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Original Article

Formulation, Optimization and Evaluation of Barbaloin-Loaded Phytosomal Gel for the Treatment of Psoriasis

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ABSTRACT

Background: Phytosomes are one such unique approach gaining popularity due to their capabilities in controlled release and targeted delivery. These advanced herbal formulations significantly enhance the bioavailability of phytochemicals, improving the therapeutic efficacy of Barbaloin by boosting solubility and absorption for the treatment of Psorisis. In this study, phytosomes were prepared using the thin film hydration method with soya lecithin and cholesterol to optimize encapsulation efficiency and particle size. **Materials and Methods:** Barbaloin, Soya lecithin, Cholesterol, Dichloromethane, Methanol, n-Hexane are all of these ingredients are were used for preparing barbaloin phytosome formulation. Carbopol 934, Polyethylene glycol 400, triethanolamine, methyl paraben and propyl paraben are used for preparation barbaloin loaded phytosomal gel. Prepared phytosomes were characterized for FTIR (Fourier transform infrared spectroscopy). It also underwent analysis for Particle size, Zeta potential, entrapment efficiency. **Conclusion:** Barbaloin phytosome was formulated using the thin film hydration technique and identified as an effective carrier for topical drug delivery. The system's properties were notably affected by the drug-to-polymer ratio. In summary, phytosome-based drug delivery can enhance the therapeutic efficacy of phytochemicals by increasing absorption and bioavailability, while also modifying their physicochemical and release properties. Therefore, barbaloin phytosomal gel is a promising alternative for drug delivery.

Keywords: Phytosomes, Bioavailability, Plant Extract, Drug Delivery, Solubility, Therapeutic Efficacy.

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INTRODUCTION

Novel Drug Delivery Systems (NDDS) represent a frontier in pharmaceutical science that aims to enhance the therapeutic efficacy and safety of drugs.[1] Traditional drug delivery methods, often face challenges like poor bioavailability, systemic side effects and lack of targeted delivery. NDDS seeks to overcome these limitations through innovative approaches that improve the precision, efficiency and patient compliance of drug therapies.[2] Pharmaceuticals made with conventional compounds obtained from botanicals as opposed to chemicals are known as phytopharmaceuticals. The body metabolizes natural chemicals more rapidly and easily. As a result, they have few adverse effects and offer improved bloodstream absorption, better penetration, leading to more comprehensive and successful therapies. Chemical-based pharmaceuticals are more likely to have unfavorable side effects. The body of a human will often reject certain chemicals that do not arise naturally. These rejections manifest as side effects, ranging in severity from slight headaches, skin irritations to potentially fatal ones. While phytopharmaceuticals have little or no negative effects, it's vital to remember that they may interact chemically with other prescription medications. Moreover, compared to herbs, they are simpler to include into contemporary drug delivery system due to their ability to be readily standardized as single, pure molecules. The existing drug delivery systems have some important limitations of rapid degradation, lack of targeted delivery, inconsistent dosage, limited controlled release options and poor skin penetration in topical formulations. Numerous research has looked on lipid-based drug delivery methods and have demonstrated their promise for targeted and regulated medication delivery. Phytosomes are drug-containing, amphophilic phospholipid complexes that attach to phospholipids and contain active hydrogen. They provide the medication superior biopharmaceutical qualities, which raises its bioavailability. Phytosomes are new substances made up of phospholipid-containing lipophilic complexes of plant-derived ingredients such as ginseng, marianum, barbaloin,

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ginkgo biloba and so on. Their medicinal effects and enhanced bioavailability are accompanied by their high lipophilicity. Using a patented procedure, specific components of herbal medicine, such as flavonolignans and terpenoids, are molecularly attached to phospholipids, such as phosphatidylcholine, through a polar end to form phytosomes.[3] The most exact secondary component identified in *aloe vera* plants, barbaloin is a naturally occurring phytoconstituent that is widely distributed due to its accessibility.[4]

Barbaloin is found in other *Aloe* species such as *Aloe barbadensis, Aloe ferox* and *Aloe socotrina.* These species are known for their traditional medicinal uses, especially in African and Asian herbal medicine. Barbaloin is an anthraquinone glycoside predominantly found in certain species of the *Aloe* genus, particularly *Aloe vera* and *Aloe barbadensis. Aloe vera* contains approximately 2-10% barbaloin in its leaf extract. The concentration can vary based on environmental factors, the age of the plant and processing methods. It is known for its various therapeutic properties, including anti-inflammatory, antioxidant and laxative effects.[5] Psoriasis can be effectively treated with "Barbaloin," a phytoconstituent derived from the *aloe vera* plant. Barbaloin has good Anti-psoriatic, anti-inflammatory and antibacterial properties, as per the experiment. Barbaloin primarily uses antioxidant and anti-inflammatory pathways to exert its protective effects.[6] Barbaloin is hydrophilic can't permit cell membrane. However, there are several limitations associated with barbaloin, which could restrict its medicinal use. The major limitations are low bioavailability, stability issues and skin irritation.[7-9]

The main objectives of the present study were to enhance the bioavailability, improve the stability and reduce the skin irritations of barbaloin. The rationale behind this study is to overcome the limitations of barbaloin, through the preparation of phytosomal formulations.

Therefore, we prepared barbaloin phytosomes which helps to improve drug stability, solubility and bioavailability of phytoconstituents.[10]

MATERIALS AND METHODS

Barbaloin is purchased from Yucca Enterprises, Mumbai. Soya Lecithin, Dichloromethane, Methyl Paraben, Propyl Paraben, was obtained from Research Lab Fine Chem industries, Mumbai. n-Hexane, Cholesterol, Triethanolamine was obtained from Loba Chemicals, Mumbai. Carbopol 934 was obtained from Molychem, Mumbai.

Preparation of phytosomes of barbaloin using thin Film hydration technique

The phytosomes of barbaloin was prepared by thin film hydration techniques. A rotating round-bottom flask containing various molar concentrations of barbaloin and soy lecithin was filled with 5 mL methanol and 15 mL dichloromethane (as shown in Table 1). The mixture was then stirred for an hour at a temperature that did not go over 40°C.[11] After obtaining a thin film of the sample, n-hexane was added and the mixture was continually agitated until a phospholipid monolayer formed. Complex of prepared phospholipids rinsed with 10 milliliters of n-hexane while being constantly stirred.[12] Permit the hydration process to continue in order to create Multi Lamellar Vesicles (MLVs), which are typically aided by mild shaking or sonication. To create Small Unilamellar Vesicles (SUVs) from the MLVs, the solution can be probe sonicate using polycarbonate membranes. For an entire day, the phytosomal suspension was kept refrigerated.[13]

Factorial Design

Using Design-expert® software (Version 7.0.0, Stat-Ease Inc., Minneapolis, USA), a three-level factorial design was developed. This meant that every conceivable combination of the three levels of each component under consideration had to be tested in the experiment. The amounts of soy lecithin (X1: 75, 150 and 225 mg) and cholesterol (X2: 20, 40, and 60 mg) are selected as the independent variables. A multilevel factorial design (3^2) was used to screen the independent variables and nine different formulations of barbaloin Phytosomes were developed. The optimal formulation was identified by evaluating particle size (Y_1) and entrapment efficiency (Y_2) after all formulations were created using the thin film hydration process.[14]

Evaluation of Phytosomes

Scanning Electron Microscopy (SEM)

SEM was performed for determination of particle size and surface morphology of phytosome. Phytosome samples were frozen at -80°C overnight and then lyophilized in a (Labconco Plus 12 lyophilizer) at 34 Pa for 8 hr with a condenser set to -43°C. A single drop of lyophilized material was put on a brass electron microscope. Representative photos of the samples were taken and particle sizes were calculated using scanning electron microscopy (UHR FESEM-GEMINI SEM 500) with a voltage of 10.0 KV and a working distance of 7.2 mm.[15]

Particle size

The particle sizes (z-average) of the generated phytosomes were measured by Dynamic Light Scattering (DLS) and Photon Correlation Spectroscopy (PCS). The Horiba Particle Size Analyzer-SZ 100 can determine the auto correlation function of the intensity of light scattered by particles, which is expected to be of a circular form. Smaller particle sizes generally enhance bioavailability due to increased surface area and better absorption. This suggests that the phytosomes are in the nanometer range, which is favorable for enhanced cellular uptake and improved bioavailability.[16]

Entrapment efficiency

Entrapment efficiency measurement was done by separating the free active compound (supernatant) from 0.5 mL of the sample using centrifugation for 15-20 min at 3000-4000 rpm. After that, the supernatant was filtered using 0.45 Whatman filter paper. The absorbance was subsequently determined in the UV at 279 nm. After the appropriate dilution. Last but not least, the entrapment efficiency was calculated by using calibration curve equation i.e. y=0.0046x+0.0039 and % Entrapment Efficiency (EE) Equation.[17]

$$\% \text{ Entrapment Efficiency} = \frac{\text{Total Amount of Drug} - \text{Free Drug in Suspension}}{\text{Total Amount of Drug}} \times 100$$

Zeta Potential

The zeta potential is a key indicator of colloidal stability and which was analyzed by Horiba SZ 100 zeta potential analyzer. Particles with high zeta potential (positive or negative) tend to repel each other, preventing aggregation. Generally, a zeta potential above ±30 mV is considered stable. Values between ±20 mV and ±30 mV indicate moderate stability, while values below ±20 mV suggest low stability and a higher tendency for aggregation.[18]

FTIR

FTIR analysis was performed by Bruker-Alpha II. Range of wave number used to capture the spectrum was 4000 to 500 cm^{-1}. Using soy lecithin as a phospholipid and the thin-layer hydration process, the phytosome was created. An investigation of the possibility of molecular interactions between formulation components was conducted using FTIR. The interaction of drug and excipients was investigated by using FTIR spectroscopy. The FTIR spectra of Phytosomes was measured and the result data were evaluated.[19]

Formulation of barbaloin loaded phytosomal gel

1% gel of Carbopol 934 was prepared by soaking overnight 1 g of Carbopol 934 in water and the pH was adjusted with triethanolamine. Methyl paraben (0.05 g) and propyl paraben (0.02 g) are included as preservatives. Polyethylene glycol 400 is used as humectant at 0.5 mL. After that the prepared 5 mL of phytosomes was incorporate in 50 g of gel to make 10% Barbaloin loaded phytosomal gel.

Evaluation of barbaloin loaded phytosomal gel

Viscosity

The measurement of viscosity of the sample was done using Brookfield Viscometer (DV-E Model). The required quantity of Gel was placed in a small volume holder and the spindle used was S63 at 10 rpm rotations speed per minute. The corresponding % Torque value and cp (centipoises) was noted.[20]

Measurement of pH

The pH of each sample was determined using a Systronic buffer solution with pH values between 4 and 7. The gel, weighing about 0.5 g, was dissolved in 50.0 mL of distilled water and the pH was recorded.[21]

Spreadability

Pair of 20 cm by 20 cm glass slides was chosen. A tiny quantity of the material was moved back and forth across both of the glass slides. To ensure that the Gel between the two slides was evenly compressed to produce a thin layer, a 20 g weight was put on the upper slide. By attaching weight to the upper plate, a stop clock was used to record how long it took the gel to spread. The most popular technique for Figuring out and measuring the spreadability of semisolid preparations is the parallel plate approach. Its benefits include relative affordability and ease of use. For this, the following formula was applied.[22]

$$\text{Spreadability (S)} = \frac{M \times L}{F}$$

Where, M=Mass of gel (g), L=Distance over which gel was spread (cm), F=Force required to spread the gel (g).

In vitro drug release

Dialysis technique was used to report drug release from the phytosome. The dissolving medium utilized in this assembly was phosphate buffer and it was all assembled on a magnetic stirrer with a 37°C temperature maintained. To put it briefly, a dialysis bag containing a phytosomal gel (10 mg) or drug solution with the corresponding drug concentration was sealed and submerged in 100 mL of Phosphate Buffer Saline (PBS), pH 6.8, which served as the release medium.[23] A magnetic bead was used to continually swirl the mixture. At predetermined intervals of time (1, 2, 3, 4, 5, 6, 7 and 8 hr) 1 mL of the solution was pipetted out of the dissolution medium and the same volume of new dissolution media was added to replace the amount removed. Following withdrawal, the sample was examined in UV spectrophotometer at 279 nm and calculated the % Cumulative Drug Release (CDR).[24]

Drug release kinetics

The release data was examined using the zero-order, first-order and Higuchi equation models to determine the likely drug release kinetics from the phytosomal gel. *In vitro* drug release profile data have been utilized to confirm the validity of the kinetic equation and to determine the drug release control mechanism.[25]

Stability Studies

The stability analysis of Barbaloin loaded Phytosomal gel was carried out at room temperature (25°C±0.5°C) in accordance with the International Conference on Harmonization (ICH) guidelines. After two months, samples were tested for the particle size, entrapment efficiency, pH as well as viscosity investigation.[26,27]

Table 1: Formulation Table of Phytosome with Factors and Responses.

Batches	Barbaloin (mg)	Soya Lecithin (X1) (mg)	Cholesterol (X2) (mg)	Methanol (mL)	Dichloro-methane (mL)	Particle Size (Y_1) (nm)	Entrapment Efficiency (Y_2) (%)
F1	50	75	20	5	10	193.6±0.2	79.06±0.4
F2	50	75	40	5	10	146.6±0.1	69.67±0.3
F3	50	75	60	5	10	150.8±0.4	72.01±0.5
F4	50	150	20	5	10	216.8±0.6	88.38±0.32
F5	50	150	40	5	10	200.7±0.3	81.08±0.54
F6	50	150	60	5	10	186.5±0.5	75.17±0.2
F7	50	225	20	5	10	135.9±0.1	65.78±0.3
F8	50	225	40	5	10	231.1±0.2	90.82±0.2
F9	50	225	60	5	10	211.1±0.3	84.84±0.4

RESULTS

Factorial Design

The result of the central composite design was statistically evaluated using Design expert software. Soya Lecithin (X_1) and Cholesterol (X_2) were investigated as independent variables and their effects on Particle size and Entrapment efficiency were examined as dependent variables. The 3^2 factorial results in 9 runs (as shown in Table 1).

Response 1: The Model F-value of 242.86 implies the model is significant. *p*-values less than 0.0500 indicate model terms are significant. In this case A, B, A^2 are significant model terms (outline in Table 2).

Response 2: The Model F-value of 5654.09 implies the model is significant. *p*-values less than 0.0500 indicate model terms are significant. In this case A, B, B^2 are significant model terms (outline in Table 3).

Optimisation

The particle size of phytosomes likewise increases when soy lecithin content rises. Because of the higher polymer content, which was thought to improve the percentage entrapment efficiency by providing more space to encapsulate the medication, the percentage entrapment efficiency also rises with increased soy lecithin and cholesterol concentrations (as shown in Figure 1). Various charts show how the concentration of the independent variable affects the dependent variables. Tables 2 and 3 present the response's Analysis of Variance (ANOVA). The model fit summary for the formulation variables on the response factors for Barbaloin indicates a quadratic relationship for both particle size and Entrapment Efficiency (% EE). For particle size, the standard deviation is 2.75, with an R^2 value of 0.9975, an adjusted R^2 of 0.9934, and a predicted R^2 of 0.9700. The adequacy precision for this response is 40.8342, signifying a highly reliable model. For % EE, the standard deviation is 0.1444, with an R^2 value of 0.9999, an adjusted R^2 of 0.9997, and a predicted R^2 of 0.9990. The adequacy precision for % EE is exceptionally high at 211.1944, confirming the model's excellent predictive ability and precision. After prepared phytosomes were mathematically modeled, the following equations were produced.

$$\textit{Particle Size (Y1)} = 193.37 + 37.62X1 + 8.18X2 + 1.27X1X2 - 11.55X12 + 0.3500X22 \ldots\ldots \text{ Eq (1)}$$

$$\textit{\% EE (Y2)} = 78.94 + 9.43X1 + 3.02X2 - 0.0625X1X2 + 0.1467X12 - 0.7533X22 \ldots\ldots \text{ Eq (2)}$$

Following the impact of cholesterol and soy lecithin levels on dependent variables including particle size and EE percentage, the level of factors was determined using a computation approach, with Y_1 and Y_2 being assumed to be 231.1 and 90.82, respectively.

Evaluation of Phytosomes

Scanning Electron Microscopy (SEM)

SEM image shows a distribution of particles with varying sizes. Some areas appear denser with tightly packed particles, while other areas have more dispersed particles. The magnification was at 6000x and scale bar is 5.00 µm. A SEM was utilized to assess the particle size and surface morphology. Figure 2 displays a SEM picture demonstrating phytosomes' extremely spherical form. The Barbaloin phytosome had an average particle size of nm 186.5±0.5 nm in the phytosome solution.

Particle size

The particle size of phytosomes is a critical factor influencing their stability, absorption and efficacy. The particle sizes range from 135.9±0.1 nm to 231.1±0.2 nm, with a mean size of 185.9 nm. The particle size distribution observed here suggests that the phytosomes are likely to be efficiently absorbed when

administered, making them a suitable formulation for delivering barbaloin effectively (Table 1).

Zeta potential

The zeta potential data provided for the phytosomes containing barbaloin is crucial for understanding the stability of the nanoparticles in suspension. Zeta potential value obtains in range from -35.9±0.11 to -15.6±0.21 mV which indicates that F8 batch show most stable (-35.9) followed by F6 batch (-31.3).

FTIR

The characteristic absorption bands of barbaloin are 2934.74 cm^{-1} and 2861.50 cm^{-1} likely due to C-H stretching vibrations indicating the presence of aliphatic hydrocarbons, C=O at 1729.57 cm^{-1} (aldehydes and ketones), C=C at 1603.96 cm^{-1} this might be indicative of stretching in alkenes or aromatic rings, 1454.98 cm^{-1} peak might be associated with CH2 bending vibrations, C-O stretching at 1223.39 cm^{-1} and 1036.94 cm^{-1} indicating the presence of alcohols, ethers, carboxylic acids and esters. The FTIR spectrum of barbaloin and phytosome were displayed along with the values of its principal peaks.

Entrapment Efficiency

The entrapment efficiency of phytosome formulation ranged from 65.78±0.3% to 90.82±0.2%. The entrapment efficiency of nine formulations (shown in Figure 3). F8 formulation shows the highest Entrapment efficiency as compare to other formulations. F8 Formulation states that the concentration of soya lecithin and cholesterol are in a right proportion to produce phytosomal vesicles.

Characterizations of Phytosomal gel

Viscosity

Carbapol 934 was used as a gelling agent in barbaloin loaded phytosomes. The viscosity of phytosomal gel ranging from 9452 to 9864 (cps) shown in Figure 3.

Measurement of pH

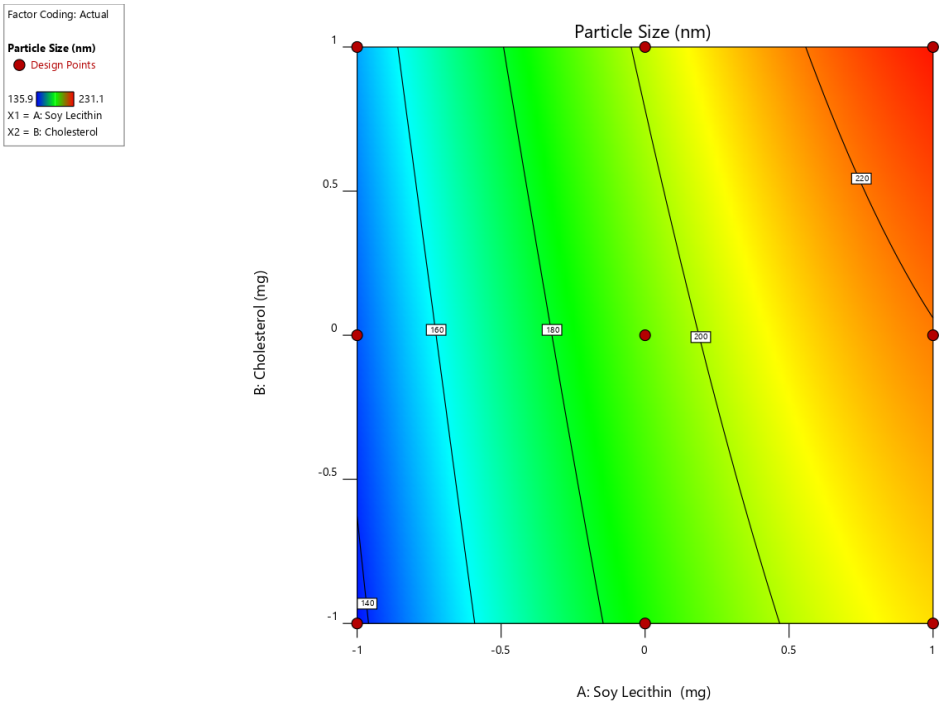
The pH of several phytosomal gels from 6.42±0.10 to 7.12±0.11 it is in a general physiological value and doesn't irritate the skin.

Spreadability

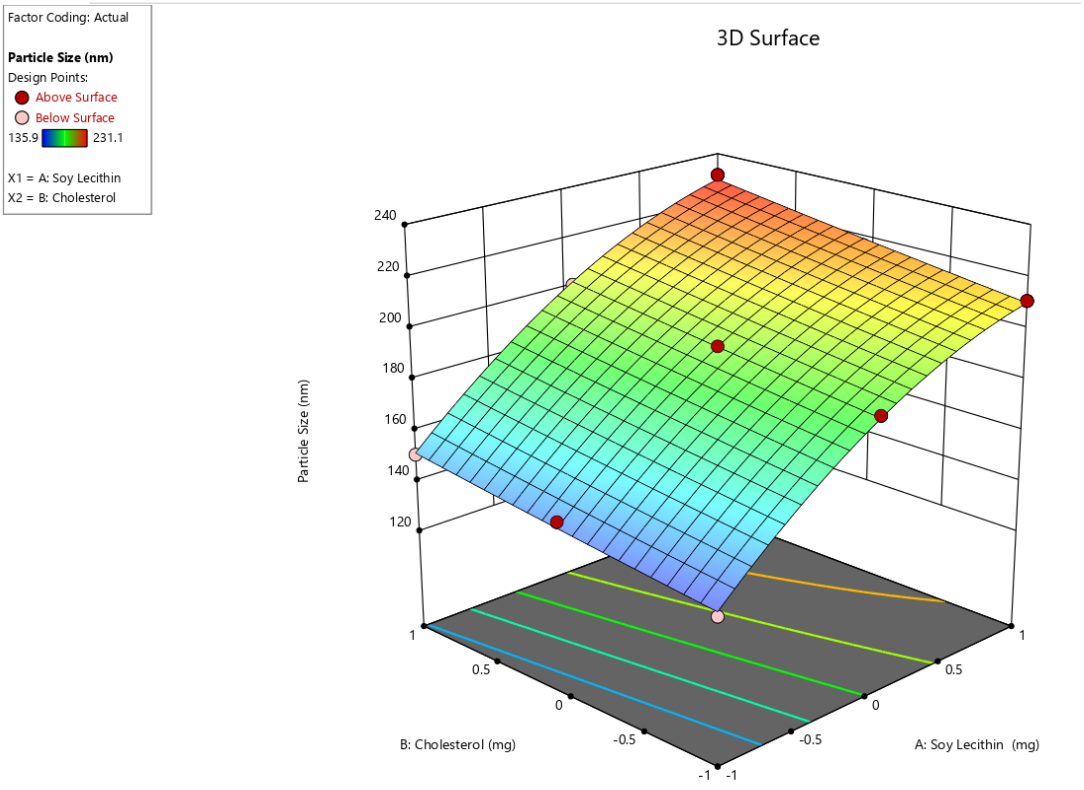
Spreadability is an important characteristic for topical formulations, influencing how easily the product can be applied and distributed on the skin or other surfaces. A higher spreadability value generally indicates better ease of application and more uniform coverage. Spredability rate ranging from 18.3 to 22.5 g.cm/sec as shown in Figure 3. F8 batch indicates good ease of spreadability for the barbaloin gel.

In vitro release study

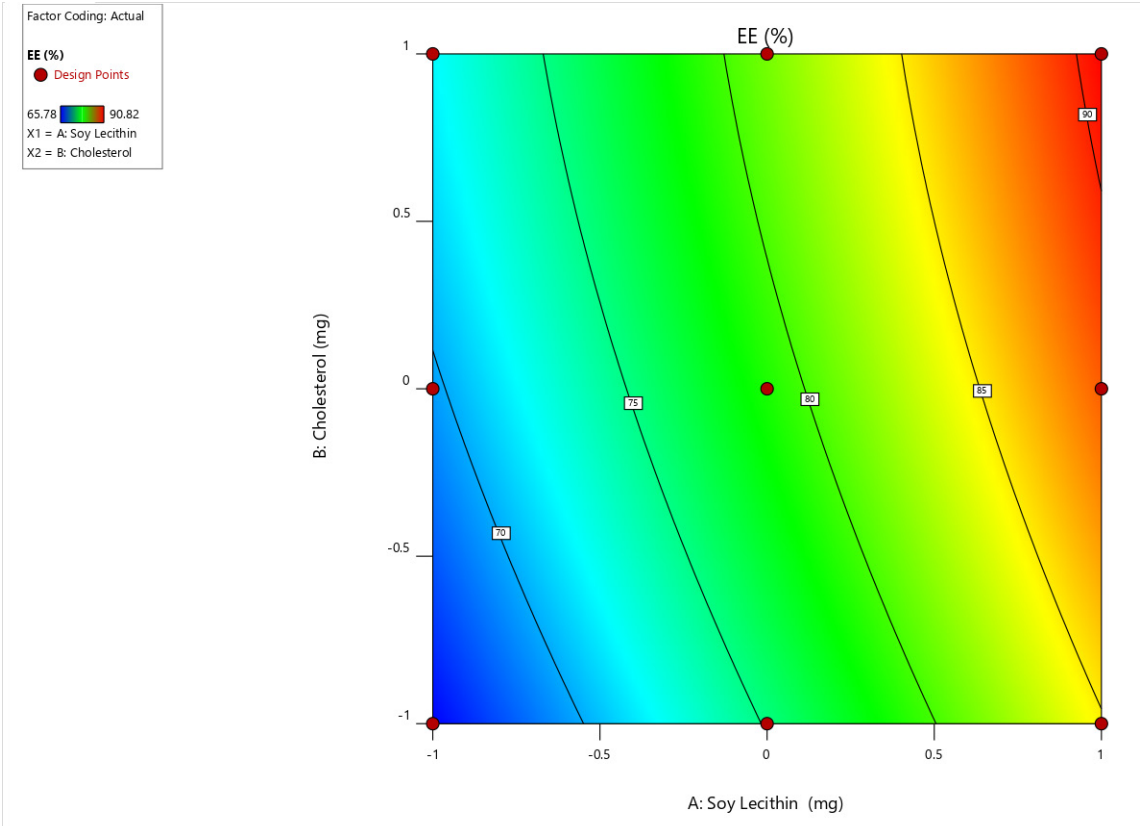
The result of *in vitro* drug release studies of barbaloin phytosomes made by thin film hydration technique are shown in Figure 4. % CDR of phytosomal gel was obtained between 78.55% to 95.05%. Most formulations show a steady increase in drug release. F5 and F8 consistently show higher cumulative release percentages due to larger particle sizes and high entrapment efficiencies. These factors work together to observe higher %CDR over time compared to other formulations. By 8 hr, F8 achieves the highest cumulative release (95.05%), indicating it releases the drug more



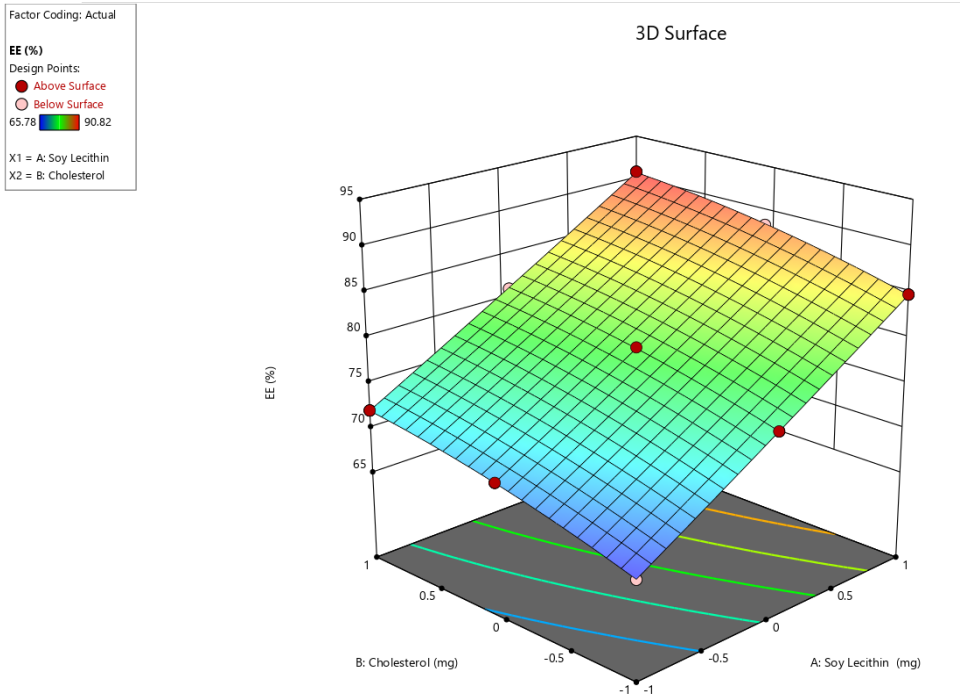
(a)


Factor Coding: Actual
Particle Size (nm)
Design Points:
Above Surface
Below Surface
135.9
231.1
X1 = A: Soy Lecithin
X2 = B: Cholesterol
3D Surface
Particle Size (nm)
240
220
200
180
160
140
120
1
0.5
0
-0.5
-1
B: Cholesterol (mg)
A: Soy Lecithin (mg)

(b)


Factor Coding: Actual
EE (%)
Design Points
65.78
90.82
X1 = A: Soy Lecithin
X2 = B: Cholesterol
EE (%)
B: Cholesterol (mg)
A: Soy Lecithin (mg)
70
75
80
85
90

(c)



(d)

Figure 1: Influence of Soy Lecithin (X_1) and Cholesterol (X_2) on Particle size (Y_1) and Entrapment efficiency (Y_2). 2D Contour plots (a, c) and 3D Response surface plots (b, d).

completely and quickly. This formulation stands out with the highest cumulative release at every time point, suggesting it has the most efficient release mechanism.

Drug release Kinetics

Different kinetic models applied to *in vitro* release data from Phytosomes. With the highest correlation coefficient (R^2) of 0.9949 for optimized Phytosome formulation, it was confirmed that the release of phytosomes formulation was zero order (Shown in Table 4).

Stability Studies

The stability study of the optimized batch (F8) for Barbaloin-loaded phytosomal suspension and gel was conducted over a period of two months. Initially, the particle size of the phytosomal suspension was 231.1 ± 0.2 nm, with an entrapment efficiency of 90.82 ± 0.2%. The pH of the phytosomal gel was 6.90 ± 0.3, and its viscosity was 9620 ± 8 cps. After two months, the particle size of the suspension slightly increased to 234.6 ± 0.19 nm, while the entrapment efficiency decreased to 89.41 ± 0.3%. The pH of the gel reduced to 6.72 ± 0.21, and its viscosity decreased to 9434 ± 10 cps. The parameters evaluated for the stability research of barbaloin loaded phytosomal gel were determined to be within limitations which indicating that the barbaloin loaded phytosomal suspension and gel has been optimized and remained stable for two months with minor alterations. The physical appearance does not change significantly after storage.

DISCUSSION

The factorial design was used to optimize key variables, such as the concentration of soya lecithin and cholesterol ratio, impacting the characteristics of the phytosomal gel. The optimization process revealed the ideal combination of variables, leading to the best balance between particle size and entrapment efficiency. The optimized formulation demonstrated superior characteristics compared to other combinations, indicating the importance of the selected variables on the gel's performance. The small particle size enhances skin penetration, which is crucial for effective psoriasis treatment. Smaller particles have a larger surface area, improving the interaction with the skin. A high absolute value of zeta potential suggests that the particles have sufficient repulsion between them, preventing aggregation and ensuring the stability of the formulation. From FTIR data we conclude that all the characteristics peaks of barbaloin was appeared in phytosome which indicate that there are no physical and chemical interactions. These mean soya lecithin and cholesterol was compatible with barbaloin. High entrapment efficiency indicates that the majority of Barbaloin was successfully encapsulated within the phytosomes, which is critical for sustained drug release and efficacy.

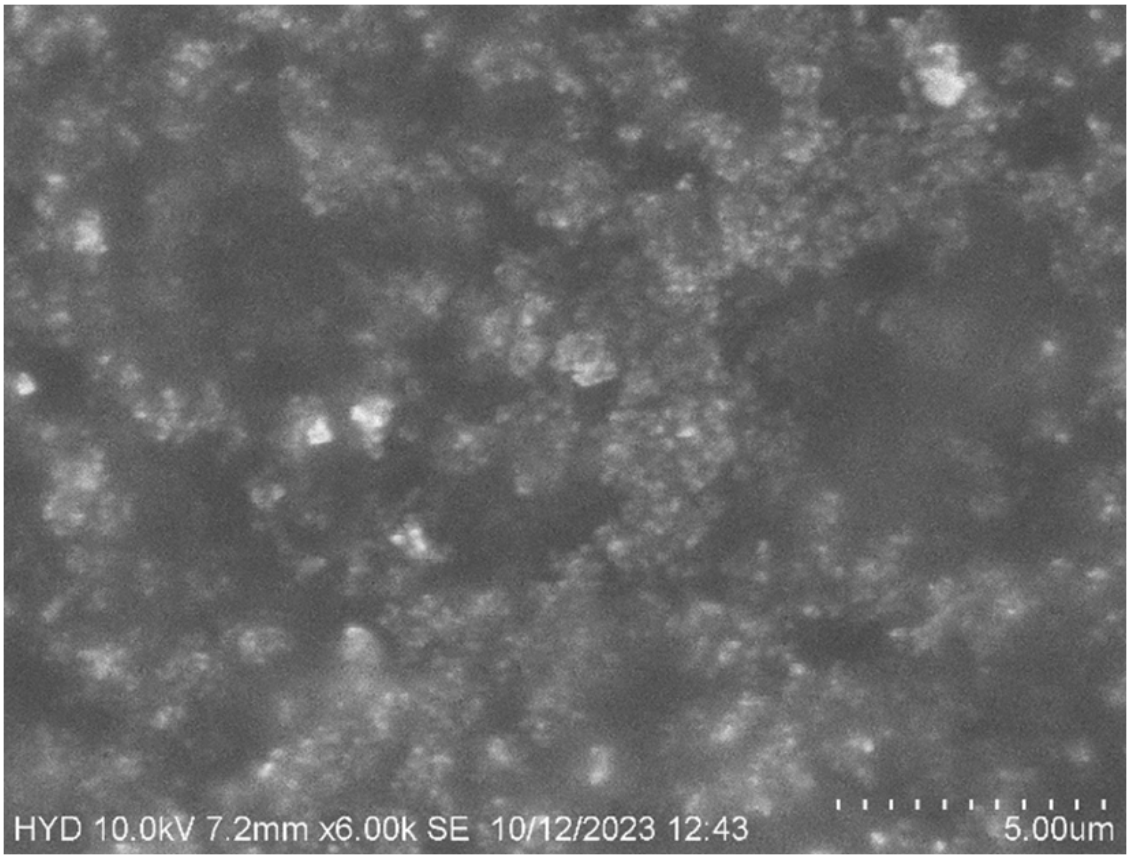


Figure 2: SEM image of barbaloin-loaded phytosomes.

Table 2: ANOVA for Response 1 Surface Quadratic model for barbaloin.

Source	Sum of Squares	d_f	Mean Square	F-value	*p*-value	
Model	9165.44	5	1833.09	242.86	0.0004	significant
A-Soy Lecithin	8490.08	1	8490.08	1124.8	<0.0001	
B-Cholesterol	401.8	1	401.8	53.23	0.0053	
AB	6.5	1	6.5	0.8615	0.4218	
A^2	266.81	1	266.81	35.35	0.0095	
B^2	0.245	1	0.245	0.0325	0.8685	
Residual	22.64	3	7.55			
Cor Total	9188.08	8				

Table 3: ANOVA for Response 2 Surface Quadratic model for barbaloin.

Source	Sum of Squares	d_f	Mean Square	F-value	*p*-value	
Model	589.47	5	117.89	5654.09	<0.0001	significant
A-Soy Lecithin	533.55	1	533.55	25588.8	<0.0001	
B-Cholesterol	54.72	1	54.72	2624.46	<0.0001	
AB	0.0156	1	0.0156	0.7494	0.4504	
A^2	0.043	1	0.043	2.06	0.2464	
B^2	1.14	1	1.14	54.44	0.0051	
Residual	0.0626	3	0.0209			
Cor Total	589.53	8				

Table 4: Analysis of Kinetic Release Model of Formulations.

Formulation Code	Regression Coefficient (R^2)		
	Zero Order	First Order	Higuchi Model
F1	0.9913	0.9133	0.8069
F2	0.9900	0.9517	0.8383
F3	0.9917	0.8973	0.7871
F4	0.9917	0.8973	0.7871
F5	0.9856	0.9318	0.8606
F6	0.9853	0.9620	0.8684
F7	0.9918	0.9086	0.8045
F8	0.9949	0.8839	0.8246
F9	0.9805	0.9349	0.8176

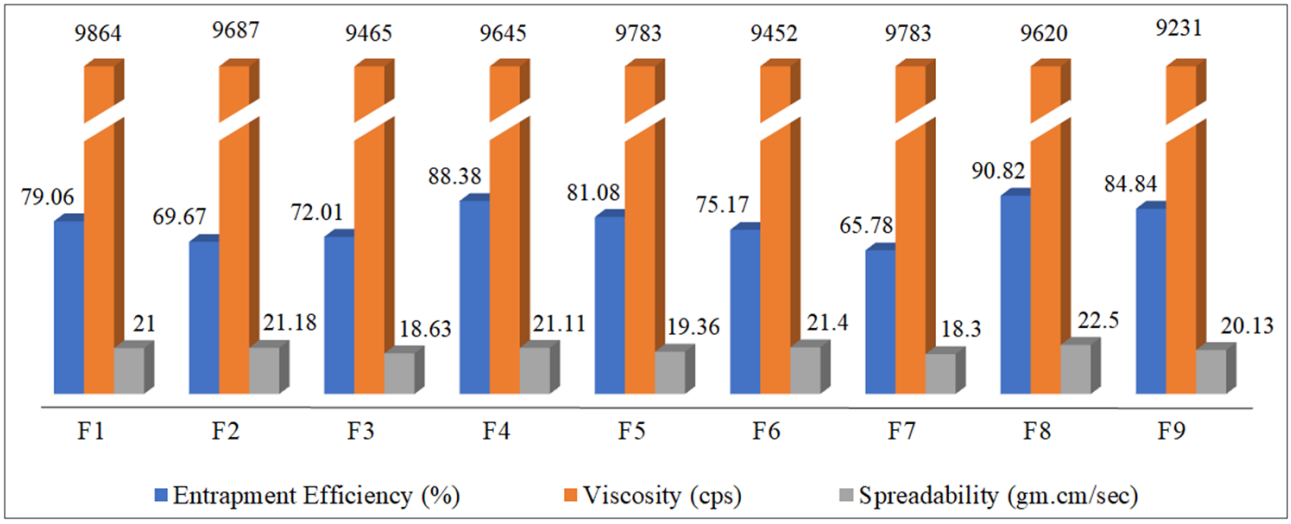


Figure 3: Evaluations of phytosome and phytosomal gel.

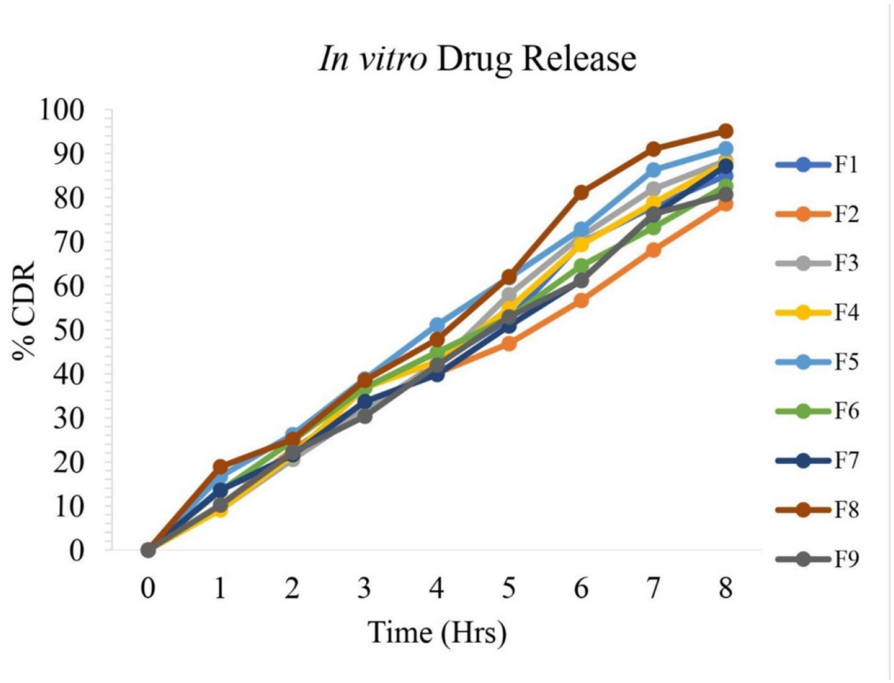


Figure 4: *In vitro Release Study.*

The viscosity affects the application and user experience; an optimal viscosity ensures that the gel stays on the skin long enough to release the drug effectively. The pH is within the acceptable range for topical applications, ensuring that the gel is non-irritating and compatible with the skin's natural pH. The spreadability of the gel was tested and found to be satisfactory, indicating easy application. Good spreadability ensures that the gel can be evenly distributed over the affected area, which is important for uniform drug delivery. The *in vitro* drug release studies showed a sustained release of Barbaloin over 8 hr. The sustained release profile is ideal for maintaining therapeutic levels of the drug in the skin over an extended period, reducing the need for frequent application. The release kinetics was analyzed and followed a specific model, such as zero order kinetics suggesting diffusion-controlled or anomalous transport release mechanisms. Understanding the release kinetics helps in predicting how the drug will behave *in vivo*, ensuring consistent therapeutic effects. The stability studies conducted over a period of 2 months showed that the gel maintained its Particle size, Entrapment efficiency, pH and Viscosity. Stability is crucial for ensuring the shelf life of the formulation. The stability studies indicate that the phytosomal gel is robust and can be stored without significant degradation.

CONCLUSION

A recent study highlights the medicinal and aesthetic benefits of plant products, especially those with flavonoids and polyphenolic compounds, through novel drug delivery methods in herbal pharmaceuticals. Despite their potential, barbaloin compounds face challenges in crossing lipid-rich biological membranes due to poor lipid solubility and large molecular size, resulting in low bioavailability. This research demonstrates, for the first time, the potential of a barbaloin phytosomal formulation to enhance bioavailability. A highly efficient phytosome was created using a combination of cholesterol and soya lecithin, with the F8 formulation showing the highest entrapment efficiency among the tested formulations. Barbaloin known for its strong anti-inflammatory, antipsoriatic, wound healing and antimicrobial properties, suffers from significant oral bioavailability issues. The study's results indicate that barbaloin phytosomes can improve the skin absorption of barbaloin, making it effective for treating inflammation-related pain in psoriasis, as well as wound healing and microbial infections, both superficial and deep. The carbopol gel was adapted to include the optimized formulation and assessed for pH, spreadability and viscosity. The phytosomal formulation showed enhanced release in *in vitro* studies, emphasizing the importance of factorial design in developing optimized formulas.

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ABBREVIATIONS

NDDS: Novel drug delivery system; **MLVs:** Multi lamellar vesicles; **SUVs:** Small unilamellar vesicles; **DLS:** Dynamic light scattering; **PCS:** Photon correlation spectroscopy; **FTIR:** Fourier transform infrared spectroscopy; **EE:** Entrapment efficiency; **CDR:** Cumulative drug release.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTION

M. V. Kapse: Methodology, investigation, software, original draft writing. J. A. S. Mulla: conceptualization, draft reviewing, supervision.

SUMMARY

In phytosome preparation, soya lecithin acts as a carrier that interacts with the active phytoconstituent (like Barbaloin) to form a complex. This complex improves the bioavailability and absorption of the active compound.

The phospholipids in soya lecithin form a lipid-compatible vesicle around the phytoconstituent, enhancing its stability, solubility and ability to penetrate biological membranes, which is particularly beneficial in topical applications like gels.

Barbaloin loaded phytosomal gel was develop for a topical treatment for psoriasis by incorporating Barbaloin, a compound known for its anti-inflammatory and healing properties, into a phytosomal gel.

The formulation process would involve optimizing the gel for maximum drug loading and stability while ensuring effective delivery of Barbaloin to the affected skin areas.

The evaluation phase would assess the gel's physicochemical properties, its ability to penetrate the skin and its therapeutic efficacy in treating psoriasis symptoms.

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