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# **Review Article**

# A Comprehensive Review on Formulation Development of Salicylic Acid Ointment

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ARTICLE INFO	ABSTRACT
Published: 30 April. 2025 Keywords: Ointment, Semi Solid Dosage Form, Formulation, Evaluation, Topical Drug Delivery. DOI: 10.5281/zenodo.15308853	A 6% salicylic acid ointment was formulated for multipurpose use in skincare, particularly targeting conditions such as acne, blackheads, psoriasis, corns, and callus. The ointment was prepared using salicylic acid powder, petroleum jelly, and glycerine as the base. The primary goal of the formulation was to utilize the keratolytic properties of salicylic acid for effective skin treatment. The prepared ointment underwent various evaluation test to assess its quality. The results indicated that the formulation had an appropriate pH, good spreadability, suitable viscosity, uniform appearance, and showed no signs of phase separation. Furthermore, the ointment did not cause any skin irritation upon application. Based on these findings, the formulated salicylic acid ointment was
	concluded to be stable, effective, and safe for topical use.

# **INTRODUCTION**

Ointments are semi-solid dosage forms commonly used in medicine to treat a variety of skin conditions. The study focuses on the formulation of salicylic acid ointment aimed at improving topical delivery of this commonly used anti-acne agent. Salicylic acid is noted for its keratolytic properties, which facilitate the shedding of dead skin cells and are effective for treating mild pimples and comedonal acne. The review emphasizes the need to enhance the solubility and penetration of the drug through the skin to optimize its therapeutic action. A variety of ointment bases were utilized, and the study involved assessing multiple physical characteristics and properties of the formulations to identify an ideal ointment that could efficiently deliver salicylic acid to the target site.<sup>[1]</sup> A prominent over-the-counter medication for acne, salicylic acid is a beta hydroxy acid that comes in a variety of forms, including facewash and ointment.<sup>[4]</sup> When creating a medicated ointment for acne and pimples, a concentration of salicylic acid around 0.5 and 6% might be utilized.<sup>[4]</sup>

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# **Mechanism Of Action**

Salicylix SF 6% contains salicylic acid, which works by reducing inflammation and unclogging blocked skin pores, aiding the shrinkage of pimples. It increases the turnover rate of skin cells, helping to shed dead skin and treat comedones (small bumps caused by acne).

#### **Features of the Suitable Ointment**

1. It ought to be steady.

2. The active component shouldn't be hampered by the base.

3. The medication should be dispersed evenly throughout.

4. The prepared formulation ought to be smooth and free of greetiness.<sup>[1]</sup>

# Ointment Types <sup>[3]</sup>

#### Unmedicated Ointments

These ointments do not contain any active drugs. They are primarily used as emollients or protectants to soothe and protect the skin.

# Medicated Ointments

These contain one or more active pharmaceutical ingredients and are used to produce local or systemic therapeutic effects.

#### **Benefits of ointment**

- 1. They improve medication bioavailability by avoiding first-pass metabolism.
- 2.Appropriate for adding bitter-tasting medications.<sup>[2]</sup>
- 3.Offer better patient compliance, especially among pediatric and geriatric populations.
- 4. Enable targeted drug delivery to specific sites.
- 5. Chemically more stable compared to some other dosage forms<sup>[2]</sup>

#### **Disadvantages of ointment**

1. The oily nature of the formulation can cause staining on clothes or surfaces.

- 2. May cause itching or become contaminated upon application.
- 3. Bulkier than solid dosage forms, making them less convenient for storage and transport.
- 4. Generally less stable than dose formulations that are solid.

#### **Application Of Ointments in Medicine**

- 1. Astringents, keratolytics, emollients, antipruritics, protectants, and antiseptics are among the many uses for topically applied lotions.
- 2. Protective ointments act as a barrier against moisture, air, sunlight, and other environmental factors.
- 3. It is essential that such ointments do not penetrate the skin barrier or facilitate the absorption of substances through the skin.

#### Uses:

This ointment is for external use only. It should be used as prescribed by your doctor.

# **Drug Profile**

#### Salicylic Acid [7]

Many plants naturally contain the beta hydroxy acid (BHA) salicylic acid, with its most well-known source being the White Willow tree (Salix alba), from which its name is derived. Its chemical formula is  $C_7H_6O_3$ , and it is also known as 2-hydroxybenzoic acid, 2-carboxyphenol, or o-hydroxy benzoic acid. Salicylic acid is classified as a keratolytic agent and as an example of the salicylate drug class, which also includes aspirin It functions by hydrating the skin and breaking down the chemical that makes skin cells adhere to each other. This action promotes the natural shedding of dead skin cells.





# Petroleum Jelly

Petroleum jelly is a semi-solid, odorless, and translucent substance derived from petroleum. <sup>[10]</sup>

Benefits: It acts as an effective moisturizer by forming a protective barrier that locks in moisture, aiding in the healing of dry or irritated skin. It is also commonly used to help prevent and reduce diaper rash in infants. Chemical Composition: Petroleum jelly is primarily a mixture of hydrocarbons, mainly from the paraffin series. It has a melting point range of  $38^{\circ}$ C to  $54^{\circ}$ C (100°F to  $130^{\circ}$ F). A representative chemical formula is C<sub>25</sub>H<sub>52</sub>.

Brand name: Vaseline.



#### **♦** Glycerine

Glycerine, also known as glycerol, is a basic triol molecule that has a viscous liquid form and is colorless and odorless. It has a sweet taste and is non-toxic. This versatile substance is widely used across various industries. In the food and beverage sector, glycerine serves to retain moisture, prevent sugar crystallization, and enhance texture. In cosmetics and healthcare, it is valued for its moisturizing, emollient, and protective qualities. Glycerine has three carbon atoms, eight hydrogen atoms, and three oxygen atoms, according to its chemical formula, C3H8O3. Although combustible, glycerine requires considerable effort to ignite, with a flash point of approximately 320°F (160°C), an autoignition temperature of 698°F, and a melting point of 64°F.



**Experimental Work** 

1} Composition

Formulation for 50 gm Ointment

Sr.	Ingredients	Quantity for	Quantity for	Quantity for
No		F1	F2	<b>F3</b>
1.	Salicylic Acid	3 gm	3 gm	3 gm
2.	Petroleum Jelly	42 gm	42.5 gm	44 gm
3.	Glycerine	5ml	4.5ml	3 ml

# **Method of Preparation**

- 1. Measure Ingredients: Accurately weigh all ingredients before starting the preparation.
- 2. Melt the Base: Gently heat the petrolatum in a heat-safe container until it is completely melted.
- 3. Add Glycerin: Once the petrolatum has melted, incorporate the glycerin and mix thoroughly.
- 4. Incorporate Salicylic Acid: Slowly add the salicylic acid to the melted mixture while stirring continuously to ensure uniform distribution.
- 5. Cool and Mix: Allow the mixture to cool, stirring occasionally. Once cooled, transfer the ointment onto an ointment slab and use a spatula to mix and spread evenly.
- 6. Packaging: Transfer the prepared ointment into suitable containers and seal properly.

#### Evaluation Test <sup>[5][6]</sup>

#### A. Physical Examination:

#### 1) Appearance

The color and consistency of the prepared ointment compositions were visually examined.

#### 2) Spreadability:

To assess Spreadability, ointments should be rubbed on the back of the hand to evaluate how easily they distribute over the skin.

#### 3) Washability:

To determine washability, the formulations were applied to the skin, and their degree and ease of removal with water were carefully assessed.

# 4) **PH Determination**: <sup>[8]</sup>

2.5gram 50 ml of water was added to a 100 ml dry beaker containing the ointment sample. After 10 minutes of heating the beaker over a water bath that was kept between 60 and 70 degrees Celsius, it was allowed to cool to room temperature before being centrifuged for 10 minutes at 3000 rpm. A pH meter was used to measure the water extract's pH. Using a digital pH meter, the glass electrode was dipped into the ointment formulation to measure the pH

#### 5) Irritancy Test:

The cream was applied to a 1 cm<sup>2</sup> mark made on the left hand's dorsal surface. The application time was noted, and the site was checked for indications of irritation, like erythema or edema, at regular intervals for up to 24 hours. These observations were recorded appropriately.

#### 6) Stability Testing:

To evaluate the formulation's long-term chemical and physical stability, stability tests were carried out in a range of temperature and humidity levels.

# 7) Viscosity:

A Digital Brookfield viscometer was used to evaluate the ointment's viscosity after reconstitution.

# **B)** Chemical Evaluation

#### 1) Assay: [8]

Weigh out 10 g of the material, then dissolve it in 20 ml of 95% ethanol and 20 ml of ether. The solution is titrated with 0.1 M sodium hydroxide while phenol red is used as an indicator. Under the same circumstances, carry out a blank titration. For each ml of 0.1 M sodium hydroxide, 0.01381 g of  $C_7H_6O_3$  are produced.



#### RESULT

#### A. Physical Test –

The evaluation result are presented in the table below.

Sr. No.	Parameter	Standard formulation	Prepared formulation	Prepared formulation (F2)	Prepared formulation
			(F1)		(F3)
1	Appearance	Smooth	Slightly smooth	Sparingly smooth	Smooth

By comparing the appearance of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation	Prepared formulation	Prepared formulation
			(F1)	(F2)	(F3)
2	Colour	White	White	White	White

By comparing the Colour of F3 is similar to that

standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation (F1)	Prepared formulation (F2)	Prepared formulation (F3)
3	Consistency	Oily or Greasy	Slightly Oily or Greasy	Sparingly Oily or Greasy	Oily or Greasy

By comparing the Consistency of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation (F1)	Prepared formulation (F2)	Prepared formulation (F3)
			(1'1)	(F <i>2</i> )	( <b>F</b> 3)
4	Spreadability	Very Good	Poor	Good	Very Good



Fig. Spreadability of standard. Fig. Spreadability of preparedformulation



By comparing the Spreadability of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation (F1)	Prepared formulation (F2)	Prepared formulation (F3)
5	Washability	Very Good	Poor	Good	Very Good



Fig. Washability of standard.



Fig. Washability of prepared formulation.

By comparing the Washability of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation (F1)	Prepared formulation (F2)	Prepared formulation (F3)
6	pН	5.00	5.01	5.05	5.00



Fig. pH of standard.

By comparing the pH of F3 is similar to that standard formulation upon comparison.

Fig. pH prepared formulation.



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Sr.	Parameter	Standard	Prepared	Prepared	Prepared
No.		formulation	formulation (F1)	formulation (F2)	formulation (F3)
7	Irritancy	No	Yes	Yes	No



Fig. Irritancy of standard. Fig. Irritancy of prepared formulation.

By comparing the irritancy of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation	Prepared formulation (F2)	Prepared formulation
			(F1)		( <b>F3</b> )
8	Stability	Very Good	Poor	Good	Very Good

By comparing the Stability of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Standard formulation	Prepared formulation (F1)	Prepared formulation (F2)	Prepared formulation (F3)
9	Viscosity	7000 CP	5000 CP	6000 CP	7000 CP





Fig. Viscosity of standard. Fig. Viscosity of prepared formulation.

By comparing the Viscosity of F3 is similar to that standard formulation upon comparison.

Sr. No.	Parameter	Observation
1	Assay	Pale Yellow

#### **B)** Chemical Evaluation



Fig. Assay

# CONCLUSION

Compared to other semisolid preparations like creams, gels, pastes, etc., ointments are more stable and can offer regulated release, which is why they are becoming more and more popular these days. By improving absorption properties, the ointment formulation can raise the drug's bioavailability. Topical ointment is a safe and efficient treatment option for the management of skin-related conditions, according to clinical evidence. The physiochemical characteristics of developed salicylic acid formulations, including pH, viscosity, spreadability, washability, irritancy, stability, and viscosity tests of different formulations, were assessed.

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