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Research Article

Development and Characterization of Caffeine-Loaded Niosome Hydrogel for Topical Delivery

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Abstract

The aim of present work is to development and characterization of caffeine-loaded niosomal hydrogel for topical delivery. The stratum corneum significantly limits the effectiveness of conventional topical drug delivery systems. Vesicular carriers such as niosomes have emerged as a promising strategy to enhance dermal penetration and provide sustained drug release. The present study focused on development and characterization of a caffeine-loaded niosomal hydr7ogel intended for its antioxidant, lipolytic, and skin stimulating properties. Niosomes were prepared using a ether injection technique with different ratios of Tween 80 and cholesterol and were subsequently incorporated into a Carbopol 934 hydrogel base. Comprehensive characterization was performed, including particle size analysis, zeta potential measurement, FTIR compatibility studies, rheological assessment, spreadability, homogeneity, drug content, entrapment efficiency, and in-vitro drug release. Among the prepared formulations, batch CG4 demonstrated the highest entrapment efficiency (86.925 ± 0.165%) and was selected as the optimized system. The optimized niosomes exhibited a mean particle size of 448.1 nm and a zeta potential of -4.877 mV, indicating satisfactory vesicle stability. The corresponding niosomal hydrogel (NG1) showed desirable physicochemical properties, including pH 6.2 ± 0.58, viscosity 14235 ± 7.12 cps, excellent spreadability (17.963 ± 0.842 g·cm/sec), uniform consistency, and absence of grittiness, drug content (92.32 ±0.42). In-vitro release studies revealed a sustained release pattern of caffeine (81.9% over 12 hours), predominantly following first-order and Higuchi release kinetics. Overall, the development and characterization of caffeine-loaded niosomal hydrogel demonstrates strong potential as an effective topical delivery system for enhanced and sustained topical drug delivery.

Keywords : Caffeine, Niosomes, Hydrogel, Viscosity, pH, Spreadability etc

INTRODUCTION

Topical drug delivery systems have received significant attention because they can deliver drugs directly to the site of action, lower systemic exposure, and improve patient compliance. However, the effectiveness of standard topical formulations is often limited by poor drug penetration through the stratum corneum, which is the main barrier of the skin. To address these issues, researchers have explored vesicular nanocarrier systems like niosomes.

Niosomes are vesicles made from non-ionic surfactants that can encase both hydrophilic and lipophilic drugs. They enhance drug penetration through the skin, improve drug stability, and allow for controlled and sustained release. Because of these benefits, niosomal systems have become promising carriers for effective dermal and transdermal drug delivery.[1]

Caffeine, a naturally occurring methylxanthine, is extensively utilized in both pharmaceutical and cosmetic formulations due to its diverse biological activities. It exhibits strong antioxidant potential, promotes lipolysis, induces vasoconstriction, and enhances skin stimulation. Owing to these properties, caffeine is frequently incorporated into topical products aimed at managing cellulite, reducing localized fat accumulation, treating alopecia, and minimizing signs of skin aging.[2] Although caffeine possesses significant therapeutic potential, its hydrophilic nature and poor skin permeability can limit its effectiveness in conventional topical formulations. Incorporating caffeine into advanced nanocarrier systems such as niosomes can overcome these limitations by enhancing transdermal permeation, increasing drug retention within the skin layers, and enabling a sustained drug release profile.

Hydrogels are three-dimensional, hydrophilic polymeric networks capable of absorbing and retaining large amounts of water while maintaining their structural stability. Carbopol 934 is widely employed in topical gel systems because of its excellent gelling efficiency, viscosity-enhancing capability, and strong bioadhesive nature. Incorporation of niosomal vesicles into a hydrogel base combines the advantages of vesicular nanocarriers with the patient-friendly properties of gels. This hybrid system can enhance skin penetration, improve drug stability, provide sustain drug release.[3]

Considering these advantages, the present study was aimed at the development and characterization of caffeine-loaded niosomal hydrogel for topical delivery and their incorporation into a Carbopol-based hydrogel for topical delivery. The prepared formulations were evaluated for entrapment efficiency, particle size, zeta potential, morphology, rheological properties, spreadability, drug content, and in-vitro drug release behavior. The objective was to develop a stable and effective niosomal hydrogel system capable of providing sustained release and enhanced topical delivery of caffeine.

MATERIAL AND METHODS

Materials

Caffeine was obtained as a gift sample. Tween 80 and cholesterol were procured from Altas chemicals industries. Carbopol 934 and Triethanolamine were purchased from a certified supplier. All other chemicals and solvents used in the study were of analytical grade. Distilled water was used throughout the experimental work.

Preparation of Niosomal vesicles

Caffeine loaded niosomes were made using a modified ether injection method with nonionic surfactants (tween 80) and cholesterol at various concentrations. Cholesterol and the surfactant were dissolved in 6 ml of diethyl ether, mixed with 10ml of methanol that contained a measured amount of caffeine. This solution was then introduced using a micro syringe into 20 ml of phosphate buffer solution (pH 7.4). The solution was stirred continuously on a magnetic stirrer while keeping the temperature at 60-65ºC. As the lipid solution was injected slowly into the aqueous phase, the ether vaporized, leading to spontaneous vesiculation and the formation of niosomes.[4]

Table 1: Formulation Design of Niosome

Name	Tween 80(mg)	Cholesterol (mg)	Drug(mg)	Methanol (ml)	Phosphate buffer 7.4(ml)	Diethyl ether (ml)
CG1	25	100	100	10	20	6
CG2	50	100	100	10	20	6
CG3	75	100	100	10	20	6
CG4	100	100	100	10	20	6
CG5	150	100	100	10	20	6
CG6	200	100	100	10	20	6

Formulation of caffeine loaded Niosomal Gel:

The developed formulation was added to 2% w/w carbopol 934. The required amount of carbopol 934 was mixed with enough niosome formulation and kept in the dark overnight. This swollen carbopol 934 was then neutralized with Triethanolamine to adjust the pH to 6.8, followed by agitation.[5]

Table 2: formulation design of niosomal hydrogel

Sr.no	Ingredients	NG1
1	Caffeine Niosome Dispersion(ml)	10
2	Carbopol 934 (%w/v)	20
3	Triethanolamine (ml)	qs

Calibration Curve of Caffeine

Distilled water was used to create a standard stock solution of caffeine. To get concentrations of 0, 2, 4, 6, 8, and 10 µg/mL, the stock solution was diluted appropriately. A UV-visible spectrophotometer was used to test each solution's absorbance at 274 nm, using distilled water as a blank. The calibration curve was obtained by plotting a graph with absorbance on the Y-axis and concentration (µg/mL) on the X-axis.[6]

Particle Size Analysis

The particle size and polydispersity index (PDI) of the niosomal formulations were measured using dynamic light scattering with a Zetasizer Nano ZS (Malvern Instruments, England). The samples were suitably diluted with phosphate buffer saline (PBS, pH 7.4) before analysis to obtain appropriate scattering intensity. Measurements were carried out under controlled conditions to ensure accuracy and reliability. Each formulation was analyzed three times to confirm the reproducibility of the results. The average values of particle size and PDI were calculated from the obtained readings. The standard deviation was determined to assess the repeatability and consistency of the measurements.[7]

Zeta potential analyser

The zeta potential of the niosomal formulations was measured using a Zetasizer (Malvern Zetasizer Nano ZS, Malvern Instruments, UK). The samples were appropriately diluted before analysis and placed in a specialized cuvette for measurement. Zeta potential for each sample was determined six times to ensure accuracy and reliability of the results. The analyzer automatically calculated the values using the Smoluchowski equation. The mean zeta potential value

and standard deviation were recorded to evaluate the reproducibility of the measurements. The obtained zeta potential values also provided information regarding the surface charge and stability of the niosomal vesicles.[8]

FTIR Spectral Analysis of Formulation

The formulation was analyzed both qualitatively and quantitatively using Fourier Transform Infrared Spectroscopy (FTIR). By producing distinctive infrared absorption spectra, FTIR analysis makes it possible to identify chemical bonds inside both organic and inorganic molecules. Functional groups were identified and potential interactions between formulation components were evaluated using the acquired spectra, which offer a distinct molecular fingerprint.[9]

Evaluation of Niosomal Gel

Appearance of Niosome Gel

The optical appearance of the Niosome gel was evaluated visually for color, clarity/turbidity, uniformity, and the presence of any visible macroscopic particles.[10]

pH Determination

A calibrated digital pH meter was used to measure the pH of each Niosome gel formulation by submerging the electrode straight into the gel sample.[11]

Drug Content

100 mL of an appropriate solvent (water) was combined with 1 g of the niosome gel that had been precisely weighed. After being sonicated, the liquid was centrifuged. UV spectrophotometry was used to determine the amount of caffeine in the resultant supernatant.[12]

Rheological Studies

A viscometer was used to assess the rheological behavior of the niosome gel. Before being measured, about 25 g of the gel sample was put in a beaker and given five minutes to equilibrate. Readings were taken using a T-spindle rotating at 10 rpm. Three duplicate readings of each measurement were taken at progressively lower spindle speeds.[13]

Spreadability Study

The glass slide method was used to assess the niosome gel spreadability. A glass slide was covered with another glass slide after a precisely weighed 0.1 g of gel was positioned inside a circle with a diameter of 1 cm. To compress the gel and achieve a consistent thickness, a 250 g weight was applied to the upper slide for five minutes. An extra 250 g weight was fastened to the upper slide following compression. As an indicator of spreadability, the amount of time (in seconds) needed for the two slides to separate was noted.[14]

Spreadability was calculated using the following equation:

$$S = \frac{m \times l}{t}$$

where
m= weight applied to the upper slide (g),
l= length of the glass slide (cm), and
t= time required for separation (s).

Homogeneity and Grittiness

To test for homogeneity, a tiny amount of the niosome gel was gently pushed between the thumb and index finger. To assess the gel's homogeneity, the existence or lack of any coarse or particle materials was recorded. In a similar manner, the grittiness of the gel was assessed through tactile sense, and the texture was noted appropriately.[15]

Entrapment Efficiency

By calculating the amount of unencapsulated caffeine, the entrapment effectiveness of niosome was ascertained. Using an appropriate diluent, a preset volume of the niosome dispersion was put into a centrifuge tube and centrifuged for 30 minutes. The amount of free (unencapsulated) caffeine was measured by collecting and analyzing the supernatant following centrifugation.[16]

The percentage entrapment efficiency was calculated using the following equation:

$$\text{EE (\%)} = \frac{W_{\text{added drug}} - W_{\text{free drug}}}{W_{\text{added drug}}} \times 100$$

where $W_{\text{added drug}}$ is the amount of caffeine added during formulation, and $W_{\text{free drug}}$ is the amount of free caffeine present in the supernatant after centrifugation.

In-vitro Drug Release Studies

A Franz diffusion cell was used to conduct in vitro drug release tests on the caffeine-loaded niosomal hydrogel. The diffusion barrier between the donor and receptor compartments was a cellophane membrane. A magnetic bead and phosphate-buffered saline (PBS, pH 7.4) were used as the diffusion medium in the 23 mL receptor compartment.

The whole assembly was set up on a magnetic stirrer and kept at 37.0 ± 0.5 °C and 100 rpm of stirring speed. One gram of the gel formulation, or half a milligram of caffeine, was added to the donor compartment on the diffusion membrane's surface. To maintain sink conditions, 1 mL samples were taken out of the receptor compartment at predefined intervals and promptly replaced with an equivalent volume of new diffusion medium. The development of air bubbles beneath the diffusion membrane was prevented.[17] UV spectrophotometry was used to evaluate the extracted materials after they had been appropriately diluted.

RESULT AND DISCUSSION

The standard calibration curve for caffeine was constructed using concentrations ranging from 2 to 10 µg/mL in distilled water. The absorbance was measured at a λmax of 274 nm using a UV spectrophotometer. The standard calibration curve showed a regression equation of y = 0.0578x+ 0.0175 with an R^2 value of 0.9957, indicating good linearity over the selected concentration range.

Table 3: Preparation of calibration curve of caffeine in water

Sl no	Concentration	Absorbance
1.	0	0
2.	2	0.135
3.	4	0.278
4.	6	0.366
5.	8	0.418
6.	10	0.512

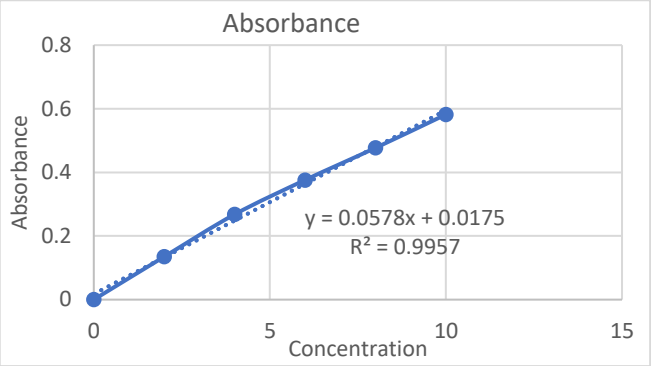
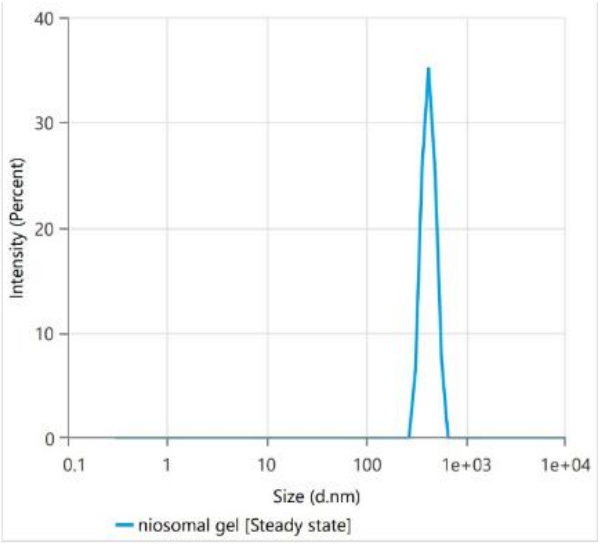


Figure 1: Plotting of calibration Curve by UV spectroscopy

Particle Size:

The particle size analysis discovered that the optimized formulation exhibited a Z-average particle size of 448.1nm. The polydispersity index (PDI) was found to be 1, indicating moderate uniformity in particle size distribution.

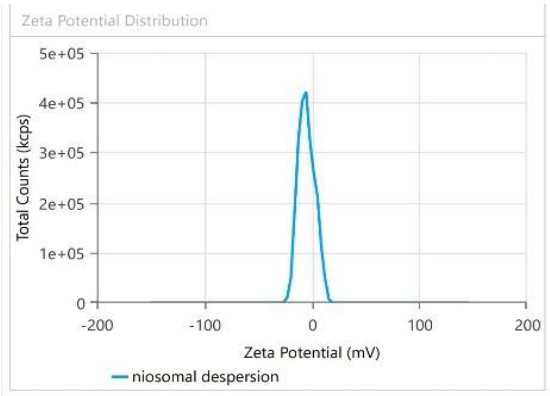


Name	Mean
Z-Average (nm)	448.1
Polydispersity Index (PI)	1
Intercept	0.7278
Fit Error	0.01335
In Range (%)	95.08
Peak 1 Mean by Intensity ordered by area (nm)	426.5

Figure 2: Particle size analysis of CG4

Zeta Potential:

The optimized formulation exhibited a zeta potential value of −4.877 mV, suggesting suitable electrostatic repulsion between particles and signifying acceptable stability of the niosomal system.



Statistics Table

Name	Mean	Standard Deviation	RSD	Minimum	Maximum
Zeta Potential (mV)	-4.877	-	-	-4.877	-4.877
Zeta Peak 1 Mean (mV)	-4.877	-	-	-4.877	-4.877
Conductivity (mS/cm)	3.393	-	-	3.393	3.393
Wall Zeta Potential (mV)	-8.774	-	-	-8.774	-8.774
Zeta Deviation (mV)	7.594	-	-	7.594	7.594
Derived Mean Count Rate (kcps)	2.439E+05	-	-	2.439E+05	2.439E+05
Reference Beam Count Rate (kcps)	1383	-	-	1383	1383
Quality Factor	2.032	-	-	2.032	2.032

Figure 3: Zeta potential of CG4

FTIR Studies:

FTIR analysis confirms drug-excipient compatibility and determines that caffeine remains chemically stable within the niosomal hydrogel formulation.

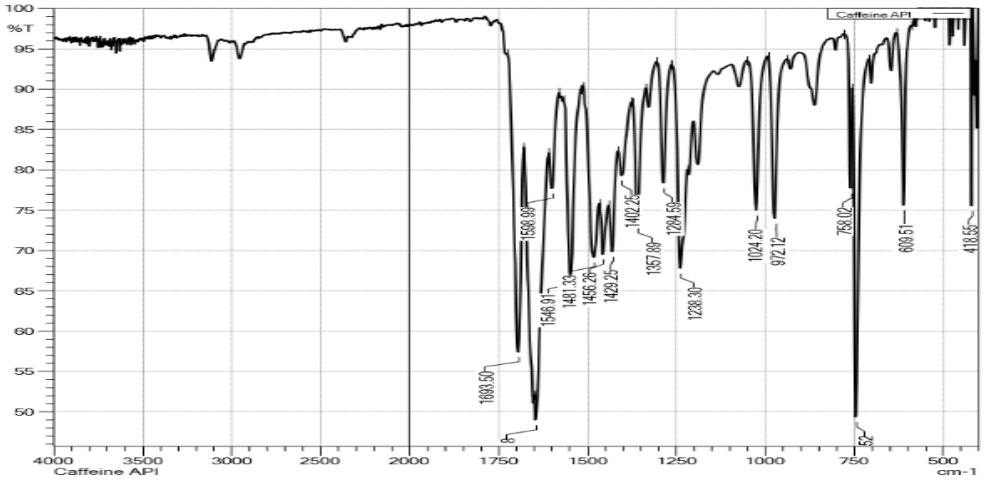


Figure 4: FTIR spectrum of caffeine

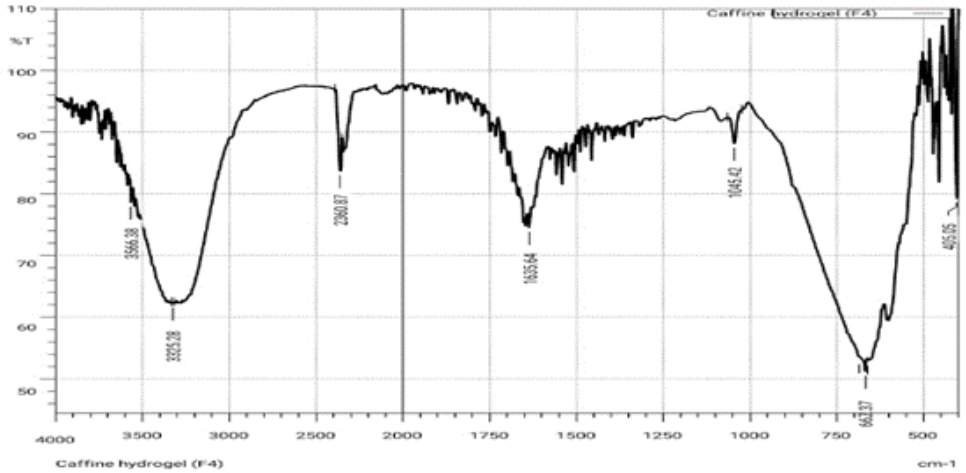


Figure 5: FTIR Spectrum of caffeine loaded niosomal hydrogel(CG4)

Visual Examination & Visual Appearance of Caffeine Loaded Niosomal Gel (NG1)

The prepared caffeine-loaded niosomal gels were visually evaluated for appearance and consistency. Batch CG4 showed a smooth, homogeneous texture without lumps and was selected for further studies. CG4 (C934-2%) appeared as a milky white gel with uniform consistency and proper vesicle dispersion.

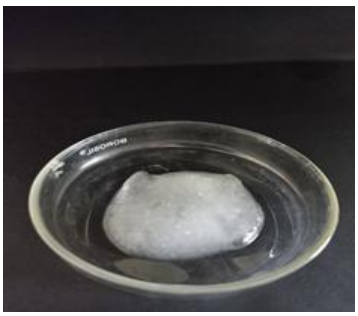


Figure 6: Visual Appearance of Caffeine Loaded Niosomal Gel

pH Determination:

The pH of formulation CG4 was found to be 6.2 ± 0.58, which lies within the physiologically acceptable range for topical gel formulations.

Drug content:

The drug content of the caffeine hydrogel(CG4) formulation was found to be 92.32± 0.42%. This value falls within the acceptable limits, indicating satisfactory uniformity of the formulation. The result confirms that caffeine was uniformly distributed throughout the gel matrix.

Rheological Studies:

The viscosity of formulation CG4 was found to be 14235 ± 7.12 cps, indicating suitable consistency for topical application.

Spreadability Study:

The spreadability of formulation CG4 was determined to be 17.963 ± 0.842 gcm/sec, demonstrating good spreadability characteristics.

Homogeneity And Grittiness:

Formulation CG4 was evaluated for homogeneity and grittiness and was found to be homogeneous with no evidence of grittiness, indicating uniform distribution of ingredients and good consistency.

Percentage Drug Entrapment:

The percentage drug entrapment efficiency of all formulations ranged from 51.374 ± 0.132% to 86.925 ± 0.165%. The findings indicate that the concentration of formulation components had a significant effect on the entrapment efficiency of caffeine-loaded niosomes. An increase in concentration resulted in a corresponding improvement in drug entrapment within the vesicular system. Among the developed formulations, CG4 demonstrated the highest entrapment efficiency (86.925 ± 0.165%). Therefore, based on the obtained results, formulation CG4 was selected as the optimized formulation for further characterization and evaluation studies.

Table 4: Percentage entrapment efficiency of caffeine in different formulation

Sr. No.	Formulation Code	% Entrapment Efficiency
1	CG1	47.842 ± 0.158
2	CG2	51.374 ± 0.132
3	CG3	78.915 ± 0.148
4	CG4	86.925 ± 0.165
5	CG5	76.312 ± 0.149
6	CG6	81.456 ± 0.176

***In-vitro* Drug Release:**

The invitro drug release of CG4 showed a sustained release, reaching 81.9% at 12hrs

Table 5: In-Vitro drug release of caffeine loaded niosomal hydrogel from formulation CG4

S. No.	Time (hr)	% Drug Release of CG4
1	0	0
2	1	12.1
3	2	38.21
4	4	51.51
5	6	69.58
6	8	76.61
7	12	81.9

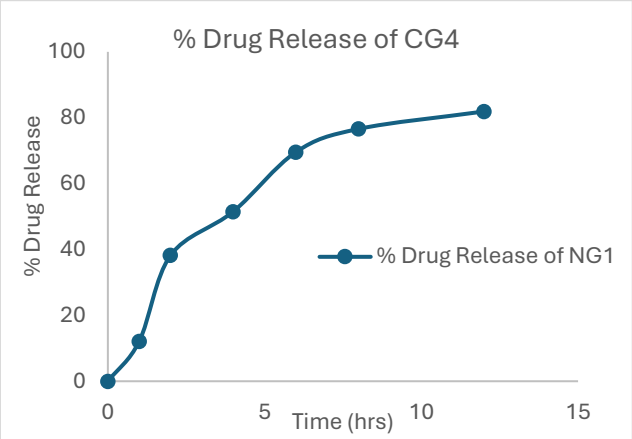


Figure 7: %Drug Release of Caffeine-loaded niosomal hydrogel

Zero order kinetics

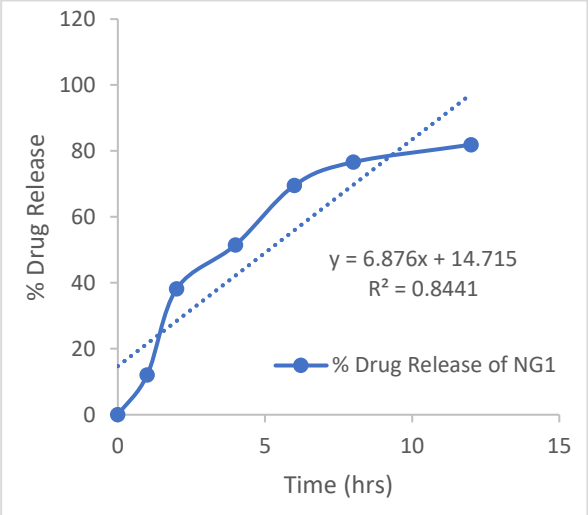


Figure 8: Zero order kinetics

First order kinetics

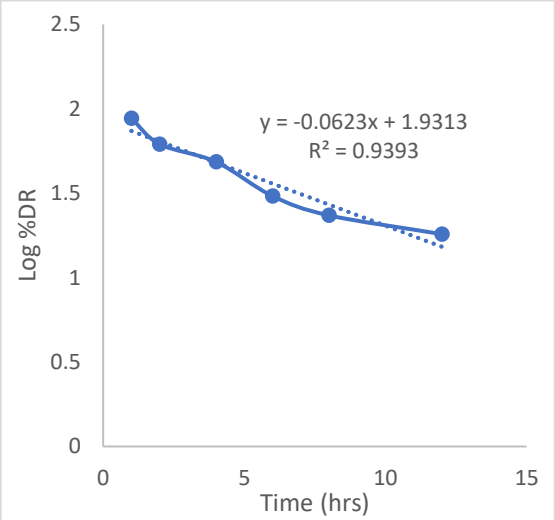


Figure 9: first order kinetics

Higuchi's Model

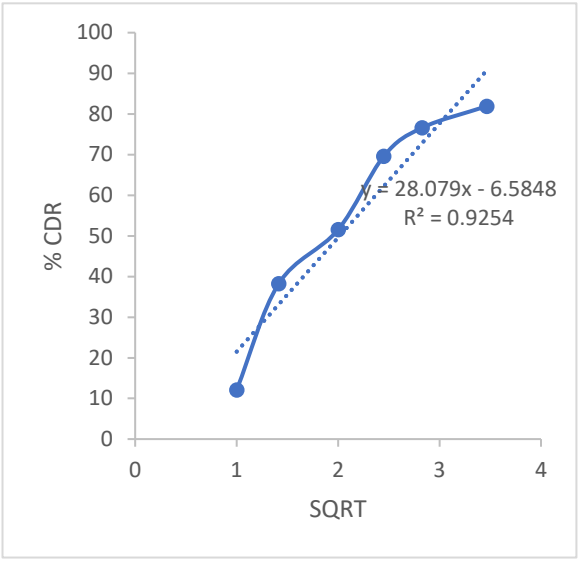


Figure 10: Higuchi's model

Korsmeyar Peppas Model

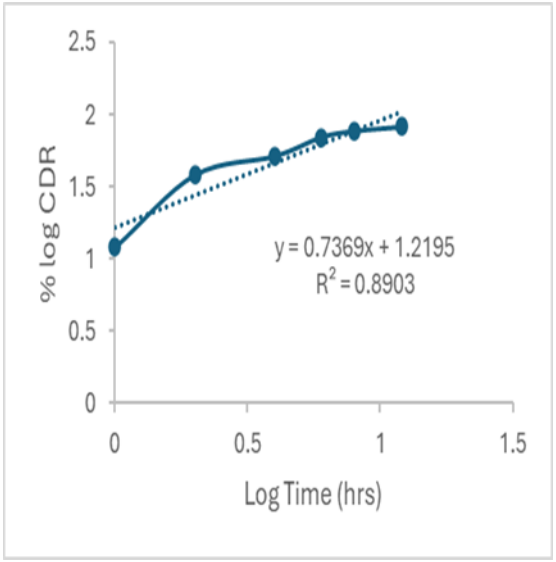


Figure 11: Korsmeyar-peppas Model

KINETIC EQUATION PARAMETER OF NG1

The release kinetics of CG4 were evaluated using zero-order, first-order, Higuchi, and Korsmeyer–Peppas models, with correlation coefficients (R^2) of 0.8441, 0.9393, 0.9254, and 0.8903, respectively, indicating that the drug release predominantly followed the Higuchi diffusion mechanism.

Table 6: Kinetic equation parameter of NG1

Formulation	Zero order	First Order	Higuchi model	Korsemeyer's model
CG4	0.8441	0.9393	0.9254	0.8903

CONCLUSION:

The present study successfully developed and characterization of caffeine-loaded niosomal hydrogel intended for sustained topical delivery. The study confirmed that the modified ether injection method effectively produced stable niosomal vesicles capable of encapsulating the hydrophilic drug caffeine. Among all batches, formulation CG4 showed the highest entrapment efficiency (86.925 ± 0.165%), indicating an optimal surfactant-cholesterol ratio. The optimized niosomes exhibited a mean particle size of 448.1 nm and a zeta potential of -4.877 mV, suggesting acceptable vesicular stability.

The selected niosomal dispersion was incorporated into a 2% Carbopol 934 hydrogel (NG1), which produced a smooth, homogeneous gel with no grittiness. The formulation showed a physiologically acceptable pH of 6.2±0.58, viscosity of 14235±7.12 cps, and good spreadability (17.963 ± 0.842 gcm/sec), drug content 92.32±0.42% confirming its suitability for topical application. FTIR studies indicated no drug-excipient incompatibility.

In-vitro release studies demonstrated sustained drug release, with 81.9% caffeine released over 12 hours, following predominantly first-order and Higuchi kinetics.

Overall, the development and characterization caffeine-loaded niosomal hydrogel for topical delivery is a stable and promising system for enhanced topical delivery and provide sustained release of caffeine compared to conventional gel system. However, additional investigations, including ex-vivo skin permeation studies, in-vivo evaluation, and extended stability testing, are necessary to fully validate the formulation's clinical potential.

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Informed Consent Statement: Not applicable.

Ethical Approval: Not applicable.

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