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RESEARCH OF FORMULATION AND EVALUATION OF ANTI-ACNE GEL

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Abstract:

The herbal ball has been used as a Thai traditional medicine for relieving many diseases including acne. However, the application process of the herbal ball in practice is complicated and time consuming. The objective of this work was to utilize an herbal ball extract to formulate a gel to reach a more favorable use of the herbal ball for acne treatment. An herbal ball consisting of the Benchalokawichian remedy and the stem bark powder of was prepared. The obtained herbal ball was steamed and squeezed to obtain the extract. Gel formulations containing the herbal ball extract at concentrations of 0.1, 1 and 5% w/w were prepared based on a carbomer gel. The herbal ball extract had antioxidant and anti activities and minimum bactericidal concentration The 5% w/w gel formulation had antimicrobial activity against P. acnes, showing an inhibition zone value of This indicates that the developed gel formulation has potential for acne treatment. In comparison to the traditional method of herbal ball usage, the application of herbal ball extract in the form of gel should be more convenient to use.

Introduction

Acne vulgaris, known as acne, is a common chronic disease caused by abnormal sebaceous production within skin follicles. This disease often affects selfconfidence. The pathological feature of acne starts when abnormal sebaceous therapeutics for acne treatment, they have a lot of side effects caused by chemical ingredients in the cosmetic products, which frequently result in skin irritation and bacterial resistance problems. Recently, many reports have demonstrated that natural active compounds such as proteins or peptides derived from plants and animals display anti-acne properties with low toxicity to humans . Hence, many efforts have been made to use these compounds in the context of supplementary cosmetic products.

Tropical regions, particularly Southeast Asia, are a rich source of biodiversity, especially with high varieties of medicinal plant and animal extracts . One medicinal derivative from animals is crocodile blood, a rich source of active proteins or peptides that demonstrate various biological properties . Previous reports have shown that crocodile blood components, such as the serum of the American alligator exhibit antibacterial activity against Escherichia coli, and is anti- virus In addition ,our reports demonstrate that Siamese crocodile blood had antibacterial activity, especially crocodile leukocytes. There are peptides that have been discovered from Siamese crocodile leukocyte extracts, These peptides exhibit broad- spectrum antimicrobial activity. Moreover, crude crocodile leukocyte extract contains several biological properties, such as antioxidant activity and anti-inflammatory activity . Crocodile leukocyte extract is believed to represent a source of biologically active peptides, which may be suitable for developing a crocodile leukocyte-based cosmetics product as an anti-acne gel. Thus, in this study, the feasibility of preparing crocodile leukocyte extract anti-acne skin-care gel products assessed.

Preparation of gel

The weighed amount of methyl paraben was dissolved in 5ml of hot water and propyl paraben was added on slight cooling of water. To this beaker carbopol 934 was dispersed with continous stirring for 20 min after addition of 50 ml of distilled water. This dispersion was kept overnight for soaking. In another beaker the required quantity of propylene glycol and polyethylene glycol (PEG 400) were added. This mixture along with concentration of aqueous extract corresponding to its MIC was incorporated to carbopol beaker with stirring. The volume was made up with distilled water and stirring was done vigorously. Triethanolamine was added form the gel by adjusting pH to 6.8

Antibacterial Activity Studies for the Gel Formulations

All the gel formulations were dissolved in methanol for the determination of the antibacterial activity against S. aureus and P. acnes. The agar well diffusion method was employed to determine the antibacterial effect of the gel formulations against S. aureus following the method described in A synthetic commercial antiacne gel was used as the positive control, and the gel base and methanol were used as the negative controls. Thereafter, the MIC of these formulations was determined by the broth microdilution method in microtitre plates following the method described in The assay was conducted in triplicate. The agar well diffusion assay

was employed under anaerobic conditions for the determination of antibacterial activity against P. acnes. were prepared using a sterilized cork borer in the blood agar plates which have been inoculated with clinical isolates of P. acnes obtained from the Medical Research Institute, Sri Lanka. The wells were filled with each of the test formulations, and the agar plates were incubated at 37°C for 48 hours in an anaerobic jar and the zones of inhibition were measured after the incubation. A commercial antiacne gel was used as the positive control while the gel base and methanol were used as the negative controls. The experiment was conducted in triplicate.

Stability of the Physical Parameters and Antibacterial Effect of the Formulations

The stability of the physical parameters (color, odor, homogeneity, washability, consistency, and pH) of all three formulations was evaluated at day 30 after the formulation of gels (storage conditions: temperature $30 \pm 2°C$ and relative humidity $75 \pm 5\%$). The antibacterial activity against S. aureus was also evaluated at day 30 in order to determine whether the gel formulations are capable of retaining their antibacterial potential over a period of time during storage.

PLAN OF WORK: -

1. Literature survey.
2. Selection and Procurement of Herbal Material.
3. Selection and procurement of excipients.
4. Material and Equipment's / Instruments.
5. Evaluation of Gel:- 6. Measurement of pH.
7. Drug of Content.
8. Viscosity Study.
9. Spread ability.
10. Extrudability Study.
11. Skin Irritation Study.
12. Stability.
13. Homogeneity.
14. Grittiness.

HERBAL MEDICINES

World health organization defines traditional herbal medicinal products as homegrown medicinal products or plant-derived substances the herbal drug industry in India is probably the oldest medical care system in the world. The herbal healing has been mentioned from the ancient era, from vedas , and even from ancient religious work. Probably it is the oldest medical care system in the world. The herbal healing deals with use of herbs, herbs extract's or natural products for the betterment of health condition herbal products are more acceptable with belief that they are safe posse's many therapeutic properties and having no or less side effects as comparing to modern chemical entities.

TOPICAL DRUG DELIVERY SYSTEM

The goal of any drug delivery system is to provide a therapeutic amount of drug to the proper site in the body to promptly achieve and then maintain the desired drug concentrations . skin is one of the most readily accessible organs on human body for topical administration and is main route of topical drug delivery system. Topical delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorders (e.g. Acne) or the cutaneous manifestations of a general disease (e.g. Psoriasis) with the intent of containing the pharmacological or other effect of the drug to the surface of the skin or within the skin.

GEL

A gel is a two-component, cross linked three-dimensional network consisting of structural materials interspersed by an adequate but proportionally large amount of liquid to form an infinite rigid network structure which immobilizes the liquid continuous phase within. The structural materials that form the gel network can be composed of inorganic particles or organic macromolecules, primarily polymers.

simple gel

Cross links can be formed via chemical or physical interactions. This leads to gel classification into chemical and physical gel systems, respectively. Chemical gels are associated with permanent covalent bonding while physical gels result from relatively weaker and reversible secondary intermolecular forces such as hydrogen bonding, electrostatic interactions, dipole di-pole interactions, Vander Waals forces and hydrophobic interactions. Gels consist of two phase system in which inorganic particles are not dissolved but merely dispersed throughout the continuous phase and large organic particles are dissolved in the continuous phase, randomly coiled in the flexible chains.

Advantages: -

1. Avoidance of first pass metabolism.
2. Convenient and easy to apply.
3. Improving physiological and pharmacological response.
4. Improve patient compliance.
5. Provide suitability for self-medication.

Disadvantages: -

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

2. Poor permeability of some drugs through the skin.
3. Possibility of allergenic reactions.

GEL FORMING SUBSTANCES

Polymers Are Used To Give The Structural Network, Which Is Essential For The Preparation Of Gels.

Gel Forming Polymers Are Classified As Follows:

Natural Polymer •

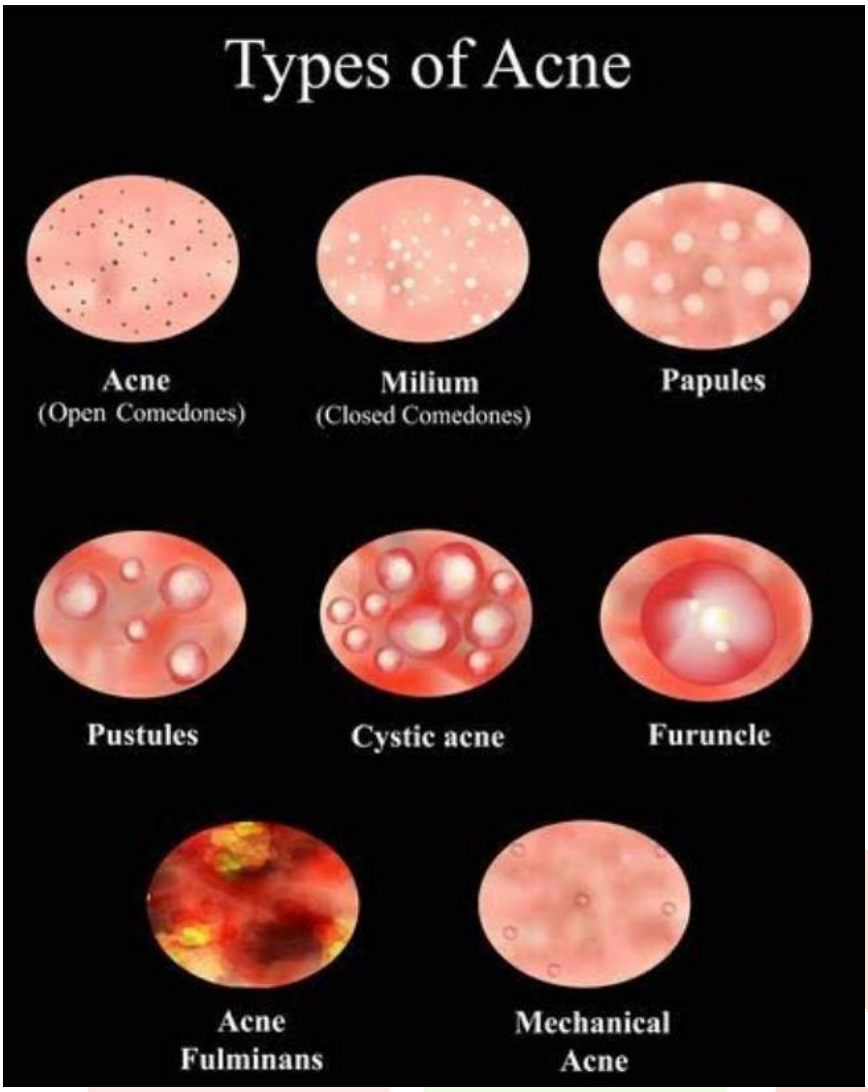
A. .Proteins I. Gelatin Ii. Collagen
B. Polysaccharides I. Alginic Acid Ii. Agar Iii. Tragacanth IV. Sodium Or Potassium Carrageenan V. Pectin Vi. Gellum Gum Vii. Xanthin Viii. Cassia Tora Ix. Guar Gum

Semi-synthetic Polymers

A. Cellulose Derivatives I. Hydroxyethyl Cellulose Ii. Methylcellulose Iii. Hydroxypropyl Methyl Cellulose IV. Hydroxypropyl Cellulose V. Carboxymethyl Cellulose.

Synthetic Polymers:

A. Carbomer I. Carbopol -941 Ii. Carbopol -940 Iii. Carbopol -934 B. Poloxamer C. Polyvinyl Alcohol D. Polyacrylamide E. Polyethylene And Its Co-polymers
B. Inorganic Substances A. Bentonite B. Aluminum Hydroxide
C. Surfactants A. Brij-96 B. Cetostearyl Alcohol.



ADVANTAGES OF GEL FORMULATIONS: -

I) Gels Are Easy To Formulate As Compared To Other Semisolid Dosage Forms.

Ii) A Gel Is An Elegant Non-greasy Formulation.

Iii) It Can Be Used As Controlled Release Formulation By Entwining The Polymer More Than Once.

Iv) Gels Have Good Adherence Property To The Site Of Application. V) They Are Biodegradable And Biocompatible.

Vi) The Retention Time Of Gels Is Higher Than Other Topical Dosage Forms.

Vii) They Have Excellent Tolerability To Certain Stress Conditions.

Viii) They Form A Protective Layer On The Application Site.

DISADVANTAGES OF GEL FORMULATIONS:

I) The Effect Of Gels Is Comparatively Slower And Sustained.

Ii) The Additives Or The Gelators May Induce Irritation.

Iii) The Water Content May Increase The Chances Of Microbial Or Fungal Attack In Gels.

Iv).Syneresis (Expulsion Of Solvent From The Gel Matrix) May Occur In Gels During Storage.

V) Solvent Evaporation From The Formulation May Result In Drying Of The Gel.

Vi).Covalent Bonds Present In Some Gels May Render Them Unbreakable

Thus Sealing The

Medicament Inside The Gel Matrix.

Vii) Flocculation In Some Gels May Produce An Unstable Gel.

SKIN

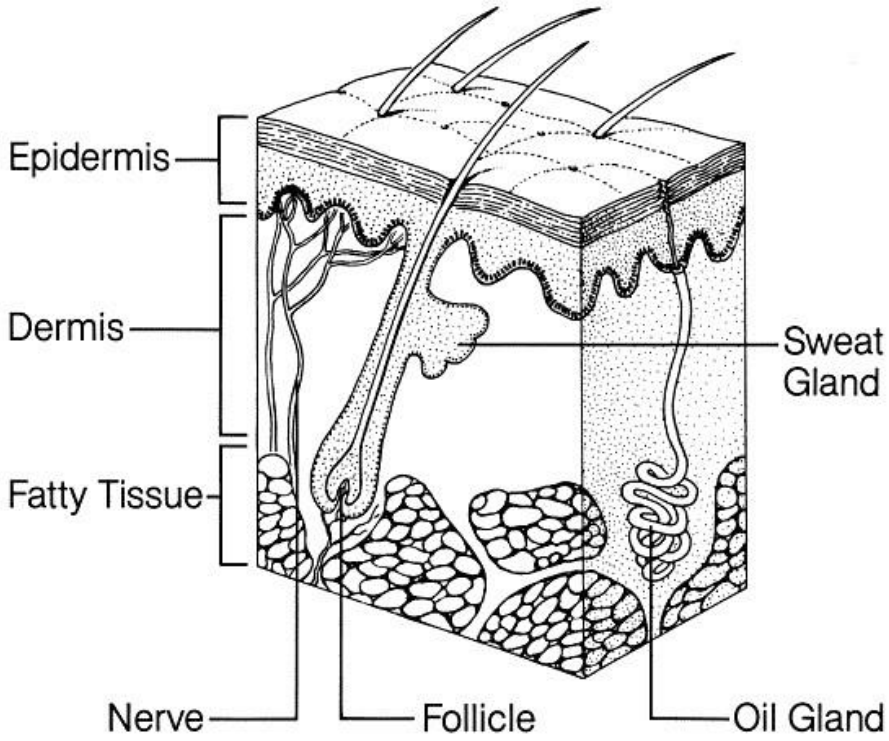
- Skin Is The Largest Organ In The Body.
- Microscopically Skin Is Composed Of Three Main Histological Layers: Epidermis, Dermis And Hypodermis (Subcutaneous Layer). At The Skin Surface,

  Drug Molecules Come In Contact With Cellular Debris, Microorganisms, And Other Materials, Which Effect Permeation. The Applied Medicinal Substance Has

  Three Pathways To The Viable Tissue-

1) Through Hair Follicles,
2) Via Sweat Duct Sand
3) Across Continuous Stratum Corneum

   Between The Appendages.



Objectives of work: -

The objective of the study was: -

✓To develop a topical gel for the treatment of acne vulgaris.

✓To restore the skin moisturization.

✓To reduces the signs of ageing.

✓To reduces skin pigmentation and regulates oil balance.

✓To promotes healthy re-growth of the skin cells.

✓To remove pigmentation marks.

✓To protects skin from harmful VU-rays.

✓To improve physiological and pharmacological response.

✓To improve patient compliance.

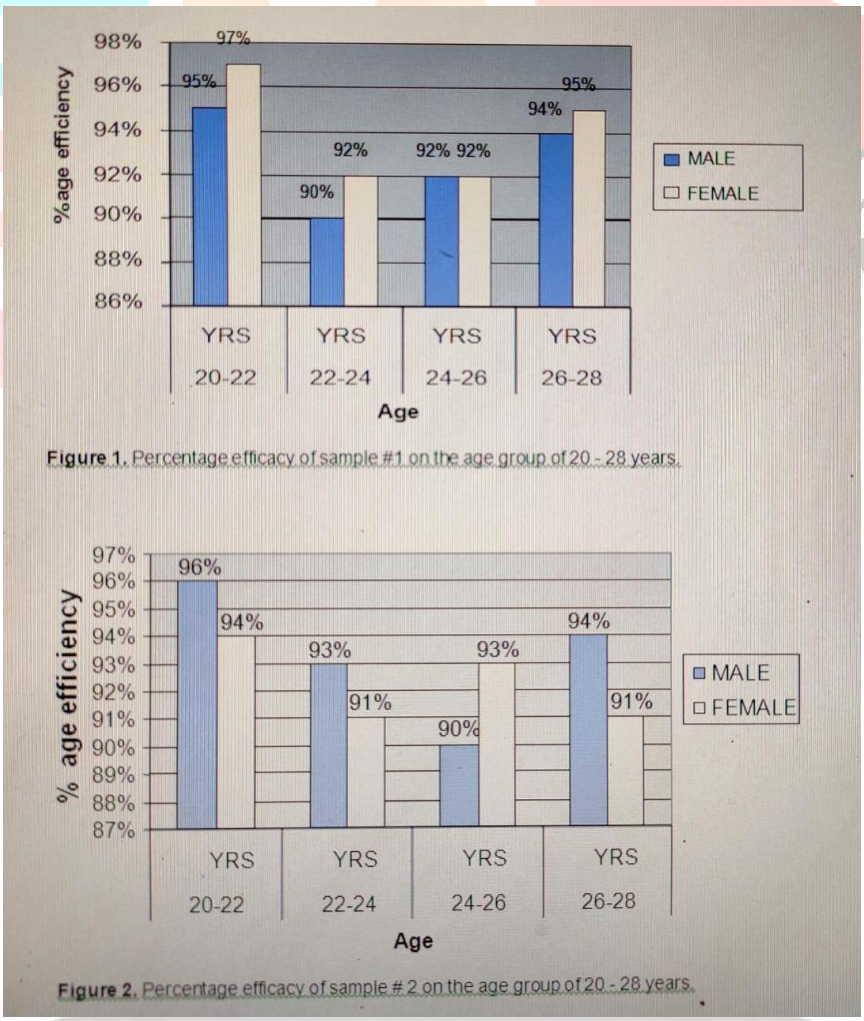


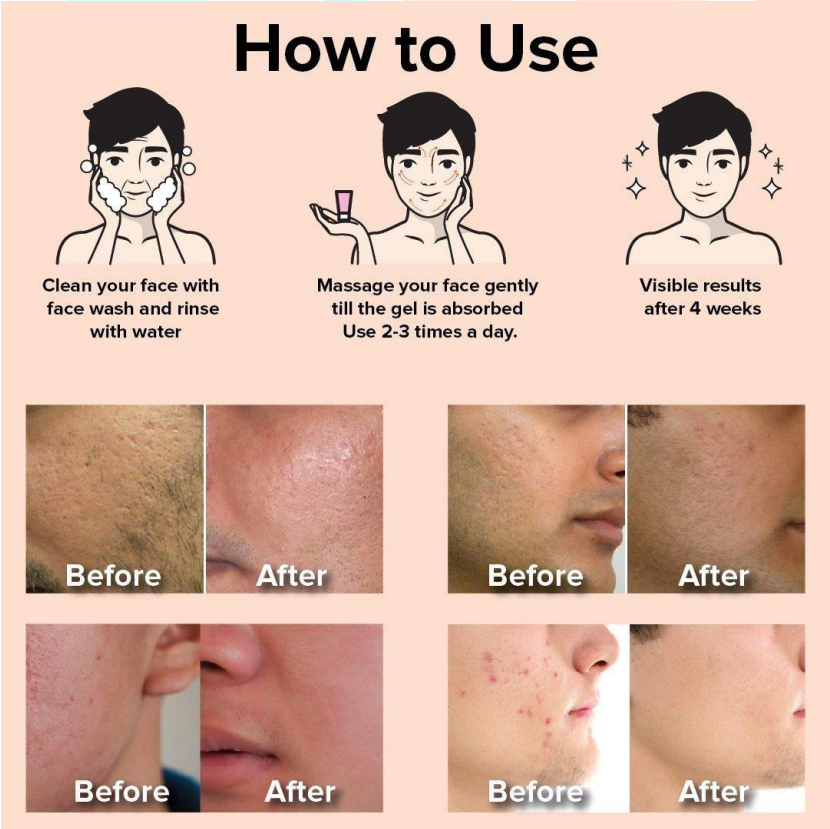
Figure 1. Percentage efficacy of sample #1 on the age group of 20 - 28 years.

Figure 2. Percentage efficacy of sample # 2 on the age group of 20 - 28 years.

Drug and excipient profile: -

SR. NO	DRUG EXCIPENTS	CATEGORY	PROPERTIES	USE	GREAD NAME
1	HPMC	Thickening agent, Solubilizing agent, viscosity increasing agent.	Soluble in water insoluble in diethyl ether, acetone.	To treat dry eyes and eye irritation.	
2	Methyl paraben	Preservative, acids, carbocyclic, benzene derivative.	Colorless, odorless, slight burning taste. slightly soluble in water very soluble in ethanol	It is used for Preservative , cosmetics , eye solutions.	
3	Propyl paraben	Preservative, acids, carbocyclic, benzene derivative.	Colorless crystal or white powder. Odorless freely soluble in alcohol slightly soluble in boiling water and chloroform.	Used against bacteria. Antiseptics and antimicrobial. pharmaceutical industry.	

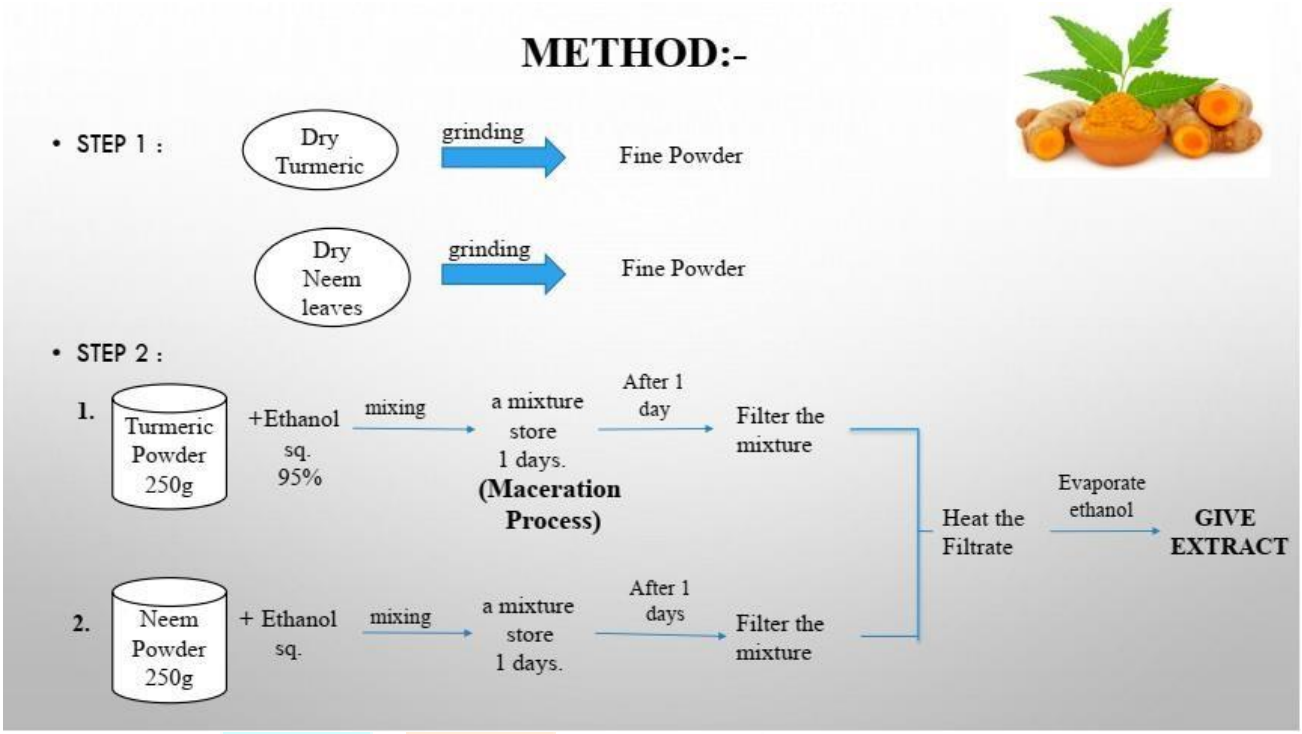
Sr. No.	Drug Excipient	Category	Properties	Uses	Gread Name
4	Propylene Glycol	Antifungal agent.	Colorless, odorless, Soluble in organic solvent.	Moisturizing agent, Lubricant, Antifungal agent.	
5	Triethanolamine	Adhesive and binding agent.	Miscible with water, Methanol, acetone. Soluble in benzene. Pale yellow viscous liquid, ammonia odor.	Antifoam agent, Softening agent, Emulsifier and plasticizer, Used as wood and paper processing.	



Sr no.	Herbal medication /	Synonam e	B.S	Properties	use	Marketed Prepration
1	Turmeric	Haldi	Dried rhizomes of *curcuma longa linn.* **FAMILY:** Zingiberacea e	Yellowish to yellowish brown odour aromatic taste practically insoluble in water. Soluble in methanol.	Antiinflammatory , antioxidant and antibacterial properties of the skin	Mamaearth (Turmeric gel). Himalaya turmeric gel
2	Neem	Azadiracht a indica	Dried leaves of azadirachta indica A. Juss. **FAMILY:** Meliaceae	Characteristi c odour and bitter taste.	Used for leprosy Eye disorder Stomach pain	Organic neem. Four seasons Ayurveda neem iol.

Material and Method: -

SR. NO	MATERIAL	USE	M.P
1	HPMC (Hydroxy propyl methyl cellulose)	Polymer , Treat dry eyes and eye irritation	°C
2	Methyl paraben	Preservatives to give longer shelf life, prevent the growth of bacteria	125-128°C
3	Propyl paraben	Preservatives to give product longer shelf life	96-99°C
4	Propylene Glycol	Prevent the dry	°C
5	Triethanolamine	Adjest the PH Used as antifoam agent , softening agent	21.60°C
6	Turmeric	Anti-inflammatory, antioxidant	183°C
7	Neem	Leprosy , Eye disorders, intestinal worms, stomach upset , Skin ulcers.	



Evaluation test: -

a) Measurement of pH :

pH was measured using a digital pH meter within 24 hrs of preparation **b) Wash-ability:**

Formulations were applied on the skin and then ease and extent of washing with water were checked manually.

c) Viscosity Study:

The viscosity of face wash was determined by using Brookfield Viscometer. The
Values Obtained for sample is noted. And laboratory scale Ostwald viscometer used.

d) Stability:

The optimized gel formulations were prepared; packed in aluminum collapsible tubes and subjected to stability studies at 400 C/75% RH for a period of 3 month as per ICH Guidelines.

e) Homogeneity:

All developed gels are tested for homogeneity by visual inspection after the gels have been set in the container. They are tested for their appearance and presence of any aggregates. **f) Spread-ability:**

$$S = M \times L / T$$

Where, S= Spreadability

M= weight in the pan (tied to upper slide),

L= Length moved by the slide,

T= Time (in sec.) **g) Skin Irritation Study.**

Conclusions:

Many plants seem to have inhibitory effects on the growth of bacteria, fungi and viruses in vitro. However, there are a few clinical evidences about the effectiveness and safety of these plants in the treatment of acne and other skin infections.

Keywords: Acne Vulgaris, Medicinal Plants, Herbal Medicines, Infectious Disease, Skin Diseases

Results:

Consumption of alternative and complementary medicine, including medicinal plants, is increasing and is common amongst patients affected by acne and infectious skin diseases. Medicinal plants have a long history of use and have beern shown to possess low side effects. These plants are a reliable source for preparation of new drugs.

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