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FORMULATION AND EVALUATION OF TOPICAL MICROEMULGEL CONTAINING COLCHICINE

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ABSTRACT

Purpose: This research aimed to develop a topical microemulgel that reduces gout activity by incorporating colchicine. Microemulgels, with their dual mechanism that combines the advantages of gel and emulsion formulations, represent a new approach in drug delivery systems. A topical microemulgel containing colchicine was developed and evaluated in this study with the goal of enhancing delivery for the treatment of gout.

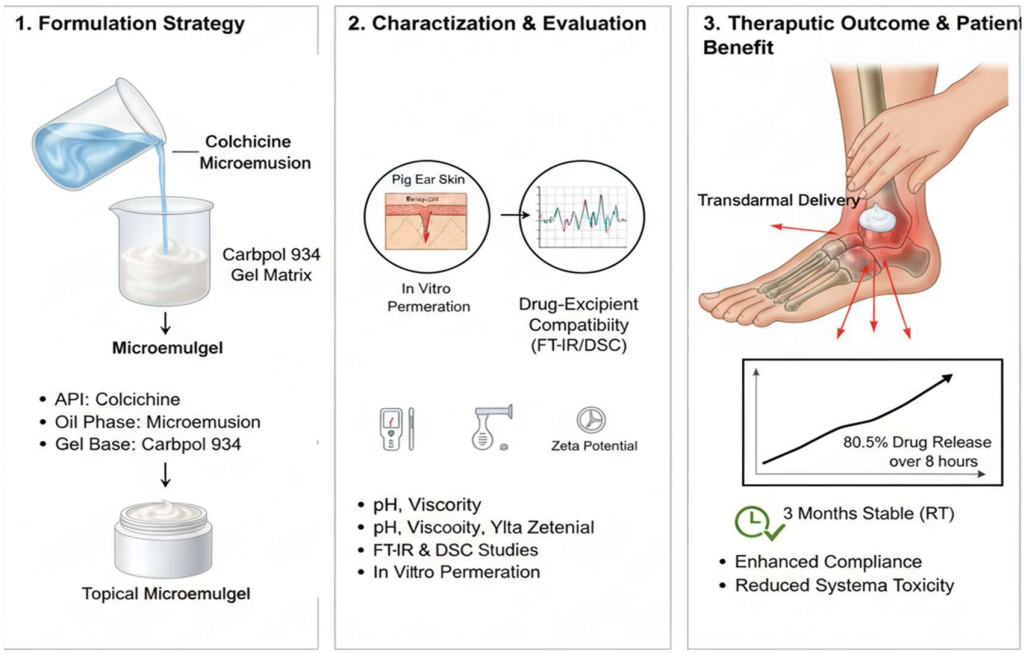
Methods: A variety of polymers, including Carbopol 934, were used to create the microemulgel by mixing gel ingredients with microemulsion. The pH, spreadability, viscosity, drug content, zeta potential, and *in vitro* drug release of the prepared microemulgel were assessed. FT-IR and DSC studies were used to evaluate the drug's compatibility with the excipients. For three months, stability tests were carried out at room temperature. Pig ear skin was used for *in vitro* permeation studies.

Results: Compatibility tests showed that the polymers and colchicine were not incompatible. Over eight hours, the *in vitro* drug release varied between 54.73% and 80.5%; the optimal formulation (F8) achieved an 80.5% release. Drug release from all formulations (F1–F9) was proven to have a zero-order release mechanism by kinetic analysis.

Conclusion: The microemulgel containing colchicine showed good drug release, stability, and excipient compatibility, suggesting that it could be a useful topical formulation for gout treatment. Through better transdermal distribution of colchicine, the optimized formulation can improve therapeutic efficacy and patient compliance.

Keywords: Microemulgel, Colchicine, Carbopol 934, Anti-gout activity, Stability studies, Kinetic analysis

Graphical abstract



INTRODUCTION

Colchicine is a medication most commonly used to treat gout, and it is used as an alternative for those unable to tolerate NSAIDs in gout **[1]**. The microemulgel containing Colchicine represents a promising approach for enhancing anti-gout activity and thus providing effective drug delivery through the skin. The dual mechanism of microemulgel, which combines gel and emulsion components, has made it one of the most promising technologies in the field of new drug delivery systems. Oil in microemulgel permits deeper penetration of the API into the skin, whereas the production of tiny droplets in microemulsions offers a large interfacial area for drug absorption and aids in maintaining the drug's solubilized condition **[2]**. With topical formulations, the medication can reach deeper layers of the skin or mucous membranes, producing targeted effects where it is applied. Although gels offer many advantages,

hydrophobic drugs are not always best delivered by them. A microemulsion-based technique, however, can overcome these limitations and enable hydrophobic drugs to benefit from gels' unique properties **[3]**. Topical medication administration, which provides local benefits without the discomfort, gastrointestinal degradation, and first-pass metabolism associated with oral therapy, is used to treat topical infections. Microemulgels created by turning a liquid microemulsion into a semisolid gel function as dual drug delivery systems and are thought to be very promising in the field of innovative drug delivery technologies due to their dual mechanism, including both emulsion and gel **[4]**. Formulations that combine the utilization of gel and microemulsion constituents in combination dosage forms are referred to as microemulgels. These formulations combine the advantages of emulgels and microemulsions. They can contain hydrophilic or hydrophobic drugs, providing a significant surface area for drug absorption **[5]**.

MATERIALS AND METHODS

Materials

Colchicine was obtained as a gift sample from Vital Laboratories Mumbai. Oleic acid and propylene glycol, HPMC, triethanolamine, methyl paraben, and propyl paraben were obtained from Karnataka Fine Chem, Bangalore. Tween 20 was supplied by Labochem Karnataka. Carbopol 934 was purchased by Yarrow Chemicals Mumbai. Potassium dihydrogen phosphate, disodium hydrogen phosphate, and sodium chloride were purchased from Karnataka Fine Chemicals for the preparation of phosphate buffer (pH 7.4).

Preparation of Topical Microemulgel Containing Colchicine

Three phases are typically involved in the formulation of microemulgel:

- Microemulsion phase preparation;
- Gel phase preparation; and
- Incorporate into the two phases for microemulgel formulation.

Preparation of o/w microemulsion: Microemulsion formulation will be prepared by simple mixing of oleic acid with the Tween 20 and propylene glycol mixture with the aid of magnetic stirring. Then, the required amount of aqueous phase will be added while mixing. Excess colchicine will be added to prepare a saturated colchicine solution, with excess crystals being included to maintain saturation.

Preparation of microemulgel: Carbopol 934 and HPMC will be suspended in water and hydrated overnight. Prepared microemulsion will be incorporated in gel phase with the ratio of 1:2 by continuous mechanical stirring **[6, 7]**.

Table 1: Formulation of topical microemulgel containing Colchicine

S. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Colchicine (g)	1	1	1	1	1	1	1	1	1
2	Tween-20 (ml)	15	15	15	15	15	15	15	15	15
3	Propylene glycol (ml)	30	30	30	30	30	30	30	30	30
4	Oleic acid (ml)	17.5	17.5	17.5	17.5	17.5	17.5	17.5	17.5	17.5
5	Carbopol 934 (g)	5	7.5	10	5	7.5	10	5	7.5	10
6	H P M C (g)	1.5	1.5	1.5	2	2	2	2.5	2.5	2.5
7	Triethanolamine (drops)	4	4	4	4	4	4	4	4	4
8	Methyl paraben (g)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
9	Propyl paraben (g)	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
10	Distilled Water (ml)	Upto 500	Upto 500	Upto 500	Upto 500	Upto 500	Upto 500	Upto 500	Upto 500	Upto 500

EVALUATION OF TOPICAL MICROEMULGEL CONTAINING COLCHICINE

The physical properties, such as color, phase separation, consistency, and homogeneity of the prepared microemulgel were all examined **[8- 10]**. The pH of the formulation was measured using a digital pH meter **[11-13]**. The prepared microemulgel's viscosity was tested using a Brookfield viscometer (Brookfield LV, Spindle no. 64) **[14-16]**.

Determination of drug content: After dispersing 1g of microemulgel sample in 100 mL of phosphate buffer (pH 7.4), the mixture was sonicated for two hours while being magnetic stirrer. The mixture was sonicated, then filtered through a 0.45µm Millipore filter before being subjected to a UV spectrophotometric analysis **[17, 18]**.

Spreadability: Spreadability of prepared microemulgel was assessed using a modified apparatus based on the Multimer et al., 1956 method, which is used to inspect the uniformity and application of transdermal formulations. The Spreadability (S) was calculated by using the formula:

$$S = M.L/T$$

Where, S = Spreadability, M = Weight tied to upper slide, L = Length of glass slides, T = Time taken to separate the slides completely from each other **[19, 20]**.

The zeta potential of a microemulsion can be determined using a Zeta sizer **[21-23]**.

***In-Vitro* diffusion studies:** The *in-vitro* drug release investigations employ a Franz diffusion cell **[24, 25]**, which has a cell volume of 15.5 mL and an effective diffusion area of 3.14 cm2. In this investigation, 200mg of microemulgel was evenly applied to the ear skin membrane of a pig. The membrane was clamped tightly between the donor and receptor chambers of the diffusion cell. A newly prepared 7.4 pH phosphate buffer solution was added to the receptor chamber in order to stabilize the medication. At the appropriate times, 1.0 ml of the samples is removed from the receptor chamber. These samples are appropriately diluted, and the drug release is measured

using a UV-Visible spectrophotometer **[26-28]**.

***In-vitro* drug release kinetics:** Hixson-Crowell Kinetics, Higuchi's model, Korsmeyer-Peppas model, zero order kinetics, and first order kinetics were used to fit the cumulative amount of Colchicine released at different time intervals from the different microsponge formulations in order to define the drug release mechanism **[29, 30]**. Zero-order release describes a system in which the rate of release is independent of the concentration. First order release explains how a drug releases from a system where the rate of release varies with concentration **[31-33]**. Higuchi derived an equation describing the release of a medication from an insoluble matrix by taking the square root of a time-dependent process based on Fickian diffusion [34]. Korsmeyer *et al*. (1983) constructed a simple formula that demonstrates the exponential relationship between the fractional drug release and the release time **[35, 36]**.

Stability studies: Stability tests were performed to confirm whether the formulation changed significantly during storage. For three months, the complete formulation was kept at room temperature **[37-48]**. The stability of the combination was confirmed using in vitro diffusion experiments, drug content, pH, and spreadability measurements of the formulation.

RESULTS

FT-IR Spectroscopy: Colchicine's FTIR spectra showed a peak at 1556 cm, which is connected to C=C stretching in aromatic rings. At 1721 cm, the matching peak for C=O stretching in ketone is visible. The C=H stretching vibration in alkane was believed to be the cause of the peak at 3233. In primary alcohol, the peaks at 3000–3500 cm are attributed to C=O stretching. COCH3 is responsible for the peaks at 2935 cm, while C-O is responsible for the peaks at 1088 cm. There is no generation of peaks and no discernible shift in peaks, despite the possibility of drug and polymer component interaction **(Figure 1)**.

Differential scanning calorimetry (DSC): DSC was used to examine the drug carbopol 934's thermal behavior. At 172.63ºC, the drug exhibited a sharp endothermic peak. It correlates with Colchicine's melting point. Sharp doublet has been observed in the Carbopol 934 near 149.42ºC–172.63ºC **(Figure 2)**.

pH, Spreadability, Viscosity and Drug content: The pH of prepared topical microemulgel (F1 – F9) was to be ranged from 4.45 ± 0.05 to 5.25 ± 0.02. The spreadability values for formulations F1–F9 ranged from 3.35 ± 0.1 to 3.8 ±0.1gm · cm/Sec. For microemulgel, the average viscosity readings ranged from 5389±0.2 to

8517±0.4 cps. The drug content of each formulation ranged from 85.10% to 101.06%. Methyl cellulose-containing F8 formulation exhibiting 95.74% greater drug release. All of the data are presented in **Table 2**.

***In-vitro* diffusion studies:** All nine formulations (F1 to F9) were evaluated to determine their *in-vitro* drug release profiles for 8 hours. Apart from all the formulations, it was found that F8 exhibited the highest drug release, which could be a critical factor in achieving the desired therapeutic action. In particular, it released between 21.8% and 80.05% of the drug during the 8-hour testing period **(Table 3)**.

Kinetic drug release: With R^2 values ranging from 0.7 to 0.9, it was evident from the results that all of the formulations followed a more linear approach to the Peppas models, indicating that the drug release mechanism is diffusion **(Table 4)**.

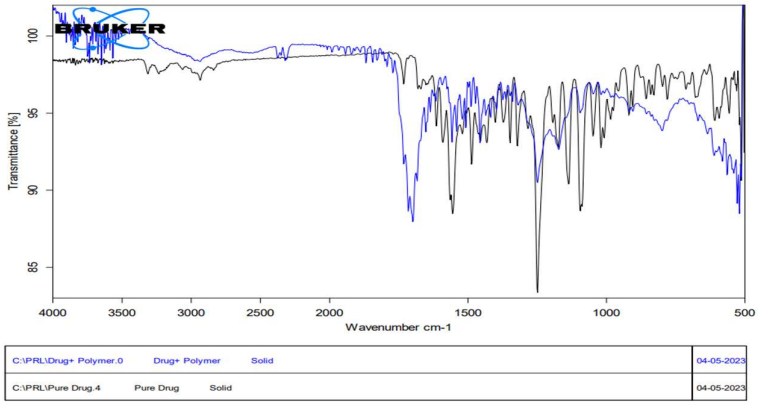


Figure 1: FT-IR of pure drug and excipients

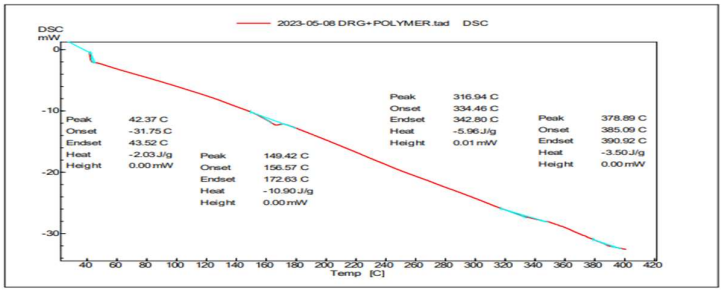


Figure 2: DSC Thermogram of Colchicine + Carbopol 934

Table 2: Data on pH, spreadability, viscosity and Drug content

Formulation code	pH	Spreadability in gm.cm/sec	Viscosity ± SD in CPS	Drug content (%)
F1	4.45±0.05	3.35±0.3	5389±0.2	95.74
F2	4.47±0.02	3.47±0.8	5640±0.5	101.06
F3	4.52±0.09	3.74±0.7	6011±0.7	90.42
F4	5.15±0.04	3.75±0.4	6660±0.7	95.74
F5	5.25±0.02	3.80±0.6	6980±0.5	85.10
F6	4.90±0.03	3.50±0.1	7120±0.3	101.06
F7	5.11±0.06	3.50±0.5	8517±0.4	90.42
F8	5.05±0.07	3.72±0.7	7310±0.2	95.74
F9	4.81±0.03	3.47±0.2	8156±0.6	95.74

Table 3: Data for the Percentage of cumulative drug release

Time in min	Percentage of cumulative drug release (%)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
60	6.9	5.8	8.5	19.65	16.47	19.14	24.45	21.8	23.93
120	11.84	21.83	21	25.36	25.04	28.28	30.59	29.83	36.13
180	15.05	24.51	28.37	30.85	29.5	33.08	40.86	37.89	40.07
240	17.98	32.54	33.07	37.8	36.3	43.35	45.5	43.8	45.65
300	22.16	45.90	41.68	45.64	41.96	47.06	51.8	50	52.01
360	29.22	52.93	51.38	52.95	54.77	55.11	60.48	61.8	61.75
420	38.95	59.56	58.07	61.6	62.16	61.44	67.5	67.8	68.95
480	54.73	66.78	66.57	69.25	69.22	69.9	77.5	80.05	77.95

Table 4: Different kinetic models of topical microemulgel containing Colchicine

Formulation code	Zero order (R^2)	First order (R^2)	Higuchi (R^2)	Peppa's (R^2)	N value
F1	0.9272	0.8165	0.9272	0.8053	0.5328
F2	0.989	0.7631	0.9797	0.9767	0.7006
F3	0.9935	0.8782	0.9818	0.961	0.5856
F4	0.995	0.991	0.9575	0.7956	0.3502
F5	0.9883	0.977	0.9525	0.8256	0.4071
F6	0.995	0.9559	0.9798	0.8753	0.3598
F7	0.9945	0.9705	0.9688	0.8343	0.3192
F8	0.9913	0.9772	0.9587	0.8401	0.3597
F9	0.9888	0.9448	0.9647	0.8627	0.3319

Stability studies: The formulation was kept for three months at room temperature, and its spreadability and pH were assessed. Following three months of storage, the drug content is 95.32%, the *in-vitro* drug permeation is 75.95%, the pH is 4.93, and the spreadability is 3.50 cm.

DISCUSSION

The UV spectrophotometric study of colchicine revealed a λmax consistent with previously reported values, validating the accuracy of the analytical technique used. The absence of significant peak shifts suggested minimal interaction between colchicine and Carbopol 934, in line with earlier research demonstrating drug–polymer compatibility in topical gels. Characteristic peaks corresponding to aromatic C=C and ketone C=O stretching, among other functional groups, were observed in FT-IR spectroscopy.

The melting point of colchicine confirmed its purity and was consistent with literature data, while solubility studies indicated rapid solubility in water and alcohol but poor solubility in nonpolar solvents, in agreement with previous reports.

The produced microemulgels exhibited pH values within the range compatible with skin, promoting patient compliance. Their spreadability and viscosity were consistent with documented ranges for topical microemulgels, reflecting the influence of gelling agent concentration on rheological properties.

Formulation F8 demonstrated the highest drug release and uniformity, attributed to higher polymer content. Diffusion-controlled release was confirmed by drug release kinetics following the Korsmeyer-Peppas model, in accordance with prior studies on emulgel formulations.

Three-month stability tests confirmed the formulation's durability and long-term suitability, with minimal changes in pH, spreadability, drug content, and in vitro penetration, consistent with results reported for similar topical gel systems. Overall, these findings support the appropriate physicochemical characteristics, controlled drug release behavior, and stability of the colchicine microemulgel, particularly formulation F8.

CONCLUSION

The goal of the current study was to create and assess a topical microemulgel containing colchicine as an effective treatment for gout. Despite its effectiveness, oral colchicine treatment is frequently linked to gastrointestinal adverse effects and systemic toxicity. To improve patient compliance, lessen adverse effects, and enable localized dispersion, a topical microemulgel was developed. Using oleic acid as the oil phase, Tween 20 as the surfactant, and various combinations of carbopol 934 and HPMC as gelling agents, nine formulations (F1–F9) were created. Zeta potential, particle size, spreadability, drug content, pH, viscosity, and *in vitro* drug diffusion were assessed for each formulation. According to *in vitro* diffusion experiments, F8 demonstrated prolonged drug release and zero-order kinetics, suggesting a steady release rate that is advantageous for the long-term treatment of gout. Short-term stability studies revealed that F8 exhibited good formulation stability by retaining its physical and chemical integrity without experiencing any notable changes in parameters such as drug content, pH, or viscosity. F8 was decided to be the best formulation for topical colchicine delivery due to its remarkable stability, physical properties, and drug diffusion performance. This microemulgel technology provides a more targeted, safe, and efficient therapeutic method for the treatment of gout.

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