

Design & Evaluation of Natural Polymer Based Topical Formulation with Herbal Extract for Keratosis Pilaris

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ABSTRACT

Keratosis pilaris is a common dermatological disorder characterized by excessive keratin deposition around hair follicles leading to rough papules and dry skin texture. The present study focuses on the development of a natural polymer-based topical formulation containing salicylic acid and Aloe vera extract for effective management of keratosis pilaris. Salicylic acid was selected as the keratolytic agent, while Aloe vera was incorporated due to its moisturizing, anti-inflammatory, and wound healing properties. Natural polymer xanthan gum was utilized as the gelling agent to improve topical applicability and patient compliance. Preformulation studies including organoleptic properties, solubility analysis, melting point determination, partition coefficient, pH determination, and FTIR compatibility studies were performed. Lipid components such as soya lecithin and cholesterol were evaluated for suitability in liposomal preparation. Aloe vera extract was analyzed for physicochemical and phytochemical characteristics. The results demonstrated acceptable physicochemical properties and compatibility between drug and excipients, indicating suitability for formulation development. The study concludes that the selected components possess significant potential for development of a stable and effective topical formulation for keratosis pilaris.

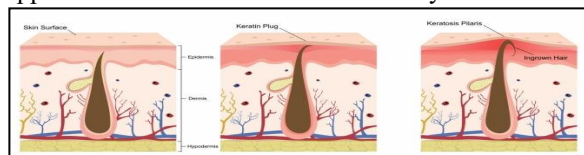
Keywords: Keratosis pilaris, Salicylic acid, Aloe vera, Xanthan gum, Liposomes, Herbal topical formulation.

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INTRODUCTION

Keratosis pilaris is a chronic benign skin condition characterized by the formation of keratin plugs within hair follicles, resulting in rough papules and dry skin appearance. The condition commonly affects the



Natural and herbal-based topical formulations have gained considerable attention due to their improved safety, biocompatibility, and patient acceptability. Salicylic acid is a widely used keratolytic agent that effectively removes excess keratin and improves

upper arms, thighs, cheeks, and buttocks. Conventional therapies often include keratolytic agents and moisturizers; however, prolonged use may lead to irritation and dryness.

Figure 1: Clinical appearance of Keratosis Pilaris

follicular desquamation. Aloe vera possesses anti-inflammatory, moisturizing, antioxidant, and wound healing activities that help soothe irritated skin and improve hydration.

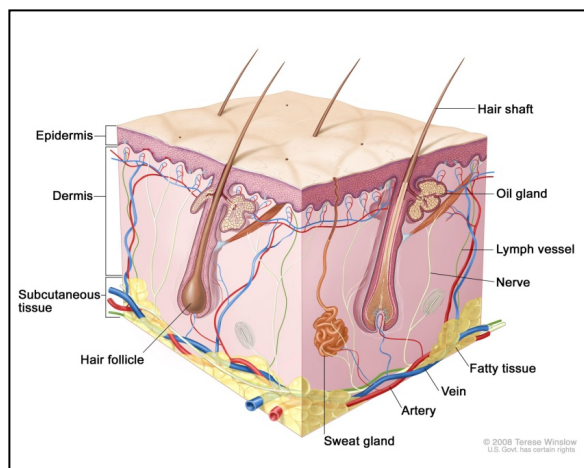


Figure 2: Structure of human skin and hair follicle

In the present investigation, a natural polymer-based liposomal gel-lotion containing salicylic acid and Aloe vera was designed using xanthan gum as a natural polymer. The study primarily focuses on drug

2. Materials and Methods

2.1 Materials

The following materials were procured from authenticated pharmaceutical and chemical suppliers:

- Salicylic acid
- Soya lecithin
- Cholesterol

3. Drug Profile

3.1 Drug Profile of Salicylic Acid

General Information

Parameter	Description
Drug Name	Salicylic Acid
Chemical Name	2-Hydroxybenzoic Acid
Molecular Formula	$C_7H_6O_3$

Mechanism of Action

Salicylic acid acts as a keratolytic agent by breaking down intercellular connections between keratinized cells in the stratum corneum. It promotes desquamation and removal of accumulated keratin plugs from hair follicles.

Role in Keratosis Pilaris

3.2 Herbal Profile of Aloe vera

General Information

Parameter	Description
Herbal Name	Aloe vera
Biological Source	Gel obtained from fresh leaves of Aloe vera

Pharmacological Activities

- Anti-inflammatory activity
- Moisturizing effect
- Wound healing property
- Antioxidant activity

profiling, procurement of materials, preformulation characterization, compatibility studies, and herbal evaluation prior to formulation development.

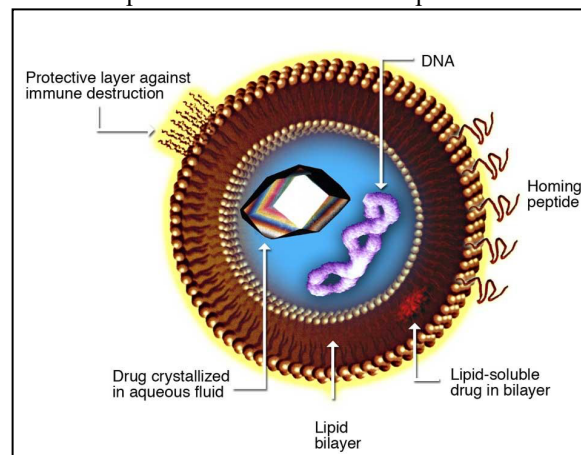


Figure 3: Schematic representation of liposome structure

- Xanthan gum
- Fresh Aloe vera leaves
- Ethanol
- Methanol
- Chloroform
- Distilled water
- Phosphate buffer pH 7.4

Molecular Weight	138.12 g/mol
Category	Keratolytic Agent
Appearance	White crystalline powder
Odor	Odorless
Melting Point	158–161°C
Solubility	Slightly soluble in water; freely soluble in alcohol and ether
pKa	2.97

- Removes excess keratin buildup
- Unclogs hair follicles
- Reduces skin roughness
- Improves texture and smoothness
- Minimizes inflammation

Family	Liliaceae
Synonyms	Ghritkumari, Barbados Aloe
Part Used	Leaves
Major Constituents	Aloin, Acemannan, Vitamins, Minerals

- Antimicrobial activity

Role in Keratosis Pilaris

Aloe vera hydrates dry skin, reduces irritation, promotes healing of inflamed follicles, and minimizes irritation caused by keratolytic agents.

4. Preformulation Studies

4.1 Organoleptic Properties of Salicylic Acid

The organoleptic properties of salicylic acid were evaluated by visual and sensory examination. The sample was observed for color, appearance, texture, and odor under normal laboratory conditions.

4.2 Solubility Analysis

Solubility studies of salicylic acid were carried out in different solvents including distilled water, ethanol, methanol, and phosphate buffer pH 7.4.

An excess quantity of salicylic acid was added separately into 10 mL of each solvent in stoppered test tubes. The mixtures were shaken using a mechanical shaker for 24 hours at room temperature. The samples were then filtered and visually observed for solubility.

Solvents Used

- Distilled water
- Ethanol
- Methanol
- Phosphate buffer pH 7.4

4.3 Melting Point Determination

The melting point of salicylic acid was determined using capillary method. A small quantity of salicylic acid was filled into a sealed capillary tube and placed in a digital melting point apparatus. The temperature at which the drug started melting and completely melted was recorded.

4.4 Partition Coefficient

The partition coefficient of salicylic acid was determined using octanol–water system. Equal volumes of n-octanol and distilled water were taken in a separating funnel and saturated with each other for 24 hours. A known quantity of salicylic acid was added and the mixture was shaken thoroughly. After equilibrium was reached, both phases were separated and analyzed spectrophotometrically.

The partition coefficient was calculated using the formula:

$$\text{Partition coefficient (P)} = \frac{\text{Concentration of drug in octanol phase}}{\text{Concentration of drug in aqueous phase}}$$

4.5 pH Determination

A 1% w/v solution of salicylic acid was prepared in distilled water. The pH of the solution was measured using a calibrated digital pH meter at room

temperature.

Procedure

- Calibrated the pH meter using standard buffer solutions.
- Immersed electrode in sample solution.
- Recorded the pH reading.

5. Drug–Excipient Compatibility Study

FTIR Spectroscopy

Fourier Transform Infrared (FTIR) spectroscopy was used to evaluate the compatibility between salicylic acid and excipients. The samples including pure drug, excipients, and physical mixtures were mixed separately with potassium bromide (KBr) and compressed into pellets using hydraulic press. The prepared pellets were analyzed using FTIR spectrophotometer over the scanning range of 4000–400 cm^{-1} .

Samples Evaluated

- Pure salicylic acid
- Salicylic acid + Lecithin
- Salicylic acid + Cholesterol
- Salicylic acid + Xanthan gum
- Aloe vera + Xanthan gum
- Salicylic acid + Aloe vera

6. UV Spectrophotometric Method Development

The UV spectrophotometric analysis of salicylic acid was performed to determine the maximum absorption wavelength (λ_{max}). A standard solution of salicylic acid was prepared in suitable solvent (phosphate buffer pH 7.4 / ethanol). The solution was scanned in the range of 200–400 nm using a UV-Visible spectrophotometer.

1. Preparation of Standard Stock Solution

An accurately weighed quantity of salicylic acid (10 mg) was dissolved in a small volume of ethanol and the volume was made up to 100 mL with phosphate buffer pH 7.4 to obtain a stock solution of 100 $\mu\text{g/mL}$. From this stock solution, serial dilutions were prepared to obtain working concentrations ranging from 5–30 $\mu\text{g/mL}$.

2. Construction of Calibration Curve

The absorbance of standard solutions was measured at 296 nm against blank using UV spectrophotometer. A calibration curve was plotted between concentration ($\mu\text{g/mL}$) and absorbance.

Concentration ($\mu\text{g/mL}$)
5
10
15
20
25
30

RESEARCH PAPER

7. Preformulation Studies of Lipid Components

a) Soya lecithin appearance test

The appearance of soya lecithin was evaluated by visual inspection under normal laboratory conditions. The lipid sample was examined for:

- Color
- Physical state
- Texture
- Presence of impurities or lumps

A small quantity of soya lecithin was placed on a clean glass slide and observed visually.

b) Cholesterol solubility test

The solubility of cholesterol was determined in different organic solvents used during liposome preparation. An excess amount of cholesterol was added separately into test tubes containing 5 mL of different solvents. The mixtures were shaken for 24 hours at room temperature and observed visually for solubility.

Solvents Used

- Chloroform
- Methanol
- Ethanol
- Distilled water

c) Lipid ratio test

Different ratios of soya lecithin and cholesterol were evaluated to optimize liposome formulation. Liposomes were prepared using thin film hydration method and evaluated for:

- Entrapment efficiency
- Physical stability
- Vesicle appearance

Different lipid ratios were prepared by varying concentrations of lecithin and cholesterol while keeping drug concentration constant.

8. Evaluation Parameters

A. Entrapment Efficiency

The prepared liposomal suspension was centrifuged to separate untrapped drug. The supernatant was analyzed spectrophotometrically for free drug content. Entrapment efficiency was calculated using the formula: $\%EE = \frac{\text{Total drug} - \text{Free drug}}{\text{Total drug}} \times 100$

B. Physical Stability

Prepared liposomal formulations were stored at room temperature and refrigerated conditions for a specified period. The formulations were observed for:

- Phase separation
- Drug precipitation
- Aggregation
- Color change

C. Vesicle Appearance

The vesicle appearance of liposomes was examined using optical microscopy. A drop of liposomal suspension was placed on a glass slide and observed under microscope for:

- Shape
- Uniformity
- Aggregation

9. Herbal Extract Evaluation

9.1 Organoleptic Evaluation of Aloe vera

Color
Odor
Appearance

7.2 Physicochemical Parameters

pH Determination

1. Accurately weigh 1 g of Aloe vera gel.
2. Transfer it into a beaker containing 10 mL of distilled water.
3. Stir the solution properly to obtain a uniform dispersion.
4. Calibrate the digital pH meter using standard buffer solutions of pH 4, 7, and 9.
5. Immerse the electrode of the pH meter into the sample solution.
6. Allow the reading to stabilize and record the pH value.
7. Perform the measurement in triplicate and calculate the average value.

Moisture Content

1. Clean and dry the porcelain dish properly.
2. Weigh the empty dish and record its weight (W_1).
3. Accurately weigh about 2–5 g of Aloe vera sample into the dish and record the combined weight (W_2).
4. Place the dish in a hot air oven maintained at 105°C .
5. Dry the sample for 3–4 hours or until constant weight is obtained.
6. Remove the dish and cool it in a desiccator for 30 minutes.
7. Weigh the dried sample and dish again (W_3).
8. Repeat drying if necessary until constant weight is achieved.

7.3 Phytochemical Screening

Simple tests for:

A. Flavonoids

Ferric chloride test- 20mg of turmeric was dissolved in 1ml of distilled water. 0.5ml of dilute ammonia solution was added to it. Conc. Sulphuric acid was added later. A yellow colour indicated the presence of flavonoids. The yellow colour disappeared on allowing the solution to stand.

B. Tannins

Lead test- 20mg of turmeric was dissolved in 1ml of distilled water in a test tube and 1-3 drops of Ferric chloride were added to the solution. Then the mixture was observed for blue or green colour.

C. Saponins

Foam test- 40 mg of turmeric was dissolved with 5ml of distilled water and shaken vigorously till a stable persistent froth was obtained. The froth was mixed with 3 drops of olive oil and shaken vigorously and then observed for emulsion.

D. Alkaloids

Wagner's test- 20mg of turmeric was dissolved in 2ml of methanol. Few drops of 1% HCl added to it. Then the mixture was heated, kept in steam and after cooling. Then the mixture was treated with few drops of Wagner's reagent. The sample was observed for turbidity or precipitation.

Result & Discussion

Preformulation Studies

1. Identification and Characterization

1.1 Organoleptic properties

The salicylic acid sample was found to be white, crystalline, odorless powder with fine texture, confirming purity and identity.

Table 1: Organoleptic Properties

Parameter	Observation
Color	White
Odor	Odorless
Appearance	Crystalline powder
Texture	Fine, smooth

The results confirm that the drug complies with standard pharmacopeial characteristics, indicating good quality raw material suitable for formulation development.

1.2 Solubility analysis

Salicylic acid exhibited poor aqueous solubility but good solubility in organic solvents.

Table 2: Solubility Profile of Salicylic Acid

Solvent	Solubility
Distilled water	Slightly soluble (0.2 mg/mL)
Ethanol	Freely soluble (12.5 mg/mL)
Methanol	Freely soluble (10.8 mg/mL)
Phosphate buffer pH 7.4	Moderate solubility (3.6 mg/mL)

Low aqueous solubility confirms the need for lipid-based systems to enhance penetration and solubilization. Good solubility in alcohol supports incorporation into topical gels and liposomal systems.

1.3 Melting point determination

Table 3: Melting Point of Salicylic Acid

Parameter	Value
Observed Melting Point	158–160°C
Literature Range	158–161°C

The observed melting point confirms drug purity with no significant impurities affecting thermal behavior.

1.4 Partition coefficient

Table 4: Partition Coefficient

Phase	Concentration (mg/mL)
Octanol phase	7.8
Aqueous phase	3.4

The moderate log P value (2.29) indicates balanced lipophilicity, favoring penetration into stratum corneum, essential for keratosis pilaris therapy.

1.5 pH determination

Table 5: pH of Salicylic Acid Solution

Parameter	Value
pH	2.8 ± 0.03

The acidic pH supports keratolytic activity but may cause irritation, justifying incorporation of Aloe vera for soothing action.

2. Compatibility Studies

Table 6: Compatibility Studies

Functional Group	Peak (cm ⁻¹)	Observation
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O–H stretching	3232	Present
C=O stretching	1671	Present
C=C aromatic	1602	Present

Table 7: Mixture Observations

Sample	Peak Shift	Interpretation
SA + Lecithin	No shift	Compatible
SA + Cholesterol	No shift	Compatible
SA + Xanthan gum	Minor variation	No interaction
SA + Aloe vera	No shift	Compatible

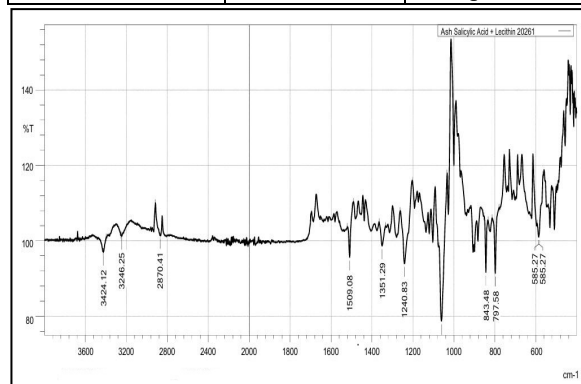


Figure 4: Compatibility study of Salicylic Acid with Lecithin

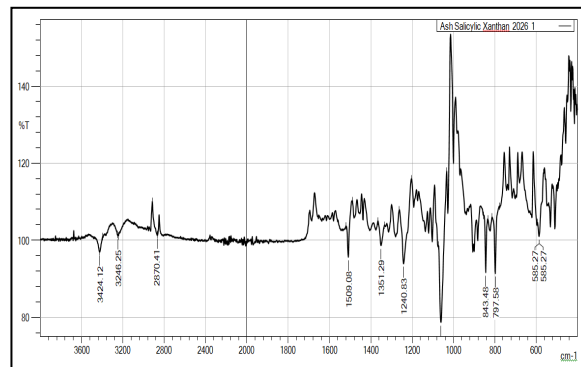


Figure 5: Compatibility study of Salicylic Acid with Xanthan Gum

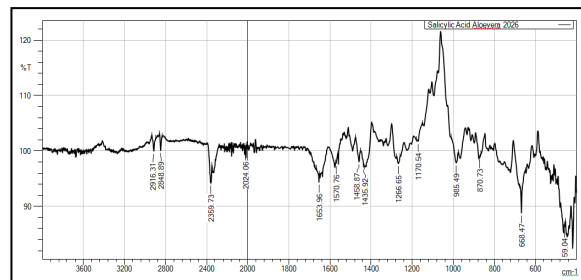


Figure 6: Compatibility study of Salicylic Acid with Aloe Vera Extract

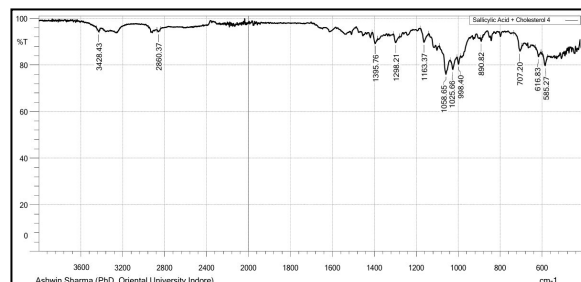


Figure 7: Compatibility study of Salicylic Acid with Cholesterol

No significant peak shifting confirms absence of chemical interaction, indicating good compatibility and stability.

3. UV Spectrophotometric Method Development

The UV spectrum of salicylic acid was recorded in the range of 200–400 nm using phosphate buffer pH 7.4 as blank. The maximum absorption wavelength (λ_{max}) was found to be:

$\lambda_{\text{max}}=296 \text{ nm}$

The λ_{max} at 296 nm confirms the presence of aromatic chromophore in salicylic acid. This wavelength was selected for all further quantitative analysis due to maximum sensitivity and reproducibility.

4. Calibration Curve Data

Table 8 : Absorbance of Salicylic Acid at 296 nm

Concentration ($\mu\text{g/mL}$)	Absorbance
5	0.112
10	0.224
15	0.335
20	0.446
25	0.558
30	0.669

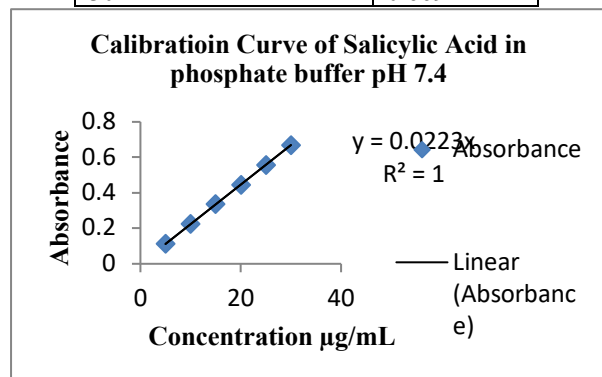


Figure 5: Calibration Curve Graph of Salicylic Acid in phosphate buffer pH 7.4

5. Preformulation Studies of Lipid Components

1. Cholesterol Solubility

Table 9: Cholesterol solubility test

Solvent	Observation
Chloroform	Fully soluble
Ethanol	Partially soluble
Methanol	Slightly soluble
Water	Insoluble

2. Lipid ratio test

Table 10: Liposomal Formulation Evaluation

Batch	Lecithin:Cholesterol	EE (%)	Vesicle Size (nm)	Stability
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9. Conclusion

The present study successfully established the preformulation profile of a natural polymer-based topical system containing salicylic acid and Aloe vera for treatment of keratosis pilaris. The obtained results demonstrated acceptable physicochemical characteristics, compatibility, and stability of selected components. Aloe vera showed promising herbal properties suitable for soothing and moisturizing dry keratotic skin, while salicylic acid provided effective keratolytic activity. The findings support further formulation and evaluation of liposomal gel-lotion systems for enhanced topical therapy in keratosis pilaris.

F1	4:1	68.4 $\pm$ 1.2	210 $\pm$ 5.4	Moderate
F2	2:1	74.1 $\pm$ 1.5	185 $\pm$ 4.2	Good
F3	2.5:1	81.3 $\pm$ 1.1	160 $\pm$ 3.8	Excellent
F4	3:1	78.0 $\pm$ 1.3	175 $\pm$ 4.6	Good

F3 showed highest entrapment efficiency and smallest vesicle size, indicating optimal lipid lance. Excess cholesterol in F4 reduced membrane fluidity, decreasing drug entrapment.

6. Herbal Extract (Aloe vera) Evaluation

1. Organoleptic Properties of Aloe vera Extract

Table 11: Organoleptic Properties of Aloe vera Extract

Parameter	Observation
Color	Light green
Odor	Characteristic
Appearance	Transparent gel

2. pH Determination of Aloe vera Extract

Table 12: pH Determination of Aloe vera Extract

Parameter	Value
pH	5.2 $\pm$ 0.1

Skin-compatible pH ensures non-irritating nature suitable for topical application.

3. Moisture Content of Aloe vera Extract

Moisture Content (%) = 96.4 $\pm$ 0.5%

High moisture content confirms excellent hydrating and skin-softening potential.

4. Phytochemical Screening of Aloe vera Extract

Table 12: Phytochemical Screening of Aloe vera Extract

Phytoconstituent	Test	Observation	Result
Flavonoids	Ferric chloride test	Yellow coloration	Present
Tannins	Lead acetate test	Green coloration	Present
Saponins	Foam test	Stable froth formed	Present
Alkaloids	Wagner's test	Brown precipitate	Present

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