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FORMULATION AND EVALUATION OF HERBAL CREAM BY USING FENNEL IN THE TREATMENT OF ACNE

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Abstract:

Herbal cream is the preparations use by human beings in the treatment of various skin infections. *Propionibacterium* acne and Staphylococcus Epidermis have been recognized as pus-forming bacteria triggering an inflammation in acne. The present research work deals with formulation and evaluation of herbal cream against this etiologic agent of acne vulgaris. The present formulation of Fennel (*Foeniculum Vulgare*), Bees wax, Liquid Paraffin, Borax Methylparaben, Rose water. The Herbal Cream is formulated by aqueous phase. The prepared Cream was evaluated for pH, Spread ability, stability, and *in-vitro* diffusion. The Cream evaluated for colour foreign particle etc. by which the present of active constituent fennel was found to be White Colour the spread ability was found to be easily spreadable on a skin surface area after application and passes all the parameters. Funnel cream is O/W type of emulsion.

Keywords - Fennel (*Foeniculum vulgare*), Anti-acne Cream, Skin, Cosmetic use.

INTRODUCTION

The word Cosmetic derived from a Greek word ‘Kosmesticos’ that means to form that time any materials used to beautification or promoting appearance is known as cosmetic. [1] Cream is classified as oil in water and water in oil emulsion. It is applied on outer part or superficial part of the skin and its main ability is to remain for a longer period of time at the site of application. [2]

Acne Vulgaris is a major issue especially for teenagers and Adolescence according to global statistic, approximately 90% of population will suffer this skin issue at a age around 11-25 years, nearly 8% adult at a age 23-34 years old and only 3% of adults having acne Vulgaris at a age 35-45 years old. [3] Pimple, acne, Sunburn, Mark and Pigmentation are issues that affected every individual at least ones during life time.

Fennel plant (*Foeniculum vulgare*), of the parsley family, having feathery leaves and umbel of small, yellow flowers. Originated in the southern Mediterranean region. Romans grew it for its aromatic seeds. Edible fleshy shoots are still a very common vegetable in southern Italy. Grown wild throughout the

Northern, Eastern, and western hemispheres, specifically in Asia, North America and Europe. Fennel plants approximately production in India 11 Acne by definition is multifactorial chronic inflammatory disease of pilosebaceous units.

Propionibacterium acnes and staphylococcus epidermidis are considered as the major skin bacteria that cause the formation of acne. Although acne does not pose serious threat to general health, it is one of the most socially distressing conditions especially for adolescents. The plants have been reported in the literature having good anti-microbial, anti-oxidant and anti-inflammatory activity. The infection of acne vulgaris exhibits wide distribution and its Prevalence increase over time. [4]

Fig No.1 ***Foeniculum vulgare***

PROCEDURE:

Heat liquid paraffin and bees wax in a borosilicate glass beaker at 75°C and maintain that heating temperature (Oil phase). In another beaker, dissolve borax, methylparaben in distilled water and heat this beaker to 75°C to dissolve borax and methylparaben and to get a clear solution (aqueous phase). Then slowly add this aqueous phase to heated oily phase. Then add measured amount of fennel extracts and stir vigorously until it forms a smooth cream. Then add few drops of rose water as a fragrance. Put this cream on the slab now add few drops of distilled water if necessary and the mix the creams in a geometric manner on the slab to give a smooth texture to the cream and to mix all the ingredients properly. This method is called as slab technique or extemporaneous method of preparations of cream. (For formulation table refer table 2, For different Cream formulation refer fig.2)

FORMULATION

Table No. 2 Formulation of anti-acne cream

Sr. No.	Ingredients	Formulation			
		F1	F2	F3	F4
1.	Fennel Extract	2 ml	3 ml	4 ml	5 ml
2.	Liquid paraffin	10 ml	15 ml	13 ml	15 ml
3.	Bees wax	4 gm	5.5 gm	5 gm	4 gm
4.	Borax	0.2 gm	0.4 gm	0.3 gm	0.5 gm
5.	Methyl paraben	0.02 gm	0.04 gm	0.03 gm	0.05 gm
6.	Rose water	Q.S	Q.S	Q.S	Q.S
7.	Distilled water	Q.S	Q.S	Q.S	Q.S

Fig No. 2 Fennel anti-acne Cream

CHARACTARIZATION OF FENNEL CREAM

A) Determination of the Type of Emulsion

A Congo red dye was mixed with the cream. A drop of the cream was placed on microscopic slide and examined under a microscopic slide and examined under the microscope. If the disperse globules appears red and the continuous phase colourless, the cream is oil in water (o/w) type, the reverse condition occurs in water in oil (w/o) type cream. [5]

B) Organoleptic Evaluation

Anti-acne cream was observed for colour; odour and texture (table no. 3).

C) Determination of pH

The pH of formulation was determined using digital pH meter. (Model EQ-610) One gram of cream was dissolved in 100 ml of demineralised water and stored for 2 hours. The measurement of pH of each formulation was done in triplicate. Instrument was calibrated before use with standard buffer solution at pH 4, 7 and 9 (Table no.4). [6]

D) Determination of Viscosity

100 gram of each formulation was weighed and transferred to a beaker. By using Brookfield viscometer (LV DV-lll Ultra), spindle No. 3 at 10 rpm for 5 min. Before measurement declaration of cream was done and the cream was filled in appropriate viscosity of formulation's were determined with the wide mouth container. Samples of the cream were allowed to settle over 30 min at the assay temperature (25 ± 1°C) before the measurements. Viscosity of formulation was determined using the formula. (Table No. 5).[7]

Viscosity (cps) = dial Reading ×Factor

E) Phase Separation

The prepared cream was kept in a closed container at a normal temperature away from light, in a sealed container. Then over the next 30-day phase separation was observed and after every 24 hours the phase separation was examined and confirmed for any changes. (Table No.6). [8]

F) Spread ability

The spread ability was expressed in terms of times in seconds taken by two slides to slip off from the cream, placed in between the slides, under certain load, lesser the time taken for separation of the two slides better the spread ability. Two sets of glass slides of standard dimension were taken. Then one slide of suitable dimension was taken and the cream formulation was placed on that slide. Then other slide was placed on the top of the formulation. Then a weight or certain load was placed on the upper slide so that the cream between the two slides was pressed uniformly to form a thin layer. Then the weight was removed and excess of formulation adhering to the slides was scrapped off. The upper slide was allowed to slip off freely by the force of weight tied to it. The time taken by the upper slide to slip off was noted. [9]

Spread ability = m×1/t

Where,

S= spread ability in gm.cm/sec.

M = standard weight which is tied to or placed over the upper slide

l = length of glass slide

t = time taken in seconds.

Length of glass slide was 11.2 cm and weight tied to upper slide was (60gm) throughout the experiment (Table No.7).

G) Homogeneity

All formulation are kept for long time; under the observation homogeniser model name Type RQ – 1 2 7A at laboratory scale. [10] (Table No.8)

H) Anti-bacterial property

Sterilization Process:

All glass wares required for anti-microbial test must be sterilized in autoclave at 120°C (250°F) for 15 min. [11]

Disc diffusion technique was selected for anti-microbial study. The test was carried out using *Propionibacterium* acne Sabouraud-dextrose agar media. An amount of 15 ml of the media with 24 h subculture of *Propionibacterium* acne was distribute in each Petridish and allowed to solidify. On solidification microbial suspension was spread with the help of sterilized cotton swab on the surface of media. The filter paper disc was prepared with Whattman' s filter paper, which then impregnated with drug *Foeniculum vulgare* present in anti-acne cream and control (extract of *Foeniculum vulgare*) on the surface of agar plates on which culture of microorganisms has been streaked. Zone of inhibition diameter was then recorded for test and control (28ºC after 24 h) and compared. The study was carried out in aseptic area. The experiment was performed in sterilized condition. [12] (table No.9)

I) *In-vitro* Drug Release

Analytical Methodology of Fennel Extract in Phosphate Buffer

UV Spectroscopy- Stock solution of drug was prepared by dissolving 10 g of drug in phosphate buffer (6.8 pH). Required dilutions of 1 ppm, 2 ppm, etc. were prepared. The prepared dilutions were scanned in the UV region of 301.0 nm.

The dissolution study were performed in six station dissolution apparatus. (33 ± 0.5°C, 50 rpm). By using phosphate buffer (pH 6.8, 900ml) for 15, 30, 60, 90, 120, 150, 180, 240, 300, 360 min. and replenished immediately with the same volume of phosphate buffer maintaining sink condition throughout the experiment. The aliquots were analysed spectrophotometrically at 301.0 nm. The concentration of drug in test samples was calculated using regression equation. (Model No- Cary 60) (Table No.10). [13]

Fig No. 3 Franz diffusion apparatus with magnetic stirrer

J) Stability Study

The stability study was carried out by storing the anti-acne cream at three different temperatures which are 10°C, 27°C and 40°C for three months. [14] (tableNo.11,12,13).

RESULTS AND DISCUSSION

A) Determination of Type of Emulsion

Formulation are confirmed by dye test. If the disperse globules appear red the continuous phase colourless, the cream is oil in water (O/W) type of emulsion cream.

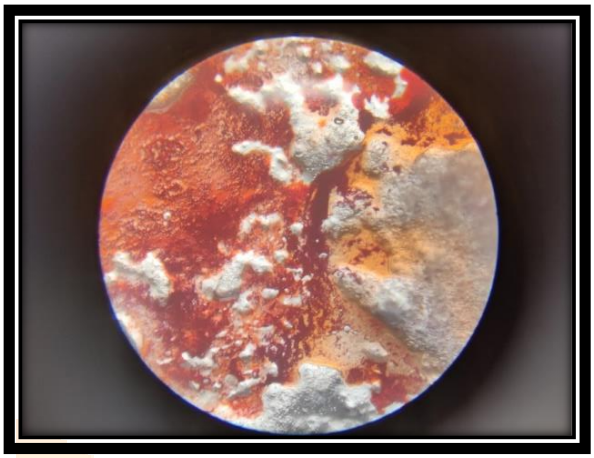


Fig. No.4 O/W type of Emulsion

B) Organoleptic Evaluation

Colour, Odour, texture was conformed in laboratory scale.

Table No. 3 Organoleptic Evaluation

Formulation	Colour	Odour	Texture
F1	White	Aromatic, Pleasant	Smooth
F2	White	Aromatic, Pleasant	Smooth
F3	White	Aromatic, Pleasant	Smooth
F4	White	Aromatic, Pleasant	Smooth

C) Determination of pH

pH of all the four formulation F1, F2, F3, F4, was found to be closer to skin pH, including that they can be safely used on skin pH of all four formulation.

Table No. 4 Determination pH

Formulation	pH
F1	4.8
F2	5.5
F3	6.2
F4	5.7

F1, F2, F4 are the suitable formulations for the skin, as skin pH is 4.8 to 6.

D) Determination of Viscosity

The viscosity of cream was measured with Brookfield viscometer.

Table No. 5 Determination of viscosity

Formulation	Viscosity(Cps)
F1	21020
F2	11810
F3	13426
F4	18821

F1, F2, F3 and F4 reading was recorded successfully.

E) Phase Separation

The prepared cream was maintained in a covered container away from light at a temperature of 25-100°C. After that, phase separation was tested for 24 hours and 30 days. The phase separation was examined and confirmed for any changes.

Table No. 6 Phase Separation

Formulation	Phase Separation
F1	No
F2	No
F3	No
F4	No

All four formulations do not show phase separation.

F) Spread ability

The spread ability of the four formulations, F1, F2, F3, and F4, was tested.

Table No. 7 Spread ability

Formulation	Spread ability
F1	32.4
F2	32.3
F3	25.3
F4	15.18

It was discovered that for F2, the time taken by the three slides to separate is less, and as stated in the assessment time taken for separation of the three slides is better, therefore F2 exhibited greater spread ability.

G) Homogeneity

Homogeneity and stability study are performed successfully. Stability studies at temperature 10°C ± 1°C in refrigerator and at 25°C ± 1°C, 40°C ± 1°C in incubator for 8 weeks.

Table No. 8 Homogeneity

Formulation	Homogeneity
F1	Homogenous
F2	Homogenous
F3	Homogenous
F4	Homogenous

All formulations are homogenous.

H) Anti-acne property of cream

Table No. 9 Zone of inhibition of sample and control

Formulations	Zone of inhibition (mm)	
	500 ppm/disc	**250 ppm/disc**
Cream	22.85 ± 1.10	19.64 ± 1.02
Control	4.64 ± 1.16	4.32 ± 0.04

Control = extract of *Foeniculum vulgare*

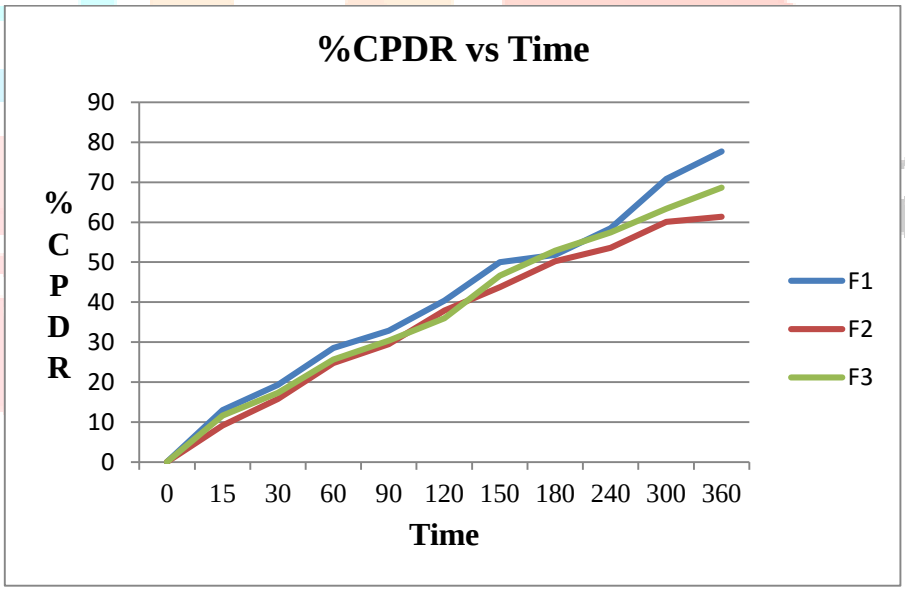
Anti-acne property of cream was evaluation using disc diffusion technique. Zone of inhibition values for the test and control were observed. The observed average ± SD values for test and control at 500 ppm/disc are 22.85 ± 1.10 and 4.64 ± 1.16, at 250 ppm/disc is 19.64 ± 1.02 and 4.32 ± 0.04 respectively. It was found that test has significantly large zone of inhibition compared to control. Thus, it possess better anti-acne property.

I) Drug Release Profile

Cumulative percentage drug release was checked for duration of 6 h was following.

Table No. 10 Cumulative percentage drug release

Time in min.	%Cumulative Percentage Drug Release		
	F1	F2	F3
0	0.0	0.0	0.0
15	12.95	9.15	11.65
30	19.32	15.75	17.33
60	28.5	24.78	25.67
90	32.88	29.48	30.34
120	40.36	37.91	35.94
150	49.97	43.74	46.59
180	51.86	50.23	52.86
240	58.45	53.59	57.48
300	66.78	60.11	63.34
360	70.69	61.39	68.66



Graph No.1 %CPDR vs Time

Drug release from F1, F2, and F3 shows that F1 has maximum drug release of 70.69 % as compared to F2 and F3 which has drug release of 61.39 % and 68.66 % respectively. So the optimized formulation F1 shows highest drug release obtained on the basis of release is F1.

J) Stability Study

There are no significant changes are observed under different temperature in stability study for 3 months for cream formulation**.**

Stability Study at **10°C**

Table No. 11 Stability study at 10°C

Parameter	0 day	15 day	30 day	90 day
pH	4.6	4.6	4.6	4.6
Viscosity	12485 Cps	13745 Cps	16975 Cps	19756 Cps
Colour	White	White	White	White
Phase separation	No	No	No	No
Consistency	No change	No change	No change	No change

Stability Study at **27°C**

Table No. 12 Stability study at 27°C

Parameter	0 day	15 day	30 day	90 day
pH	4.5	4.5	4.5	4.5
Viscosity	10385 Cps	12644 Cps	14773 Cps	15286 Cps
Colour	White	White	White	White
Phase separation	No	No	No	No
Consistency	No change	No change	No change	No change

Stability Study at **40°C**

Table No. 13 Stability study at 40°C

Parameter	0 day	15 day	30 day	90 day
pH	4.4	4.4	4.4	4.4
Viscosity	9485 Cps	11359 Cps	12921 Cps	14619 Cps
Colour	White	White	White	White
Phase separation	No	No	No	No
Consistency	No change	No change	No change	No change

CONCLUSION

Acne is an extremely common skin disorder that affects virtually all individuals at least once during life. Three formulation were prepared and were optimized on the basis of *in-vitro* release study F1 formulation is better than F2and F3. This could be an effective formulation made from fennel and has cosmetic benefits like Anti-Inflammatory, Anti-Oxidants and are more acceptable in the belief that they are safer with fewer side effects than the synthetic ones, so herbal anti-acne cream which is non-toxic, safe and effective was formulated.

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