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Research Article

DESIGN AND DEVELOPMENT OF HERBAL FORMULATIONS FOR THE TREATMENT OF TOPICAL SKIN DISORDERS

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ABSTRACT

The present study aimed to design, develop, and evaluate a polyherbal topical formulation for the treatment of skin infections and related dermatological disorders. Selected medicinal plants including Ocimum sanctum, Rubia cordifolia, Glycyrrhiza glabra, Pterocarpus marsupium, Nerium oleander, and Punica granatum were collected, authenticated, and extracted using Soxhlet extraction with suitable solvents. The developed formulations were evaluated for physicochemical properties such as pH, viscosity, spreadability, and extrudability. In-vitro drug diffusion studies were conducted using a Franz diffusion cell, while stability studies were carried out under ICH guidelines. The optimized polyherbal formulation exhibited acceptable physicochemical properties, good spreadability, and skin-compatible pH. FTIR analysis confirmed compatibility between extracts and excipients. The formulation demonstrated satisfactory drug diffusion and remained stable under accelerated stability conditions. The developed polyherbal topical formulation showed promising physicochemical characteristics, stability, and broad-spectrum antimicrobial activity. These findings suggest that the formulation may serve as a safe and effective alternative for the management of skin infections. Further in vivo and clinical investigations are required to confirm its therapeutic potential.

Keywords: Polyherbal formulation, Topical ointment, Medicinal plants, Antimicrobial activity, Herbal drug.

INTRODUCTION

The skin is the largest organ of the body and serves as the primary protective barrier against microorganisms, ultraviolet (UV) radiation, oxidative stress, and environmental damage. It functions as an interface between the internal body and the external environment while regulating temperature, sensation, and immune defence. When the integrity of the skin barrier is compromised, its protective ability declines, leading to increased susceptibility to infections and disorders (Lee, 2022- Aida Maranduca M,2020). Skin diseases are among the most common global health problems, affecting nearly 900 million people worldwide. Conditions such as pruritus, eczema, impetigo, warts, and scabies constitute a major proportion of dermatological disorders and represent a significant cause of non-fatal disease burden. Skin infections may be primary (occurring on normal skin and caused by organisms such as *Staphylococcus aureus* or *Streptococcus pyogenes*) or secondary (superimposed on already diseased skin). Many skin conditions are persistent, difficult to treat, and negatively impact quality of life, sometimes leading to disfigurement and social stigma (Hay R. J, 2010- Goldsmith L, 2012).

Modern (allopathic) medicine provides rapid symptomatic relief; however, it may be associated with adverse effects and limitations in managing chronic skin conditions. This has encouraged growing interest in alternative and complementary systems of medicine. Ayurveda, meaning "Science of Life," is a traditional Indian medical system practiced for over 5000 years. According to WHO reports, nearly 80% of populations in certain regions rely on traditional medicine for primary healthcare due to its accessibility and affordability. Herbal therapies have long been used for the treatment of skin disorders and infections. India alone utilizes over 6000 medicinal plants in traditional practice. Several plants such

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as *Azadirachta indica*, *Aloe vera*, *Curcuma longa*, *Ocimum sanctum*, *Glycyrrhiza glabra*, and *Punica granatum* have demonstrated antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties. Although traditional claims support their efficacy, many herbal remedies still require systematic scientific validation, safety evaluation, and formulation development to ensure consistent therapeutic outcomes (Cowan, 1999; Tyagi, 2015). Considering the increasing global demand for herbal medicines and the need for safer, effective topical therapies, scientific formulation and standardization of herbal products have become essential.

MATERIALS AND METHODS

Collection and Identification of Medicinal Plants

The selected medicinal plants *Ocimum sanctum*, *Rubia cordifolia*, *Glycyrrhiza glabra*, *Pterocarpus marsupium*, *Nerium oleander*, and *Punica granatum* were procured from the local market and authenticated. The required plant parts were cleaned, shade-dried, and powdered for extraction.

Drugs and Chemicals

All chemicals and reagents of analytical grade (AR) were obtained from certified local vendors.

Microorganisms

Microbial strains including *Staphylococcus aureus*, *Escherichia coli*, *Bacillus subtilis*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Aspergillus niger* were procured from Acharya Nagarjuna University, Guntur, India.

Equipment

Major instruments used included UV–Visible Spectrophotometer, FTIR, Brookfield Viscometer, Digital pH meter, Centrifuge, Incubator, Franz Diffusion Cell, Laminar Air Flow, Stability Chamber, HPTLC, TLC, NMR, and Mass Spectroscopy instruments.

Extraction of Plant Materials (Azwanida N. N, 2015-Tiwari P, 2011)

Twelve extracts (polar and non-polar) were prepared from six selected plants using Soxhlet extraction. For polar extracts, coarse powdered drugs were initially defatted with petroleum ether and further extracted using suitable solvents: Hydroalcoholic (60:40) for *Ocimum sanctum*, *Rubia cordifolia*, *Glycyrrhiza glabra*, and *Nerium oleander*. Ethanol for *Pterocarpus marsupium*. Water for *Punica granatum.* For non-polar extracts, respective non-polar solvents (petroleum ether, chloroform, or diethyl ether) were used. Extracts were filtered, concentrated to dryness, and stored under refrigeration.

Preliminary Phytochemical Screening (World Health Organization, 1998)

Extracts were subjected to qualitative phytochemical analysis to detect major constituents using standard procedures. Steroids & Triterpenoids – Salkowski and Liebermann–Burchard tests. Glycosides – Keller–Killiani, Legal's, Balget's, and Borntrager's tests. Alkaloids – Mayer's, Hager's, and Dragendorff's tests. Flavonoids – Shinoda and Ferric chloride tests. Tannins – Ferric chloride test. Saponins – Foam test. Carbohydrates – Molisch's, Fehling's, Benedict's, and Barfoed's tests. Proteins & Amino acids – Biuret, Ninhydrin, Millon's, and Xanthoproteic tests. Based on phytochemical screening, four promising extracts were shortlisted for further evaluation.

Pharmacognostic Evaluation (Chaudhary G. D, 2015)

Shortlisted extracts were subjected to pharmacognostic and physicochemical evaluation. Ash Values, Total ash, Acid-insoluble ash**,** Water-soluble ash

Loss on Drying

Determined at 105°C to evaluate moisture content.

Extractive Values

Alcohol-soluble extractive value. Water-soluble extractive value These parameters ensured purity, identity, and quality of crude extracts.

Compatibility Studies

FTIR analysis was performed to assess compatibility between extracts and excipients. Samples were prepared using KBr pellet method and scanned in the range of 400–4000 cm^{-1}.

Formulation Development

Preparation of Polyherbal Ointment

An emulsifying ointment base was prepared using: Emulsifying wax (30 g), White soft paraffin (50 g), Liquid paraffin (20 g). Ingredients were melted in descending order of melting point with continuous stirring to obtain a uniform base. bThree batches (O1, O2, O3) were formulated by incorporating hydroalcoholic extracts of: *Ocimum sanctum*, *Rubia cordifolia*, *Glycyrrhiza glabra* Concentrations used O1: 2% each extract, O2: 4% each extract, O3: 6% each extract, The quantity was adjusted to 100 g with ointment base.

Evaluation of Polyherbal Ointment (Pandey A, 2020-Gupta R, 2020)

Physical Evaluation

Color, appearance, and consistency were evaluated visually.

pH

Measured using calibrated digital pH meter (1% aqueous solution).

Viscosity

Determined using Brookfield Viscometer (Spindle 50, 50 rpm).

Spreadability

Measured using glass slide method. Spreadability= (weight x Length)/Time

Extrudability

Assessed by measuring percentage of formulation extruded from collapsible tube under applied weight.

In Vitro Diffusion Study

Drug release was evaluated using Franz Diffusion Cell (25 ml receptor volume). Membrane: Cellophane membrane, Receptor medium: Phosphate buffer pH 7.4, Temperature: Maintained with stirring, Samples were withdrawn at predetermined intervals and analyzed at 270 nm using UV–Visible spectrophotometer. Cumulative drug release was calculated.

Stability Studies

Optimized formulation was subjected to stability studies for six months under ICH conditions: 25°C ± 2°C / 60% RH ± 5%, 40°C ± 2°C / 75% RH ± 5%, Physical parameters were evaluated periodically.

Antimicrobial Activity

Test Microorganisms

Gram-positive: *Staphylococcus aureus*, *Bacillus subtilis*, Gram-negative: *Escherichia coli*, *Pseudomonas aeruginosa*, Fungi: *Candida albicans*, *Aspergillus niger*

Cup and Plate Method

Nutrient agar plates were prepared and inoculated with standardized microbial suspension (0.5 McFarland standard). Wells were created and filled with polyherbal ointment and reference standard (Candiderma Plus cream). Plates were incubated at 37°C for 24 hours. Zones of inhibition were measured and recorded as mean of triplicate experiments.

RESULTS AND DISCUSSION

The organoleptic characteristics of shatdhauta ghrita (SDG) like appearance, color, odour and texture were observed. The observations are shown Table.2. The drug sample was subjected to IR spectroscopy, and the functional groups were analysed based on the structure. It was determined that the functional groups matched accurately to the drug's structure. FTIR spectrum of quercetin, the spectrum showed characteristics peaks at 3340.47- O-H, 2923.11-C=O, 1635.32 C=O Stretching, 1396.31-C-H-Bending, 1265 –C-O-C confirming the received sample was quercetin (Raza A *et.al* 2016).

Table 1. Composition of preliminary polyherbal topical ointment.

	O1	O2	O3
Ocimum sanctum extract	2%	4%	6%
Rubia cordifolia extract	2%	4%	6%
Glychyrriza glabra extract	2%	4%	6%
Emulsifying ointment (Ointment base)	q.s 100gm	q.s 100gm	q.s 100gm

Table.2. Organoleptic evaluation of effect on number of washing on SDG formulation.

Number of washings	Colour	Odour	Texture
0	Golden yellow	Characteristic ghee like	Oily Granular
10	Colour slight changed	Ghee like	Oily Granular
20	Creamish yellow	Ghee like	Oily yellow cream
40	Slightly creamish	Slightly change	Oily homogenous cream
60	Pale yellow	Slightly Change	Oily homogenous cream
80	Pale yellow	Odorless	Oily homogenous Cream
100	Light Pale yellow	Odorless	Homogenous cream
120	White	Odorless	Homogenous cream
140	White	Odorless	Homogenous cream

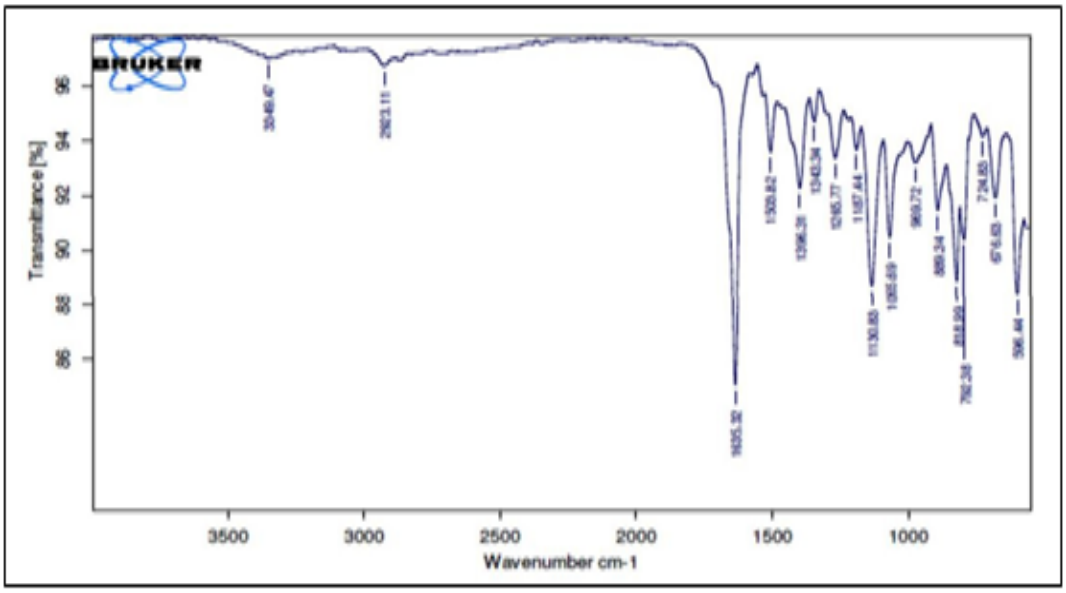

Figure 1. FTIR spectrum of quercetin.

The thermal behavior of the quercetin was evaluated by DSC analysis. The melting peak at 368.50oC for quercetin appeared in the thermogram, along with a characteristic broad endothermic peak (138.92°C) associated with water molecules loss. However, reported melting point of quercetin was observe at 365-371oC. Using UV spectroscopy, the quercetin concentration of 10µg/mL was analyzed in a wavelength range of 200–400 nm. The scan spectrums curve, obtained from the following study, indicates that quercetin shows the λ-max at 370 nm. The reported λ-max of quercetin was found at 371nm (Chaudhari SP et al. 2020). Calibration curve of quercetin in different media/ solvents was obtained by plotting concentration (µg/mL) vs. absorbance. Calibration curves have been established to investigate the relationship between concentration and absorbance according to Beer-Lambert's law. The R^2 value and slope were found to be 0.9968 and 0.0437 respectively. A solubility investigation of quercetin was carried out using different solvents including water, HCl (pH 1.2), Phosphate buffer (pH 6.8), Phosphate buffer (pH 7.4), methanol, and ethanol. It was established that according to the solubility parameters in water, buffer solutions with pH of 1.2, 6.8 and 7.4, quercetin refers to practically insoluble and soluble in ethanol. The chosen excipients for the preparation of shatadhauta cream were mixed with the silymarin and then stored at a temperature of 25 ± 2°C. The samples had been verified for any physical changes. (physical states of mixture, odor etc). The observations were recorded as shown in Table 4. Thereafter FTIR spectra of various mixtures were recorded (quercetin +stearic acid) and (quercetin+ shatdhauta ghrita) (Figure.8, and Figure 9). The peak was observed at wave number 2954.85, 2850.79, 1712.79, 1463.9, 1296.16cm.$^{-1}$ and3257.72, 2717.70, 1668.43,1519.91,1319.31cm.$^{-1}$ There was no significance changes in characteristics peaks of quercetin in FTIR spectra of drug with screened excipients was observed. Thus, quercetin is compatible with selected excipients. The shatdhauta ghrita base was optimized by addition of steric acid. It is observed that steric acid has positive effect on the viscosity and spreadability, increase in the concentration of steric acid, increase the viscosity and decrease the spreadability. The desire range of spreadability is between 10 to 30. F2 batch showed good viscosity and spreadability as compared to another batch.

Table 3. Solubility studies of quercetin in different solvent.

Solvent	Solubility mg/ml
Water	0.062±0.001
HCl (pH 1.2)	0.096±0.012
Phosphate buffer (pH 6.8)	0.316±0.026
Phosphate buffer (pH7.4)	0.273±0.021
Methanol	0.977±0.018
Ethanol	1.135±0.065

(Data presented as mean ± SD; n= 3)

Table.4. Result of drug excipients compatibility study of quercetin.

Drug/ excipients	Description	Temperature 25°C ± 2°C	
		Colour	Physical form
Quercetin	Pale yellow	No change	No change
Quercetin: Stearic acid	Light yellow	No change	No change
Quercetin: Shatdhauta ghrita cream	Light Yellow	No change	No change

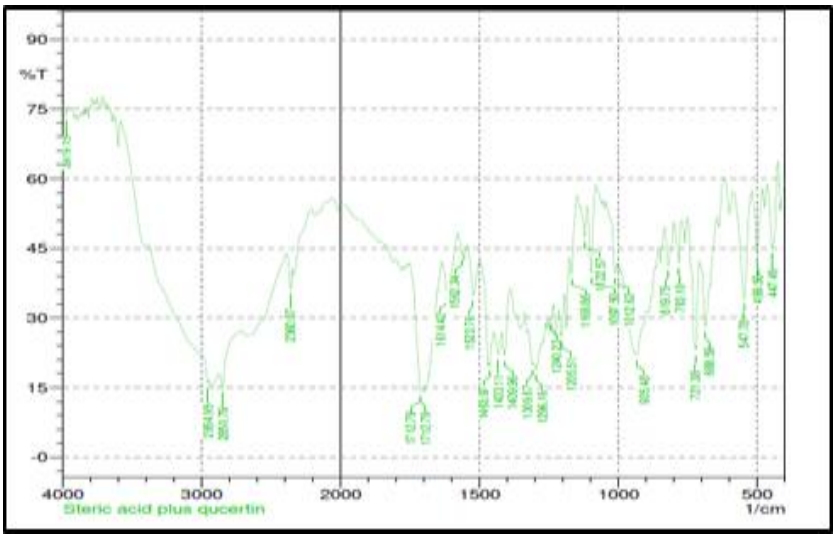

Figure .2. FTIR spectra of stearic acid: Quercetin.

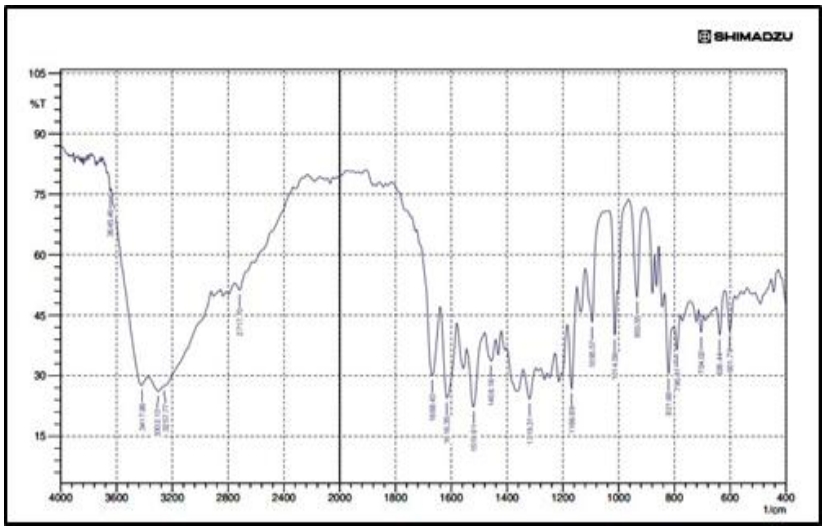

Figure 3. FTIR spectra of Quercetin: Shatdhauta ghrita.

Table 5. Optimization result of SDG Base.

Batch	SDG (gm)	Stearic acid (%)	Separability (g.cm/sec)	Viscosity (cp)
F1	100.0	0	16.22±0.32	9561.267±1.10
F2	99.5	0.5	15.38±0.07	10506.03±1.05
F3	99	1	9.22±0.06	13811.33±1.52
F4	98.5	1.5	10.60±0.21	14198.97±1.05
F5	98	2	7.42±0.12	15001.33±1.53

Skin infections constitute a significant global health burden and are frequently complicated by antimicrobial resistance, mixed infections, and recurrence. Conventional topical therapies, although effective, are associated with adverse effects, resistance development, and limitations during long-term use. These challenges necessitate safer, broad-spectrum, and patient-friendly alternatives. The present study aimed to develop and scientifically validate a polyherbal topical formulation for the management of skin infections. Preliminary phytochemical screening revealed that hydroalcoholic extracts of *Ocimum sanctum*, *Rubia cordifolia*, and *Glycyrrhiza glabra* were rich in flavonoids, tannins, glycosides, triterpenoids, steroids, and alkaloids-classes of compounds known for antimicrobial, anti-inflammatory, and antioxidant properties. Although *Punica granatum* demonstrated phytochemical richness, mild dermal irritation observed during safety assessment led to its exclusion, prioritizing dermal safety in formulation development. Three ointment formulations (O1–O3) were developed with increasing extract concentrations. All formulations exhibited skin-compatible pH (5.6–5.8), acceptable viscosity, and good spreadability. Drug release studies demonstrated concentration-dependent diffusion, with O3 showing the highest release (82.1%). Stability studies under accelerated conditions revealed no significant changes in physicochemical properties or release profile, confirming robustness of the optimized formulation. Rheological analysis showed pseudoplastic (non-Newtonian) behavior, characterized by reduced viscosity under shear stress.

This property ensures ease of application and structural stability at rest, thereby improving patient compliance—an essential factor in long-term dermatological therapy. The polyherbal cream exhibited significant antimicrobial activity against common pathogens, particularly *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Importantly, the formulation demonstrated superior activity compared to individual extracts, confirming synergistic enhancement. This finding is clinically relevant given the increasing prevalence of resistant and mixed infections. In addition to antimicrobial action, the selected plant components provide complementary therapeutic benefits, including anti-inflammatory, antioxidant, skin-protective, and potential antidiabetic supportive effects. Unlike topical corticosteroids, which may cause skin thinning and systemic adverse effects, the developed formulation demonstrated dermal safety without irritation. Overall, the study successfully transformed traditional herbal knowledge into a standardized, optimized, and scientifically validated topical formulation. The synergistic antimicrobial efficacy, favorable physicochemical properties, stability, and dermal safety establish the developed polyherbal cream as a promising candidate for dermatological applications. Further in vivo and clinical studies are warranted to confirm therapeutic effectiveness and facilitate regulatory approval.

CONCLUSION

The present study successfully developed and optimized a scientifically validated polyherbal topical cream for the management of skin infections. The formulation demonstrated significant antimicrobial activity against all tested pathogens and showed superior efficacy compared to individual extracts, confirming synergistic phytochemical interaction. The optimized polyherbal cream exhibited desirable physicochemical characteristics, stable release profile, acceptable rheological behavior, and dermal safety without signs of irritation or toxicity. The absence of extract–excipient incompatibility further supports its formulation stability. Importantly, the developed formulation offers broad-spectrum antibacterial and antifungal activity along with complementary therapeutic benefits derived from its multi-component herbal composition. Such synergistic action may reduce dependence on multiple synthetic drugs, thereby minimizing the risk of adverse effects, resistance development, and polypharmacy-related complications. Overall, the polyherbal cream represents a promising, safe, and cost-effective alternative for dermatological applications. Further in vivo and clinical investigations are warranted to establish its therapeutic potential and facilitate translation into clinical practice.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

FUNDING

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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