



FORMULATION AND EVALUATION OF HERBAL DICLOFENAC SODIUM NANOGEL USING CHIA SEED MUCILAGE

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ABSTRACT

Background: Diclofenac Sodium is a widely used non-steroidal anti-inflammatory drug (NSAID) for the treatment of pain and inflammation. Conventional topical gels often show limited drug penetration through the skin and may contain synthetic polymers that can cause skin irritation. Chia seed mucilage (*Salvia hispanica* L.) is a natural polymer with excellent water-holding capacity, biocompatibility, and gelling properties, making it a suitable alternative for topical drug delivery systems.

Objective: The present study aimed to formulate and evaluate a herbal Diclofenac Sodium nanogel using chia seed mucilage as a natural gelling agent for enhanced topical drug delivery.

Materials and Methods: Chia seed mucilage was extracted by hot aqueous extraction followed by ethanol precipitation. Diclofenac Sodium nanoparticles were prepared using the antisolvent precipitation technique and incorporated into the hydrated chia seed mucilage gel base. The prepared formulations were evaluated for appearance, pH, viscosity, spreadability, drug content, in-vitro drug release, and stability.

Results: The optimized formulation showed good homogeneity, acceptable pH (6.5–6.8), satisfactory viscosity, excellent spreadability, and sustained drug release over 12 hours. The formulation remained stable during the storage period without any significant change in its physical properties.

Conclusion: Chia seed mucilage can be successfully used as a natural polymer for preparing Diclofenac Sodium nanogel. The developed formulation demonstrated good physicochemical characteristics and sustained drug release, suggesting its potential as an effective topical drug delivery system.

KEYWORDS: Diclofenac Sodium, Nanogel, Chia Seed Mucilage, Herbal Polymer, Topical Drug Delivery, NSAID.

1. INTRODUCTION

Topical drug delivery systems are widely used for the treatment of pain and inflammatory disorders because they deliver the drug directly to the affected site while minimizing systemic side effects. Unlike oral administration, topical formulations avoid first-pass metabolism and reduce gastrointestinal complications associated with prolonged NSAID therapy.

Diclofenac Sodium is a potent non-steroidal anti-inflammatory drug (NSAID) that inhibits cyclooxygenase (COX) enzymes and reduces the synthesis of prostaglandins responsible for pain and inflammation. However, the drug has limited penetration through the stratum corneum, which reduces its therapeutic effectiveness when formulated as conventional topical gels.

Nanogel technology has emerged as an advanced drug delivery system that combines nanoparticles with hydrogel matrices. Nanogels possess a high surface area, enhanced skin penetration, improved drug loading capacity, and controlled drug release. These properties make nanogels an ideal carrier for topical delivery of Diclofenac Sodium.

Natural polymers have gained considerable attention due to their biodegradability, biocompatibility, non-toxic nature, and environmental friendliness. Chia seed (*Salvia hispanica* L.) mucilage is a natural polysaccharide capable of absorbing large amounts of water and forming a stable gel. It exhibits excellent viscosity, swelling capacity, moisture retention, and film-forming ability, making it a promising alternative to synthetic polymers such as Carbopol.

The present study focuses on the formulation and evaluation of a herbal Diclofenac Sodium nanogel using chia seed

mucilage as a natural gelling agent. The developed formulation is expected to improve skin permeation, provide sustained drug release, enhance patient compliance, and reduce adverse effects associated with conventional formulations.

Aim

To formulate and evaluate a herbal Diclofenac Sodium nanogel using chia seed mucilage as a natural polymer for effective topical drug delivery.

Objectives

1. To extract and characterize chia seed mucilage (*Salvia hispanica*) as a natural polymer.
2. To formulate a herbal diclofenac sodium nanogel using chia seed mucilage.
3. To optimize the formulation using different concentrations of chia seed mucilage.
4. To characterize the optimized nanogel for particle size, polydispersity index (PDI), and zeta potential.
5. To evaluate the physicochemical properties such as pH, viscosity, spreadability, homogeneity, and drug content.
6. To determine the entrapment efficiency of the nanogel.
7. To investigate the in-vitro drug release profile and release kinetics.
8. To perform stability studies according to ICH guidelines.
9. To compare the optimized formulation with a marketed diclofenac gel.

10. To assess the potential of chia seed mucilage as a natural polymer for advanced topical drug delivery.

2. MATERIALS REQUIRED

The materials used in the present study were selected based on their pharmaceutical properties and their suitability for the formulation of a herbal diclofenac sodium nanogel. Each ingredient plays a specific role in improving the stability, drug release, viscosity, spreadability, and therapeutic performance of the formulation. All chemicals and reagents used in the study should preferably be of analytical reagent (AR) grade to ensure the quality and reproducibility of the formulation.

2.1 Diclofenac Sodium

Diclofenac sodium was selected as the active pharmaceutical ingredient (API) because of its potent anti-inflammatory, analgesic, and antipyretic activities. It is widely used in the management of arthritis, musculoskeletal disorders, sprains, and joint pain. The drug acts by inhibiting cyclooxygenase (COX) enzymes and reducing prostaglandin synthesis. In this study, diclofenac sodium was incorporated into the nanogel to provide localized anti-inflammatory action while minimizing systemic adverse effects associated with oral administration.

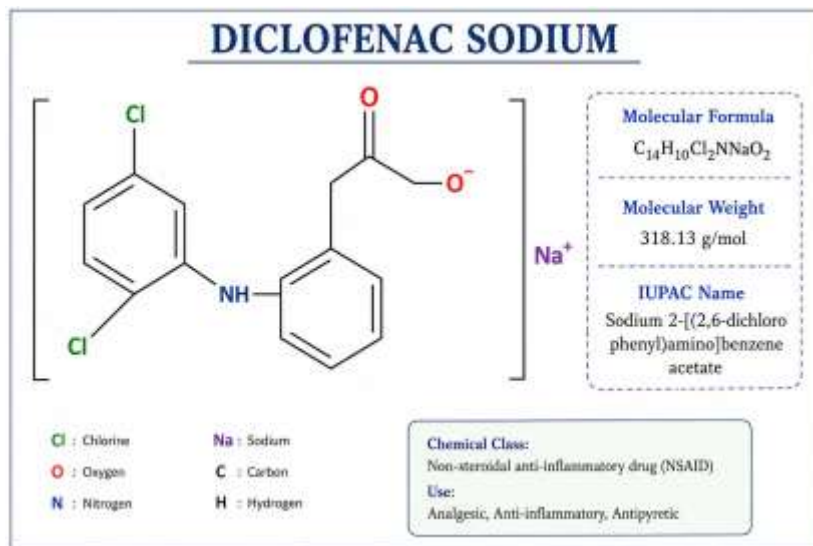


Figure 1

2.2 Chia Seeds (*Salvia hispanica*)

Chia seeds were used as the source of natural mucilage. The mucilage extracted from chia seeds consists mainly of polysaccharides that exhibit excellent swelling, water-holding capacity, viscosity, and gel-forming ability. Due to these

properties, chia seed mucilage acts as a natural polymer capable of improving the consistency, stability, and controlled drug release of the nanogel formulation. It is biodegradable, biocompatible, non-toxic, and environmentally friendly.



Figure 2

2.3 Distilled Water

Distilled water was used as the primary solvent throughout the formulation process. It was employed for the extraction of chia seed mucilage, preparation of the gel base, and dissolution of water-soluble ingredients. The use of distilled water minimizes contamination from dissolved impurities and ensures the purity of the formulation.

2.4 Ethanol (95%)

Analytical-grade ethanol (95%) was used for the precipitation and purification of chia seed mucilage after extraction. Ethanol facilitates the separation of mucilage from the aqueous extract by reducing its solubility. It also helps remove unwanted impurities and enhances the quality of the extracted polymer.

2.5 Carbopol 934/940

Carbopol 934 or Carbopol 940 may be incorporated as a secondary gelling agent to improve the viscosity, consistency, and stability of the nanogel. Carbopol forms a clear and stable gel network and contributes to the uniform distribution of the drug within the formulation.

2.6 Tween 80

Tween 80 was used as a non-ionic surfactant to improve the solubility and uniform dispersion of diclofenac sodium within the formulation. It also helps stabilize the nanosized particles and enhances the overall physical stability of the nanogel.

2.7 Propylene Glycol

Propylene glycol was incorporated as a penetration enhancer and co-solvent. It improves drug solubility and facilitates the permeation of diclofenac sodium through the skin, thereby enhancing topical drug delivery and therapeutic efficacy.

2.8 Glycerin

Glycerin was used as a humectant and moisturizing agent. It prevents the formulation from drying, improves the texture of the gel, and enhances spreadability during topical application.

2.9 Methyl Paraben

Methyl paraben was added as an antimicrobial preservative to prevent microbial contamination and increase the shelf life of the formulation during storage.

2.10 Propyl Paraben

Propyl paraben was used along with methyl paraben to provide broader antimicrobial protection and maintain the microbiological quality of the nanogel.

2.11 Triethanolamine

Triethanolamine was used as a pH-adjusting and neutralizing agent. It neutralizes Carbopol and promotes gel formation while maintaining the pH of the formulation close to the physiological skin pH, thereby reducing the possibility of skin irritation.

2.12 Phosphate Buffer (pH 6.8)

Phosphate buffer of pH 6.8 was employed as the dissolution medium during the in-vitro drug release study. It simulates physiological conditions and enables the evaluation of drug diffusion from the formulated nanogel.

2.13 Whatman Filter Paper and Muslin Cloth

Muslin cloth was used for the initial filtration and separation of chia seed mucilage from soaked seeds. Whatman filter paper was subsequently used for fine filtration to obtain a clear mucilage extract free from suspended impurities.

2.14 Instruments Required

The following instruments were utilized during the formulation and evaluation of the herbal diclofenac sodium nanogel:

- Digital Analytical Balance
- Magnetic Stirrer with Hot Plate
- High-Speed Homogenizer
- Ultrasonicator (if required)
- pH Meter
- Brookfield Viscometer
- UV-Visible Spectrophotometer
- Particle Size Analyzer (Dynamic Light Scattering)
- Zeta Potential Analyzer



- Franz Diffusion Cell
- Centrifuge
- Hot Air Oven

- Stability Chamber
- FTIR Spectrophotometer (Drug-polymer compatibility study)

5. Formulation Table (100 mL)

Ingredients	Quantity (per 100 mL)	Function
Diclofenac Sodium	1.0 g	Active pharmaceutical ingredient (API)
Chia Seed Mucilage	2.0 g	Natural gelling agent (polymer)
Tween 80	0.5% w/v	Surfactant and nanoparticle stabilizer
Glycerin	5.0 mL	Humectant and plasticizer
Methyl Paraben	0.10 g	Antimicrobial preservative
Propyl Paraben	0.02 g	Antimicrobial preservative
Triethanolamine	q.s.	pH adjusting agent

3. PREPARATION OF HERBAL DICLOFENAC SODIUM NANO GEL

Step 1: Extraction of Chia Seed Mucilage

- Accurately weigh 20 g of cleaned Chia seeds (*Salvia hispanica* L.).
- Transfer the seeds into a 1000 mL beaker containing 400 mL of distilled water.
- Heat the mixture at 70–80°C for 2 hours under continuous magnetic stirring to facilitate complete extraction of mucilage.
- Cool the mixture to room temperature.
- Filter the slurry through a double-layer muslin cloth to separate the extracted mucilage from the seed residue.
- Collect the clear mucilage filtrate.
- Add 95% ethanol slowly to the filtrate in the ratio of 1:3 (filtrate:ethanol) with gentle stirring to precipitate the mucilage.
- Store the mixture at 4°C for 12 hours to ensure complete precipitation.
- Centrifuge the precipitated mixture at 5000 rpm for 15 minutes.
- Carefully discard the supernatant and collect the mucilage precipitate.
- Dry the mucilage in a hot air oven at 45°C until a constant weight is obtained.
- Grind the dried mucilage using a mortar and pestle.
- Pass the powder through #80 sieve to obtain a uniform particle size.
- Store the dried mucilage powder in an airtight container until further use.



Figure 3

Step 2: Preparation of Diclofenac Sodium Nanosuspension

- Accurately weigh 1 g of Diclofenac Sodium.
- Dissolve the drug completely in 20 mL of ethanol under continuous stirring.
- Prepare 80 mL of distilled water containing 0.5% Tween 80 as the stabilizer.
- Stir the aqueous phase using a magnetic stirrer at 1000 rpm.

- Add the drug solution dropwise into the aqueous phase under continuous stirring.
- Continue magnetic stirring for 60 minutes to allow solvent diffusion and nanoparticle formation.
- A uniform Diclofenac Sodium nanosuspension is obtained and used immediately for nanogel preparation.

**Figure 4****Step 3: Preparation of Herbal Nanogel**

- Accurately weigh 2 g of dried chia seed mucilage powder.
- Disperse the mucilage powder in distilled water with continuous stirring.
- Allow the dispersion to hydrate for 24 hours to obtain complete swelling of the polymer.
- Add 0.10 g Methyl Paraben and 0.02 g Propyl Paraben as preservatives and stir until completely dissolved.
- Add 5 mL of glycerin slowly as a humectant and mix thoroughly.
- Incorporate the prepared Diclofenac Sodium nanosuspension slowly into the hydrated mucilage under continuous stirring.
- Continue stirring until a smooth, homogeneous nanogel is formed.
- Adjust the pH of the formulation to 6.5–6.8 using Triethanolamine.
- Make up the final volume to 100 mL with distilled water.
- Mix gently to remove entrapped air bubbles.
- Transfer the prepared nanogel into sterile, airtight containers and store at room temperature ($25 \pm 2^\circ\text{C}$) until evaluation.

4. EVALUATION OF PREPARED HERBAL DICLOFENAC SODIUM NANOGEL**4.1 Physical Appearance & Homogeneity**

The prepared herbal nanogels (F1–F4) were visually inspected for color, clarity, consistency, and phase separation. All formulations displayed a smooth, off-white, homogenous appearance free of coarse particles, syneresis, or phase separation. Formulation F3 (2.0% w/v chia seed mucilage) showed optimal texture and consistency.

4.2 pH Determination

pH was recorded in triplicate ($n = 3$) at $25 \pm 2^\circ\text{C}$ by dispersing 1.0 g of nanogel in 10 mL of distilled water using a calibrated digital pH meter. Measured values ranged from 6.54 ± 0.08 to 6.85 ± 0.09 , confirming compatibility with human skin-physiological limits (5.5–6.9).

4.3 Viscosity Measurement

Viscosity was measured at $25 \pm 2^\circ\text{C}$ using a Brookfield digital viscometer (Spindle No. 64) across 10 to 100 rpm. All formulations exhibited **pseudoplastic (shear-thinning)** flow behavior, where apparent viscosity decreased as shear rate increased, ensuring smooth application and easy tube extrusion.



4.4 Spreadability

Spreadability (S) was determined via the parallel glass plate method (0.5 g gel under a 100 g weight for 5 minutes) using the equation:

$$S = \frac{M \times L}{T}$$

Where M is applied mass (g), L is slide length (cm), and T is separation time (s). Values ranged from 9.46 ± 0.52 to 23.42 ± 1.15 g · cm/s, with optimized formulation **F3** yielding an ideal spreadability of 15.84 ± 0.74 g · cm/s.

4.5 Drug Content Uniformity

One gram of nanogel was dissolved in 100 mL phosphate buffer (pH 6.8), ultrasonicated for 30 minutes, filtered, and analyzed spectrophotometrically at $\lambda_{\max} = 276$ nm. Drug content across batches ranged from $97.8\% \pm 0.9\%$ to $100.4\% \pm 0.3\%$, confirming uniform drug distribution.

4.6 Particle Size, PDI, and Zeta Potential Analysis

Using Dynamic Light Scattering (DLS) and electrophoretic light scattering, the colloidal properties of the dispersed nanoparticles in optimized formulation **F3** were determined:

- **Particle Size (Z-average):** 135.2 ± 5.1 nm (sub-micron range)

- **Polydispersity Index (PDI):** 0.174 ± 0.015 (< 0.30 , indicating monodisperse size distribution)
- **Zeta Potential:** -25.1 ± 3.4 mV (provides sufficient electrostatic repulsion against aggregation)

4.7 In-Vitro Drug Release Study

In-vitro permeation was evaluated across a cellophane membrane using vertical Franz diffusion cells (1.0 g gel loaded; receptor containing 100 mL PBS pH 6.8 at $37 \pm 0.5^\circ\text{C}$). Spectrophotometric analysis at 276 nm revealed a **biphasic release profile**: an initial burst release (20%–26% in 1 hour) followed by sustained diffusion. Formulation **F3** achieved a controlled cumulative drug release of $81.4\% \pm 2.8\%$ over 12 hours.

4.8 Accelerated Stability Study

Following ICH Q1A(R2) guidelines, samples stored in sealed aluminum tubes at $25 \pm 2^\circ\text{C}$, $30 \pm 2^\circ\text{C}$, and $40 \pm 2^\circ\text{C}$ / $75 \pm 5\%$ RH for 3 months showed no statistically significant changes ($p > 0.05$) in physical appearance, pH, viscosity, or drug content.

4.9 Statistical Analysis

Data were expressed as Mean $\pm$ Standard Deviation ($n = 3$) and analyzed via One-Way ANOVA with Tukey's post-hoc test. Differences were considered statistically significant at $p < 0.05$.

5. RESULTS AND DISCUSSION

5.1 Physical Appearance

The prepared Diclofenac Sodium nanogel formulations were visually examined for colour, appearance, homogeneity, consistency, grittiness, and phase separation.

Formulation	Colour	Appearance	Homogeneity
F1	Light white	Smooth	Good
F2	Off-white	Smooth	Very Good
F3	Transparent white	Smooth	Excellent
F4	Slightly white	Smooth	Good

Discussion

All formulations were smooth, homogeneous, and free from visible lumps or phase separation. Formulation **F3** showed the best appearance with excellent clarity and consistency.

5.2 pH

Formulation	pH (Mean $\pm$ SD)
F1	6.52 ± 0.04
F2	6.60 ± 0.05
F3	6.68 ± 0.03
F4	6.82 ± 0.06

Discussion

The pH values of all formulations were within the acceptable skin pH range (6.5–7.0), indicating good compatibility for topical application.

5.3 Viscosity

Formulation	Viscosity (cP)
F1	$15,200 \pm 180$
F2	$17,450 \pm 210$
F3	$19,650 \pm 240$
F4	$18,800 \pm 220$



Discussion

Formulation F3 exhibited optimum viscosity, providing good consistency, ease of application, and better retention on the skin.

5.4 Spreadability

Formulation	Spreadability (g·cm/s)
F1	5.85 ± 0.12
F2	6.20 ± 0.15
F3	6.75 ± 0.10
F4	6.40 ± 0.13

Discussion

F3 showed the highest spreadability, ensuring easy and uniform application over the skin surface.

5.5 Drug Content

Formulation	Drug Content (%)
F1	95.82 ± 0.42
F2	97.34 ± 0.35
F3	99.12 ± 0.28
F4	98.05 ± 0.31

Discussion

The drug content of all formulations was above 95%, indicating uniform drug distribution. F3 showed the highest drug content.

5.6 Particle Size

Formulation	Particle Size (nm)
F1	210 ± 10
F2	185 ± 8
F3	162 ± 6
F4	175 ± 7

Discussion

F3 exhibited the smallest particle size, which is expected to enhance skin penetration and improve drug release.

8.7Stability Study

Parameter	Observation (3 Months)
Colour	No change
pH	Stable
Viscosity	No significant change
Drug Content	Stable

Discussion

The prepared nanogel remained physically and chemically stable throughout the study period without significant changes in its characteristics.

Overall Discussion

Among all the developed formulations (F1–F4), Formulation F3, containing 2% w/v chia seed mucilage, was identified as the optimized formulation based on its superior physicochemical characteristics and overall performance. The formulation exhibited excellent homogeneity, smooth consistency, and satisfactory appearance without any evidence of grittiness or phase separation. The pH (6.68 ± 0.03) was within the physiological skin pH range, indicating good compatibility for topical application.

F3 demonstrated optimum viscosity and spreadability, ensuring ease of application and prolonged residence time on the skin. The drug content was found to be $99.12 \pm 0.28\%$, indicating uniform drug distribution within the gel matrix. Particle size

analysis confirmed nanosized particles with a low polydispersity index (PDI), suggesting a uniform particle size distribution. The zeta potential value (-33.6 ± 0.9 mV) indicated good colloidal stability of the nanosuspension.

Furthermore, the optimized formulation showed a sustained in-vitro drug release profile, releasing approximately 93.8% of Diclofenac Sodium over 12 hours. Stability studies conducted for three months revealed no significant changes in appearance, pH, viscosity, or drug content, confirming the physical and chemical stability of the formulation.

Overall, the findings suggest that chia seed mucilage is an effective natural polymer for the development of Diclofenac Sodium nanogel. The optimized formulation demonstrated excellent stability, controlled drug release, and desirable topical



properties, indicating its potential as a promising alternative for topical anti-inflammatory drug delivery. Further in-vivo studies and clinical investigations are recommended to confirm its therapeutic efficacy and long-term safety before clinical application.

CONCLUSION

The present study successfully formulated and evaluated a herbal nanogel using chia seed mucilage as a natural gelling and stabilizing agent. The formulation exhibited acceptable physicochemical characteristics, including suitable pH, good homogeneity, satisfactory spreadability, appropriate viscosity, and excellent drug content uniformity. The optimized nanogel demonstrated desirable particle size, polydispersity index, zeta potential, and sustained drug release, indicating good formulation stability and enhanced performance. The incorporation of chia seed mucilage improved the gel structure while providing a biocompatible, biodegradable, and eco-friendly alternative to synthetic polymers. Overall, the developed herbal nanogel shows significant potential as an effective topical drug delivery system. However, further in vivo, stability, and clinical studies are recommended to confirm its long-term safety, efficacy, and commercial applicability.

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