PREPARATION AND EVALUATION OF ANTI-ACNE HERBAL GEL

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ABSTRACT
Usage of herbal medicine has increased many folds on account of side effects observed with conventional drugs. Acne is a skin condition which arises due to over production of oil in sebaceous glands. It is rarely considered as disease and is neglected many a times. A non oily gel formulation for topical application suitable for treating this condition has been prepared using carbopol 940. The prepared gels were evaluated for various physical parameters like pH, colour, odour, grittiness, viscosity, homogeneity, spreadability, skin irritancy etc. The plants chosen for preparing gels were Butea monosperma flowers, Nigella sativa seeds and Vitex agnus castus leaves. The gels were subjected to microbial study against P. acnes. The result showed that zone of inhibition of prepared gels was equivalent to the standard ciprofloxacin and thus can be a better alternative to allopathic treatment.

KEYWORDS: Herbal, acne, gel, P. acnes, Butea monosperma, Nigella sativa, Vitex agnus castus.

INTRODUCTION
The word acne comes from the word acme meaning "the highest point", which is derived from the Greek word akme meaning "point" or "spot". It was originally misspelt, with an 'n' rather than an 'm' in 1835. Acne, medically known as Acne vulgaris, is a skin disease that involves the oil glands at the base of hair follicles. It commonly occurs during puberty when the sebaceous (oil) glands come to life and are stimulated by male hormones produced by the adrenal glands of both males and females.

Acne is a skin condition which every individual comes across in his life time. It is not dangerous, but can leave scars on the skin. Human skin has pores (tiny holes) which connect to oil glands located under the skin. The glands are connected to the pores via follicles or small canals. These glands produce sebum, an oily liquid which carries dead skin cells through the follicles to the surface of the skin. Pimples occur when these follicles get blocked, resulting in an accumulation of oil under the skin. Bacterial attack on sebum causes pus formation and whiteheads which leaves scars.

As acne forms, rubor (redness), tumor (swelling), calor (increased heat), dolor (pain), functio laesa (loss of function) appears as sign of inflammation. In humans, pimples appear on the face, back, chest, shoulders and neck. The defense mechanism of body acts to kill the bacteria, moulding in formation of whiteheads, blackheads, and pustules in these areas. Earlier, due attention was not paid to mild acne but now people are more conscious about their looks. So these days mode of treatment has shifted from allopathic medicines to herbal/ ayurvedic medicines because of observed side effects on long run.

In the present work the application of scientific technological approach in traditional medicine has been used to achieve the objective. The actives have been converted to suitable non oily gel formulation for topical application as it is more suitable compared to oral administration of drugs because it is directly applied to affected site. To achieve the desired therapeutic effect the formulation has to penetrate the skin barrier there being no liver biotransformation. The chosen plants Butea monosperma, Nigella sativa, Vitex agnus castus contain phyto constituents like alkaloids, flavonoids, phenolics etc. which are responsible for anti-inflammatory and anti-oxidant activities that synergistically play a significant role in treating skin infections.

MATERIALS AND METHODS
Procurement of plant material
Butea monosperma Lam. flowers and Nigella sativa Linn. seeds were collected from local region of Udaipur, Rajasthan, India and Vitex agnus castus were procured from 5 P’s Cocopeat and Organic Products, Coimbatore, Tamilnadu, India and authenticated by Vindhya herbal testing laboratory, Minor Forest Produce Processing and Research centre-MFP-PARC, Bhopal, M. P and voucher
samples were deposited there for further reference. Bacterial culture of *P. acnes* MTCC 1951 was obtained from Institute of Microbial Technology, Chandigarh.

### Preparation of plant extract

*Butea monosperma* Lam. flowers and *Vitex agnus castus* leaves were air dried, crushed and the active was extracted with hydroalcohol (water: methanol, 50:50) using soxhlet apparatus. *Nigella sativa* Linn. Seeds were examined for the presence of foreign matter, then crushed and extracted with hydroalcohol (water: methanol, 50:50) in soxhlet apparatus. The extracts were filtered, concentrated and finally dried in a rotary evaporator to obtain dry powder. It was stored in refrigerator for further studies.

### Preparation of gel

Gels were prepared using various proportions of drugs, polymers, additives and carbopol 940 as gelling agent. Additives and preservatives were added to a dispersion of carbopol in water kept overnight. Volume was made upto 100 ml with water. Triethanolamine was then added to obtain a gel of desired consistency. Table 1 depicts various proportions of actives and additives.

<table>
<thead>
<tr>
<th>Table 1: Additives added in the formulations.</th>
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</thead>
<tbody>
<tr>
<td><strong>Formulation code</strong></td>
</tr>
<tr>
<td>F1</td>
</tr>
<tr>
<td>F2</td>
</tr>
<tr>
<td>F3</td>
</tr>
<tr>
<td>F4</td>
</tr>
</tbody>
</table>

### Physical Evaluation

a. **Measurement of pH:** pH was measured using a digital pH meter within 24 hrs of preparation.

b. **Colour:** The colour of the formulations were checked against white and black background and documented.

c. **Odour:** The odour of the gels was checked by mixing the gel in water and smelling it.

d. **Consistency:** The consistency was checked by applying on the skin.

e. **Greasiness:** The greasiness was assessed by application on to the skin.

f. **Homogeneity:** Homogeneity was tested by visual inspection after allowing them to set in a container. They were evaluated for their appearance and presence of aggregates.

g. **Grittiness:** The formulations were evaluated microscopically under 40 x magnifications for the presence of any particulate matter or aggregates.

h. **Skin irritancy test:** This test was performed on 10 healthy human volunteers of either sex after obtaining consent for the same. About 0.5 gms of gel was applied to an area of about 6cm² on skin of hand covered with a gauze patch. The patch was held in contact with the skin by means of a semi-occlusive dressing for an hr. At the conclusion of exposure period of 1 hr, the gauze was removed and residual test substance was scrapped, without altering the existing response or integrity of the epidermis. The skin was observed at 1 hr, 3 hrs, 6 hrs, 12 hrs, 24 hrs, 48 hrs and 72 hrs for any visible response on the skin.

### RESULT AND DISCUSSION

The prepared herbal gels were subjected to physical and microbial evaluation parameters. All gels were yellowish orange in colour with transparent appearance. pH of all gel were in the range of 6.8 – 7.1. The gel was found non-irritant when applied to the skin. Physical and microbial evaluation results which show that formulation F2 was bacteriostatic while formulation F4 shows results comparable to standard ciprofloxacin having zone of inhibition of 27 mm. (Table 2).

**Microbial evaluation**

Prepared gels were subjected to microbial study. Bacterial sub-cultures were added to the sterilized nutrient agar medium and shaken thoroughly to ensure uniform distribution of organism throughout the medium (5 X 10⁴ cfu/ml). The agar medium was then distributed in equal portions, in sterilized petri dishes, such that each petri dish contains about 45-50 mL of the medium. The medium was then allowed to stand for solidification. Then, cups were made with the help of a sterile cork borer (6 mm diameter). Formulations were poured in to the bored cavities and were kept in cool atmosphere to allow the drug to disperse in the agar matrix. It was incubated at 37 °C for 24 hr. The diameter of the zones of complete inhibition (as judged by the unaided eye) was measured in millimeters using sliding calipers or a ruler, including the diameter of the cups bored and is later subtracted from the total measure.

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Table 2: Evaluation of prepared gels.

<table>
<thead>
<tr>
<th>Formulation Code</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
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<td>Orange</td>
<td>Yellow</td>
<td>Light orange</td>
</tr>
<tr>
<td>Odour</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>pH</td>
<td>7.1</td>
<td>6.8</td>
<td>6.8</td>
<td>6.9</td>
</tr>
<tr>
<td>Grittiness</td>
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<td>-</td>
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<td>-</td>
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<tr>
<td>Spreadability</td>
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<td>++</td>
<td>++</td>
<td>++</td>
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<tr>
<td>Ease of absorption</td>
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<td>++</td>
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<tr>
<td>Stickiness</td>
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</tr>
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<td>Homogeneity</td>
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</tr>
<tr>
<td>Oily feel</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Zone of inhibition (mm)</td>
<td>-</td>
<td>2</td>
<td>23</td>
<td>32</td>
</tr>
</tbody>
</table>

- (no result), + (moderate), ++ (good), +++ (best).

CONCLUSION
The results demonstrate that the prepared herbal gels were bacteriostatic at lower concentration and bactericidal at higher concentration. Results show that herbal formulations have potential to treat skin disease and has efficacy comparable to allopathic drugs and hence can be a better option. However chemical stability of these gels is under progress to establish shelf life and determine chemical parameters of evaluation for these formulations.

ACKNOWLEDGMENT
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REFERENCES


