Development And Evaluation Of A Nanostructured Herbal Gel Containing Helicteres Isora For Anti-Inflammatory Activity: A Research

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ABSTRACT

Background: Although the body uses inflammation as a defence against damage and infection, persistent inflammation can result in dangerous illnesses. Long-term usage of conventional anti-inflammatory medications frequently results in adverse effects, such as skin rashes and gastric irritation. As a result, the safety and therapeutic potential of herbal medications are drawing attention. Flavonoids, tannins, and phenolic compounds, bioactive substances with anti-inflammatory and antioxidant properties, are found in Helicteres isora Herbal preparations; however, they could exhibit low bioavailability and restricted skin penetration. Because they increase the stability, controlled drug release, and permeability of herbal medications, nanogel drug delivery methods are employed to get around these restrictions. The development and assessment of a nanostructured herbal gel containing Helicteres isora to improve therapeutic efficacy and enhance anti-inflammatory activity are the main goals of this work.

Materials and Methods: Helicteres isora fruits were gathered, dried, ground into a powder, and then extracted with ethanol. Soy lecithin and Tween-80 were used to create a nanodispersion via solvent evaporation and ultrasonication. To increase skin penetration, the resulting nanosuspension was incorporated into a Carbopol 934 gel base containing propylene glycol as a penetration enhancer. The appearance, homogeneity, pH, viscosity, spreadability, particle size, and drug content of the formulation were assessed. Franz diffusion cells were used to investigate in vitro drug release. Additionally assessed were the stability and anti-inflammatory effects of the improved nanogel formulation.

Results: Helicteres isora-containing nano-structured herbal gel demonstrated good appearance, homogeneity, and satisfactory physicochemical characteristics. The formulation's pH was determined to be 6.4 ± 0.12, suggesting that it is suitable for skin application. The drug content was found to be 96.7 ± 1.4%, indicating that the herbal extract was uniformly distributed throughout the gel. Additionally, the formulation demonstrated good viscosity, spreadability, and sustained in vitro drug release, indicating its promise as a topical anti-inflammatory nanogel system.

Conclusion: According to the results, the nano-structured herbal gel containing Helicteres isora can release the herbal medication over an extended period and could be a promising topical delivery method for the treatment of inflammation. The formulation demonstrated good drug content, appropriate skin compatibility, and satisfactory physicochemical characteristics, indicating its efficacy as a novel herbal nanogel system.

Keywords: Nanotechnology, Herbal medicines, Anti-inflammatory, Nanogels, Drug delivery.

How to cite this article: Patra BS, Wamankar S, Chandra D, Sahu S, Nishad JK, Neelam. Development and evaluation of a nanostructured herbal gel containing Helicteres isora for anti-inflammatory activity: a research. Int J Drug Deliv Technol. 2026;16(74s): 2220-2228. DOI: 10.25258/ijddt.16.74s.184

INTRODUCTION

In many chronic illnesses, including rheumatoid arthritis, osteoarthritis, and skin-inflamed problems, inflammation is the primary source of pain and tissue damage. There is a need for safer and more efficient herbal medicine delivery methods because long-term usage of conventional anti-inflammatory therapy frequently results in side effects. Because of their minimised adverse effects, biocompatibility, and therapeutic efficacy, herbal medications have attracted considerable research interest. [1] [17]

The botanical medicine Helicteres isora has long been utilised for its analgesic, antibacterial, antioxidant, and anti-inflammatory qualities. Although the plant's bioactive phytoconstituents exhibit intriguing medicinal activity, their low skin penetration and poor solubility may limit their efficacy in traditional use. [30] An innovative method for enhancing the stability, permeability, and controlled release of herbal medications is the use of nanostructured drug delivery devices. Herbal extract boosts bioavailability, enhances drug penetration through the skin and provides sustained therapeutic effects when incorporated into a nanogel-based system. Other benefits of nanogels include their non-greasy texture, simplicity of application, improved patient compliance, and extended drug release. [17] [18] [38]

Thus, the synthesis and assessment of a nanostructured herbal gel based on Helicteres isora for anti-inflammatory activity is the main goal of this study. To assess the formulated nanogel's suitability as a topical drug delivery system, physicochemical properties, drug content, spreadability, pH, viscosity, and in vitro drug release were assessed. [30] [38] [14] [15] [20] [22]

MATERIALS AND METHOD

Materials:

Helicteres isora extraction served as the active herbal ingredient in the materials used in this study. On December 24, 2025, the Department of Botany at Government V.Y.T. P.G. College, Durg (C.G.) carried out the identification and authentication of the plant material. The nano dispersion was prepared using Tween-80 and soy lecithin. It was discovered that soy lecithin has a 1.4% loss on drying (LOD). Propylene glycol served as a penetration enhancer, & Carbopol 934 as the gelling agent. Triethanolamine was added to alter the pH, and methyl paraben was used as a preservative. The solvents utilised were distilled water and ethanol. Every chemical and reagent utilised was of analytical quality. [30] [32] [29]

Methods:

Extraction procedure of Helicteres isora:

The dried Helicteres isora fruits were gathered, cleaned, shade-dried, and then ground into a coarse powder using a mechanical grinder. A Soxhlet apparatus was used to extract 70% ethanol from about 100 g of powdered substance in a thimble over the course of 6–8 hours. Until the plant material was exhausted, the extraction process was carried out. After filtering and concentrating the extract, the solvent was evaporated at a regulated temperature to produce a semisolid bulk. The extract's practical yield was 18.5 g, or 18.5% of the total. [30]

Phytochemical screening:

Using common chemical tests, the ethanolic extract of Heliteres isora was first screened for phytochemicals. The extract contained tannins, alkaloids, flavonoids, phenolic compounds, coumarins, and carbohydrates, according to the phytochemical analysis shown in table no 1. The anti-inflammatory, antioxidant, and therapeutic properties of these bioactive phytoconstituents demonstrate the plant extract's therapeutic potential for the creation of herbal nanogel. [38] [6]

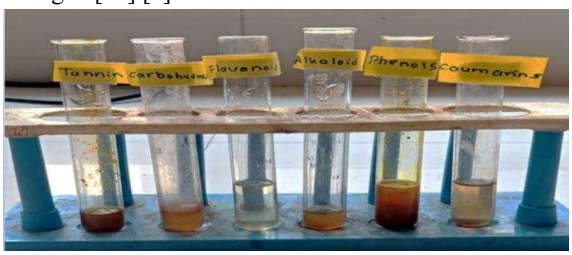

Figure 01 Phytochemical screening of Helicteres isora

Preparation of Nano dispersion:

The Helicteres isora extract-containing nanogel formulation was created using the solvent evaporation and ultrasonication methods. The organic phase was intended by dissolving 1 g of precisely weighed plant extract and 2 g of soy lecithin in 20 mL of ethanol. In a separate experiment, the aqueous phase consisted of 25 mL of distilled water and 1 mL of Tween-80. To create a

coarse dispersion, the aqueous phase was gradually incorporated into the organic phase while being continuously stirred magnetically at 1000 rpm. To generate a stable Nano dispersion and minimise particle size, the obtained dispersion was ultrasonicated for 10 minutes. [30] [38] [24] [29]

Table 01: Observation of phytochemical screening

Phytochemical	Method	Observation	Result
Tannins	Ferric Chloride Test	Dark brown precipitate	Present
Carbohydrates	Benedict's Reagents Test	Yellow/orange color	Present
Flavonoids	Alkaline reagent test	Pale yellow color	Slightly Present
Alkaloids	Mayer's Test	Turbidity/precipitate	Present
Phenols	Ferric Chloride Test	Dark coloration	Strongly Present
Coumarins	NaoH TEST	Light yellow color	Present

Incorporation into gel base:

1 gm of Carbopol 934 was dissolved in 50 ml of distilled water and left to hydrate for a complete day to prepare the gel base. After that, the gel base was continuously stirred to include the tailored Nano dispersion. Methyl paraben (0.2 g) was employed as a preservative, while propylene glycol (5 mL) was used as a humectant and penetration enhancer. To achieve a smooth, homogeneous nanogel composition and control the pH, triethanolamine was finally added dropwise. [38] [32] Among all samples, the F2 formulation exhibited better particle-size distribution, homogeneity, spreadability, drug content, and sustained drug-release profile; therefore, it was selected as the optimised nanogel formulation.

Table 02: Composition of Helicteres isora Nanogel Formulation

Ingredients	F1	F2	F3	Function
Helicteres isora Extract	1 g	1 g	1 g	Active drug
Soy Lecithin	1 g	2 g	3 g	Lipid carrier
Tween-80	0.5 mL	1 mL	1.5 mL	Surfactant
Ethanol	20 mL	20 mL	20 mL	Organic solvent
Distilled Water	50 mL	50 mL	50 mL	Aqueous phase
Carbopol 934	1 % w/w	1 % w/w	1 % w/w	Gelling agent
Propylene Glycol	5 mL	5 mL	5 mL	Penetration enhancer
Triethanolamine	q.s.	q.s.	q.s.	pH adjustment
Methyl Paraben	0.20%	0.20%	0.20%	Preservative

3. Evaluation of nanogel

3.1 Physicochemical Test

3.1.1 Appearance, Homogeneity

The formulated Helicteres isora nanogel formulations were visually assessed for colour, clarity, consistency, phase separation, and overall appearance shown in table no 3.

Result: There was no discernible grittiness or phase separation, and all formulations had a homogeneous, smooth, and semisolid appearance. With a glossy brownish appearance and acceptable consistency, the

optimised formulation (F2) demonstrated good homogeneity.

3.1.2 pH

A calibrated digital pH meter was used to measure the pH of the manufactured Helicteres isora nanogel formulations. The pH was tested at room temperature after dispersing around 1 g of gel in 10 mL of distilled water. [30] [38]

Table 04: pH of Nanogel Formulations

Formulation	pH (Mean ± SD)
F1	6.4
F2	6.8
F3	7.2

Result: All of the formulations' pH levels were found to be within the permitted range for topical administration, indicating good skin compatibility. The pH of the optimum formulation (F2) was 6.8 ± 0.2.

3.1.3 Spreadability

Spreadability of the nanogel formulations was evaluated by placing the gel between two glass slides and applying a specific weight over the upper slide. It was noted how long it took for the upper slide to travel a specific distance. [38] [14]

Table 5: Spreadability of Nanogel Formulations

Formulation	Spreadability (g·cm/sec)
F1	12.4
F2	15.8
F3	13.1

Result: The optimised formulation (F2) exhibited good spreadability, indicating easy application over the skin surface and better patient compliance.

3.1.4 Viscosity Determination

Using an Ostwald Viscometer, the optimised Helicteres isora Nanogel's viscosity was determined to be 1057 ± 8.5 cP at ambient temperature (25 ± 2°C). The obtained viscosity demonstrated the nanogel formulation's good consistency, smooth texture, and adequate spreadability, making it appropriate for topical application. [30] [38]

Table 03: Appearance and Homogeneity of Nanogel Formulation

Formulation	Appearance	Colour	Consistency	Homogeneity	Phase Separation
F1	Smooth semisolid gel	Light Brown	Slightly thin	Good	Absent
F2	Smooth glossy gel	Brown	Optimum	Excellent	Absent
F3	Thick semisolid gel	Dark Brown	Highly viscous	Good	Absent

Table 06: Viscosity Determination of Nanogel Formulation

S. No.	Sample	Drug Content (%)
1	**F1**	**95.8**
2	**F2**	**96.7**
3	**F3**	**97.6**

Result: With a drug content of 96.7 ± 1.2% in the optimised nanogel formulation, the herbal extract was distributed uniformly throughout the gel matrix, demonstrating good formulation consistency.

3.2 Particle & Stability Analysis

3.2.1 Particle Size

Dynamic Light Scattering (DLS) was used to analyse the improved Helicteres isora nanogel's particle size. A stable nanogel system was successfully created, as evidenced by the formulation's nanosized particles with good homogeneity. [30]

Table 08: Determination of particle size

Formulation	Particle Size (nm)	PDI	Observation
F1	210	0.36	Moderate distribution
F2 (Optimised)	178	0.31	Improved uniformity
F3	145	0.28	Stable nanoparticles

Result: The F2 formulation showed uniform nanosized particles with good stability, demonstrated by the lowest particle size. Results showed that F2 was the best nanogel formulation for topical drug delivery.

3.2.2 PDI (Poly Dispersity Index)

The polydispersity index (PDI) shows how evenly the particle sizes are spread out in a nanogel formulation. [38] [24]

PDI < 0.3 → Uniform and stable nanoparticles

Higher PDI → Non-uniform particle distribution

Table 09: Determination of PDI

Formulation	PDI	Interpretation
F1	0.36	Moderate distribution
F2 (Optimised)	0.31	Improved uniformity
F3	0.28	Uniform nanoparticles

Result: The PDI values show that the formulations had a good dispersion of nanomaterials. F2 had been selected as the best formulation because it had the most uniformly distributed particles.

3.2.3 Freeze-thaw study

The F2's freeze-thaw stability analysis. The stability of the *Helicteres isora* nanogel formulation during temperature fluctuations was assessed. Three consecutive freeze-thaw cycles, each lasting 24 hours, were applied to the formulation between −20°C and 25 ± 2°C. The formulation's appearance, homogeneity, viscosity, and phase separation did not significantly alter when the investigation was over. The F2 formulation showed good stability during handling and storage conditions, as evidenced by the physicochemical characteristics being within acceptable bounds. [30] [38] [15] [16]

Table 10: Freeze-thaw study

Evaluation Parameter	Before Study	After 3 Cycles	Observation
Appearance	Smooth translucent gel	No change	Stable
Homogeneity	Uniform	Uniform	No phase separation
pH	6.7	6.6	Stable

Spreadability (g·cm/sec)	7.1	7	Slight variation
Viscosity (cP)	4095	4058	Stable consistency
Drug Content (%)	95.8	95.1	Negligible drug loss
Particle Size (nm)	178	183	Stable nanosize
PDI	0.31	0.33	Acceptable distribution

Result: The F2's freeze-thaw stability analysis. After three freeze-thaw cycles, the appearance, homogeneity, viscosity, and phase separation of the Helicteres isora nanogel formulation did not significantly alter. The formulation's stability was demonstrated by the physicochemical characteristics, which included pH, drug content, particle size, and PDI, all of which stayed within permissible bounds.

***In-vitro* drug release study**

The Helicteres isora nanogel formulations were applied to an in vitro drug release assay at 37 ± 0.5°C using phosphate buffer pH 6.8. Over 12 hours, the improved F2 formulation showed a consistent and regulated drug release pattern. The formulation demonstrated effective extended-release behaviour appropriate for topical application, as evidenced by the progressive drug diffusion from the nanogel matrix. [30] [38] [15] [24] [16]

Table 11: In Vitro Drug Release Study of F2 Nanogel Formulation

Time (h)	Cumulative Drug Release (%)
0	0
1	18.4
2	31.6
4	49.8
6	65.2
8	78.5
10	86.3
12	92.4

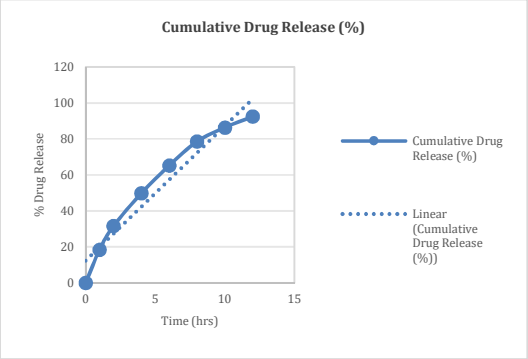

Figure no 2: Graphical Representation *In Vitro* Drug Release of F2 Nanogel

Cumulative drug release profile of optimised Helicteres isora nanogel formulation over 12 hours.

Result: Within 12 hours, the improved F2 nanogel formulation demonstrated sustained and regulated drug release behaviour with a maximum total drug release of 92.4 ± 1.8%. The findings imply that the created nanogel formulation can improve topical medication distribution and have a long-lasting therapeutic effect.

Permeation study

Phosphate buffer pH 6.8 was used as the receptor medium in a Franz diffusion cell for the in vitro permeation investigation of the improved F2 Helicteres isora nanogel formulation. Over the course of 12 hours, the study was carried out at 37 ± 0.5°C to assess the drug's penetration behaviour through the membrane. Because of its higher penetration ability and nanosized particles, the amended formulation exhibited continuous and sustained drug permeation. [30] [38] [21]

Table 12: *In-Vitro* Permeation Study of F2 Nanogel Formulation

Time (h)	Cumulative Drug Permeation (%)
0	0

1	14.2
2	26.8
4	43.5
6	58.7
8	71.4
10	82.1
12	89.3

Cumulative drug permeation profile of optimised Helicteres isora nanogel formulation over 12 hours.

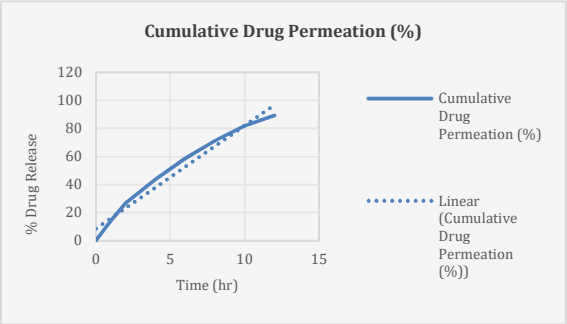

Figure no 3. Graphical Representation *In-Vitro* Permeation Study of F2 Nanogel

Result:

Effective permeation and sustained release characteristics have been shown by the improved F2 nanogel formulation, which showed 89.3 ± 1.8% cumulative drug penetration in 12 hours. The nanoparticles and penetration enhancers in the formulation could be important for the improved permeability behaviour.

Stability studies

To assess the formulation's chemical and physical stability while being stored, a stability study of the optimised F2 Helicteres isora nanogel formulation was conducted. For three months, the formulation was kept in both room temperature (25 ± 2°C) and accelerated settings (40 ± 2°C/75 ± 5% RH). Periodically, samples were examined for homogeneity, pH, viscosity, drug content, and appearance,which shown in Table no 13.[30] [38] [15]

The produced nanogel formulation showed good stability throughout the study period, as evidenced by no appreciable changes in colour, consistency, phase separation, or drug content. [38]

Table 13: Stability Study of Optimised F2 Nanogel Formulation

Evaluation parameter	Initial	After 3 Months	Observation
Appearance	Smooth translucent gel	No significant change	Stable
Homogeneity	Uniform	Uniform	No phase separation
pH	6.7	6.6	Stable
Viscosity (cP)	4095	4052	Slight variation
Drug Content (%)	95.8	94.9	Acceptable
Particle Size (nm)	178	182	Stable nanosized
PDI	0.31	0.33	Acceptable distribution

RESULT: The optimised F2 nanogel formulation maintained adequate physical and chemical stability throughout storage, according to the stability study results. There were only minor alterations in pH, viscosity, particle size, and drug content, all of which remain within acceptable pharmaceutical limits. [38] [15] [24]

Results and discussion

The current work effectively created and assessed a nanostructured herbal gel with anti-inflammatory properties that contained extract from Helicteres isora. Every formulation had a favourable appearance, was homogeneous, and had a pH that was appropriate for topical use. F2 produced the best results out of all the formulations, exhibiting homogeneous drug content, good spreadability, and satisfactory viscosity.

Nanosized particles with a low polydispersity index, which indicates good stability and uniform distribution, were verified by particle size analysis. While permeation experiments revealed improved membrane penetration, the in vitro drug release research showed sustained drug release. The formulation's stability was confirmed by

stability and freeze-thaw tests, which showed no appreciable alterations in physicochemical characteristics.

Conclusion

The anti-inflammatory properties of a nanostructured herbal gel containing Helicteres isora were successfully created and assessed in this work. Good appearance, homogeneity, appropriate pH, viscosity, spreadability, and drug content were among the desirable physicochemical properties of the prepared nanogel. Out of all the formulations, F2 showed the best outcomes, including improved stability, prolonged drug release behaviour, and a superior particle size distribution.

The enhanced release of the herbal active components from the nanogel system was verified by the in vitro diffusion and permeation investigations. According to stability testing, the improved formulation did not significantly alter in terms of drug content or physical appearance over the course of the study. As a result, the created nanostructured herbal gel may be viewed as a viable topical medication delivery method for efficient anti-inflammatory treatment with increased therapeutic efficacy and patient compliance.

Acknowledgement

The Rungta Institute of Pharmaceutical Sciences provided the facilities, assistance, and professional environment required for the effective completion of this research project, for which the authors are truly grateful. Our authors are delighted to express their sincere gratitude to their esteemed mentor for his invaluable advice, unwavering support, and encouragement during the project's completion. The authors also sincerely thank their parents and other family members for their unwavering encouragement, moral support, and drive throughout the entire research project.

To conclude, we wish to say thanks for thanks to all of the friends and academics who helped this research project be completed successfully, whether directly or indirectly.

Conflict of Interest: No Conflict of Interest.

Fund: No fund is Granted

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