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Original Article

Formulation and Evaluation of Beclomethasone Dipropionate Loaded Niosomal Gel for Topical Use

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ABSTRACT

Background: The present study focuses on the formulation and evaluation of a niosomal gel containing beclomethasone dipropionate for topical delivery, with the objective of enhancing skin permeability and achieving sustained drug release. Niosomes, which are spherical vesicles composed of non-ionic surfactants, offer several advantages over conventional drug delivery systems, including higher drug loading capacity, controlled release, and reduced systemic side effects. **Materials and Methods:** In this study, niosomes were prepared using the thin-film hydration technique by optimizing the ratios of Span 60 and cholesterol. The prepared niosomal dispersions were subsequently incorporated into a Carbopol-based gel and subjected to comprehensive evaluation. Evaluation Parameters: Various parameters, including vesicle size, entrapment efficiency, pH, spreadability, drug content, and in vitro drug release, were assessed. **Results/Conclusion:** The results demonstrated that the optimized niosomal gel possessed favorable physicochemical properties, exhibited sustained drug release, and showed significant potential as an effective topical drug delivery system.

Keywords: Carbopol gel, Controlled Release, Niosomes, Non-ionic Surfactants, Thin-Film Hydration Method, Topical Drug Delivery.

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INTRODUCTION

Skin, being one of the most accessible organs of the human body, serves as a vital route for the administration of topical medications. Depending on the formulation design and mechanism of action, topical drug delivery systems can produce superficial, localized, or even systemic therapeutic effects.[1,2] In many cases, the formulation base itself plays a functional role by acting as an emollient, protectant, or soothing agent, while simultaneously serving as a carrier for the active pharmaceutical ingredient. Among the advanced drug delivery systems, niosomes vesicular structures composed of non-ionic surfactants and cholesterol have gained considerable attention due to their ability to enhance drug stability and improve therapeutic efficacy.[2] Niosomes possess an amphiphilic bilayer structure, in which the hydrophilic head groups are oriented outward while the hydrophobic tails form the inner region. This unique arrangement enables the encapsulation of both hydrophilic and lipophilic drugs. Niosomes may exist as either unilamellar or multilamellar vesicles and are widely regarded as a stable and cost-effective alternative to liposomes. Furthermore, they offer additional advantages, including improved chemical stability and greater versatility in drug delivery applications (Figures 1-7).[3-5]

Plaque psoriasis, the predominant clinical subtype of psoriasis, is characterized by erythematous, scaly plaques localized to the epidermis. The pathogenesis of psoriasis involves aberrant immune signalling, wherein activated T-cells and associated cytokines accelerate keratinocyte proliferation, resulting in premature epidermal turnover.[6-9] Beclomethasone dipropionate, a synthetic corticosteroid, is employed via topical, inhalational, and intranasal routes for the management of inflammatory conditions, including psoriasis, allergic rhinitis, and asthma, owing to its potent anti-inflammatory and immunosuppressive properties. Niosomal gels, comprising vesicular systems formed from non-ionic surfactants and cholesterol, represent an advanced topical drug delivery platform.[10-12] Their favourable attributes including enhanced physicochemical stability, controlled drug release, and improved dermal penetration render them suitable carriers for corticosteroids in the treatment of psoriasis.[13,14]

Psoriasis is a chronic, non-contagious, immune-mediated inflammatory skin disorder affecting approximately 2-3% of the global population. It is characterized by abnormal keratinocyte proliferation and differentiation, resulting in the formation

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of well-demarcated, erythematous plaques covered with silvery-white scales.[15-18]

The condition arises from a complex interplay of genetic predisposition and environmental triggers, leading to dysregulation of the immune system and accelerated skin cell turnover. Clinically, psoriasis commonly affects areas such as the scalp, elbows, knees, palms, soles, and lower back, often presenting in a symmetrical pattern. The most prevalent form, plaque psoriasis, manifests as thickened, scaly lesions primarily involving the epidermis.[19]

The disease typically follows a relapsing-remitting course, with periods of exacerbation and remission. In addition to cutaneous manifestations, psoriasis is associated with systemic complications, including psoriatic arthritis, cardiovascular disorders, and psychological conditions such as anxiety and depression, significantly impacting patients' quality of life.[20]

MATERIALS AND METHODS

Materials

Beclomethasone dipropionate was procured from LUPIN Ltd., Waluj, Chhatrapati Sambhajinagar. All other essential excipients were obtained from Research Lab Fine Chem Industries, Mumbai, India, and were of analytical grade.

Methods

Preparation of Niosomes

Niosomes were prepared using the thin film hydration technique. Various formulations were developed by varying the concentration of cholesterol while keeping the non-ionic surfactant (Span 60) constant, as shown in Tables 1-9.

Briefly, Span 60 and cholesterol were accurately weighed and dissolved in chloroform. Beclomethasone dipropionate was then added to this organic phase. The resulting solution was transferred to a round-bottom flask and subjected to rotary evaporation at 40-60°C with a rotation speed of 150 rpm to remove the organic solvent and form a thin lipid film on the inner wall of the flask.

The formed thin film was subsequently hydrated with distilled water and allowed to rotate for 30 min to facilitate the formation of niosomal vesicles.[21]

Preparation of Niosomal Gel

The niosomal gel was prepared using Carbopol 934 as the gelling agent. Carbopol 934 was slowly dispersed in distilled water under continuous stirring to avoid lump formation and was allowed to hydrate and swell for 24 hr.

After complete hydration, the prepared niosomal suspension was gradually incorporated into the gel base with gentle stirring to ensure uniform distribution. The pH of the formulation was adjusted to neutral by adding 1-2 drops of triethanolamine. The mixture was stirred continuously until a homogeneous niosomal gel was obtained.[22]

Evaluation of Beclomethasone Dipropionate (BDP)-Loaded Niosomes

Following the preparation of niosomes, the formulations were evaluated for various physicochemical parameters. The drug content was determined to ensure uniform incorporation of the drug within the vesicles. Spreadability of the gel was assessed to understand its ease of application. The viscosity was measured using a Brookfield viscometer to study the flow behavior of the formulation.

Entrapment Efficiency (%EE) was evaluated to estimate the extent of drug encapsulation within the niosomal vesicles. The prepared formulations were also examined visually for their organoleptic properties such as appearance and odour.[23]

The pH of the formulation was measured using a digital pH meter to ensure suitability for topical application. *In vitro* drug release studies were carried out using a diffusion technique to evaluate the release pattern of the drug from the niosomal system.

Particle size analysis was performed using a HORIBA SZ-100 particle size analyzer, and the zeta potential was also determined using the same instrument to assess the stability of the vesicles. Surface morphology of the niosomes was examined using Scanning Electron Microscopy (SEM). In addition, stability studies were conducted to evaluate the integrity of the formulation under different storage conditions.[24-26]

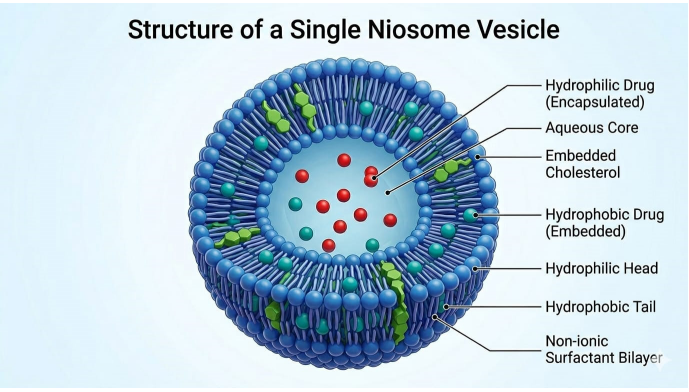

Figure 1: Niosomes.

QbD Study of Beclomethasone dipropionatem

The BDP loaded Niosomes were optimized using 3^2 full factorial experimental designs.

Experimental Design

ANOVA for Quadratic model

Response 1: %EE

Factor coding is Coded. Sum of squares is Type III - Partial

The Model F-value of 61.63 implies the model is highly significant. There's only a 0.32% chance this large an F-value could arise from noise alone.

p-values < 0.0500 indicate significant model terms. Here,**A, B, and B²** are significant. Terms with *p*-values > 0.1000 are not significant.

Response 2: % Drug release

Factor coding is Coded. Sum of squares is Type III - Partial

The Model F-value of 1063.63 implies the model is highly significant. There's only a 0.01% chance this large an F-value could arise from noise alone.

p-values < 0.0500 indicate significant model terms. Here, A and B are significant. Terms with *p*-values > 0.1000 are not significant.

RESULTS AND DISCUSSION

Preformulation study of pure drug

The Beclomethasone dipropionate-loaded niosomal dispersion was observed to be white in color, odorless, and fluid in nature. The formulation appeared physically stable with no signs of sedimentation upon storage. The pH of the dispersion was found to be within the range of 5.1-6.9, which is suitable for topical application.

The melting point of Beclomethasone dipropionate was determined to be in the range of 117°C to 119°C, which is in close agreement with the value reported in the Indian Pharmacopoeia, indicating the purity of the drug.

In methanol, Beclomethasone dipropionate exhibited a maximum absorbance (λ_{max}) at 241 nm. The calibration curve of Beclomethasone dipropionate was constructed using UV spectrophotometry and is presented below.

The infrared spectrum of a pure Beclomethasone dipropionate sample collected by the FTIR spectrometer is shown.

Entrapment Efficiency

The % Entrapment Efficiency (%EE) across all niosomal formulations ranged from 62-80%. Formulation F5 achieved the highest %EE at 80%.

$$\% \text{ Entrapment Efficiency} = [(\text{Total Drug} - \text{Free Drug}) / \text{Total Drug}] \times 100$$

The vesicles ranged in size from 206 nm to 400 nm. The generated niosomes loaded with Beclomethasone dipropionate are appropriate for topical gel because, based on the particle size results, their particles are less than 400 nm. Beclomethasone dipropionate-loaded niosomes of Formulation F5 were found to have a zeta potential of -43.9 mV. The formulations percentages of drug release ranged from 70% to 88%. After 12 hr, the formulation F5 batch displayed an 85.22% niosomal gel release.

Niosomes <400 nm, as observed across formulations, demonstrate superior dermal penetration compared to larger vesicles (>500 nm), which face diffusion barriers in the stratum corneum. The F5 formulation's sizing (~206-300 nm, based on Span 60: cholesterol optimization) correlates with the significant linear effects of A (Span 60) and B (cholesterol) from ANOVA, where increased surfactant packing density reduces vesicle diameter without compromising bilayer integrity.

Table 1: Composition of BDP-Loaded Niosomes.

Formulations	Drug (mg)	Cholesterol (mg)	Span 60 (mg)	Chloroform (mL)	Distilled Water (mL)
F1	10	50	150	10	10
F2	10	25	100	10	10
F3	10	75	150	10	10
F4	10	50	100	10	10
F5	10	25	50	10	10
F6	10	50	50	10	10
F7	10	75	50	10	10
F8	10	75	100	10	10
F9	10	25	150	10	10

Table 2: **Experimental design.**

Formulation	Factor 1 A Span 60 (mg)	Factor 2 B Cholesterol (mg)	Response 1 *In vitro* Drug release	Response 2 Entrapment efficiency
F1	150	50	74.11	65.12
F2	100	25	85.73	75.42
F3	150	75	68.18	62.31
F4	100	50	79.25	67.51
F5	50	25	89.69	80.41
F6	50	50	84.49	72.62
F7	50	75	8.13	70.10
F8	100	75	73.11	66.22
F9	150	25	80.42	70.13

Table 3: **ANOVA for Response 1: %EE.**

Source	Sum of Squares	d_f	Mean Square	F-value	*p*-value	
Model	239.67	5	47.93	61.63	0.0032	significant
A-Span 60	104.17	1	104.17	133.93	0.0014	
B-Cholesterol	121.50	1	121.50	156.21	0.0011	
AB	1.0000	1	1.0000	1.29	0.3393	
A^2	0.5000	1	0.5000	0.6429	0.4813	
B^2	12.50	1	12.50	16.07	0.0278	
Residual	2.33	3	0.7778			
Cor Total	242.00	8				

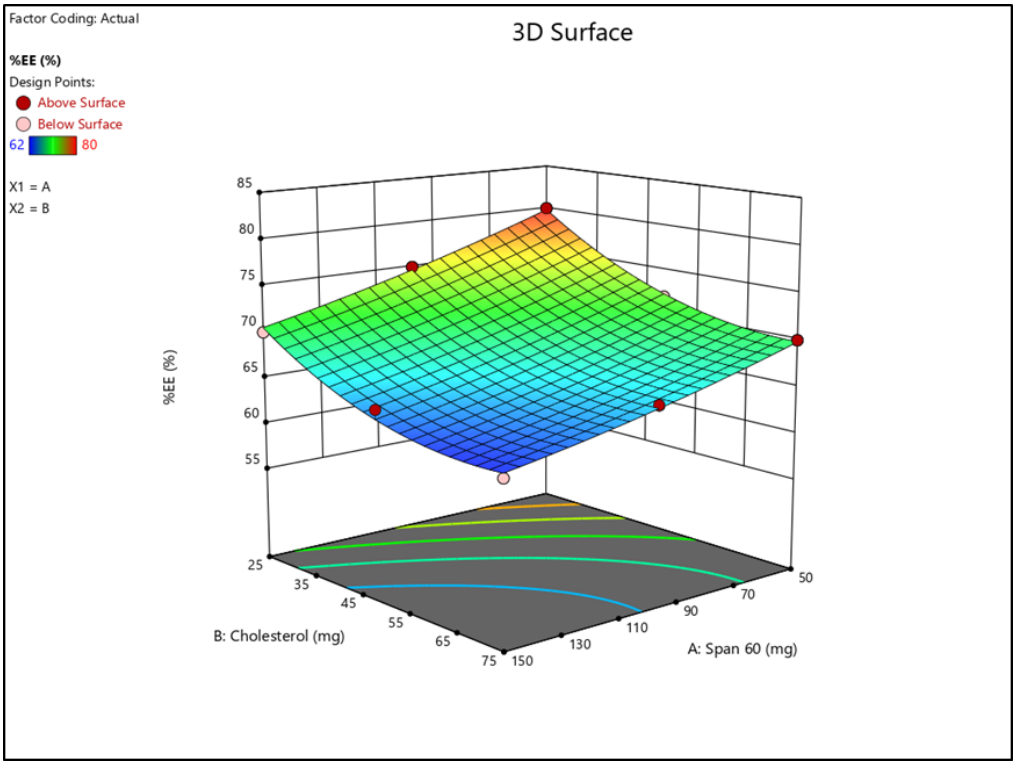

Figure 2: 3D Surface plot showing effect of surfactant and stabilizer concentration on % Entrapment efficiency.

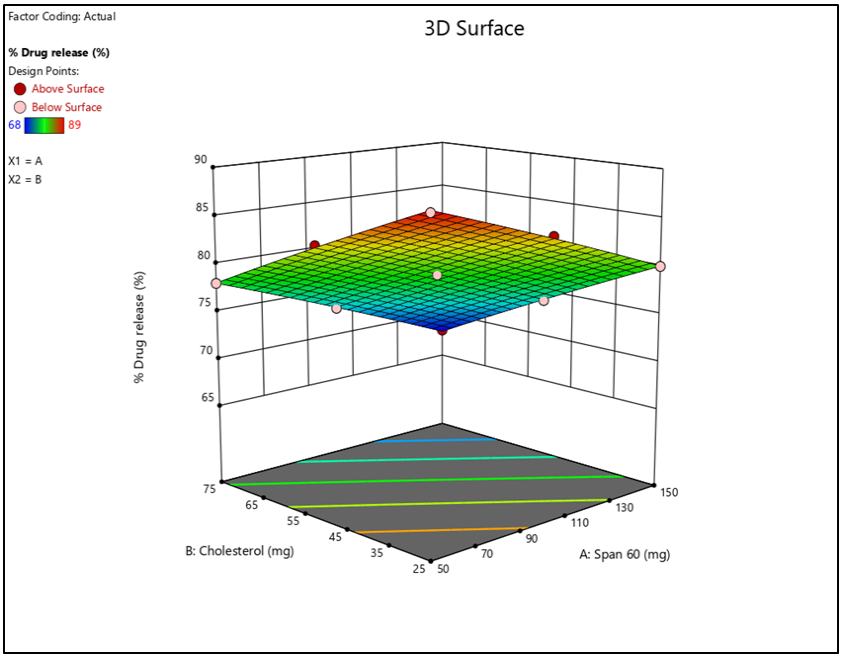

Figure 3: 3D Surface plot showing effect of surfactant and stabilizer concentration on *in vitro* Drug release.

Table 4: ANOVA for Response 2: % Drug release

Source	Sum of Squares	d_f	Mean Square	F-value	*p*-value	
Model	344.69	5	68.94	1063.63	<0.0001	Significant
A-Span 60	140.17	1	140.17	2162.57	<0.0001	
B-Cholesterol	204.17	1	204.17	3150.00	<0.0001	
AB	0.2500	1	0.2500	3.86	0.1443	
A^2	0.0556	1	0.0556	0.8571	0.4228	
B^2	0.0556	1	0.0556	0.8571	0.4228	
Residual	0.1944	3	0.0648			
Cor Total	344.89	8				

Table 5: Organoleptic properties of Drug.

Properties	Specification as per IP 2007	Result
Colour	White	White
Odour	No characteristics odour	No characteristics odour
Nature	Amorphous Powder	Amorphous Powder

Table 6: FT-IR spectrum of BDP.

Sl. No.	Functional Group	Observed Wave number (cm^{-1})
1.	O-H	3462.7, 3421.7, 3272.6 cm^{-1}
2.	C=O	1729.5 cm^{-1}
3.	C-Cl	697.0 cm^{-1}
4.	C-H	2940.9, 2896.1 cm^{-1}
5.	C-O	1185.3, 1121.9, 1051.1, 1002.7 cm^{-1}
6.	C=C	1658.7, 1610.2 cm^{-1}

In vitro Drug Release Studies

The *in vitro* diffusion of beclomethasone dipropionate from the Niosome was varied in amount according to concentration of span 60 and cholesterol used in formulation. Among all formulations F5 shows 89.69% of drug release at the end of 12 hr.

Scanning Electron Microscopy

One effective technique for seeing the shape and surface morphology of niosomes is scanning electron microscopy, or SEM. Using Scanning Electron Microscopy (SEM), the obtained niosomal formulation's morphology was investigated.

Determination Particle Size Analysis

The prepared beclomethasone dipropionate niosomes were tested for particle size from the obtained results it was found that niosomes prepared with concentration of Span 60 have a

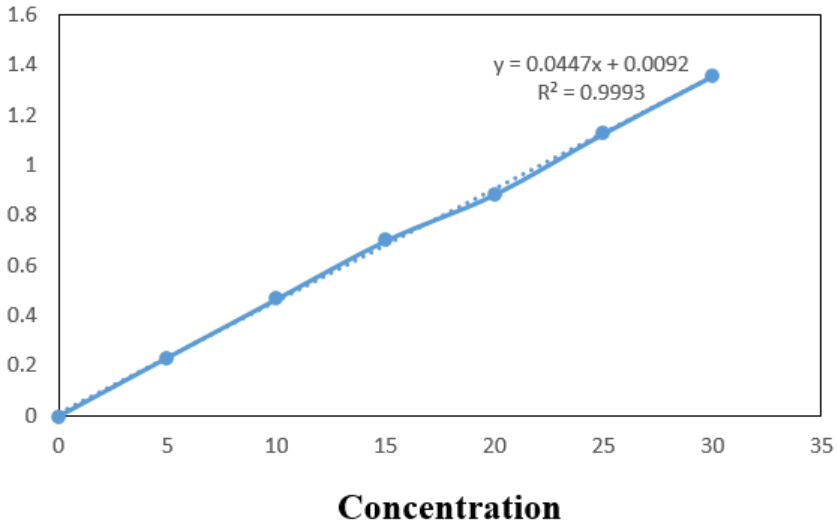

Figure 4: Calibration curve of BDP.

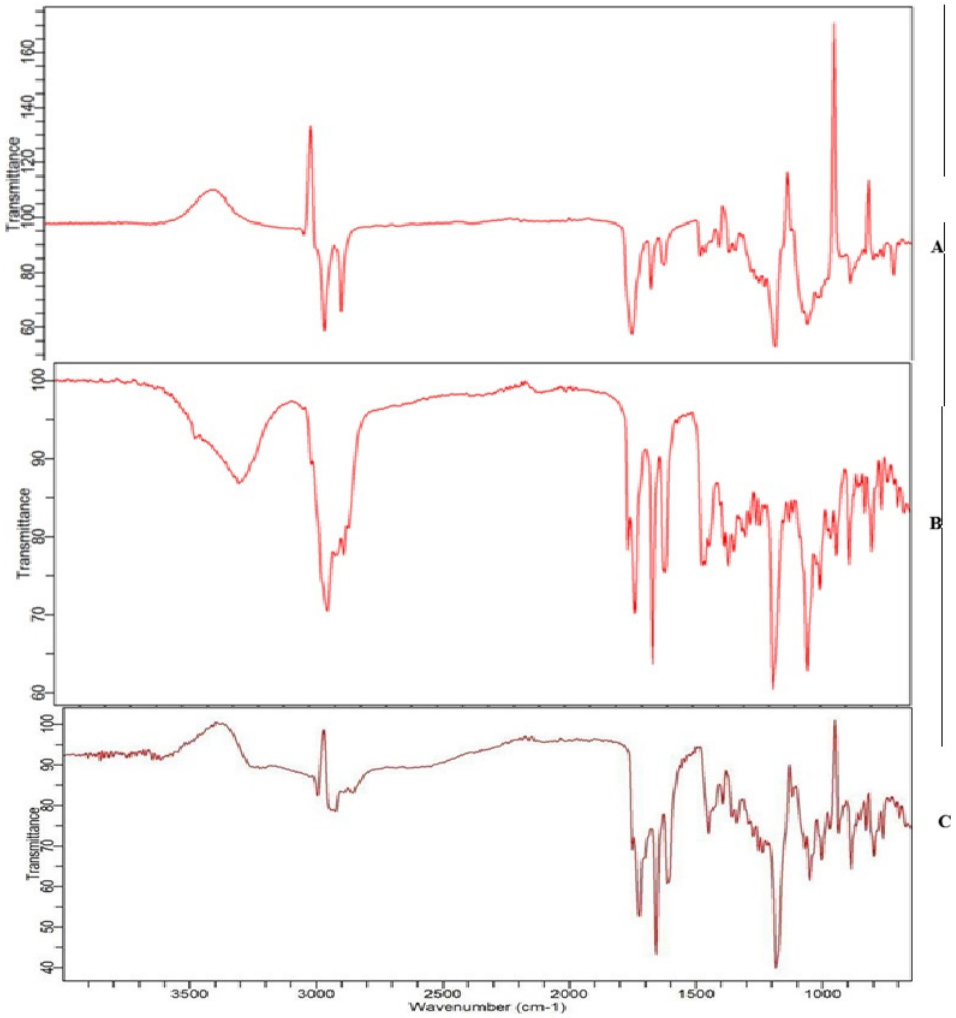

Figure 5: A: FTIR Spectrum of Beclomethasone dipropionate with Span 60, B: FTIR Spectrum of Beclomethasone Dipropionate with Cholesterol, C: FTIR Spectrum of Beclomethasone Dipropionate and Carbopol 934.

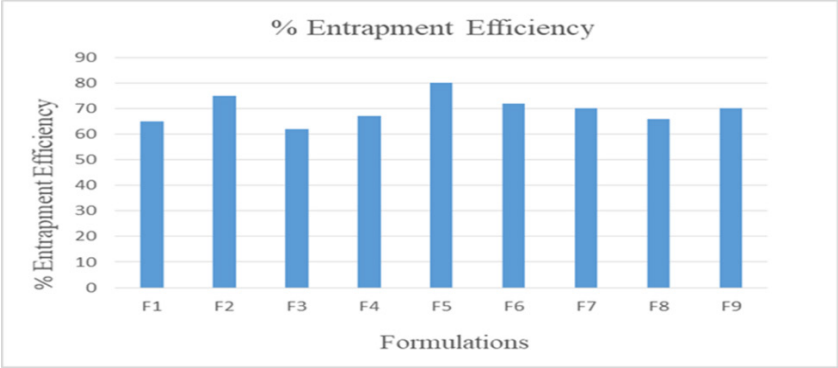

Figure 6: Entrapment Efficiency of Niosome Formulations.

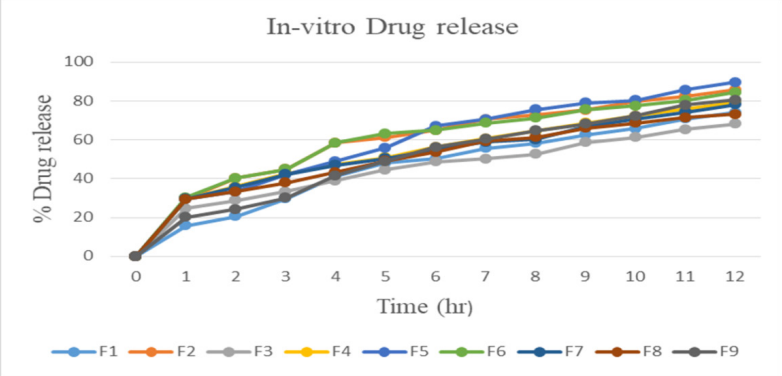

Figure 7: *In vitro* drug release of Niosomal formulation.

Table 7: Evaluation of Beclomethasone dipropionate Niosomal Gel formulations.

Formulations	Clarity	Spreadibility	Homogeneity
F1	Good	Better	Excellent
F2	Good	Better	Excellent
F3	Good	Good	Very good
F4	Good	Good	Very good
F5	Very clear	Better	Excellent
F6	Very clear	Better	Excellent
F7	Turbid	Good	Good
F8	Turbid	Good	Good
F9	Turbid	Average	Good

Table 8: Evaluation of BDP loaded Niosomal Gel formulations.

Formulations	Viscosity	pH	Drug Content (%)	*In vitro* Drug release (%)
F1	7870	6.3	72%	70.61%
F2	6975	5.4	80%	81.61%
F3	5106	5.6	75%	74.13%
F4	5158	6.4	73%	72.22%
F5	8166	6.81	87%	85.22%
F6	8023	6.80	80%	75.74%
F7	6582	6.3	81%	78.63%
F8	5921	5.4	84%	82.43%
F9	5236	5.5	76%	71.57%

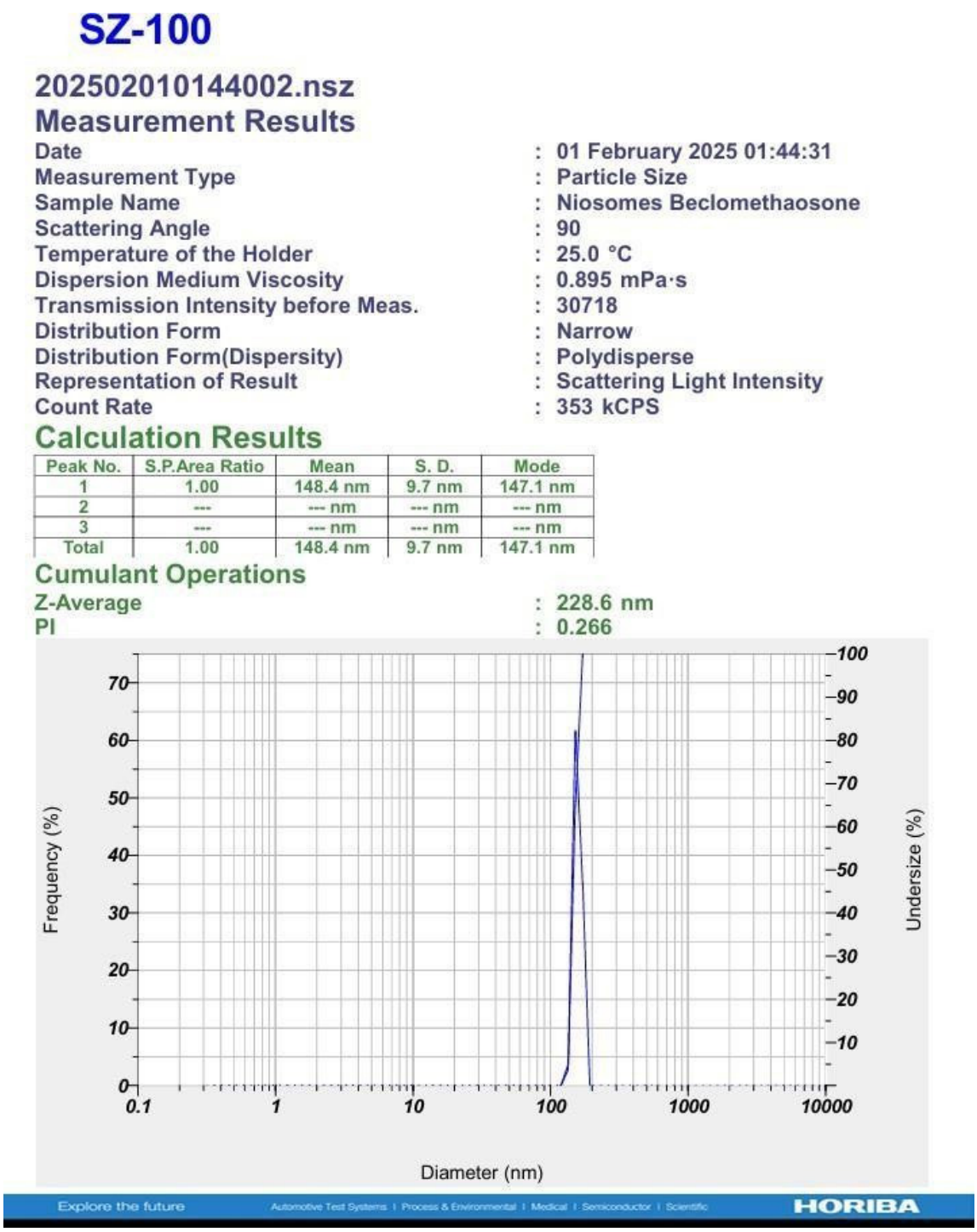

Figure 8: Particle size analysis of niosomes formulation.

larger vesicle size. This may be attributed to the general concept of the use of surfactant with a higher HLB which resulted in the preparation of vesicles with larger Sizes. The Vesicle size ranged from 206 nm to 400 nm for. From the results of particle size, it was found that prepared beclomethasone dipropionate niosomes have a Particle size less than 400 nm, and as such effective for topical gel.

Zeta Potential

Zeta potential of beclomethasone dipropionate loaded niosomes of Formulation F5 was found to be -43.9 mV.

Evaluation of Niosomal gel formulation

Clarity, Spreadibility and Homogeneity

All nine batches of Beclomethasone dipropionate noisome batches were subjected to preparation of niosomal gel and Gel

Table 9: Stability study of Niosomal gel.

Sl. No.	Parameter	Day 0	1-month	2-months	3-months
1.	Appearance	Milky white gel	Milky white gel	Milky white gel	Milky white gel
2.	Viscosity (cPs)	8166	8150	8130	8090
3.	pH	6.81	6.81	6.79	6.74
4.	Drug content (%)	87.70%	85.09%	83.32%	82.01%
5.	*In vitro* drug release (%)	85.22%	82.53%	80.42%	78.52%

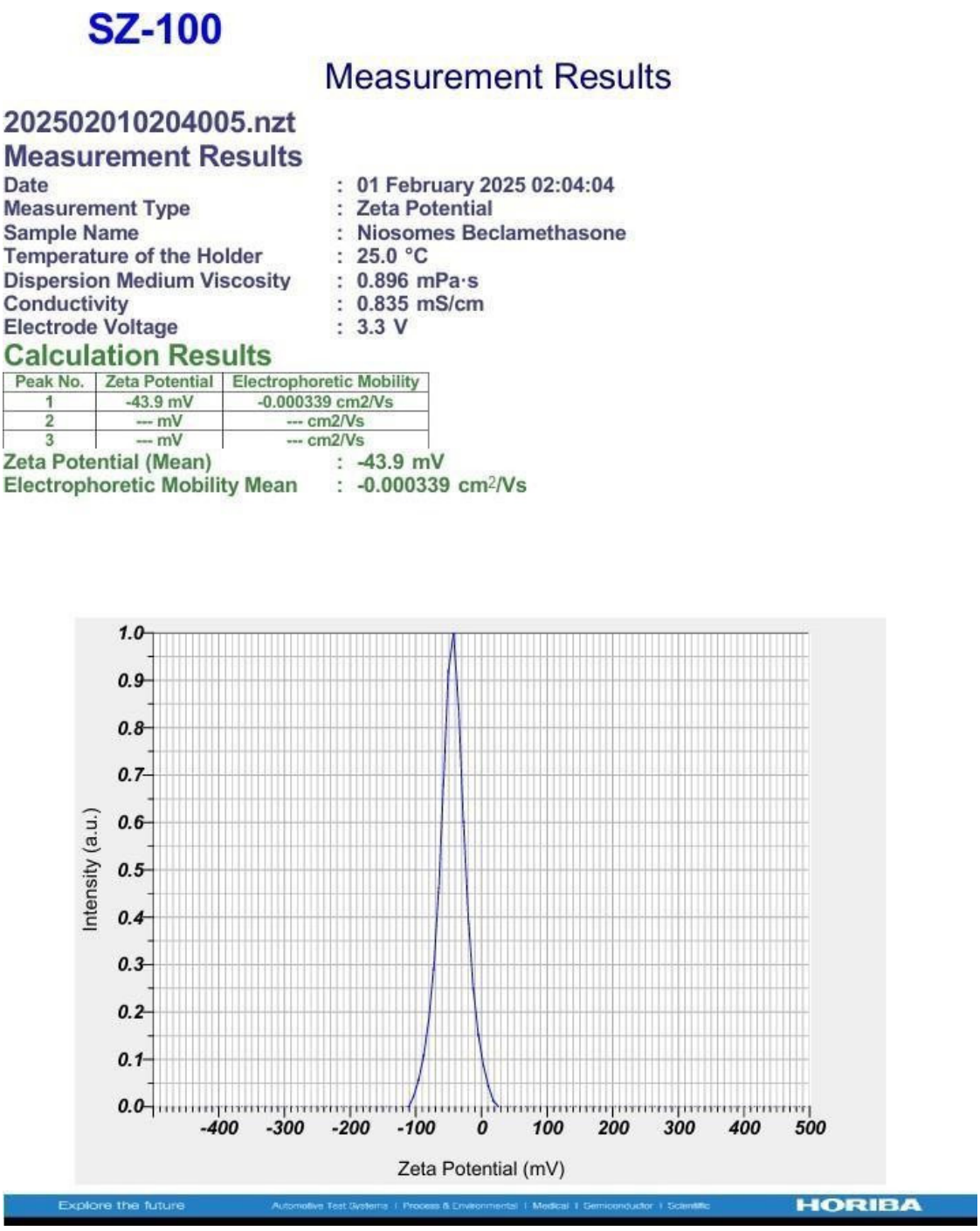

Figure 9: Zeta potential of niosomes Formulation.

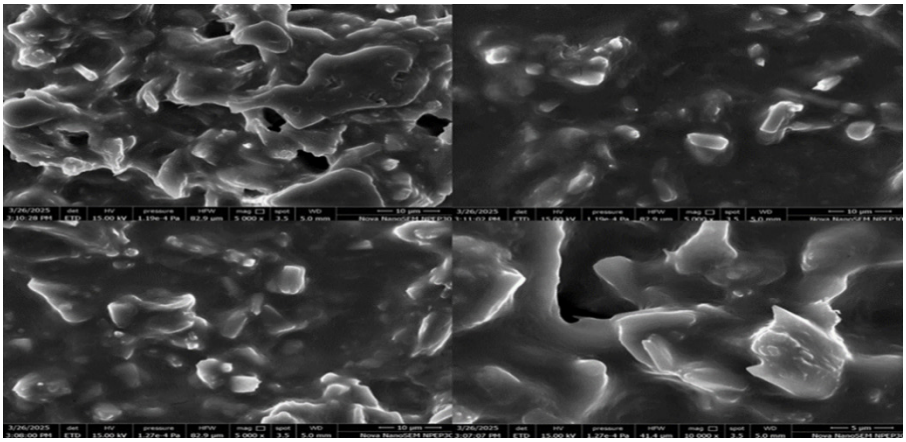

Figure 10: SEM analysis of Beclomethasone dipropionate loaded niosomes.

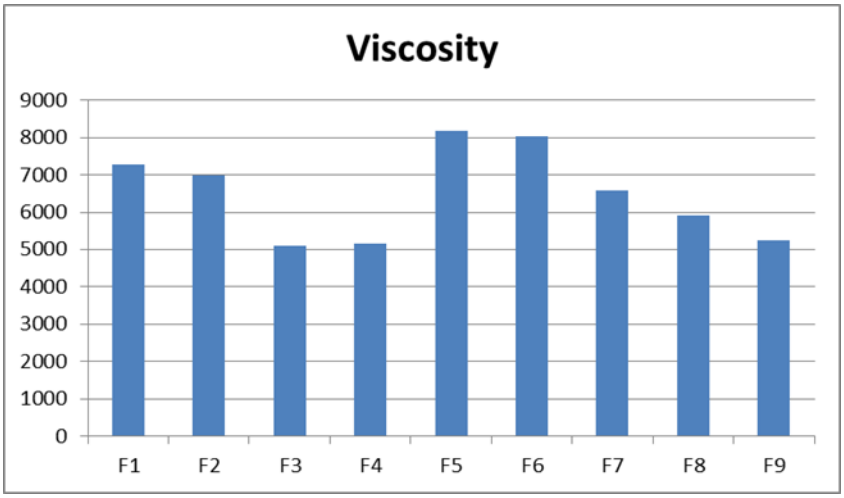

Figure 11: Viscosity of Niosomal gel.

preparations were then evaluated as per the clarity, its spread ability and homogeneity. Among all the formulations the gel formed F5 was found to be clearest with better spread ability and with excellent homogeneity.

The viscosity of niosomal gel formulations were carried out by using Brookfield viscometer and result of formulations are shown in Figures 8-11. The Viscosity of the all formulations were found to be 5106 to 8166 cps.

Stability Study

The gel was stored at ambient temperature conditions (25±5ºC). The physicochemical parameters of optimized niosomal gel batch F5 were evaluated after every 30 days for up to 3 months.

CONCLUSION

The work used the thin film hydration approach to successfully produce and optimize a niosomal gel filled with BDP. High entrapment effectiveness, prolonged drug release, and suitable physicochemical characteristics for topical administration were all displayed by the optimised Formulation (F5). Carbopol 934 offered an efficient gel basis for topical administration, and the addition of Span 60 and cholesterol significantly improved the niosomes' stability and functionality. These results imply that niosomal gel formulations may be a viable vehicle for the topical administration of Beclomethasone dipropionate, which could enhance its therapeutic effectiveness and reduce systemic adverse effects. To assess the optimized formulation's clinical effectiveness and skin permeability, more *in vivo* research is advised.

ACKNOWLEDGEMENT

None.

ABBREVIATIONS

BDP: Beclomethasone Dipropionate; **API:** Active Pharmaceutical Ingredient; **EE:** Entrapment Efficiency; **%EE:** Percentage Entrapment Efficiency; **SEM:** Scanning Electron Microscopy; **FTIR:** Fourier Transform Infrared Spectroscopy; **ANOVA:** Analysis of Variance; **QbD:** Quality by Design; **rpm:** Revolutions per Minute; **ºC:** Degree Celsius; **nm:** Nanometer; **cPs:** Centipoise; **pH:** Potential of Hydrogen; **IP:** Indian Pharmacopoeia.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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