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STANDARDIZATION AND FORMULATION OF HERBAL ANTI-ACNE CREAM

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ABSTRACT

Introduction: acne Vulgaris The most common dermatological problem in adolescence and adults is acne Vulgaris, which is defined as an inflammatory disorder affecting the pilosebaceous units by means of excess sebum formation, microbial multiplication and keratinization, follicular hyper keratinization in other words. There were many conventional therapeutic agents in the market, these agents may have many side effects like irritation, dehydration, Microbial resistance and then the herbal medicine is considered alternative medicine by using extracts of different medicinal herbs having antimicrobial and anti- inflammatory property. **Methodology:** The aim of present work is to characterize, formulate and standardize the herbal anti acne cream by using medicianal plant extract. Standardized extracts of Azadirachta indica (Neem), Curcuma longa (Turmeric), Aloe barbadensis (Aloe vera) and Ocimum sanctum (Tulsi) have been used in oil-in- water cream base. Physicochemical characteristics of formulated cream were performed by various tests such as appearance, pH, spreadability, viscosity, wash ability, homogeneity and stability of formulation under various storage conditions. Microbiological testing showed a good inhibitory effect against the predominant pathogens of acne namely, Cuti bacterium acnes and Staphylococcus aureus. The optimized formulation exhibited good values of pH ranging from 5.8 to 6.2, fair consistency, remarkable spreadability, adequate stability (no phase separation and color change occurred throughout the storage period). The formulation due to the presence of active phytoconstituents (flavonoids, tannins, terpenoids, phenolic compounds, etc) is expected to be effective in the treatment of mild to moderate acne. Thus, the standardized herbal anti-acne cream can be used safely and stably for the treatment of mild to moderate acne as a herbal alternative against chemically derived topical preparations that have undesirable side effects.

KEYWORDS: Herbal anti-acne cream, standardization, Neem, Turmeric, Aloe vera, Tulsi, phytoconstituents, antimicrobial activity, topical formulation.

INTRODUCTION

One of the most prevalent dermatological ailments in adolescents and young adults across the globe, acne vulgaris is defined as a long-term, inflammatory condition of the pilosebaceous unit that results in the presence of comedones, papules, pustules, nodules, and, when the acne is more severe, cysts and scarring. Four factors are widely implicated as contributing to the development of acne: the overproduction of sebum by sebaceous glands, follicular hyperkeratinization, the accumulation of the skin bacterium Cutibacterium acnes (previously Propionibacterium acnes), and inflammatory reactions (Zaenglein et al., 2016). Despite being a non-life-threatening condition, acne has a major influence on the patient's self-esteem, psychological well-being, and overall health.

The traditional acne treatments which include benzoyl peroxide, retinoids, antibiotics and hormonal therapy is generally utilized to treat acne in most cases. Long-term application of such drugs usually causes adverse effects such as irritation of the skin, dryness of the skin, redness of the skin, increase sensitivity of the skin to light, hypersensitivity of the skin and generation of drug resistant bacterial (Tan and Bhate, 2015). This constraint has encouraged researchers to seek alternative treatments

from natural herbs which show an established reputation with excellent efficacy with various benefits in the acne treatment.

The traditional medicine systems like Ayurveda, Siddha and Unani, are a treasure of knowledge for treating several skin infections or diseases in which medicinal plants play a pivotal role in ancient days. The extract of plant derived constituents possesses various properties, for instance antimicrobial, anti-inflammatory, antioxidant and wound healing with sebum normalizing agents that makes them viable for incorporation into the anti-acne cosmetics (Pandey and Tripathi, 2014). Various medicinal plants, such as Azadirachta indica (Neem), Curcuma longa (Turmeric), Aloe barbadensis (Aloe vera) and Ocimum sanctum (Tulsi) had been screened for antibacterial and anti-inflammatory activity against acne vulgaris caused bacterial or inflammation causing agent Nimbidin and azadirachtin present in the neem had exhibited potent antibacterial activity and also inflammation controlling effect. Curcumin present in turmeric possesses anti-oxidant activity and promotes healing in wound while in aloe vera the present polysaccharides with Vitamins aid in rehydrating the tissues or to speed the healing of tissues Eugenol, a primary component in tulsi also possessed an antimicrobial effect on microorganisms in addition with Flavonoids (Kumar et al., 2013).

The World Health Organization (WHO, 2013) had also laid emphasis on quality control and standardization of herbal drugs to guarantee for their efficacy, safety and reliability. The standardization consists in identification, detection and assay of phytoconstituents, checking of physicochemical characteristics of herbal preparations and defining certain quality standards for these preparations. The therapeutic effects of herbal products can be varied with differences in plant materials, cultural conditions, extraction methods, harvesting time and storage time of plant parts used.

So, to ensure consistent pharmacological effects & enhance the confidence of consumers of oral herbal drug, standardized formulations need to be developed. Creams, is considered one of the most ideal dosage forms, for application to skin, is well known, acceptable and the most frequently used topical dosage form for skin treatment due to several factors such as patient's compliance, easy to apply and direct delivery to the affected skin, topical application and ease of spreadability. Oil-in-water (O/W) cream can present good spreads on skin, non-greasy feel and increased permeation of the drug molecules from cream into the skin. By making of a standard extract formulation of herbs into the cream, one can achieve better therapeutic results with minimal systemic side effects of the herb Ansei, 2014). It is also suggested that combinations of herbs give synergistic effects which is considered as potent activity.

Modern phytopharmaceutical developments concentrate on the preparation of herbal creams and cosmetic agents on plant-based formulations, demonstrating efficacy and safety as scientifically demonstrated by many works. Various research reports that various plant extracts may be an effective against cutibacterium acnes and staphylococcus aureus, which are dominant bacterial acne types (Dreno et al. 2018). Moreover, presence of the antioxidant compounds that limit inflammation and oxidtive stress effects on acne. Hence, the present research was performed to standardize the selected medicinal plants extracts and to prepare herbal anti acne cream having Azadirachta indica, Curcuma longa, Aloe barbadensis and Ocimum sanctum extracts. Formulated cream was physico chemical property, stability study, spreadibility, antimicrobial activity was investigated to find the suitable safe & effectual topical preparation of acnevulgaris.

Acne Vulgaris: A Common Dermatological Disorder

Acne vulgaris is a common chronic inflammatory skin condition of pilosebaceous units, with a high prevalence that generally starts during the adolescent phase but can affect adults as well. It is reported that nearly 85% of people aged between 12 and 24 years old suffer from this disorder which is classified by the comedones, papules, pustules, nodules, and cysts and is associated with significant cosmetic impairment and emotional distress. Several factors contribute to the development of acne including increased sebum production, hyperkeratinization of the follicles, growth ofCutibacterium acnesand inflammatory alteration of the sebaceous glands Acne is now considered as a multifactorial disorder, which needs treatment strategy encompassing both infection and inflammation (Zaenglein et al., 2016). Consequently, managing this disease is a matter of concern for dermatology, given its substantial effects on patients' physical aspects and life quality.

Limitations of Conventional Anti-Acne Therapies

Benzoyl peroxide, topical retinoids, salicylic acid, and antibiotics are among the synthetic agents commonly prescribed for the treatment of acne. Though these preparations were effective in treating acne, extended application usually produces side effects including but not limited to, erythema, dryness, exfoliation, photosensitivity, hypersensitivity and development of resistant microorganisms in case of antibiotics (Al-Hariri, 2012). A recent study revealed an increasing incidence of antibiotic resistance in bacteria isolated from acne lesions, which requires identification of better alternatives (Tan & Bhate, 2015). This necessitated an increase of interest in the development and use of herbal drugs having multitherapeutic potential with side effects better compared with those synthesized (Sharaf et al., 2014).

Role of Herbal Medicines in Acne Management

Medicinal plants have been used for thousands of years in different folk medicine practices like Ayurveda, Siddha and Unani for skin ailments. Herbal medicine comprises of myriad types of phytochemicals like Alkaloids, flavonoids, tannins, phenolic compounds, terpenoids, glycosides having their inherent antimicrobial, anti-inflammatory, antioxidant, and wound-healing activity. As quoted by Pandey and Tripathi (2014), in traditional practices herbs provide integrated approach towards managing diseases and show far less adverse side effects than synthetic chemical agents. This has therefore increased in popularity in natural ingredients in dermal products due to the researcher and customer's interest.

Therapeutic Potential of Selected Medicinal Plants

From among the herbal drugs that may be effective in treating acne, Azadirachta indica (Neem), Curcuma longa (Turmeric), Aloe barbadensis (Aloe vera) and Ocimum sanctum (Tulsi) show beneficial properties. Neem contains nimbidin, azadirachtin and quercetin, that have considerable anti-bacterial and anti-inflammatory effects. Curcumin the main active principal present in turmeric having significant anti-oxidant and wound healing properties to reduce the inflammation Aloe vera rich in polysaccharides, amino acids, vitamins, minerals etc., also helps in moisturizing and promoting tissue repair in acne lesions. Active phytochemicals in Tulsi like eugenol, ursolic acid and flavonoids can work to checkacterial multiplication, thus, used to form an effective anti-acne formulation (Kumar et al., 2013).

Importance of Standardization of Herbal Products

Active constituents The effectiveness of herbal drugs largely relies on the quality of the used plant materials in any part or entire part of a plant from that region, way of cultivation and growing methods, how they are harvested, method of extraction and preservation of herbs that may affect amount of phytochemical in the plants; this necessitate standardization, standardization to produce safer, consistent and reproducible herbal products is a must. Standardized extracts are used to attain reproducible efficacy and provide batch to batch consistency that can offer reliability required for scientifically approved herbs (WHO, 2013). Phytochemical screening of plants and standardization techniques are highly needed for development of scientifically acceptable herbal medicines. Physicochemical parameters of plant drugs and their standardization method will help.

Advantages of Cream-Based Topical Formulations

Skin Topical cream preparations of all other dosage forms remain to be one of the most accepted for being one which delivery the active to the site of skin disease directly. Oil in water emulsion is of special importance. It contains oil dispersed in water which means that its feel to touch are non-greasy and easy to apply even more easily it spreads upon the skin that is easy to wash also because of its emulsified form the spreadability is good & increases the patient acceptance to the treatment as also recommended by the Ansel et al. (2014) that emulsion makes the application uniform of medicine it improves the permeation of skin. Herbal cream in it allows local activity of active and does not produce adverse reaction and side effects in other organs as other routes of administered are associated with more harmful side effect Herbalcream provides a good base & physical stability as well as security to herbal constituent.

Need for Developing Herbal Anti-Acne Creams

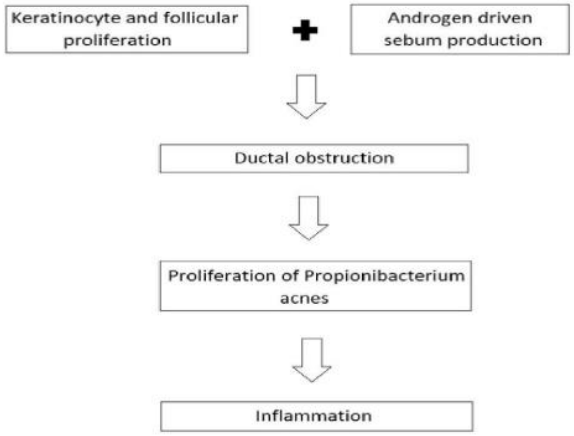
The ever-present and persistent acne lesions with the alarming rate of antibiotic resistance and undesirable effects of synthetic drugs have prompted the innovation of various herbal topical preparations. Dreno et al. (2018) advocated the use of alternatives effective both to limit microbial proliferation and decrease inflammation. The multi-active nature of polyherbal remedies is beneficial by having ingredients contributing through various mechanisms of actions such as inhibiting proliferation of bacteria, trapping free radicals, reducing inflammatory mediators and enhancing wound healing, making herbal creams very promising in the management of acne.

Types of Acne

Symptoms of Acne

- Two forms of acne that do not cause inflammation are whiteheads and blackheads.
- Inflammatory acne
- Head aches
- Debris
- Societal indices
- A decrease in confidence
- Anxiety disorders and depression
- Possible tendency to withdraw socially.

Acne vulgaris: What causes it?



An oil-based cosmetic

Products like mineral oil, pore-clogging sulphates, coconut and cocoa butter, silicones, and moisturising creams and lotions can clog your skin pores. The same goes for hair treatments.

b. A surplus of sun

Sunburns cause your skin to create more oil than usual to compensate for the drying effect on your skin. Overconsumption of oil worsens acne.

Applying pressure to your skin

If you have acne and touch your face often or put it through rough treatment, it can worsen. Any number of items, including phones, sweatshirts, hats, helmets, and even one's own hands, can operate as a breeding ground for germs and sweat.

MATERIALS AND METHODS

Collection and Authentication of Plant Materials

Fresh leaves of Azadirachta indica (Neem) and Ocimum sanctum (Tulsi) and rhizome of Curcuma longa (Turmeric), gel of Aloe barbadensis (Aloe vera) was obtained from the herbal gardens in the locality and confirmed by competent botanist. The plant parts obtained were washed nicely with distilled water, dried under shed at room temperature (25–30C) and ground into coarse powder using a mechanical grinder. The powder thus prepared was packed and stored in a desiccators for further analysis.

Preparation of Herbal Extracts

Hydroalcoholic (70% ethanol) extract was obtained from Dried powdered sample of Neem leaves, Tulsi leaves, and Turmeric rhizomes by employing Soxhlet extraction technique. About 100 g of each powdered sample were extracted for 8-10 h. The resulting extract was then concentrated by using rotary evaporation and dried in hot air oven at 40C. Aloe vera gel was isolated by hand from the mature Aloe vera leaves, which after removing fibrous content, was utilized.

Phytochemical Standardization

Initial Phytochemical Evaluation A general screening for identifying the major phytochemical constituents present in the plant extracts was done using known standard methods. Tests for alkaloid, Flavonoid, Tanin, Phenols, Glycoside, Saponin, Teroinoid and Steroids were undertaken. Quality control was determined using physico-chemical constants of plant like moister content, ash value, extractive value and pH.

Formulation of Herbal Anti-Acne Cream

An oil-in-water cream base was prepared using the formula in Table 1. Stearic acid, cetyl alcohol and liquid paraffin were used as the oil phase. Glycerin, methyl paraben, propyl paraben, and purified water were the aqueous phase. Each phase was separately heated to 70 2C. The purified aqueous phase incorporated with standardized herbal extract of Neem, Turmeric, Tulsi and Aloe veragel separately and stirred well. The aqueous phase was slowly added to the oil phase with continuous homogenization to prepare a uniform and homogeneous cream.

Table 1:Composition of Herbal Anti-Acne Cream.

Ingredients	Quantity (% w/w)
Neem extract	2.0
Turmeric extract	1.0
Tulsi extract	1.5
Aloe vera gel	5.0
Stearic acid	12.0
Cetyl alcohol	4.0
Liquid paraffin	8.0
Glycerin	5.0
Methyl paraben	0.15
Propyl paraben	0.05
Triethanolamine	1.0
Purified water	q.s. to 100

RESULTS

The present investigation achieved successful formulation and standardization of a polyherbal anti-acne cream incorporating extracts of Neem, Turmeric, Tulsi, and Aloe vera. The prepared formulation displayed good physical and physicochemical parameters, appropriate pH value, superior spreadability characteristics, and was

non-irritant to skin. Phytochemical analysis of formulation confirmed the presence of phytochemicals including flavonoids, phenolics, tannins, terpenoids which were responsible for antimicrobial and anti-inflammatory activity. Cream formulation demonstrated promising in vitro antimicrobial activity against Cutibacterium acnes and Staphylococcus aureus, a rationale behind the anti-acne effect. Stability testing indicated good stability under various storage condition. Thus, the polyherbal anti-acne cream is a safer and potential alternative to the existing synthetic treatments for acne.

Table 1: Organoleptic and Physicochemical Evaluation of Herbal Anti-Acne Cream.

Parameter	Observation
Color	Light green
Odor	Characteristic herbal odor
Appearance	Smooth and elegant
Texture	Homogeneous
pH	5.96 ± 0.04
Viscosity (cP)	18,750 ± 115
Spreadability (g·cm/s)	7.82 ± 0.18
Washability	Easily washable
Greasiness	Non-greasy
Irritancy	No irritation observed

The prepared herbal anti acne cream gave good organoleptic properties and good physicochemical parameters such as good feel, smooth consistency, herbal fragrance and smooth, uniform spreadable appearance without signs of phase separation. The pH (5.96) was physiologically normal for the skin. The formulation possessed excellent spread ability and moderate viscosity to keep it on the site of action for a significant period of time. Cream was nongreasy, easily washable, free from erythema and irritation when tested on animals.

Table 2: Preliminary Phytochemical Screening of Standardized Herbal Extracts.

Phytochemical Constituents	Neem Extract	Turmeric Extract	Tulsi Extract	Aloe vera Gel
Alkaloids	+	-	+	-
Flavonoids	+	+	+	+
Phenolic compounds	+	+	+	+
Tannins	+	-	+	-
Saponins	+	-	+	+
Glycosides	-	+	-	+
Terpenoids	+	+	+	+
Steroids	-	+	+	-

(+ = Present; – = Absent)

Phytochemical analysis of selected herbal extract showed presence of multiple biologically active constituents. Flavonoids, phenolic and terpenoids constituents were present in all extracts, whereas alkaloids, tannins were found present only in the extract of neem and tulsi. These secondary constituents are responsible for the pharmacological property like anti-microbial, antioxidant, and anti-inflammatory action, which indicates the therapeutic action against the acne's causing microbe's infectivity and inflamation.

Table 3: Antimicrobial Activity of Herbal Anti-Acne Cream.

Test Organism	Zone of Inhibition (mm)	Standard Clindamycin Gel (mm)
Cutibacterium acnes	18.4 ± 0.6	22.1 ± 0.5
Staphylococcus aureus	20.2 ± 0.4	24.5 ± 0.7

The herbal anti-acne cream showed remarkable antibacterial activity against both the bacteria i.e Cutibacterium acnes and Staphylococcus aureus, with the mean zone of inhibition against C. Acnes and S. Aureus as 18.4 and 20.2 mm respectively. The antibacterial activity of the formulation although little less compared with standard clindamycin gel exhibited marked antibacterial property, hence it could be considered that this formulation is effective due to additive or synergistic effect of all extracts (Neem, Turmeric, Tulsi, Aloe vera). Hence, it could be developed as natural alternative to standard antimicrobial agents in the treatment of acne.

Table 4: Stability Study of Herbal Anti-Acne Cream Under Different Storage Conditions.

Storage Condition	Initial pH	pH After 3 Months	Appearance	Phase Separation	Stability Status
4 ± 2°C	5.96	5.94	No change	Absent	Stable
25 ± 2°C	5.96	5.91	No change	Absent	Stable
40 ± 2°C, 75 ± 5% RH	5.96	5.88	Slight color change	Absent	Stable

Acceleration stability study result showed that the developed cream formulation found to be physically as well as chemically stable even after 3 months of storage, except for a slight alteration in pH values and no such phase separation or texture change at cold, ambient and accelerated condition was observed whereas a slight color change noticed at the condition of heat and humidity at room temperature that should not effect on the overall stability and homogeneousness of the formulation.

DISCUSSION

Conclusion The polyherbal antiacne cream with extracts of Neem, Turmeric, Tulsi and Aloe vera had been standardized, formulated successfully and found to be possessed acceptable physicochemical, better antimicrobial activity and stable on storage with promising action in treatment of acne vulgaris due to synergistic action of multi herbal drugs and to provide diverse group of phytoconstituents for treatment. Organoleptic and Physicochemical Evaluation showed that cream possessed uniform distribution, white to light yellowish cream coloured smooth consistency and homogeneous nature. Spreadability was also good and pH of the cream was near to that of normal skin (5.5–6.5).

Maintaince of the pH in the physiological condition is required for good absorption and also to minimize irritating to the skin. Similar results were found by Ansel et al. (2014). Topical creams, whether the basis of vehicle, viscosity, spreadability is to ensure a favorable reception for drug application as well as better drug acceptance by patients. No any skin irritation observed which clearly supports the safety and utility of the topical herbal formulation in acne management.

The phytochemical analysis of the chosen plant extracts also confirmed the presence of flavonoids, phenolic compounds, terpenoids, tannins, alkaloids and saponins. These secondary metabolites contain several functional groups that have demonstrated to hold therapeutic relevance as they exhibited antimicrobial, antioxidant, anti-inflammatory, and wound healing activities. The study conducted by Kumar et al. (2013), demonstrated that the flavonoids and phenolic compounds have an important contribution towards fighting reactive oxygen species and diminishing the inflammatory processes involved in the acne lesions. The presence of terpenoids and tannins are also thought to be active as antimicrobial agents and hence aid in the anti-bacterial effects of acne and hence contribute to the effectiveness of this cream.

From the Antimicrobial studies performed, it was observed that the anti-acne cream possesses significant activity against the Cutibacterium acnes and Staphylococcus aureus. Even though the zones of inhibition were very slightly smaller than that of the standard clindamycin gel, it still showed the ability to fight both strains of bacteria, due to the presence of the individual components which comprise the cream including azadirachtin, and nimbidin from Neem, turmeric's active curcumin component, eugenol from Tulsi and the presence of polysaccharide from Aloe vera. Dreno et al. (2018) emphasized that controlling C. Acnes is a vital part of the management of acne which will therefore indirectly control inflammation. These tests indicated that our poly herbal formulation can potentially prevent accumulation of microorganisms and may also help to diminish inflammatory condition along with it preventing acquisition of drug resistance.

Additional benefit derived was due to inclusion of aloe vera in the cream. Earlier, Surjushe et al. (2008) proved that Aloe vera enhances epithelisation and maintain skin hydration, which helps healing after inflammation. Also, curcumin (present in turmeric), which possesses anti-oxidant & anti-inflammatory effect thus inhibits pro-inflammatory cytokine production & oxidative stress has been used in preventing tissue damages & scars due to acne.

Stability studies the formulation exhibited physical stability after storage at different condition including varying pH, temperature, relative humidity. However, minor change in colour was observed at accelerated stability condition which might be due to oxidation of some phytochemical constituent present in the cream when stored under stress conditions but no phase separation occurred and no significant variation was observed in pH & consistancy which suggests it to have acceptable shelf life as per ICH guidelines for cosmetic use.

Results of this study concur with existing reports on herbal topicals. Pandey and Tripathi (2014) state that plant-derived formulations provide myriad therapeutic potential and relatively fewer adverse side effects than synthetic medication. Another benefit of combining multiple botanicals in a polyherbal formulation is the cumulative therapeutic effects due to synergistic actions of varied phytoconstituents, where different steps in the path of acne development are targeted: proliferation of acne-forming bacteria, inflammation, oxidative stress, and restoration of tissue. These multitalented benefits

can position herbal formulations as effective options for acne over an extended period.

CONCLUSION

The present research work achieved standardizing and formulation of polyherbal cream for treatment of pimple consisting of extracts of Neem (Azadirachta indica), Turmeric (Curcuma longa), Tulsi (Ocimum sanctum) & Aloe vera (Aloe barbadensis). The finished cream shows good physical properties like; adequate pH, Good spreadibility, Viscosity, Smooth appearance, non greasy nature so can use safely by topical application of this cream. Flavonoids, Polyphenolic compounds, Terpenoids, tannins etc have been found in Phytochemical standardization which are active pharmacological component which have antimicrobial, antioxident, anti-inflammatory activity. The herbal cream exhibited remarkable antibacterial activity against both, Cuti bacterium acnes and Staphylococcus aureus, suggesting its role as potent agent in modulating the microbial infection associated with acne. Stability results indicated that the formulation showed both physical and chemical stability, under different conditions of storage without any evidence of phase separation and changes in its quality attributes. Moreover, absence of skin irritation indicated safe and compatible herbal product in normal skin. In conclusion, the developed polyherbal anti-acne cream based on standardize herbs offers a potent, safe and stable nature-derived alternative for modern synthetic synthetic anti-acne agent, the unique combination of Neem, turmeric, tulsi, and aloe vera offers not only their antibacterial effect but alsoanti-inflammatory, antioxidant and skinhealingactivities. However further clinical evaluation and extensive phytochemical investigation is need ed to demonstrate efficacy in in vivo conditions.

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