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FORMULATION AND EVALUATION OF ANTI-ACNE GEL FROM POLYHERBAL OILS

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Abstract: Natural remedies are more acceptable in the faith that they are safer with less side effects than the synthetic ones. Herbal formulations have rising demand in the world market. The present work deals with the development & evaluation of the herbal anti-acne gel containing extract of Cinamum (Cinnamomum zeylanicum), Clove (aromaticum), Turmeric (Curcuma Longa), Ashwagandha (Withania somnifera), Basil (Ocimum basilicum L.) and Rose oil (Rosa) Although various topical herbal formulations for acne are available in the market, we propose to make polyherbal formulation using different herbal & synthetic ingredient. The plants have been reported in literature having good anti-microbial, anti-oxidant & anti-inflammatory activity. Various formulation batches i.e., F1 to F3 were prepared using polymers in varied concentrations. Prepared formulations (F1 to F3) were evaluated for various parameters like colour, appearance, consistency, washability, extrudability, pH , determination of formulations sensitivity,stability studies,irritancy test,spreadability and microbial evaluation . Amongst all the formulation studies batch F3 was found optimum for all the parameter. It was very good attempt to establish the herbal anti-acne face wash containing extract of Cinamum (Cinnamomum zeylanicum), Clove (aromaticum), Turmeric (Curcuma Longa), Ashwagandha (Withania somnifera), Basil (Ocimum basilicum L.) and Rose oil (Rosa).

Key Words Cinamum (Cinnamomum zeylanicum), Clove (aromaticum), Turmeric (Curcuma Longa), Ashwagandha (Withania somnifera), Basil (Ocimum basilicum L.) and Rose oil (Rosa),Carbapol, Propyline Glycol, Methyl Parabeen, Triethalamine, E-coli Bacteria, Antimicrobial Activity, polyherbal gel.

INTRODUCTION.

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. The route of administration has a significant impact on the therapeutic outcome of a drug. 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. Semi-solid formulation in all their diversity dominate the system for topical delivery, but foams, spray, medicated powders, solutions, as well as medicated adhesive systems are also in use.

•External topical that are spread, sprayed, or otherwise dispersed on to cutaneous tissues to cover the affected area.

•Internal topical that are applied to the mucous membrane orally, vaginally or on anorectal tissues for local activity.

The word acne comes from the word acme meaning "the highest point", which is derived from the Greek word akme meaning "point" or "spot". 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 skin is multi-layered organ and anatomically has many histological layers. Skin is an anatomic barrier between the body and its environment and contributes to about 16- 18% of normal body weight. The overlaying outer layer is called epidermis; the layer below epidermis is called dermis. Beneath the dermis are subcutaneous fatty tissues.

Acne is a long-term skin disease that arises when hair sacs are blocked with departed skin cells. The common name for acne is Acne vulgaris. 70% - 80% of patients affected by this are aged 11-25 years old. It is characterized by the formation of inflammatory and non-inflammatory lesions of the hair follicles and /or sebaceous glands commonly referred to as the pilosebaceous unit. A slight degree of acne is typical at puberty, but a serious case can cause unsightly appearance and leaves scarring in many cases even after treatment. In practical terms, acne may be grouped in terms of severity of the symptoms; i.e. mild, moderate and severe.

The most common form of acne; usually affects people from puberty to young adult hood. Hickey, pimple, zit A small inflamed elevation of the skin; a pustule or papules which are common symptoms in acne. Difference between a pimple and acne: Unlike common acne, rosacea is not primarily a disease of teenagers but occurs most often in adults (ages 30-50), especially in those with fair skin. Different than acne, there are usually no blackheads or whiteheads in rosacea. Certain people get one or two spots off and on while others get frequent eruption of spots with lots of pus-filled pimples indicates acne which is a chronic or prolonged condition that affects many teens and adults. More or less all human beings in the world gets pimples at some point of time sooner the body enter into puberty stage at the age of 12, there commence to release hormones and start to function in the bodies of man or woman irrespectively and at this juncture food or pollution, ought to upset hormonal balance thereafter.

A gel is a solid or semisolid system of at least two constituents, consisting of a condensed mass solids enclosing and interpenetrated by a liquid. Gels and jellies are composed of small number of dispersed in relatively large amount of liquid, yet they possess more solid-like than liquid-like character. The characteristic of gel and jelly is the presence of some form of cutaneous structure, which provides solid-like properties.

Materials and Methods.

Material –

table 1 : list of chemicals used

Sr.no.	chemical
1.	Ethanol
2.	Carbopol 940
3.	Propylene glycol
4.	Methyl paraben
5.	Propyl paraben
6	Triethanolamine

Methods.

Extraction of Herbs.

Extraction of Turmeric oil.

In order to extract turmeric oil, we have used steam distillation, hydro-distillation, and extraction using hexane. Hexane was combined with the oils after curcumin extraction and heated to 60 °C three times for one hour. The solvent was removed, which resulted in successful turmeric oil extraction

Extraction of Clove oil.

To carry out hydro-distillation, dried clove sample is taken into 500 mL volumetric flask and subjected to hydro-distillation for 4–6 hours. Subsequently, the volatile distillate is collected and saturated with sodium chloride following the addition of petroleum ether or other suitable organic solvent.

Extraction of Ashwagandha.

Preparation of crude alcoholic extract of Ashwagandha leaves Briefly, dried roots or leaf powder was suspended in 85% ethanol in a ratio of 1:30 and incubated at 85°C for 2 h in a reflux system. The collected extract was filtered and concentrated by evaporation at 60°C.

Extraction of Basil.

The extraction was done in a Clevenger apparatus, coupled to a bottom flask of 500 mL. It was added 30 g of crushed leaves of basil and 300 mL of water into the flask. The extraction time was fixed at 4 hours. The extract oil was diluted in hexane and filtered after separation.

Extraction of Cinnamon.

Amount of 100 to 150 g of mashed cinnamon sticks were introduced into the distillation flask (1L), which was connected to the steam generator via a glass tube and to a condenser to retrieve the oil. The essential oils were volatilized with boiling water at temperature 100°C for 5 and 10 hours. The recovered mixture was allowed to settle and the oil was withdrawn . After the steam distillation process, the product was collected and separated using separatory funnel. The essential oils settled at the bottom layer of the separatory funnel and were separated several times until no oil was left in the separatory funnel.

Extraction of Rose oil

Rose oil is the essential oil extracted from the petals of various types of rose. Rose ottos are extracted through steam distillation, while rose absolutes are obtained through solvent extraction, the absolute being used more commonly in perfumery.

Phytochemical investigation of the extract

Poly herbal gel was evaluated for phytochemical parameters showed in the Table 2. It was found to be a presence of phytoconstituents such as carbohydrates, alkaloids, glycosides, Saponins and Flavonoids which act as good nourisher for the skin

table 2: phytochemical evalution

Test for Phenol 2ml. extraxt + 2ml.ferric chloride	Appearance of dark green or bluish green color
Test for tannins 2ml. Extract +few drops lead acetate	Appearance of yellow colour
Test for flavonoids 200 mg extract + sodium hydroxide +few drops HCL	Colour changes from deep yellow to colourless
Test for Glycosides Extract + 1 ml of glacial acetic acid +1 ml Con. Sulphuric acid	appearance of greenish blue color
Test for Steroids 200 µl extraxt +few drops of conc. H_2SO_4	change in color of lower layer to yellowish and reddish upper layer.
Test for Alkaloids 200 µl extract +few drops of Wagner's reagent	A reddish brown precipitate was formed

Procedure of Gel Formulation –

1. Gel of polyherbal extract was made using a varying concentration of carbopol as a gelling agent.
2. In this gel base, distilled water was used as the solvent, methylparaben as a preservative, and propylene glycol as a humectant, the formula can be seen in table 3.
3. The carbopol was dissolved in demineralized water which has been heated to a temperature of 70 °C inside the mortal, then stirred slowly to form a homogeneous dispersion.
4. propylene glycol was dissolved in demineralized water separately and stirred.
5. The Extract of turmeric , clove , cinnamon , ashwagandha , basil , rose oil which has been added as mentioned in table no.3 and Methyl-paraben and has been diluted with ethanol was added to carbopol solution and stirred until homogeneous solution was obtained.The propylene glycol solution and Triethanolamine was added and stirred until consistent gel was obtained.
6. The gel was kept for 24 hr until the bubbles were disappeared, then the pH and gel viscosity was measured.

Formulation Table:

table 3:formulation table

Sr.no.	Ingredients	F1 Qty.	F2 Qty.	F3 Qty.
1	Turmeric	5 ml.	5 ml.	6 ml.
2	Clove (Oil)	3 ml.	4 ml.	5 ml.
3	Cinnamon	2 ml.	2 ml.	2 ml.
4	Basil	5 ml.	5 ml.	5 ml.
5	Ashwagandha	5 ml.	4 ml.	5 ml.
6	Rose water	6 ml.	7 ml.	10 ml.
7	Carbopol	1 gm.	1 gm.	1 gm.
8	Propylenglycol	10 ml.	10 ml.	10 ml.
9	methyl paraben	500 mg.	500 mg.	500 mg.
10	demineralized water	100 ml.	100 ml.	100 ml.

Evaluation of Gel

1. Appearance and consistency.

The physical appearance was visually checked for the texture of polyherbal gel formulations.

2. Washability.

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

3. Extrudability determination of formulations.

The polyherbal gel formulations were filled into collapsible metal tubes or aluminium collapsible tubes. The tubes were pressed to extrude the material and the extrudability of the formulation was checked.

4. Sensitivity.

A portion of cream was applied on the forearms of 6 volunteers and left for 20 min. After 20 min any kind of irritation if occurred was noted .

5. Determination of spreadability.

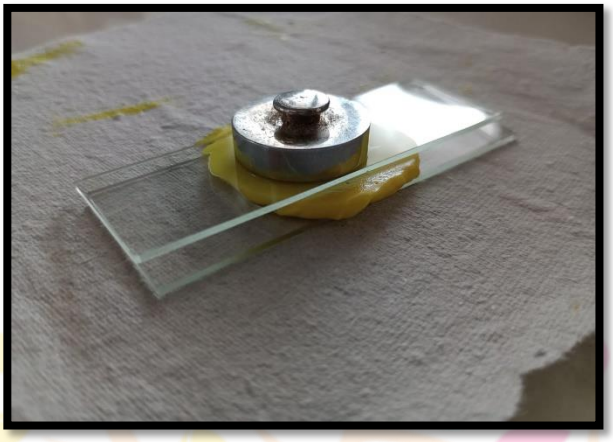
The spreadability was expressed in terms of time in seconds taken by two sides to slip off from. Gel placed in between the sides , under certain load Lesser the time taken for separation of the two sides after the spreadablity . Two slides of glass sides of standard dimension were taken . Then one side of suitable dimension was taken and the gel formulation was placed on that side . Then other side was placed on the top of the formulation Then a weight or certain load was placed on the upper side so that the gel between the two sides was pressed uniformly to form a thin layer . Then the weight was removed and excess of

formulation adhering to the sides was scrapped off the upper side was allowed to sip off freely by the force of weight tide to it . The time taken by the upper side to sip off was noted .

Spreadability can be calculated by using following formula :

$$\text{Spreadability} = \frac{m \times l}{t}$$

Where, S=Spreadability (gcm/sec), m = weight tied to the upper slide (20 grams), l= length of glass slide (5cms), t = time taken is seconds.



(fig no.1: Spreadability)

6. Determination of pH.

Small Quantity of gel was taken for the determination of pH by using the pH paper

(fig no.2: pH)

7) Morphological Evaluation.

Formulated herbal gel was further evaluated by using the following physical parameters. Colours, odour, appearance , clogging homogeneity .

8) Irritancy Test.

Mark an area (1 sq.cm) on the left hand dorsal surface. The gel was applied to the specified area and the time was noted .irritancy, erythema , edema was checked if any for regular intervals up to 24 hrs and reported.

9) Stability Studies.

Stability of the gel formulation were studied at different storage condition (room temp. and 40°C) Samples were withdrawn at 7, 15 and 30 days and checked for their physical characteristics like appearance, homogeneity, pH, viscosity and spreadability.

10) In-vitro anti acne activity.

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 105 cfu/ml). The agar medium was then distributed in equal portions, in sterilized petri dish, 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 ℃ for 24 hr. The diameter of the zones of complete inhibition (as judged by the Antibiotic zone reader) was measured in millimetres.

RESULT AND DISCUSSION

1)Phytochemical screening of the extract.

Polyherbal gel was evaluated for phytochemical parameters showed in the Table 4. It was found to be a presence of phytoconstituents such as Phenols, alkaloids, glycosides, Steroids , Flavonoids and tannins .

table 4: phytochemical evalution

Sr. No	Phytoconstituents	F1	F2	F3
1	Steroids	Present	Present	Present
2	Alkaloids	Present	Present	Present
3	Glycosides	Present	Present	Present
4	Phenol	Present	Present	Present
5	Flavonoids	Present	Present	Present
6	Tannins	Present	Present	Present

2)Morphological Evaluation.

Polyherbal gel was evaluated for morphological parameters showed in the Table 5. The colour of formulation was pale yellow. The odour of prepared formulations was pleasant and good acceptable which is desirable to cosmetic formulations. Texture and smoothness was acceptable as per requirement of cosmetic formulations.

table 5:- morphological evalution

Sr. No.	Parameter	F1	F2	F3
1	Color	Pale yellow	Pale yellow	Canary
2	Odour	Pleasant	Pleasant	Pleasant
3	Apperance	Smooth Fine	Smooth Fine	Smooth Fine
4	Clogging	Absent	Absent	Absent
5	Homogeneity	Good	Good	Good

3) Physical test evaluation.

Physical test such as Washability, Extrudability, Spreadability, pH, Viscosity are carried out, And formulated gel evaluated for this parameters.

- **pH**

The pH of formulation were found to be nearer to the skin pH so it can be used safely used on the skin.

- **Washability**

Washability test was carried out by applying a small amount of gel on the hand and then washing it with the tap water. The formulation was easily washable.

- **Spreadability**

The Spreadability of the gel formulation was carried out and time taken by the two slides to spate it less so as said in the description of evaluation test lesser the time taken form sepearation of the two slide better the Spreadability so according to this statement formulation showed better Spreadability

- **Viscocity**

The viscocity of gel was done by using Brooke field viscometer at the temp.of 25℃ using spindle no 63 at 5 rpm. According to the result formulation show adequate viscocity.

- **Extrudability**

In the present study, the method adopted for evaluating gel formulation for extrudability was based upon the quantity in percentage cream extruded from tube on application of finger pressure. More quantity extruded better was extrudability. Th formulation under study was filled in a clean, lacquered aluminium collapsible 5 gm tube with a nasal tip of 5 mm opening and applied the pressure on the tube by the help of finger. Tube extrudability was then determined by measuring the amount of gel extruded and it was found to be that 3 gm of gel extruded from 5 gm of gel and it shows a good

table no.6: results of washability, extrudability, spreadability, pH, viscosity

Formulation batch	Washability	Extrudability	Spreadability (gcm/sec)	pH	Viscosity (cps)
F1	Good	Average	14.28	7.3	3365±18
F2	Good	Average	12.5	7.2	3458±20
F3	Good	Average	11.11	7.0	3654±25

4) Irritancy Test.

The results of irritancy test were shown in Table 7. The formulation showed absence of irritation, redness and swelling during irritancy studies. This formulation have safe to use on skin.

table 7: irritancy test

Sr. No.	Parameter	F1	F2	F3
1	Irritation	No	No	No
2	Redness	No	No	No
3	Swelling	No	No	No

5) Stability Studies.

The results of stability were shown in Table no:9. No change in color, odour, texture and smoothness was observed at mentioned conditions of stability except pH. The stability studies showed a slight change in pH of formulation at 40C.

table 8:- stability test room temperature.

Sr. No	Parameters	F1	F2	F3
1	Color	No change	No change	No change
2	Odour	No change	No change	No change
3	pH	7.3	7.2	7.0
4	Clogging	No	No	No
5	Homogeneity	Good	Good	Good

table 9 :- stability test 40°C temperture.

Sr. No.	Parameters	F1	F2	F3
1	Color	No change	No change	No change
2	Odour	No change	No change	No change
3	pH	7.5	7.4	7.3
4	Clogging	No	No	No
5	Homogeneity	Good	Good	Good

6) Microbial evaluation.

The antimicrobial activity testing was performed by measuring and comparing the diameter of zones of inhibition (in mm). The zone of inhibition can be defined as the clear region around the well that contains an antimicrobial agent. It is known that the larger the zone of inhibition, the more potent the antimicrobial agent. Formulated gel observed for its antimicrobial property towards the organism such as *Escherchia coli* . From the result it was observed that there was no microbial contamination observed and it showed good zone of inhibition.and the results were shown in Table No.10.

table 10.:- zone of inhibition of the formulated polyherbal gel

Batch name	Zone of inhibition	Mean
F1	17.8	18.0 ± 0.23
F2	18.2	
F3	18.0	

(fig.3: photographs of zone of inhibition toward E. Coli)

(fig.4: antibiotic zone reader)

Conclusion:

All these investigations have brought out ultimate factors which leads to the following conclusions This study targets the chronic skin condition acne with the aim of formulating an effective and safe Polyherbal gel. The ethanolic extract of *turmeric ,clove ,cinnamon ,ashwagandha* And *basil* were incorporated in to optimized Carbopol gel base The combination of these herbal constituents may produce an effect to minimize the Acne problem. Antimicrobial study shows that there was no microbial contamination observed and it showed good zone of inhibition and skin irritation study results showed that there was no skin lesions like defatting of skin, adverse skin reactions, local systemic change. Overall, this study reports concluded that the formulation of polyherbal gel may offer an effective and safe dosage form which leads to patient adherence and compliance to the therapy.

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