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Formulation, Development of Organogel Containing Dexamethasone and Diclofenac for the Treatment of Inflammation

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Abstract:

The present study aimed to develop and evaluate an organogel formulation containing dexamethasone and diclofenac for topical drug delivery to enhance anti-inflammatory activity and improve patient compliance. Organogels were prepared using different polymers such as Carbopol 934, HPMC, and Tween 80 in varying concentrations. A total of nine formulations (F1–F9) were developed and evaluated for physicochemical parameters including pH, viscosity, spreadability, gel strength, drug content uniformity, and in vitro drug release. Pre-formulation studies confirmed the purity and compatibility of drugs using FTIR, UV spectroscopy, and melting point determination. The pH of all formulations was found within the acceptable range (6.1–6.7), indicating suitability for topical application. Viscosity and spreadability results showed that formulations exhibited good consistency and ease of application. Drug content uniformity ranged from 97.5% to 101%, confirming uniform distribution.

In vitro drug release studies revealed that formulation F7 showed the highest drug release (98.7% at 8 hours). Drug release kinetics followed the Higuchi model, indicating diffusion-controlled release. Thus, the developed organogel formulation can be considered a promising topical drug delivery system for effective management of inflammation.

Keywords: Organogel, Dexamethasone, Diclofenac, Topical drug delivery, Drug release kinetics.

Introduction

Topical drug delivery systems have gained significant importance due to their ability to deliver drugs directly to the site of action, thereby minimizing systemic side effects and improving therapeutic efficacy. Organogels are semi-solid systems in which an organic phase is immobilized within a three-dimensional network formed by gelators. Dexamethasone is a potent corticosteroid with anti-inflammatory properties, while diclofenac is a non-steroidal anti-inflammatory drug (NSAID) widely used for pain and inflammation management. The combination of these drugs in an organogel system offers synergistic therapeutic effects. Organogels provide advantages such as enhanced drug penetration, improved stability, and better patient compliance. Therefore, the present study focuses on the formulation and evaluation of an organogel containing dexamethasone and diclofenac. [1-6]

Classification of Gels:

Gels may be classified supported colloidal phases, nature of solvent used, physical nature and rheological properties.

1. Based on nature of solvent

Hydro gels (water based)

Here they contain water as their continuous liquid phase E.g. bentonite, derivatives of cellulose, carpooler, and synthetic poloxamer gel. Example-plastibase (low molecular wt. polyethylene dissolved in oil) Olag (aerosol) gel and dispersion of metallic stearate in oils.

Hydrogel

A Hydrogel, is a semisolid formulation of gel dosage forms, which has an immobilized external apolar phase. The apolar phase is immobilized within spaces of the 3D network structure formed due to the physical interactions amongst all polymers the self-assembling structures of compounds regarded as gelators. [7]

Xerogels

Solid gels with low solvent concentration are called xerogels. These are produced by evaporation of solvent or freeze drying, leaving the gel framework behind on contact with fresh fluid, they swells and may be reconstituted. E.g. Tragacanth ribbons, acacia tear β1-cyclodextrin, dry cellulose and polystyrene. [8]

2. Based on colloidal phases:

They're classified into Inorganic (two phase system) kind of force that's accountable for the linkages determine the structure of the network and therefore the properties of the gel. [8] Single-phase system these contain large organic molecules existing on the twisted strands dissolved during a continuous phase.

3. Based on rheological properties:

Usually the gels show non-Newtonian flow properties. They're classified into, a) Plastic gels b) Pseudo plastic gels c) Thixotropic gels. (a) Plastic gels E.g. - Bingham bodies, flocculated suspensions of aluminium hydroxide exhibit a plastic flow and also the plot of rheogram gives the yield value of the gels above which the elastic gel distorts and begins to flow. (b) Pseudo-plastic gels E.g. - Liquid tragacanth dispersion, sodium alginate, Na Carboxy methyl cellulose etc. exhibits pseudo-plastic flow. [9]

4. Based on physical nature:

(a) Elastic gels Gels of agar, pectin, guar gum and alginates exhibit an elastic behavior. The fibrous molecules being linked at the purpose of junction by relatively weak bonds like hydrogen bonds and dipole attraction. E.g.: Alginate and Carbapol. (b) Rigid gels this may be formed from macromolecule within which the framework linked by primary valance bond. E.g.: In colloid, silic acid molecules are held by Si-O-Si-O bond to provide a polymer structure possessing a network of pores.

Preparation of Gels:

Gels are generally prepared at the industrial scale under room temperature. However few of polymers such-Synthetic and Natural need special treatment before processing. Gels are also prepared by following methods. [10-11]

1. Thermal changes
2. Flocculation
3. Chemical process/ reaction

Materials and Methods

Materials

The materials used in the present study included dexamethasone and diclofenac sodium as active pharmaceutical ingredients. Carbopol 934 and hydroxypropyl methylcellulose (HPMC) were used as gelling agents, while Tween 80 served as a surfactant. Propylene glycol was used as a penetration enhancer, and ethanol was used as a solvent. Methyl paraben and propyl paraben were incorporated as preservatives. All chemicals and reagents used were of analytical grade.

Methods

The organogel formulations containing dexamethasone and diclofenac were prepared using a combination of aqueous and organic phases. In the aqueous phase, the required quantity of Carbopol 934 or HPMC was dispersed in distilled water and allowed to swell completely to form a uniform gel base. Preservatives such as methyl paraben and propyl paraben were then added with continuous stirring. Dexamethasone, being water-soluble, was dissolved in the aqueous phase. In the organic phase, diclofenac sodium was dissolved in ethanol along with propylene glycol and Tween 80 to enhance solubility and stability. The organic phase was then slowly added to the aqueous phase under constant stirring to ensure uniform mixing and to avoid phase separation. Triethanolamine was added dropwise to adjust the pH of the formulation to a skin-compatible range (approximately 6.5–7.0) and to facilitate gel formation.

The final formulation was stirred thoroughly until a smooth, homogeneous organogel was obtained. The prepared organogels were then transferred into suitable containers, properly labeled, and stored in a cool and dry place for further evaluation.[11-15]

Results and Discussion

Drug–Excipients Compatibility Studies

Drug–excipient compatibility studies were performed using FTIR spectroscopy to evaluate possible interactions between the drug and excipients. The IR spectra of the pure drug and the formulated organogel exhibited similar characteristic peaks and patterns. The absence of any significant shift or disappearance of peaks confirmed that there were no chemical interactions between the drug and the polymers, indicating good compatibility and stability of the formulation.

Visual Inspection

Visual inspection of the developed organogels was carried out to assess their physical appearance, color, and homogeneity. All formulations were found to be smooth, homogeneous, and free from lumps or phase separation. This indicates that the formulations were properly prepared and possessed acceptable aesthetic properties for topical application.

Determination of pH

The pH of all prepared organogel formulations was measured and found to be in the range of 6.1–6.7. This pH range is considered suitable for topical application as it is close to the natural skin pH, thereby minimizing the risk of irritation and enhancing patient acceptability.

Spreadability

Spreadability is an important parameter that determines the ease of application of the gel. The spreadability test was performed for all formulations, and the results indicated good spreading behavior. This ensures that the gel can be easily applied over the skin surface with minimal effort, providing uniform drug distribution.

Determination of Drug Content

The drug content of the formulated organogels was determined to evaluate the uniform distribution of active ingredients. The results showed that the drug content ranged between 97% and 101%, indicating that both dexamethasone and diclofenac were uniformly distributed throughout the gel matrix.

Viscosity and Percentage Yield

Viscosity plays a crucial role in determining the consistency and performance of topical formulations. The viscosity of the prepared organogels varied depending on the type and concentration of polymers used. Higher polymer concentrations resulted in increased viscosity. The percentage yield of all formulations was found to be satisfactory, indicating efficient formulation development and minimal loss during preparation.

In Vitro Drug Release

The in vitro drug release study was carried out using a Franz diffusion cell to evaluate the release profile of the drugs from the organogel formulations.

The results demonstrated a controlled and sustained release pattern for all formulations. Among them, formulation F7 exhibited the highest drug release, indicating its superior performance. The drug release data were further analyzed and represented graphically to understand the release kinetics and mechanism.

Table 1: Organogel Preparation (without API/ placebo)

S.N	INGREDIENTS %w/w	DF N1	DF N2	DF N3	DF N4	DN F5	DN F6	DN F7	DN F8	DN F9
1	Carbapol 934	2.0	4.0	6.0	-	-	-	-	-	-
2	HPMC	-	-	-	2.0	4.0	6.0	-	-	-
3	Tween 80	-	-	-	-	-	-	2.0	4.0	6.0
4	Propylene glycol	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
5	Ethanol	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
6	Triethanolamine	0.5	0.4	0.3	0.5	0.4	0.3	0.5	0.4	0.3
7	Methyl paraben	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
8	Propyl paraben	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
9	Distilled water q.s	qs	qs	qs	qs	qs	qs	qs	qs	qs

Table 2: Organogel preparation (with API)

S.No	Ingredients(%w/w)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Dexamethasone	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
2	Diclofenac	5	5	5	5	5	5	5	5	5
3	Carbapol 934	2.0	4.0	6.0	-	-	-	-	-	-
4	HPMC	-	-	-	2.0	4.0	6.0	-	-	-
5	Tween 80	-	-	-	-	-	-	2.0	4.0	6.0
6	Propylene glycol	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
7	Ethanol (95%)	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
8	Triethanolamine	0.3	0.4	0.5	0.3	0.4	0.5	0.3	0.4	0.5
9	Methyl paraben	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
10	Propylparaben	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
11	Distilled water	67.38	65.28	63.18	67.38	65.28	63.18	67.38	65.28	63.18
12	**Total**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Table 3: Melting points of Dexamethasone and Diclofenac

Drug Name	Melting Point (°C)	Observation	Method
Dexamethasone	262–264°C	Sharp melting point; no decomposition	Capillary tube method
Diclofenac Sodium	283–285°C	Melts with decomposition; may show discoloration	Capillary tube method

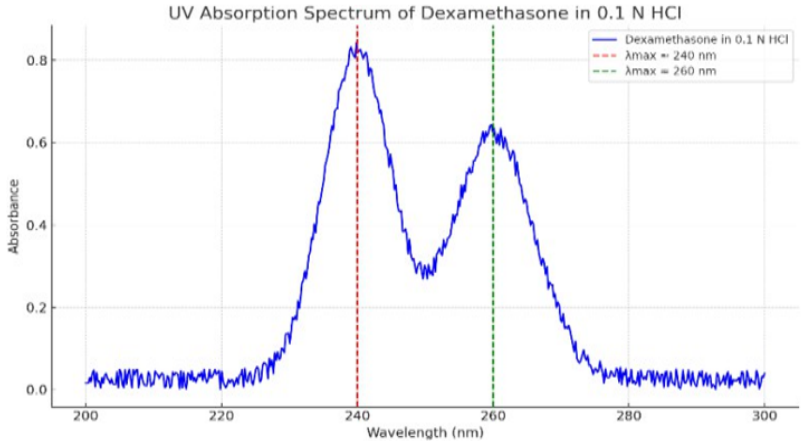

Figure 1. UV spectrum of dexamethasone in 0.1N HCL

Preparation of standard curve of dexamethasone in 0.1 N HCL

Table 4: concentration and absorbance

S. No.	Concentration (µg/mL)	Absorbance at λmax (e.g., 240 nm)
1	2	0.112
2	4	0.223
3	6	0.335
4	8	0.445
5	10	0.556
6	12	0.668

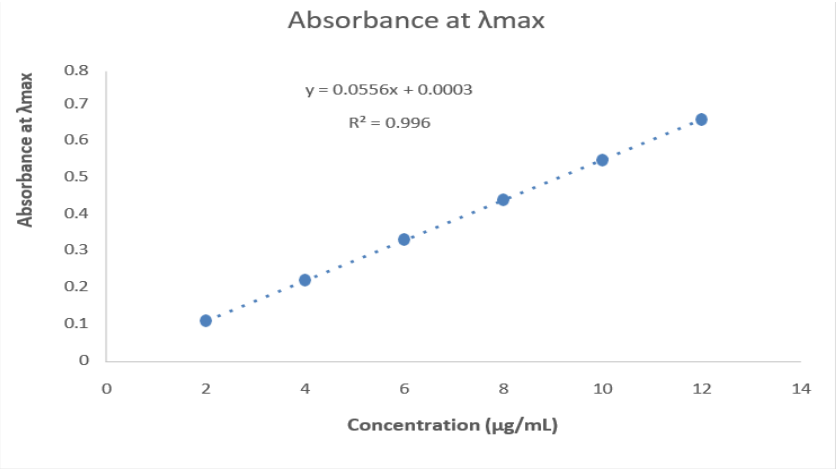

Figure 2: Graph of standard calibration curve of dexamethasone in 0.1N HCL

Table 5: Result of regression analysis of UV spectroscopy of dexamethasone

S No	Statistical parameters	Result
1	λ max	260 nm
2	Regression equation Y = mx+c	Y= 0.0556+0.0003
3	Slope (b)	0.0556
4	Intercept (C)	0.0003
5	Correlation coefficient ($r^{2)}$	0.996

Discussion: The calibration curve of dexamethasone was obtained by using the 2 -10 µg/ml concentration of dexamethasone in 0.1N HCL.

The absorbance was measured at 260nm. The calibration curve shown in the graph indicates the regression equation Y= 0.0556+0.0003 and R^2 value 0.996, which shows good linearity as shown in table and figure 8.1.3.1

Diclofenac:

The absorption maxima of dexamethasone was found to be λmax = 276 nm

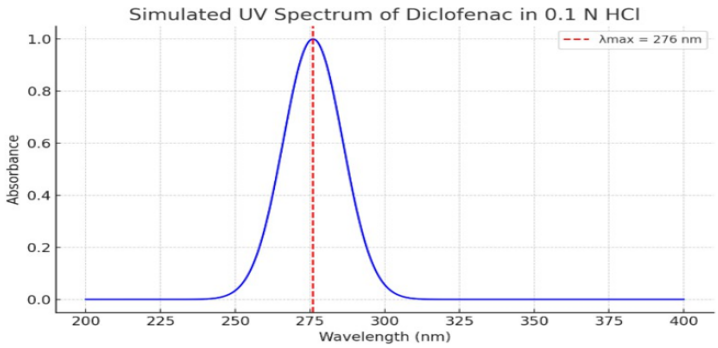

Figure 3: UV spectrum Diclofenac in 0.1N HCL

Table 6: Preparation of standard curve of diclofenac in 0.1 N HCL

S. No.	Concentration (µg/mL)	Absorbance at 276 nm
1	20	0.122
2	40	0.245
3	60	0.368
4	80	0.489
5	100	0.612
6	120	0.735

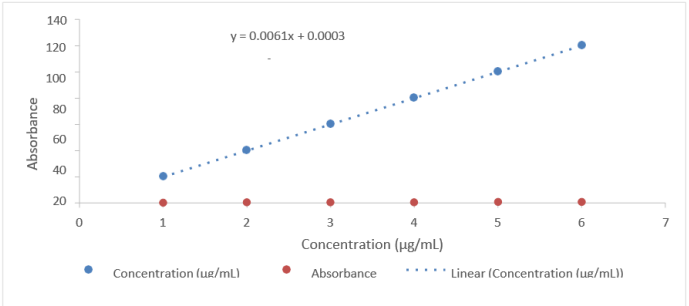

Figure 4: Standard curve of diclofenac

Table 7: Result of regression analysis of UV spectroscopy of diclofenac

S No	Statistical parameters	Result
1	λ max	276 nm
2	Regression equation Y = mx+c	Y = 0.0061x + 0.0003
3	Slope (b)	0.0061
4	Intercept (C)	0.0003
5	Correlation coefficient ($r^{2)}$	0.993

Table 8: Drug Release

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	12.5	10.4	8.3	13.1	11.2	9.5	14.2	12.4	10.2
1.0	22.7	19.1	15.6	24.4	21.0	17.8	26.2	23.5	19.7
2.0	35.8	31.0	26.7	38.2	34.5	29.3	40.8	37.6	32.9
3.0	46.3	41.2	35.4	50.1	47.8	40.9	53.6	50.2	45.5
4.0	58.7	52.9	44.0	63.8	60.6	51.3	66.7	63.1	56.2
5.0	70.1	63.4	54.7	75.4	71.2	63.0	78.6	75.0	68.3
6.0	81.4	74.1	63.6	85.3	82.1	73.5	89.4	86.3	78.5
7.0	89.6	82.7	72.4	92.0	89.3	81.9	95.2	92.4	85.1
8.0	95.1	88.9	79.0	96.7	94.2	88.0	98.7	96.1	91.0

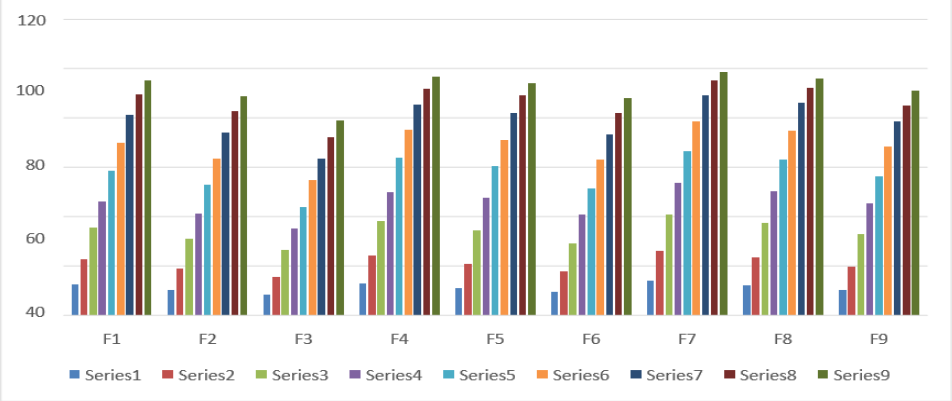

Figure 5: Drug Release of different Formulations

Discussion

The present study was designed to develop and evaluate an organogel formulation containing dexamethasone and diclofenac for effective topical drug delivery. The overall results obtained from preformulation, formulation, and evaluation studies indicate that the organogel system is a suitable and efficient carrier for the combined delivery of anti-inflammatory drugs. Preformulation studies played a crucial role in confirming the identity, purity, and compatibility of the selected drugs with the excipients. The melting point determination indicated that both dexamethasone and diclofenac were pure and free from impurities.

FTIR spectral analysis further confirmed the absence of any significant interaction between the drugs and polymers, ensuring the chemical stability of the formulation. UV spectroscopy and calibration curve studies demonstrated good linearity, which ensured accurate estimation of drug content in the formulations. The evaluation parameters of

the developed organogels revealed satisfactory physicochemical characteristics. The pH of all formulations was found to be within the range of 6.1–6.7, which is close to the physiological pH of the skin. This ensures that the formulations are non-irritant and suitable for topical application. Viscosity measurements indicated that the polymer concentration significantly influenced the consistency of the gel. Formulations containing higher concentrations of polymers exhibited higher viscosity, which contributed to better stability but also influenced the drug release rate.

Spreadability studies demonstrated that the formulations were easily applicable and could spread uniformly over the skin surface, which is essential for effective topical drug delivery. Gel strength values confirmed that the formulations possessed adequate mechanical strength, ensuring stability during handling and application. Drug content uniformity results showed that the active ingredients were uniformly distributed within the gel matrix, ensuring consistent dosing and therapeutic efficacy.

In vitro drug release studies revealed a sustained release profile for all formulations, which is beneficial for prolonged therapeutic action. Among all the formulations, F7 exhibited the highest drug release (98.7% within 8 hours), along with good spreadability and acceptable viscosity. This superior performance can be attributed to the optimal combination of polymer and surfactant concentration, which facilitated enhanced drug diffusion. The drug release kinetics study indicated that the release profile best fitted the Higuchi model (R^2 = 0.983), suggesting a diffusion-controlled release mechanism. The Korsmeyer–Peppas model further supported this finding, indicating a non-Fickian transport mechanism. Overall, the study highlights the importance of formulation variables in controlling the physicochemical properties and drug release behavior of organogels.

Conclusion

The present investigation successfully focused on the formulation, development, and evaluation of an organogel containing dexamethasone and diclofenac for topical application. The study demonstrated that organogels are promising drug delivery systems capable of enhancing the therapeutic efficacy of drugs while minimizing systemic side effects.

All the prepared formulations showed satisfactory physicochemical properties, including appropriate pH, viscosity, spreadability, gel strength, and drug content uniformity. The pH values were found to be within the acceptable range for skin application, ensuring minimal irritation and better patient compliance. The viscosity and spreadability results indicated that the formulations possessed good consistency and ease of application, which are essential characteristics for topical dosage forms. The drug content uniformity results confirmed that both drugs were evenly distributed throughout the gel matrix, ensuring consistent dosing. The in vitro drug release studies revealed a sustained and controlled release pattern, which is advantageous for maintaining prolonged therapeutic action and reducing the frequency of application.

Among all the developed formulations, F7 was identified as the optimized formulation due to its superior performance in terms of drug release, spreadability, and overall physicochemical properties. The formulation exhibited a maximum drug release of 98.7% within 8 hours, indicating efficient drug delivery. The release kinetics followed the Higuchi model, confirming that the drug release was primarily governed by diffusion from the gel matrix.

The findings of this study suggest that the developed organogel formulation can serve as an effective topical drug delivery system for the treatment of inflammation. The combination of dexamethasone and diclofenac in a single formulation provides enhanced anti-inflammatory effects, making it a valuable therapeutic option.

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