History of Medicine, 2025, 11(2): 67-73

DOI: 10.48047/HM. V11.I2.2025.67-73

Development and Characterization of Clobetasol Propionate-Loaded Hydrogel for Psoriasis Management

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Abstract:
Psoriasis is a chronic inflammatory skin condition characterized by hyperproliferation of keratinocytes and immune dysregulation. Topical corticosteroids remain the first-line treatment, with Clobetasol Propionate being one of the most potent. However, conventional formulations often suffer from poor patient compliance, limited skin penetration, and side effects. This project aims to develop and characterize a Clobetasol Propionate-loaded hydrogel using a biocompatible polymeric base to enhance localized delivery, improve drug stability, reduce systemic side effects, and provide sustained release for better therapeutic outcomes. The hydrogel formulation will undergo thorough physicochemical and in vitro evaluations, including rheological, pH, swelling behavior, drug content, and release kinetics studies, followed by ex vivo skin permeation studies and antimicrobial activity assessments to ensure its potential for psoriasis management.
Keywords : Psoriasis, Clobetasol Propionate, Hydrogel, Topical drug delivery, Controlled release

Introduction

Psoriasis is a chronic, immune-mediated inflammatory skin disease that affects approximately 2–3% of the global population. It is characterized by excessive proliferation of keratinocytes, epidermal thickening, and inflammatory infiltration, resulting in erythematous plaques with silvery scales. This condition significantly impairs the quality of life due to its recurrent nature, visibility, and associated comorbidities such as arthritis, cardiovascular disorders, and psychological stress. While the exact etiology of psoriasis remains unclear, it is understood to involve a complex interplay of genetic, environmental, and immunological factors.[1]

Topical corticosteroids are the mainstay treatment for mild to moderate psoriasis, with Clobetasol Propionate (CP) being among the most potent. It exerts anti-inflammatory, antiproliferative, and immunosuppressive effects, providing rapid symptom relief. However, conventional formulations of CP, such as ointments and creams, are associated with several limitations including poor skin penetration, systemic absorption, skin irritation, and poor patient adherence due to greasiness and frequent application. Long-term use can lead to adverse

DOI: 10.48047/HM. V11.I2.2025.67-73

effects such as skin atrophy, telangiectasia, and tachyphylaxis. Therefore, an improved delivery system that enhances local drug delivery while minimizing side effects is essential.[2]

Hydrogels have emerged as promising carriers for topical drug delivery owing to their high water content, biocompatibility, and non-greasy texture. They provide a cooling effect, enhance drug permeation through the stratum corneum, and allow sustained drug release. Incorporating Clobetasol Propionate into a hydrogel matrix can offer improved therapeutic outcomes through better skin adherence, reduced systemic exposure, and enhanced patient compliance.[3]

The present study aims to develop and characterize a Clobetasol Propionate-loaded hydrogel using biocompatible polymers such as Carbopol 934 and HPMC. The formulation is evaluated for physicochemical parameters, drug release behavior, skin permeation, antimicrobial activity, and stability. This work seeks to provide a more effective, patient-friendly alternative to traditional topical corticosteroid therapies in the management of psoriasis.[4]

Materials and Methods

Clobetasol Propionate was procured as a gift sample from a certified pharmaceutical manufacturer. The polymers Carbopol 934 and Hydroxypropyl Methylcellulose (HPMC) were selected as gelling agents for their known biocompatibility and viscosity-modifying properties and were obtained from Loba Chemie Pvt. Ltd., India. Triethanolamine and sodium hydroxide were used as pH-adjusting agents, while ethanol served as a co-solvent for solubilizing the active pharmaceutical ingredient. All other chemicals and reagents used were of analytical grade and were used without further purification.[5]

To begin the formulation development, preformulation studies were carried out. The solubility of Clobetasol Propionate was assessed in various solvents to identify the most suitable medium for incorporation into the hydrogel matrix. Drug-polymer compatibility was studied using Fourier Transform Infrared (FTIR) spectroscopy, where spectra of the pure drug, individual polymers, and physical mixtures were compared to detect any possible interactions between functional groups that could compromise the stability or performance of the final formulation.[6]

The hydrogels were prepared using a dispersion technique. Carbopol 934 or HPMC was slowly dispersed into distilled water under continuous stirring using a magnetic stirrer until a uniform gel base was formed. Clobetasol Propionate was dissolved in a minimal amount of ethanol and incorporated into the gel base under constant stirring. The pH of the formulation was adjusted to the skin-friendly range of 5.5–6.5 using triethanolamine or sodium hydroxide. The final hydrogel formulations were stored in tightly closed containers for further analysis.[7]

The formulated hydrogels were evaluated for physicochemical parameters including appearance, homogeneity, pH, viscosity, spreadability, swelling index, and drug content. In vitro drug release was studied using the dialysis membrane method in phosphate buffer (pH 7.4), and the release data were fitted to various kinetic models. Ex vivo skin permeation studies were conducted using excised goat skin mounted on Franz diffusion cells. [9] Antimicrobial activity was assessed using the agar well diffusion method against Staphylococcus aureus. Stability studies were performed under accelerated conditions as per ICH guidelines for up to three months.[8]

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Results and Discussion

The Clobetasol Propionate-loaded hydrogel formulations were successfully prepared using Carbopol 934 and HPMC as polymeric gelling agents. Among the different batches, CP-HG3 demonstrated optimal performance and was selected as the optimized formulation based on its physicochemical and functional characteristics. The physical appearance of CP-HG3 was smooth, translucent, and homogenous with no signs of phase separation or grittiness, indicating proper drug incorporation and polymer dispersion.

The pH of CP-HG3 was found to be 6.1 ± 0.02, which lies within the acceptable dermal range, ensuring compatibility with skin. The viscosity of CP-HG3 was 23,600 ± 1,245 cps, providing the formulation with adequate consistency for topical application and retention. The spreadability was measured at 18.4 ± 0.9 g·cm/sec, reflecting ease of application and uniform distribution over the affected skin surface. The swelling index, indicative of hydration potential and gel stability, was 182.4 ± 4.5%, providing a suitable matrix for sustained drug release.

Drug content analysis revealed 98.6 ± 0.8% uniform incorporation of Clobetasol Propionate into the hydrogel matrix. In vitro drug release studies showed that CP-HG3 achieved 87.5% release over 8 hours, following Higuchi kinetics and indicating a diffusion-controlled release pattern. Ex vivo skin permeation using goat skin mounted on Franz diffusion cells showed significant permeation (76.8 ± 1.9%), supporting its potential for dermal drug delivery. Antimicrobial testing demonstrated a 23.2 ± 1.5 mm zone of inhibition against *Staphylococcus aureus*, suggesting that the formulation retained effective bioactivity. The stability of CP-HG3 was confirmed under accelerated conditions over three months with no significant changes observed.

These findings confirm that CP-HG3 possesses ideal physicochemical properties, excellent release behavior, and enhanced skin permeation, making it a promising candidate for topical psoriasis therapy.

Parameter	**CP-HG1**	**CP-HG3 (Optimized)**	**CP-HG5**
Appearance	Slightly thin gel	Smooth & homogenous	Thick & less elegant
pH	5.9 ± 0.05	6.1 ± 0.02	6.3 ± 0.01
Viscosity (cps)	17,200 ± 1,150	23,600 ± 1,245	31,400 ± 1,030
Spreadability (g·cm/sec)	15.6 ± 0.6	18.4 ± 0.9	11.2 ± 1.0
Swelling Index (%)	210.3 ± 3.9	182.4 ± 4.5	123.6 ± 5.1
Drug Content (%)	95.2 ± 1.4	98.6 ± 0.8	94.8 ± 1.2
Cumulative Drug Release (%)	58.1 ± 1.7	76.8 ± 1.9	47.6 ± 2.0

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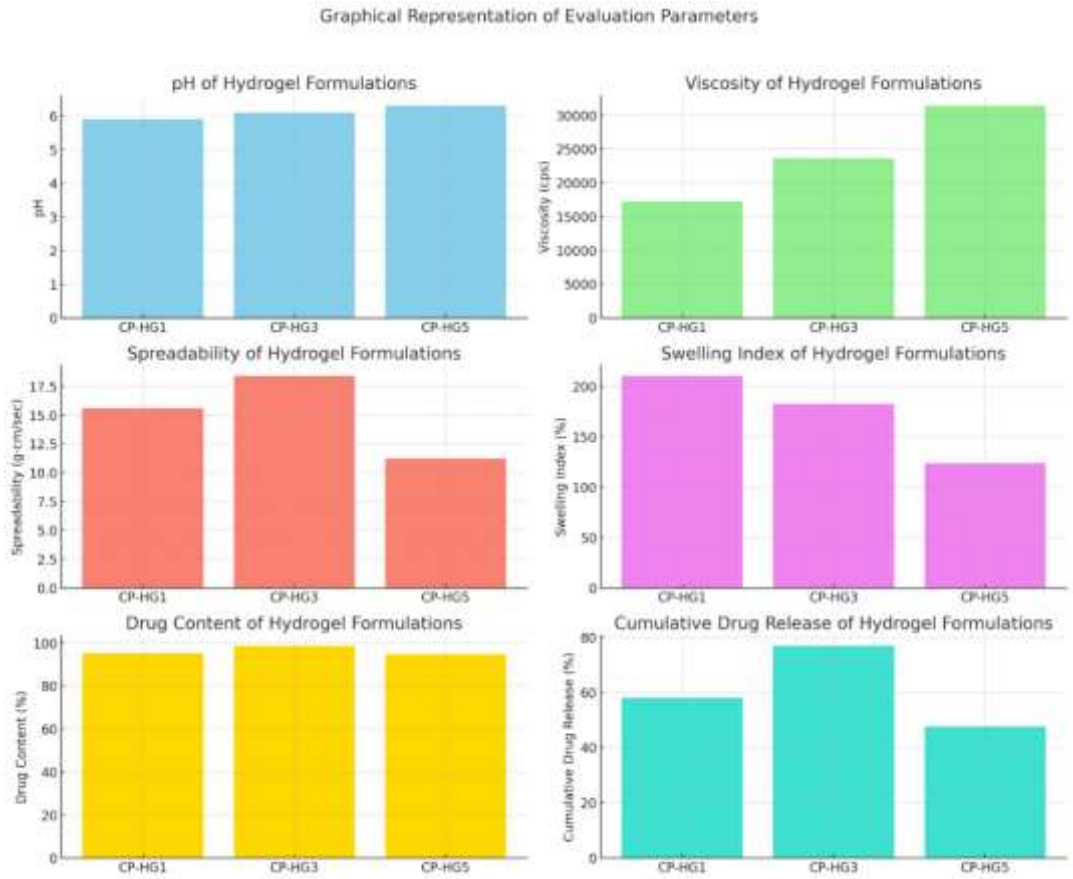
Zone of Inhibition (mm)	21.2 ± 1.6	23.2 ± 1.5	19.1 ± 1.2
Stability Changes	Minor	Stable	Slight separation

Table 1 : Evaluation Parameters of Hydrogel Formulations



Graph 1 : Graphical representations of the evaluation parameters for the Clobetasol Propionate-loaded hydrogel formulations (CP-HG1, CP-HG3, and CP-HG5)

Conclusion

The current study successfully developed and characterized a Clobetasol Propionate-loaded hydrogel intended for enhanced topical delivery in the treatment of psoriasis. The formulation strategy aimed to overcome the limitations of conventional corticosteroid-based topical treatments, such as poor skin penetration, rapid drug clearance, patient discomfort, and the potential for systemic side effects. By incorporating Clobetasol Propionate into a hydrogel matrix composed of biocompatible polymers like Carbopol 934 and Hydroxypropyl Methylcellulose (HPMC), a non-greasy, patient-friendly, and stable topical delivery system was achieved.

Among the various formulations prepared, CP-HG3 emerged as the most promising based on comprehensive evaluation of physicochemical properties, drug content, spreadability, rheology, and drug release profile. The optimized formulation demonstrated a smooth texture, suitable viscosity, skin-friendly pH, and high drug-loading efficiency. The spreadability of CP-HG3 was ideal for topical application, ensuring ease of use and uniform application over psoriatic plaques.

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The in vitro drug release study confirmed a sustained release profile for CP-HG3, following Higuchi kinetics and indicating a diffusion-based mechanism. This is beneficial in providing long-lasting therapeutic action and reducing the need for frequent application. The ex vivo permeation studies further supported the hydrogel's ability to deliver Clobetasol Propionate efficiently through the skin, potentially enhancing its local action while minimizing systemic exposure. The antimicrobial activity assay showed significant inhibition against *Staphylococcus aureus*, suggesting additional benefit in preventing secondary infections common in psoriasis.

Stability studies conducted under ICH-recommended conditions demonstrated that the optimized formulation retained its physicochemical integrity over a three-month period, confirming its suitability for storage and clinical use. Overall, the results validate that the Clobetasol Propionate-loaded hydrogel offers a novel, effective, and patient-compliant approach for the management of psoriasis.

Further in vivo studies and clinical trials are warranted to evaluate the therapeutic efficacy, long-term safety, and patient acceptability of this hydrogel formulation in real-world settings. Nevertheless, this work lays a strong foundation for the development of advanced topical corticosteroid therapies using hydrogel-based delivery systems.

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