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Research Paper

Development and Evaluation of Hydrocortisone Nanosponges loaded Hydrogel for the Topical Treatment of Psoriasis

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ABSTRACT

Psoriasis is a chronic, immune-mediated inflammatory skin disorder characterized by hyperproliferation of keratinocytes. The present study aims to develop and evaluate a novel hydrocortisone nanosponges loaded hydrogel for enhanced topical delivery in the management of psoriasis.Hydrocortisone nanosponges were prepared using the emulsion solvent diffusion method employing ethyl cellulose as a polymer and polyvinyl alcohol as a stabilizer. The prepared nanosponges were optimized based on particle size, entrapment efficiency, and in-vitro drug release. The optimized formulation was incorporated into a Carbopol 934-based hydrogel system to enhance patient compliance and drug retention at the site of action.The nanosponge formulations were characterized for particle size, drug content, and entrapment efficiency. The hydrogel formulations were evaluated for pH, viscosity, spreadability, drug content, and in-vitro drug release using Franz diffusion cell and stability studies were performed as per ICH guidelines.The optimized nanosponge hydrogel showed controlled and sustained drug release, improved skin permeation, and better retention compared to conventional formulations. The study concludes that hydrocortisone nanosponges loaded hydrogel is a promising approach for effective topical delivery in psoriasis with enhanced therapeutic efficacy and reduced side effects.

INTRODUCTION

Psoriasis

Psoriasis is a chronic, immune-mediated inflammatory skin disorder characterized by accelerated epidermal turnover, resulting in the formation of distinct erythematous plaques covered with silvery scales [1, 2]. This condition affects approximately 2-5% of the global population, with prevalence varying across geographical regions and ethnicities [3, 4]. The disease manifests in several clinical forms, with psoriasis vulgaris (chronic plaque psoriasis) being

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the most prevalent, accounting for nearly 90% of cases [5]. Other variants include guttate psoriasis, inverse psoriasis, pustular psoriasis, and erythrodermic psoriasis, the latter representing a medical emergency requiring immediate intervention [5, 6].

The pathophysiology of psoriasis involves a complex interplay between genetic predisposition and environmental triggers. Genome-wide association studies have identified susceptibility loci, including the HLA-Cw6 gene and psoriasis susceptibility 1 (PSORS1) gene, which significantly increase disease risk [7, 8]. Environmental factors such as stress, infections (particularly streptococcal upper respiratory infections), trauma (Koebner phenomenon), medications (lithium, beta-blockers, antimalarials), and lifestyle factors including smoking and alcohol consumption can precipitate or exacerbate the condition [8, 9].

At the molecular level, psoriasis is driven by dysregulation of the immune system, particularly involving T-helper 17 (Th17), Th22, and Th1 cell subsets [10]. These activated T cells infiltrate the dermis and epidermis, releasing pro-inflammatory cytokines including interleukin (IL)-17, IL-22, IL-23, tumor necrosis factor-alpha (TNF-α), and interferon-gamma (IFN-γ) [10, 11]. This cytokine cascade activates keratinocytes, promoting their hyperproliferation and abnormal differentiation. While normal keratinocyte maturation and shedding occur over approximately 30 days, in psoriatic skin this process is accelerated to merely 6-8 days [3, 12]. The rapidly proliferating keratinocytes accumulate without adequate desquamation, forming the characteristic plaques and scales observed clinically [3, 12].

The disease burden extends beyond physical manifestations, significantly impairing patients' quality of life through psychosocial distress, stigmatization, and association with multiple comorbidities [4, 13]. These comorbidities include psoriatic arthritis affecting up to 30% of patients, cardiovascular disease, metabolic syndrome, obesity, depression, and inflammatory bowel disease [8, 13].

Nanosponge-Loaded Hydrogels: A Synergistic Approach

The integration of nanosponges within hydrogel matrices represents an innovative convergence of two advanced drug delivery technologies, creating composite systems with synergistic advantages [23, 32, 33]. Nanosponge-loaded hydrogels combine the high drug loading capacity, controlled release, and skin reservoir formation of nanosponges with the excellent spreading properties, patient compliance, and moisturizing effects of hydrogels [23, 32, 33].

From a formulation perspective, this approach addresses limitations inherent to each individual system. Nanosponges alone, while excellent drug carriers, may exhibit poor retention on the skin surface and require incorporation into a suitable vehicle for practical application [23]. Conversely, hydrogels alone demonstrate limited capacity for hydrophobic drug encapsulation and uncontrolled drug release kinetics for many therapeutic agents [3, 33]. The composite system overcomes these drawbacks: nanosponges provide efficient encapsulation and sustained release of hydrophobic drugs like hydrocortisone, while the hydrogel matrix ensures uniform application, prolonged skin contact, and enhanced patient acceptability [23, 33].

The drug release mechanism from nanosponge-loaded hydrogels involves multiple kinetic processes: diffusion of drug from nanosponge nanocavities, partitioning between nanosponge and hydrogel phases, and subsequent diffusion through the hydrogel matrix to the skin surface [23, 32]. This complex release profile typically follows sustained kinetics, reducing application

frequency and minimizing peak concentration-related side effects [23, 33].

Recent investigations have demonstrated the efficacy of this approach for various therapeutic agents in dermatological disorders. Kumar and colleagues developed clobetasol propionate-loaded cyclodextrin nanosponge hydrogel for psoriasis treatment, reporting significantly enhanced drug solubility (45-fold increase), controlled *in-vitro* release (86.25% over 24 hours), and superior in -vivo antipsoriatic activity in the mouse tail model compared to conventional hydrogel [41]. The nanosponge formulation demonstrated remarkable increase in orthokeratosis degree and reduction in epidermal thickness, with improved biochemical parameters including oxidative stress biomarkers [41]. Similarly, studies on nanosponge hydrogels containing anti-inflammatory agents have confirmed improved therapeutic outcomes with reduced local and systemic toxicity [32, 33].

AIM AND OBJECTIVES

The present work entitles "Development and Evaluation of Hydrocortisone Nanosponges Loaded Hydrogel for the Topical Treatment of Psoriasis"

Aim

The primary aim of this research is to develop and evaluate hydrocortisone-loaded nanosponges incorporated into a hydrogel system as a novel topical drug delivery approach for the effective treatment of psoriasis. The study focuses on enhancing drug retention, controlled release, skin permeation, stability, and therapeutic efficacy of hydrocortisone through nanosponge-based hydrogel formulation, thereby improving patient compliance and minimizing adverse effects associated with conventional topical therapies.

Objectives

- To enhance the topical delivery and therapeutic efficacy of hydrocortisone by encapsulating the drug into nanosponge carriers.
- To formulate hydrocortisone-loaded nanosponges using suitable polymers and stabilizers for sustained and controlled drug release.
- To incorporate the optimized hydrocortisone nanosponges into a suitable hydrogel base for effective topical application in psoriasis management.
- To use suitable polymers (e.g., ethyl cellulose, polyvinyl alcohol, carbopol) for the preparation of stable and porous nanosponge structures compatible with hydrocortisone.

Drug and Excipients profile

Drug Profile

Hydrocortisone is a corticosteroid widely used in the management of inflammatory and autoimmune skin disorders such as psoriasis, eczema, dermatitis, and allergic skin conditions. It exerts anti-inflammatory, antipruritic, and vasoconstrictive effects by inhibiting the release of inflammatory mediators including prostaglandins and leukotrienes. Hydrocortisone suppresses the migration of polymorphonuclear leukocytes and reverses capillary permeability, thereby reducing erythema, edema, and itching associated with psoriatic lesions [65-67].

Despite its therapeutic effectiveness, the conventional topical administration of hydrocortisone is associated with limitations such as poor skin penetration, rapid drug removal from the skin surface, low retention time, and systemic side effects upon prolonged use. The hyperkeratotic nature of psoriatic skin further reduces drug permeation [68].

To overcome these limitations, hydrocortisone was formulated into nanosponges. Nanosponges are porous polymeric nanocarriers capable of entrapping drugs and providing controlled drug release with enhanced skin penetration and retention [67].

Hydrocortisone (API)

Table: Drug profile of Hydrocortisone

Parameter	Description
Synonyms	Cortisol, Hydrocortisone acetate
IUPAC Name	11β,17α,21-Trihydroxypregn-4-ene-3,20-dione
Molecular Formula	C21H30O5
Molecular Weight	362.46 g/mol
Solubility	Slightly soluble in water; freely soluble in ethanol and methanol
Melting Point	215–220°C [65]
Pharmacodynamics	Anti-inflammatory corticosteroid used for suppression of inflammatory responses
MOA	Inhibits phospholipase A2 activity and inflammatory mediator release
Half Life	Approximately 1.5–2 hours
Absorption	Absorbed through skin after topical application
Distribution	Widely distributed and highly protein bound
Metabolism	Metabolized primarily in liver
Excretion	Excreted through urine [70]

Excipients Profile

In the formulation of hydrocortisone nanosponges loaded hydrogel, excipients such as ethyl cellulose, PVA, dichloromethane, DMSO, Carbopol 934, and triethanolamine play important roles in nanosponge formation and hydrogel preparation.

Ethyl cellulose acts as a polymer forming the nanosponge matrix and provides sustained release characteristics. PVA acts as a stabilizer and emulsifying agent. DCM serves as an organic solvent during nanosponge preparation. DMSO enhances drug solubility and permeation. Carbopol 934 is used as a gelling agent to prepare hydrogel, while triethanolamine neutralizes Carbopol and adjusts pH [71].

Ethyl Cellulose

Table: Excipient profile of Ethyl Cellulose

Parameter	Description
Chemical Name	Ethyl cellulose
State	White odorless powder
Solubility	Insoluble in water; soluble in organic solvents
Application	Sustained release polymer and nanosponge former [72]

Polyvinyl Alcohol (PVA)

Table: Excipient profile of PVA

Parameter	Description
Chemical Name	Polyvinyl alcohol
State	White powder
Solubility	Soluble in water
Application	Stabilizer and emulsifying agent [73]

Dichloromethane (DCM)

Table: Excipient profile of Dichloromethane

Parameter	Description
Chemical Name	Dichloromethane
State	Colorless volatile liquid
Solubility	Miscible with organic solvents
Application	Organic solvent in solvent evaporation technique [74]

Carbopol 934

Table: Excipient profile of Carbopol 934

Parameter	Description
Chemical Name	Carbopol 934
State	White fluffy powder
Solubility	Swells in water
Application	Gelling agent for hydrogel preparation [75]

Formulation of Hydrocortisone Nanosponges

(Solvent Emulsion Evaporation Method)

Hydrocortisone-loaded nanosponges were prepared using solvent emulsion evaporation method employing ethyl cellulose as polymer and PVA as stabilizer [64,85].

Materials Used

Table-Materials used for formulation

Sr. No.	Material	Use	Quantity
1.	Hydrocortisone	API	50 mg
2.	Ethyl Cellulose	Polymer	100 mg
3.	PVA (0.5% w/v)	Stabilizer	100 mL
4.	Dichloromethane	Solvent	10 mL
5.	DMSO	Co-solvent	0.5 mL

Procedure

Preparation of Organic Phase

Ethyl cellulose was dissolved in dichloromethane under magnetic stirring. Hydrocortisone was dissolved separately in DMSO and added into polymeric solution.

Preparation of Aqueous Phase

PVA solution (0.5% w/v) was prepared in distilled water under heating and stirring.

Emulsification

Organic phase was added dropwise into aqueous phase under continuous stirring at 1000–1500 rpm for 2 hours for evaporation of DCM and formation of nanosponges.

Collection and Drying

Nanosponges were collected by centrifugation at 10,000 rpm for 20 minutes and washed with distilled water. The product was dried in vacuum oven at 40°C [76,80,85,86].

Preparation of Hydrocortisone Nanosponge Loaded Hydrogel

Hydrogel containing hydrocortisone-loaded nanosponges was prepared using Carbopol 934 as gelling agent.

Procedure:

1. Carbopol 934 (1% w/w) was dispersed in distilled water with continuous stirring.
2. The dispersion was allowed to hydrate overnight.
3. Prepared nanosponges were incorporated into hydrated Carbopol gel.
4. Propylene glycol was added as humectant and penetration enhancer.
5. Triethanolamine was added dropwise to adjust pH and obtain clear hydrogel.
6. Final hydrogel was packed in airtight containers [71,76,80,87].

Evaluation of Nanosponges and Hydrogel

Particle Size and Polydispersity Index

Particle size and PDI were determined using Dynamic Light Scattering (DLS).

Table No: Polydispersity index [80,88,89]

Polydispersity Index	Nature of Dispersion
0–0.05	Monodisperse
0.05–0.08	Nearly monodisperse
0.08–0.7	Mid-range polydispersity
>0.7	Very polydisperse

Surface Morphology

Surface morphology of nanosponges was studied using Scanning Electron Microscopy (SEM) [80,90].

Zeta Potential

Zeta potential was determined using zeta sizer to evaluate stability of nanosponge dispersion [88,91,92].

Entrapment Efficiency

Entrapment efficiency was determined by dissolving nanosponges in methanol and analyzing drug content [80,86].

$$\text{Entrapment Efficiency (\%)} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 100$$

Production Yield [80,85]

$$\text{Production Yield (\%)} = \frac{\text{Practical mass of nanosponges}}{\text{Theoretical mass of drug + polymer}} \times 100$$

pH Determination

The pH of hydrogel was determined using digital pH meter [79].

Viscosity

Viscosity of hydrogel formulation was measured using Brookfield viscometer [93].

Spreadability

Spreadability was determined by measuring spreading diameter between two glass slides [94].

Drug Content

Drug content was analyzed by dissolving hydrogel in suitable solvent followed by UV or HPLC analysis [78,79].

In-Vitro Drug Release Study

Drug release study was carried out using Franz diffusion cell with phosphate buffer pH 7.4 as receptor medium.

Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically [79,95,96].

Stability Studies

Stability studies were conducted according to ICH guidelines at different storage conditions to evaluate physical appearance, pH, viscosity, and drug content [79,97,98,99].

RESULTS AND DISCUSSION

Preformulation Studies

Organoleptic Properties

The organoleptic properties of Hydrocortisone were evaluated visually to confirm its identity and purity before formulation development.

Table: Organoleptic properties of Hydrocortisone

Property	Hydrocortisone
Appearance	White to off-white crystalline powder
Odor	Odorless
Taste	Slightly bitter
Solubility	Slightly soluble in water, freely soluble in methanol and DMSO

Discussion

The observed organoleptic properties of hydrocortisone matched standard pharmacopeial specifications. The drug appeared as a white crystalline powder without any characteristic odor, confirming its acceptable quality and purity for formulation purposes.

Solubility Studies

Solubility studies were carried out in various solvents to identify suitable solvents for nanosponge preparation and analytical studies.

Table No 5.2: Solubility studies of Hydrocortisone

Solvent	Solubility of Hydrocortisone (mg/mL)
Distilled Water	0.28
Dichloromethane (DCM)	2.5
DMSO	5.4
Ethanol	3.1
Methanol	4.7
Phosphate Buffer pH 7.4	0.65

Discussion

Hydrocortisone exhibited poor aqueous solubility and comparatively higher solubility in organic solvents such as DMSO, methanol, and dichloromethane. These findings supported the use of DCM and DMSO in nanosponge preparation by solvent evaporation method.

Conclusion

The low aqueous solubility of hydrocortisone justified the need for nanosponge formulation to enhance drug solubility and topical delivery.

Melting Point Determination

Melting point determination was performed using capillary melting point apparatus to confirm identity and purity of hydrocortisone.

Table: Melting point determination of Hydrocortisone

Drug	Reported MP (°C)	Observed MP (°C)
Hydrocortisone	215–220	218

Discussion

The observed melting point was found within the official range reported in literature, indicating purity of the drug sample and absence of impurities.

High Performance Liquid Chromatography (HPLC)

Objective

To develop a reliable and reproducible HPLC method for quantitative estimation of hydrocortisone during formulation and evaluation studies.

Chromatographic Conditions

- Instrument: Shimadzu HPLC with UV detector
- Column: C18 Column (250 mm × 4.6 mm, 5 µm)
- Mobile Phase: Methanol: Water (70:30 v/v)
- Flow Rate: 1.0 mL/min
- Detection Wavelength: 242 nm
- Injection Volume: 20 µL
- Run Time: 10 minutes
- Column Temperature: Ambient

Table: Observations from chromatogram of Hydrocortisone

Parameter	Value
Retention Time (Rt)	9.25 min
Peak Shape	Sharp and symmetrical
Peak Height	~0.30 AU
Baseline Interference	None observed
Additional Peaks	None detected
Total Run Time	10 minutes

Discussion

A sharp and symmetrical peak was observed at retention time 9.25 min without any baseline interference. The absence of additional peaks confirmed purity and specificity of the method.

Conclusion

The developed HPLC method was found suitable for estimation of hydrocortisone in nanosponge formulations and drug release studies.

pKa Determination

Table: pKa determination

Drug	pKa Value	Implication
Hydrocortisone	12.5	Weakly acidic steroid compound

Discussion

The pKa value suggested that hydrocortisone remains predominantly unionized at physiological pH, favoring skin permeation and topical absorption.

Post-formulation Studies

Visual Inspection and Surface Morphology

Method

Prepared nanosponge suspensions were visually examined for color, uniformity, and aggregation. SEM analysis was performed to evaluate morphology.

Result

Table: Visual inspection and surface morphology

Observation	Result
Color	White to off-white
Appearance	Homogeneous
Sedimentation	Absent
Morphology (SEM)	Spherical and porous

The prepared formulation appeared homogeneous without phase separation or aggregation. SEM analysis showed spherical porous nanosponges, confirming successful nanosponge formation.

Particle Size and Polydispersity Index (PDI)

Particle size and PDI were measured using Dynamic Light Scattering (DLS).

Table: Particle size and PDI

Formulation	Average Particle Size (nm)	PDI
F1	178.3 ± 4.4	0.216
F2	196.5 ± 5.2	0.231
F3	221.7 ± 5.9	0.286

Discussion

The particle size ranged between 178–222 nm, which is suitable for topical drug delivery. PDI values below 0.3 indicated uniform particle distribution and good formulation homogeneity.

Visual Inspection and Surface Morphology Method

Prepared nanosponge suspensions were visually examined for uniformity, color, turbidity, and sedimentation. Surface morphology was observed under Scanning Electron Microscopy (SEM). Result:

- The formulation appeared as a milky white, homogeneous suspension without any phase separation or aggregation**.**
- SEM images revealed spherical, porous structures with rough surfaces, characteristic of nanosponges.

Table: Visual Inspection and Surface Morphology

Observation	Result
Color	White to off-white
Appearance	Homogeneous, smooth
Sedimentation	Absent
Morphology (SEM)	Spherical, porous

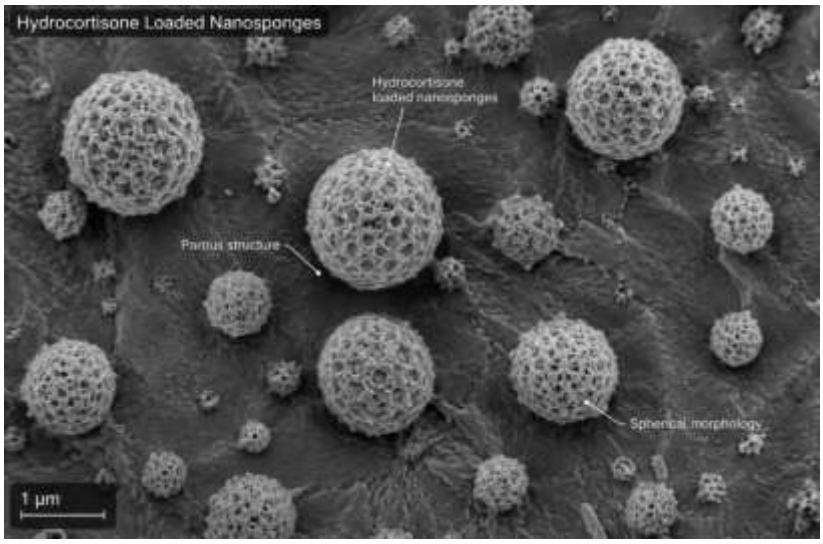

Figure: SEM of Hydrocortisone loaded Nanosponges

Drug Content and Entrapment Efficiency

$$EE\,(\%) = \left(\frac{\text{Total Drug} - \text{Free Drug in Supernatant}}{\text{Total Drug}}\right) \times 100$$

Entrapment efficiency was determined using UV spectrophotometric analysis.

Table: Entrapment efficiency and drug content

Formulation	Entrapment Efficiency (%)	Drug Content (%)
F1	83.8 ± 2.1	88.6 ± 1.5
F2	87.5 ± 1.8	91.3 ± 1.4
F3	81.9 ± 2.3	86.9 ± 1.7

Discussion

The high entrapment efficiency confirmed successful encapsulation of hydrocortisone within nanosponge matrix. F2 formulation showed highest entrapment efficiency due to optimized polymer concentration.

Evaluation of Hydrogel

pH of Hydrogel

Table: pH of hydrogel

Formulation	pH
F1	6.4
F2	6.8
F3	6.6

Discussion

The pH values were found within acceptable skin pH range, indicating suitability for topical application without causing irritation.

Viscosity

Table: Viscosity of hydrogel

Formulation	Viscosity (cps)
F1	4280
F2	4520
F3	4395

Discussion

The viscosity values indicated good consistency and spreadability of hydrogel formulations suitable for topical administration.

Spreadability

Table: Spreadability of hydrogel

Formulation	Spreadability (g·cm/sec)
F1	18.6
F2	20.4
F3	19.1

DISCUSSION

Hydrogel formulations exhibited good spreadability, ensuring easy application over affected psoriatic skin.

Stability Studies

The optimized formulation was subjected to accelerated stability studies at 40°C ± 2°C / 75% RH for one month.

Table: Stability studies

Parameter	Initial	After 1 Month
Appearance	White, homogeneous	No significant change
Particle Size (nm)	178.3 ± 4.4	186.5 ± 5.0
Entrapment Efficiency (%)	87.5 ± 1.8	84.9 ± 2.0
Drug Content (%)	91.3 ± 1.4	88.6 ± 1.5

Discussion

No significant changes were observed in physical appearance, particle size, drug content, or entrapment efficiency after stability studies, indicating acceptable stability of the optimized hydrocortisone nanosponge hydrogel formulation.

CONCLUSION

The present study was undertaken with the objective of developing and evaluating a hydrocortisone nanosponges loaded hydrogel for topical delivery in the management of psoriasis. Psoriasis is a chronic inflammatory skin disorder that requires long-term therapy, and conventional

topical formulations often suffer from limitations such as poor skin penetration, low bioavailability, frequent dosing, and associated side effects. Therefore, the development of an advanced drug delivery system capable of overcoming these limitations was considered essential.

In this research, hydrocortisone was selected as the model drug due to its well-established anti-inflammatory and immunosuppressive activity. The formulation strategy involved the preparation of nanosponges using the emulsion solvent diffusion method, followed by their incorporation into a Carbopol-based hydrogel. This dual delivery system was designed to achieve controlled drug release, enhanced skin retention, and improved therapeutic efficacy.

The nanosponges were successfully formulated with desirable physicochemical characteristics. The optimized formulation exhibited nanoscale particle size, uniform distribution, and porous morphology, which are essential for effective drug encapsulation and release. The entrapment efficiency was found to be satisfactory, indicating efficient incorporation of hydrocortisone within the nanosponge structure. These results confirmed that the selected method was suitable for the preparation of stable and efficient nanocarriers.

The incorporation of nanosponges into the hydrogel base was achieved without any compatibility issues. The prepared hydrogel exhibited acceptable physical properties, including smooth texture, good homogeneity, appropriate viscosity, and excellent spreadability. The pH of the formulation was found to be within the acceptable range for topical application, ensuring minimal risk of skin irritation. These characteristics indicate that the formulation is patient-friendly and suitable for dermal use.

In-vitro drug release studies demonstrated that the nanosponge formulation provided a controlled release profile, which was further prolonged upon incorporation into the hydrogel. The release pattern showed sustained drug delivery over an extended period, with no significant burst release observed. This behavior can be attributed to the porous structure of nanosponges, which act as reservoirs for the drug, and the hydrogel matrix, which provides an additional barrier to drug diffusion. Such a sustained release profile is highly beneficial in reducing the frequency of application and improving patient compliance.

The drug release kinetics analysis indicated that the release mechanism followed diffusion-controlled behavior, best described by the Higuchi and Korsmeyer–Peppas models. This suggests that the drug release is governed by a combination of diffusion and matrix-controlled mechanisms, which is ideal for achieving sustained therapeutic action.

Stability studies conducted under accelerated conditions demonstrated that the formulation remained stable with minimal changes in drug content and physical properties over time. This confirms the robustness and suitability of the formulation for long-term storage and practical use.

Overall, the findings of the study clearly indicate that the hydrocortisone nanosponges loaded hydrogel is a promising and effective topical drug delivery system. The formulation successfully addresses the limitations of conventional therapies by providing controlled drug release, enhanced skin permeation, improved stability, and better patient compliance. The integration of nanosponges with a hydrogel base offers a synergistic effect, resulting in a dual-controlled release system that enhances therapeutic performance.

In conclusion, the developed formulation represents a significant advancement in topical drug delivery for psoriasis management. It has the potential to improve treatment outcomes, reduce side effects, and enhance patient adherence. The study provides a strong foundation for further

research and development in this area and supports the application of nanotechnology-based systems in dermatological therapy.

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