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Preparation And Evaluation Of Phytosome Based Gel Formation Exhibiting Potent Anti Inflammatory Activity

Black turmeric and cassia fistula

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Abstract: The primary aim of the topic is to formulate and evaluate a phytosome–based topical gel containing extract of Black Turmeric (Curcuma caesia) and Cassia fistula with objective of enhancing phytoconstituent bioavailability and assessing its anti-inflammatory. The present study focuses on the formulation and evaluation of a phytosome-based topical herbal gel containing extracts of Black Turmeric (Curcuma caesia) and Cassia fistula for enhanced anti-inflammatory activity. Herbal extracts often show limited therapeutic effectiveness due to poor solubility and low bioavailability; therefore, phytosome technology using phospholipids such as soya lecithin was employed to improve their absorption and stability. The extracts were prepared using suitable extraction methods and formulated into phytosomes, which were then incorporated into a topical gel base. The prepared formulation was evaluated for parameters such as particle size, entrapment efficiency, pH, viscosity, spreadability, stability, and in vitro drug release. Black Turmeric possesses anti-inflammatory, antioxidant, and analgesic properties, while Cassia fistula is known for its anti-inflammatory and wound-healing effects. The phytosomal gel formulation is expected to improve bioavailability, enhance skin permeation, and provide better therapeutic efficacy compared to conventional herbal formulations .

Index Terms : Phytosomal gel, Cassia fistula , Curcuma caesia , Phytosome , Herbal drug delivery, Anti-inflammatory activity.

I. INTRODUCTION

Phytosomes are created in non-polar solvents when water-soluble polyphenolic compounds interact with the water-containing portion of phospholipid and when the polyphenolic group of phytochemicals establishes hydrogen bonds with the phosphate group of phospholipid.(1) Components of herbal extracts are shielded from intestinal bacteria and digestive fluids by phytosomes. They increase pharmacokinetics and bioavailability, which enables them to enter the bloodstream through lipid-rich biomembranes. Phytosomes have a crucial role in reducing toxicity, slowing the clearance of fast-metabolizable drugs, and extending the drug's circulation. Because the medication is coupled with lipids to form persistent vesicles that efficiently encapsulate theactivechemicals,phytosomes have a high entrapment capacity.

By enhancing the therapeutic efficacy and safety profile of plant extracts, phytosomes provide clinical benefits. Better clinical outcomes result from their improved delivery and absorption (2). Phosphatidylcholine is highly absorbed when given orally and is miscible in both the water and oil/lipid phases. The primary molecular component of cell membranes is phosphatidylcholine, which is nearly perfect for its phytosome function because to its molecular characteristics. The unit phytosome is typically a flavonoid molecule connected to at least one phosphatidylcholine molecule, according to chemical analysis.Phytosomes and

liposomes differ in: A stoichiometric amount of the phospholipid reacts with the chosen polyphenol (such as simple flavonoids) in a non-polar solvent to form phytosomes.(3)

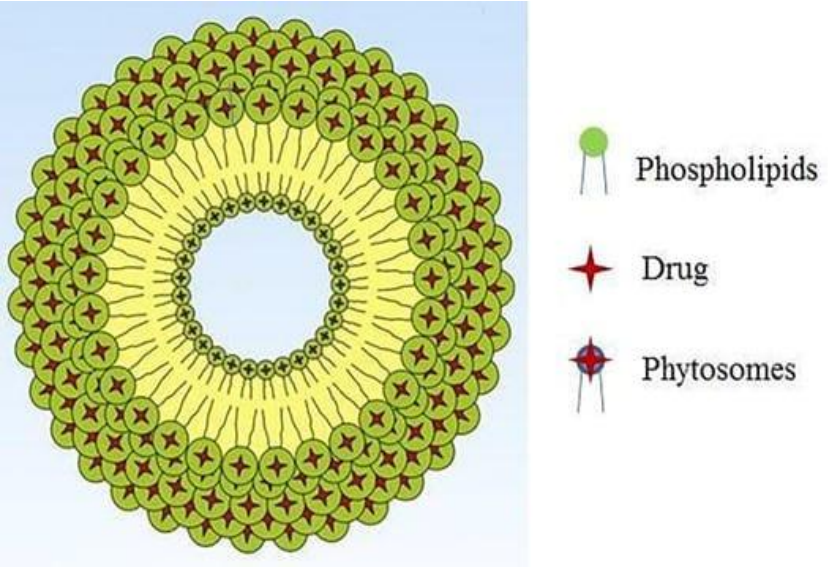

Fig 1: Structure of phytosome

II.OBJECTIVE

Objectives:

The objective of this review comprehensively evaluate the role of phytosome-based topical gel preparation by enhancing phytoconstituent bioavailability and assessing anti-inflammatory action of the herbal drug with a focus on its principle methodologies, clinical application and impact on treatment outcome it aim to:

1.To prepare extracts of Black Turmeric (Curcuma caesia) and Cassia fistula using a suitable extraction method.

2.To formulation phytosomes of the selected herbal extracts using an appropriate phospholipid (e.g., soya lecithin) to enhance bioavailability.

3.To incorporate the prepared phytosomes into a topical gel base and develop a stable phytosome-based herbal gel formulation.

4.To evaluate the physicochemical properties of the phytosomes, including particle size, morphology, and entrapment efficiency.

5.To evaluate the formulated gel for parameters such as pH, viscosity, spreadability, homogeneity, and stability.

6.To assess in vitro drug release and skin permeation of the phytosomal gel formulation.

7.To evaluate the anti-inflammatory activity of the developed formulation using suitable in vitro or in vivo models.market and the investors can earn only normal profit. Jarque bera test is used to test the normality of data.

III. METHODOLOGY:

3.1 DRUG USED:

-BLACK TURMERIC

-CASSIA FISTULA

BLACK TURMERIC AND CASSIA FISTULA INFORMATION:

- **BLACK TURMERIC:**

Scientific Name: Curcuma caesia Roxb.

Family: Zingiberaceae

Common Name: Black Turmeric, Kali Haldi

Part Used: Principally the rhizomes, although leaves are also used for aromatic oils.

Habitat: Native to India (Himalayan region, Central/Eastern India), often found in forests and cultivated for traditional remedies.

Key Chemical Constituents:

Black turmeric rhizomes contain a rich mix of secondary metabolites, with the characteristic color originating from high concentrations of anthocyanins.(4)

Often referred to as "Kali Haldi," black turmeric (Curcuma caesia Roxb.) is a special perennial herb that is a member of the Zingiberaceae family. This amazing plant, which is native to Southeast Asia, is becoming more well-known for its potent therapeutic properties and high curcumin and camphor content. The vivid blue color inside its rhizome and the blue pigment in the mid-ribs of its leaves make it stand out. It is referred to as "Kali Haldi" in Hindu ritual practice in honor of the goddess Kali, signifying both its profound cultural and spiritual significance and its powerful therapeutic qualities. The plant is easily recognized by its unusual deep violet-red streak running the length of its leaves, bluish-black rhizome, and potent camphor-like scent. (5)

Essential oils and bioactive substances such camphor, ar-turmerone, (Z)-ß-ocimene, ar-curcumene, 1,8-cineole, ß-elemene, borneol, bornyl acetate, tropolone, ß-elemenone, and α-bulnesene are found in fragrant rhizomes and leaves. (6)

Fig 2 : Black Turmeric

- **CASSIA FISTULA**

Scientific Name: Cassia fistula L.

Family: Fabaceae (formerly Caesalpiniaceae)

Common Names: Golden Shower Tree, Amaltas, Indian Laburnum, Purging Cassia, and Aragvadha

Part(s) Used: Almost all parts have medicinal value, including the fruit pulp (most common), roots, bark, leaves, and seeds

Habitat: Native to the Indian subcontinent and adjacent Southeast Asian regions. It thrives in tropical climates and is commonly found in deciduous forests and hilly tracts

Key Chemical Constituents: Anthraquinones: Rhein, chrysophanol, emodin, and physcion

Flavonoids: Kaempferol, quercetin, and catechin

Others:

Sennosides A & B (leaves), fistucacidin (bark), and galactomannan (seeds)

Linn. Cassia fistula. The common plant (Leguminosae) is well-known for its therapeutic qualities. This herb has been used to cure rheumatism, hematemesis, pruritus, leucoderma, diabetes, and skin conditions as well as liver problems and tuberculous glands, according to Indian literature.Additionally, it has been shown to have hypoglycemic and anti-inflammatory properties, and it is frequently used as a mild laxative that is safe for children and expectant mothers.[3] There are numerous reports on C. fistula's hepatoprotective, antifertility, and antioxidant qualities. Along with various other Indian medicinal plants, research has also been done on the antibacterial properties of C. fistula flower and seed.The antibacterial properties of this plant's leaves are only partially revealed by these research.(8)

Fig2: *Cassia fistula*

3.2MATERIAL AND METHODS:

3.2.1. Collection, Identification and Processing of Plant Material

Dried pulp of Cassia fistula and rhizomes of Curcuma caesia were procured from a reliable herbal source. The plant materials were authenticated by a qualified pharmacognosist, and voucher specimens were preserved.
The collected materials were cleaned to remove extraneous matter and shade-dried at room temperature to prevent degradation of active constituents. The dried materials were coarsely powdered using a mechanical grinder and passed through sieve no. 40. The powders were stored in airtight containers for further use.

3.2.2. Preparation of Extracts by Maceration Method

(i) Extraction of Cassia fistula

Accurately weighed 50 g of powdered Cassia fistula pulp was transferred into a clean, dry conical flask. About 250 mL of ethanol (or hydroalcoholic solvent, ethanol:water 70:30) was added. The flask was tightly sealed and kept for 72 hours at room temperature. The mixture was shaken intermittently every 6–8 hours to enhance extraction efficiency.
After completion of maceration, the extract was filtered first through muslin cloth and then through Whatman filter paper. The filtrate was concentrated using a rotary evaporator at 40–45°C under reduced pressure to remove the solvent. The concentrated extract was further dried to obtain a semisolid mass and stored in a desiccator until further use((9,10).

(ii) Extraction of Black Turmeric (Curcuma caesia)

Similarly, 50 g of powdered rhizomes of Curcuma caesia were transferred into a conical flask containing 250 mL ethanol. The mixture was allowed to macerate for 72 hours with intermittent shaking.After maceration, the extract was filtered using muslin cloth followed by Whatman filter paper. The filtrate was concentrated under reduced pressure using a rotary evaporator at 40–45°C to obtain a semisolid extract rich in curcuminoids. The extract was stored in an airtight container(10).

3.2.3. Preparation of Phytosomal Complex by Solvent Evaporation Method

The phytosomal complex was prepared using the solvent evaporation technique.
Accurately weighed quantities of Cassia fistula extract (100 mg) and Black turmeric extract (100 mg) were mixed. To this mixture, soy lecithin (200 mg) was added in a drug:phospholipid ratio of 1:2.
The mixture was transferred into a round-bottom flask and dissolved in 20–30 mL of ethanol or chloroform. The solution was refluxed at 50–60°C for 2 hours with continuous stirring to facilitate complex formation between phospholipids and phytoconstituents.
After refluxing, the solvent was removed using a rotary evaporator under reduced pressure. A thin film of phytosomal complex formed on the inner walls of the flask. The film was scraped and kept in a desiccator overnight to remove residual solvent.
The dried phytosomal complex was collected, lightly powdered, and stored in an airtight container(11,12).

Table1: Formultion table for Phytosomal Complex

Ingredient	F1	F2	F3	F4	F5
Herbal Extract	100mg	100mg	100mg	100mg	100mg
Soy lecithin	100mg	150mg	200mg	250mg	300mg
Ethanol	20ml	20ml	20ml	20ml	20ml

3.2.4. Preparation of Gel Base

The gel base was prepared using Carbopol 934 as a gelling agent.
Carbopol 934 (1–2% w/w) was accurately weighed and slowly dispersed in distilled water with continuous stirring to avoid lump formation. The dispersion was allowed to hydrate and swell for 24 hours.Propylene glycol was added as a humectant and penetration enhancer. Preservatives such as methyl paraben and propyl paraben were dissolved separately and incorporated into the gel.The pH of the gel was adjusted to 6.5–7.0 using triethanolamine, resulting in the formation of a clear, homogeneous gel base(13).

3.2.5. Incorporation of Phytosomal Complex into Gel

The prepared phytosomal complex was incorporated into the gel base by gradual mixing.
The required quantity of phytosomal complex was slowly added to the Carbopol gel base with continuous stirring using a mechanical stirrer to ensure uniform dispersion. The mixing was continued until a smooth and homogeneous gel was obtained.
The formulation was then kept in a desiccator to remove entrapped air bubbles. The final phytosomal gel was transferred into clean, airtight containers and stored at room temperature(14).

3.2.6. Storage of Formulation

The final phytosomal gel was stored in well-closed containers, protected from light, heat, and moisture to maintain stability and prevent degradation of active constituents.

Table2: Formulation table of phytosomal gel

Ingredient	F1	F2	F3	F4	F5
Phytosomal suspension	10ml	10ml	10ml	10ml	10ml
Carbopol 934	0.5g	0.75g	1g	0.9g	0.8g
Propylene glycol	5ml	5ml	5ml	5ml	5ml
Methyl parabean	0.1g	0.1g	0.1g	0.1g	0.1g
Triethanolamine	q.s.	q.s	q.s	q.s	q.s
Water	Up to 100 ml	Up to 100ml	Up to 100 ml	Up to 100 ml	Up to 100ml

Fig 3 : Formulation of batches of gel F1,F2,F3,F4,F5 respectively

3.3 EVALUATION OF PHYTOSOMES

3.3.1. Microscopic view

The complex was examined using optical microscopy. It was first dispersed in a buffer solution, and a drop of this suspension was placed on a glass slide and covered with a coverslip. The sample was then observed under a microscope at 45× magnification to study its microscopic characteristics(15).

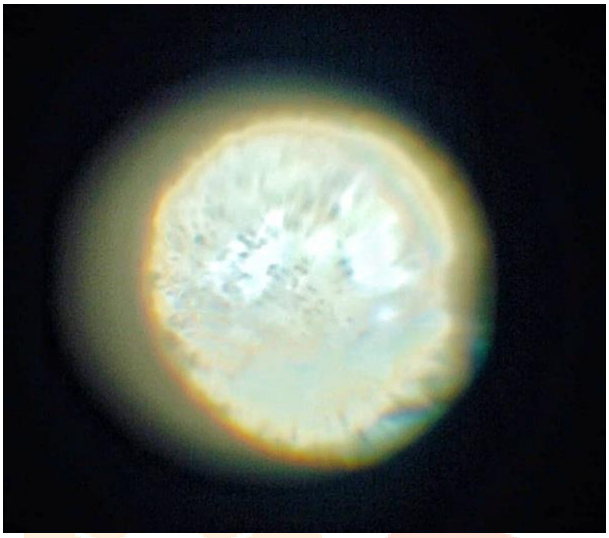

Fig4: Microscopic view of phytosome

3.3.2. Entrapment efficiency

A total of 100 mg of the phytosomal complex was centrifuged at 2000 rpm for 30 minutes utilizing a Rami centrifuge to isolate the Phytosome from the unentrapped drug. The concentration of the free drug in the supernatant was assessed by measuring the absorbance at 268 nm with a UV-visible spectrophotometer.(16) The percentage of drug entrapment was calculated using the formula,

$$\text{Entrapment efficiency (\%)} = \frac{(\text{total amount of drug} - \text{amount of free drug})}{\text{total amount of drug}} \times 100 /$$

$$\text{Entrapment effcency(\%)} = \frac{100\text{mg}-20\text{mg}}{100\text{mg}} \times 100$$

$$= 80\%$$

3.3.3.Percentage practical yeild:

The % practical yield is computed to determine the efficiency or yield percentage of any method, which aids in the selection of an appropriate production method.7The prepared phytosomes were gathered and weighed in order to calculate the practical yield using the following formula:
(%) yield is equal to (actual yield)/(theoretical yield) x 100 (17).

3.4 EVALUATION OF PHYTOSOMAL GEL

3.4.1. Physical evaluation:

The formulation was manually inspected to look for differences in texture, colour, and odour.(17)

3.4.2. pH measurement:

A pH meter was used to measure the pH of each formulation. This was previously calibrated using buffer solutions with pH values of 4, 7, and 9.(17)

3.4.3. Determination of Viscosity:

A Brookfield viscometer was used to measure the viscosity of phytosomal gels. A 50 ml beaker containing 30 g of gel preparation was held at room temperature and spun at 5, 10, 20, 50, and 100 rpm.(16)

3.4.4.Spreadability

Spreadability of the gel was determined using the glass slide method. A known quantity of gel was placed between two glass slides, and a specified weight (e.g., 500 g) was placed on the upper slide to form a thin uniform layer. After removing excess gel , the time taken by the upper slide to move a certain distance under the influence of weight was recorded. (17)

Spreadability was calculated using the formula.

$$S = M \times L / T$$

Where:

S = Spreadability

M = Weight tied to the upper slide (g)

L = Length moved by the slide (cm)

T = Time taken (sec)

Higher spreadability indicates better ease of application on the skin.

3.4.5. Stability study:

Stability studies were carried out to assess the physical and chemical stability of the formulation. The prepared gel store in airtight containers at different conditions such as:

Room temperature (25+2C)

Accelerated conditions (40+2 C)

The formulations were observed over a period of 1-3 months for changes in:

Appearance (color, phase separation), pH, Viscosity, Homogenisity

Any signs of instability such as phase separation, discoloration, or change in consistency were recorded. Formulations showing no significant changes were considered stable.(20)

4. RESULT AND DISCUSSION

4.1 Evaluation study of phytosomal gel

Table3: Evaluation Table of phytosomal gel

Parameter	**F1**	**F2**	**F3**	**F4**	**F5**
Appearance	Light brown,Slightly uneven	Light brown,Smooth	Dark brown	**Light brown, smooth& glossy**	Brown, slight color variation
pH	6.3	6.7	6.8	**6.5**	6.4
Viscosity(cp)	3200	4100	5200	**4500**	3900
Spreadability(g.cm /sec)	18	15	12	**17**	14

The evaluation of all formulations (F1 –F2) revealed significant differences in their physiochemical properties based on the variation in composition. The F1 formulation, containing a lower concentrations of carbopol,exhibited low viscosity and high spreadability; however, it showed poor stability with signs of phase separation, making it less suitable for long-term use despite easy application. In contrast F2 demonstrated a more balanced composition with moderate viscosity and good spreadiability, along with improved stability, indicating better performance better than F1.

The F3 formulation, containing higher concentrations of carbopol and aloe vera, showed very high viscosity, which resulted in reduced spreadability and a thicker consistency. Although it remained stable, its excessive

thickness may negatively affect user acceptability and ease of application Among all formulations, F4 was identified as the optimized batch, as it exhibited a balanced composition of carbopol and Aloe vera, resulting in optimal viscosity that was neither too thick nor too fluid. It also showed good spreadability, excellent stability, and an elegant appearance. Additionally, the Ph of F4 (6.5) was found to be ideal for skin compatibility.

4.2 Stability study:

Table4: Stability study

Formulation	Storage condition	Appearance	Ph change	Viscosity	Homogenisity
F1	25 ± 2°C	Slight phase separation	6.8-6.3	**Decreased**	Non-uniform
	40 ± 2°C	Phase separation observed	6.8-6.0	**Highly decreased**	Poor
F2	25 ± 2°C	No change	6.9-6.7	**Slight decrease**	Good
	40 ± 2°C	Slight change	6.9-6.5	**Moderate decrease**	Acceptable
F3	25 ± 2°C	No visible change	7.0-6.8	**Slight increase**	Good
	40 ± 2°C	Slight thickening	7.0-6.6	**Increased**	Good
F4	25 ± 2°C	No change(stable)	6.8-6.8	**No significant change**	Excellent
	40 ± 2°C	No change	6.8-6.7	Stable	Excellent
F5	25 ± 2°C	Slight color change	6.7-6.5	Slight decrease	Good
	40 ± 2°C	Color darkening	6.7-6.3	Moderate decrease	Acceptable

The stability evaluation revealed that F4 was the most stable formulation, as it exhibited no notable changes in appearance, pH, viscosity, or homogeneity under both storage conditions (25 ± 2°C and 40 ± 2°C). F2 and F3 also showed satisfactory stability with only slight variations. F5 demonstrated minor instability at higher temperatures, whereas F1 was identified as the least stable formulation due to phase separation and considerable changes in its physicochemical properties.

4.3 Entrapment Efficiency:

Formulation	Entrapment Efficiency (%)
F1	68±1.2
F2	72±1.5
F3	78±1.3
F4	80±1.1
F5	76±1.2

The graph shows a gradual increase in entrapment efficiency from F1 to F4.
F4 exhibits the highest EE (80%), indicating optimal formulation conditions.
A slight decrease in F4 suggests excess phospholipid or formulation imbalance.
Overall, the trend confirms efficient phytosome formation, especially in F4.

4.4 Determination of λmax by UV Spectroscopy:

The maximum wavelength (λmax) of the phytosomal formulation of Black turmeric and Cassia fistula was identified by UV-visible spectroscopic analysis. The formulation exhibited peak absorbance in the range of 370–375 nm, confirming the presence of bioactive phytoconstituents. This λmax value was further utilized for evaluation parameters including drug content and entrapment efficiency studies.

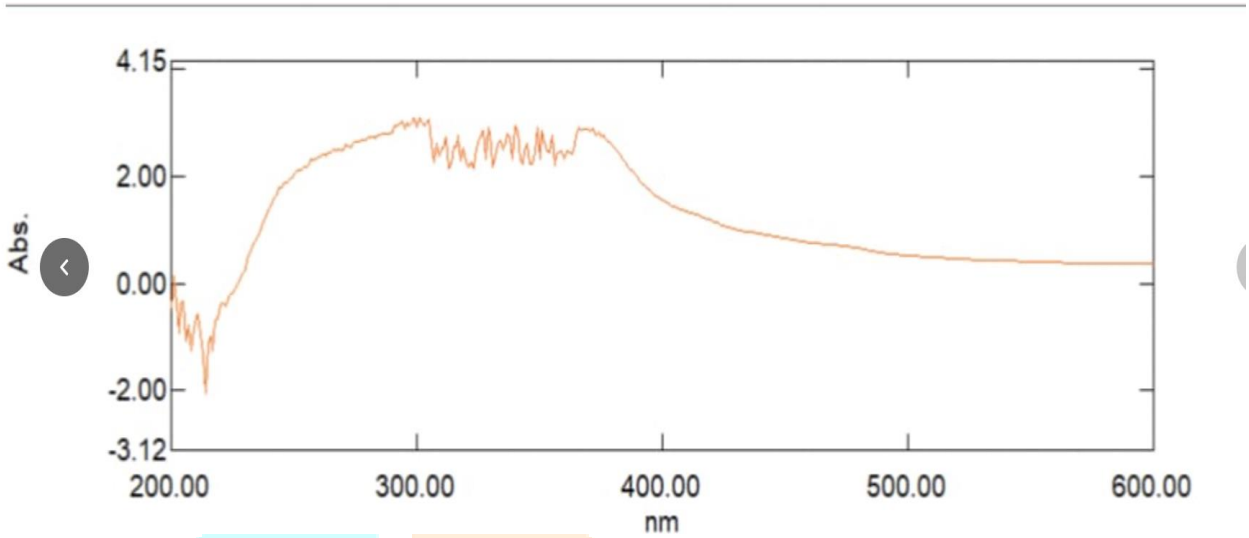

Fig 5: UV –Visible spectroscopy

5. CONCLUSION

The present graph shows a gradual increase in entrapment efficiency from F1 to F4.
F4 exhibits the highest EE (80%), indicating optimal formulation conditions.
A slight decrease in F5 suggests excess phospholipid or formulation imbalance.
Overall, the trend confirms efficient phytosome formation, especially in F4.

Paraphrase this research successfully formulated and evaluated a phytosomal gel incorporating extracts of Cassia fistula and Curcuma caesia. The phytosome-based approach was found to be effective in improving the bioavailability and dermal absorption of the herbal constituents through complex formation with phospholipids.The developed gel exhibited desirable physicochemical characteristics such as suitable pH, uniform consistency, proper viscosity, and good spreadability, making it appropriate for topical use. Evaluation parameters including entrapment efficiency, drug content uniformity, and in vitro release studies indicated that the formulation was stable and capable of delivering the active components in a controlled manner. Moreover, ex vivo permeation studies demonstrated enhanced skin penetration compared to non-phytosomal formulations.The synergistic combination of Cassia fistula and Black Turmeric in phytosomal form showed significant anti-inflammatory and therapeutic potential due to their rich phytochemical profile. Stability testing further confirmed that the formulation maintained its integrity with minimal variations in physical and chemical properties over time.In conclusion, the formulated phytosomal gel represents an effective and promising herbal delivery system for topical applications, offering improved therapeutic efficacy and patient acceptability. However, further in vivo and clinical investigations are necessary to confirm its overall safety and effectiveness.

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