. Primary and secondary infections can occur in these conditions. Therapeutically, secondary skin infections, such as dermatoses in atopic dermatitis, psoriasis, and infected wounds, are more problematic than original skin infections.[1,2]

One of the dermatitis kinds in which primary and secondary infections are likely to occur is atopic dermatitis (AD). Due to skin sores that were damaged by scratching and became vulnerable to bacterial infections, impetigo became prevalent in AD.[3] Pustules and crusts are the first symptoms of secondarily infected atopic dermatitis. because secondary symptoms of AD are associated with increased *stratum corneum Staphylococcus aureus* colonization, alteration of the epidermal barrier, and faulty innate immunological responses.[4] When a person has pustular psoriasis (PP), Staphylococcus aureus can cause secondary infections that can arise from pustules and, in rare cases, blood cultures.[5] Topical fusidic acid, topical mupirocin, oral penicillins that are resistant to penicillinase, including oxacillin, and oral cephalosporin are the antibiotics prescribed for secondary infections of AD.

It is recommended for the topical treatment of primary and secondary skin infections in primary pyodermas like impetigo, folliculitis, furunculosis, and ecthyma, as well as secondary infected dermatoses like eczema, psoriasis, and AD. Mupirocin is a novel topical antibacterial agent and metabolite of *Pseudomonas fluorescens* fermentation. In order to effectively block bacterial protein synthesis, mupirocin forms a link with the enzyme isoleucyl-t-RNA synthetase. This prevents isoleucine from being incorporated into protein chains. Mupirocin exhibits activity against gram-positive cocci *in vitro*, including *Streptococcus pyogenes*, *Staphylococcus aureus*, and other b-hemolytic streptococci. Due to its fast break down into an inactive metabolite in the plasma when administered systemically, mupirozin is only utilized as a topical agent.[6,7]

To directly treat cutaneous problems, a topical administration device applies a drug-containing formulation to any external body surface by injunction, spraying, dusting, or injection. Topical gel is suitable for the treatment of dermatological conditions, including in scalp conditions like psoriasis, because it is simple to apply and wash off, easy to apply on hair-bearing areas, and nongreasy. The hydrophobic drug delivery is more difficult and results in a nonocclusive film, which restricts their usefulness as an occlusive emolliating vehicle.[8]

In essence, emulgels, also known as emulsified gels, are biphasic systems that have an aqueous gel mixed with a lipid phase, closely resembling a cream. Greaseless, calming, protecting, thixotropic, readily spreadable, quickly removed, emollient, good adhesion and extrusion, water-soluble, longer shelf life, nonstaning, and compatible with a variety of excipients are just a few of its beneficial features for dermatological problems.[9] This

study's goals were to boost topical administration of hydrophobic drugs and investigate the impact of different gelling agents' concentrations (carbopol 940, carbopol 934, and xanthum gum) on the viscosity and drug release of the mupirocin emulgel.

MATERIALS AND METHODS

Mupirocin (Concord Biotech Limited, Ahmadabad, India) liquid paraffin and propylene glycol, carbomer, xanthum gum, methyl and ethyl paraben (Loba Chemie, Mumbai) 80 Span, 80 Tween (Mohini Organics Pvt. Ltd., Mumbai, India). Other compounds were all of the analytical variety.

Preparation of Mupirocin Emulgel

In order to generate the gel base for the mupirocin emulgel, a weighted amount of the gelling ingredient was mixed with previously heated filtered water at 75°C. A weighted quantity of the medication was thoroughly dissolved in propylene glycol before methyl and propyl parabens were added. Drug that was dissolved in propylene glycol was added to the gel basis, and the combination was continually swirled for 20 min at a speed of 800 rpm until it was homogeneous and free of lumps. In a separate beaker, weighted amounts of light liquid paraffin, span 80, and tween 80 were added to create an oily phase. Following the addition of the oily phase, the pH of the aqueous phase was altered using triethanolamine to create an emulgel.[10,11] Table 1 lists the formulations' optimized concentrations and composition following preliminary tests.

Characterization of Mupirocin Emulgel

Physical parameter

Emulgel samples were examined visually for homogeneity, phase separation, colour, and appearance.

pH

A digital pH meter was used to measure the pH, and it was calibrated with a standard buffer solution of 4, 7, and 9.

Photomicrography

The prepared emulgel was appropriately diluted before being put on a glass slide and examined under a 40x optical microscope.

Globule size

Malvern Zetasizer Instrument was used to measure the size of the globules in the emulgel formulations (DTS Ver.5.10).

Spreadability

Mupirocin emulgel weighing 2 g was placed between the two slides. To remove air between slides and create a consistent emulgel film, a 1000 g weight is placed on slides and left to rest there for five minutes. The upper slide was pulled 80 g while the lower slide was fixed. Slides had to be entirely separated within the specified number of seconds. Spreadability was determined using the formula S = M x L/ T. where S = Spreadability, M = Pan Weight, and L = Glass Slide Length, T = the number of seconds it took to entirely separate the slides fabricated equipment is displayed in Figure. 1.

Rheological Study

R/S-CPS rheometer (7030107) with measurement system C75-2 was used to measure the viscosities of the emulgel. The measurement was performed at room temperature.

Drug Content

PBS 7.4 solution was used to dissolve 0.5 g of emulgel. For 2 hr, this solution was shaken in a rotary shaker. After the solution had been filtered, a UV-Vis spectrophotometer (JASCO V-730) was used to measure the amount of medication present at 221 nm.

In-vitro Drug Release Study

Between both the donor and receptor compartments of the Franz diffusion cell's cellulose acetate membrane, emulgel 0.5 g, equivalent to 10 mg of medication, was applied. At 0, 1, 2, 3, 4, 5, 6, and 12 hr, 0.5 ml

Figure 1: Fabricated apparatus for spreadability.

Table 1: Optimized concentrations and composition of formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Mupirocin (g)	2	2	2	2	2	2	2	2	2
Carbopol 940 (g)	0.6	0.8	1	-	-	-	-	-	-
Carbopol 934 (g)	-	-	-	0.8	1	1.2	-	-	-
Xanthum Gum (g)	-	-	-	-	-	-	1	1.5	2
Light liquid paraffin (ml)	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25	6.25
Span 80 (ml)	1	1	1	1	1	1	1	1	1
Tween 80 (ml)	2	2	2	2	2	2	2	2	2
Propylene glycol (ml)	5	5	5	5	5	5	5	5	5
Methyl paraben (g)	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Propyl paraben (g)	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Water	q. s	q. s	q. s	q. s	q. s	q. s	q. s	q. s	q. s

Table 2: pH, Globule size, Spreadability, viscosity and drug content of formulated batches of emulgel.

Formulation code	pH	Globule size (µm)	Spreadability (g.cm/sec)	viscosity (cp)	Drug content (%)
F1	5.91 ± 0.21	4.499 ± 0.78	44.44 ± 0.1	4710.4 ± 0.63	96.45 ± 0.22
F2	5.89 ± 0.19	4.638 ± 0.69	26.66 ± 0.42	5963.2 ± 0.79	95.79 ± 0.36
F3	5.93 ± 0.11	4.972 ± 0.75	19.04 ± 0.31	6657.3 ± 0.84	95.12 ± 0.41
F4	5.9 ± 0.09	4.019 ± 0.70	50.14 ± 0.21	4117.0 ± 0.59	96.82 ± 0.10
F5	5.86 ± 0.10	4.172 ± 0.68	33.33 ± 0.28	4675.6 ± 0.98	96.08 ± 0.27
F6	5.81 ± 0.12	4.282 ± 0.61	25.30 ± 0.11	5062.7 ± 0.67	95.61 ± 0.31
F7	5.90 ± 0.39	1.710 ± 0.68	87.36 ± 0.23	682.0 ± 0.63	95.23 ± 0.49
F8	5.84 ± 0.44	1.915 ± 0.58	65.02 ± 0.19	961.0 ± 0.76	95.09 ± 0.49
F9	5.87 ± 0.37	2.302 ± 0.57	51.96 ± 0.18	1569.3 ± 0.82	95.85 ± 0.45

Represents mean ± S.D. (n = 3)

of solution from the receptor compartment was removed and replaced with an equivalent volume of fresh medium (PBS 7.4) for UV-visible spectrophotometer analysis at 221 nm.[12,13]

2.2.9 *Ex vivo* permeation and retention study

Franz diffusion cell with 1.44 cm^2 of diffusion area was used for optimized batch F4 on Wistar albino rat skin. The Appasaheb Birnale College of Pharmacy's CPCSEA Committee, which oversees institutional animal ethics, gave its approval for the use of animals (IAEC/ABCP/09/2018-19). Over the removed skin, 0.5 g of mupirozin emulgel was administered. The receptor media was PBS 7.4 (12 ml volume), and the temperature was maintained at 37°C. At predetermined intervals of 1, 2, 3, 4, 5, 6, and 12 hr, samples were removed, replaced with an equivalent volume of new medium, and then examined using a UV-visible spectrophotometer at 221 nm. At the conclusion of the trial, the amount of remaining medication on the skin was assessed by thoroughly washing it three to four times and digesting it with 10 ml of PBS 7.4 for an overnight period at 40°C. Skin was divided into small portions and placed in an ultrasonicator for 30 min in order to estimate the drug retention in the skin. After centrifugation, the material was filtered, the supernatant removed, and it was then subjected to UV-visible spectrophotometer analysis at 221 nm. Mupirocin eye ointment was used as a benchmark.[14,15]

Skin Irritation Study

Then, on three albino rats (200-250 gm) each group of three, a 0.5 g sample of each of the three standards control, test, and standard was applied to every site (two sites per rat, one intact, and the opposite abraded) in an area of skin that was around 1"*1" square. For three days, any erythema and oedema on the animal skin were observed visually.[16, °]

Antimicrobial Efficacy Assay

The bacterial strain used in this investigation, which comprises Staphylococcus aureus, was purchased from the National Chemical Laboratory in Maharashtra (NCIM No. 5345 and ATCC No. 6538). By employing the agar well plate diffusion technique, the antibacterial efficiency of the control, optimized emulgel, and standard were all evaluated. To gauge effectiveness, the diameter of the zone of inhibition was measured.[18,19]

Stability Study

The emulgel F4 formulation stability study was conducted out for an improved formulation.

Over the course of six months at 40°C, 20°C, 75 percent relative humidity, and 5 percent heat, it was examined for homogeneity, phase separation, viscosity, and drug concentration.[20]

RESULTS

Characterization of Mupirocin Emulgel Formulation

Physical parameter

Both the xanthum gum and the carbomer were white or off-white in colour. All batches showed no phase separation and excellent homogeneity.

pH

According to Table 2, the pH values of all created batches of mupirocin emulgel ranged from 5.810.12 to 5.930.11.

Photomicrography

Photomicroscopic analyses revealed the existence of globules, which suggested that an emulsion had formed in the gel basis.

Average Globule Size

The average globule size of the droplets in the mupirocin emulgel was found to be between 1.710 and 4.972 um in Table 2, indicating that the emulgel is a macro-emulsion gel.

Spreadability

According to Table 2, the spreadability among all formulated emulgel formulations ranged from 19.04±0.31 to 87.36±0.23g.cm/sec

Rheological Study

According to Table 2, the average viscosity of the emulgel formulation ranges from 682.0± 0.63 to 6657.3± 0.84cp. All emulgel batches with thixotropic behavior exhibit pseudoplastic flow.

Drug Content

The range of 96.09±0.49 to 96.82±0.10 percent for the percentage drug concentration of all mupirocin emulgel formulations is presented in Table 2.

In vitro Drug Release Study

Table 3 lists the percentage of medication diffused at 12 hr for several batches of emulgel.

Drug release from the aforementioned formulation was influenced by viscosity, gelling agent concentration, and viscosity. Drug release reduces with increasing viscosity as gelling agent concentration rises. Hence release from Carbopol 940, F1>F2>F3, Carbopol 934, F4>F5>F6, and from xanthum gum polymer, F7>F8>F9. Due to the greater percentage of polymer, drug release from batches F3, F6, and F9 was significantly lower than that of other batches. The maximum drug release and ideal viscosity were produced by batch F4 batch is therefore regarded as an optimum formulation.

Table 3: *In vitro* drug release study of emulgel formulations.

	% Cumulative drug release*								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	8.68±0.38	7.34±0.40	6.01±0.73	9.87±0.65	8.59±0.57	7.60±0.58	6.41±0.43	5.00±0.61	4.06±0.64
2	15.60±0.38	13.09±0.63	11.7±0.68	18.74±0.63	17.4±0.90	14.95±0.77	10.7±0.54	10.7±0.73	8.00±0.61
3	23.46±0.42	21.07±0.70	18.7±0.50	27.5±0.72	25.5±0.88	24.72±0.68	17.33±0.87	15.6±0.68	12.5±0.47
4	31.45±0.66	24.61±0.72	24.0±0.80	36.99±0.49	34.8±0.63	33.01±0.85	23.43±0.67	21.3±0.81	17.8±0.94
5	38.85±0.61	35.08±0.71	29.0±0.60	45.75±0.77	43.7±0.62	42.1±0.60	30.92±0.30	27.9±0.56	22.3±0.79
6	47.03±0.83	44.07±0.68	34.8±0.65	54.84±0.79	52.1±0.76	48.63±0.71	40.96±0.71	34.7±0.34	28.1±0.66
12	73.80±0.27	68.26±0.80	64.7±0.78	82.54±0.39	77.6±0.41	72.87±0.69	81.23±0.69	76.6±0.50	67.8±0.97

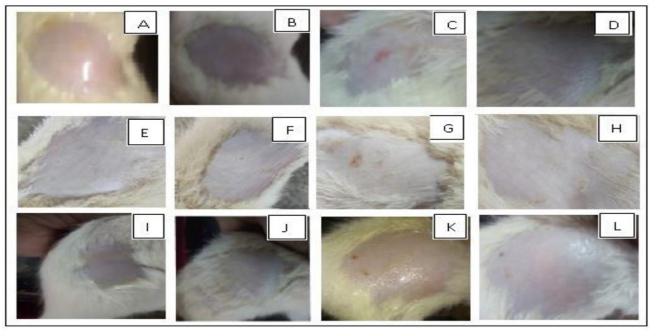

Figure 2: Skin irritation test of Control-intact skin A)Day 1 B) Day 3and Control- abraded skin C) Day 1 D)Day3, Skin irritation test of test sample-intact skin E)Day 1 F) Day 3 and Test abraded skin G)Day 1 H) Day 3, Skin irritation test of Std. intact skin i)Day 1 j) Day 3 and Std. abraded skin k)Day 1 l) Day 3

Figure 3: Petri plates showing zone of inhibition for antimicrobial efficacy.

In-vitro Skin Permeation and Retention Studies

The cumulative amount of medication that permeated for 12 hr from the emulgel was 16.032±0.263% and the amount that permeated for 12 hr from the commercial ointment was 12.16±0.41%.and retention of medication from emulgel 70.75±0.442% and from commercially available ointment 63.64±0.51%. In comparison to commercial ointments, the emulgel formulation improved the retention of mupirocin in the skin.

Skin Irritation Study

On undamaged rat skin and skin that has been damaged but is healing adequately, Figure 2 shows that the control, test, and standard did not cause any skin irritation.

Antimicrobial Efficacy Assay

The test results demonstrated that the basic emulgel base was inert to the staphylococcus strain microbiologically. Inhibition zones for normal optimized emulgels and standard are 0 mm, 20 mm, and 21 mm, respectively, in Figure 3.

Thus, it can be said that the zone of inhibition of the optimized emulgel is similar to the typical commercial formulation of mupirocin, and that inhibition of a specific antibacterial agent is better.

Stability Study

Throughout the course of the study, homogeneity, pH, viscosity, and medication content remained the same without phase separation or other changes.

DISCUSSION

Both carbomer and xanthum gum exhibit excellent water retention and are quite effective. They exhibit the better performance in terms of spreading behavior and gel strength. As according preliminary trials, the gel base was highly viscous when carbopol 940 and carbopol 934 were utilized at concentrations greater than 1 percent and 1.2 percent, respectively, and it was very poor at concentrations lower than 0.6 percent and 0.8 percent.

Similar to how xanthum gum behaves when used below 1%, it becomes very little viscous above 2%, and the appearance and feel of the thicker product on the skin may give off an unpleasant sticky impression. The concentration of oil, emulsifiers, and co - surfactants were chosen on the basis on phase separation and stability. Because emulsifiers', carbomer, and xanthum gum inhibited phase separation in all batches of emulgel, it was obvious that these substances also served as stabilizers. The pH was within the range for skin, thus no skin responses will result. The spreadability of a topical product affects its therapeutic efficacy because it controls how well the dosage is applied to the target location, how easily it can be applied to a surface, how easily it can be removed from the packaging, and—most importantly how well it will appeal to consumers.[22] All prepared emulgels spread effortlessly without the need for rubbing. By combining an increase in gelling agent concentration with an increase in viscosity, it was discovered that mupirocin emulgels were becoming less spreadable. Emulgel viscosity rises as gelling agent concentration rises, as in the cases of F1 <F2 <F3 (Carbopol 940), F4 <F5 < F6 (Carbopol 934), and F7 <F8 <F9 (Xanthum gum), where the greatest gelling agent concentration was found to have the maximum viscosity. Due to stronger connections between polymer molecules, which result in the creation of a hard, dense, and compact mass, viscosity increases with the concentration of the gelling agent. This hardness is caused by the fact that there is less liquid in gels with high gelling agent concentrations than in gels with low gelling agent concentrations, or, to put it another way, a greater gelling agent concentration requires more shear stress.[23] The drug content test results show that the drug is

evenly distributed throughout the mupirocin emulgels' formulation. To determine the release of the medication from the formulation matrix and demonstrate that this process has no impact on the product's efficacy, an *in vitro* release research was carried out. Drug release reduces with increasing viscosity as gelling agent concentration rises. Therefore, carbopol 940 was released first, followed by carbopol 934, F1>F2>F3, then xanthum gum polymer, F7>F8>F9. Due to the greater proportion of polymer, drug release from formulation batches F3, F6, and F9 was significantly lower than in other batches. Release rate was delayed as gelling agent concentration rose.

Given that the F4 batch (0.8 percent Carbopol 934) has the maximum drug release and the ideal viscosity, it can be said to have an optimized formulation. In comparison to commercial ointments, the emulgel formulation improved the retention of mupirocin in the skin. Drug concentrations in the skin during skin permeation experiments using Franz cells are indicators of topical distribution, whereas drug concentrations in the receptor phase are indicators of transdermal delivery.[24] Due to greater drug retention in the skin and minimal drug quantification in the receptor solution. Thus, it was determined that mupirocin's created emulgel was more effective when applied topically. From research on skin irritation, it was discovered that mupirocin emulgel without medication (control) and test (optimal emulgel) were non-irritant and that it recovered rubbed skin faster than usual due to excipient, confirming the safety of the material concentration used to prepare the emulgel. The antibacterial effectiveness of the optimized emulgel is good. According to the stability research, under expedited and regulated settings, the topical mupirocin emulgel was adequate.

It can be said that the mupirocin emulgel produced for topical application is successful.

CONCLUSION

By addressing the shortcomings of conventional ointments, creams, and lotions, mupirocin was successfully integrated into topical emulgel formulation for the targeted drug delivery system of primary and secondary infection in dry skin conditions. The effect of concentration of different gelling agents on viscosity as well as the drug release of prepared mupirocin emulgel was examined using a variety of gelling agents (carbopol 940, carbopol 934, and xanthum gum), which shows that as the concentration of the gelling agent increases, the release of drug decreases with increasing viscosity. The mupirocin emulgel (F4) made with carbopol 934 (0.8 percent w/w) had the maximum drug release (82.54±0.39%) and the optimal viscosity (4117.0±0.59%) among all emulgel formulations. The improved batch exhibits favorable physical characteristics, spreadability, pH, optimal viscosity with thixotropy, drug content, and drug release. According to the ex vivo permeability and retention investigation, the emulgel formulation of mupirocin had minimal systemic absorption and the required drug retention in skin. The improved batch also demonstrated good antibacterial activity and stability with no skin irritation.

CONFLICT OF INTEREST

The author declare no conflict of interest.

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