

ORIGINAL ARTICLE

Development and Evaluation of the Herbal Niosomel Gel for the treatment of Vitiligo

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ABSTRACT

Vitiligo also called as leukoderma occurs when there less secretion of the melanin from melanocytes and destruction in the number of the melanocytes. *Psoralea corylifolia* extracts has reported furanocoumarins, which contain Psoralens, which stimulates the skin to produce melanin pigment and increase the proliferation of the melanocytes. The available treatment for vitiligo is the steroid, JAK- Status Kinase inhibitor which has adverse effects on body. The plant origin drug has fewer side effects and toxicity. Niosomes were utilised to boost the permeability and effectiveness of the phytoconstituents since they are less permeable through skin. Therefore, The goal of the study was to create and characterise a niosomel gel that was loaded with *Psoralea corylifolia* extract and used to treat vitiligo. The *Psoralea corylifolia* extract-containing niosomes were synthesised via the ether injection method. A central composite design approach was used where a two-factor system with cholesterol and Span 60 was used to determine vesicle size and entrapment efficiency. Optimised niosomes and extract were added to 1% Carbopol gels to create 10% of niosomel and conventional gel. Comparative study was done by Using the Franz diffusion cell technique, in vitro drug release research was conducted on produced niosomel gel and normal gel. Independent factors had a considerable impact on vesicle size and entrapment efficiency, as demonstrated by the statistical study. It was discovered that the optimised batch's vesicle size was 710 nm, and its entrapment effectiveness was 97.48%.The in vitro niosome drug release investigation demonstrates the sustained and extended release from niosomes.Three different temperatures were used for the niosome stability investigation, and 4°C was shown to be the stable temperature.The comparative study between the Niosomel gel and Normal gel indicate sustained release of the drug compared to the Normal gel. These findings revealed that niosomel gel represents a promising carrier system having sustained release of *Psoralea corylifolia* through niosomes. The niosomel gel was formulated and evaluated successfully for various parameter. Further preclinical and clinical trials need to be carried out to prove antivitamin activity, safety and efficacy of gel for the treatment of the vitiligo.

Keywords: Vitiligo, Niosomes, Phytoconstituent, cholesterol, non-ionic surfactant

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INTRODUCTION

Any herbal formulation's ability to function correctly depends on how well the phytoactives are delivered to the intended location. The formulation has a limited bioavailability when taken orally. The creation of a unique medication delivery technology that improves the stability and bioavailability of phytoconstituents can help get over this restriction. Similar in structure to liposomes, niosomes are vesicular drug delivery systems that offer improved stability and skin penetration. The non-ionic surfactant used in niosome manufacture is non-carcinogenic, unlike lipids, which may be harmful to the body. vitiligo is a condition in which there is less secretion of melanin which is the skin pigment and destruction of melanocytes leads to white patches on the body [1]. Patients with vitiligo suffers physical, psychological and social consequences. Many treatments are available to reduce the size of white patches, and slowing down the disease progression by proliferation of the melanocytes, as well as increase the melanin secretion and increasing the tyrosinase activity which ultimately leads to increase in the secretion of the melanin [2]. Psoralen is a phytoconstituent found in *Psoralea corylifolia* L plant, Family

Leguminosae. Seeds and leaves of plant *Psoralea corylifolia* L. contains Psoralen as an active phytoconstituent which in traditional topical formulations caused negative responses because of their weak skin deposition and limited skin penetration, which necessitated repeated administration. Furthermore, severe sunburn, blisters, and increased pigmentation darkening result from free drug direct exposure to sunlight. These issues related to the conventional formulation necessitates the development of *Psoralea corylifolia* loaded niosomal gel. So, to overcome the side effects of herbal drug, and obtain efficacy, we have incorporated *Psoralea corylifolia* extract in niosomes to form a stable antiviral formulation [3].

MATERIAL AND METHODS

Psoralea corylifolia seeds extract was obtained from Janani organics. All other chemicals and solvents used like ethanol, span 60, cholesterol, diethyl ether, methanol, Carbopol 934 were of analytical grade.

Phytochemical and pharmacognostic study of *Psoralea corylifolia* Linn;

A preliminary test for extract of *Psoralea corylifolia* Linn was carried out by traditional methods. The extract of *Psoralea corylifolia* Linn was screened with different chemicals as well as for physical tests such as test for alkaloids, test for glycoside, test for saponin, test for carbohydrates, tannins [4].

Identification of compound by using FTIR: The main active constituent in the extract was identified by comparing the FTIR of the Psoralen marker with the extract [5].

Estimation of extract using UV spectroscopic method.

Calibration curve for the extract of *Psoralea corylifolia* Linn:-

The standard dilutions of drug extract were prepared according to the experimental procedure in the standard prepared stock solution was tested by UV-Visible spectroscopy. They are individually scanned by UV-Visible spectroscopy in the range of 200-400nm to determine the maximum wavelength. The maximum wavelength of *Psoralea corylifolia* Linn extract was found to be 247nm. The Standard solutions form of volumetric flasks, and the volume in the volumetric flask was made up of distilled water and the absorbances of these solutions were measured. The standard graph of *Psoralea corylifolia* Linn gives good linearity which is observed standard graph of served as 0.992, which indicates that this obeys Beer's- Lambert's law in the concentration range of 0-10 µg/ml.

Drug Excipient compatibility studies:

FTIR: The extract was then analysed using FTIR spectroscopy where the main peak and that of reference standard were determined. Furthermore, they were performed to check the compatibility of extracts constituents for instance cholesterol, Span 60 in case of niosomal extracts. The FTIR of the extract and the optimised niosomal formulation was done using the Alpha Bruker spectrophotometer. This study was compared reference peak for any incompatibilities once getting the FTIR spectra of the samples.

DSC: DSC of Drug and Drug excipient combination was carried out for assessing drug excipient compatibility. The thermal study was carried out between 30°C and 400°C at a heating rate of 10°C/min in a nitrogen environment [6].

Formulation of Herbal Niosomes:

Using a modified ether injection approach, niosomes containing *Psoreliya coryfolia* were created by varying the quantities of cholesterol and a nonionic surfactant (span 60). In a mixture of 2 ml ethanol and 6 ml diethyl ether containing a weighed quantity of drug, the surfactant and cholesterol were dissolved. Using a microsyringe, the resultant solution was gradually injected into 15 ml of phosphate buffer (pH 7.4) hydrating solution at a rate of 1 ml/min. The temperature of the solution was kept between 60°C and 65°C, while it was constantly agitated using a magnetic stirrer. The fast vaporisation of ether caused by the sluggish injection of the lipid solution into the aqueous phase due to temperature variations between the phases causes vesiculation and the creation of niosomes. According to the previously described basic procedure, multiple batches of niosomes were prepared in order to determine the composition of the final formula [7].

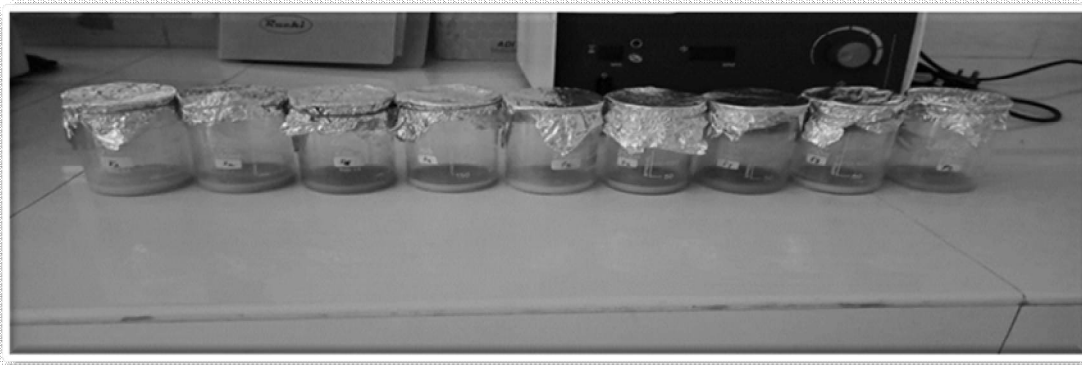


Fig no 1: 9 runs of the niosomes of different concentration of cholesterol and the surfactant

Evaluation Of Niosomes:

Vesicle Size: Optical microscopy at 45 x resolution was used to validate the vesicle production process. After covering a glass slide with the niosomal solution and allowing it to dry at room temperature, a dry thin layer of the niosome suspension was observed for the development of vesicles [8].

Particle Size, and size distribution: It was estimated using the Dynamic light scattering technique at $25 \pm 1^\circ\text{C}$ and a 90-degree scattering angle, using a computerised inspection system (Zetasizer, HAS 3000; Malvern Instruments, Malvern, United Kingdom).

Zeta potential: The Zetasizer, also known as the Malven Zetasizer, gauges the zeta potential of niosome solutions by putting the formulation in a clear, single-use Zeta cell and monitoring the results. The cuvettes are cleaned with methanol before the sample is added for the experiment. Malvern Zeta Sizer Nano Essential was used to calculate zeta potential. The niosomal formulation Zeta potential and the stability of the niosomal vesicle are connected. Excellent stability and a high degree of vesicle repulsion are indicated by a high zeta potential value. Meaning that the dispersion will fend off aggregation [9]

Entrapment efficiency: According to Jones et al cooling centrifuge, the entrapment efficiency of niosomes was determined. The niosome formulations were subjected to centrifugation for 30 minutes at 4°C using speed of 12000rpm. The free drug contents were further ascertained by UV/visible spectrophotometer (uvikon XL, Bio-Tec, Instrument, Bad Friedrichshall Germany) at λ_{max} of 246 nm after the separation of the supernant.

Next, the %EE was computed using the following formula:

Total drug - Drug in supernatant / Total drug x 100 = Drug entrapment percentage [10].

In Vitro Drug release study: The Franz diffusion device and the cellulose membrane were used in the in vitro drug release investigation of the niosomes. Surface area of the receptor was 1.76 cm square, and its volume capacity was 12 ml. Between the donor and the receptor compartment of the flow-through cell was a cellulose membrane. The receptor part was filled with phosphate buffer solution, which has a pH of 7.4. Its function was to replicate blood medium. Temperatures of 37°C and a stirring speed of 300 rpm were set for the device. The niosome formulation was uniformly distributed over the membrane. For the duration of the eight hours, a sample of two millilitres was taken out at regular intervals, and the same volume of buffer solution was supplied to receptor compartment to keep the sink condition. A UV-visible spectrophotometer was used to measure absorbance. A graph was created by plotting the total amount of medication absorbed over time [11].

Differential scanning calorimetry analysis: The sample of the optimal niosomal formulation was placed in perforated aluminium pans and sealed hermetically. It was then heated to a temperature range of 30 to 300°C at a rate of $10^\circ\text{C}/\text{min}$ using a differential scanning calorimeter (Schimadzu, model DSC-50, Japan)[12].

Stability study of the Niosomes: The stability study is conducted at three different temperatures according to the ICH guidelines in the period of 2 month.

Physical stability study : To find out if drugs leach from niosomes stored in a refrigerator, at room temperature, or at an increased temperature, a physical stability investigation of the manufactured niosomes was conducted. The portion of drug entrapment that is still present in niosomes composed of cholesterol and span 60 at varying molar ratios after 15, 30, 45, and 60 minutes[13].

Chemical stability: FTIR spectroscopy was used to estimate the chemical stability during four separate time periods.

Preparation of the niosomes -based gel

Based on the analysis of *Psoralea corylifolia*-loaded niosomes, the F6 batch's niosomes were chosen to be included in the gel dosage form. Using a homogenizer, 1 g of carbopol 934 was added to 100 ml of distilled water at 50°C and continuously stirred at 450 rpm to create the simple gel in the first stage. The gel was preservative-treated with trace amounts of methyl and propyl paraben (0.02%). The formed Carbopol gel was fully combined with the ultracentrifuged niosomal formulation of the F6 batch, which is equivalent to 50 mg of *Psoralea corylifolia*. Ultimately, a measured amount of triethanolamine added to the neutralizer to raise the pH of the produced Carbopol 934 combination to 6.4, at which point gel formation took place [14].

Evaluation of the Niosomal gel:

Organoleptic properties: Clarity, colour, homogeneity, and the presence of foreign particles were assessed in the produced gel.

pH Determination: A digital pH metre was used to measure the pH of several gel formulations. After giving the formulation, a minute to equilibrate, the pH of the mixture was measured using a pH metre. pH is a crucial factor in preventing the formulation from irritating the skin's membrane.

Viscosity study: A Brookfield digital viscometer (model DV-1+, Brookfield Engineering Laboratory, INC, USA) was utilised to determine gel compositions' viscosity (in poise). Spindle number RV 7 was utilised to record the viscosity of different formulations at 20 RPM [15].

Spreadability Study: 0.5 g of the gel was spread out on a glass plate to test the gel's spreadability, and then another glass plate was used. To determine the formulation's spreadability, a defined amount of weight (in grammes) was put to a moving glass slide pan for a certain amount of time (in minutes). The distance the slide moved was measured (in centimetres), and the results were entered into a formula.

Drug content : Research on the medication's uniform distribution across the whole formulation was conducted by drug content experiments. The procedure involved selecting a unit dose at random from the formulation, dissolving it in 20 millilitres of distilled water, and then increasing the volume to 100 millilitres. After that, 1 millilitre of the resulting solution was removed and the volume was increased to 10 millilitres using distilled water (this is where the dilution factor increases to 10,000). Using a UV-visible spectrophotometer, the absorbance of the final solution at a specified λ_{max} was obtained, and the drug content was calculated using the provided formula [16].

Drug content = Absorbance/Slope $\times$ Dilution factor $\times$ 1/1000

In vitro Drug release Study: For this investigation, the Franz Diffusion cell was employed. The donor part was tightly sealed with a cellophane membrane to keep the formulation clearly, and the receptor section was filled with a pH 7.4 buffer. Designated volume of solution was removed from the receptor section at regular intervals while keeping the sink condition at 37°C. A UV-Visible spectrophotometer set to λ_{max} 246 nm was used to measure the quantity of drug present [17].

Comparative study between Normal Gel and the Niosomal Gel : The in vitro drug release parameter was evaluated in order to do a comparison study between the Niosomal gel and Normal gel [18].

RESULTS

Phytochemical test of *Psoralea corylifolia* extract:

Table no 1: Phytochemical test of the *psoralea corylifolia* extract

Sr No	Test performed	Results
1	Alkaloids	+
2	Glycoside	+
3	Saponins	+
4	Carbohydrate	+
5	Tannins	-

Identification of the compound: When FTIR spectra of the psoralen marker and the ethanolic extract were compared, it was found that the predominant peak in both spectra was the same as that of fig. no.2, suggesting the presence of psoralen in the *Psoralea corylifolia* seeds' ethanolic extract.

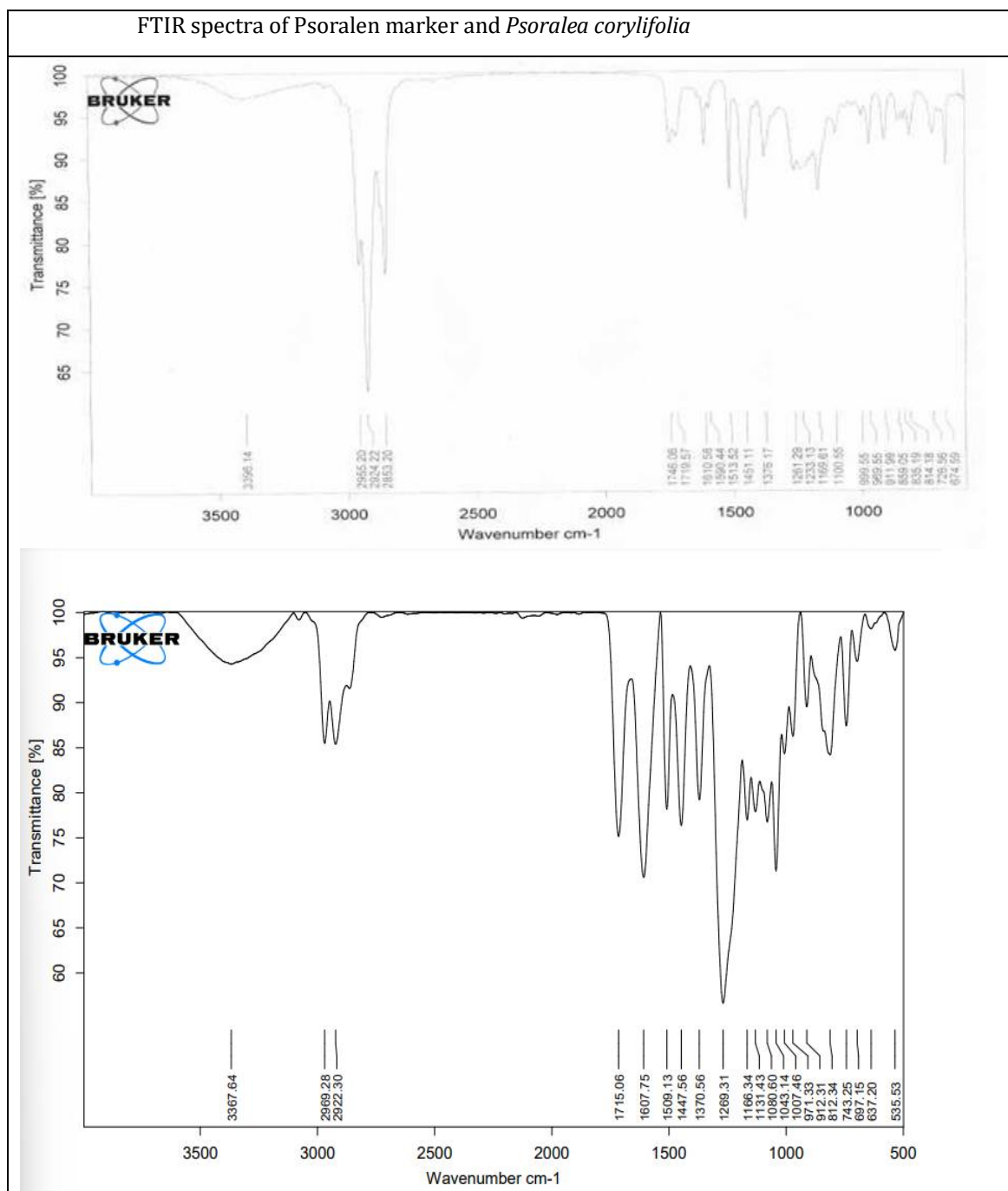
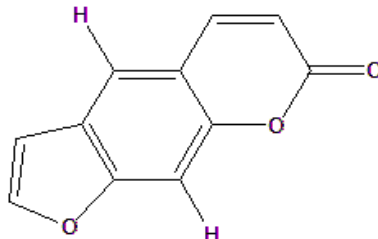


Fig no 2: FTIR spectra of the psoralen marker and *Psoralea corylifolia*
 Structure of the Psoralen Active constituent.



The structure of psoralen consist of (C=C-C) (C=C-C), (C-H), (C-O-C), (C=O) stretching and this groups was detected in the given range of the FTIR which indicate the presence of the psoralen in the extract

Table no 2 : Interpretation of the ethanolic extract's main peaks and the psoralen marker's FTIR spectra

FTIR spectrum of the marker psoralen	FTIR spectra of the psoralen-containing ethanolic extract of <i>Psoralea corylifolia</i> seeds
Major peak interpretation :- 1)1746.06cm⁻¹,1719.5cm⁻¹ Verifies the presence of the carbonyl group (C=O) in the structure 2)1100.55cm⁻¹,1169.61cm⁻¹,1233.13cm⁻¹,1261.29cm⁻¹ Verifies the presence of the ether group (C-O-C) in the structure 3)2955.20cm⁻¹,2924.22cm⁻¹,2853.20cm⁻¹ Verify the presence of an aromatic group and vinyl hydrocarbon (C-H) in the structure. 4) 1610.58cm⁻¹ Verifies the C=C group in the structure 5)1590.44cm⁻¹,1513.52cm⁻¹,1451.11cm⁻¹ Verifies the presence of an aromatic ring inside the structure	Major peak interpretation :- 1)1715.06 cm⁻¹ Verifies the presence of the carbonyl group (C=O) in the structure 2)1269.31 cm⁻¹ Verifies the presence of the ether group (C-O-C) in the structure 3)2922.30 cm⁻¹ Verifies the presence of a vinyl hydrocarbon group (C-H) and an aromatic group in the structure. 4) 1607.75cm⁻¹ Verifies the C=C group in the structure 5)1509.13 cm⁻¹ Verifies the presence of an aromatic ring inside the structure

UV calibration curve :UV spectrum of *Psoralea corylifolia* Linn extract (maximum wavelength was found to be 246nm)

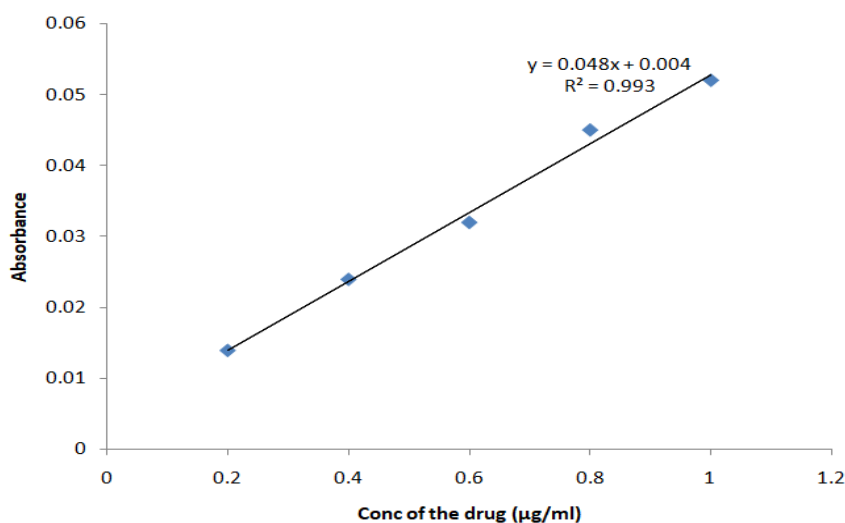


Fig no 3: UV calibration curve

Drug – Excipient compatibility study

Compatibility study by using FTIR spectroscopy: one of the most crucial analytical instruments for examining formulation stability and the molecular interactions between medications and the excipients being employed.

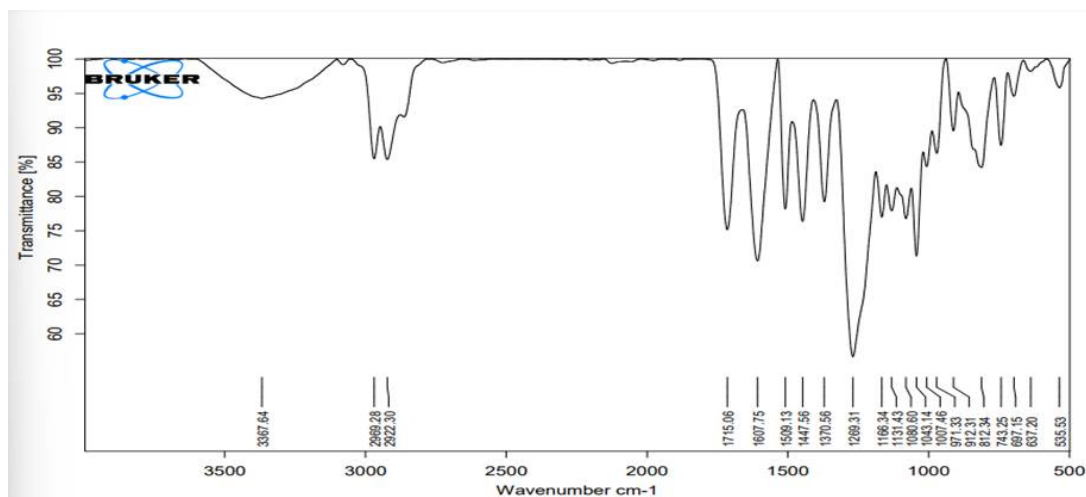


Fig no 4: FTIR of Extract

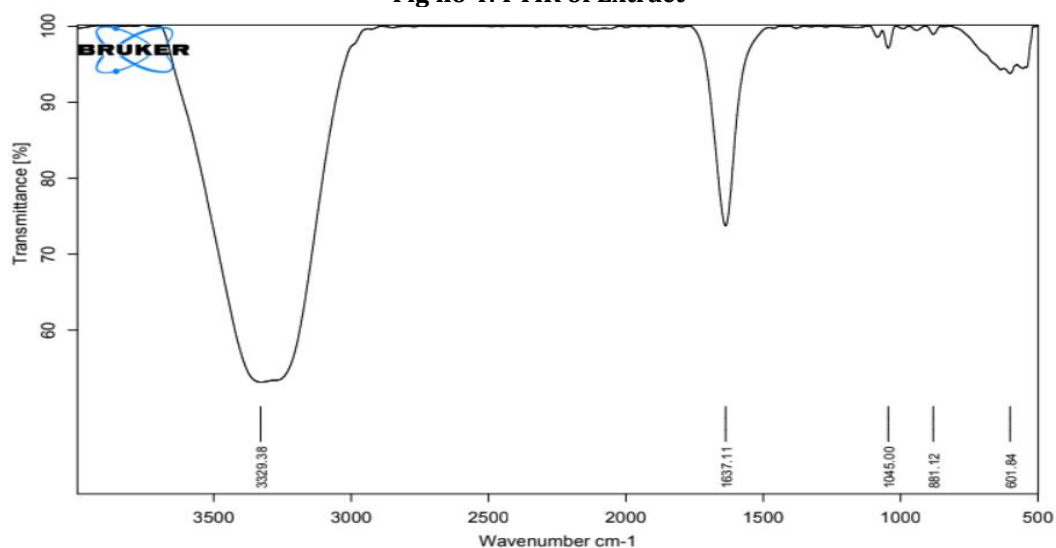


Fig no 5: FTIR spectra of the formulation

The FTIR spectrum of the formulation does not contain any unwanted peak and the frequency range lies is nearly similar to the frequency region of the extract.

Compatibility study by DSC :

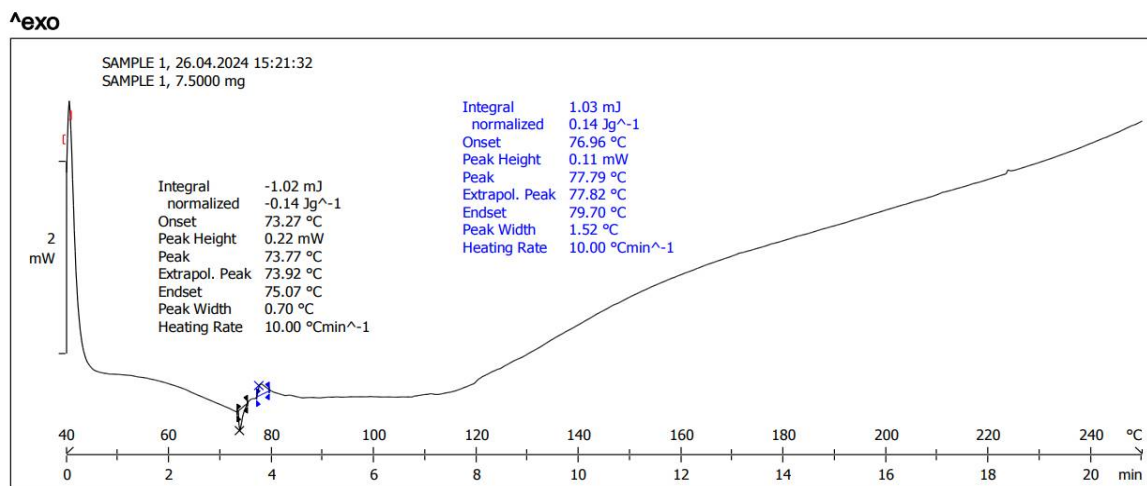


Fig no 6: Thermogram of the Extract

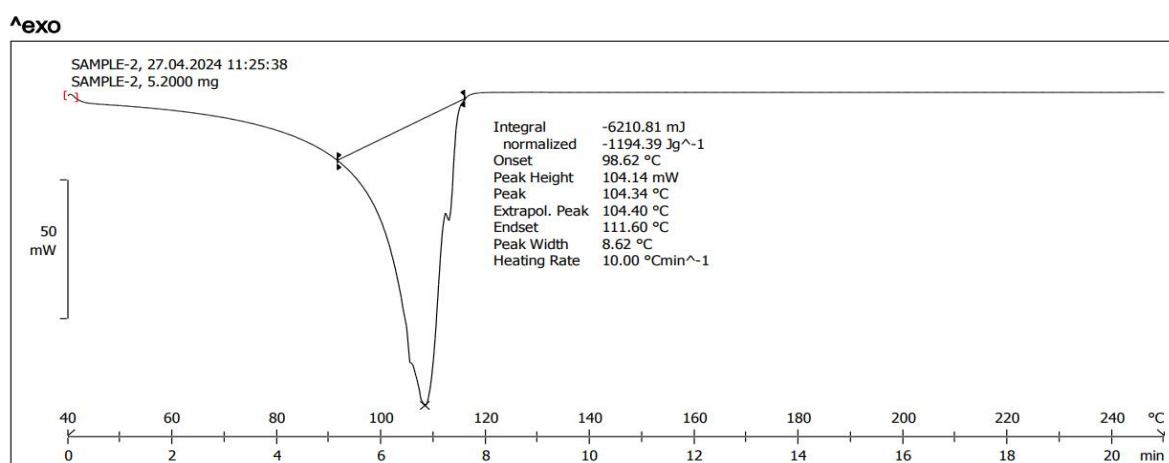


Fig no 7 : Thermogram of the Niosomes

The span 60 showed endotherms at 54.63, 122.96 and 271.2°C and the cholesterol shows endotherm peak at 150 as per given in the research articles. The extract showed endothermic peak at 77.79°C while the formulation of niosomes containing the mixture of extract, span 60 and cholesterol shows endothermic peak at 104.34°C. The shifting of the endothermic peak to the highest temperature is may be possible due to entrapment of the extract within the non-ionic surfactant bilayer, and as there was no extra peak seen in the formulation, which confirmed that there was no any physical interaction between extract *Psoralea corylifolia* and the excipients. 3.5) Preparation of the Niosomes: Using the ether injection method, the *Psoralea corylifolia* loaded niosomes were successfully manufactured by employing central composite design, leading to the final optimised formula. The final recipe is optimised based on vesicle size and entrapment efficiency data. In addition, the optimised formula was characterised for factors such as particle size, shape, in vitro release, and surface morphology. *Psoralea corylifolia* loaded Niosomal gel was created by loading this final, optimised formulation onto a gel foundation.

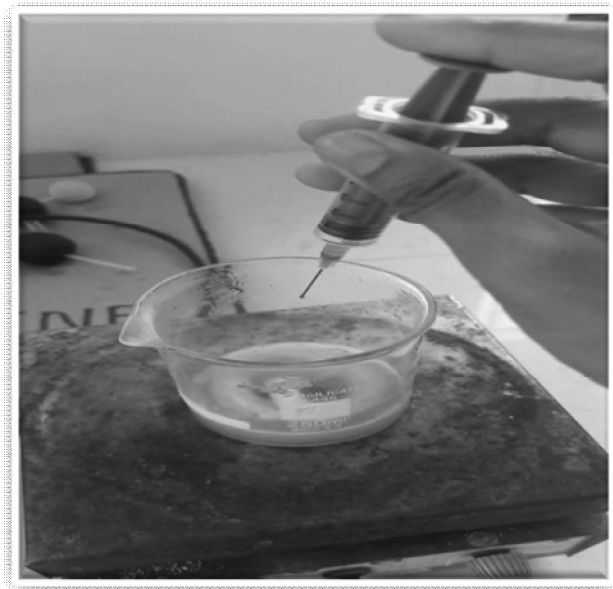


Fig no 8: Preparation of the niosomes

Statistical analysis of experimental design

Utilising a core composite design, the niosome-loaded extract was effectively created, allowing researchers to determine how the niosomal component span 60 and cholesterol impact its properties. After formulation of 9 batches of niosomes, the result of particle size and entrapment efficiency were analysed to obtained ANOVA for quadratic model, regression coefficient and regression equation. Mathematical equations were generated using multiple linear regression analysis. This equation

represent quantitative effect of concentration and interaction of cholesterol and span 60 on vesicle size and entrapment efficiency.

Table no 3: 9 runs with varying con of the two factor and their responses.

Run	Conc of span 60(mg) Factor 1	Conc of cholesterol(mg) Factor 2	Vesicle size(nm) Response 1	Entrapment efficiency (%) Response 2
1	100	170.711	710	97.00
2	50	50	670	95.96
3	150	150	747	97.48
4	170.711	100	800	97.02
5	150	50	740	96.97
6	100	100	710	97.48
7	100	29.2893	700	97.47
8	50	150	645	95.55
9	29.2893	100	635	94.93

Vesicle size: Table 2 and Figure No. 9 illustrate how cholesterol and span 60 affect vesicle size. It was discovered that vesicle size increased with surfactant content. Every formulation's vesicle size was recorded in Table No 3. The size of the vesicles varies from 635 to 800nm

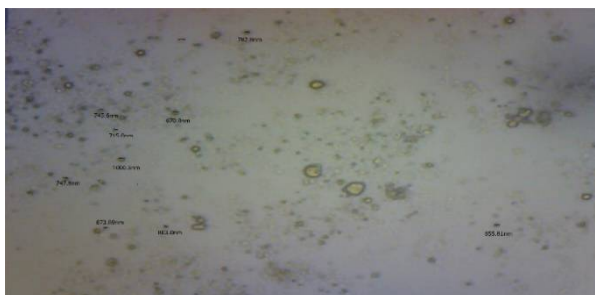


Fig no 9: Vesicle size of the niosomes by using optical microscopy

Table no 4 : ANOVA for vesicle size

Source	Sum of squares	df	Mean square	F-value	p-value	
Model	20967.34	5	4193.47	15.15	0.0244	significant
A-conc of SPan 60	20538.10	1	20538.10	74.18	0.0033	
B- conc of cholesterol	1.86	1	1.86	0.0067	0.9398	
AB	256.00	1	256.00	0.9246	0.4072	
A	3.28	1	3.28	0.0119	0.9201	
B	78.28	1	78.28	0.2827	0.6318	
Residual	830.66	3	276.89			
Cor Total	21798.00	8				

Interpretation from table no 3 is as follows

The model F value of 15.15 implies the model is significant. There is only a 2.44% chance that an F-value this large occur due to noise.

P- value less than 0.0500 indicate the model is significant. In this case A, is a significant model term.

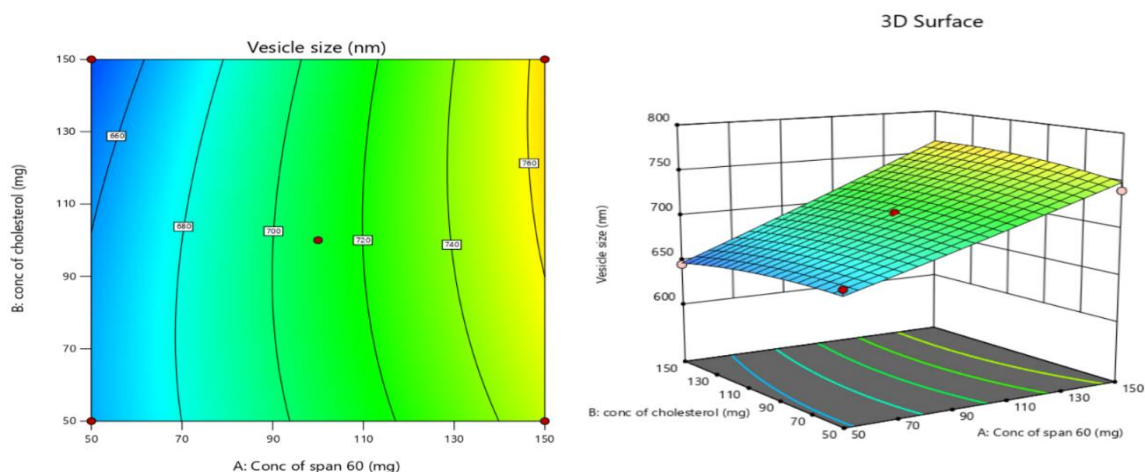


Fig no 10: Responses surface curve representing a) Contour and b) 3D effect of span 60 and cholesterol on vesicle size

Entrapment Efficiency: Table No. 2 illustrates how the percentage entrapment efficiency increased very little when the span 60 concentration increased at all cholesterol concentrations. The range of the entrapment efficiency was found to be 95.55% to 97.48%.



Fig no 11: Determination of the Entrapment efficiency by Cooling-centrifugation technique

Table no 5: ANOVA for the Entrapment efficiency

Source	Sum of squares	df	Mean square	F-Value	p-Value	
Model	6.96	5	1.39	41.92	0.0056	Significant
A-conc of span 60	4.34	1	4.34	130.91	0.0014	
B-conc of cholesterol	0.0399	1	0.0399	1.20	0.3532	
AB	0.2116	1	0.2116	6.38	0.0858	
A ²	1.78	1	1.78	53.49	0.0053	
B ²	0.0666	1	0.0666	2.01	0.2517	
Residual	0.0996	3	0.0332			
Cor Total	7.06	8				

Interpretation from table no 4 is follows:-

The model F-value of 41.92 implies the model is significant. There is only a 0.56% chance that an F- value this large occur due to noise.

P- values less than 0.0500 indicate model terms are significant. In this case A, A² are significant model terms.

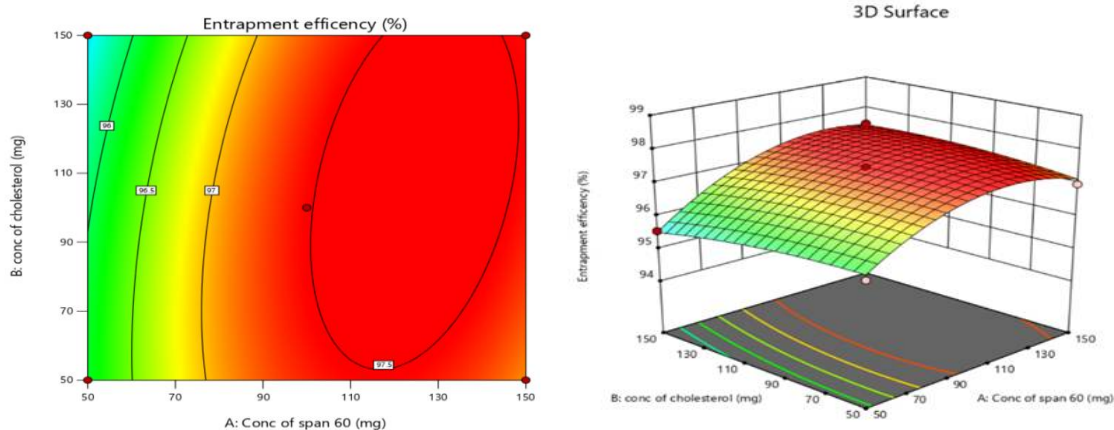


Figure no 12 : Responses surface curve representing a) Contour b) 3D effect of span 60 and cholesterol on entrapment efficiency.

Optimization of niosomes loaded with extract: The minimal vesicle size and highest %Entrapment efficiency were used to optimise niosomes. The programme provided solutions, and they were used to produce the desired and selected formulations. The remaining evaluation parameter is further examined for the optimised formulation.

Zeta potential: The surface charge is measured by the zeta potential, which provides insight into the properties of niosomes and establishes their stability. The range between -10 to -30, or the zeta potential, was determined to be -13.34, indicating the niosomal formulation's early stability. The surfactant's increased hydrophilicity might be the cause of this.

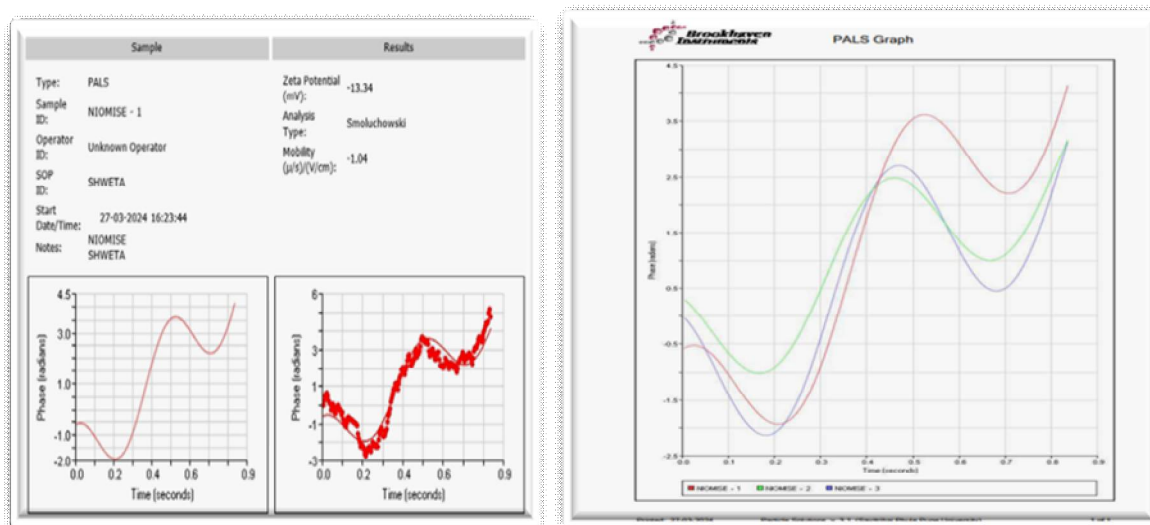


Fig no 13 : Zeta potential of the niosomes

Particle size and polydispersity index : Polydispersity index and mean particle size as calculated by DLS are

displayed in Figure No. 14. The polydispersity index of 0.357 and the mean particle size of 701.70 nm indicate that the system has a homogenous distribution.

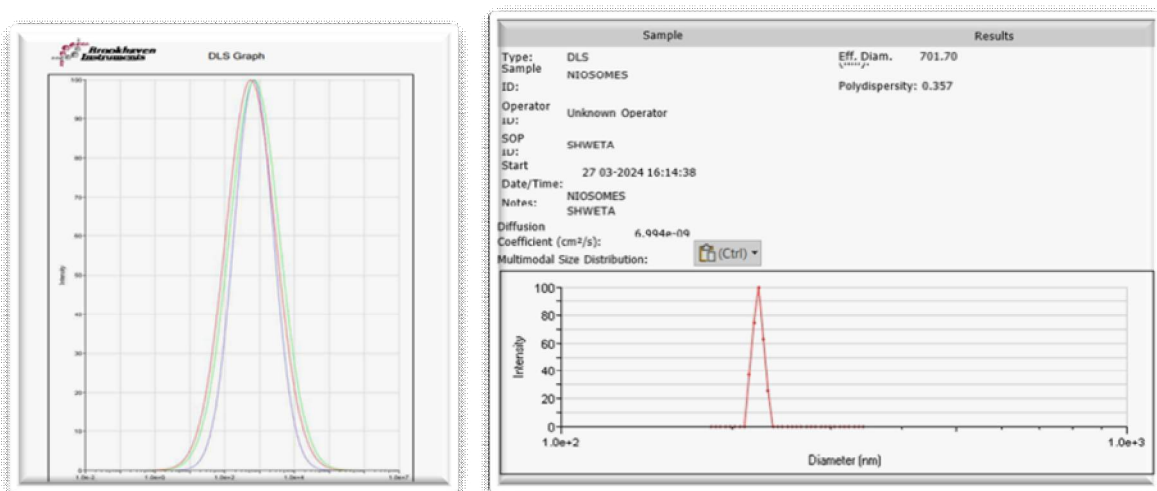


Fig no 14: Mean particle size and polydispersity index

Differential scanning calorimetry analysis: The DSC thermogram of *Psoralea corylifolia* loaded niosomes was represented in Fig no 14. The niosomes shows an endothermic peak at 104.34°C. It revealed that the extract's melting endotherm vanished around 73. 77°C. Absence of the melting endotherm of extract and shifting and/or broadening of the endotherms in the formulation of niosomes, suggest the enhanced entrapment of extract into niosomes.

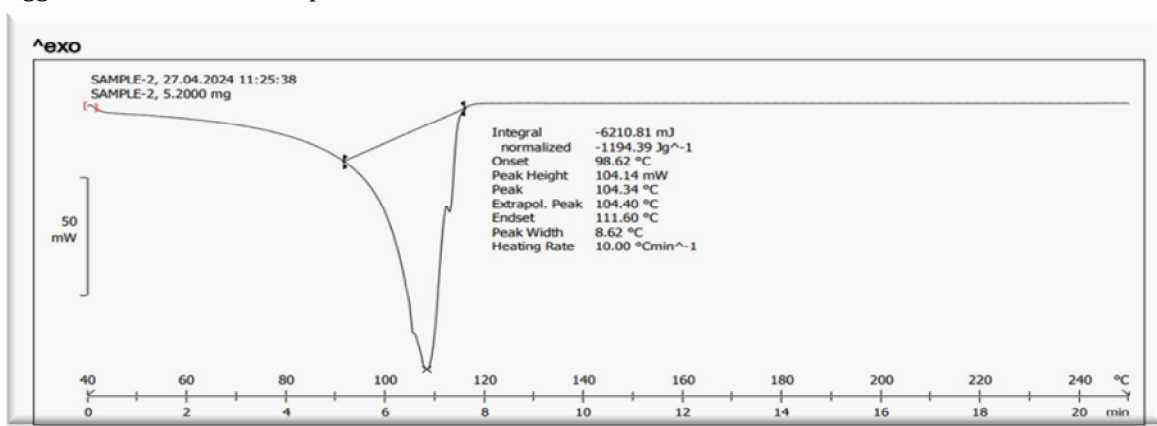


Fig no 15: DSC Thermogram of Niosomes

In vitro drug release: % cumulative release for niosomes shows an initial release of 9.088%. The vesicular carrier was able to sustain the release of *Psoralea corylifolia* extract upto 7 hours and achieve release of 80.58% at the end of 7 hours.

Percentage cumulative drug release of Niosomes

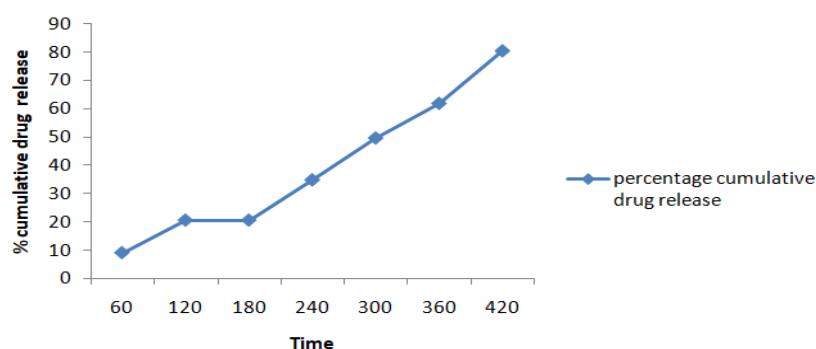


Fig no 16: *In vitro* drug release of the niosomes

Stability study:

Physical stability study:

Table no 6: Stability study

Temperature	Percentage Entrapment efficiency at different days of interval			
	15	30	45	50
4	97.48	97.03	96.00	92.01
RT	90.33	89.14	80.21	75.00
37	82.11	70.83	62.99	53.24

Temperature	Vesicle size of niosomes at different days of interval			
	15	30	45	50
4	747	738	715	707
RT	710	670	645	635
37	670	665	640	625

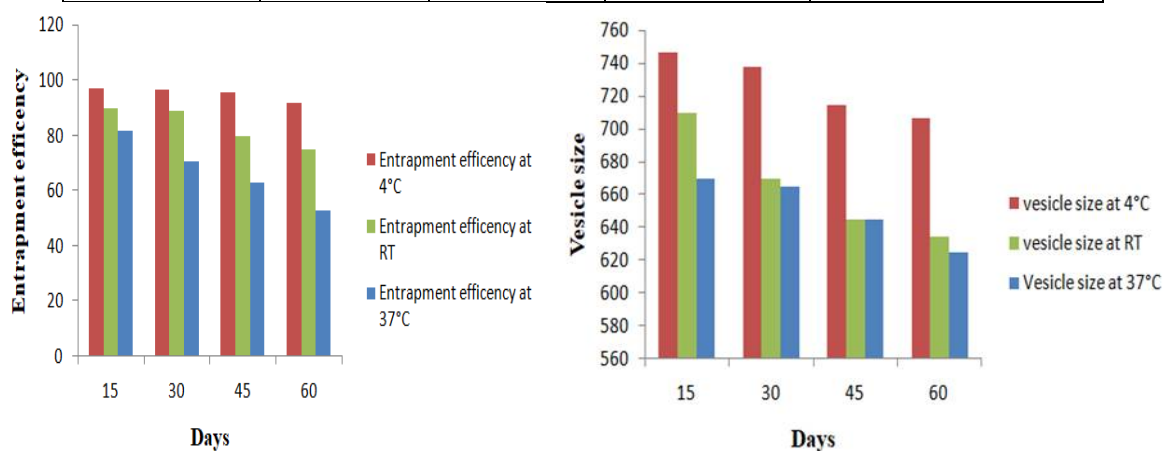


Fig no 17 : Stability study of the niosomes at three different temperature by evaluating the entrapment efficiency and the vesicle size.

Chemical stability: It was assessed by estimation of FTIR spectroscopy

Preparation of the Normal gel and Niosomal gel: *Psoralea corylifolia* extract loaded niosomal gel and Normal gel was formulated using Carbopol 934 grade polymer and comparative evaluation were done.



Fig no 18 : Preparation of the Normal gel and Niosomal gel

Evaluation of the Niosomel gel:

Organoleptic properties

Upon visual inspection, the freshly manufactured *Psoralea corylifolia* gel formulation was uniform, light orange, and transparent.

pH measurement

pH of the niosomel gel was found to be 7.4.

viscosity

Viscosity of the *Psoralea corylifolia* loaded niosomel gel was 22540 cps.

Spreadability:

Spreadability diameter was found to be 3.66 cm for niosomel gel

In vitro drug release study:

% Cumulative Drug Release was found to be 7.5% in 1 hour and 40.9% in 7 hour. Drug release from niosomel gel was found in very sustained and controlled manner.

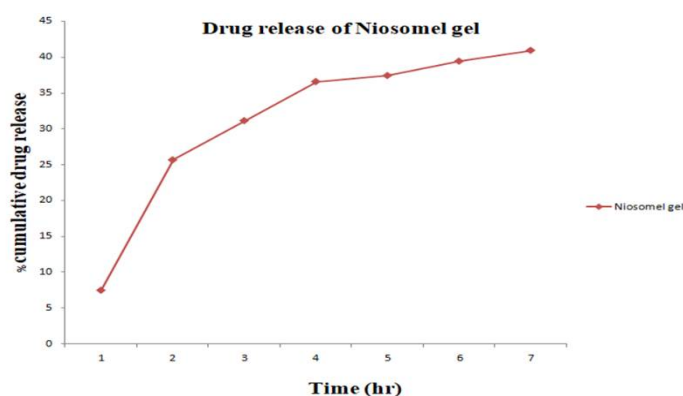


Fig no 19: % cumulative drug release of the Niosomel gel

Comparative study of the Niosomel gel and Plain Gel:

Niosomel gel equivalent to 50 mg of drug was taken for the release studies and the result were compared with that of the Normal gel. The results indicate sustained release of the drug compared to the Normal gel. Fig no 20 shows the comparison between the two gel.

Table 7 : Comparative study of two gel

In vitro drug release of the Niosomel gel versus Normal gel		
Time	Niosomel Gel	Normal Gel
1	7.5	4.5
2	25.66	9.25
3	31.12	11.666
4	36.56	14.166
5	37.4	23.582
6	39.4	32.8332
7	40.9	33.164

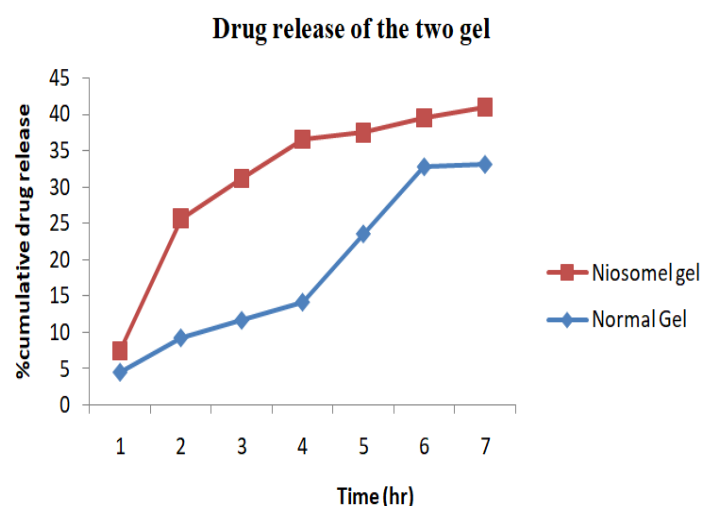


Fig no 20: Comparison of the Normal gel and the Niosomel gel by comparing the drug release profile of two gel.

CONCLUSION

The novel drug delivery system is significantly important in pharmacotherapy as it addresses many issues associated with conventional drug delivery systems, such as limited bioavailability, stability concerns, first-pass metabolism, and adverse effects, by integrating the drug into the innovative delivery mechanism. The extract of *Psoreliya corylifolia*, which contains psoralen, a phytoconstituent with notable antivittiligo activity, exhibits certain limitations and adverse drug reactions, such as severe erythema and sunburn, when free drugs come into direct contact with the skin. To mitigate these issues, the extract is incorporated into niosomes. Niosomes were successfully synthesised using the ether injection approach. The compatibility of *Psoreliya corylifolia* extract with other excipients in the formulation was established using FTIR and DSC analysis. The optimisation was conducted via the central composite design. The attributes of optimised niosomes encompassed vesicle size, entrapment efficiency, zeta potential analysis, and *In vitro* drug release. The produced niosomes were subsequently incorporated into a 1% Carbopol gel. All evaluation factors, including appearance, drug content, pH, viscosity, spreadability, and *in vitro* drug release studies, were conducted. The formulated *Psoreliya corylifolia*-loaded niosomal gel exhibits a significant *in vitro* release compared to the plain gel. The study concludes that the *Psoralea corylifolia*-loaded Niosomel gel was effectively designed, optimised, and assessed, exhibiting superior features and release compared to standard formulations.

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