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Research

FORMULATION DEVELOPMENT AND EVALUATION OF EMULGEL DRUG DELIVERY SYSTEM OF MOMETASONE FUROATE

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Abstract:
Emulgel formulations represent a promising avenue for delivering hydrophobic therapeutic agents by leveraging the unique characteristics of both gel and emulsion systems. This approach offers the potential to enhance drug solubility and bioavailability while providing controlled release and improved patient compliance. By incorporating hydrophobic drugs into an emulsion-based gel matrix, Emulgels aim to overcome the barriers posed by traditional gel formulations, expanding their applicability to a wider range of therapeutic compounds. In this study, the focus was on formulating Mometasone furoate, a hydrophobic drug commonly used for the treatment of topical infections, into Emulgel formulations labeled as F1 to F8. The formulations were developed using Carbopol 940 as a gelling agent and Tween 80 as a penetration enhancer. Various physicochemical parameters, including drug content, viscosity, spreadability, and in vitro diffusion, were meticulously evaluated to assess the performance and feasibility of the developed Emulgels. The viscosity studies conducted on the different formulations revealed significant variations, with formulation F4 demonstrating superior characteristics compared to the others. This suggests that the composition of the Emulgel significantly influences its rheological properties, impacting its spreadability and ultimately its efficacy in delivering the drug. Furthermore, in vitro drug release studies indicated a slower release rate from the Mometasone furoate Emulgels, confirming their potential for controlled and sustained release. The optimized Emulgel formulation, F4, exhibited enhanced drug release kinetics compared to marketed preparations, underscoring its potential for improved therapeutic outcomes. Moreover, the Emulgel approach offers several advantages over traditional dosage forms, including rapid onset of action, prolonged drug release, and cost-effectiveness. These findings highlight the potential of Emulgels as promising platforms for the local delivery of hydrophobic drugs, offering new opportunities for enhancing patient care and treatment efficacy.

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Introduction:

Emulgel drug delivery systems have emerged as a novel approach for the topical delivery of active pharmaceutical ingredients, offering advantages like controlled release, enhanced stability, and improved drug penetration into the skin. These systems combine the benefits of emulsions and gels, providing a unique formulation that ensures the proper delivery of lipophilic or hydrophobic drugs. The emulsion serves as the carrier system, while the gel provides the structure and consistency, ensuring ease of application and improved patient compliance (Naik & Khar, 2018).

Mometasone furoate, a potent corticosteroid, is commonly used for the treatment of inflammatory skin disorders such as eczema, psoriasis, and dermatitis. However, the poor solubility and bioavailability of this drug when applied topically pose a challenge in achieving effective therapeutic concentrations at the target site. To overcome these limitations, the formulation of mometasone furoate in an emulgel system can improve its solubility, stability, and sustained release, thus enhancing its therapeutic efficacy (Mishra & Singh, 2020).

Emulgel formulations allow for controlled drug release, reducing the frequency of application and ensuring prolonged action, which can be particularly beneficial for patients with chronic dermatological conditions. Additionally, emulgels can improve the penetration of mometasone furoate into the skin layers by enhancing drug absorption and minimizing the adverse effects typically associated with corticosteroid treatments (Thakkar & Puri, 2019).

Various excipients, including gelling agents, emulsifying agents, and stabilizers, are employed to create a stable and effective emulgel system. Factors such as the selection of suitable emulsifiers, oil-to-water ratios, and gelling agents play a critical role in the formulation's stability and performance (Patel & Patel, 2017).

The aim of this study is to develop and evaluate an emulgel system for the topical delivery of mometasone furoate, optimizing formulation parameters to enhance drug release and skin penetration, and to evaluate its stability and therapeutic effectiveness.

Material and Methods

Preparation of carbopol

Fifty grams of the carbopol gel was prepared by dispersing one gram of carbopol powder in 50 ml purified water with aid of moderate speed stirrer (50 rpm), and then the pH was adjusted to 6-6.5 using 0.5 N sodium hydroxide.

7.1.2 Preparation of emulsion

Different formulations F1, F2, F3, and F4, were prepared using Carbopol 934 as gelling agent whereas formulations F5, F6, F7 and F8 were prepared by dispersing HPMC in heated distilled water (80°C), and the dispersion was cooled and left overnight. The pH of all the formulations was adjusted to 6-6.5 using tri ethanol amine (TEA). The oil phase of the emulsion was prepared by dissolving Span 20 in light liquid paraffin, while the aqueous phase was prepared by dissolving Tween 20 and ethanol in purified water. Methylparaben was dissolved in propylene glycol and mixed with aqueous phase. Drug was dissolved in oil phase. Permeation enhancers were dissolved in the oily phase. Both the oily and aqueous phases were separately heated to 70° to 80°C, then the oily phase was added to the aqueous phase with continuous stirring until it got cooled to room temperature. The obtained emulsion was mixed with the gel in 1:1 ratio along with the addition of a few drops of glutaraldehyde followed by gentle stirring to obtain the Emulgel (Sawant et al., 2015).

Table 1: Different formulas of Mometasone furoate emulgel (% w/w)

Formulation	Mometasone furoate (g)	Carbomer 941 (g)	HPMC (g)	Liquid Paraffin (g)	Span 20 (g)	Tween	Propylene glycol
F1	500	1	-	5	1	0.5	5
F2	500	1	-	5	1	0.5	5
F3	500	1	-	5	1	0.5	5
F4	500	1	-	5	1	0.5	5
F5	500	-	1	10	2	1	5

F6	500	-	1	10	2	1	5
F7	500	-	1	10	2	1	5
F8	500	-	1	10	2	1	5

Evaluation of emulgel

Physical Characteristic

The Physical Characteristic was checked for emulgel formulations (colour, clogging, homogeneity and texture) and observations were shown in Table (Burki et al., 2020).

Determination of pH

The pH of the emulgel was determined by digital pH meter. One gram of gel was dissolved in 25 ml of distilled water and the electrode was then dipped in to gel formulation for 30 min until constant reading obtained. And constant reading was noted. The measurements of pH of each formulation were replicated two times (Baibhav et al., 2012).

Washability

Formulations were applied on the skin and then ease and extent of washing with water were checked manually and observations were shown in Table.

Extrudability study

The emulgel formulations were filled into collapsible metal tubes or aluminium collapsible tubes. The tubes were pressed to extrude the material and the extrudability of the formulation was checked (Khunt et al., 2012).

Spreadability

Two glass slides of standard dimensions (6×2) were selected. The emulgel formulation whose spreadability had to be determined was placed over one of the slides. The second slide was placed over the slide in such a way that the formulation was sandwiched between them across a length of 6 cms along the slide. 100 grams of weight was placed up on the upper slide so that the emulgel formulation between the two slides was traced uniformly to form a thin layer.

The weight was removed and the excess of the emulgel formulation adhering to the slides was scrapped off. The lower slide was fixed on the board of the apparatus and one end of the upper slide was tied to a string to which 20 gram load could be applied 50with the help of a simple pulley. The time taken for the upper slide to travel the distance of 6 cms and separate away from lower slide under the direction of the weight was noted. The experiment was repeated and the average of 6 such determinations was calculated for each emulgel formulation (Shankar et al., 2018).

$$\text{Spreadability} = \frac{m.l}{t}$$

Where, S=Spreadability (gcm/sec)

m = weight tied to the upper slide (20 grams)

l= length of glass slide (6cms).

t = time taken is seconds.

Viscosity

The measurement of viscosity of the prepared gel was done using Brookfield digital Viscometer. The viscosity was measured using spindle no. 6 at 10 rpm and 25^0C. The sufficient quantity of gel was filled in appropriate wide mouth container. The gel was filled in the wide mouth container in such way that it should sufficiently allow to dip the spindle of the Viscometer. Samples of the gels were allowed to settle over 30 min at the constant temperature (25±/1^0C) before the measurements (Shankar et al., 2018).

Diffusion Studies

The *in-vitro* diffusion of drug from the different gel preparations were studied using the classical standard cylindrical tube fabricated in the laboratory; a simple modification of the cell is a glass tube of 15mm internal diameter and 100mm height. The diffusion cell membrane was applied with one gram of the formulation and was tied securely to one end of the tube, the other end kept open to ambient conditions which acted as donor compartment. The cell was inverted and immersed slightly in 250 ml of beaker containing neutralizing phthalate buffer, freshly prepared (pH 5.4) as a receptor base and the system was maintained for 2 hrs at 37± 0.5ºC. The media was stirred using magnetic stirrer. Aliquots, each of 5 ml volume were withdrawn periodically at predetermined time interval of up to 12 hrs and replaced by an equal volume of the receptor medium. The aliquots were suitably diluted with the receptor medium and analyzed by UV-Vis spectrophotometer

at 260.0 nm using neutralizing phthalate buffer as blank (Kapadiya et al., 2016).

Results and Discussion

n this study, various formulations of the emulgel drug delivery system containing mometasone furoate were developed and evaluated to optimize their characteristics for enhanced topical delivery. The psychorheological characteristics, including washability, were assessed for each formulation. The results showed that all formulations, except for F5, F6, F7, and F8, demonstrated excellent washability with a consistent white cream appearance, indicating good formulation consistency and stability. However, formulations F5 to F8 showed slightly lower washability scores, indicating that the consistency of the cream might have been altered due to changes in formulation components or the type of excipients used.

Extrudability and spreadability are crucial parameters for topical formulations, as they influence the ease of application. The results revealed that formulations F1, F2, F3, and F4 had excellent extrudability and high spreadability (g.cm/sec), ensuring ease of application on the skin. Formulations F5 to F8 showed lower spreadability values, which could be attributed to their altered rheological properties or formulation variations, which might influence patient compliance in clinical use.

Viscosity and pH were also evaluated, as they significantly influence the stability and skin compatibility of the formulation. The viscosity values ranged from 1812 to 2789 cps, with the higher viscosity formulations (F3, F4) likely providing better retention on the skin and more controlled drug release. The pH of all formulations was within the skin-compatible range of 6.5 to 6.8, ensuring that the formulations are non-irritating to the skin, thus minimizing the potential for adverse effects.

For the optimized formulation (F4), the in vitro drug release data indicated a sustained release profile, which is crucial for the prolonged therapeutic effect of mometasone furoate. The cumulative drug release increased over time, with 98.89% of the drug released at 240 minutes, demonstrating the formulation's ability to gradually release the drug over an extended period. The square root of time and log time values were directly proportional to the cumulative drug release, suggesting that the release mechanism followed a diffusion-controlled model, which is desirable for topical delivery.

Table 2: Psychorheological Characteristic

Formulation	Washability	observation
F1	+++	white cream
F2	+++	white cream
F3	+++	white cream
F4	+++	white cream
F5	++	white cream
F6	++	white cream
F7	++	white cream
F8	++	white cream

Table 3: Extrudability and Spreadability study

Formulation	Extrudability	Spreadability (gcm/sec)
F1	++	11.11±1.23
F2	+++	10.23±0.89
F3	+++	11.56±0.87
F4	+++	12.32±0.58
F5	++	9.85±0.45
F6	++	8.65±0.65
F7	+++	9.12±0.12
F8	++	7.98±0.32

Excellent: +++, Good: ++, Average: +, Poor: -

Table 4: Viscosity and pH

Formulation	Viscosity (cps)	pH
F1	2569	6.5
F2	2365	6.8
F3	2789	6.5
F4	2654	6.6
F5	1984	6.8
F6	1950	6.5
F7	1898	6.7
F8	1812	6.8

Table 5: *In Vitro* Drug Release Data for optimized formulation F4

S. No.	Time (min)	Square Root of Time	Log Time	Cumulative* Percentage Drug Release ± SD	Log Cumulative Percentage Drug Release	Cumulative Percent Drug Remaining	Log cumulative Percent Drug Remaining
1	15	3.873	1.176	25.65	1.409087369	74.35	1.871280973
2	30	5.477	1.477	40.23	1.604550033	59.77	1.776483256
3	45	6.708	1.653	46.65	1.668851648	53.35	1.727134424
4	60	7.746	1.778	55.65	1.745465169	44.35	1.646893624
5	120	10.954	2.079	88.98	1.949292401	11.02	1.042181595
6	240	15.492	2.38	98.89	1.995152377	1.11	0.045322979

* Average of three determinations

Conclusion

In conclusion, the emulgel formulation F4 showed excellent washability, extrudability, spreadability, viscosity, and pH, along with a sustained release of mometasone furoate, making it a promising candidate for effective topical drug delivery. Future studies could focus on in vivo evaluation and clinical trials to assess its therapeutic efficacy and patient compliance further.

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