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Original Research Paper

Pharmacy

FORMULATION AND EVALUATION OF TOPICAL DRUG DELIVERY SYSTEM

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ABSTRACT Topical drug administration is a localized drug delivery method that can be applied topically to any part of the body via the skin, rectal, vaginal, or ocular pathways. Skin is the primary channel of topical drug delivery and one of the human body's most accessible organs for topical administration. the average human being covers an area of about 1.5-2m square and about 16%of body Wright There are two types of gels : chemical gels and physical gels . chemical gels are usually covalently cross –linked gels and physical gels consist of tiny molecules or chemical chains that are physically cross linked form network . There are various factors affecting tropical drug delivery. Physiological factor like lipid profile, skin thickness, skin temperature, blood flow etc.

KEYWORDS : Anti Acne Gel, Herbal Drug, Antioxidants, Salmalia Malabarica

INTRODUCTION

ACNE [1,2]

A skin condition that occurs when hair follicles plug with oil and dead skin cells. *Acne vulgaris* know as acne, is a common chronic caused by abnormal sebaceous production within skin follicles. 70% - 80% of patients affected by the aged 11-25 years old.

Causes of Acne:

1. Hormonal changes that result in skin oilier.
2. High humidity and swatting.
3. Certain drugs (such as steroids, testosterone, estrogen and phenytoin). Birth control devices such as some drug containing IUDs, can make acne worse.

Advantage of Topical Drug Delivery [3]

1. Preventing first-pass metabolism
2. Increasing patient acceptance and complaints
3. Easy to use and convenient

Disadvantages of Topical Drug Delivery

1. The medication or excipient may cause skin irritation .
2. Certain drugs have poor skin permeability.
3. An allergic response could occur.

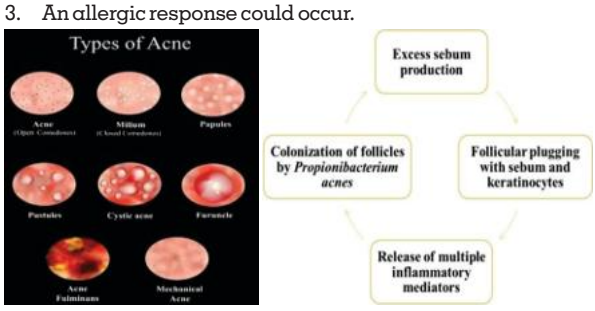

Fig No1:- Type of Acne

GELS [4,5]

The term 'Gel' was introduced in the late1800 to name some semi solid material according to their physiological characteristics rather than molecular composition. A gel is a two- component, cross-linked three-dimensional network consisting of structural materials interspersed by an adequate but proportionally large amount of liquid to form an infinite rigid network structure which immobilizes the liquid continuous phase.

1.5.2.Ideal Properties of Gel

1. Thegel should be clear and homogenous.
2. The gel should be easily broken when shear or force is applied during shaking the container.
3. Thegel should be inert in nature.
4. Thegel should be not sticky.
5. The gel should be never interacting with other formulation component.
6. Thegel should be stable.
7. It should not be irate the skin or any part where the gel is applied.
8. The viscosity is optimum.
9. It should a anti-microbial activity.

MATERIAL AND METHODS

Materials :-

Table no 1: Ingredient Name and their Roles :

Ingredients	Role of ingredients
Salamalia malabarica	Anti–inflammatory, oil–controlling properties
Carbopol 940	Gelling agent
Propylene Glycol 400	Humectants PH adjuster ,emulsifier
Triethanol amine	PH adjuster , emulsifier
Methyl Paraben / Propyl Paraben	Preservative

Detail Profile of Material Used

Salamalia Malabarica [6,7]

Botanical Name: *Salmalia malabarica; Bombax ceibaL.;*

Bombax malabaricum
Kingdom: Plantae
Division: Magnioliophyta
Class: Magniolipsida
Order: Malvales
Family: Maleae
Genu: Bombax
Species: B. ceiba

Figure No 2: *Salmalia Malabarica* Plant

Pharmacological Used :
Anti- inflammatory, antimicrobial, astringent .

Geographical Source:[8]
It is an important medicinal plant cultivated in Pakistan, India, China and Australia[1]

Chemical Constituent :
Flavonoids , sterols, tanning and phenolic acids , coumarins.

METHOD:
Extraction Procedure: [9]
The chop leaves were place in the filter paper bag and place into the Soxhlet device

⇩

The vapors were condensed after the excreted solvent in the flask was heated.

⇩

The powder leaves in the filter paper bag were dripped with the condenses extract .

⇩

The liquid in the chamber syphon was collected into the flask when the liquid leaves to the top of he syphon tube .

⇩

These Procedure were repeated until the syphon tube was empty the collected extract was then evaporated by rotavapor to total remove the solvent, and the crude extract was recovered in a semisolid and sticky form.

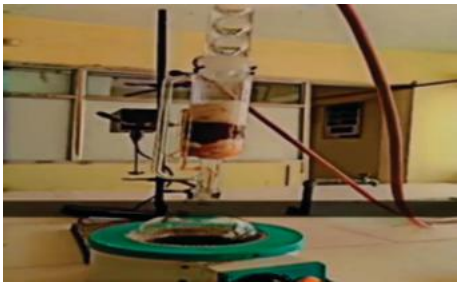

Fig No 3: Soxhlet Extraction Procedure

Procedure for Preparation of Gel:
Gelling agent was dispersed in sufficient quantity of water with continuous stirring. Propylene glycol 400 which is used as humectants or plasticizer was added to the dispersion. Other excipients such as methylparaben and propyl paraben was added with continuous stirring. In Carbopol gels, pH often vehicle was brought to neutral by using TEA (Triethanolamine). The final weight of the gel was adjusted to 50 gm with distilled water. Then the mixture was stirred by using propeller for 2 hours at 500 rpm. After stirring, this homogenous gel appeared to be free of bubbles. It was kept at room temperature for 24 hours to check the consistency and stability of gel.

Table No.2: Composition of Gel

Ingredients	F1	F2	F3	F4
Carbopol940(gm)	0.5	1	1.5	2
Methyl Paraben(gm)	0.15	0.15	0.15	0.15
Propyl Paraben(gm)	0.3	0.3	0.3	0.3
Propylene Glycol400(ml)	5	5	5	5
Triethanol amine(ml)	1	1	1	1
Extract(ml)	3	3	3	3
Water	q. s.	q. s.	q. s.	q. s.

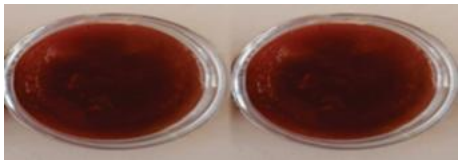

Fig No 4 : Gel

Evaluation Of Extract
The extract was examined for the following parameters:
- Color
- Oduor
- Solubility in water , ethanol, methanol.

Phytochemical Screening of Extract[10,11]
Preliminary qualitative phytochemical analysis was carried out to identify the active constituents present in the alcoholic extracts of *Salmalia Malabarica*. The following procedures were adopted to test for the presence of various constituents in the *Salmalia Malabarica* extract

Test for Alkaloids
- Dragendroff's reagent test: Treated the solution with Dragendroff reagent. Orange brown ppt are formed.
- Mayers's reagent test: Treat the solution with Mayer's reagent. Cream ppt or turbidity are formed.

Test for Carbohydrates
- **Molisch Test:** Crude extract was mixed with 2ml.of Molisch's reagent & the mixture was shaken properly .After that 2ml of conc.112 SO4 was poured carefully a long the side of the test tube. Appearance of violet ring at the interphase indicated the presence of carbohydrate.
- **Barfoed's Test:** The filtrate solution treated with Barfoed's reagent and heated for 2 min. A red precipitate formed.

Test for Reducing Sugar
- **Benedict's Test:** The filtrate solution treated with Bendict's reagent and boil for 2 min. Green/ yellow/ red color formed.
- **Fehling's Test:** Equal volume of Fehling A & B reagent was mixed together & 2ml of it was added to crude extract & gently boiled. A brick red precipitate appeared at the bottom of the test tube indicated the presence of reducing sugars.

Test for Glycosides
- **Keller Killani Test:** In filtrate solution, glacial acetic acid and drop of 5% ferric chloride. Then conc. H_2SO_4 added along the side of test tube. A blue colored solution is formed.
- **Brown Water Test:** Plant extract added in few ml of bromine water. A yellow precipitate formed.

Protein and Amino Acid
- **Millon's Test:** Crude extract when mixed with 2ml of Millon's reagent, white ppt appeared which turned red upon heating that confirmed the presence of protein
- **Ninhydrin Test:** Crude extract when boiled with 2ml of

0.2% solution of ninhydrin, violet color appeared suggesting the presence of amino acid and protein.

Test for Flavonoids

- Alkaline reagent test: Crude extract was mixed with 2ml of 2% solution of NaOH. Intense yellow color was formed which turned colorless on addition of few drops of diluted acid which indicated the presence of flavonoids.
- Conc. H_2SO_4: Plant extract treated with conc .H_2SO_4. Anangeon or formed.

Test for Phytosterol

- **Salkowski's Test:** The plant extract treated with few drops of conc. H_2SO_4, shake well and allow to stand. Red color is appeared in lower layer.
- **Liberman-Burchard's Test:** The plant extract dissolved in 2 ml of acetic anhydride and few drops of conc. H_2SO_4added along the side of test tube. An array of color change.

Test for Phenol and Tannins

- **Ferric Chloride Test:** 10mg extracts were treated with few drops of ferric chloride solution. Formation of bluish black color indicates that the presence of phenol &tannins.

Test for Terpenoids

- Liberman-Burchard's test: The plant extract dissolved in 2 ml of acetic anhydride and few drops of conc. H_2SO_4added along the side of test tube. An array of color change.

Evaluation of Gel : [12]

The prepared polyherbal gel were subjected to physical characterization such as color, appearance, pH, viscosity, spread ability. It was also evaluated for its stability property, antioxidant activity and in vivo skin irritation study. The above formulated gel formulation was subjected to evaluation of following parameters:

Physical Observation

Physical parameters such as color, appearance and feeling on application were recorded. Color, appearance and feeling on application and other visual factors like clarity and color of formulation are first thing decides quality of formulation.

- **Color:** The color of the formulation was checked visually.
- **Odour:** The odour of the gel was checked by mixing the gel in water and taking smell.
- **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.
- **Consistency:** The consistency of the formulation was checked visually. Determination of pH

The pH of all formulations was determined by a pH meter (Digital pH meter). The pH meter was calibrated with a standard buffer solution having pH 4 and 7before use. 0.5gof the cream was weighed and dissolved in 50.0 ml of distilled water and its pH was measured.

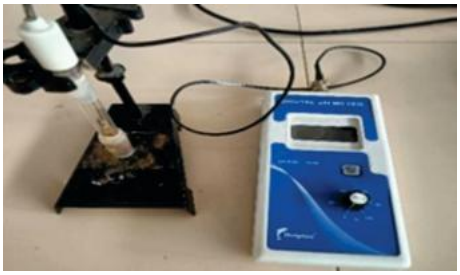

Figure no 5: Digital pH Meter

Determination of Viscosity[13]

The viscosity of cream was determined by LVT Brookfield viscometer. The sample was placed in a clean and dried container and viscosity was checked as per standard operating procedure of viscometer by using spindle no. 64 at speed 100 rpm. After the dial reading viscosity was calculated in the centipoises (cps). Following formula is used for the calculation of the viscosity:

Viscosity in centipoises(cps)=Dial reading× Factor.

Figure No 6: Brook Field Viscometer

For calculation of viscosity put the factor value corresponding to the speed and the spindle number.

Determination of Spread Ability

Two sets of glass slides of standard dimensions were taken. The herbal cream formulation was placed over one of the slides. The other slide was placed on the top of the cream ,such that the cream was sandwiched between the two slides in an area occupied by a distance of 7.5 cm along the slide. 100g weight was placed upon the upper slides so that the cream between the two slides was pressed uniformly to form a thin layer. The weight was removed and the excess of cream adhering to the slides were scrapped off. The two slides in position were fixed to a stand without slightest disturbance and in such a way that only the upper slide to slip off freely by the force of weight tied to it. A 100g weight was tied to the upper slide carefully. The time taken for the upper slide to travel the distance of 7.5 cm and separated away from the lower slide under the influence of the weight was noted. Spread ability was calculated by using the following formula.

$$S = M XL/T$$

Where, S=Sread ability

L=Length of the glass slide(7.5cm)

M= Weight of upper slide (100 gm)

T=Time taken to separate the slide completely from each other.

Skin Irritation Test[14,15]

A set of five mice was used in the study. The gel formulation was applied on the properly shaven skin of mice. Undesirable skin changes, i.e. change in color and changes in skin morphology, were observed for a period of 24 h.

Stability Study

Stability may be defined as the ability of the drug to retain its property within specified limits throughout its shelf life. Improper storage of cosmetic product can lead to their physical deterioration & chemical degradation resulting in reduced activity and occasionally in the form of toxic degradation product. So, stability studies are carried out foreach product .The present stability studies are carried out according to guidelines given by International Council for Harmonization of Technical Requirements for Phar-

maceuticals for Human Use (ICII). The cream filled in bottle and kept in humidity chamber maintained at 30 ± 2 °C/ 65 ± 5% RH and 40 ± 2°C/ 75 ± 5% RH for three months. At the end of studies, samples were analyzed for the physical properties and viscosity.

Figure No 7: Stability Chamber

RESULT AND DISCUSSIONS

Analysis of Extract

Table No 3.:Physical Appearance of Extract

Properties	Observations
Color	Brown
Odour	Characteristic
State	Semisolid
Solubility	Soluble in water, ethanol, methanol

Table No.4: Preliminary Phytochemical Analysis

Chemical test	Salmalia Malabarica
Alkaloids	+
Carbohydrates	+
Reducing sugar	+
Glycosides	+
Proteins and Amino acids	-
Flavonoids	+
Phytosterols	+
Tannins	+
Terpenoids	-

Presence(+),absence(-)

Evaluation of Antioxidant Activity of Plant Extract

Table No.5:% Inhibition Activity for Ascorbic Acid and *Salmalia Malabarica* Thorns Hydroalcoholic Extract

Conc. µg /ml	%inhibition by ascorbic acid	% inhibition by Salmalia Malabarica thorns extract
20	34.95	23.91
40	52.80	33.23
60	54.56	45.45
80	63.71	56.75
100	74.96	62.80
Ic50 value	44.3	73.57

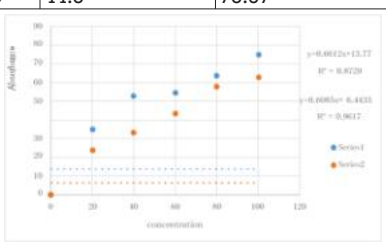

Figure no 8: Graph of% Inhibition of Ascorbic Acid, Salmalia Malabarica

Table no.6: Animal Skin Irritation Test

Group	Time	Erythema	Edema
1.Control(A)	24 hrs.	0	0
2.Gel(B)	24 hrs.	0	0

A B C

Figure No 9 : Skin Irritation Study on Rat (A, B, C)

Stability Study

The stability study for optimized formulation (F4) was carried out one for month and results revealed that all gel shows better stability and 40 ^{0}C and 30 ^{0}C. There were no significant changes found in color, homogeneity, consistency, and phase separation always. Also, the pH, spread ability, thermal stability and viscosity of optimized batch F4 were not shown any markable changes at all times shown in table no. 14.

In Vitro Drug Release[12]

By Franz diffusion cell apparatus using semi permeable membrane (0.8 μm pore size) was taken and the herbal cream was placed. Phosphate Buffer with pH 7.0 used as receptor chamber. About 1ml of sample was withdrawn from the membrane at predetermine interval and the fresh equal volume was replaced simultaneously. The samples were withdrawn till one week and were diluted and analyzed by UV Visible spectrophotometer at suitable λ max. The experiment was repeated trice and the cumulative amount of drug release was calculated from the reading.

Table No.10: Determination of Physical Properties of Formulated Gels In-vitro Release/ Permeation Studies:

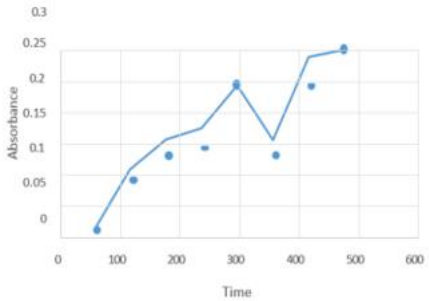

Figure No 11: Graph of Diffusion Study

Table No 7: Result of Evaluation Test of Gel

Sr.no	Formulation	F1	F2	F3	F4
1.	Color	Brown	Brown	Brown	Brown

2.	Homo-geneity	Homo-geneous	Homo-geneous	Homo-geneous	Homo-geneous
3.	Consistency	Gel like semisolid	Gel like semisolid	Gel like semisolid	Gel like semisolid
4.	Phase separation	NO	NO	NO	NO
5.	Viscosity (cps)	4900	5250	5764	5324
6.	Spread ability	12.42	13.35	15	20.33
7.	pH	5.54	5.66	5.75	5.96

Figure 12: Spread Ability Graph

Table No. 8: Diffusion Study

Sr. No.	Time	Absorbance
1	60 min	0.0110
2	120 min	0.0914
3	180 min	0.1309
4	240 min	0.1462
5	300 min	0.2030
6	360 min	0.1304
7	420 min	0.2404
8	480 min	0.2502

Antibacterial Assay of Formulation Prepared

Antibacterial assays were taken in triplicates for each formulation, and at the end mean was taken out. Results for the antibacterial assay are shown in table no. 12

Figure: 13 Antibacterial Assay of the Gel Formulation Prepared Against the Acne Causing Bacteria

Bacteria	Formulations	Zone of Inhibitions (in mm)
Staphylococcus aureus	F1	9.8
	F2	11.6
	F3	13
	F4	13.8
	Clindamycin	28.9
Propionibacterium acnes	F1	9.83
	F2	11.3
	F3	12.6
	F4	15.3
	Clindamycin	30.16

This data contains the mean value of the triplicates of the zone of inhibitions for the antibacterial activity.

Staphylococcus Aureus: Propionibacterium Acnes

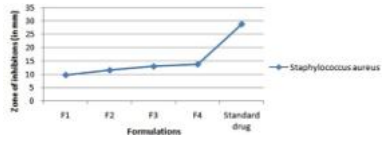

Figure 14: Graphical Representation Zone of Inhibitions Against *S. Aureus*

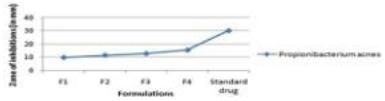

Figure 15: Graphical Representation of Zone of Inhibitions Against *P. acnes*

Zone of Inhibitions: Zone of inhibitions for both the bacteria are measured in triplicates and the results are shown in figure 15 and figure 16.

Staphylococcus Aureus

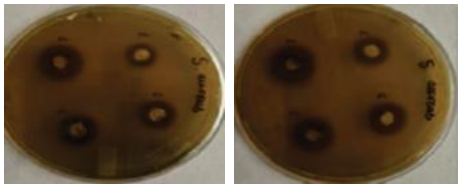

Figure16: (I), (II)Shows the Zone of Inhibition Against *S. aureus Propioni Bacterium Acnes*:

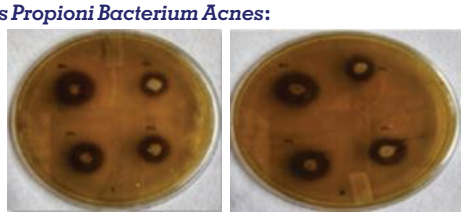

Figure17: (I), (II)Shows the Zone of Inhibition Against *P.*

Zone of Inhibition of Standard Drug (Clindamycin): Shown in Figure 17 and 18

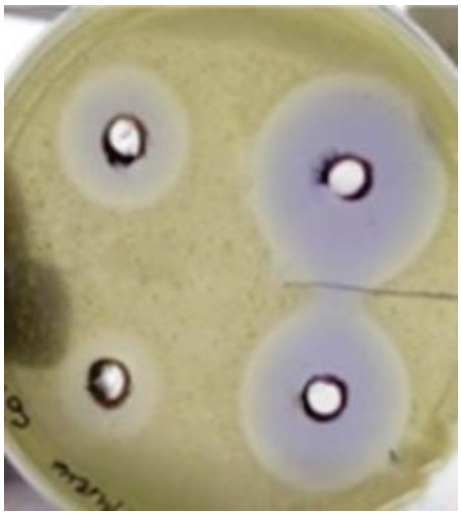

Figure 18: Zone of Inhibition of Std. Drug Clindamycin Against *S. aureus*

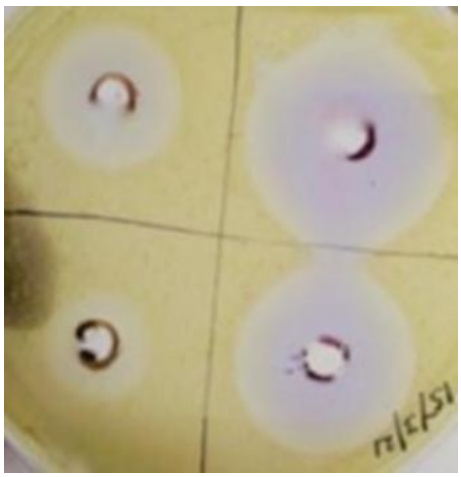

Figure 19: Zone of Inhibition of Std. Drug Clindamycin Against *P. acne*

DISCUSSION

In this study, formulation of anti-ace gel using natural herb such as *Salmalia Malabaricaof* there extract. Multipurpose

Based Gel was constructed for cosmetic utility. Various formulation factors were evaluated to find out for stable formulation. The formulations consist of Carbopol 940, Methyl Paraben, Propyl Paraben, Triethanolamine, Propylene glycol 400, and extract in different concentration. Similarly in the study, topical gel of natural herbs i.e. *Salmalia Malabarica* was formulated and subjected to physicochemical studies i.e. pH, spreading coefficient studies. Safety assessment was carried out by skin irritation test.

Formulated multipurpose herbal gel showed acceptable physical properties and antioxidant activity, which remained unchanged upon storage for 1 month. The physical appearance was brown, pH was in between 5.5-6, formulations showed better spreading coefficient. However, the extract in its low concentration-based gel with the formulation codeF4 proved to be the formula of choice, since it showed better antioxidant activity i.e. 60.41%.

SUMMARY AND CONCLUSION

In the present thesis work the natural *Salmalia Malabarica* thorn Csextract has been chosen to formulate and evaluate its potency to skin disorders so, it would be valuable for the cosmetic utility. Thus, the present study was undertaken to formulate the topical preparation of gel containing extract. Phytochemical screening was carried & indicates the presence of alkaloid glycoside, carbohydrate, Reducing sugar and Tannins. *Salmalia Malabarica* thorns extract is rich source of flavonoids and phytosterols (β-sitosterol) and has potential for antioxidant and anti-acne activity. Antioxidants protect human skin from free radicals produced by UV radiations. Based on the results of analysis for presence of flavonoids in the extract, the study was undertaken to evaluate the antioxidant potency of gel.

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