TOPICAL ADMINISTRATION OF SOLANESOL LOADED GEL: PREPARATION, PHYSICOCHEMICAL CHARACTERIZATION, AND INVITRO PHARMACOKINETIC PROFILING

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Abstract

Solanesol is a natural compound found in tobacco leaves, eggplants, and tomato plants. It has been reported to possess anti-inflammatory, anti-tumor, and anti-viral properties. In this study, Solanesol loaded gel was prepared using carbopol 940, propylene glycol, and distilled water. The gel was then evaluated for various parameters such as pH, viscosity, spreadability, drug content, and skin irritation. The results showed that the formulated gel for pH, viscosity and good spreadability. The drug content was found to be 98%, indicating that Solanesol was uniformly distributed in the gel. The skin irritation test showed that the gel was safe for topical application. The in vitro release study showed that the Solanesol gel had a sustained release pattern over a period of 8 hours. In conclusion, the formulated Solanesol gel showed sustained release and ideal physicochemical characterization, indicating its potential for use in the treatment of wound healing studies. Further studies are needed to evaluate its efficacy in humans.

Keywords: - Formulation, Evaluation, Solanesol, Topical Delivery

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1. INTRODUCTION

The gel based topical formulations are widely used in the cosmetic and pharmaceutical industries due to their easy application, quick absorption, and beneficial effects on the skin. The use of natural components incorporated pharmaceutical gels has gained popularity due to their perceived safety and efficacy [1,2]. Solanesol is a natural compound found in tobacco leaves, eggplants, and other plants. It has antioxidant and anti-inflammatory properties and has been shown to have potential applications in the treatment of skin disorders such as psoriasis and eczema [3,4]. In recent years, there has been a growing interest in the use of solanesol in skincare products. The incorporation of solanesol into gels could overcome these solubility issues and provide a convenient method for topical delivery of solanesol to the skin [5]. This study aims to formulate and evaluate the solanesol loaded gels. The gel will be evaluated for its physicochemical properties, stability, and in vitro release profile. The potential of the solanesol gel to improve skin health will also be investigated. Overall, the use of solanesol igels could provide a natural and effective approach for the treatment of skin disorders, while also offering potential benefits for skin health and anti-aging [6,7, 8].

2. MATERIALS AND METHOD

Solanesol was obtained from the Tokyo India PVT ltd. All ingredients used were of analytical reagent grade Chitosan, Sodium alginate, Carbopol-934, Acetic acid, Triethanolamine, Methyl paraben, Propyl paraben, were obtained from the Spectrum India PVT ltd.

Standard calibration curve of Solanesol by UV Spectroscopy method

Chemicals and Reagents

The instruments used were a SHIMADZU 1700 double beam UV / Visible Spectrophotometer and a SHIMADZU AX200 analytical balance. All chemicals and reagents used were of analytical grade.

Preparation of the standard stock solution

A standard drug solution of Solanesol was prepared by dissolving 10 mg of Solanesol in 10 ml methanol, and this was transferred into a 100 ml volumetric flask. The volume was brought up to the mark with methanol to obtain a stock solution of Solanesol with 100 µg/ml final concentration [9]. The solution was further sonicated for 15 minutes to obtain a clear solution.

Preparation of the working solution

From the above stock solution, a 2 ml sample was transferred into a 10 ml volumetric flask and the volume was made up to the mark with methanol to prepare a concentration of 20 µg/ml. The sample was further scanned by a UV-VIS Spectrophotometer in the range of 200 – 400 nm, using methanol as a blank. The wavelength corresponding to the maximum absorbance (λmax) was found to be 215 nm. This was further utilized to obtain a calibration curve.

Preparation of the calibration curve

Aliquots of 0.2 to 2 ml stock solutions were transferred to a series of 10 ml volumetric flasks, with subsequent volume adjustment by methanol up to 10 ml. The solutions were scanned in a double beam UV-VIS spectrophotometer. The samples were analyzed for their respective absorbance at 215 λmax. The calibration curve was plotted, and the optical characteristics summarized [Table 1].

Table 1. Data of standard calibrations curve using HPLC method

Concentration in µg/mL	Absorbance at 215nm
10	0.155
15	0.245
20	0.334
25	0.476
30	0.528
35	0.615
40	0.752

45	0.867
50	0.965

Drug – Polymer interaction study

Interaction studies were performed by infrared spectroscopy and DSC on various forms such as drug, polymer alone and physical mixture of drug and polymers [10].

Interaction study by FTIR

IR spectroscopy studies were carried out using Perkin Elmer model 2000 at Laila Impex Research centre, Vijayawada, Andhra Pradesh, India by KBr pellet method. Materials were compressed under 10 tones pressure in a hydraulic press to form a homogeneous sample/KBr pellet. The pellet was scanned over the frequency range from 4400 to 400 cm^{-1} and peaks obtained were identified.

Interaction study by DSC

Differential scanning colorimetric analysis were performed to characterize the drug – polymer compatibility. The DSC thermograms of pure drug, polymer, and physical mixtures were recorded in a DSC analyzer model Universal V4.5A, Diya Labs, Mumbai, India at a heating rate of 20°C / min from 0 to 350°C in a nitrogen atmosphere.

Drug excipient physical compatibility studies

All drugs and polymers were subjected for preliminary identification test as specified in Indian Pharmacopoeia [11, 12]. About 100 mg of drug was taken with various excipients in 1:1 ratio in glass vials and kept at various accelerated condition of 30°C/65%RH, 40°C/75%RH and 60°C/80%RH in stability chamber (Ostwald Stability Chamber, India) for one month in open and closed condition. The samples were withdrawn on the 1^{st}, 2^{nd}, 3^{rd}, 4^{th}, 5^{th}, 6^{th}, 7^{th}, 14^{th}, 21^{st} and 30^{th} day and physical characteristics like color change, if any, were recorded. Finally, the mixtures with no color change were selected for formulation.

Formulation of Solanesol gel

Blank formulations of trails were prepared during the pre-formulation studies. Formulation of gels were finalized after many attempts of trial formulation and satisfied with its gel texture. Drug loaded formulations were prepared with different concentrations of various polymers. Polymers were obtained from natural, semi synthetic, and synthetic sources for comparison of efficacy of the formulations.

Solanesol gel was prepared using different concentrations (1%, 1.5%, 2% w/v) of natural polymer such as Chitosan, semi synthetic polymer such as Sodium alginate and synthetic polymer such as Carbopol-934 (Table 1). All polymers were also acting as a gelling agent. Polymers were dissolved in a small amount of acetic acid solution (0.5% w/v) until dissolved then were stirred with deionized water under a magnetic stirrer at 250 rpm for 4 hours. The pH of the gel was adjusted to neutral, using a few drops of triethanolamine with continuous stirring. Solanesol (1 % w/v) was added to the gel and stirred for sufficient time to get homogeneous gel. Appropriate quantities of methyl paraben and propyl paraben were added with continuous stirring. Formulations were kept overnight at room temperature in well closed vials for removal of air bubbles. Then, formulated gel was filled in collapsible tubes and stored in a cool and dry place until evaluation.

Table 2. Formulations of Solanesol gel

Ingredients (%w/w)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Solanesol	1	1	1	1	1	1	1	1	1
Chitosan	1	1.5	2	--	--	--	--	--	--
Sodium alginate	--	--	--	1	1.5	2	--	--	--
Carbopol-934	--	--	--	--	--	--	1	1.5	2
Acetic acid solution (0.5% w/v)	QS	QS	QS	QS	QS	QS	QS	QS	QS
Triethanolamine	QS	QS	QS	QS	QS	QS	QS	QS	QS
Methyl paraben	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Propyl paraben	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2

Deionized water	QS	QS	QS	QS	QS	QS	QS	QS	QS

Evaluation of Solanesol gels

The Solanesol was characterized by IR, Mass, and NMR studies (Figures 5, 6). The spectra obtained was analysed and data are shown in results [13, 14]. Formulated gels were evaluated for various physicochemical parameters such as colour, pH, homogeneity, viscosity, spreadability and drug content.

Measurement of pH

Five grams of gel formulation was dispersed separately in 45 ml of water, and the pH of the suspension was determined, using digital pH meter (Digital pH meter, Systronics, Noroda, Ahmedabad). Experiments were performed in triplicate and the average values were recorded.

Homogeneity

Gel formulations were tested for homogeneity visually after the preparation. Gels were tested for their appearance and presence of any aggregates (Hideaka Fukuwa, 1970).

Viscosity

The viscosity of gel was determined by using a Brookfield Viscometer DVII model with a T-Bar spindle in combination with a helipath stand. Fifty grams of gel was filled in a 100 ml beaker. T- bar spindle (T95) was used for the measurement of viscosity of all the gels. The helipath T-bar spindle was moved up and down and viscosity was measured at 10 rpm.

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Spreadability

Spreadability was determined by wooden block and glass slide apparatus.

$$S = M \times L/T$$

where, S = Spreadability, M = Weight in the pan (tied to the upper slide), L = length of glass slide, T = Time (in sec) taken to separate the slide completely from each other.

Drug content

Drug content was determined by dissolving accurately weighed 1 g of gel in a phosphate buffer of pH 6. After suitable dilution, drug content was determined, using a UV-visible spectrophotometer at 215 nm.

In vitro diffusion study

Drug diffusion characteristics of the developed wound healing gels of Solanesol as carried out using Franz diffusion cell with skin mounted between compartments.

Method

The abdominal skin of Albino mice weighing about 15-20 gm of a week old used for the in vitro diffusion study. The skin hairs were removed using a hand razor and cleaned with saline water. About 5 gm of Solanesol gel was applied uniformly to the prepared skin. The skin was mounted between the two compartments of Franz diffusion cell with stratum corneum facing the donor compartment [16]. 25 mL of phosphate buffer pH 6.8 was filled in the receptor compartment of Franz diffusion cell and temperature of the medium was set at 37°C ± 0.5°C and the rotational speed was set at 25 rpm using magnetic stirrer. The stirring speed was adjusted until the vortex come in contact with skin.

5mL of sample was withdrawn at a predetermined time interval of everyone hour for up to 12 hours and the same volume of fresh medium was replaced immediately to maintain the constant volume. The 2.5mL from

withdrawn sample was diluted to 25mL in volumetric flask and filtered through 0.45µ membrane filter. The resultant samples were analyzed for drug content against blank solution at 215 nm using UV-Visible spectrophotometer. The amount of drug diffused was calculated using the following expression (1). The percentage cumulative drug release was also calculated using the following expression (2).

$$Amount\ of\ drug = \frac{Absorbance\ of\ sample}{Absorbance\ of\ standard} \times \frac{Amount\ of\ drug\ taken\ in\ mg}{200} \times \frac{10}{100} \times \frac{25}{1} \times \frac{10}{5} \times 1 \times \frac{\%\ purity\ of\ standard}{100} \times \frac{100}{25} - - - -(1)$$

$$Cumulative\ percentage\ drug\ release \frac{Amount\ of\ drug\ released}{Amount\ of\ drug\ loaded} \times 100 — (2)$$

The *In vitro* drug release profiles of gels are given in Table from 6.20 to 6.49. The plot of cumulative percentage drug release v/s Time in hrs was plotted for each batch and depicted from Figure to Figure.

Treatment of dissolution data with different kinetic model

The quantity of drug released from gel was analyzed as a function of the square root of time, which is typical for systems where drug release is governed by diffusion. However, the use of this relationship in a gelling system is not justified completely as such a system can be erodible and the contribution of the relaxation of polymeric chains to drug transport has to be taken into account. Therefore, analysis of drug release from gels must be performed with a flexible model that can identify the contribution to overall kinetics, an equation proposed by Ritger and Peppas[123, 173]. For finding out the mechanism of drug release from gels, the drug release data obtained from the above experiments were treated with the following different release kinetic models.

Zero order release (Cumulative percent drug released Vs time) equation

$Q = K_0 t$ ---------- (1)

Higuchi's (Cumulative percent drug released Vs square root of time) equation

$Q = K_H t^{½}$ ---------- (2)

Korsmeyer and Peppas (Log cumulative percent drug released versus log time) equation

$F = (M_t/M) = K_m t^n$ ---------- (3)

Where,

Q is amount of drug release at time t, M_t is drug release at time t, M is total amount of drug in dosage form, F is fraction of drug release at time t, K_0 is zero order release rate constant, K_H is Higuchi's square root of time release rate constant, K_m is constant depend on geometry of dosage form and n is diffusion exponent values indicating the mechanism of drug release [17].

Stability study

The ICH guidelines for evaluation of stability data describe when and how extrapolation should be considered while proposing a retest period for a drug substance or a shelf life for a drug product that extends beyond the period covered by available data from the stability under the long-term storage condition.

Method

Accelerated stability study was carried out as per ICH guideline 'Q1E Evaluation for stability Data using Ostwald stability chamber for F3 was selected as an optimum formulation and the stability study was carried out at room temperature as well as different accelerated temperature and humidity conditions for a period of twelve months.

3. RESULTS

Standard calibration curve of Solanesol by UV Spectroscopy method

The drug was characterized by UV studies. The calibration curve is given below

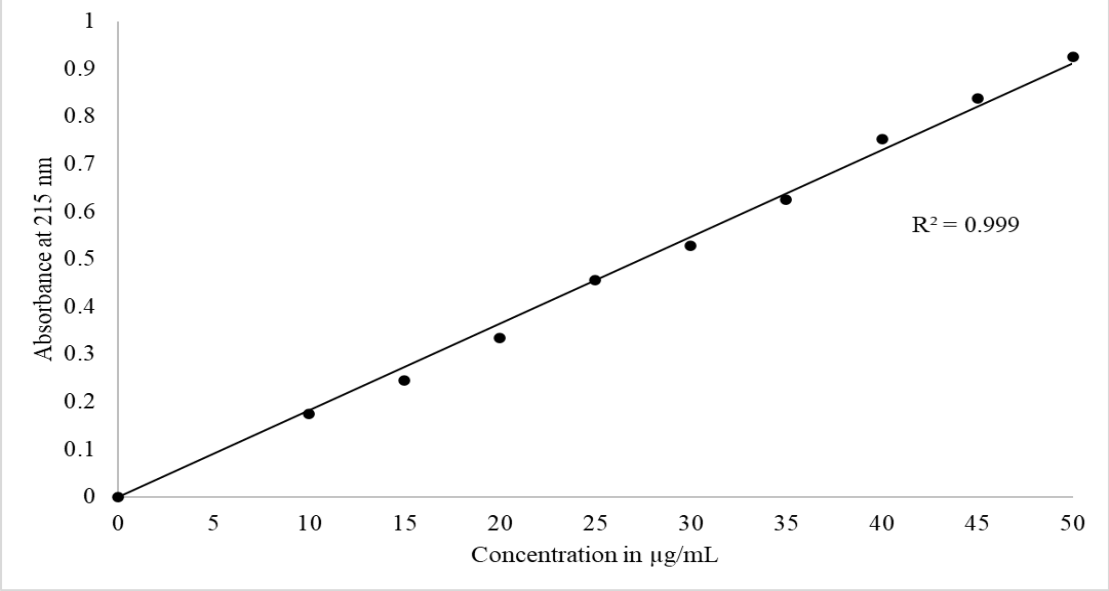

Figure 1. Standard calibration curve of Solanesol

Interaction study by FTIR

FTIR spectra are shown from Figure and interpretations of spectral data are presented in Table 3.

Table 3. Interpretation of IR spectral data of polymers alone

Frequency cm^{-1}	Group Assigned
3358, 83	C-Br stretch
2922, 25	C-H out of plane
2853, 43	C-Cl stretch
1665, 87	S-OR esters
1447, 60	C-N stretch
1383, 64	C-O stretch
1108, 84	C-F stretch, C-C stretch
997, 79	N=O nitroso
837, 84	C-C stretch
600, 94	CH stretch

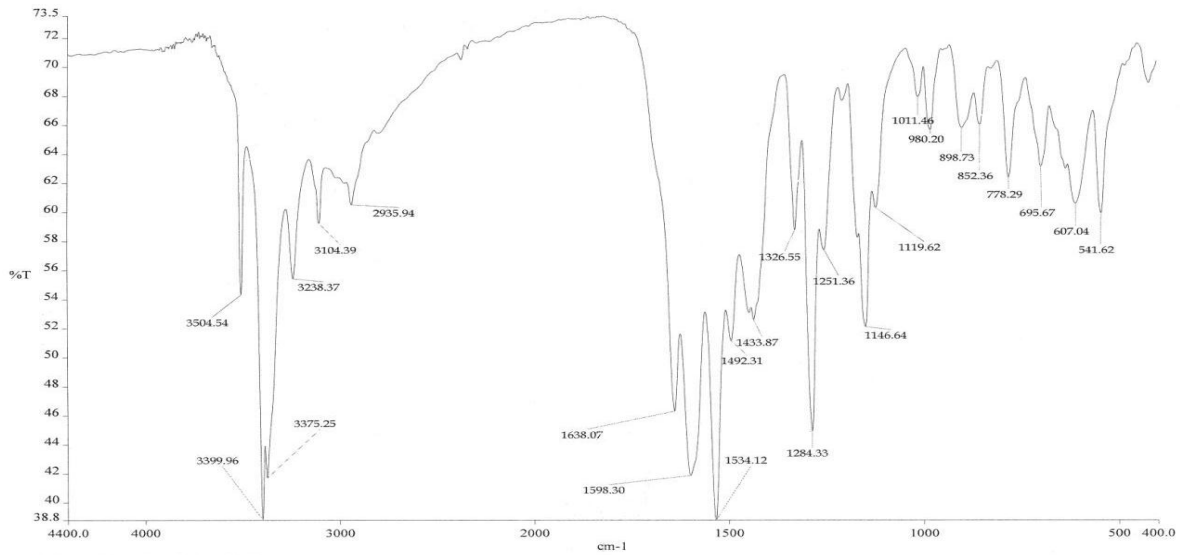

Figure 2. FTIR spectra of Solanesol

Interaction study by DSC

Differential scanning colorimetric analysis were performed to characterize the DSC spectra are shown from Figure 3 and interpretations of spectral data are presented in Table 4.

Table 4. Interpretation of DSC spectral data

Substance	Temperature °C	Heat Flow (W/g)
Solanesol	141.8	-2.92
HPMC K100	149.3	-0.45
Chitosan-C	121.7	-3.38
Sodium alginate	137.4	-4.16
Solanesol with Carbopol-934	142.3	-5.13
Solanesol with Chitosan	142.9	-4.17
Solanesol with Sodium alginate	144.2	-4.21

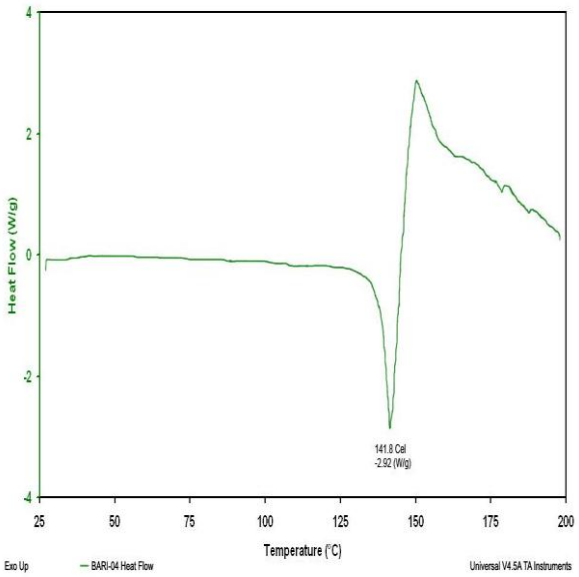

Figure 3 (a) DSC spectra of Solanesol

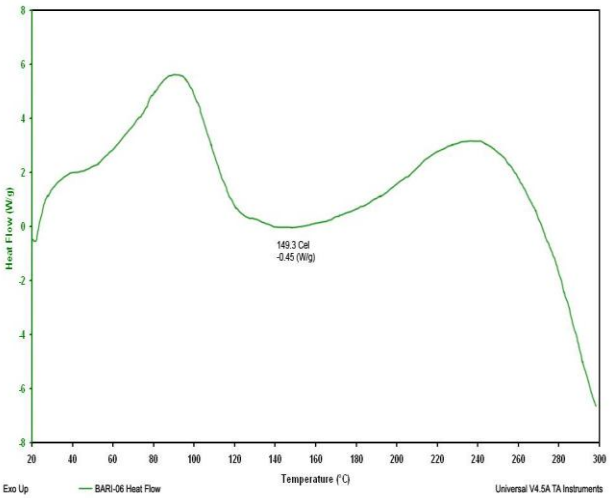

Figure 3 (b) DSC spectra of Carbopol-934

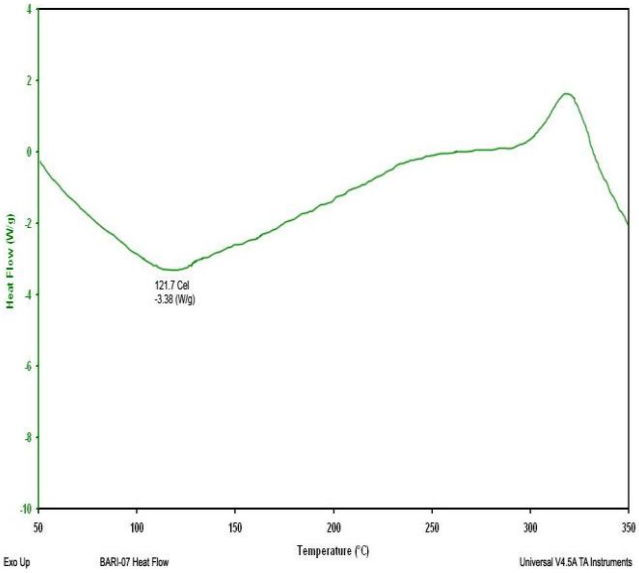

Figure 3 (c) DSC spectra of Chitosan

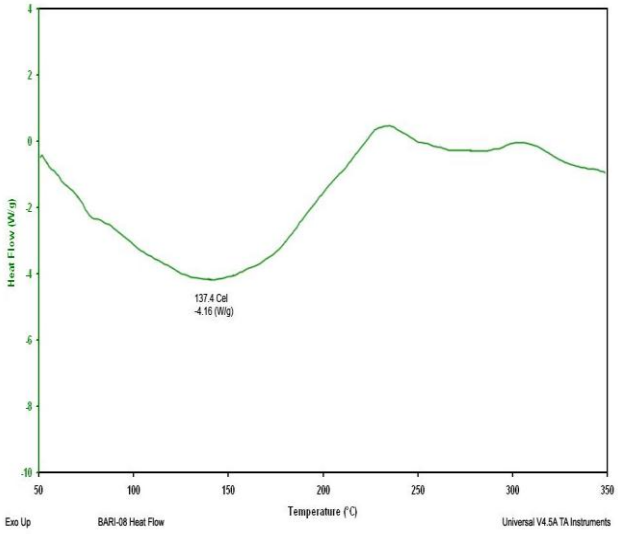

Figure 3 (d) DSC spectra of Sodium alginate

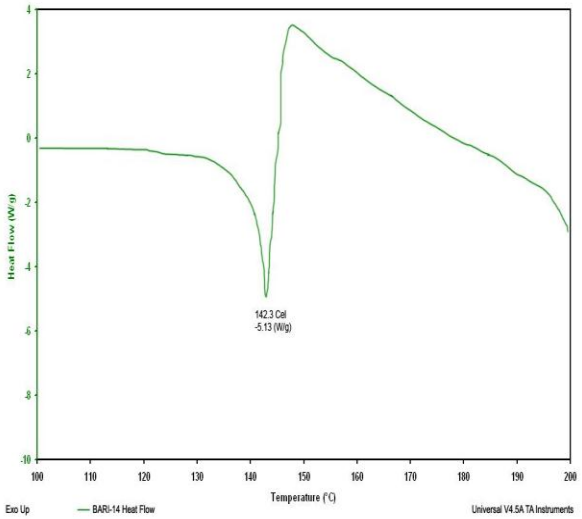

Figure 3 (e) DSC Spectra of mixture of Solanesol and Carbopol-934

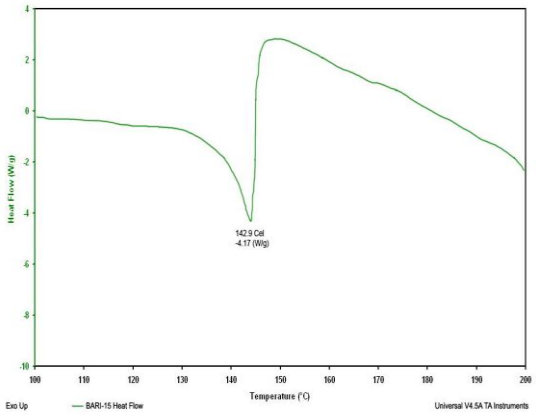

Figure 3 (f) DSC Spectra of mixture of Solanesol and Chitosan

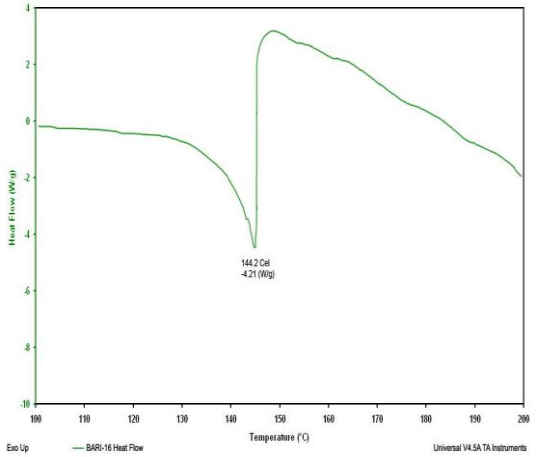

Figure 3 (g) DSC Spectra of mixture of Solanesol and Sodium alginate

Evaluation of Solanesol gels

All the prepared gel formulations were evaluated for various physicochemical parameters.

Table 5. Evaluation of Solanesol gel

	pH	Viscosity (cps)	Spreadability (gcm/sec)	Drug content (%)
F1	6.5 ± 0.06	9546 ± 54	21.05 ± 2.15	97.4 ± 2.16
F2	6.9 ± 0.02	8641 ± 68	19.48 ± 1.59	96.8 ± 3.54
F3	6.8 ± 0.05	8482 ± 88	22.46 ± 2.44	98.6 ± 4.62
F4	6.5 ± 0.11	9422 ± 75	25.64 ± 3.15	95.3 ± 4.68
F5	6.2 ± 0.08	8611 ± 45	24.68 ± 3.44	96.88 ± 5.46
F6	6.3 ± 0.04	9872 ± 65	28.21 ± 4.64	95.63 ± 3.55
F7	6.6 ± 0.14	9258 ± 88	26.15 ± 5.14	97.65 ± 3.18
F8	6.5 ± 0.07	8644 ± 69	24.85 ± 6.48	96.82 ± 4.36
F9	6.4 ± 0.15	9468 ± 81	22.05 ± 3.69	94.45 ± 6.25

Colour and appearance: Brownish and translucent; Homogeneity: Good in all formulations

In vitro diffusion study

Drug diffusion characteristics of the developed wound healing gels of Solanesol as carried out using Franz diffusion cell with skin mounted between compartments.

Table 6. Diffusion exponent values indicating drug release mechanism

S. No.	Diffusion exponent value (n)	Drug release mechanism
1	< 0.45	Fickian release
2	0.45 to 0.89	non-Fickian transport
3	0.89	Case II transport
4	> 0.89	Super case II transport

The results of kinetic treatment applied to the drug release pattern of the best formulation are given in Table. Graphs are shown from *in vitro* drug release, Higuchi and Peppa's data for all formulations are given in Table from 6.20 to 6.31 and graphs are shown from Figure.

Table 7. Kinetic treatment to dissolution data of tablets of best formulation F3

Kinetic model	R^2 value	Slope	Intercept
Zero order	0.9347	7.2109	20.4593
Higuchi's	0.9942	28.7339	-0.9244
Korsemeyer Peppas	0.5801	1.0756	0.9558

Table 8. *In vitro* drug release and Higuchi data for F1-F9

Time (hrs)	Square root time	Cumulative % drug released								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	1.00	15.63	26.95	30.92	13.34	12.72	15.47	17.47	14.87	11.96
2	1.41	30.47	34.13	39.34	20.42	17.14	22.14	25.09	20.35	16.34
3	1.73	38.94	42.78	48.33	27.36	23.28	29.96	33.12	24.72	19.32
4	2.00	47.56	49.16	53.37	34.35	29.43	34.52	40.65	31.94	24.45
5	2.24	57.42	54.85	58.68	42.16	37.85	41.26	47.53	36.78	28.74
6	2.45	63.68	62.68	67.24	45.51	44.67	48.92	51.49	41.43	33.47
7	2.65	68.53	70.51	76.18	52.24	51.26	55.94	56.56	47.71	40.85
8	2.83	73.26	79.44	82.24	57.66	57.24	62.65	62.86	52.75	43.37
9	3.00	79.91	85.24	86.67	62.22	61.18	67.24	65.82	55.84	48.83
10	3.16	86.58	89.93	91.42	66.87	65.12	74.16	70.35	61.45	53.44
11	3.32	90.96	93.36	95.78	70.68	68.77	79.57	74.87	67.95	59.15
12	3.46	93.25	95.34	98.25	74.52	71.47	84.56	78.94	69.97	62.57

Table 9. Peppa's data for F1-F9

Log time	Log cumulative % drug released								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.00	1.19	1.43	1.49	1.13	1.10	1.19	1.24	1.17	1.08
0.30	1.48	1.53	1.59	1.31	1.23	1.35	1.40	1.31	1.21
0.48	1.59	1.63	1.68	1.44	1.37	1.48	1.52	1.39	1.29
0.60	1.68	1.69	1.73	1.54	1.47	1.54	1.61	1.50	1.39
0.70	1.76	1.74	1.77	1.62	1.58	1.62	1.68	1.57	1.46
0.78	1.80	1.80	1.83	1.66	1.65	1.69	1.71	1.62	1.52
0.85	1.84	1.85	1.88	1.72	1.71	1.75	1.75	1.68	1.61
0.90	1.86	1.90	1.92	1.76	1.76	1.80	1.80	1.72	1.64
0.95	1.90	1.93	1.94	1.79	1.79	1.83	1.82	1.75	1.69
1.00	1.94	1.95	1.96	1.83	1.81	1.87	1.85	1.79	1.73
1.04	1.96	1.97	1.98	1.85	1.84	1.90	1.87	1.83	1.77
1.08	1.97	1.98	1.99	1.87	1.85	1.93	1.90	1.84	1.80

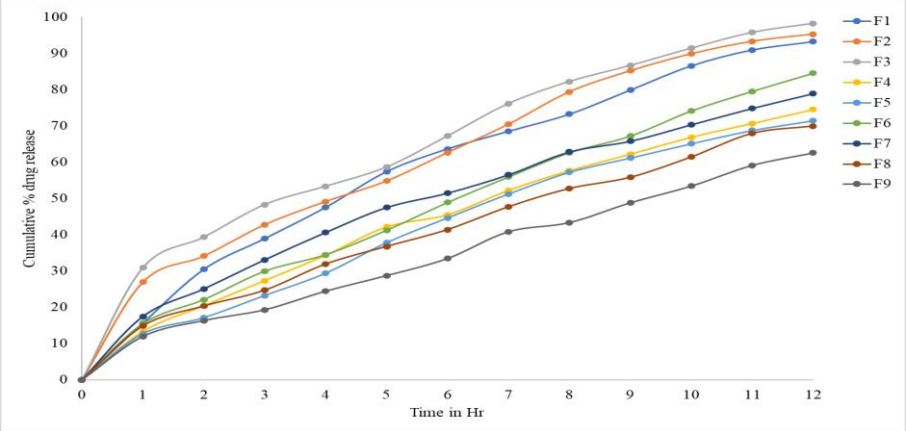

Figure 4. *In vitro* drug release plot of F1-F9

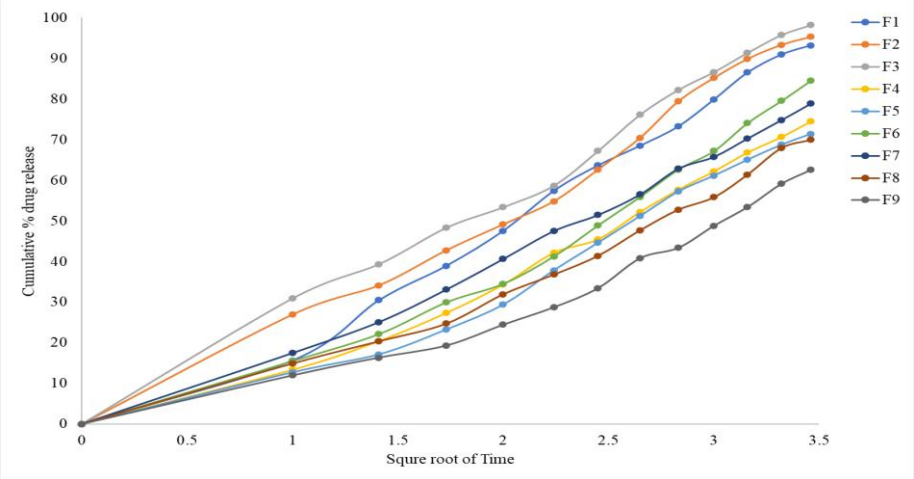

Figure 5. Higuchi's plot of F1-F9

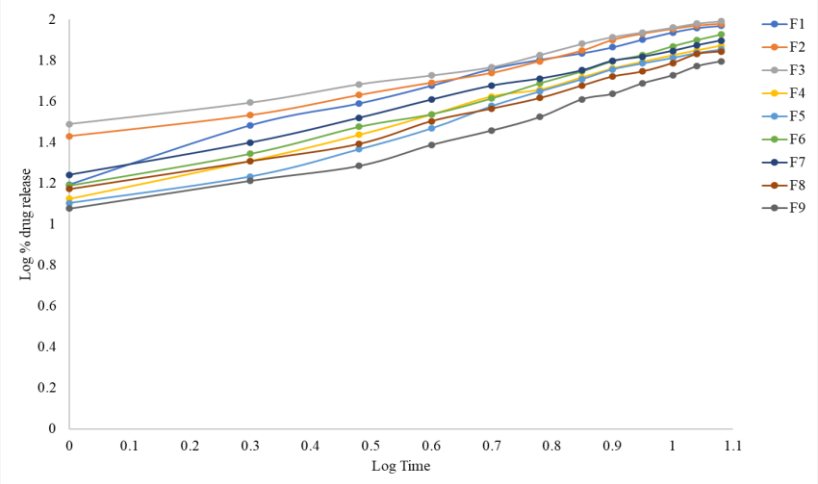

Figure 6. Peppa's plot of F1-F9

Stability study

The ICH guidelines for evaluation of stability data describe when and how extrapolation should be considered while proposing a retest period for a drug substance or a shelf life for a drug product that extends beyond the period covered by available data from the stability under the long-term storage condition.

Table 10. Comparison of observed with calculated assay of best formulation F3 subjected to stability study

Time in months	Observed Assay (%) Mean ± SD	Calculated Assay (%) Mean ± SD
1	102.25 ± 0.48	102.82 ± 0.25
2	101.68 ± 1.03	101.49 ± 0.37
4	100.92 ± 1.13	100.84 ± 0.53
6	100.36 ± 1.05	99.86 ± 0.46
8	99.52 ± 0.49	98.89 ± 0.32
10	98.34 ± 0.78	97.91 ± 0.43
12	97.48 ± 0.48	96.82 ± 0.63

Each value represents the mean ± standard deviation (n=3)

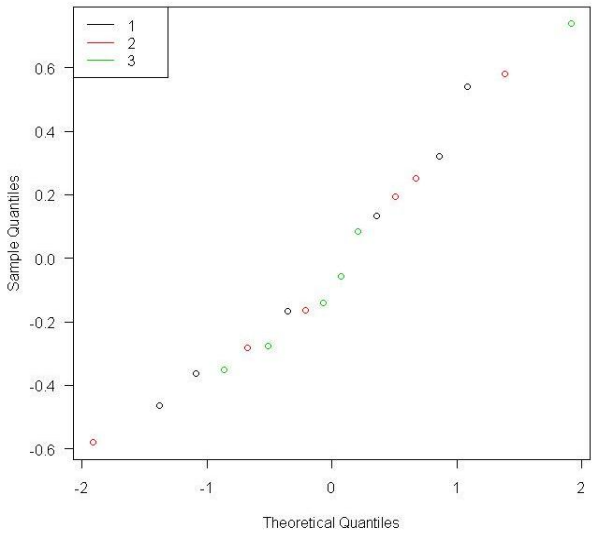

Figure 7. Normal Q-Q plot of residuals obtained from calculated values of F3 batch subjected for stability study

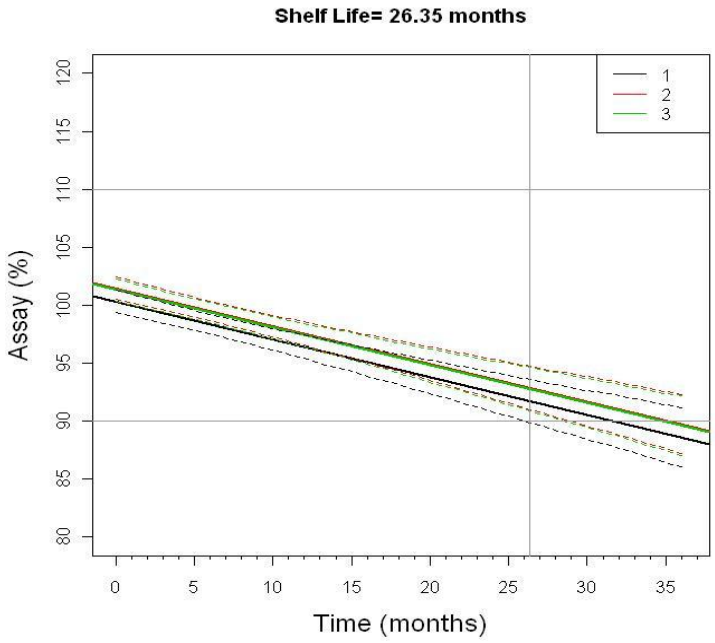

Figure 8. Graph showing predicted shelf life of F3

4. DISCUSSION

The formulation and evaluation of a Solanesol loaded gel is an interesting topic of study in the field of pharmaceutical sciences. Solanesol is a natural compound found in tobacco leaves and is known to have a wide range of pharmacological activities, including anti-inflammatory, antioxidant, and anticancer properties. In recent years, there has been an increasing interest in the use of solanesol as a potential therapeutic agent in the treatment of various diseases. The formulation of the Solanesol loaded gel involves the use of natural polymers, such as carbopol, which acts as a gelling agent, and aloe vera gel, which acts as a moisturizing and soothing agent. The formulation also includes other ingredients, such as propylene glycol, which acts as a humectant and enhances the solubility of solanesol, and triethanolamine, which is used as a pH adjuster. The formulation of the gel was optimized by adjusting the concentration of the polymers, the pH, and the concentration of the solanesol to achieve the desired viscosity and consistency. The evaluation of the Solanesol loaded gel was carried out by various parameters, including physical appearance, pH, viscosity, spreadability, drug content, and in vitro release. The results of the evaluation showed that the formulated gel had a smooth texture, a pH within the range of skin pH, and good viscosity and spreadability. The drug content of the gel was found to be within the acceptable range, and the in vitro release of solanesol from the gel was found to be sustained over a period of 12 hours. The development of a Solanesol loaded gel has several advantages over other conventional dosage forms, such as tablets and capsules. Gels are easy to apply, have a prolonged residence time, and provide a localized effect, which can enhance the therapeutic efficacy of the drug. The use of natural polymers in the formulation of the gel also makes it a safe and eco-friendly alternative to synthetic polymers. The incorporation of solanesol in the gel can also provide an additional advantage by providing antioxidant and anti-inflammatory properties, which can enhance the therapeutic potential of the gel.

5. CONCLUSION

The formulation and evaluation of a Solanesol loaded gel is a promising approach for the development of a novel therapeutic agent. The use of natural polymers in the formulation of the gel makes it a safe and eco-friendly alternative to synthetic polymers. The incorporation of solanesol in the gel can also provide additional pharmacological activities, such as antioxidant and anti-inflammatory properties, which can enhance the therapeutic potential of the gel. Further studies are required to evaluate the safety and efficacy of the formulated gel in vivo, and to explore its potential use in the treatment of various diseases.

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Conflict of Interest
None

6. REFERENCES

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