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DEVELOPMENT AND EVALUATION OF ICHTHAMMOL-LOADED NIOSOMAL GEL FOR ENHANCED TOPICAL DERMAL DELIVERY IN THE MANAGEMENT OF ECZEMA AND PSORIASIS

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ABSTRACT

Ichthammol is a widely used topical agent for inflammatory dermatomes such as eczema and psoriasis. However, conventional formulations suffer from limitations including poor skin penetration and limited drug retention at the target site. The present study aimed to develop and evaluate an Ichthammol-loaded niosomal gel for improved dermal drug delivery. Ichthammol niosomes were prepared by thin-film hydration cum sonication method using Span 60 or Tween 80, combined with cholesterol in varying ratios. Six formulations (F1–F6) were prepared and best formulation was selected based on entrapment efficiency (%EE) and *in vitro* release. Among all F3 formulation (Span 60: cholesterol ratio1:1.5) exhibited 89.18 ± 0.84% EE, and 91.81 % *in vitro* drug release. Further, it shows excellent mean particle size 210 nm, PDI 0.235, and zeta potential −29.8 mV. The best niosomal dispersion F3 was incorporated into a Carbopol 940 gel. The final niosomal gel showed pH 6.4 ± 0.12, Spreadability 18.6 ± 0.45 g·cm/s, viscosity 32,500 ± 210 cps, drug content 98.72 ± 0.84%, and no skin irritation. *In vitro* diffusion studies demonstrated 91.81% cumulative release over 12 h, significantly higher than the marketed Ichthammol gel (60.2%).Release kinetics followed the Higuchi model, indicating diffusion-controlled release. These findings suggest that Ichthammol niosomal gel offers enhanced penetration, sustained release, and improved therapeutic potential for chronic inflammatory skin conditions.

Keywords *Ichthammol; Niosomes; Topical gel; Entrapment efficiency; In vitro release; Eczema; Psoriasis; Dermal delivery.*

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INTRODUCTION

Eczema (atopic dermatitis) and psoriasis are chronic inflammatory dermatomes affecting millions worldwide, characterised by intense pruritus, erythema, scaling, and barrier dysfunction. Conventional topical therapies, including corticosteroids, calcineurin inhibitors, and traditional agents like Ichthammol (ammonium bituminosulfonate), often provide symptomatic relief but are limited by poor penetration, and limited drug retention at the target site Ichthammol, a sulfonated shale oil derivative, possesses anti-inflammatory, antimicrobial, and keratoplastic properties, making it suitable for sub-acute and chronic eczematous conditions and certain psoriatic lesions [1]. However, its use in conventional gel is hampered by low bioavailability and patient compliance issues.

Niosomes, non-ionic surfactant vesicles, offer advantages over liposomes, including greater chemical stability, lower cost, and improved skin interaction [2-4]. They enhance drug entrapment, control release, and improve dermal penetration via interaction with *stratum corneum* lipids. The present work aimed to formulate Ichthammol-loaded niosomes, optimize composition, incorporate the dispersion into a Carbopol gel, and evaluate physicochemical properties, *in vitro* release, and comparative performance against a conventional marketed gel.

MATERIALS AND METHODOLOGY

Materials

Ichthammol was purchased from Yarrow Chem Products, Mumbai. span 60, tween 80, cholesterol, Carbopol 940, triethanolamine, methyl paraben, glycerine, chloroform was procured from Loba Chemie Pvt. Ltd., Mumbai. All chemicals used were of analytical grade. Hi Media diffusion cell membrane with MWCO (Molecular Weight Cut Off) 12-14 kDa was used for diffusion studies.

Pre-formulation Studies

Determination of λmax of Ichthammol

The maximum absorption wavelength (λmax) of Ichthammol was determined using a UV–Visible spectrophotometer (Model UV-1800, Shimadzu). A suitable dilution of the drug was prepared using phosphate buffer pH 7.4. The solution was scanned in the wavelength range of 200–400 nm and the wavelength showing maximum absorbance was recorded as the λmax.

Construction of Calibration Curve

A standard calibration curve of Ichthammol was prepared by preparing drug solutions in phosphate buffer pH 7.4 with concentrations of 10, 20, 30, 40 and 50 µg/ml. The absorbance of each solution was measured at the previously determined λmax using a UV–Visible spectrophotometer. A calibration curve was plotted between concentration and absorbance.

Drug–Excipient Compatibility Studies

Drug–excipient interaction studies were carried out using Fourier Transform Infrared (FTIR) spectroscopy (Model Alpha 11, Bruker). The spectra of pure drug, individual excipients and physical mixture of drug with excipients were recorded and compared to detect any possible chemical interaction.

Preparation of Ichthammol Niosomes

Ichthammol niosomes were prepared by the thin film hydration–sonication method. The drug (50 mg) was dissolved in a mixture of chloroform and methanol (2:1). Required amounts of surfactant and cholesterol were added to this solution according to formulation ratios. The solvent mixture was evaporated to form a thin lipid film. The film was hydrated with 10 mL distilled water at 55–60°C, followed by sonication using a bath sonicator (5 cycles, each cycle containing 3 minutes sonication with on/off intervals). Six different formulations (F1–F6) were prepared by varying surfactant and cholesterol ratios [5,6].

Table 1. Composition of Ichthammol-Loaded Niosomal Formulations

Formulation	Surfactant	Ratio (Surfactant: Cholesterol)	Surfactant (mg)	Cholesterol (mg)	Ichthammol (mg)
F1	Span 60	1 : 0.5	200	100	50
F2	Span 60	1 : 1.0	150	150	50
F3	Span 60	1 : 1.5	120	180	50
F4	Tween 80	1 : 0.5	200	100	50
F5	Tween 80	1 : 1.0	150	150	50
F6	Tween 80	1 : 1.5	120	180	50

Preparation of Ichthammol Niosomal Gel

Ichthammol niosomal gel was prepared using the optimised niosomal formulation (F3). Initially, an empty gel base was prepared using Carbopol 940. Carbopol 940 was slowly dispersed in distilled water under continuous stirring and allowed to hydrate for 30 minutes. Glycerine and methyl paraben were added and mixed uniformly. The final volume was adjusted with distilled water. Triethanolamine (TEA) was added dropwise to adjust the pH to 6.0. The gel was allowed to stand overnight to remove entrapped air. After cooling the gel base to room temperature (20–25°C), the niosomal suspension was chilled to 4–8°C and slowly incorporated into the gel base with gentle stirring. The final pH of the gel was adjusted to 6.4 using TEA. The prepared gel was stored in a wide-mouthed container at 4–8°C [7,8].

Table 2. Composition of Empty Gel Base (100 g)

S. No	Ingredient	Category	Amount (g)
1	Carbopol 940	Gelling agent	2
2	Glycerine	Humectant	8
3	Methyl Paraben	Preservative	0.5
4	Water	Solvent	89.5
	Total		**100 g**

Evaluation of Ichthammol Niosomes

Entrapment Efficiency

The niosomal dispersion was centrifuged at 15,000 rpm for 45 minutes at 4°C to separate free drug from vesicles. The supernatant containing unentrapped drug was collected and analyzed using a UV–Visible spectrophotometer at 210 nm. The entrapment efficiency was calculated by comparing total drug content with the amount of free drug [9].

In Vitro Membrane Diffusion Study

Drug release from niosomal formulations was evaluated using a Franz diffusion cell with a dialysis membrane. The receptor compartment was filled with phosphate buffer (pH 7.4) and maintained at 37 ± 0.5°C with continuous stirring. Five milliliters of formulation were placed in the donor compartment. Samples were withdrawn at predetermined intervals (2, 4, 6, 8, 10 and 12 h) and analyzed at 210 nm using a UV spectrophotometer [10].

Particle Size and PDI

Particle size and polydispersity index (PDI) were determined using a Dynamic Light Scattering based particle size analyzer (Malvern Zetasizer). The sample was diluted with distilled water (1:20) and measurements were carried out at 25°C [11].

Zeta Potential

Zeta potential was measured using a Zetasizer based on electrophoretic light scattering to determine the stability of the vesicles [12].

Evaluation of Ichthammol Niosomal Gel

The prepared Ichthammol niosomal gel was evaluated for physicochemical properties including pH, spreadability, viscosity, skin irritation, and drug content assay to ensure suitability for topical application [13-19].

Determination of pH

The pH of the Ichthammol niosomal gel was determined to ensure compatibility with skin pH and to avoid irritation upon application. Approximately 1 g of gel was accurately weighed and dispersed in 100 mL of distilled water. The dispersion was allowed to stand for 2 hours for complete equilibration. The pH was then measured using a calibrated digital pH meter at room temperature (25 ± 2°C). Measurements were performed in triplicate and the average value was recorded.

Spreadability Test

Spreadability was determined using the slip and drag method to evaluate the ease of application of the gel. Approximately 0.5 g of gel was placed between two glass slides. A weight of 500 g was placed over the upper slide for 5 minutes to obtain a uniform film. The time taken for the upper slide to move a specified distance (6 cm) under the influence of an additional 20 g weight was recorded and spreadability was calculated.

Viscosity Measurement

The viscosity of the gel formulation was measured using a Brookfield viscometer to determine the consistency and suitability of the gel for topical application. The gel sample was placed in the viscometer spindle and measurements were recorded at room temperature.

Skin Irritation Study

The skin irritation study was performed to evaluate the safety of the formulation for topical application. The test was conducted on the dorsal surface of the skin, which was shaved 24 hours prior to the experiment. Approximately 0.5 g of gel was applied to the test site and observed for 24–72 hours for signs of erythema, edema, or any visible skin reaction. Observations were graded according to a standard irritation scoring scale.

Drug Content Assay

The drug content of the Ichthammol niosomal gel was determined to confirm uniform distribution of drug within the formulation. Approximately 1 g of gel was accurately weighed and dissolved in 100 mL phosphate buffer (pH 7.4). The solution was sonicated for 30 minutes to ensure complete drug extraction and filtered through Whatman filter paper. The absorbance was measured using a UV–Visible spectrophotometer at 210 nm, and the drug concentration was calculated using the previously constructed calibration curve.

Comparative In Vitro Drug Release Study

A comparative in vitro drug release study was carried out between the optimized Ichthammol niosomal gel (F3) and a marketed Ichthammol ointment (20%, Globe Pharmaceuticals).The study was performed using a Franz diffusion cell with a dialysis membrane. The receptor compartment was filled with phosphate buffer (pH 7.4) and maintained at 37 ± 0.5°C with continuous stirring. The dialysis membrane was hydrated before use. A suitable quantity of the gel formulation was placed in the donor compartment. Samples were withdrawn at predetermined intervals (2, 4, 6, 8, 10 and 12 hours) and replaced with fresh buffer to maintain sink conditions. The collected samples were analyzed using a UV–Visible spectrophotometer at 210 nm to determine cumulative drug release [20-21].

RESULTS AND DISCUSSION

Determination of λmax

The UV spectrum of Ichthammol in phosphate buffer pH 7.4 showed maximum absorbance at 210 nm, which was selected for further analytical studies.

Calibration Curve

The calibration curve of Ichthammol showed a linear relationship between concentration and absorbance within the range of **10–50 µg/ml**.

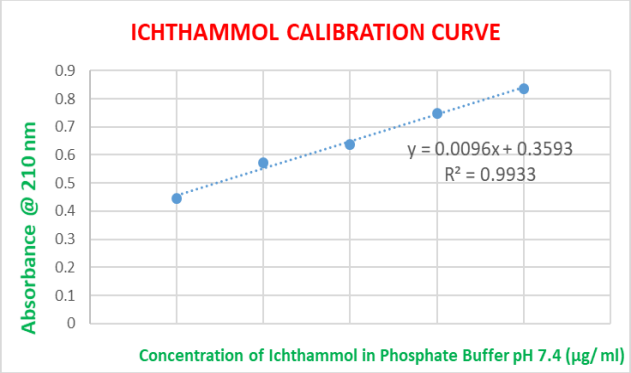

Figure 1. Calibration Curve of Ichthammol in Phosphate Buffer pH 7.4

Drug–Excipient Compatibility Study

FTIR spectra of pure drug, excipients and their physical mixture showed no significant shift or disappearance of characteristic peaks. This confirmed the absence of drug–excipient interaction and indicated that the chemical structure of Ichthammol remained stable in the formulation.

Entrapment Efficiency

Among all formulations, F3 showed the highest entrapment efficiency (89.18%). This may be attributed to the optimum surfactant-to-cholesterol ratio, which improves vesicle rigidity and enhances drug encapsulation.

Table 3. Percentage Entrapment Efficiency of Ichthammol Niosomes

Formulation	% Entrapment Efficiency (Mean ± SD)
F1	68.42 ± 1.12
F2	74.36 ± 0.95
F3	89.18 ± 0.84
F4	81.25 ± 1.03
F5	76.84 ± 0.78
F6	72.63 ± 1.18

In Vitro Drug Release Study

The optimized formulation F3 exhibited the highest drug release (91.81%) at 12 hours, indicating sustained drug release characteristics.

Table 4. Percentage Drug Release of Ichthammol Niosomes

Time (h)	F1	F2	F3	F4	F5	F6
2	52.64	61.39	64.72	40.56	42.02	45.97
4	54.31	63.06	68.89	41.81	48.06	50.35
6	58.47	68.89	75.14	45.97	52.43	56.81
8	70.97	73.47	79.31	48.89	54.72	60.56
10	75.14	77.48	85.56	50.14	57.22	62.64
12	81.39	79.72	**91.81**	54.52	70.98	85.56

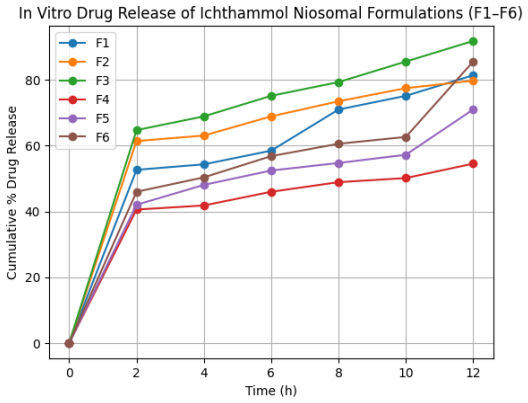

Figure 2. Percentage Drug Release of Ichthammol Niosomes

Particle Size, PDI and Zeta Potential

The optimized formulation followed the Higuchi release model, indicating diffusion-controlled drug release from the niosomal matrix.

Table 5. Key Evaluation Parameters of Optimized Formulation (F3)

Parameter	Result	Significance
Entrapment Efficiency	89.18 ± 0.84 %	High drug loading
Particle Size	210 nm	Enhanced skin penetration
PDI	0.235	Uniform particle distribution
Zeta Potential	−29.8 mV	Good stability
Drug Release (12 h)	91.81 %	Sustained release

Physicochemical Evaluation of Ichthammol Niosomal Gel

The optimised Ichthammol niosomal gel exhibited pH within the physiological skin range, indicating its suitability for topical application without causing irritation. The formulation showed good spreadability, ensuring ease of application over the skin surface. The viscosity value indicated an appropriate gel consistency, which helps in prolonged retention at the site of application. The drug content was close to 100%, confirming uniform distribution of the drug throughout the gel matrix. The skin irritation study showed no signs of erythema or edema, indicating that the formulation is safe and non-irritant for topical use.

Table 6. Physicochemical Evaluation of Optimized Ichthammol Niosomal Gel (F3)

Parameter	Result	Inference / Remark
pH	6.4 ± 0.12	Compatible with skin pH (5.5–7.0)
Spreadability	18.6 ± 0.45 g·cm/s	Excellent spreadability
Viscosity	32,500 ± 210 cps	Suitable consistency for dermal retention
Drug Content	98.72 ± 0.84 %	Uniform drug distribution
Skin Irritation Score	0	Non-irritant

Comparative In Vitro Drug Release Study

The comparative drug release study demonstrated that the niosomal gel formulation showed significantly higher drug release than the marketed Ichthammol ointment at all time intervals. The optimized formulation (F3) exhibited 91.81% drug release at 12 hours, whereas the marketed product showed only 60.2% release. The enhancement factor ranged between 1.52 and 1.66, indicating improved drug diffusion and sustained release behavior of the niosomal system. This improvement may be attributed to the nano-sized vesicles and enhanced permeation ability of the niosomal carrier system, which facilitates better drug release and penetration through the membrane.

Table 7. Comparative In Vitro Cumulative % Drug Release – Niosomal Gel vs Marketed Ointment

Time (h)	Niosomal Gel (F3) (%)	Marketed Ointment (%)	Enhancement Factor
0	0	0	0
2	64.72	39.0	1.66
4	68.89	43.3	1.59
6	75.14	49.5	1.52
8	79.31	52.3	1.52
10	85.56	55.7	1.54
12	91.81	60.2	1.52

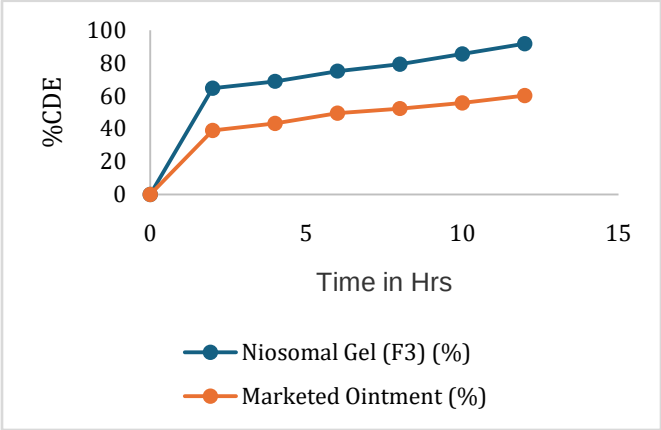

Figure 3. Comparative In Vitro Cumulative % Drug Release – Niosomal Gel vs Marketed Ointment

CONCLUSION

The present study successfully developed and evaluated an Ichthammol niosomal gel for enhanced dermal drug delivery. Among the prepared formulations, formulation F3 showed optimized vesicle characteristics and a superior drug release profile. The developed niosomal gel exhibited controlled drug release, improved dermal penetration, and better therapeutic potential compared to the marketed Ichthammol gel. The formulation also demonstrated good physicochemical properties and was safe for topical application. Therefore, the developed Ichthammol niosomal gel may serve as a promising topical drug delivery system for the treatment of inflammatory dermatological conditions such as eczema and psoriasis.

AUTHOR CONTRIBUTIONS

N. Venkateswara Reddy contributed to the conceptualization of the study, supervision of the research work, review of experimental results, and final editing of the manuscript. A. Venkata Badarinath carried out the experimental work, data collection, analysis of results, preparation of figures and tables, and drafting of the manuscript. Both authors reviewed and approved the final version of the manuscript.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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