

FORMULATION DEVELOPMENT AND EVALUATION OF NOVASOMES LOADED NOVEL TOPICAL SUNSCREEN GEL FOR ENHANCED PHOTO PROTECTIVE EFFICACY

Lavanya V.^{1*}, Abinaya M.², Harikrishnan M.³, Saravana Velu K.⁴, Vani P. S.⁵, Dhanesh Kumar M. R.⁶

^{1,2,3,4,5}Undergraduate Research Scholar, GRD College of Pharmacy, Thiruvallur, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai.

⁶Assistant Professor, GRD College of Pharmacy, Thiruvallur, Affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai.

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*Corresponding Author

Lavanya V.

Undergraduate Research Scholar,
GRD College of Pharmacy,
Thiruvallur, Affiliated to The Tamil
Nadu Dr. M.G.R Medical University,
Chennai.



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ABSTRACT

Ultraviolet (UV) radiation is a major environmental factor responsible for sunburn, hyperpigmentation, photoaging, oxidative stress and skin cancer. Conventional sunscreen formulations may exhibit limitations such as inadequate skin retention, photodegradation and frequent reapplication. The present study aimed to develop and evaluate a ZnO–TiO₂ loaded novasomal topical sunscreen gel to enhance photoprotective efficacy and prolong sunscreen activity. Novasomes containing zinc oxide and titanium dioxide were prepared by the ethanol injection method using Span 60, Tween 80, cholesterol and oleic acid. Five formulations (F1–F5) were prepared with varying concentrations of the sunscreen agents and evaluated for entrapment efficiency and in-vitro drug release. The entrapment efficiency ranged from 62.75% to 78.19%, while cumulative drug release ranged from 20.01% to 73.24%. Formulation F4 was selected as the optimized

formulation based on its entrapment efficiency and drug-release characteristics. F4 exhibited a percentage yield of 96.51% and drug content of 94.49%, with spherical and discrete vesicular morphology. The optimized novasomal dispersion was incorporated into a Carbopol-based gel, which demonstrated acceptable appearance, pH, viscosity, drug content

and prolonged in-vitro diffusion. The developed ZnO–TiO₂ novasomal sunscreen gel showed promising potential for sustained topical photoprotection and improved sunscreen performance.

KEYWORDS: Sunscreen, SPF, Zinc Oxide, Titanium Dioxide, Novasomes.

INTRODUCTION

The cosmetic industry has experienced significant growth, increasingly intersecting with dermatology, particularly in areas like cosmetic dermatology and dermatologic surgery. This evolution necessitates that dermatologists gain knowledge about cosmetic products that contribute to skin health. The U.S. Food and Drug Administration (FDA) regulates cosmetics and drugs under the Food, Drug, and Cosmetic Act, ensuring their safety. Products that claim to alter the body's structure or function are classified as drugs and fall under stricter regulations. Topical sunscreens play a crucial role in preventing sun damage, yet certain UV-absorbing ingredients can penetrate the skin, raising health concerns due to potential systemic circulation effects.

Sun exposure heightens the risk of skin cancers, including melanoma, basal cell carcinoma, and squamous cell carcinoma. Regular use of sunscreens mitigates UV radiation harmful effects, aiding in the prevention of skin cancer and photoaging. Photoprotection, a vital method for skin defense against UV radiation, becomes essential given that prolonged UVA and UVB exposure can result in oxidative stress, inflammation, erythema, photoaging, hyperpigmentation, DNA damage, and increased skin cancer risk.

Effective photoprotection relies on topical sunscreens; however, conventional formulations often fall short, facing challenges such as poor photostability, inadequate skin retention, uneven distribution, and the necessity for frequent reapplication, all of which diminish their efficacy. Recent advancements in nanotechnology have introduced Novel Vesicular Drug Delivery systems, like novasomes—multi-bilayer vesicular carriers made from surfactants, cholesterol, and free fatty acids—that address these shortcomings. Their structural advantages enable high drug entrapment efficiency, enhanced stability, controlled drug release, and improved skin adhesion, ultimately prolonging active ingredient retention in the epidermis. By incorporating sunscreen agents into novasomes, photoprotective performance can be enhanced while reducing degradation and improving patient compliance.

Incorporating Novasome-loaded sunscreen into topical gels enhances photoprotective efficacy and stability, providing sustained protection against UV damage. Sunscreen gels are favored for their non-greasy texture, ease of application, and better absorption, especially for oily and acne-prone skin. However, conventional formulations face challenges like poor ingredient stability and limited skin penetration. Novel vesicular drug delivery systems, which include liposomes and niosomes, improve stability and release of active agents, but they still encounter issues such as entrapment efficiency. The skin's stratum corneum barrier limits the effectiveness of topical agents, making advanced delivery systems essential for improved retention and efficacy in sunscreen applications.

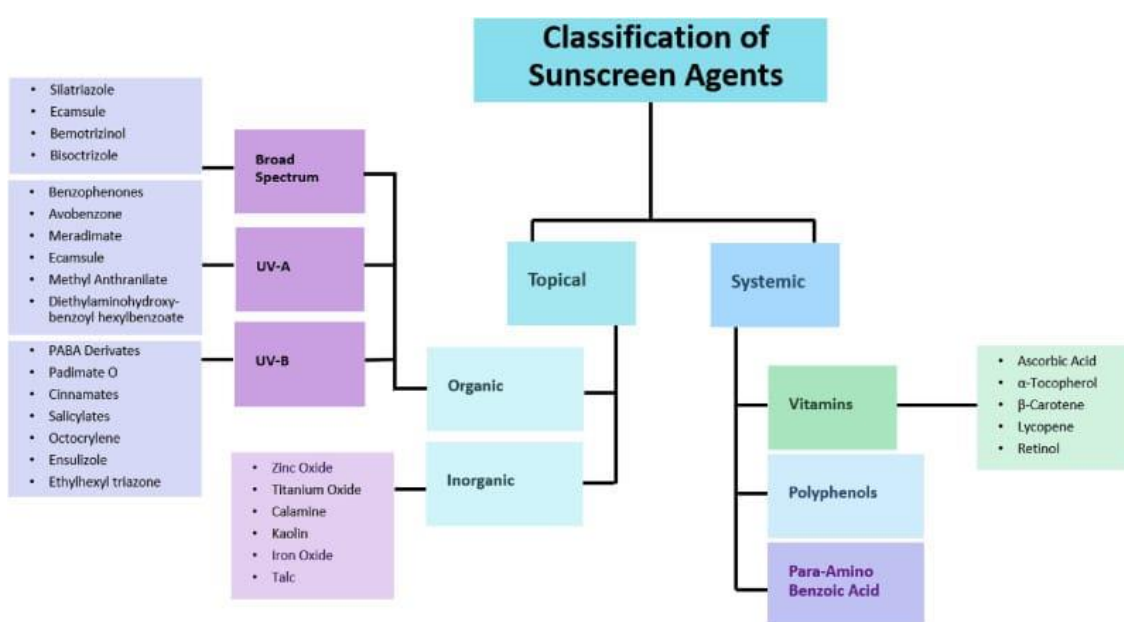


Fig. 1: Classification of Sunscreen Agents.

Novasomes are an advanced vesicular drug delivery system, composed of surfactants, cholesterol, and free fatty acids, enabling the encapsulation of large amounts of active ingredients. They enhance skin penetration and improve the stability and photostability of sunscreen agents against UV degradation, leading to prolonged efficacy. Integrating sunscreen agents into novasomes and formulating them into gel systems offers improved skin adherence, stability, controlled release, and enhanced photoprotection. This innovative approach represents a significant advancement in cosmetic science for effective UV protection. The concept of targeted drug delivery, originally developed by Paul Ehrlich in 1909, has evolved over the years to include various carriers like liposomes and microspheres.

Novasomes are specialized vesicular drug delivery systems that improve the efficacy of pharmaceutical and cosmetic ingredients by enhancing their penetration through the skin. Composed of multiple bilayer membranes made from non-ionic surfactants, cholesterol, and free fatty acids, novasomes offer better stability and drug-loading capacity than traditional vesicular systems. They address limitations of conventional topical formulations, such as poor skin penetration and instability, by efficiently transporting active compounds while protecting them from degradation. In sunscreen formulations, novasomes enhance the encapsulation and distribution of UV filters, resulting in improved photoprotection and user compliance. Additionally, they provide sustained release of active ingredients, maintaining effective concentrations and preventing irritation. Their multilamellar structure enhances stability against environmental factors, making novasomes a promising carrier system for advanced topical sunscreen gels. With size ranging from 0.1 to 1.0 μm , novasomes can encapsulate both hydrophilic and lipophilic compounds, utilizing their components to create a stable and effective drug delivery system.

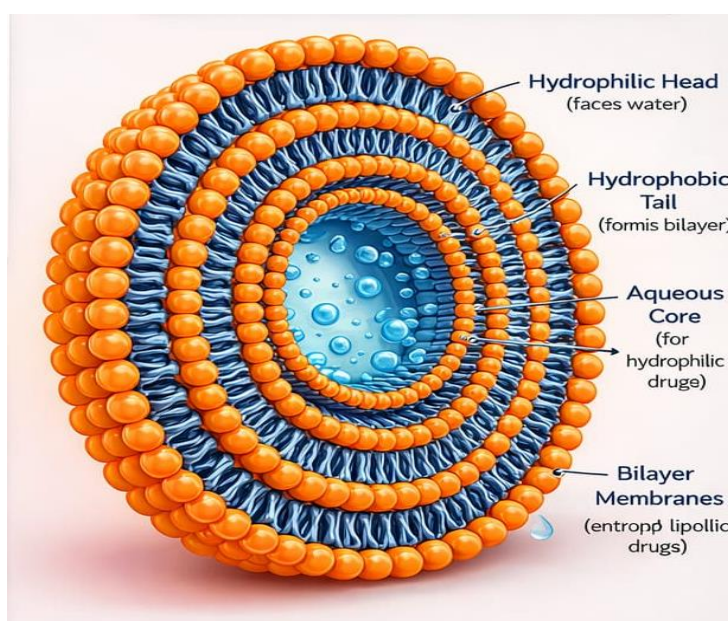


Fig. 2: Structure of Novasomes.

Novasomes provide significant advantages in drug delivery, particularly for sunscreen formulations. Their multilamellar structure allows high entrapment efficiency of UV filters, enhancing photoprotective effectiveness. By interacting with the lipid components of the stratum corneum, novasomes improve skin permeation and retention of active ingredients, thereby increasing topical efficacy while minimizing systemic absorption. The controlled release of encapsulated agents ensures sustained UV protection, reducing the need for

frequent reapplication and enhancing patient compliance. Additionally, their biocompatibility and low toxicity make them suitable for long-term use without skin irritation. Novasomes enhance the Sun Protection Factor (SPF) through uniform distribution and improved film formation on the skin, while also providing oxidative stress protection by delivering antioxidants to neutralize free radicals and prevent photoaging.

Table 1: Parameter differences between Liposomes, Niosomes & Novasomes.

PARAMETER	LIPOSOMES	NIOSOMES	NOVASOMES
Definition	Vesicular carriers composed mainly of phospholipids forming one or more lipid bilayer	Vesicles formed by non-ionic surfactants with cholesterol forming a bilayer structure	Advanced vesicular carriers made of polyoxymethylene fatty acids ester, cholesterol and free fatty acids
Main components	Phospholipids and cholesterol	Non-ionic surfactants and cholesterol	Polyoxymethylene fatty acids monoesters, cholesterol, free fatty acids
Structure	Uni-lamellar or multi lamellar lipid bilayer vesicles	Bilayer vesicular system	Multi-bilayer vesicles with large internal core
Stability	Less stable due to phospholipid oxidation	More stable than liposomes	Highly stable vesicular system
Cost of Preparation	Expensive	Economical	Expensive
Drug entrapment capacity	Moderate	Moderate	High drug loading capacity
Skin penetration	Good	Better than liposomes	Excellent penetration ability
Storage stability	limited stability	Better storage stability	Very good storage stability
Toxicity	Very low due to natural lipids	Low toxicity	Low toxicity
Applications	Drug delivery, vaccines, cosmetics	Transdermal and topical drug delivery	Cosmetic and dermatological formulation such as sunscreen

Advantages of Novasomes in Topical Delivery

- They help maintain skin moisture by reducing transepidermal water loss.
- Novasomes can encapsulate a large amount of active ingredients for improving formulation effectiveness.
- They facilitate deeper penetration of drugs through the skin layers.
- Novasomes provide sustained release of active ingredients over an extended period.

- They protect encapsulated compounds from degradation caused by light, heat and oxidation.
- Novasomes improves the efficacy of sunscreen agents by increasing their retention on the skin.
- Encapsulation minimizes direct contact of active ingredients with the skin, thereby reducing irritation.
- Novasomes enhance the availability of active ingredients at the target site.
- They remain on the skin for a longer duration and improve therapeutic effectiveness.
- Their non-greasy nature and reduced application frequency improve patient compliance.

Zinc Oxide and Titanium Dioxide

Zinc oxide (ZnO) and titanium dioxide (TiO₂) are inorganic/mineral sunscreen agents that protect the skin mainly by acting as physical UV filters. They form a protective layer on the skin and reflect and scatter ultraviolet (UV) radiation, thereby reducing the amount of harmful UV rays reaching the skin. ZnO provides broad-spectrum protection against UVA and UVB radiation, while TiO₂ is particularly effective in blocking UVB and shorter-wavelength UVA radiation. Their incorporation into a sunscreen formulation helps reduce UV-induced skin damage such as sunburn, premature photoaging, and pigmentation.

RESEARCH METHODOLOGY

MATERIALS

The materials used in this study, along with their respective suppliers, are listed below: Microionized zinc oxide (Twenty first century pharmaceuticals, Chennai); Microionized titanium dioxide (Twenty first century pharmaceuticals, Chennai); Span 60 (Mohini Organics Pvt. Ltd., Mumbai); Tween 80 (Mohini Organics Pvt. Ltd., Mumbai); Cholesterol (Lab Chemicals, Chennai); Carbopol 934 (Saimirra Innopharma Pvt. Ltd., Chennai); Sodium Benzoate (Saimirra Innopharma Pvt. Ltd., Chennai).

METHODOLOGY

(a) Preformulation Study

The drug and excipients selected for the formulation were evaluated for both physical and chemical compatibility studies to ensure stability and effectiveness of the formulation.

(b) Formulation of Novasomes-loaded Sunscreen Gel

The sunscreen gel was prepared using a polymeric gel base containing UV filters incorporated through novasomal vesicles. The gel base was prepared by dispersing Carbopol 934 in purified water under constant stirring until a clear dispersion was obtained. The pH of the gel was adjusted to 6–6.5 using triethanolamine (TEA) to obtain a transparent gel. For the preparation of novasomes, the oil phase consisting of cholesterol, span 60, oleic acid, and sunscreen agents such as zinc oxide and titanium dioxide was dissolved in ethanol. The aqueous phase containing tween 20 and propylene glycol was prepared separately. Both phases were heated about 60–70°C. The oil phase was slowly added to the aqueous phase with continuous stirring at 2000 rpm for 15 minutes using a mechanical stirrer to form novasomal vesicles. The dispersion was allowed to cool to room temperature. The prepared novasomes were then incorporated into the gel base with continuous stirring to obtain a uniform sunscreen gel formulation.

Table 2: Formulation of Zinc Oxide and Titanium dioxide.

INGREDIENTS	FORMULATION CODE DRUG (mg)				
	F1	F2	F3	F4	F5
zinc oxide	200	225	250	275	300
Titanium dioxide	10	15	20	25	30
Span 60	500	500	500	500	500
Ethanol	10ml	10ml	10ml	10ml	10ml
Oleic acid	100	100	100	100	100
Tween 80	750	750	750	750	750
Cholesterol	750	750	750	750	750
Carbopol 934	500	500	500	500	500
Sodium bezoate	100	100	100	100	100
Sandalwood oil	q.s	q.s	q.s	q.s	q.s
Distilled water	q.s	q.s	q.s	q.s	q.s

CHARACTERIZATION OF NOVASOMES LOADED NOVEL SUNSCREEN GEL

(a) Physical Examination

The prepared sunscreen gel formulations were evaluated visually for color, homogeneity, consistency, clarity, and presence of any phase separation or grittiness.

(b) Spreadability Test

A sample of 0.5 g of sunscreen gel was placed between two glass slides and pressed with a known weight for a specific time (5 minutes). The diameter of the spread gel was measured in cm and used to determine spreadability.

(c) Determination of pH

The pH of the sunscreen gel was measured using a calibrated digital pH meter. About 1 g of gel was dispersed in 20 mL of distilled water and the electrode was dipped into the solution to record the pH. Measurements were performed in triplicate.

(d) Determination of Viscosity

The viscosity of the sunscreen gel formulations was measured using a Brookfield viscometer at controlled temperature. Appropriate spindles and speed were selected based on the consistency of the gel.

(f) Determination of Drug Content

The drug content of the prepared sunscreen gel was determined by dissolving a weighed quantity of gel (about 1 g) in a 100 mL volumetric flask containing a suitable solvent system (ethanol and phosphate buffer pH 7.4). The solution was sonicated for 15 minutes to ensure complete solubilization of active ingredients such as zinc oxide and titanium dioxide. The resulting solution was filtered through a 0.45 μm membrane filter. Appropriate dilution was carried out, and the absorbance was measured using a UV–Visible spectrophotometer at λ_{max} . The drug content was calculated using a previously prepared calibration curve.

(g) In-vitro Drug Diffusion Study

An *in-vitro* drug diffusion study was performed using a Franz diffusion cell apparatus. The receptor compartment was filled with phosphate buffer solution (pH 7.4), while the donor compartment contained the sunscreen gel formulation. A dialysis membrane previously soaked in buffer solution for 24 hours was placed between the donor and receptor compartments. Care was taken to avoid air bubbles. The temperature was maintained at $37 \pm 0.5^\circ\text{C}$ and stirred at 50 rpm using a magnetic stirrer. At predetermined time intervals, 1 mL of sample was withdrawn from the receptor compartment and replaced with fresh buffer to maintain sink conditions. The samples were analyzed spectrophotometrically at λ_{max} .

(h) Entrapment Efficiency

Entrapment efficiency was determined to measure the amount of sunscreen agents entrapped within the novasomes. The formulation was centrifuged, and the untrapped drug present in the supernatant was analysed using UV-Visible spectrophotometry. Entrapment efficiency was calculated using the standard formula.

(i) Stability Studies

Stability studies were performed according to ICH guidelines by storing the formulation at different temperature and humidity conditions. The formulation was evaluated periodically for changes in appearance, pH, viscosity, and drug content to determine its stability over time

RESULT AND DISCUSSION

(a) Pre-formulation Studies

Drug- Excipients Compatibility Studies

Physical compatibility is shown in Table. They were evaluated for 10,20 and 30 days at room temperature and at 40 °C $\pm$ 2°C and 75% RH $\pm$ 5%. There was no change in color. Therefore, drug and excipients are physically compatible with each other. Exceptions which are compatible with the drug are selected for formulation.

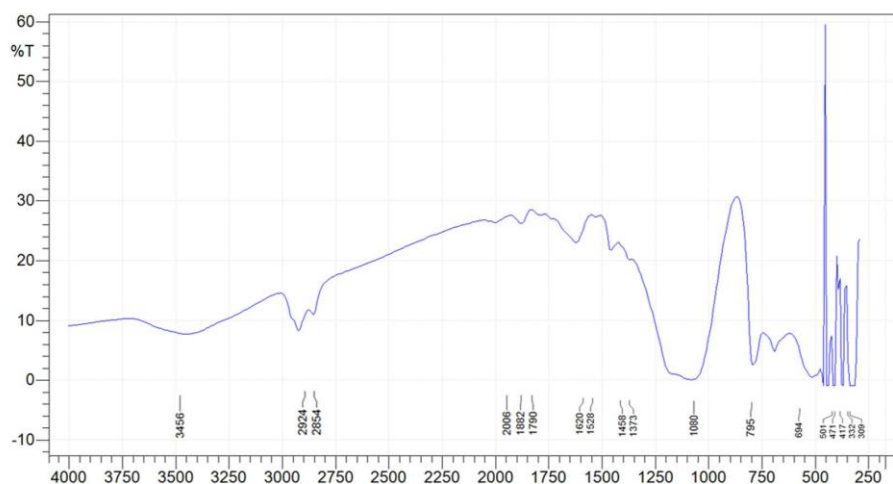


Fig. 3: FTIR Spectrum of ZnO, TiO₂ and Excipients.

The peaks observed in the FTIR spectrum of zinc oxide, Titanium dioxide, span 60, Carbopol and cholesterol showed no shift and no disappearance of the characteristic peaks of drug. This suggests that there is no interaction between the drug and the excipients.

Determination of λ_{max} for Zinc Oxide and Titanium Dioxide

The maximum absorbance of the Zinc oxide was studied. The maximum absorbance of the drug Zinc oxide and Titanium Dioxide was found to be 367 nm and 362 nm respectively.

Standard Calibration Curve of Zinc Oxide and Titanium Dioxide

The Ultraviolet Spectrophotometric method was used to analyse the calibration curve of Zinc oxide and Titanium dioxide. The absorbance of the drug in acidic medium of concentration

ranging from 1 - 10 $\mu\text{g/ml}$ was measured at a wavelength of 210-230 nm and 320-350 nm respectively against blank. The results are given in Table 2. It was found that both zinc oxide and titanium dioxide show linearity ($R^2 = 0.9976$ and 0.9961) in absorbance at the concentration of 1-5 $\mu\text{g/ml}$ and obeys Beer Lamberts law.

Table 3: Standard calibration curve of Zinc oxide and Titanium dioxide.

S. NO	Concentration ($\mu\text{g / ml}$)	Absorbance (nm) ZnO	Absorbance (nm) TiO ₂
1	0	0	0
2	1	0.098	0.086
3	2	0.180	0.192
4	3	0.251	0.283
5	4	0.330	0.352
6	5	0.407	0.434

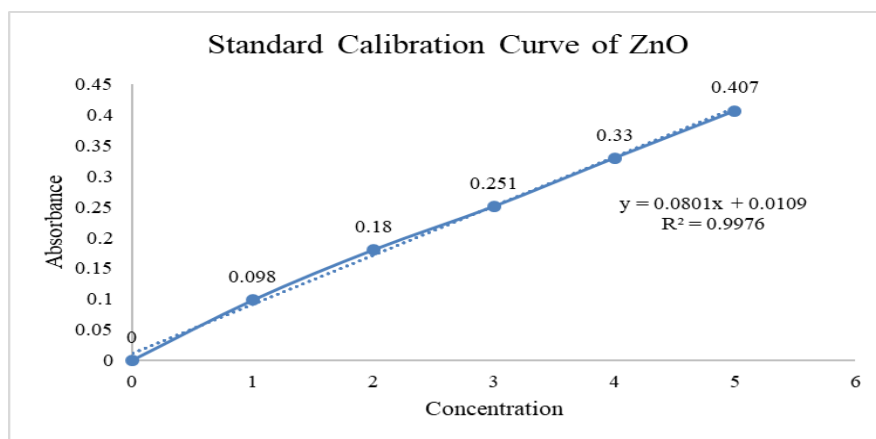


Fig. 4: Standard Calibration curve of Zinc oxide.

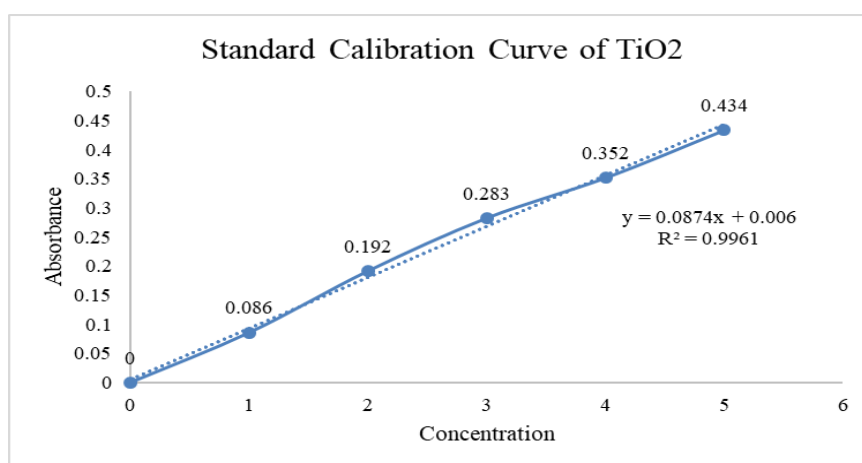


Fig. 5: Standard Calibration curve of Titanium dioxide.

Formulation of Drug Loaded Novasomes

Drug loaded novasomes were prepared by Ethanol injection method using Span 60, Tween 80, Cholesterol using different drug ratio concentrations.



Fig. 6: Drug loaded Novasomal dispersion F1–F5.

Characterization of Drug Loaded Novasomes

(a) Entrapment Efficiency

The entrapment efficiency of Drug loaded Novasomal formulations (F1–F5) were determined and the entrapment efficiency of the formulations was observed to be between 62.75 – 78.19%.

Table 4: Percentage Entrapment efficiency for Drug loaded Novasomes (F1–F5).

Formulation code	Entrapment Efficiency (%)
F1	68.12
F2	64.91
F3	62.75
F4	78.19
F5	75.94

(b) *in-vitro* Drug Release

The drug Release of the ZnO-TiO₂ formulation (F1-F5) was determined, and the drug release of the formulation was observed to be between 20.01 - 73.24 %.

Table 5: Cumulative percentage drug release.

Time (hrs)	Cumulative percentage drug release				
	F1	F2	F3	F4	F5
1	22.97	32.39	20.01	28.82	25.16
2	38.62	36.3	24.92	32.76	38.37
3	47.97	39.41	27.58	39.16	48.16
4	56.07	42.76	36.11	48.23	56.82

5	68.69	45.6	43.79	51.52	62.04
6	58.36	56.79	50.02	69.20	70.79
10	59.36	58.54	55.68	73.24	71.16

Based on entrapment efficiency and in vitro drug release **Formulation F4** has been chosen as optimal one. Further characterization of formulation F4 has been done.

(c) Morphology of Novasomes by Scanning Electron Microscopy (SEM) Analysis

SEM image of Novasomes formulations was recorded. The particles were almost spherical and homogeneous. The results shows that the ZnO-TiO₂ loaded Novasomes have a spherical shape with smooth surface and discrete without any aggregation or agglomeration.

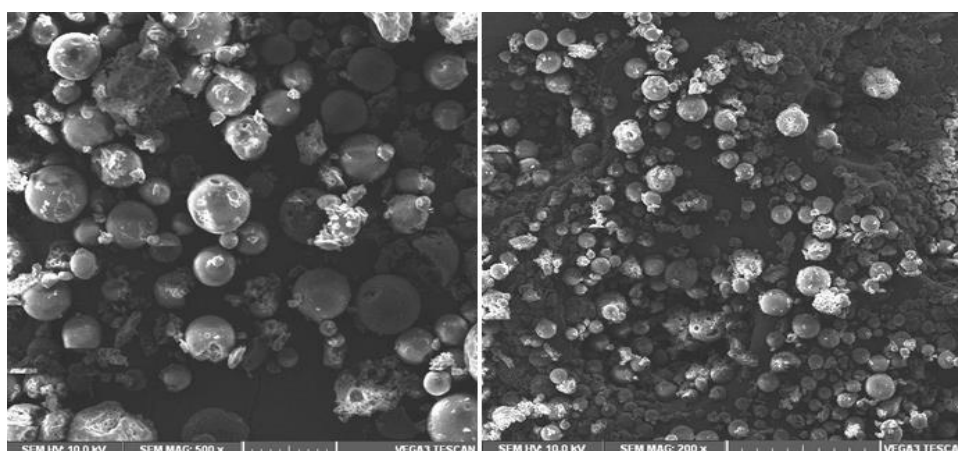


Fig. 7: SEM image of Formulation (F4).

Formulation of ZnO-TiO₂ Loaded Novasomal Sunscreen Gel

The ZnO-TiO₂ Loaded Novasomes were prepared with Carbopol as gelling agent, which may result in an increased residence time of drug at the site of absorption.

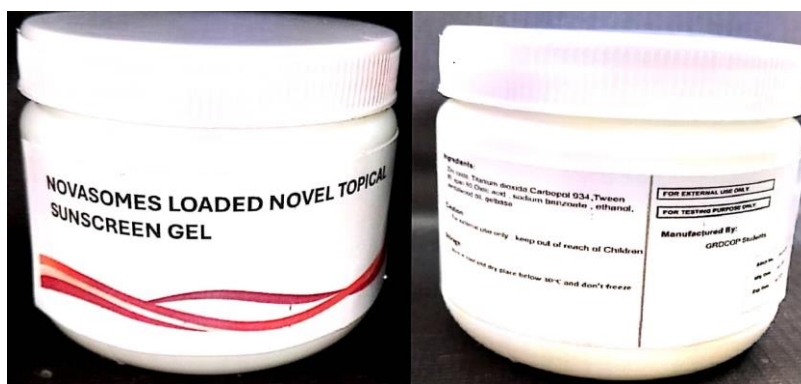


Fig. 8: ZnO-TiO₂ Loaded Novasomal Sunscreen Gel.

Characterization of ZnO-TiO₂ Loaded Novasomal Sunscreen Gel

(a) Visual Appearance of Gel

The formed gel was found translucent. It had no visible particles. The gel had good texture and clarity suggesting suitability for delivery by Topical route.

(b) pH of Gel

The pH of Zn-TiO₂ Loaded Novasomes Gel was found to be 6.1 ± 1.2 suggesting suitability for delivery by Topical route.

(c) Viscosity

The viscosity of the formulation was found to be **89.71** centipoises before gelation and **3476 Centipoises** after gelation, exhibiting good consistency. It was observed that the gelling agent Carbopol 940 contributed in maintaining the gel viscosity.

(d) Drug Content Determination of Gel

The UV-Visible Spectrophotometric was used to determine the percentage drug content of the Novasomal Gel and was found the be **94.78%**

(e) Entrapment Efficiency

The entrapment efficiency of the Novasomal Gel and was found to be **77.62%**

(f) *in-vitro* Drug Diffusion Study

The *in vitro* drug diffusion study of ZnO-TiO₂ Loaded Novasomal Sunscreen gel was performed using Franz diffusion cell assembly using phosphate buffer pH 7.4 as the diffusion medium. The results are shown in Table 6 and Figure 9. The cumulative % drug release of ZnO-TiO₂ Loaded Novasomal Sunscreen gel was found to be 77.62%.

Table 6: *In vitro* drug diffusion of Zn-TiO₂ Loaded Novasomal Sunscreen Gel.

Time (hours)	Cumulative % drug release
	ZnO-TiO ₂ Loaded Novasomal Sunscreen Gel
0.5	18.34
1	32.73
1.5	44.83
2	48.52
2.5	53.93
3	76.93
4	77.15
5	77.58
6	77.62

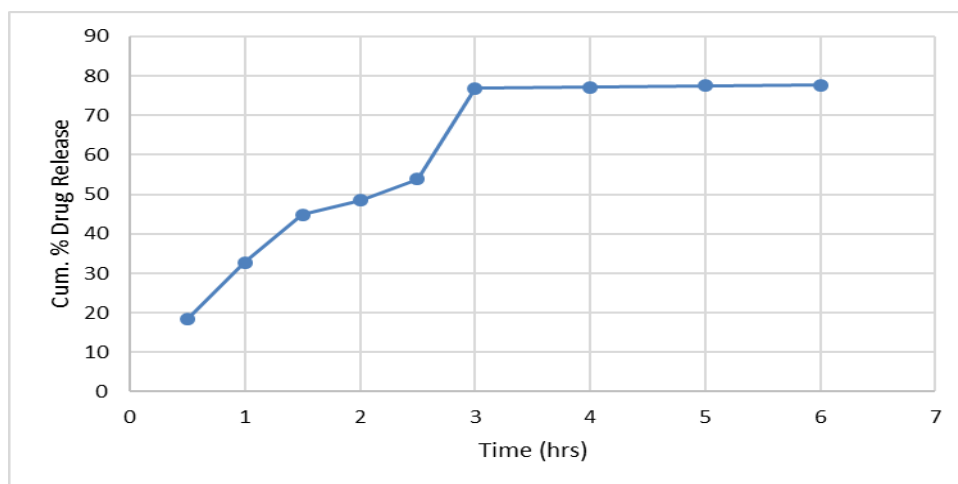


Fig. 9: *in-vitro* drug permeation study of ZnO-TiO₂ Loaded Novasomal Sunscreen Gel.

(g) Stability Studies Formulation

No significant changes in physical appearance, entrapment efficiency and drug content at storage condition of $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ / $75 \pm 5\%$ RH, $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and at room temperature after the end of 30 days.

Table 7: Stability study of formulation.

Stability condition	Physical appearance			Entrapment efficiency (%)			SPF		
	Initial	After 15 days	After 30 days	Initial	After 15 days	After 30 days	Initial	After 15 days	After 30 days
Room temperature	NC	NC	NC	77.71	77.59	77.42	32	31	31
$4^{\circ}\text{C} \pm 2^{\circ}\text{C}$	NC	NC	NC	77.71	77.68	77.57	32	32	32
$40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ $75 \pm 5\% \text{RH}$	NC	NC	NC	77.71	76.62	77.34	31	31	31

CONCLUSION

The notion of this research was to formulate ZnO-TiO₂ incorporated Novasomal Sunscreen Gel to improve the release of drug to improve the patient compliance by reducing the dose and dosing frequency of the sunscreen. The use of Sunscreen in recent years has been significantly increased across the world. Rising greenhouse gases and global warming pose a threat to the human health. The increasing depletion ozone layer had increased the concern for sunscreen usage. Sunscreen not only acts as a cosmetic but also plays a vital role in conservation of human health. Sunscreen agents plays a major role in preventing not only minor concerns of sunburns, tanning but also helps in preventing melanoma and mutations of the skin. Chemical sunscreens although has superiority over mineral sunscreens but it itself

pose a threat to the human health as well as affect environment especially marine life. To increase the superiority of mineral sunscreens and to reduce the adverse effects, mineral sunscreen agents were formulated as novasomes.

The formulated Novasomal Sunscreen gel was characterized for the physical appearance, pH, viscosity, drug content, in vitro drug diffusion and SPF determination. The entrapment efficiency of the F4 Novasomal Sunscreen Gel was determined, and its entrapment efficiency was observed to be 77.62%. The UV-visible Spectrophotometric method was used to determine the drug content of ZnO-TiO₂ loaded Novasomal Sunscreen gel. The drug content was found to be 94.78%. *In vitro* diffusion of ZnO-TiO₂ Novasomal Sunscreen gel showed good release. The cumulative % drug release was 77.14% at 6 hrs. It showed prolonged release compared to marketed formulation. The formulation was subjected to room temperature, accelerated stability study (40°C±2°C and 75±5% RH) and refrigerator temperature (4±2°C). The results show no significant change in appearance, SPF, drug entrapment efficiency and drug content of formulation after one month.

The foregoing results attempt to suggest that ZnO-TiO₂ Novasomal Sunscreen gel could be a promising future for Sunscreen, as it enhances the permeability via topical route and provides a good SPF over a period of time. This formulation could reduce the applying frequency of sunscreen and the adverse effects of harmful chemical sunscreen ingredients on human health and environment. The choice between chemical and mineral sunscreens depends on individual preferences, skin type, and specific needs. Novasomal sunscreens offer a promising alternative to conventional formulations, addressing key issues of stability, efficacy, and user acceptability. Continued research and development in this area are essential to fully realize their potential, ensuring that they meet consumer needs while providing effective sun protection.

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