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Development and Evaluation of Acitretin-Loaded Hydrogels for Enhanced Topical Delivery in Psoriasis

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ABSTRACT:

Background: Acitretin is an effective retinoid for psoriasis; however, its physicochemical limitations and potential irritation associated with conventional topical administration may affect therapeutic acceptability. The present study aimed to develop and optimize an Acitretin-loaded hydrogel for controlled topical drug delivery.

Methods: The hydrogel was optimized using a three-factor, three-level Box–Behnken design. Polymer concentration, neutralizer percentage, and crosslinking density were selected as independent variables, while viscosity, pH, drug content, spreadability, and in-vitro drug release were evaluated as responses. Fifteen experimental formulations were prepared and statistically analyzed. The optimized formulation was further evaluated for physicochemical properties, swelling, extrudability, and drug release using a Franz diffusion cell.

Results: The optimized formulation contained 1.5% w/w polymer, 0.3% w/w neutralizer, and 0.1% w/w crosslinking density. It exhibited a smooth, homogeneous appearance, pH of 5.71 ± 0.06, viscosity of 3468 ± 42.5 cP, spreadability of 24.8 ± 0.5 cm/g, extrudability of 92.4 ± 1.3%, swelling index of 68.5 ± 2.1%, and drug content of 93.8 ± 0.6%. Cumulative drug release reached 88.0 ± 0.7% at 12 h.

1. INTRODUCTION

Psoriasis is a chronic, immune-mediated inflammatory skin disorder characterized by abnormal keratinocyte proliferation and differentiation, epidermal hyperplasia, and persistent cutaneous inflammation. The disease commonly presents as well-demarcated erythematous plaques covered with silvery scales, although several clinical variants, including guttate, inverse, pustular, erythrodermic, and nail psoriasis, may occur. Psoriasis follows a relapsing–remitting course and can substantially impair physical functioning, psychological well-being, social interaction, and quality of life [1,2]. Although primarily manifested in the skin, psoriasis is increasingly recognized as a systemic inflammatory disorder associated with comorbidities such as psoriatic arthritis, metabolic abnormalities, and cardiovascular disease [1,3]. The chronic nature of the disease necessitates long-term treatment strategies that provide sustained efficacy while maintaining patient safety and adherence.

The pathogenesis of psoriasis involves a complex interaction between genetic susceptibility, environmental triggers, keratinocytes, dendritic cells, and T lymphocytes. Among the various inflammatory pathways, the interleukin (IL)-23/IL-17 axis plays a central role in initiation and maintenance of psoriatic inflammation [4,5]. Activated dendritic cells produce IL-23, which promotes the differentiation and persistence of T-helper 17 cells. These cells release IL-17 and IL-22, which stimulate

keratinocyte proliferation and the production of additional inflammatory mediators, thereby establishing a self-amplifying inflammatory loop [4,5]. Consequently, abnormal keratinocyte differentiation, epidermal thickening, hyperkeratosis, and scaling develop within psoriatic plaques. The altered architecture of the stratum corneum consequently presents an important barrier to efficient topical drug delivery [6].

Current therapeutic approaches for psoriasis include topical agents, phototherapy, conventional systemic drugs, and biologic therapies. Topical corticosteroids, vitamin D analogues, retinoids, keratolytics, calcineurin inhibitors, and emollients remain important, particularly for mild-to-moderate disease and as adjunctive therapy in more extensive psoriasis [1,7]. However, prolonged use of corticosteroids can produce cutaneous adverse effects, whereas topical retinoids may cause irritation and erythema. Phototherapy requires repeated clinical visits, while conventional systemic therapies may be associated with organ toxicity and other treatment-related limitations. Biologic agents targeting TNF-α, IL-17, and IL-23 have substantially improved the management of moderate-to-severe psoriasis, but their cost, parenteral administration, accessibility, and requirement for long-term monitoring remain important limitations [2,7]. These limitations emphasize the need for optimized topical delivery systems capable of improving local therapeutic efficacy while reducing unnecessary systemic exposure.

Retinoids are particularly relevant to psoriasis because they regulate epidermal proliferation and differentiation through nuclear retinoid receptors. Acitretin is a second-generation aromatic retinoid that has established efficacy in psoriasis, particularly in pustular and erythrodermic forms and in selected patients with plaque psoriasis [8,9]. Its therapeutic action is primarily associated with normalization of keratinocyte differentiation and reduction of hyperkeratosis, while its immunomodulatory effects may additionally influence inflammatory processes within psoriatic lesions [8,10]. Unlike immunosuppressive agents, acitretin does not directly produce broad immunosuppression, representing an important therapeutic advantage in selected patients [8].

Despite its efficacy, systemic administration of acitretin is associated with important limitations. Mucocutaneous adverse effects, xerosis, cheilitis, hair abnormalities, nail changes, dyslipidemia, and potential hepatotoxicity can compromise treatment tolerability [8,11]. More importantly, acitretin has pronounced teratogenic potential, requiring stringent pregnancy-prevention measures in women of childbearing potential [11]. These limitations provide a strong rationale for exploring localized delivery approaches that could concentrate acitretin at psoriatic lesions while potentially minimizing systemic exposure. However, development of an effective topical acitretin formulation is challenging because the drug is highly lipophilic, poorly water-soluble, and susceptible to degradation, while psoriatic plaques possess a thickened and abnormal stratum corneum that can restrict uniform drug penetration [12,13]. Conventional topical formulations may therefore provide inadequate drug solubilization, limited penetration, short residence time, and rapid release, while high local drug concentrations may contribute to retinoid-associated irritation.

Advanced topical drug-delivery systems have consequently attracted increasing attention for psoriasis because they can improve drug stability, skin retention, penetration, and controlled release [6,14]. Among these systems, hydrogels represent an attractive platform because they consist of three-dimensional hydrophilic polymeric networks capable of retaining substantial quantities of water. Their high water content, biocompatibility, spreadability, and cooling sensation make them particularly suitable for application to inflamed and sensitive skin [14,15]. Hydrogels can maintain intimate contact with the skin, hydrate the stratum corneum, soften hyperkeratotic scales, and facilitate drug diffusion into the epidermis. Furthermore, their polymer concentration, cross-linking density, swelling behavior, and rheological properties can be adjusted to regulate drug release and residence time [15,16].

Importantly, hydrogel systems can overcome several limitations associated with conventional topical formulations. Controlled release from the hydrated polymeric network can reduce rapid drug liberation and thereby minimize excessive local drug concentrations, while prolonged residence on the lesion can maintain drug availability over an extended period [14,16]. Recent developments have further demonstrated the potential of smart and hybrid hydrogels incorporating nanocarriers to improve the solubilization, protection, penetration, and controlled release of poorly soluble drugs [17]. Such approaches are particularly relevant for acitretin because its physicochemical characteristics and irritation potential demand a formulation capable of balancing drug loading, stability, release, and skin deposition.

Therefore, development of an acitretin-loaded hydrogel represents a rational strategy for enhancing topical delivery in psoriasis. A suitably optimized hydrogel may improve acitretinsolubilization and stability, prolong its residence at the application site, facilitate penetration through psoriatic skin, and provide controlled drug release while potentially reducing

systemic exposure and local irritation. Accordingly, the present study focuses on the development and evaluation of acitretin-loaded hydrogels for enhanced topical delivery in psoriasis, with emphasis on formulation optimization, physicochemical characterization, drug-release behavior, and performance parameters relevant to effective and patient-acceptable topical therapy.

2. MATERIALS AND METHODS

Acitretin, used as the active pharmaceutical ingredient (API) in the present study, was procured from Taj Pharma Ltd., Vapi, Gujarat, India. The polymers and excipients employed for the preparation of Acitretin-loaded hydrogel formulations, including Carbopol 934, hydroxypropyl methylcellulose (HPMC), chitosan, triethanolamine, glycerol, propylene glycol, and other formulation additives, were obtained from Merck Pvt. Ltd., India, and Qualigens Fine Chemicals, India.

Preformulation Studies

Preformulation studies of Acitretin were performed to evaluate its physicochemical characteristics and stability prior to hydrogel formulation. The drug was evaluated for organoleptic properties, melting point, solubility, partition coefficient, photostability, thermal stability, and pH stability. The color, appearance, and physical state were assessed by visual inspection, while the melting point was determined by the capillary method using 2–3 mg of drug. Solubility was evaluated in distilled water, ethanol, methanol, propylene glycol, and phosphate buffers of pH 6.8 and 7.4 after 24 h equilibration at 25 ± 2°C, followed by UV–Visible spectrophotometric analysis. Drug–excipient compatibility was evaluated using Fourier Transform Infrared Spectroscopy to identify possible interactions and changes in the thermal and crystalline characteristics of the drug. The results of these studies were used to establish the suitability of Acitretin and the selected excipients for subsequent hydrogel formulation development. [18].

Preparation of Acitretin-Loaded Hydrogels

Acitretin-loaded hydrogels were prepared by in situ free-radical copolymerization of acrylic acid and acrylamide. Acrylamide was dissolved in distilled water, followed by the gradual addition of acrylic acid under continuous stirring. Acitretin was separately dissolved in ethanol and propylene glycol and incorporated into the monomeric solution. N,N'-Methylenebisacrylamide was used as the crosslinking agent, while ammonium persulfate and N,N,N',N'-tetramethylethylenediamine were used as the initiator–accelerator system. Polymer concentration (1.0–2.0% w/w), neutralizer concentration (0.3–0.9% w/w), and crosslinking density (0.1–0.5% w/w) were varied according to the experimental design. The reaction mixture was transferred into suitable molds and maintained under controlled conditions until gel formation. The formed hydrogels were washed repeatedly with distilled water to remove unreacted monomers and soluble residues and were subsequently stored in airtight containers until further evaluation. [19].

Optimization of Hydrogel Formulation Using Design of Experiments

The Acitretin-loaded hydrogel formulation was optimized using a Box–Behnken Design (BBD) based on response surface methodology. Three independent variables were selected: polymer concentration (A: 1.0, 1.5, and 2.0% w/w), neutralizer percentage (B: 0.3, 0.6, and 0.9% w/w), and crosslinking density (C: 0.1, 0.3, and 0.5% w/w). The selected dependent responses were viscosity, pH, drug content, spreadability, and in-vitro drug release. A total of 15 experimental formulations were generated and evaluated according to the BBD matrix. The experimental data were analyzed using Design-Expert software, and polynomial equations, response surface plots, contour plots, and desirability analysis were used to determine the influence of formulation variables on the selected responses. The optimized formulation was selected based on maximum desirability and the desired balance of all critical formulation responses and was subsequently prepared and evaluated for model validation.

Table 01: Independent Variable

Factor Code	Independent Variable	Low (−1)	Medium (0)	High (+1)
A	Polymer concentration (% w/w)	1.0	1.5	2.0
B	Neutralizer percentage (% w/w)	0.3	0.6	0.9
C	Crosslinking density (% w/w)	0.1	0.3	0.5

Evaluation of Prepared Hydrogels

The prepared Acitretin-loaded hydrogels were evaluated for their physicochemical, mechanical, and performance characteristics.

Physical Appearance: The formulations were visually examined for color, homogeneity, clarity, phase separation, air bubbles, and particulate matter. A smooth and uniform gel was considered acceptable for topical application.

pH: The pH was determined by dispersing 1 g of hydrogel in 10 mL of distilled water and measuring with a digital pH meter at 25 ± 2°C. Measurements were performed in triplicate, with a target pH of 5.0–5.5 for skin compatibility.

Viscosity: Viscosity was measured using a Brookfield digital viscometer with spindle No. 64 at 10, 20, 50, and 100 rpm at 25°C. The viscosity was expressed in centipoise (cP).

Spreadability: Spreadability was determined by placing 0.5 g of hydrogel between two glass slides and applying a 500 g weight for 5 min. The spreading area was measured and expressed as cm/g using the appropriate spreadability equation.

Extrudability: Extrudability was assessed using a collapsible aluminum tube containing 10 g of hydrogel. A 500 g weight was applied for 10 s, and the quantity of gel extruded was recorded to assess ease of application.

Swelling Index: The swelling capacity was determined by immersing 1 g of hydrogel in 25 mL of distilled water for 1 h. The swollen sample was weighed after removal of excess surface water, and the swelling index was calculated from the initial and swollen weights.

Rheological Behavior: Rheological characteristics were evaluated using a Brookfield Texture Analyzer at 25 ± 2°C over a shear range corresponding to 10–100 rpm. The flow behavior of the formulations was assessed to determine their suitability for topical application.

Drug Content: Acitretin content was determined by accurately weighing 1 g of hydrogel and extracting it with 25 mL of ethanol buffer pH 7.4 (1:1). The sample was sonicated for 15 min, filtered, suitably diluted, and analyzed at 352 nm using a UV–Visible spectrophotometer. Drug content was calculated using the Acitretin calibration curve.

In-Vitro Drug Release Study

The in-vitro release of Acitretin from the prepared hydrogels was evaluated using a Franz diffusion cell with a hydrated dialysis/synthetic membrane as the diffusion barrier. The membrane was pre-soaked in phosphate buffer for 12 h before mounting between the donor and receptor compartments. Hydrogel equivalent to 10 mg of Acitretin was placed in the donor compartment, while the receptor compartment contained 20 mL of phosphate buffer pH 7.4 containing 30% ethanol. The receptor medium was maintained at 37 ± 0.5°C and stirred continuously at 600 rpm. Samples (1 mL) were withdrawn at predetermined intervals up to 12 h and replaced with an equal volume of fresh receptor medium. The samples were filtered, suitably diluted, and analyzed spectrophotometrically at 352 nm. [20].

3. RESULT

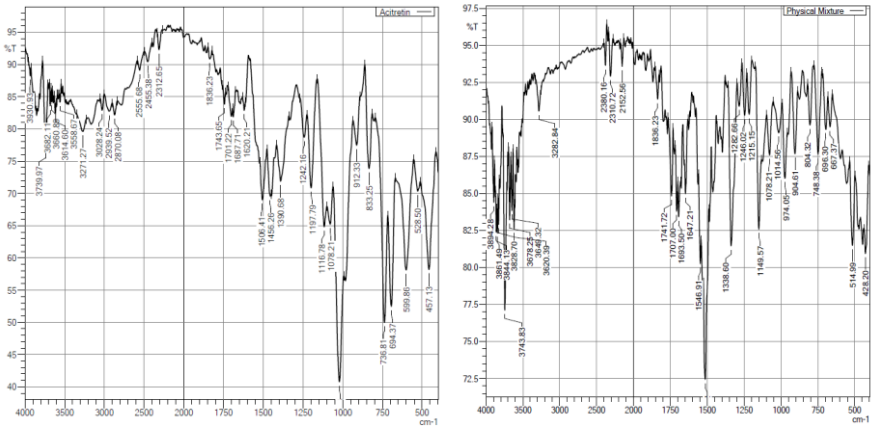
Preformulation Studies

The preformulation assessment established the physicochemical characteristics of Acitretin relevant to topical hydrogel development. Acitretin exhibited a characteristic yellow to greenish-yellow crystalline appearance and a melting point of 229 ± 1.00°C, indicating a crystalline and relatively pure drug. The developed UV spectrophotometric method demonstrated

satisfactory linearity over 2–20 µg/mL (R^2 = 0.9989), supporting its applicability for quantitative drug estimation. Acitretin exhibited markedly poor aqueous solubility, whereas substantially higher solubility was observed in ethanol, methanol, and propylene glycol, confirming its lipophilic character. The experimentally determined log P (3.91 ± 0.01) further indicated a strong affinity for lipidic environments, which may favor partitioning into the stratum corneum but potentially restrict subsequent diffusion into deeper skin layers. Stability studies demonstrated greater susceptibility to photodegradation and alkaline stress, while comparatively minor degradation occurred under thermal stress. Collectively, these findings justified the selection of suitable cosolvents, light-protective conditions, and a mildly acidic formulation pH (5.0–5.5) for development of an Acitretin-loaded topical hydrogel.

Drug-Excipient Compatibility Studies

FTIR spectrum confirmed characteristic functional groups of Acitretin without structural alterations, indicating drug identity, purity, and compatibility.



(A) **(B)**

Figure 1: FTIR spectrum of Acitretin (A) and physical mixture(B)

Optimization Study Using Box–Behnken Design

The Acitretin-loaded hydrogel was optimized using a three-factor, three-level Box–Behnken Design to investigate the effects of polymer concentration (A), neutralizer percentage (B), and crosslinking density (C) on viscosity (Y_1), pH (Y_2), drug content (Y_3), spreadability (Y_4), and in-vitro drug release (Y_5). Fifteen experimental formulations were prepared and evaluated. The observed responses showed considerable variation, with viscosity ranging from 3105–5522 cP, pH from 5.01–6.88, drug content from 92.8–98.7%, spreadability from 20.8–29.5 cm/g, and drug release from 70.1–88.0%.

The quadratic models were statistically significant for all responses ($p < 0.05$), with R^2 values ranging from 0.9032 to 0.9518, confirming satisfactory model fitting. Polymer concentration predominantly influenced viscosity and spreadability, whereas crosslinking density markedly affected drug content and drug release. Increased polymer concentration enhanced viscosity but reduced spreadability, while higher crosslinking density restricted drug diffusion and reduced drug release

Table 02: Box–Behnken Design Matrix with Observed Responses

Run	A: Polymer concentration (% w/w)	B: Neutralizer percentage (% w/w)	C: Crosslinking density (% w/w)	Viscosity (cP)	pH	Drug content (%)	Spreadability (cm/g)	In-vitro drug release (%)
1	2.0	0.6	0.1	5283	5.01	94.2	21.7	87.2
2	1.0	0.6	0.1	3210	5.11	93.4	29.5	86.1
3	1.5	0.9	0.1	4127	5.07	92.8	24.8	85.7
4	1.0	0.6	0.5	5285	6.01	98.7	28.3	70.1
5	1.5	0.3	0.1	3468	5.71	93.8	24.8	88.0

6	1.0	0.3	0.3	3105	5.86	96.0	27.9	76.8
7	1.5	0.3	0.5	3856	6.88	97.3	23.1	71.5
8	2.0	0.9	0.3	5522	5.13	97.1	21.3	73.2
9	1.5	0.9	0.5	3786	5.97	96.5	24.2	72.1
10	1.5	0.6	0.3	3841	5.64	97.7	25.0	78.5
11	1.5	0.6	0.3	3957	5.61	96.3	24.2	79.4
12	1.5	0.6	0.3	4089	5.76	98.0	23.1	73.3
13	1.0	0.9	0.3	3874	5.82	97.1	28.7	79.8
14	2.0	0.6	0.5	5217	6.12	97.0	20.8	71.9
15	2.0	0.3	0.3	5098	5.83	97.2	25.8	80.7

Optimized Formulation

Based on the desirability approach, Run 5 was selected as the optimized formulation, containing 1.5% w/w polymer, 0.3% w/w neutralizer, and 0.1% w/w crosslinking density. The predicted responses were viscosity 3144.09 cP, pH 5.62, drug content 93.34%, spreadability 25.37 cm/g, and drug release 88.51%, while the experimental values were 3468 cP, 5.71, 93.8%, 24.8 cm/g, and 88.0%, respectively. The low prediction errors confirmed satisfactory agreement between predicted and experimental responses.

Thus, the optimized Acitretin-loaded hydrogel demonstrated suitable physicochemical characteristics and controlled drug-release performance and was selected for further evaluation.

Table 3: Predicted and Observed Responses of Optimized Acitretin-Loaded Hydrogel

Response	Predicted value	Observed value	% Error
Viscosity	3144.09 cP	3468 cP	9.34
pH	5.62	5.71	1.58
Drug content	93.34%	93.8%	0.49
Spreadability	25.37 cm/g	24.8 cm/g	2.30
In-vitro drug release	88.51%	88.0%	0.58

Evaluation of Floating-Bioadhesive Matrix Tablets

Evaluation of Optimized Acitretin-Loaded Hydrogel

The optimized Acitretin-loaded hydrogel exhibited satisfactory pharmaceutical performance and physicochemical characteristics. The formulation showed a pH of 5.71 ± 0.06 and viscosity of 3468 ± 42.5 cP, indicating suitable consistency and topical applicability. The hydrogel demonstrated good spreadability of 24.8 ± 0.5 cm/g and extrudability of 92.4 ± 1.3%, confirming ease of application and removal from the container. The formulation exhibited a swelling index of 68.5 ± 2.1% after 1 h, indicating satisfactory hydration of the polymeric matrix. The drug content was 93.8 ± 0.6%, confirming successful incorporation and relatively uniform distribution of Acitretin within the hydrogel matrix. Overall, the optimized hydrogel demonstrated suitable physical, rheological, application, and drug-content characteristics for topical delivery of Acitretin.

Table 4: Evaluation of Optimized Acitretin-Loaded Hydrogel

Evaluation parameter	Result (Mean ± SD)
Physical appearance	Smooth, pale yellow hydrogel
Homogeneity	Homogeneous
pH	5.71 ± 0.06
Viscosity	3468 ± 42.5 cP
Spreadability	24.8 ± 0.5 cm/g
Extrudability	92.4 ± 1.3%

Swelling index (1 h)	68.5 ± 2.1%
Drug content	93.8 ± 0.6%
Grittiness	Absent
Phase separation	Absent
Air bubbles	Absent

In-Vitro Drug Release Study

The optimized Acitretin-loaded hydrogel demonstrated a gradual and sustained drug-release profile over 12 h. The cumulative drug release increased progressively from 18.6 ± 0.9% at 0.5 h to 88.0 ± 0.7% at 12 h. The initial release was attributed to diffusion of drug present near the hydrogel surface, followed by slower diffusion through the hydrated polymeric network. The sustained release profile indicated that the optimized hydrogel could provide controlled delivery of Acitretin and may be suitable for topical application.

Table 5: In-vitro drug release profile of optimized tablets.

Time (h)	Mean ± SD Drug Release (%)
0.5	18.6 ± 0.9
1	31.4 ± 1.1
2	45.2 ± 1.3
4	59.8 ± 1.4
6	71.6 ± 1.2
8	79.3 ± 1.0
10	84.5 ± 0.8
12	**1.1 ± 0.7**

4. CONCLUSION

The present study successfully developed and optimized an Acitretin-loaded hydrogel using a systematic Box–Behnken experimental design approach. The formulation variables, namely polymer concentration, neutralizer percentage, and crosslinking density, significantly influenced the physicochemical and drug-release characteristics of the hydrogel. Among the investigated formulations, the optimized composition containing 1.5% w/w polymer, 0.3% w/w neutralizer, and 0.1% w/w crosslinking density demonstrated an appropriate balance of formulation properties.

The optimized hydrogel exhibited a smooth, homogeneous appearance without visible grittiness or phase separation and showed a pH of 5.71 ± 0.06, viscosity of 3468 ± 42.5 cP, spreadability of 24.8 ± 0.5 cm/g, and extrudability of 92.4 ± 1.3%. The swelling index of 68.5 ± 2.1% indicated satisfactory hydration of the polymeric network, while drug content of 93.8 ± 0.6% confirmed effective drug incorporation. In-vitro diffusion studies demonstrated a progressive and sustained release of Acitretin, reaching 88.0 ± 0.7% after 12 h. Collectively, these findings establish that the optimized hydrogel possesses suitable physicochemical, application, and controlled-release characteristics and may serve as a promising topical delivery platform for Acitretin in psoriasis management. Further in-vivo and clinical investigations are warranted to establish its therapeutic efficacy and long-term safety.

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