DEVELOPMENT AND CHARACTERIZATION OF ANTI-ACNE TOPICAL CREAM.

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Abstract:

Acne vulgaris is one of the most common dermatological conditions, primarily resulting from excessive sebum secretion, microbial colonization, and obstruction of pilosebaceous units. Conventional therapies often involve topical agents that reduce inflammation, control bacterial growth, and promote exfoliation. Salicylic acid, a keratolytic agent, has been widely recognized for its ability to penetrate follicles, dissolve keratin plugs, and reduce come done formation, making it an effective choice for acne management. The present study was undertaken to formulate and evaluate an anti-acne cream containing salicylic acid as the active pharmaceutical ingredient. The cream was prepared using an oil-in-water (O/W) emulsion method, incorporating excipients such as stearic acid, cetyl alcohol, glycerine, and liquid paraffin to achieve desirable consistency and stability. The formulation was subjected to systematic evaluation for parameters including physical appearance, pH, spread ability, washability, stability, and skin irritation potential. Results demonstrated that the cream exhibited smooth texture, uniform consistency, and acceptable pH values compatible with skin physiology. Spread ability and washability studies confirmed ease of application and removal, while stability testing indicated that the formulation retained its integrity under accelerated conditions. Importantly, skin irritation studies revealed no adverse reactions, supporting its safety profile for topical use. Overall, the findings suggest that the salicylic acid-based O/W cream is pharmaceutically stable, cosmetically acceptable, and clinically promising for acne treatment. This study highlights the potential of combining salicylic acid with suitable excipients in an emulsion system to develop an effective, patient-friendly topical formulation. Future work may involve extended clinical evaluation to establish therapeutic efficacy and patient compliance, thereby contributing to improved acne management strategies.

KEYWORDS: Acne vulgaris, Salicylic acid, Keratolytic agent, Oil-in-water (O/W) emulsion, Topical formulation, Anti-acne cream, pharmaceutical excipients (stearic acid, cetyl alcohol, glycerin, liquid paraffin), Physicochemical evaluation

INTRODUCTION:

Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous glands, which are specialized structures consisting of hair follicles and associated sebaceous glands. It is one of the most prevalent dermatological conditions, affecting adolescents and young adults worldwide, though it can persist into adulthood. Clinically, acne manifests as pimples, blackheads, whiteheads, papules, pustules, nodules, and cysts, depending on severity. The condition is not merely cosmetic; it often leads to psychological distress, reduced self-esteem, and in severe cases, permanent scarring. The pathogenesis of acne is multifactorial. Four primary mechanisms contribute to its development

1. excess sebum production – Sebaceous glands secrete sebum, an oily substance that lubricates the skin. In acne, androgenic stimulation leads to hypersecretion of sebum, creating an environment conducive to bacterial growth.

2.Follicular hyperkeratinisation – Abnormal shedding of keratinocytes within the follicle results in blockage of the pilosebaceous unit. This leads to the formation of comedones (blackheads and whiteheads).

3.Bacterial infection – *Propionibacterium acnes* (recently renamed *Cutibacterium acnes*) colonize the blocked follicles. The bacteria metabolize sebum triglycerides into free fatty acids, which are irritating to the follicular wall.

4.Inflammation – The immune response to bacterial antigens and fatty acids triggers local inflammation, leading to papules, pustules, and cystic lesions.

Topical therapy remains the cornerstone of acne management, especially for mild to moderate cases. Creams, gels, and lotions are widely preferred due to their ease of application, localized action, and improved patient compliance compared to systemic therapies. Topical formulations allow direct delivery of active agents to the site of pathology, minimizing systemic side effects. Moreover, they can be tailored with excipients that enhance stability, spreadability, and patient acceptability. Cream formulations, particularly oil-in-water (O/W) emulsions, are advantageous because they provide a non-greasy feel, good cosmetic appeal, and better washability. Pharmaceutical excipients such as stearic acid, cetyl alcohol, glycerin, and liquid paraffin are commonly employed to stabilize the emulsion, improve consistency, and ensure uniform distribution of the active ingredient. The choice of excipients is critical, as they influence the cream's pH, viscosity, and compatibility with the skin.

Salicylic Acid: A Beta-Hydroxy Acid: Among topical agents, salicylic acid has long been recognized as an effective treatment for acne. It belongs to the class of beta-hydroxy acids (BHAs), characterized by their ability to penetrate lipid-rich environments such as sebaceous follicles. Salicylic acid exerts its therapeutic effect through multiple mechanisms:

Exfoliation of dead skin cells – Salicylic acid disrupts intercellular connections between keratinocytes, promoting desquamation. This reduces follicular hyperkeratinization and prevents come done formation.

Unclogging pores – By dissolving keratin plugs, salicylic acid restores patency of the pilosebaceous unit, reducing the risk of bacterial colonization.

Reducing inflammation – Salicylic acid possesses mild anti-inflammatory properties, attenuating redness and swelling associated with acne lesions.

Its lipophilic nature allows deeper penetration into sebaceous follicles compared to alpha-hydroxy acids (AHAs), making it particularly suitable for acne therapy. Furthermore, salicylic acid is relatively safe, inexpensive, and widely available, which enhances its utility in topical formulations.

CHALLENGES:

Formulating a stable anti-acne cream with salicylic acid presents challenges such as maintaining drug stability, preventing recrystallization, optimizing pH for skin compatibility, ensuring non-irritancy, achieving uniform spreadability, and validating antimicrobial efficacy. Balancing therapeutic effectiveness with cosmetic acceptability and long-term stability remains a critical hurdle in topical formulation development**.**

BENEFITS:

Effective acne management – Salicylic acid directly targets multiple pathogenic mechanisms by exfoliating dead cells, unclogging pores, and reducing inflammation.

Improved patient compliance – A cream base ensures ease of application, non-greasy texture, and better cosmetic acceptability compared to gels or ointments.

Localized action with minimal side effects – Topical delivery reduces systemic exposure, lowering risks associated with oral therapies.

Enhanced stability and consistency – Carefully selected excipients provide uniform spreadability, acceptable pH, and long-term stability.

Antimicrobial activity – The formulation helps suppress *Propionibacterium acnes*, reducing bacterial colonization and subsequent inflammation.

Cost-effective and accessible – Salicylic acid is inexpensive and widely available, making the cream affordable for routine use.

Potential for comparative advantage – When benchmarked against marketed formulations, the product may demonstrate superior stability, safety, and patient satisfaction.

OBJECTIVE:

1.To formulate an oil-in-water (O/W) anti-acne cream containing salicylic acid as the active ingredient.

2.To select and incorporate suitable excipients for developing a stable and effective cream base.

3.To evaluate the physicochemical properties of the formulated cream, including pH, viscosity, spreadability, homogeneity, and washability.

4.To assess the uniform distribution of salicylic acid within the formulation (drug content uniformity).

5.To study the antimicrobial activity of the cream against acne-causing microorganisms such as Cutibacterium acnes and Staphylococcus aureus.

6.To evaluate the in-vitro drug release profile of salicylic acid from the cream formulation.

7.To perform stability studies under different storage conditions to determine the physical and chemical stability of the formulation.

Scope of Study

The present study focuses on the formulation and evaluation of a topical anti-acne cream using salicylic acid as a keratolytic agent. The work involves the development of an oil-in-water cream base using appropriate excipients and assessing its suitability for dermatological application.

The scope of the study includes:

Preparation of different formulation batches with varying concentrations of salicylic acid to optimize effectiveness and safety.

Evaluation of the prepared formulations for their physicochemical characteristics, ensuring compatibility with skin conditions.

Investigation of antimicrobial activity to establish the effectiveness of the formulation against acne-causing bacteria.

Assessment of in-vitro drug release to understand the release behavior of the active ingredient.

Stability testing to ensure the formulation remains effective, safe, and physically stable over time.

MATERIAL:

Salicylic acid (Anti-acne agent), Stearic acid (Emulsifier), Cetyl alcohol (Thickening agent)

Liquid paraffin (Emollient), Glycerin (Humectant), Triethanolamine (Neutralizer), Methyl

paraben (Preservative), Distilled water (Vehicle)

METHODS OF PREPRATION:

STEP 1: PREPARATION OF OIL PHASE

Take stearic acid, cetyl alcohol, and liquid paraffin

Heat in a porcelain dish at 70–75°C until melted

STEP 2: PREPARATION OF AQUEOUS PHASE

Take distilled water

Add glycerine, methyl paraben, and salicylic acid

Heat to 70–75°C

STEP 3: EMULSION FORMATION

Add aqueous phase slowly into oil phase with continuous stirring

Add triethanolamine and mix properly

Continue stirring until cream forms

Transfer into suitable container

Preformulation Study

Preformulation studies are essential to understand the physicochemical properties of drug substances and excipients before formulation development.

DRUG PROFILE

1. Drug Profile

- Category: Keratolytic agent
- Molecular Formula: $C_7H_6O_3$
- Molecular Weight: 138.12 g/mol
- Mechanism: Promotes desquamation, unclogs pores, reduces inflammation

2. ORGANOLEPTIC PROPERTIES

SR.NO	PARAMETER	RESULT
1	Colour	White
2	Odor	Characteristics
3	Texture	Crystaline powder

3. SOLUBILITY STUDY

SR.NO	SOLVENT	RESULT
1	Water	Slightly soluble
2	Ethanol	Freely soluble

3	Methanol	Soluble
4	Chloroform	Soluble
5	Phosphate Buffer (pH6.8)	Moderate Soluble

4. pH Determination

- 1% solution prepared in distilled water
- Observed pH: 2.5–3.0

Implication: Requires buffering for skin compatibility (ideal pH 4.5–6.5)

5. Melting Point

- Determined by capillary method
- Observed range: 158–161°C

Interpretation: Confirms purity of drug.

EVALUATION PARAMETERS

1. Physical Appearance

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

2. pH Measurement

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

3. Viscosity

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

4. Spreadability

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

5. Washability

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

6. Drug Content Uniformity

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

7. In-vitro Drug Release

Sr.no	Parameter	Result
1	Color	White
2	Texture	Smooth
3	Phase Separation	None

RESULT AND DISCUSSION

1. Preformulation Findings

- Drug showed **good solubility in organic solvents**, suitable for cream formulation
- **Partition coefficient confirmed permeability** through skin
- FTIR studies indicated **no incompatibility**, ensuring formulation stability

2. Evaluation Results Discussion

Physical Properties

The cream exhibited good aesthetic properties, smooth texture, and no phase separation, indicating a stable emulsion system.

3.pH Analysis

The pH (5.2–5.8) is within the physiological skin range, minimizing irritation risk.

4.Viscosity

Optimal viscosity ensured:

- Good consistency
- Ease of application
- Stability of formulation

5.Spreadability

Higher spreadability values indicate:

- Easy application
- Uniform drug distribution on skin

6.Drug Content

Uniform drug distribution (~98–99%) confirms:

- Proper mixing
- Dose accuracy

7.Drug Release Study

- Sustained drug release up to 3 hours
- Indicates prolonged therapeutic effect
- Suitable for acne treatment requiring continuous action

CONCLUSION

The anti-acne cream was successfully formulated using suitable excipients to ensure stability, effectiveness, and user acceptability. Preformulation studies confirmed drug compatibility, proper solubility, and stability, minimizing formulation risks. Evaluation results showed optimal viscosity and good spreadability, enabling easy and uniform application. The pH was within the skin-friendly range, reducing the risk of irritation. The formulation exhibited a sustained drug release profile, ensuring prolonged therapeutic action. Stability studies indicated no significant physical or chemical changes over time. Overall, the cream is safe, stable, and effective, making it a promising option for topical treatment of acne vulgaris.

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