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Formulation and Evaluation of Terbinafine Proniosmal Gels

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ABSTRACT

The present research work of Terbinafine Proniosomal gel focuses on improving patient compliance by reducing the side effects of conventional intravenous injections and minimizing the problem of physical stability and to localize drug at site of action. The results of the study indicated that Terbinafine proniosomal gel containing lecithin, cholesterol, and surfactant Span and Tween formulations were prepared successfully using the coacervation phase separation method. The F5 formulation showed the highest efficiency. The proniosomal gel formulations were evaluated for their entrapment efficiency, drug content, UV-visible spectroscopy, viscosity, vesicle size and shape with SEM, and the results were found to be within the acceptable range. The study found that F5 has antifungal activity after 48 h, indicating that the developed proniosomal gel was more effective than the control. The results showed that F5 containing span 60 is the most appropriate surfactant for the formation of proniosomes. *In-vitro* release studies proved that the proniosomal gel contains terbinafine, which is considered to be a successful topical drug delivery system and provides a sustained release of the encapsulated drug. *In-vitro* release studies showed satisfactory results, and the permeation studies showed good control release for a prolonged period of time. Permeation studies showed the highest permeation of proniosomal gel formulation F5, and *In-vitro* goat skin permeation studies proved that a good amount of drug is permeated and has good stability characteristics. The study showed that the proniosomal gel formulation was quite stable at room temperature and accelerated temperature as well.

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INTRODUCTION

Proniosome gel preparations have been semisolid liquid crystal items like non-ionic detergents made by dissolving their surfactant in a required minimum of an eluent (organic solvent such as ethanol) and aqueous solution (water). Such constructions have been liquid crystals compressed niosomes hybrid vehicles that can instantly transform into niosomes on such moisture. proniosome gel through topical/dermal delivery doesn't require hydration before the application. Instead, these could be implemented as a whole or filled on such a base material as emulsifiers, gel, lotion, etc. Before the application [1]. proniosome gel has a better potential to decrease the adverse effects of medication and enhance therapeutic success. proniosomes could abduct either hydrophobic or hydrophilic opioids. All those are usually current through translucent, transparent but rather pale semisolid gel surface, which tends to make those physiologically steady throughout transport and storage. All such incor-

porate non-ionic emulsifiers and fats accompanied by moisture in aqueous solutions [2]. Its emulsifier molecule is straightforward itself such that the hydrophilic ends of a non-ionic emulsifier orient upward as well as water-insoluble comes to a lot has been focused towards the reverse direction of about form its bilayer terbinafine is exceptionally efficient through fungi of a bunch oxygenates and also some yeast strains within genus *candida (e.g., candida glabrata*) as either a cream rather than flour, it can be used topically such as external skin conditions such like jock itch (tinea cruris), athlete's foot (tinea pedis), as well as other kinds of scabies (tinea corporis) [3].

Terbinafine would be an oral and peripherally practical allylamine fungistatic operator used to treat opportunistic fungal skin infections and nails [4]. Terbinafine has already been related to rare situations like significant liver damage, which can be severe and sometimes fatal. Its tablets could, rarely, cause hepatotoxicity; as such, patients have been warned of it and could be controlled for liver function [5].

MATERIALS AND METHODS

Materials

Terbinafine was a generous gift sample from Torrent pharmaceutical LTD, Gandhinagar. Cholesterol, soya lecithin, and tween 60 were procured from Thorab Pharma and research laboratory, Puducherry, and span 40 (Rohm Gmbh & CoKG, Germany), span 60 (India sea foods, cochin, India), tween 20 (Pharmaceutical Pvt Ltd, Navi Mumbai).

Methodology

FTIR Study

FTIR has been used to analyze pure drug terbinafine, fats, soya lecithin, non-ionic emulsifiers (span 40, span 60), and carbopol, as well as with their physiological mix in the same quantity. Compatibility like terbinafine as for excipients has been confirmed through FTIR analysis. Its FTIR research utilized the potassium bromide (kbr) disc (pellet) technique [6].

Preparation of Proniosomal Suspension

Proniosomes have been developed using the coacervation phase inversion technique, with some advancements utilizing distinctive emulsifiers through the span and tween as a topical application. Its Concentration of different Proniosomal preparations is printed, such as in Table 1. In such a glass beaker, 10 mg of terbinafine has been added, including the emulsifiers and fats. Add a necessary quantity like ethyl and warmth over a steam bath at around 60-70°c for five minutes by closing its glass tube to avoid a lack of solutes while shaking until the dissolution of cholesterol. After the complete abolition of the solution, add 1 ml of phosphate buffer saline and warm for 5 minutes until a prominent, relatively transparent solution is formed. Its composition has been allowed to cool at room temperature to provide an obvious chalky white solution like proniosomes [7].

Preparation of Proniosomal Gel

In deionized water, a solution like carbopol 934 (2% w/v) has been permitted to swell such as 3-4 h. 2 ml of proniosomal suspension has been got to add into the carbopol 934, usually contains glycerin and methylparaben but also blended as for malfunction constant agitation. Triethanolamine has been adjusted by adding ph and was sonicated, such 15 min, and managed to keep times to remove flocs [8].

Evaluation of Proniosomal Suspension

Vesicle Size and Shape

Through an optical microscope, proniosomal suspension (0.2g) was dissolved for phosphate-buffered ph 7.4 (10 ml) and sonicated for around two minutes. A drop has been positioned on such a glass slide. Still, the form like vesicles has been evaluated that used a high magnification there as magnifying forces like 10x, 45x as well as pictograms have been recorded [9].

Measurement of Vesicle Size

The average crystal size diameter and size distribution (polydispersity index, pi) have been ascertained even by the Malvern zeta sizer [10]. So every specimen was passed three times, and analysis proceeded at about as 25°c with such a scattering angle as 173°c.

By Scanning Electron Microscope

A specimen has been analyzed underneath a scanning electron microscope, such as a vesicular frame, and after that picture. The surface morphology, like proniosomes, has been researched through scanning electron microscopy (SEM). the form of composition and the sizes of a vesicle has been ascertained through sem. A fall-like proniosomal suspension has been positioned upon that samples stub which has been encased as for carbon and with gold vapor phase did appear using just a Hitachi vacuum evaporator [11].

Determination of Zeta Potential

A zeta potential of a proniosomal composition has been analyzed there as 25°c utilizing a zeta sizer. proniosomal suspension has been dissolved a hundred times as for doubled-distilled water. Voltage

Table 1: Composition of Proniosomal Suspension

Formulation Ingredients	Formulation Code						
	F1	F2	F3	F4	F5	F6	F7
Terbinafine (mg)	20	20	20	20	10	10	10
Cholesterol (mg)	30	30	30	30	20	20	20
Soya Lecithin (mg)	60	60	60	60	40	40	40
Span 40 (mg)	300	-	-	-	-	200	-
Span 60 (mg)	-	-	-	300	200	-	-
Tween 20 (mg)	-	-	300	-	-	-	200
Tween 60 (mg)	-	300	-	-	-	-	-
Ethanol (ml)	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Phosphate buffer saline (ml)	Up to 2 ml	Up to 2 ml	Up to 2 ml	Up to 2 ml	Up to 2 ml	Up to 2 ml	Up to 2 ml

was measured there as 1.4 v, and electrodes were placed through diffusion again for measuring systems like zeta potential [12]. So every specimen was passed three times, and analysis proceeded there at 25°c with such a diffracted angle as 173°C.

Determination of Entrapment Efficiency

The proniosomal suspension (0.2g) was taken inside a test tube and reconstructed for 10 ml isosmotic phosphate-buffered like ph 7.4. One such aqueous medium has been sonicated inside an ultrasonic bath.

Its opioid usually contains niosomes that have been kept separate from diffusion through centrifugation at 3000 rpm for 30 min at about 20 °c. Its supernatant (1 ml) has been begun taking as well as dissolved for phosphate-buffered (in 10 ml volumetric flask).

But also again, from standard solutions, 1 ml has been discharged and transmitted to either a 10 ml volumetric flask but also thought up towards the mark as for buffer [13].

A drug concentration as in standard solution has been analyzed through the UV-visible spectroscopy technique. The proportion like drug entrapment has been measured even by following equations:

$$EE(\%) = [(Ct - Cr)/Ct] \times 100$$

Where

EE= Entrapment Efficiency,

Ct = Concentration of total drug,

Cr = Concentration of unentrapped drug.

Evaluation of Proniosomal Gel

Physical Appearance and Homogeneity

The physical features and homogeneity of the ability to prepare gels have been examined through vivid observational data just after the gel had already been fixed within the vessel.

Those that have been concerned for their contour and also the occurrence of almost any coarse aggregate [14].

Viscosity

Monitoring such vicious and able-to-prepare proniosomal gel has been performed with a Brookfield viscometer (DV-E).

Ten grams of gel formulation has been evaluated by spinning a spindle 64 there at 12 rpm, about 37 °C, even though gel did come underneath the highly viscous (HA) categorization [15].

Measurement of pH

Ph measurements were done, such as triplicate, using a digital ph meter. Once the measurement results were, its ph meter was recalculated, and readings were recorded by sinking a glass electrode into gel preparations [16].

Spreadability

The spreadability has been recognized only with the process: 1.0g of the gel has been placed inside a circular 1 cm radius premarked on a glass plate within which a 2nd glass substrate has been positioned. A weight of 50g has been permitted to stay on a topmost glass substrate.

Because of the spreading of gels, its radius has been enhanced but also mentioned. Its duration through s involved in the order of about two separate slides has been assessed just like spreadability.

Its mean diameter was resolute through recurring its research three times [17].

$$S = m \times L/t$$

Where S: Spreadability; m: weight of the load; L: length traveled by upper slide; t: time in seconds.

Drug Content

Sample preparation measured 3g of gel containing 15 mg like Opioid and added 1 ml of alcohol and 4 ml of phosphate - buffered to such a 10 ml volumetric flask but also sonicated till diluted. Make it up to the ultimate quantity only with buffer. Its resulting solution has been filtrated utilizing Whatman filter paper, but also 1 ml of the filtrated solution has been begun taking but also transmitted into a measuring cylinder, usually contains 10 ml of phosphate-buffered pH 7.4, and also the volume was made towards the mark as for phosphate - buffered pH 7.4 but also absorbance was recorded about as 283 nm [18].

Extrudability

First, the extruder of a gel from tubular is a crucial facet throughout its application and client admittance. One such research is helpful by expounding if the gel can eliminate itself from the foldable tube throughout the application. Viscosity gels may still not extrusion process quickly from the line, while the fewer viscosity gels could stream freely. Therefore, appropriate uniformity is needed to extrude its gel from the tube. Lines have been emphasized about extruding 0.5 cm like gel through 10s, and the extrudability-like designs have been examined. Compositions have been loaded into collapsible aluminum tubes [19].

In-vitro Drug Release Study

In-vitro drug release research like proniosomal gel has been done using a dialysis bag with such a 70μ pore size even as a donation compartment. Proniosomal gel similar to 10 mg was taken in a dialysis bag, positioned in a buffer containing phosphate-buffered solution ph 7.4, which functioned just like the binding site storage area. Before being used, a typical dialysis membrane has been drenched through ph 7.4 for 24 h but can also be flooded through warm water for 10 min. Either end has been enclosed for thread through trying to add a proniosomal gel formulation. Its dialysis membrane, as for gel, has been attached to the paddle equipment with a dissolution medium (phosphate buffer ph 7.4) 500 ml at a rate of 50 rpm but also retained at about 37°c. At a specified interval of 24 h, specimens were forced to withdraw [20].

They also tried to replace it with 3 ml of a clean phosphate-buffered system to maintain its sink throughout the research. A model forced to start has been solubilized and evaluated by a UV-visible spectrophotometer at 238 nm.

Stability Study

The stability of a proniosomal suspension has been conducted according to the international council over standardization (ich) guidance such as three months, significant quantities of proniosomal gel compositions have been enclosed through 10g collapsible aluminum tubes in triplicate [21]. Specimens have been forced to withdraw each month over three months, and discharge of Opioids from the composition has been assessed, such as drug content using a UV visible spectrophotometer.

RESULTS AND DISCUSSION

Drug Excipient Compatibility Studies by FTIR

The Fourier Transform Infrared Radiation (FT-IR) spectral range is like terbinafine. A structural characterization like fats has been conducted by capturing specimens' FTIR spectroscopic. The outcomes demonstrate similar spectroscopic for the such evaluated particle as well as the reference. In which, characteristic peak value as well as other basic concept peak value [Table 2]. There have been substantial peak transitions but no early stages of a new peak, even though there would be no possible interaction between opioids and emigrants [Figure 1, Figure 2, Figure 3, Figure 4 and Figure 5].

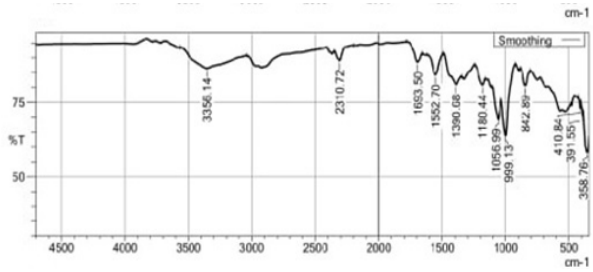

Figure 1: FTIR Spectrum of Pure Terbinafine

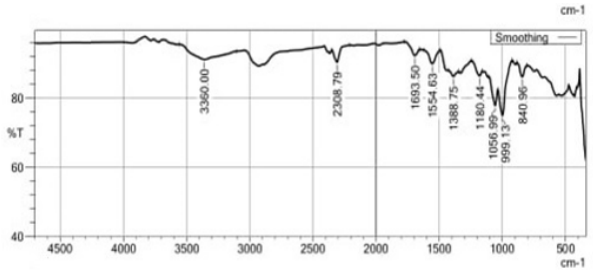

Figure 2: FTIR Spectrum of Cholesterol

Evaluation of Prepared Proniosomal Suspension

Vesicle Size and Shape

By Optical Microscope

Optical microscope below 45x had shown the size range like vesicles had been lowered in sequential

Table 2: FTIR Spectral Assignment for Terbinafine and Excipient

Functional group	Reported frequency (cm^{-1})	Frequency of drug (cm^{-1})	Frequency of cholesterol (cm^{-1})	Frequency of soya lecithin (cm^{-1})	Frequency Carbopol (cm^{-1})	Frequency of Mixture (cm^{-1})
O-H (S)	3500-3200	3356.14	3360.00	3352.28	3358.07	-
C=O(S)	1760-1690	1693.50	1693.50	1732.08	1693.50	1693.50
=C-H bend	1000-650	999.13	999.13	999.13	997.30	999.13
C-O (S)	1300-1000	1180.44	1180.44	1178.51	1180.44	1174.65
N-H Aromatic	3250-3400	3356.14	3360.00	3352.28	3358.07	-

Table 3: Evaluation of Proniosomal Suspension of Terbinafine

Formulation Code	Drug Content (%)	Entrapment Efficiency (%)
F1	88.62 ± 0.42	83.37 ± 0.36
F2	94.25 ± 0.31	95.31 ± 0.31
F3	93.17 ± 0.34	81.23 ± 0.25
F4	92.25 ± 0.31	87.44 ± 0.41
F5	98.64 ± 0.11	86.27 ± 0.26
F6	92.84 ± 0.31	78.63 ± 0.15
F7	93.71 ± 0.22	77.44 ± 0.28

All Data are Given in mean ± SD, n=3

Table 4: Evaluation of Proniosomal Gel of Terbinafine

Formulation Code	Viscosity (cps)	pH	Spreadability (cm)	Drug Content (%)	Extrudability
F1	522 ± 0.5	5.3 ± 0.2	4.51 ± 0.2	93.71 ± 0.23	++
F2	535 ± 0.3	6.7 ± 0.3	4.21 ± 0.4	96.14 ± 0.65	+++
F3	524 ± 0.6	5.7 ± 0.4	4.06 ± 0.7	94.41 ± 0.25	+
F4	525 ± 0.4	5.2 ± 0.3	5.42 ± 0.4	95.51 ± 0.63	++
F5	527 ± 0.6	5.3 ± 0.4	5.75 ± 0.7	98.45 ± 0.52	+++
F6	532 ± 0.3	5.2 ± 0.2	5.42 ± 0.2	96.64 ± 0.73	++
F7	528 ± 0.7	6.8 ± 0.3	4.26 ± 0.6	95.84 ± 0.27	+

+ = Less viscous gels
++ = Medium thick gels
+++ = More viscous gels

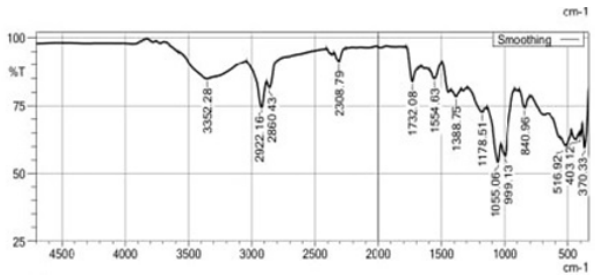

Figure 3: FTIR Spectrum of Soya Lecithin

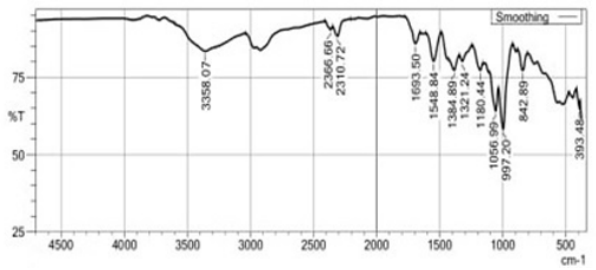

Figure 4: FTIR Spectrum of Carbopol 934

like f1>f2>f3, and it correlated to span 40 and 60, respectively. The outcomes acquired as seen in Figure 6. Usually, an emulsifier is for prolonged alkyl groups with shorter sessions of vesicles because

Table 5: *In-vitro* Drug Release of Terbinafine Proniosomal Gel

Time	Cumulative % Drug Release						
	F1	F2	F3	F4	F5	F6	F7
15 min	6.41 ± 0.01	6.70±0.01	6.40±0.03	5.28±0.01	6.26±0.05	4.85±0.03	6.90±0.07
30 min	13.88±0.04	15.55±0.03	11.57±0.01	12.78±0.03	12.85±0.02	12.59±0.06	12.82±0.05
45 min	25.34 ± 0.07	26.33±0.14	22.23±0.04	21.52±0.08	19.48±0.04	28.61±0.12	27.90±0.08
1 h	31.82±0.03	40.58±0.11	31.82±0.13	31.20±0.17	29.25±0.08	34.72±0.17	39.02±0.06
2 h	46.49±0.01	55.76±0.22	44.46±0.11	46.29±0.16	56.31±0.07	42.58±0.15	43.69±0.02
4h	60.81±0.04	79.28±0.25	62.10±0.07	61.27±0.11	71.81±0.08	58.20±0.06	59.10±0.07
6h	70.74±0.02	85.59±0.23	72.26±0.05	71.31±0.09	69.88±0.06	70.47±0.12	69.55±0.06
8h	81.92±003	85.01±0.22	81.28±0.06	80.56±0.07	71.79±0.03	80.45±0.14	70.12±0.05
12h	85.65±0.03	91.85±0.30	86.76±0.06	86.31±0.08	75.39±0.01	86.85±0.06	72.56±0.0
24h	92.26±0.05	94.61±0.42	91.22±0.05	91.13±0.05	98.29±0.07	93.06±0.05	87.73±0.05

Table 6: Short Term at 25°C and Accelerated Stability at 40°C Studies of Optimized Batch F5

Time	25° ± 2 °C/60% RH ± 5% RH Drug Content (%)	40° ± 2°C/75% RH ± 5% RH Drug Content (%)
0	97.05±0.19	96.78 ± 0.01
30	96.81±0.01	96.54 ± 0.01
60	96.62±0.05	96.33 ± 0.01
90	96.45±0.05	96.28 ± 0.01

All Data are Given in mean ± SD, n=3

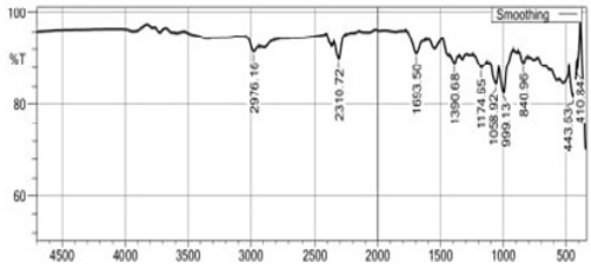

Figure 5: FTIR Spectrum of Terbinafine and Physical Mixture (Mixture)

radius-like vesicles depend upon the duration of an alkyl group like emulsifiers.

Measurement of Vesicle Size

The distribution of particle size description like proniosomal suspension (particle size d. nm vs. intensity %) has been doing fine also to be 211.5 nm. a mono diffused as well as conformity like vesicular length is decided through polydispersity index values, wherein the decrease the deal, the further consistency through shape. Its polydispersity index value has pi= 0.956, which would evaluate a standardization-like proniosome size within the formulation. The lesser its pi value, even more, homogeneous its diffusion.

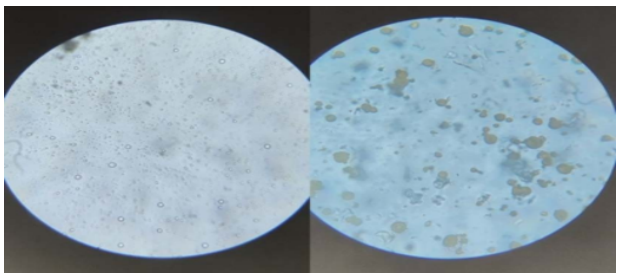

Figure 6: F5 Proniosomal Vesicles Under Optical Microscope 45x, (A) Without Drug and (B) Entrapped Drug (2 ml)

Scanning Electron Microscope (SEM)

SEM obtained surface morphological properties of formula F5 nano-size vesicles. The vesicular properties of these drug carriers form double layers, as shown in Figure 7. SEM revealed the morphology of the vesicle.

Determination of Zeta Potential

The preparation F5, which would have been confined to zeta potential assessment, had a value of 1.86mv. This would quantify like a net charge of pro-

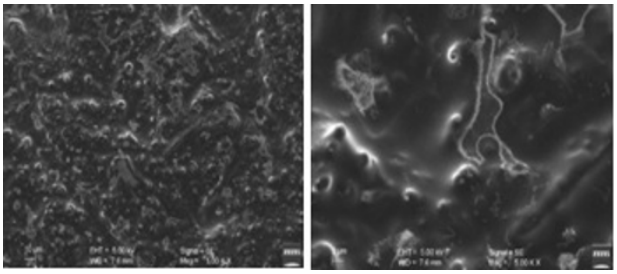

Figure 7: Scanning Electron Micrographs of Proniosomal Formula F5

niosomes. A high specific surface area cost provides adequate electrostatic repulsion between the vesicles, which tends to make those steady by trying to prevent agglomeration [Figure 8].

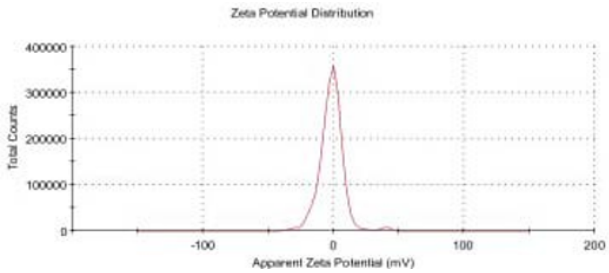

Figure 8: Zeta Potential Analysis of Proniosomal Suspension

Determination like encapsulation efficiency through emulsification greater encapsulation efficiency of a blister of such a preparation containing surfactant span 60 is predicted because of its greater alkyl chain size. An F5 formulation showed the best encapsulation efficiency, like 86.27 ± 0.26, which may have optimized emulsifiers saturated fat proportion to provide a rising encapsulation like terbinafine. This was noticed that such a composition with a very high triglyceride concentration (F5) had a slight influence through drug encapsulation. This may be because saturated fat above a certain level interrupts its periodic bi-layered structure, leading to the lack of drug encapsulation.

Drug Content

the percent of drug content for all compositions F1 to F7 has been acquired within scope, like 88.62 ± 0.42 to 98.64 ± 0.11. The outcomes given in Table 3 imply that such an Opioid has uniformly distributed across all film compositions, and it will produce a dose of opioids accurately [Table 3].

Evaluation of Prepared Proniosomal Gel

Physical Appearance and Homogeneity

Viscous in all proniosomal gel compositions used to have enough gel-like flowability. All its proniosomal gel compositions would have pale yellow of about vibrant yellow color, have been translucent throughout appearance, unrestricted through the existence like particulate, as well as showed some good uniformity only with lack of lumps. Viscous has been found in the range of 522 ± 0.5 cps to 532 ± 0.3 cps seen in Table 4.

Measurement of pH

The pH has been stated through a ph meter by soaking into gel formulation and letting such as equilibrium. A pH among all gels has been found to have been in the value of 5.2 ± 0.2 to 6.7 ± 0.3 pH given in the Table 4, where it lies with the standard range of pH of an epidermis. All of the composition portions exhibit ph inside the neutral range, which signifies a lack of skin irritation.

Spreadability

It plays a significant role as it demonstrates the behavior patterns of a gel, and it comes out from the tubular. The results of spreadability seen in Table 4 imply that such polymer was using offered a little bit of shear towards the gel. The dispersed circles' diameters ranged from 4.21 ± 0.4cm to 5.75 ± 0.7cm. An increase in the Concentration of gelling agents creates a lessen in spreadability.

Drug Content

After a variety of compositions like terbutaline gel, the drug content of a formulated gel has been approximated. The outcomes were within its official restrictions, ranging from 93.71 ± 0.23 to 98.45 ± 0.52. A drug content determination as well had shown that such an Opioid had uniform distribution all through the gel, and it would deliver a dose like opioid precisely as seen in Table 4.

Extrudability

With its significant rise in fabric flow rate, all gel compositions result in a more considerable extruder pressure. Its enhanced dosage may lead to an increase in shear yield stress as well as flow uniformity, which will also lead to higher extruder pressure. Table 4 demonstrates the outcomes like extrudability tests.

In-vitro Drug Release

The *In-vitro* release study of terbinafine has been performed through phosphate-buffered pH 7.4 for release studies with a dialysis bag like terbinafine proniosomal gel. Such a moderate all through sustained sink situations, and therefore release studies have been conducted. A release of drug pattern for twenty-four h has been represented in Figure 8. The discharge profile demonstrated a biphasic discharge like terbinafine from proniosomes. A composition f5 has been chosen like a prepared formulation predi-

cated on that *In-vitro* release studies, where it had shown satisfying drug release, like 98.29±0.07 in 24 h. The selected, prepared formulations f5 have been used further for analysis, like ex vivo permeation research thru all the sheep epidermis [Figure 9 and Table 5].

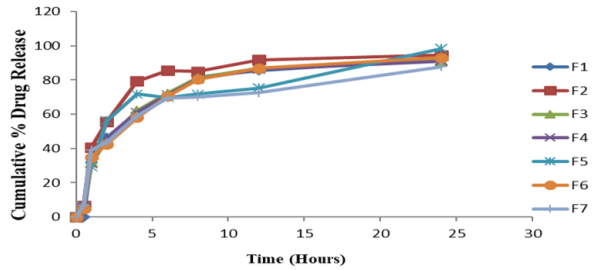

Figure 9: *In-vitro* Drug Release Profile of Terbinafine Proniosomal Gel Stability Studies

Based on the above outcomes, stability studies have been performed for only optimized formulation F5. First, from stability studies, this was recognized a precisely optimized formulation of F5 had also stabilization through human skin; there has been no change in color as well as the viscosity of the proniosomal gel. Stability data has been conducted upon that prepared formulations F5 there as temps 25°c±2 as well as 60%±5 humidity levels (RH) and even at 40°C±2 but also 75%±5 RH, for briefphrase but also accelerated studies, respectively, for such period like three months. A proniosomal gel has been evaluated, such as drug content and *In-vitro* drug release. There had been a slight lessen in all of the parametric. Hence, the outcomes like composition F5 shown in Table 6 have been implied as stable.

CONCLUSION

The proniosomal gel preparations have been evaluated for their encapsulation efficiency, drug content, UV-visible spectroscopy, viscosity, vesicle size, and shape as for sem. Also, the findings were obtained to be within the accepted range. The outcomes of research suggested that a specific Terbinafine proniosomal gel containing lecithin, saturated fat, and emulsifiers span but also tween compositions have been able to prepare effectively using coacervation phase separation technique. The F5 formulation showed the best effectiveness. A study revealed that F5 had antimicrobial activities for 48 h, implying that such an established proniosomal gel was much more efficient than the regulation. The outcomes had shown that a specific F5 usually contains span 60 is the most suitable emulsifier for forming proniosomes. *In-vitro* release studies demonstrated that such proniosomal gel contains terbinafine, which would be considered an effective topical drug delivery system and provide a sustained release of an encapsulated drug. *In-vitro* release studies have shown positive outcomes, and the permeability research indicates good control release for an extended time. Permeation research suggests the best permeability, like proniosomal gel formulation F5. Then *In-vitro* skin penetration studies indicate that even a good amount of Opioid has been penetrated and has excellent stabilization features. Research demonstrates that such proniosomal gel formulation was relatively steady there at room temp as well as accelerated temp though too.

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Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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