

# project similarity

by Madhuri Gaikwad



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## ANTI-ACNE FORMULATION

Submitted in partial fulfillment of the requirements for the degree of Bachelor of  
Pharmacy

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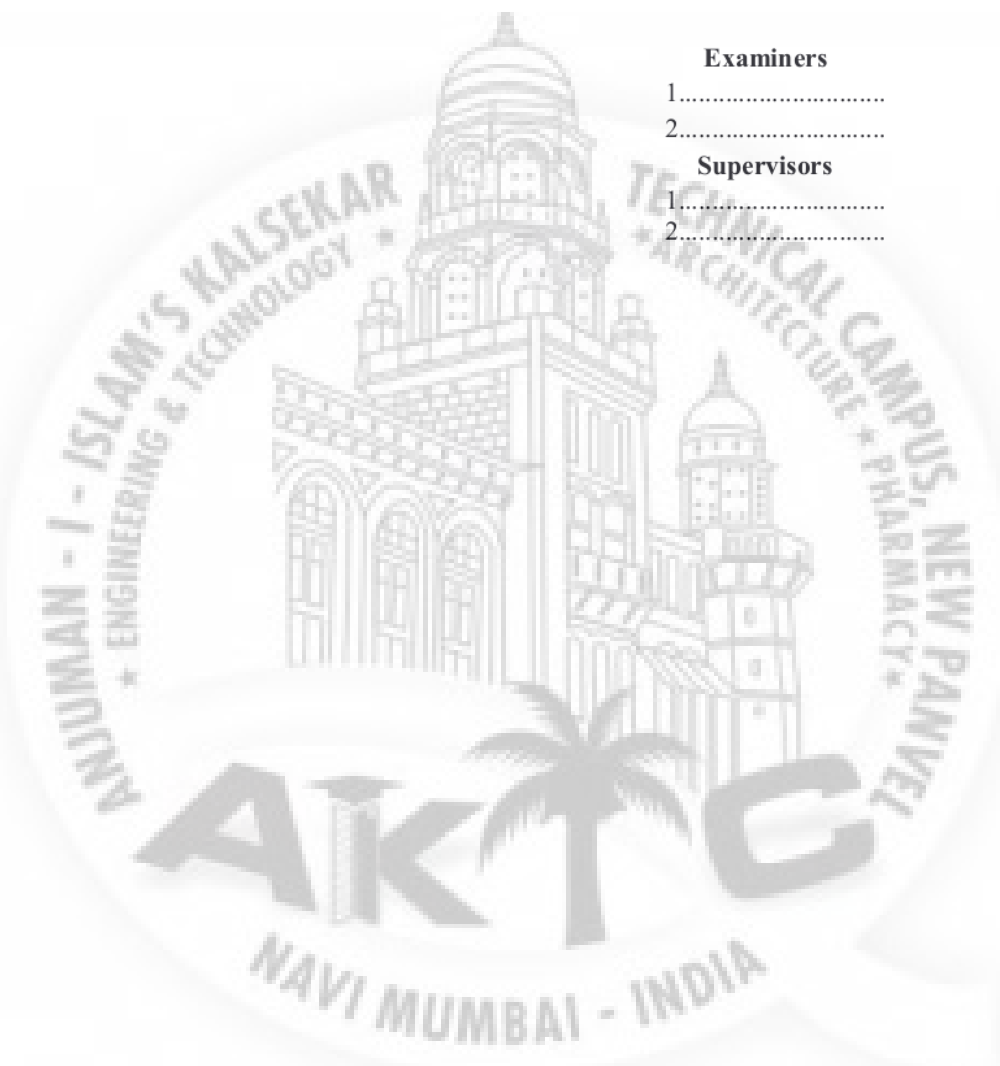
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### Declaration

I declare that this written submission represents my ideas in my own words and where others ideas or words have been included, I have adequately cited and referenced the original sources. I also declare that I have adhered to all principles of academic honesty and integrity and have not misrepresented or fabricated or falsified any idea/data/fact/source in my submission. I understand that any violation of the above will be cause for disciplinary action by the Institute and can also evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been taken when ended.

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### ABSTRACT

Acne often debuts during changes in hormonal level in pre-teens and also caused by the bacteria *P. Acnes*. The isolation of the herbal active principle and the determination of their structure, in order that they are synthesized or simply extracted more efficiently. Allopathy means modern scientific medicine which leads to adverse drug reaction as allopathic drugs are in chemical form. As Dr. Manoj Nesari joint adviser department of Ayush states that "there is rising trend towards Ayurveda". And the demand for herbal products world-wide has increased at an annual rate of 8%. Manjistha commonly known as *Rubia Cordifolia* works on *P. Acnes* and its anthraquinone rich constituent also contains anti-inflammatory, anti-bacterial and anti-oxidant property. The cream, gel and ointment formulations are prepared using alcoholic, water and alcoholic extract respectively. The formulations are characterized and evaluated on the basis of its organoleptic properties, pH values, viscosity measurement, spreadability, stress testing and determination of invitro anti-acne activity. The organoleptic properties shows that the formulations are cosmetically appealing. Cream was found to be oil soluble and pH values of formulations was found to be stable after 2 weeks. Viscosity was found to be 1500-2000 cp. Spreadability of formulations was found to be in range of 10-25 mm. Stress testing shows that the formulation has good shelf-life. And the antimicrobial activity is compared between cream, gel and ointment.

#### Key words

Acne, *P.acnes*, herbal products, Manjistha, anti-inflammatory property, anti-bacterial property, anti-oxidant, property, gel, cream, ointment, anti-acne activity, anti-microbial activity.

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Keywords and Glossary:

Topical formulations, anti-acne property, anti-microbial property, anti-bacterial property, anti-inflammatory property, anti-oxidant property, Manjistha, kokum butter, extracts, evaluation.

## **1.INTRODUCTION**

### **1.1 INTRODUCTION TO ACNE<sup>1</sup>:**

A medical term acne vulgaris is a skin disease where in oil glands are accumulated with dead skin cells and oil and these oil glands are located at the hair follicles. The part of skin which are rich in number of oil glands are affected the most specially the areas of face, back and upper part of chest. The principle characteristics of this disease production of oily sebum are blackheads, whiteheads, pimples, excess production of oily sebum, pustules, etc. Acne often debuts during changes in hormonal levels in pre-teens; however, it is also very common as an adult-onset condition often associated with hormonal fluctuation during menstrual cycle & pregnancy. It has been studied extensively by immunologists for its ability to stimulate the reticuloendothelial system. One of the great ironies of this organism is that it is a powerful non-specific immune stimulant that resides naturally in the skin its role as an immunostimulant. *P. acnes* produces an extracellular lipase that hydrolyses sebum triglycerides to glycerol and free fatty acids, which may contribute to comedone formation. In addition, enzymes produced by *p-acnes* lead to the larger inflammatory lesions. Neutrophils attracted by bacterial chemoattractant release inflammatory mediators such as lysosomal enzymes resulting in the formation of free radicals and other reactive oxygen species. *P. acnes* can tolerate the exposure to oxygen for several hours and is capable in vitro to survive under anaerobic conditions for up to 8 months. The later observation suggests that *P. acnes* can also survive for a prolonged period in human tissues with low oxidation potential. The optimum temperature for growth is 37°C.

### **1.2 PATHOGENESIS OF ACNE<sup>1</sup>:**

*P. acnes* apparently only triggers the disease when it meets favourable dermato-physiological part of skin. *P. acnes* colonization of the skin is therefore necessary but not sufficient for the establishment of the pathology. The 4 major recognized pathophysiological features of acne include androgen stimulated seborrhoea hyperkeratinization and obstruction of the follicular epithelium proliferation of *p. acnes* and then inflammation. Comedogenesis the transformation of the pilosebaceous follicle into the primary acne lesion, the comedone is the product of abnormal follicular keratinization related to excessive sebum secretion. During this process *P. acnes* often gets trapped in layers of corneocytes and sebum and rapidly colonizes the comedial kernel resulting in a microcomedone. A microcomedone can develop into larger structures called comedones. Comedones can be a closed structure that appears like a coloured bump on the skin or an open structure. In inflammatory acne comedones rupture and the follicular material becomes dispersed in the dermis rather than on the skin surface. A break in the lining of the comedones was initially attributed to free fatty acids generated by *P. acnes* -mediated triglyceride hydrolysis, but for several reasons, it is now thought that substances produced by *P. acnes* are directly involved in the rupture of the comedone epithelial lining. The bacteria secrete many polypeptides, among which are numerous extracellular enzymes such as proteases, hyaluronidases, neuraminidase and others that could be involved in epithelium permeabilization and inflammatory infiltration. The infiltrate of an early inflamed lesion consists of polymorphonuclear cells that certainly contribute to the lining breakage, but eventually as time goes by and infection becomes chronic, these cells attract and are replaced by mononuclear cells, predominantly T-cells of

the CD4 phenotype. Antibody against *P. acnes* antigenic determinants are found in the blood of most adults, whether they have had acne or not, amounts may vary between the two populations and possibly the nature of the determinants the antibodies recognize.

### 1.3 SYMPTOMS<sup>2</sup>:

#### 1.Whiteheads:

They are the closed plugged pores.

#### 2.Blackheads:

They are the open plugged pores.

#### 3.Papules:

They are small red tender bumps.

#### 4.Pustules:

These are also known as pimples; they are the papules with pus present at their tips

#### 5.Nodules:

These are the bumps situated beneath the skin surface, they are often large solid and little painful.

#### 6.Cystic lesions:

They are also the bumps situated beneath the surface of skin they are pus filled bump and also painful.

#### 7.Physical symptoms:

There are physical symptoms as well for example itching, pain, soreness, etc.

Acne vulgaris results in scarring.

-Scars are due to the inflammation in the dermal layer of the skin.

-Scars are formed because of irregular healing process of this inflammation.

### 1.4 TYPES OF ACNE<sup>3</sup>.

#### Mild:

People with mild acne have comedones. These are clogged pores in the skin. The dark color of blackheads has nothing to do with dirt. They look dark because this kind of blackhead is open and the skin pigment melanin reacts with oxygen in the air. Whiteheads are closed, and have a white or yellowish head. The more oil builds up, the more likely it is that bacteria will multiply and lead to inflammatory acne. Acne is described as mild if there are only a few acne pimples, or none at all.

#### Moderate:

People with moderate acne typically have between 20 and 100 comedones, and 15 to 50 inflammatory lesions.

#### Severe:

When an individual is diagnosed with severe acne, a dermatologist not only considers comedones and surface lesions, but they'll also look to see if there are any cystic lesions present. Severe acne is categorized using the following metrics:

- ★ 5 pseudo cysts or more.
- ★ 100 comedones or more.
- ★ 50 inflammatory lesions or more.

### 1.5 CAUSES<sup>2</sup>:

Four main causes of acne:

- Excess oil production
- Hair follicles clogged by oil and dead skin cells
- Bacteria
- Excess activity of a type of hormone (androgens).

### 1.6 ETIOLOGY<sup>1</sup>.

Affecting more than 45 million individuals in the United States. It is estimated that nearly 20% of all visits to dermatologist.

### 1.7 HISTORY<sup>1</sup>.

P. acnes was previously known by the name corynebacterium parvum.

### 1.8 NEED OF THE STUDY<sup>4</sup>:

The traditional medicines have always met the global healthcare need. Ayurveda is originated in India and is playing an important role in present and shall be more powerful in the near future. According to Dr. Manoj Nesari joint adviser department of AYUSH, 'there is rising trend towards Ayurveda.

### 1.9 MARKET SCENARIO OF AYURVEDIC FORMULATIONS<sup>4</sup>.

Demand for herbal products world-wide has increased at an annual rate of 8% during the period of 1994-2001, and according to WHO precast, the global herbal market would be worth \$5trillion by the year 2050. As of today, Europe and the USA are two major herbal product markets in the world, with a market share of 41% and 20% respectively. According to the above mentioned research and importance of ayurvedic formulation with lesser side effect and growing demand, we found it appropriate to prefer ayurvedic formulations rather than any other formulation. Also, the chemical used in allopathic medicines are so harsh at times that they develop newer side effect and symptoms. We aim to provide prolonged effects, lesser side effect, no generation of new disease, natural and cheap health care services. To fulfil these requirements, ayurvedic formulation fits the best.

## 2. REVIEW OF LITERATURE.

**Athena Ip et. al.** has mentioned that Acne vulgaris is a common skin condition affecting approximately 95% of adolescents to some extent. First line treatments are topical preparations but nonadherence is common.

-So we felt a need to prepare herbal formulations as first line treatment for curing acne<sup>5</sup>.

**Vandana Meena et. al.** states that Methanol extract of Rubia cordifolia inhibit proliferation of P.acne. It is moderately effective against TNF-alpha and show low activity against IL-8. It is regarded as astringent and useful in external inflammations like ulcers and skin diseases. The anthraquinone rich fraction of R.cordifolia in a gel formulation showed the anti-acne activity against Propionibacterium acne, Staphylococcus epidermidis, Malassezia furfur when compared with standard Clindamycin gel.

It also has anti inflammatory and anti bacterial activities<sup>6</sup>.

**Mei X. Chen et. al.** had carried out certain physical evaluation of the topical formulations such as Organoleptic characteristics, spreadability, pH values, viscosity measurements. He has also carried out In Vitro Antibacterial Activity which includes 1) Preparation of Mueller-Hinton (MH) Agar Plates.

2)Preparation of Inoculum

3)Inoculation of the MH Plate

4) Preparation of Agar Well Diffusion Assay

Following are the evaluation parameters we chose to perform for the characterization of the formulation.

(1) Organoleptic Characteristics. All blank formulations (i.e., formulations without any active ingredients or preservatives) and drug-loaded formulations were tested for physical appearance, color, texture, phase separation, and homogeneity. These characteristics were evaluated by visual observation.

(2) Spreadability: Spreadability of the formulations was determined by measuring the spreading diameter of 1 g of sample between two horizontal glass plates (10 cm × 20 cm) after one minute. The standard weight applied to the upper plate was 25 g. Each formulation was tested three times.

(3) pH Values: One gram of each formulation (including the blank, i.e., formulation without any active ingredients or preservatives, and drug-loaded formulation) was dispersed in 25 mL of deionized water, and the pH was determined using a pH meter

(4) Viscosity measurement : A Brookfield viscometer was used<sup>7</sup>.

**Swati S. Patil et. al.** has mentioned that Acne vulgaris is the most common dermatological disorder among the individuals. The Propionibacterium acnes plays a vital role in pathogenesis of acne inflammation. The P. acnes release neutrophil chemotactic factors which attracts polymorphonuclear leukocytes at site of infection. A Polymorphonuclear leukocyte induces the reactive oxygen species to create an oxidative stress which is responsible for acne inflammation. Conventional medical treatment has its own side effects

besides the high cost. Ethanobotanical search reveals use of many traditional herbs in treatment of acne, which are usually free from side effects, are economical and also accessible to humans. *Rubia cordifolia* a well known plant traditionally being used as medicine in various skin disorders. It was thus thought worthwhile to evaluate antibacterial activity against *Propionibacterium acnes* by broth dilution and cup plate diffusion method. *R. cordifolia* extracts were also evaluated for antioxidant and lipid peroxidation inhibitory activity by 1, 1-diphenyl-2-picryl-hydrazyl and TBARs Thiobarbituric acid reactive substances method respectively. The study throws light on use of *R. cordifolia* in prevention and treatment of acne<sup>8</sup>.

**Radha Gupta et. al.** has mentioned that in this world, there are so many old and new emerging diseases, which have insufficient management. Ayurveda is an ancient science, which gives basic philosophy of diagnosis, prevention, and management of any disease. Ayurveda also suppose that there is no need to nomenclature of diseases for treatment, but the diseases can be cure by knowing the nidan, dosha, and dushya vikrati. Thus, Ayurveda is able to manage any new challenges in health. The aim of this study was to collect, elaborate, evaluate, and discussed the medicinal properties of Manjishtha along with therapeutic indications. The text book of Ayurveda, its commentaries and text book of modern medicine has been reviewed thoroughly along with index medicinal journal. Manjishtha is the magic drug, which is described in all the textbook of Ayurvedic science including Brihatrayi, Laghutrayi, and Nighantues. The description of the Manjishtha for its Ayurvedic yogas and its therapeutic utilization are varied and described to cure various diseases. Manjishtha has blood purifying property; it gives best results in the various skin diseases. Current laboratory research proves that it is best for acne vulgaris. As Manjishtha have varnya in property, it enhances the glow of the face. Though none of the text has mentioned about the anti-mutagenic activity of Manjishtha, the current laboratory and experimental research shows that it gives significant result in cancer. However, there is need to further investigation along with clinical research. The Manjishtha however is very effective in the patient of acne vulgaris along with other skin diseases<sup>9</sup>.

**Dr. Vijayalaxmi et. al.** has mentioned that Acne vulgaris is the most common bacteria causing chronic inflammatory skin disorder of pilosebaceous unit that affects areas containing the largest oil glands, including the face involving abnormalities in sebum production. Acne vulgaris is characterized by both inflammatory (papules, pustules, and nodules) and non-inflammatory (comedones, open and closed) lesions. Acne is a universal disease occurring in all races and affecting 95% of boys and 83% of girls.

**METHODOLOGY:** *Propionibacterium acnes* and *Staphylococcus aureus* are common pus-forming microbes responsible for the development of various forms of Acne vulgaris and the same organisms were isolated from the human volunteer. This research mainly focuses on the treatment of acne using various herbs and making a poly herbal formulation. The comparative analysis of both solvent and aqueous extraction was done to reveal the fact that the selected ingredient can be used as a poly herbal face care powder for cosmetic purpose. **Result:** The aqueous and methanolic extraction shows better antibacterial activity against the isolated organisms. Thus in the present work, herbs having good properties for the face care powder formulation have been identified. **CONCLUSION:** Natural herbal extracts in combination can

be effectively utilized for the treatment of Acne. Use of such products is far better than the use of synthetic ointments for the control of Acne<sup>10</sup>.

**S. Narendra et. al.** has mentioned that Manjishtha [ *Rubia cordifolia* Linn] from Rubiaceae family is a useful medicinal plant used in the treatment of shotha (inflammation), udar, amavat, skin disorder. In market Deshi-indigenous and Irani manjishtha is available. This study is aimed at assessing the scientific evaluation of deshi and irani *Rubia cordifolia* in the course of pharmacognostical and phytochemical analysis, which mainly covered the macroscopic and microscopic features of the roots and stem and Phytochemical parameters such as pH, total ash value, water-soluble extract values were assessed in the preliminary physicochemical screening. Thin layer chromatography (TLC) and fluorescence analysis were carried out for the separation of components<sup>11</sup>.

**Ashutosh Chauhan et. al.** has mentioned that Ayurveda is a science of life with a holistic approach to health and personalized medicine. It is one of the oldest medical systems, which comprises thousands of medical concepts and hypothesis.

Interestingly, Ayurveda has ability to treat many chronic diseases such as cancer, diabetes, arthritis, and asthma, which are untreatable in modern medicine. Unfortunately, due to lack of scientific validation in various concepts, this precious gift from our ancestors is trailing. Hence, evidence-based research is highly needed for global recognition and acceptance of Ayurveda, which needs further advancements in the research methodology. The present review highlights various fields of research including literary, fundamental, drug, pharmaceutical, and clinical research in Ayurveda. The review further focuses to improve the research methodology for Ayurveda with main emphasis on the fundamental research. This attempt will certainly encourage young researchers to work on various areas of research for the development and promotion of Ayurveda<sup>12</sup>.

**Kathryn et. al.** has mentioned that, *Acne vulgaris*, a common skin disorder speculated in the age group of 15-25 years begins with increased production of sebum followed by the attack of *Propionibacterium acne*. Most of the synthetic anti-acne drugs tend to exhibit mild to severe side effects along with peeling and darkening of skin, ultimately leading to social withdrawal. Hence, there arises a need to develop a safe and effective anti-acne formulation that would cure and also prevent recurrence of acne. Considering the fact that roots of *R. cordifolia* (Rubiaceae) are rich in anthraquinones characterized for their anti-inflammatory as well as wound healing property, (Singh, 2004) a gel formulation of anthraquinone rich fraction was developed and evaluated for its anti-acne potential using Cup plate diffusion method. A gel formulation containing 0.1 % of anthraquinone rich fraction exhibited optimum anti-acne activity against *P.acne*, *S.epidermidis*, *M. furfur* (zone of inhibition- 28.9, 20.4, 24.6 mm respectively) when compared with standard i.e. Clindamycin gel (zone of inhibition- 36.7, 35.3, 32.7 mm respectively). Thus anthraquinone rich fraction in a gel formulation is proved to have a better potential in treating acne. Industrial relevance: *Rubia cordifolia*, often known as Common Madder, Indian Madder or Manjistha is highly recommended in skin<sup>13</sup>.



**Bashir Ahmed Bhat et. al.** has mentioned that Rubia Cordifolia has tremendous applications in medicine. He studied about the MACROSCOPIC AND MICROSCOPIC EXAMINATION, PHYTOCHEMICAL STUDIES, TRADITIONAL USES, PHARMACOGNOSTICAL STUDIES and came to a conclusion that Rubia Cordifolia has Anti microbial activity, Anti inflammatory activity and Anti oxidant activity which all are required in the treatment of Acne Vulgaris<sup>14</sup>.

**Rashmi Saxena Pal et. al.** has mentioned that, a large number of cosmetic formulations have been developed based on herbs. Indian women have been using herbs such as sandalwood, aloe for skincare protection, since ages. In India, the rich cultural heritage is behind the materials used in cosmetics from the earliest period of medical and cosmetic art. Continuous application of synthetic compounds on the skin causes many adverse effects such as skin irritation, allergy, discoloration, rashes along with skin cancer. The aim of this review article is to explore herbs for different skincare needs. A literature search was done on various herbs used for skin nourishment, cleansing, sun-screens, bleach, anti-ageing, moisturization and other skin requirements. There are various herbs present in nature. They improve and clarify skin gently in an utmost manner.

These herbs are full of phytoconstituents, having natural goodness to fulfill the different demands of skin<sup>15</sup>.

**Madhavi Gaur et. al.** has mentioned that Plants as medicines have been used for thousands of years. Herbal extracts and formulations have long been regarded as a source of new and useful pharmaceuticals. The chemical composition of plant based medicines has become a new interest these days. Several bioactive constituents of plants have been isolated and studied for various pharmacological studies.

Rubia species is one of the earliest plant resources that possessed commercial and important medicinal values. They were used as natural dyes in old days and used as drugs. We aimed to estimate the In Vitro antioxidant activity, total phenolic and total flavonoid contents of Rubia cordifolia. 2, 2- diphenyl-1-picryl-hydrazyl (DPPH•), superoxide scavenging and reducing power assay were used to assess the antioxidant activity of the plant. The results of phytochemical investigation revealed the presence of most of the phytoconstituents, reasonable amount of flavonoids and phenolic contents. Ethanolic extract of Rubia cordifolia leaves showed significant scavenging activity against DPPH and ample reducing power and superoxide scavenging activity<sup>16</sup>.

**Archana Gorle et. al.** states that Acne is disorder of pilosebaceous unit, and generally characterized by formation of seborrhea, comedones, inflammatory lesions and presence of bacteria Propionibacterium acnes in the follicular canal and sebum production. Each of these factors provides a potential target for treatment. Propionibacterium acnes are the pharmacological target site of anti-acne drugs. methanolic extract was prepared and evaluated for antioxidant and antibacterial activity The aim of present study was to prepare herbal gel formulation containing methanolic extract of Rubia cordifolia on acne. Topical gel formulation was designed by using methanolic extract of roots and stems of Rubia cordifolia in varied concentrations. The gel was prepared by using carbopol 940(1%w/v), Rubia cordifolia Extract, ethanol, propylene glycol, methyl paraben, propyl paraben, EDTA

disodium, tri-ethanolamine and required amount of distilled water. The prepared gels were evaluated for physical appearance, pH, drug content, diffusion study, viscosity, antibacterial activity. Thus, it may be concluded that gel formulations were good antibacterial and antioxidant activity can be used in antiacne activity<sup>17</sup>.

### **3. AIM AND OBJECTIVE**

Topical preparation is the first line treatment in case of mild to moderate acne. Allopathic OTC acne products like salicylic acid, benzoyl peroxide may produce the most common side effects such as skin dryness and irritation<sup>18</sup>.

The best anti acne treatments inhibit sebum production, limit bacterial growth, or encourage shedding of skin cells to unclog pores. While benzoyl peroxide works by destroying the bacteria associated with acne but it does not affect sebum production or the way the skin follicle cells are shed<sup>19</sup>. Whereas salicylic acid helps to correct the abnormal shedding of cells, it does not have any effect on sebum production and does not kill bacteria.

Manjistha is antibacterial and anti-inflammatory. It's clear up acne and combats dry skin it works topically on dry skin and removes flaky skin and removes the scar<sup>20</sup>.

Furthermore the cost of first line treatment in allopathic formulation is more compared to ayurvedic preparations.

Manjistha is also used as fairness ingredient when used topically

Kokum butter is also evolved as a new wax in cream which is having excellent emollient property.

### **4. PLAN OF WORK:**

- ❖ Drug Profile
  - Monograph
    1. Manjistha
    2. Kokum Butter
- ❖ Experimental works
  - Selection of plant material
  - Optimization of Extraction Process
    1. Water extract
    2. Alcoholic extract
    3. Soxhlet extract
  - Characterization of Extraction
  - Preparation of Formulations
    1. Cream
    2. Gel
    3. Ointment
  - Characterization of Formulations
    1. Organoleptic characteristics of Formulations
      - Organoleptic characteristics of Cream
        - Identification of Cream
          - a. Solubility of Cream
          - b. Microscopic characteristics of Cream

2. pH
3. Viscosity Measurement
4. Spreadability
5. Stress testing
  - a. Centrifugation
6. Determination of Invitro Anti-ance Activity

## **5. DRUG PROFILE**

### **5.1 MONOGRAPHS:**

#### **5.1.1 *Manjistha*<sup>21</sup>:**

Mañjisthā consists of the dried root of *Rubia cordifolia* L. (Fam. Rubiaceae), a perennial herbaceous creeper or climber, with hooked prickles and whorls of four leaves, but without interpetiolar stipules, found throughout the country ascending to 3750 m. It contains not less than 0.04 percent of rubiadin when assayed.

Synonyms: Yojanavallī, Tāmravallī, Vastrarañjinī, Raktā.

Other/Regional Language Names: Assamese: Phuvva; Bengali: Manjishtha, Manjith; English: Indian Madder; Gujarati: Manjitha; Hindi: Manjitha, Manjit; Kannada: Manjustha; Malayalam: Manjatti, Manchatti; Marathi: Manjishtha; Punjabi: Manjistha, Manjit; Tamil: Manatte, Manjitti; Telugu: Manjishtha.

Description:

Macroscopic:

Root - Cylindrical, often surmounted by a knotty crown of root stock ; about 2 to 9 cm in length and 0.2 to 0.6 cm in width; surface smooth finely striated longitudinally and occasionally grooved, often exhibiting lateral root scars; dark reddish brown both externally and internally. Fracture short, taste sweetish, acrid and disagreeable, odour pleasant.

Microscopic:

TS of root shows a well developed cork, consisting of 3 to 8 layered radially arranged cells, occasionally filled with reddish brown content, followed by a cortex of 3 to 10 cell layers; some cortical cells filled with acicular and sandy crystals of calcium oxalate more towards periphery. Phloem 8 to 12 layers wide, consists of sieve tubes, companion cells and phloem parenchyma. Xylem consists of vessels, fibres, tracheids and xylem parenchyma. Vessels are broader towards the peripheral region of the xylem. The size of vessels vary from 30 to 270 micrometer in length and 18 to 90 micrometer in breadth. Medullary rays are uni-to multi seriate and oval to circular starch grains present in cortical and phloem parenchyma cells.

Powder:

Shows numerous fragments of cork, lignified xylem vessels, tracheids and fibres, raphides, clusters and sandy oxalate crystals, parenchyma with red content and starch grains.

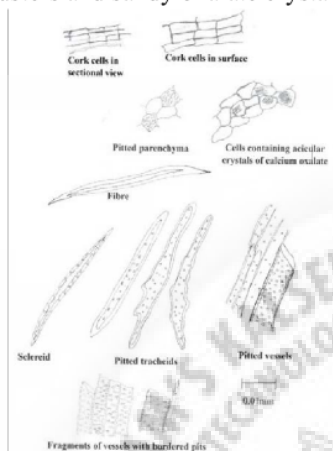


Fig. 1: Powdered drug of MAÑJISTHĀ (*Rubia cordifolia L.*)

Quantitative parameters:

Foreign matter: not more than 2.0 percent; loss on drying: not more than 12.0 percent; Total ash: not more than 12.0 percent; Acid insoluble ash: not more than 0.5 percent; Alcohol-soluble extractive: not less than 3.0 percent; water-soluble extractive: not less than 10.0 percent

Other requirements:

Heavy metals: Complies with the prescribed limits, (Appendix 3.1); Microbial contamination: Complies with the prescribed limits, (Appendix 3.2); Pesticide residues: Complies with the prescribed limits, (Appendix 3.3); Aflatoxins: Complies with the prescribed limits, (Appendix 3.4).

Additional requirements:

Storage: Store in well closed container protected from heat, light, moisture and against attack by insects and rodents.

Labelling: The label states the official name, followed by the Latin binominal name and the part of the plant contained in the article.

API reference standard:

API Rubiadin RS

Constituents: Rubiadin, anthraquinones, alizarin, purpurin, purpuroxanthin, ruberythric acid, 1,3-dihydroxy-2-ethoxymethyl-9,10-anthraquinone, lucidin primeveroside, 2-methyl-1,3,6-trihydroxy-9,10-anthraquinone 3-O-(6'-O-acetyl)-alpha-rhamnosyl(1->2)-beta-glucoside, furomollugin, rubilactone, 2-carboxymethyl-3-prenyl-2,3-epoxy-1,4-naphthoquinone, 1-hydroxy-2-hydroxymethyl-9,10-anthraquinone, 2-methyl-1,3,6-hydroxy-9,10-anthraquinone, rubioncolin B, 1-hydroxy-2-methylanthraquinone, nordamnacanthal, physcion, 1,4-dihydroxy-6-methylanthraquinone, 1,4-dihydroxy-2-methylanthraquinone, 1,5-dihydroxy-2-methylanthraquinone, 3-prenyl-5-methoxy-1,4-naphthoquinone, 1,4-dihydroxy-2-methyl-5-(or 8)-methoxyanthraquinone, 1,3-dimethoxy-2-carboxyanthraquinone.

Properties and Action: Rasa: Kasāya, Tikta, Madhura; Guna: Laghu, Rūkṣa; Vīrya: Śīta; Vipāka: Katu; Karma: Pittasāśamana, Sandhānīya, Varnya, Vranaropānī.

Important Formulations: Methikādicūrṇa, Palāśapuspāsava, Yogarājāsava.

Therapeutic uses: Bhagna (fracture), Garbhapāta (abortion), Pakvātisāra (chronic diarrhoea), Tvakroga (skin disease), Vrana (wound), Vyanga (dark shade on face due to stress and excessive exercise).

Dose: 3-6g.

### 5.1.2 Kokum butter<sup>21</sup>:

#### DHĀRĀ VRKSĀMLA

Dhārā Vrksāmla consists of dried fruit of *Garcinia gummi-gutta* (L.) Rob. syn. *Garcinia cambogia* (Gaertn.) Desr. (Fam. Clusiaceae); a small tree, common in evergreen forests of Western ghats, from Konkan southwards to Travancore, and in the Shola forests of the Nilgiris up to an altitude of 1800 m. Dhārā Vrksāmla contains not less than 5 per cent of hydroxycitric acid and not less than 5 per cent of lactone when assayed.

Synonym: Ksīrī Vrksāmla

Regional Language Names: English: Malabar Tamarind, Kokum Butter Tree; Gujarati: Kokam, Kokan; Hindi: Kokam; Kannada: Murginhuli, Murgala; Malayalam: Panampuli; Marathi: Kokam, Ratamba, Amsol, Amsul, Ratambi; Oriya: Raktasrava; Tamil: Kodukkappuli; Telugu: Vrksamta, Simachinta

Description:

Macroscopic:

Fruits are ovoid, yellow or red when ripe and become black when dried. 6-8 grooves are seen up to the middle. Dried pieces of drug consists of longitudinal fragments of pericarp of various size and shapes strongly inwardly curved, boat or half moon shaped, dark brownish black, wrinkled irregularly and internally smooth. Odour characteristic, taste sour, astringent and slightly bitter.

Microscopic:

TS of pericarp shows a layer of epicarp, composed of rectangular to tangentially elongated cells covered externally with thin cuticle; mesocarp very wide composed of 100 to 150 rows of parenchymatous cells of various size and shape which possess simple and compound starch grains and prismatic crystals of calcium oxalate; vascular bundles consists of phloem and xylem with spiral vessels, rectangular to irregular shaped parenchyma cells, traversing throughout the mesocarp but more prominently in inner zone of pericarp.

#### Powder:

Shows isolated cells of mesocarp, containing dark reddish brown gummy exudates, prismatic crystals of calcium oxalate and starch grains; fragments of longitudinally cut spiral and annular vessels.

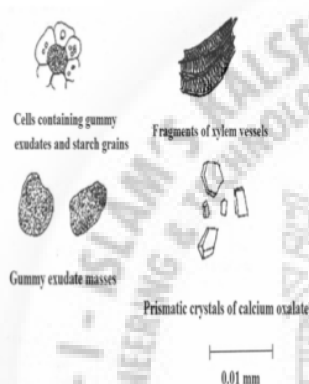


Fig.2: Powdered drug of DHĀRĀ VRKSĀMLA (Garciniagummi-gutta (L.) Rob.)

#### Identity, Purity and Strength:

#### Identification:

##### High performance liquid chromatography (HPLC):

Carry out liquid chromatography using (-)-hydroxycitric acid lactone and calcium (-)-hydroxycitrate as a reference standards. Test solution, Standard solution, Chromatographic system, Mobile phase, Injection volume, Detection and Procedure follow as mentioned under Assay. The chromatogram obtained with test solution shows peaks corresponding to the retention time of (-)-hydroxycitric acid lactone and (-)-hydroxycitric acid.

#### Quantitative parameters:

Foreign matter: not more than 2.0 per cent; Loss on drying: not more than 20.0 percent; Total ash: not more than 8.0 per cent; Acid-insoluble ash: not more than 1.5 percent; Alcohol-soluble extractive: not less than 20.0 per cent; Water-soluble extractive: not less than 35 percent

#### Other requirements:

Heavy metals: Complies with the prescribed limits,; Microbial contamination: Complies with the prescribed limits, Pesticide residues: Complies with the prescribed limits, Aflatoxins: Complieswiththeprescribed limits.

Additional requirements:

Storage: Store in well closed container protected from heat, light, moisture and against attack by insects and rodents.

Labelling: The label states the official name, followed by the Latin binominal name and the part of the plant contained in the article.

API reference standards:

API (-)-Hydroxycitric acid lactone RS and Calcium (-)-hydroxycitrate RS  
 Constituents: (-)-Hydroxycitric acid, (-)- hydroxycitric acid lactone, citric acid, tartaric acid  
 Properties and Action: Rasa: Amla; Guna: Laghu, Rūkṣa; Vīrya: Usna; Vipāka: Amla; Karma: Arśoghna, Dīpana, Kapha-vātahara, Rucya, Sandhāñīya, Śūlaghna, Trsnāñigratona

Therapeutic uses: Agnimāndya (digestive impairment), Arśa (piles), Gulma (abdominal lump), Śūla (pain), Vibandha (constipation)

Dose: Cūrṇa (powder): 3-6 g

## **6. EXPERIMENTAL WORKS**

### **6.1 SELECTION OF PLANT MATERIAL<sup>22</sup>:**

Manjishtha (*Rubia cordifolia*)

Asset:

It works on *P. acnes*.

It cools and detoxifies the blood.

It heals damaged skin tissues by injury or infection.

It also act as Anti-inflammatory, Anti-bacterial, Anti-oxidant.

The well known constituent of Manjishtha is Anthraquinone.

It contains Anti-bacterial properties which promotes to immune function.

### **6.2 OPTIMIZATION OF EXTRACTION PROCESS:**

#### **6.2.1 WATER EXTRACT:**

In 100ml round bottom flask manjista and distilled water was taken in a ratio of 1:8. Reflux condenser was attached and heated the mixture on boiling water bath for 3

hours. Temperature was maintained upto 70-80° C. The above condensate was collected in a beaker and then filtered using a normal filter paper. The filtrate is then concentrated using on hot plate at temperature 60°C.

#### 6.2.2 ALOCOHOLIC EXTRACT:

The powdered drug and distilled water was taken in a ratio of 1:20 in round bottom flask attach to a reflux condenser and heat the mixture on a water bath for 3 hours. The above condensate was collected in a beaker and then filtered using a normal filter paper, The filtrate is then concentrated using a hot plate at temperature 60°C.

#### 6.2.3 SOXHELET EXTRACTION:

The powdered drug and mixture of ethanol and distilled water (1:1) was taken in a ratio of 1:20 in 1000ml flask. Attach a soxhlet apparatus and heat the mixture on a heating mantel for 4 hours. Temperature was maintained at about 60°C to 70°C. The above condensate was collected in beaker and then filtered using a normal filter paper, The filtrate is then concentrated using a hot plate at temperature 60°C.

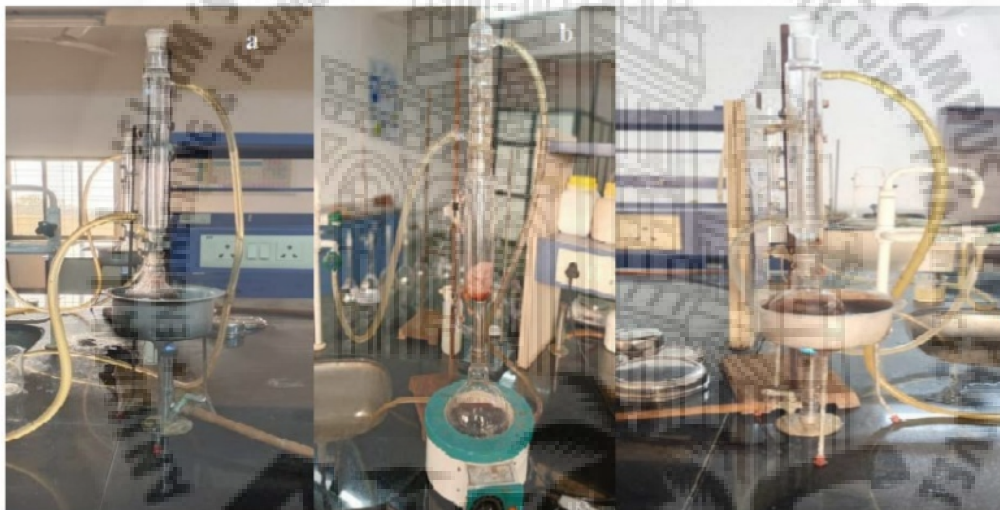


Fig.3 a) Alcoholic extract b) Soxhlet extract c) Water extract.

#### 6.3 CHARACTERIZATION OF EXTRACT:

The extracts were further centrifuged and diluted for the study of UV spectroscopy. The extract was centrifuged at 1000rpm for 40 mins. 1ml of centrifuged extract was diluted to 100ml with respective solvents and this forms solution A. 1ml of solution A was then further diluted to 10ml with respective solvent and this forms solution B. And this dilutions were further analyzed using UV spectroscopy.

#### 6.4 PREPARATION OF FORMULATIONS:

- Cream:



Ingredients	BC1	BC2	BC3	BC4	BC5	BC6	BC7
Cetostearyl alcohol	5%	5%	8%	12%	10%	10%	10%
Kokum Butter	50%	50%	40%	40%	40%	40%	40%
Glyceryl Monostearate	1%	1%	3%	5%	4%	6%	6%
Methyl Paraben	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Propyl Paraben	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Lanolin	2%	2%	2%	2%	2%	2%	2%
Glycerin		3%	3%	3%	3%	3%	3%
Isopropyl myristate						2%	2%
Triethanol Amine						2%	2%
BHA			3%	3%	3%	3%	3%
Span 80						1%	1%
Manjistha extract	5% (Hydro-alcoholic)	5% (Hydro-alcoholic)	5% (Hydro-alcoholic)	5% (Hydro-alcoholic)	5% (Hydro-alcoholic)	5% (Hydro-alcoholic)	5% (Alcoholic)

Table No.1: Modifications in cream.

In a porcelain dish weigh all the ingredients of oil phase i.e. cetostearyl alcohol, kokum butter, glyceryl monostearate, propyl paraben, isopropyl myristate, lanolin and span 80 and BHA and melt it on a water bath. In another beaker water phase was prepared by adding methyl paraben, glycerin, triethanolamine and extract. Water phase was added to the oil phase by maintaining the temperature at 60°C with constant stirring with the help of glass rod until the cream consistency was obtained.

➤ Gel:

Ingredients	BG1	BG2
Carbopol	1%	0.8%
Propylene glycol	20%	20%
Triethanol Amine	q.s	q.s
Extract (water)	5%	5%

Water	q.s. to 100	q.s. to 100
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Table No.2: Modifications in Gel.

Carbopol dispersed in distilled water and it was kept under room temperature until the carbopol was completely dissolved. Manjistha water extract was dissolved in propylene glycol. This mixture was added in previous mixture. Then triethanolamine was added dropwise with constant stirring until a gel consistency was obtained.

➤ Ointment:

Ingredients	BO1	BO2
Extract (alcoholic)	5%	5%
Liquid Paraffin	5%	5%
White soft Paraffin	10%	10%
Glycerin	30%	30%
Cetostearyl alcohol	8%	8%
Methyl Paraben	0.3%	0.3%
Lanolin		2%
Polysorbate	3.6%	3.6%
Glyceryl Monostearate	2%	2%

Table No.3: Oleaginous base formula for ointment.

Ingredients	BO3	BO4	BO5	BO6	BO7
PEG 400	70%	60%	90%	80%	85%
PEG 6000	30%	40%	10%	20%	15%
Extract (Alcoholic)	5%	5%	5%	5%	5%

Table No.4:Hydrophilic ointment.

Ointment was prepared by oleaginous as well as hydrophilic formula.

Oleagenous ointment: Accurately weighed quantities of all ingredients were taken in porcelain dish, allowed to melt and then congealed to solidify at roomtemperature.

Hydrophilic ointment:Polyethylene glycol 6000 and PEG 400 were melted in a porcelain dish on water bath. alcoholic extract was then added to the mixture and stirred constantly until until congealedto semisolid form at room temperature.

## 6.5 CHARACTERIZATION OF FORMULATIONS

### 6.5.1 ORGANOLEPTIC CHARACTERISTICS OF FORMULATIONS<sup>7</sup>.

All blank formulation and drug loaded formulations were tested for physical appearance, colour, texture, phase separation, and homogeneity. These characteristics were evaluated by visual observation. Homogeneity and texture were tested by pressing a small quantity of the formulated cream and gels between the thumb and index finger. The consistency of the formulation and presence of core particles were used to evaluate the texture and homogeneity of the formulations. Immediate skin feel was also evaluated.

#### 6.5.1.1 Organoleptic characterization of cream

Identification of cream:

- Solubility of cream<sup>23</sup>.

Solubility testing is used to determine the type of the cream.

1 gram of the formulation was dissolved in 10 ml of water and if it gets dissolved in water it is oil in water type of cream. And 1 gm of formulation was dissolved in 10 ml of paraffin oil and if it gets dissolved then it is water in oil type of cream.

- Microscopic characteristics of cream:

A compound microscope was used to determine the microscopic characteristics of cream. A thin smear was made on a glass slide, the glass slide was covered with a cover slip and observed under microscope using 10X lens.

### 6.5.2 pH<sup>7</sup>.

1 gm of each formulation was dispersed in 10 ml of distilled water and the pH was determined using a pH meter. (HANNA instrument; model no: HformulpH/ORP meter). Measurements were made in triplicate. pH meter was calibrated with standard buffer solution (pH 4, 7 and 10) before each evaluation.

### 6.5.3 VISCOSITY MEASUREMENT<sup>7</sup>.

A viscometer was used with concentric cylinder spindle #4 to determine the viscosity of different topical formulations. The tests were carried out at 17°C. The spindle was rotated at 100 rpm. All measurements were made in triplicate.

### 6.5.4 SPREADABILITY<sup>7</sup>.

Spreadability of a semisolid formulation that is the ability of a cream, gel and ointment plays an important role in application. Spreadability of a formulation was determined by measuring the spreading diameter of 0.1 gm of sample between two glass slides, after putting weight of 25 gm on upper glass slide. Each formulation was tested 3 times.

### 6.5.5 STRESS TESTING OF CREAM<sup>24</sup>.

#### 6.5.5.1 CENTRIFUGATION:

For evaluation of physical stability 6 gm samples of formulation were submitted to three cycles of 3000 rpm for the duration of 30 minutes. At the end of each cycle the samples were checked to see whether there were any changes.

#### 6.5.6 DETERMINATION OF INVITRO ANTI-ACNE ACTIVITY<sup>25</sup>.

The susceptibility of microorganisms to drug is determined by measuring zone of inhibition which is dependent on activity and rate of diffusion of formulation into medium, nature of composition of medium, its thickening, pH and time of incubation of interaction with test microorganism. The paper disc agar diffusion method is commonly used to determine the zone of inhibition towards microorganism.

Microorganism and culture media:

- Collection of bacterial stains:  
Anaerobic bacteria: P. Acnes was obtained from private institute supplier (Himanshu Science House)
- Growth conditions and culture medium:  
The freeze and dried microorganism was activated by suspending bacteria in 0.9% sodium chloride which was kept at 37°C for half an hour. The suspension of P. Acnes was cultured in Nutrient Agar and incubated anaerobically at 37°C for 48 hours.
- Antimicrobial activity of cream, gel and ointment:  
Antimicrobial activity of cream, gel and ointment was tested using paper disc agar diffusion method. In order to evaluate antimicrobial activity of cream, gel and ointment P. Acnes was incubated in Nutrient agar. Disinfect the working table with disinfectant solution. Pour sterile base medium (Nutrient agar) to sterile petriplate aseptically in between two burner in quantity of 15-20 ml per plate and allow it to solidify. 0.1 ml of activated suspended bacteria in 0.9% sodium chloride is now uniformly spreaded on solidified medium in plate. Previously soaked disc of 10% of cream solution, 10% of gel solution and 10% of ointment solution was taken using sterile forcep and placed it on agar plate carefully. Keep these plates in incubator for 24-48 hours at 37°C. Each formulation was tested two times.

## **7. RESULT AND DISCUSSION**

### **7.1 EXPERIMENTAL:**

#### **7.1.1 CHARACTERIZATION OF EXTRACT:**

After centrifugation, diluted extracts was run for the absorbance using UV/Visible spectroscopy. Hydroalcoholic extract was run between 230-340nm and the maximum absorbance was found to be 0.599846 at 280.9nm. Ethanolic extract was run between 230-350nm and the maximum absorbance was found to be 0.225803 at 241.1 nm. Water extract was run between 220 - 340 nm and the maximum absorbance was found to be 0.55871 at 269.1nm.

### 7.1.2 PREPARATION OF FORMULATIONS:

#### 7.1.2.1 Cream:

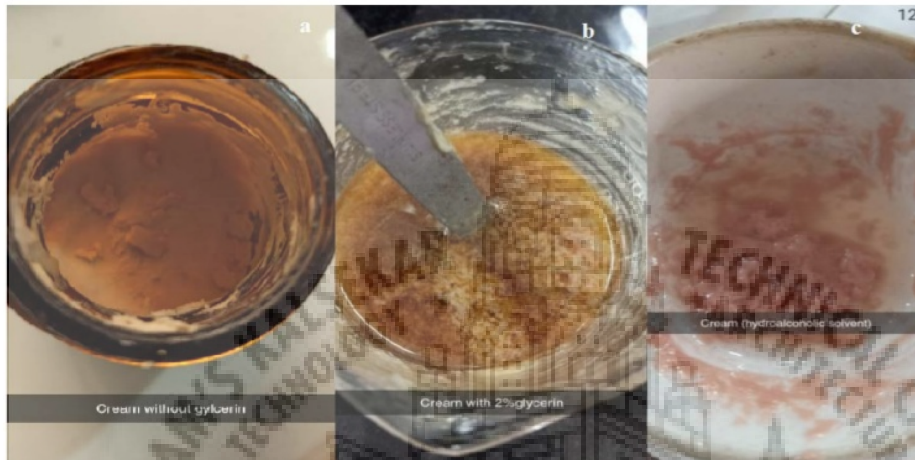


Fig.4 a) Cream without glycerin b) Cream with 2% glycerin C) Cream (hydroalcoholic solvent)

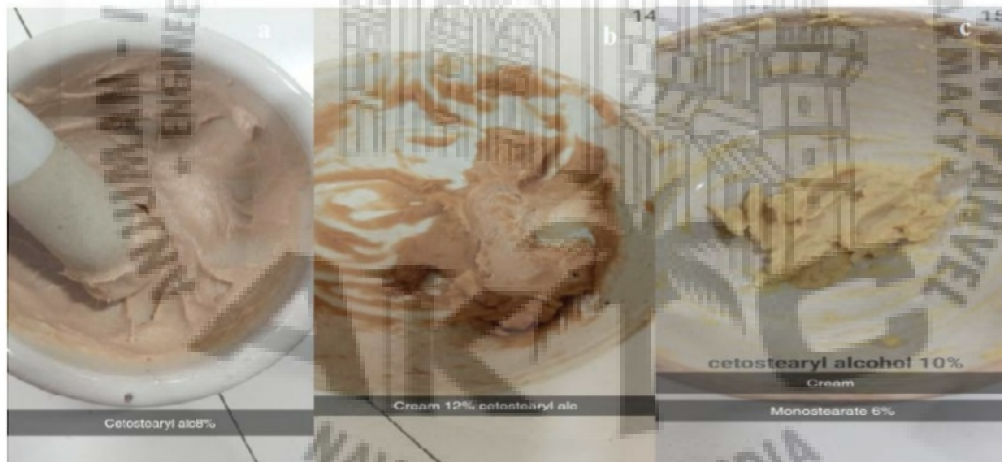


Fig.5 a) 8% Cetostearyl alcohol b) 12% cetostearyl alcohol c) 6% Glyceryl Monostearate.

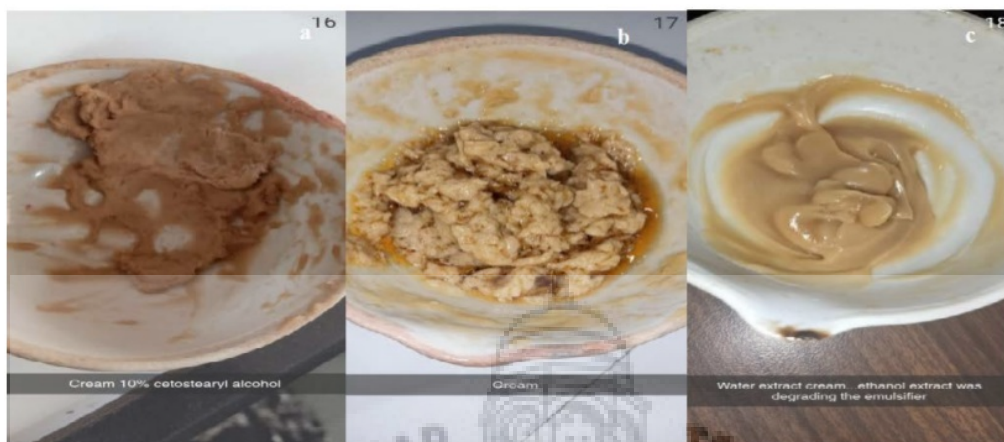


Fig.6: a) 10% Cetostearyl alcohol b) Cream with Hydroalcoholic extract c) Cream with Ethanolic extract.

BC1: The formulated cream from batch 1 was hard and it was not capable enough to spread.

BC2: To overcome the problem seen in batch 1 we opted to choose glycerin as humectant which was added in water phase.

BC3: The formulated cream from batch 2 was way too greasy, therefore cetostearyl alcohol being viscosity enhancing agent was increased from 5% to 8%, kokum butter acts as an emollient and was too greasy hence quantity was decreased to 40%; glyceryl monostearate being an emulsifier the quantity was increased to 3%.

BC4: The formulated cream from batch 3 was further observed separated therefore quantity of cetostearyl alcohol and glyceryl monostearate were modified.

BC5: The formulated cream from batch 4 was hard, hence the formula was updated.

BC6: As per the formulated cream from batch 5 was not stable, therefore we modified the formula by adding triethanol amine, isopropyl myristate and span 80 according to their properties.

BC7: Hydroalcoholic extract of drug was degrading the emulsifier so we switched to alcoholic extract.

#### 7.1.2.2 Gel:

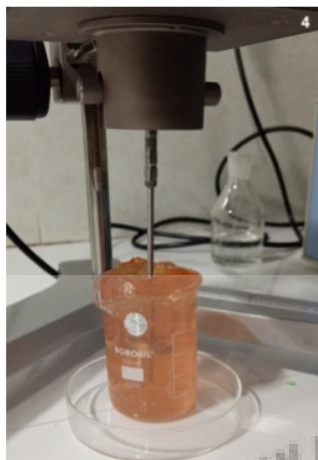


Fig.7: Gel of batch 1.

Initially gel was formulated with 1% carbopol which resulted in formation of lumps; therefore 1% was reduced to 0.8% which avoids the formation of lumps.

#### 7.1.2.3 Ointment:

Batch BO1 was not stable as the alcoholic extract was incompatible with waxes and tends to separate out the waxes and liquid phase.

Lanolin being a stabilizer, it was added in the formulation (BO 2) to prevent the separation of waxes from the liquid phase, but it fails to stabilize. Hence switched the formula containing PEG of different grades in ratio as the base formula.



Fig.8: a) Ratio of 10:90 b) Ratio of 30:70 c) Ratio of 15:85

BO3 Resulted formulation was too hard and gritty.

BO 4 was comparatively less hard and gritty.

BO 5 was only gritty.

BO6 consistency was not proper, hence BO7 with 85:15 optimized.

## 7.2 ANALYTICAL :

### 7.2.1 CHARACTERIZATION OF OPTIMIZED FORMULATIONS:

#### 7.2.1.1 ORGANOLEPTIC CHARACTERISTICS OF FORMULATIONS<sup>7</sup>.

The organoleptic properties, including physical appearance, colour, texture, separation, homogeneity, and immediate skin feel of the cream, gel and ointment are displayed in the Table No.5. Results showed that the cream, gel, ointment had a cosmetically elegant appearance and smooth texture, and they were all homogenous w. All formulations gave characteristic colour due to mangistha.

Formulation	Physical Appearance	Color	Texture	Phase Separation	Homogeneity	Immediate skin feel
Cream	Opaque	Pale brown	Smooth	No	Homogeneous	Moisturizing, light weight, non-greasy.
Gel	Transparent	Pale orange	Smooth	No	Homogeneous	Refreshing and soothing.
Ointment	Opaque	Pale pink	Smooth	NO	Homogeneous	Moisturizing, no grittiness and no greasiness.

Table No.5: Physicochemical Evaluation of selected topical formulations.

#### i) Organoleptic characterization of cream:

##### Identification of cream

- Solubility of cream<sup>23</sup>.

According to the above procedure the formulated cream dissolves in paraffin oil and hence shows the characteristics of water in oil type of cream.



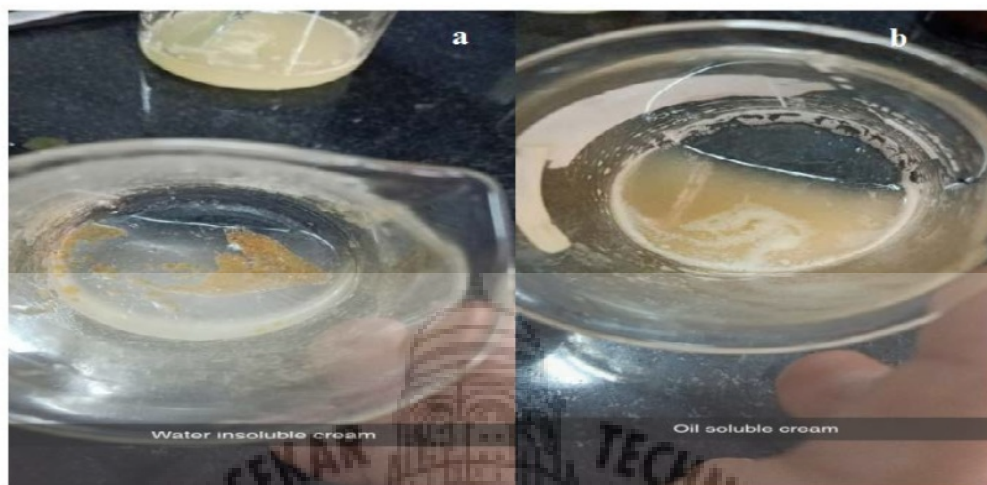


Fig.9: a)Solubility test in water b)Solubility test in oil.

- Microscopic characteristics of cream:  
As the cream is water in oil (w/o) type of cream. This is composed of small droplets of water dispersed in a continuous oily phase. Drug released more readily from a water in oil cream rather than oil in water type of cream<sup>26</sup>. W/O creams are also more moisturizing as they provide an oily barrier which reduces water loss from the outermost layer of the skin.

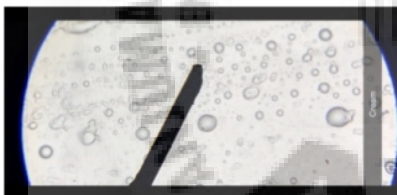


Fig. 10: Microscopic test of cream.

#### 7.2.1.2 pH<sup>7</sup>.

The pH values for optimized formulations were given in table no. 6. The pH of the cream and gel was more base than that of the skin. While the pH of ointment was similar to the skins normal pH value.

Fig.1 1a) pH of cream b) pH of gel c) pH of ointment.

Formulations	Drug loaded formulations at day 1 (mean±SD)	Drug loaded formulations after 2 weeks (mean±SD)
Cream	7.89 ± 0.028	7.94 ± 0.064
Gel	7.01± 0.01	7.04 ± 0.01
Ointment	5.96 ± 0.02	5.97 ± 0.01

Table No.6: pH of drug loaded formulations at day 1 and after 2 weeks.

### 7.2.1.3 VISCOSITY MEASUREMENT<sup>7</sup>.

Viscosity values for the cream, gel and ointment are shown in table no.7. All the formulations were measured at 100 rpm at spindle 4.

Formulations	Viscosity values (mean±SD)
Cream	1856.6 ± 0.17
Gel	1906.3 ± 0.14
Ointment	1893.7 ± 0.26

Table No.7: Viscosity values of cream, gel and ointment.



Fig.12: a)Viscosity of ointment b) Viscosity of cream c) Viscosity of gel.

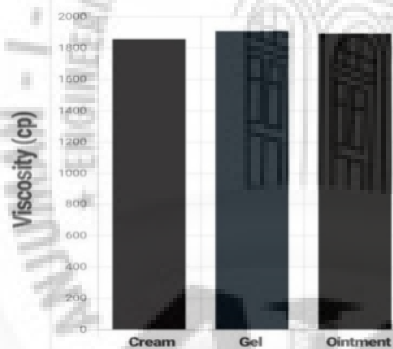


Fig.13: Viscosity values for cream, gel and ointment.

7.2.1.4 SPREADABILITY<sup>7</sup>.

The values refer to the extent to which the formulations readily spread on the application surface by applying a small amount of shear/ Fig. No 14 a), 14 b) and 14 c) shows the spreadability values after one minute. Results indicate the cream, gel, ointment had comparable spreadability.

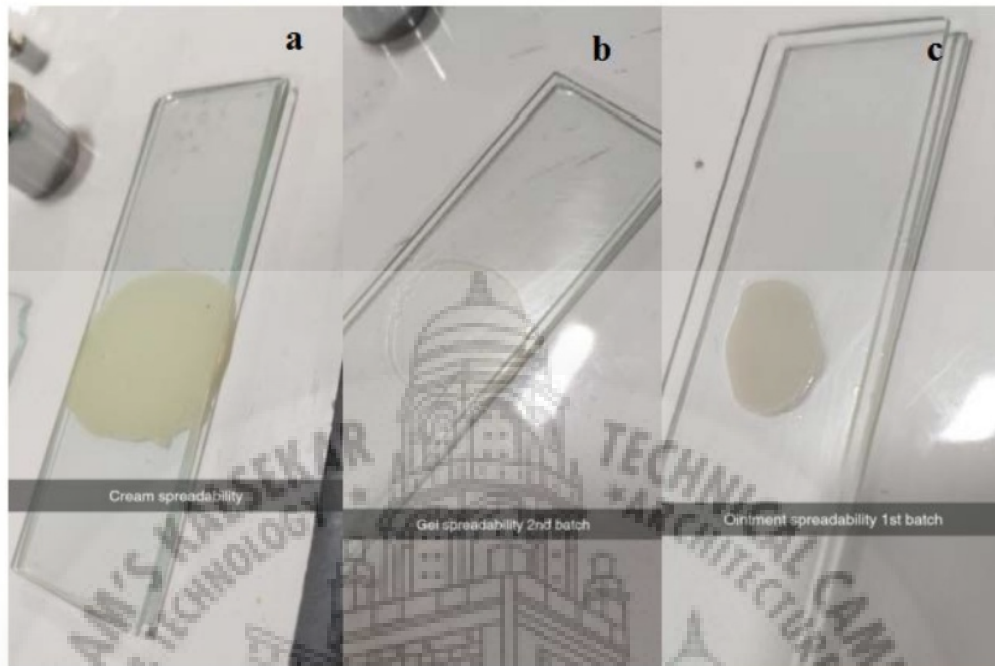


Fig.14 a) Spreadability of cream b) Spreadability of gel c) Spreadability of ointment.

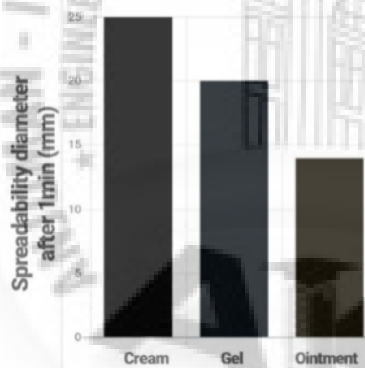


Fig.15: Spreadability values for the cream, gel and ointment.

#### 7.2.1.5) STRESS TESTING

##### 7.2.1.5.1 CENTRIFUGATION<sup>24</sup>.

There were no changes after three centrifugation cycle of 3000 rpm for 30 minutes each,



Fig.16: Centrifugation test of cream.

### 7.3 PHARMACOLOGICAL:

#### 7.3.1) DETERMINATION OF INVITRO ANTI ACNE ACTIVITY<sup>25</sup>.

Antimicrobial activity was calculated by measuring the diameter of the growth inhibition zone (mm). Three soaked disc were placed in each plate of different formulation for comparative study.

Fig.17: Antimicrobial test of cream, gel and ointment.

Formulation	Zone of inhibition (average) (mm) (mean±SD)
Cream	6.06 ± 0.01
Gel	5.23 ± 0.02
Ointment	5.91 ± 0.01

Table No.8: Values of zone of inhibition of cream, gel and ointment.

## **8. CONCLUSION AND SUMMARY**

Acne vulgaris or Acne is caused by the accumulation of oil glands with dead skin cell and oil. P. Acnes apparently triggers the condition by releasing numerous extracellular enzymes which leads to excessive sebum secretion and relates to microcomedone, this microcomedone can develop into comedones, acnes and inflammation. As it is most likely seen in pre-teens and teenager and is estimated that nearly 20% of all visits to dermatologist. It has been stated that 'there is rising trend towards Ayurveda' as the demands has increased at an annual rate of 8%. To clinch the scenario, ayurvedic topical formulation fits in the best. The views strike us to Rubia Cordifolia (Manjistha) considering it as our core drug to treat as it consists of anti-inflammatory, anti-bacterial and anti-androgenic property. Manjistha has the efficacy to inhibit the proliferation of P. Acnes. Topical formulations are used as first line treatment in mild to moderate case of acne. Allopathic topical formulations works on abnormal shedding of cells which does not effect the sebum production and does not kill the bacteria whereas the studies conclude that the root of Manjistha treats the bacteria and removes the damaged skin cells and clears the scar. The raw powdered drug is coordinated into extracts i.e., water extract, alcoholic extract and hydroalcoholic extract. The water and alcoholic extracts were prepared using reflux condenser whereas hydroalcoholic extract was prepared using soxhlet apparatus. Water and alcoholic extract were used for the formulation of gel and ointment respectively. However hydroalcoholic extract was supposed for the formulation of cream. But it tends to degrade the emulsifier so it eventually resulted with the replacement of hydroalcoholic extract to alcoholic extract. The base formula was estimated using Pharmacopoeia's which was then modified and concluded to the above mentioned formula. In gel formulation, the concentration of carbopol was adjusted to attain the optimum consistency of gel. In ointment containing paraffin oil and other oil phase was not showing appropriate and stable results, therefore we tend to changed it to the formula containing PEG. For the formulation of cream, the results were inappropriate and unstable, so on the trail and error basis we finally concluded to ideal base formula of the cream. The topical formulations had been assessed on parameters of organoleptic properties of formulations which had shown that all the formulations are cosmetically appealing. The cream was identified on the basis of solubility, which was found to be oil soluble and its internal phase was dispersed well in external phase. The slight changes was observed in the pH of the formulations after the span of 2 weeks. The viscosity of all the formulations was found to be in the range of 1500-2000cp. The spreadability of all the formulations was measured between two glass slides which was found to be in the range of 10-25mm. Stress testing was stick to cream formulation which shows that it can withstand the mechanical strength and hence has a good shelf life. Antimicrobial activity of gel was found to be less effective as compared to cream and ointment against P. Acnes. These ayurvedic topical formulation has the urge to work against P. Acnes bacteria and treat acne excel in the forte of topical formulation.

## **9. FUTURE SCOPE**

The base formula of the formulated cream, gel and ointment has ideally surpass the formulations. The analytical or evaluation tests also prove the formulations to be optimum. The same base formula can also be extend by using different ayurvedic drugs and which may result in manufacturing of different topical formulations for several other diseases to cure. If it says the rising trends towards ayurvedic is more as that of allopathy, as the prominent drawbacks of allopathy are its side effects because of chemicals mostly they do not cure the root cause of the disease and works partially which do not cure the disease permanently. The allopathy topical formulations tends to cause skin rashes, skin drying and skin peeling whereas in ayurvedic formulations possibly low. This base formula of topical formulations can be used to inoculate different other ayurvedic drugs which will result in the production of other topical formulations having several other properties to cure the disease.



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## 11.APPENDIX

BHA- Butylated hydroxyanisole.

CD4- Cluster of differentiation 4.

HPLC- High Performance Liquid Chromatography.

P.Acnes- Propionibacterium Acnes.

PEG- Polyethylene glycol.

RPM- Rotation per minute.

TLC- Thin Layer Chromatography.

UV- Ultra violet.

WHO- World Health Organization.



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