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Research Article

DEVELOPMENT AND ASSESSMENT OF POLY HERBAL ANTI-ACNE CREAM

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ABSTRACT
The present study aimed to develop a novel cream formulation containing Alo vera, neem,and tulsi extract for the treatment of Acne infections. Topical application is considered the most suitable approach for such infections, as it offers multiple advantages over conventional drug delivery methods, including localized action, minimal systemic side effects, and enhanced patient compliance. the formulation was evaluated using in-vitro diffusion studies. The results confirmed that the developed herbal anti acne cream is safe and effective for managing skin infections

INTRODUCTION
TOPICAL DRUG DELIVERY SYSTEM
Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, rectal, vaginal, and skin as topical routes. Skin is one of the most readily accessible organs on the human body for topical administration and is the main route of the topical drug delivery system. This review is concerned with all detailed information regarding the rational approach to topical formulations, principles of topical permeation, and basic components of topical drug delivery systems.[1]
Topical products are classified to those that are applied to produce local and systemic effects. These systems are commonly used for localized skin infections when other routes of administration have failed.

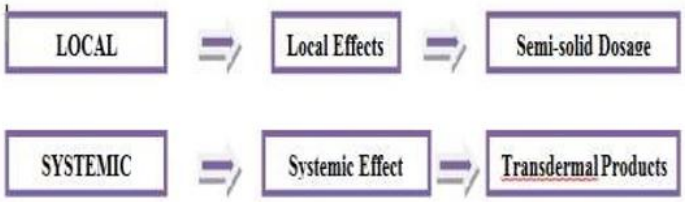

Figure.1 Topical Drug delivery

FACTORS AFFECTING TOPICAL PERMEABILITY:

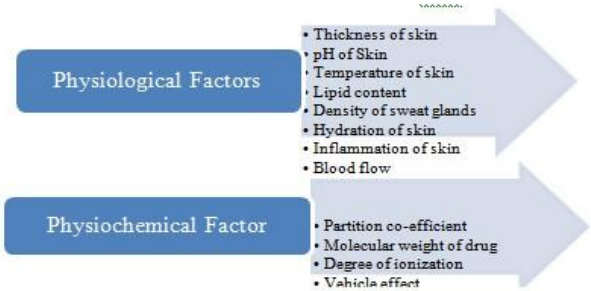

Figure.2 factors affecting topical permeability

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Mechanism

Topical Drug Transport Across Skin

1. Application

Drug applied on skin surface diffuses into the stratum corneum (outermost layer).

2. Possible Routes of Transport

Appendageal route (First cut):

Drug enters via sweat glands or hair follicles.

Helps bypass the stratum corneum barrier.

Paracellular route:

Drug passes between cells of the stratum corneum.

Travels through lipid-rich junctions.

Transcellular route:

Drug passes through the cells.

Crosses lipid bilayers and aqueous domains inside cells.

3. Stratum Corneum Barrier

Contains bilayered lipids (fatty environment).

Drug molecules must diffuse through this to reach deeper layers.

4. Deeper Transport

After crossing the stratum corneum, the drug reaches the epidermis and subcutaneous layer.

5. Binding

During transport, the drug may bind to keratin proteins in the stratum corneum4.

ADVANTAGES

- Avoidance of first pass metabolism.
- Convenient and easy to apply.
- Avoid risk.
- Inconveniences of intravenous therapy and the varied conditions of absorption, like pH changes, presence of enzymes, gastric emptying time, etc[3].

Disadvantages

• Skin irritation of contact dermatitis may occur due to the drug and / or excipients

• Poor permeability of some drugs through the skin

• Possibility of allergic reactions

• Can be used only for drugs which require a very small plasma concentration for action[4]

Ideal Characteristics of a Topical Drug:

- **Water solubility:** Before a medicine may penetrate a membrane, it must first be dissolved in aqueous bodily fluids.
- **Log P**: The medication must have enough lipophilicity to pass through membranes.
- **Enzymatic degradation**: Before reaching their target, several medications may be significantly destroyed by a variety of enzymes[5].

CREAMS:

Creams are a type of topical product that can be applied to the skin. Creams are "viscous liquid or semi-solid emulsions of either the oil-in-water or water-in-oil type," the consistency of which varies depending on the amount of oil and water used. Creams can be used for a variety of cosmetic objectives, including cleansing, beautifying, improving looks, and protecting as well as for medicinal purposes. These items are intended to be used topically to increase drug delivery to specific skin locations for skin diseases.

TYPES OF SKIN CREAMS

They are divided into two types:

Oil-in-Water (O/W) creams, which are composed of small droplets of oil dispersed in a continuous phase, and an emulsion in which the oil is dispersed as droplets throughout the aqueous phase, are termed an oil-in-water (O/W) emulsion.

Water-in-Oil (W/O) creams, which are composed of small droplets of water dispersed in a continuous oily phase. When water is the dispersed phase and an oil the dispersion medium, the emulsion is of the water-in-oil (W/O) type[4].

Benefits of All Purposes of Creams:

- All-purpose creams are designed to serve multiple functions, reducing the need for consumers to purchase and use multiple specialized products.
- It may be less expensive to use one all-purpose cream rather than several specialty ones.
- People with busy lifestyles can save time by streamlining their skincare routine with an all-purpose cream.

Drawbacks of All-purpose cream

- These creams might not be specialised to treat particular skin conditions because they are meant for everyday usage.
- Treatments specific to conditions like psoriasis, eczema, or extreme dryness may be necessary; an all-purpose cream may not be sufficient for these conditions.
- Certain components found in all-purpose creams, like thick emollients or occlusive agents, may clog pores[6]

MATERIALS AND METHODS

Materials

Collection of sample:

Neem, Aloe vera, Tulsi extract, beeswax, borax, methyl paraben. and almond oil was collected from the local market.

Methods

Preparation of Cream Formulation:

Preparation of Herbal Cream Using Slab Technique (Extemporaneous Method)

1. Oil Phase Preparation

In a borosilicate glass beaker, heat liquid paraffin and beeswax to 75 °C, and maintain this temperature until both components are completely melted and homogeneous.

2. Aqueous Phase Preparation

In a separate beaker, dissolve borax and methylparaben in distilled water, and heat this mixture to 75 °C until a clear solution is obtained.

3. Emulsification

Slowly add the heated aqueous phase to the oil phase while maintaining a constant temperature of 75 °C, with continuous stirring to ensure proper emulsification.

4. Incorporation of Herbal Extracts

Once emulsification is complete, add measured quantities of Aloe vera gel, Neem extract, and Tulsi extract. Stir vigorously to ensure a uniform and smooth cream base.

5. Fragrance Addition

Add a few drops of Almond oil to the mixture as a natural fragrance and mix thoroughly.

6. Final Mixing (Slab Technique)

Transfer the cream onto a clean ointment slab. If required, add a few drops of distilled water to adjust the consistency. Mix the cream using geometric dilution technique with a stainless-steel spatula to achieve a uniform, smooth, and well-textured final product.

This method of preparation is known as the Slab Technique or Extemporaneous Method for cream formulation[7]

Table.1 Formulation Details for Anti-Acne Cream

Sl No	Ingredients	F_1	F_2	F_3	F_4
1	Aloe Vera gel	9ml	10ml	11ml	12ml
2	Tulsi	0.5ml	1ml	1.5ml	2ml
3	Neem	1ml	1.5ml	2ml	2.5ml
4	Bees wax	1.5mg	2gm	2.5gm	3gm
5	Liquid paraffin	10ml	10ml	10ml	10ml
6	Borax	0.8g	0.8g	0.8g	0.8g
8	Almond oil	0.5ml	0.5ml	0.5ml	0.5ml
9	Distilled water	QS	QS	QS	QS
10					

PRE-FORMULATION STUDIES

Organoleptic properties:

A natural substance's organoleptic quality refers to its appearance, odour, colour, and taste. The study's initial stage is to characterize these characteristics, which aids in the primary identification of the Natural substance as well as determining the likelihood of patient acceptability of the raw materials' aroma, taste, and colour, as well as their likely inclusion in the final dose form. Changes in the colour and odour of a formulation's raw material might sometimes signal that the formulation's stability has deteriorated (under identical conditions).

IR Spectra Analysis

These compatibility studies are conducted by using an ATR-FTIR spectrophotometer, and the spectrum was recorded in the wave number region of 4000 to 400cm-1.[8].

EVALUATION TEST

1. PHYSICAL EVALUATION: The physical parameters of the cream, like colour, odour, consistency, and state of formulation, were used to evaluate the formulation further.

2. pH OF CREAM: The pH of the cream should be in the range of 4.5-6.5, to avoid irritancy to the skin[9]

3. IRRITANCY: Mark the area (1 cm2) on the left-hand dorsal surface. Then the cream was applied to that area, and the time was noted. Then it is checked for irritancy, erythema, and edema, if any, for an interval up to 24 h and reported.

4. PHASE SEPARATION: Prepared cream was kept in a closed container at a temperature of 25-100 ℃ away from light. Then, phase separation was checked for 24 h over 30 days. Any change in the phase separation was observed/checked[10].

5. VISCOSITY: The Viscosity of formulated creams can be determined by using a Brookfield Viscometer.

6. HOMOGENEITY: The formulation was tested for homogeneity by visual appearance and by touch.

7. WASHABILITY: The ease of removal of the creams applied was examined by washing the applied part with tap water[11]

RESULT AND DISCUSSION

5.1.1 ORGANOLEPTIC PROPERTIES:

The present study was carried out to develop an Anti-Acne cream by using aloe vera gel, Tulsi, and neem extract. Assessment of the physical description /organoleptic property of the drug is the primary step for drug substance recognition. It helps to check the feasibility of a drug for formulating into the intended dosage form. This also helps in assessing the patient acceptability factors such as colour, nature, odour, and texture, which eventually leads to better patient compliance.

Table.2 List of Organoleptic Properties

Slno	Properties	F1	F2	F3	F4
1	Colour	Pale green	Pale green	Pale green	Pale green
2	Odour	Pleasant	Pleasant	Pleasant	Pleasant
3	Texture	Smooth	Smooth	Smooth	Smooth

The color, odour, nature, and texture of the API were evaluated, and it was observed as specified in the monograph. Based on the observation, it was found satisfactory for the formulation of the cream, and no discomfort was likely to arise in patient compliance.

IR- SPECTRA ANALYSIS:

ATR-FTIR spectrum of pure drug and prepared cream was compared to the study of drug with the excipients, and the spectrum was recorded in the wave number region of 4000 to 400cm.

PHASE SEPARATION

Prepared cream was kept in a closed container at a temperature of 25-100 ℃ away from light. Then, phase separation was checked for 24 h over 30 days. Any change in the phase separation was observed/checked. According to the results, no phase separation was observed in all four formulations.

pH MEASUREMENT:

Using a digital pH meter, pH measurements of the prepared cream were taken by immersing the glass electrode entirely into the cream system and covering it. pH is one of the major evaluation factors in the cream preparation purpose of avoiding the irritation of the skin upon application. Using a pH meter, it was discovered that the pH ranges from 5.6 to 7.5, which is basic in nature. F2 has the most compatibility with skin pH compared to other formulations The pH should not be too acidic, as this might cause skin irritation, nor should it be too alkaline, as this can result in scaly skin.

Table.3 PH Measurement

Formulation	pH
F1	4.3
F2	5.6
F3	6.3
F4	7

pH Measuring Meter

Figure.3 pH Meter

pH Measuring Meter

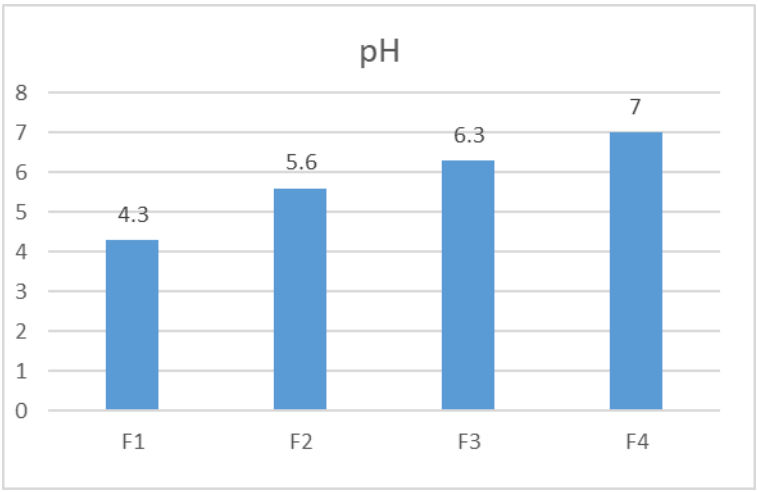

Figure.2 Graphical representation pH

IRRITANCY TEST:

Mark area (1sq.cm) on the left-hand dorsal surface. The cream was applied to the specified area, and the time was noted. Irritancy, erythema, and edema were checked if regular intervals up to 24 hours and reported. From the above result, it was concluded that no irritancy was observed in all formulations

Table.4 Irritancy test

Sl no	Formulation	Irritant effect
1	F1	Nil
2	F2	Nil
3	F3	Nil
4	F4	Nil

Figure.4 Irritancy test

DETERMINATION OF VISCOSITY: The viscosity of the formulation was measured by Brookfield Viscometer LVD using spindle 594 at varying speeds and shear rates. The measurements were done over the range of speed settings from 0.10, 0.20, 0.30, 0.40, and 0.50 rpm in 60s between two successive speeds as equilibration with shear rate ranging from 0.20s-1 to 1.0s-1. The results show the viscosity of all the formulations ranges from 20000 to 30000cps.. F2 shows a better consistency with a viscosity level of 26000 cps.

Table.5 Viscosity Measurement:

Formulation	Viscocity(cps)
F1	29,000cps
F2	26,000cps
F3	22,000 cps
F4	19,000 cps

Figure.5 Viscometer

Determination of Spreadability:

The spreadability of the cream was based on the viscosity, and it was evaluated from all 4 formulations. It was discovered that the spreadability ranges from 12 to 15. F2 has better spreadability compared to other formulations. The F2 has better consistency, so the cream was easily spreadable by a small amount of shear.

Table.6 Spreadability test

Formulation	Spreadability(gmcm/sec)
F1	15.3
F2	13.2
F3	14.5
F4	12.7

Figure.6 Spreadability test

Appearance: The prepared cream was visually inspected for appearance, colour, and texture. All the prepared formulations were Pale green in colour, with a smooth texture, and they were all homogeneous with no signs of phase separation.

Washability: The ease of removal of the cream applied was examined by washing the applied part with tap. All formulation was easily removed with normal water.

Table.7 Washability

Sl. No.	Formulation	Washability
1.	F1H	Easily Washable
2.	F2H	Easily Washable
3.	F3H	Easily Washable
4	F4H	Easily Washable

Figure.8 Washability test

CONCLUSION:

From the experimental results, it can be concluded that:

The prepared anti-acne creams were evaluated for general appearance, Irritation test, determination of pH, Spreadability studies, and washability test. All the formulations were found to be good, and all the formulations passed the test. By preparing with the various quantities of aloe vera gel, neem, and Tulsi extract with excipients. The F2 shows better consistency compared to all. In the irritancy test, all the formulations are applied to the skin; formulations (F1, F2, F3 & F4) do not show redness, irritation, edema & erythema. All the formulations show the spreadability values within the standard value. F2 shows better spreadability compared to the other spreadability. The pH of all the formulations is found in the range of 5.6 to 7.5. This is well within the range for topically administered formulations, and formulation F2 has shown a pH of 5.6; therefore, there is no need for adjusting the pH of the formulation. Based on the results of all evaluation tests, the F2 formulation was identified as the ideal and better formulation among all formulations. From the above study, it can be concluded that the F2 formulation is good, and also concluded that the herbal anti-acne cream containing aloe vera gel, neem, and Tulsi extract is safe to use as it is developed from herbal extract. Natural remedies are more acceptable in the belief that they are safer with fewer side effects than synthetic ones. Further detailed stability studies are needed to improve the overall quality of the product.

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