

Formulation and Evaluation of Antiseptic Cream

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Abstract: *The main aim of the study was to formulate and evaluate the antiseptic cream containing neem oil by using oil in water method for the purpose of antibacterial action for the bacterial skin disease this cream is prepared by using neem oil and honey. Quality evaluation of the formulated product was assessed by using different evaluation methods. No change of the physical properties was observed in formulation. The formulated cream showed good consistency and spreadability, pH and there is no evidence of phase separation during study period of the formulation. Stability parameter like visual appearance, nature, viscosity of the formulated cream showed that there was no significant variation during the study period. These cream shows the good antimicrobial action against the gram positive and gram negative bacteria the antimicrobial action was checked against the *S.aureus* and *P.aeruginosa* by using the modified agar well diffusion method.*

Keywords: Staphylococcus aureus, Pseudomonas aeruginosa, antibacterial.

I. INTRODUCTION

Topical drug administration is a localized drug delivery system anywhere in the body through skin, vaginal, ophthalmic as topical routes. 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 preparations are applied to the skin for surface, local or systemic effect.

Topical drug delivery is well recognized, as it allows a controlled transfer of a drug with minimum side effects, good efficiency, and maintenance of a therapeutic dose throughout topical administration and these formulations, which deliver the drug via the skin to achieve systemic therapeutic effect, avoid the challenges associated with first-pass metabolism, as systemic circulation is achieved without being impacted by the phenomenon of the first pass effect.

Topical drug delivery system includes solid powders, semisolids, liquid preparations, and sprays among other pharmaceutical dosage forms. Gels, creams and ointments are the most often used semisolid preparations for topical medication delivery.

Human Skin:

The skin is the body's largest organ. It covers the entire body. It serves as a protective shield against heat, light, injury and infection.

The skin also:

- Regulates body temperature.
- Stores water and fat.
- Is a sensory organ.
- Prevents water loss.
- Acts as a barrier between the organism and its environment.

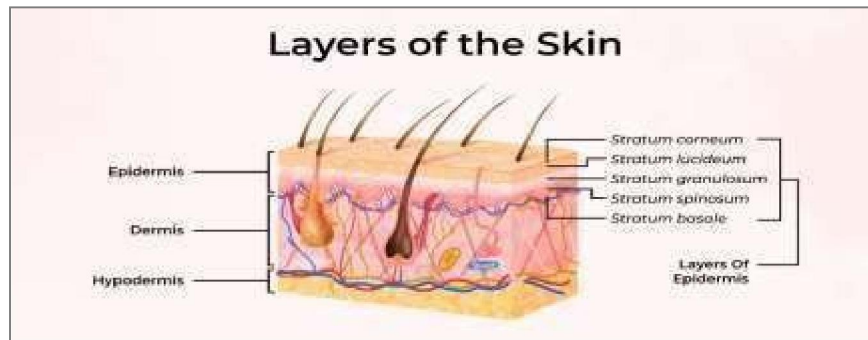


Fig : Anatomy of skin

Skin infection:

A skin infection is an infection of the skin in humans and other animals, that can also affect the associated soft tissues such as loose connective tissue and mucous membranes. More than 1000 skin or skin-related diseases are listed above according to the 10 categories of human diseases in the International Classification of Diseases.

The main aim of our work is to develop the antiseptic cream which can be used in the treatment of various skin infections like Impetigo, folliculitis and cellulitis.

Table : Types of skin diseases

Infection	Pathogens
Impetigo	<i>Staphylococcus aureus</i>
Folliculitis	<i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i>
Cellulitis	<i>Staphylococcus aureus</i>

Cream is defined as semisolid emulsions which are oil in water (o/w) or water in oil (w/o) type and these semisolid emulsions are intended for external application. Cream is classified as oil in water and water in oil emulsion. It is applied on the 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.

We have used neem oil as a main ingredient in our preparation which has strong anti-septic, anti-fungal, anti-bacterial, anti-inflammatory properties and it is also used to reduce scar, pigmentation, wounds, redness and itching of the skin. The other ingredients include honey which gives the good antibacterial as well as soothing effect to the skin. We also use other ingredients such as olive oil, bees wax, borax, liquid paraffin, rose water. The olive oil is a source of vitamin E and it is helpful to moisturize and soften the skin. Bees wax is used as an emulsifying agent and rose water is used as a flavoring agent.

II. MATERIALS AND EQUIPMENTS

List of Drugs:

Drugs and materials used in dissertation work are listed in Table along with their supplier.

Table : List of drugs used in dissertation work

Sr. No.	Drugs	Supplier
1	Neem oil	Kolhapur Locality
2	Honey	Kolhapur Locality
3	Olive Oil	Kolhapur Locality
4	Bees wax	LOBA Chemie, India
5	Borax	LOBA Chemie, India
6	Rose Water	Kolhapur Locality
7	Liquid Paraffin	LOBA Chemie, India

List of Materials:

Materials used in dissertation work is listed in Table along with their manufacturers.

Table : List of materials used in dissertation work

Sr. No	Materials	Manufacturer
1	Stirrer	Paper distributor, India
2	Pair of tongue	Garg Process Glass, India
3	Beakers	J-SIL, India
4	Petri dish	Pioneer Impex, India
5	Container	Kolhapur Locality

List of Equipment:

Equipment used in dissertation work is listed in Table along with their manufacturers.

Table : List of equipment's used in dissertation work

Sr. No.	Equipment	Manufacturer
1	Digital weighing balance	CONTECH, India
2	Thermostat Water bath	Bio Technics , India
3	Digital pH meter	J-SIL, India
4	TLC Plate	Coslab Pvt.Ltd.India
5	Brookfield Viscometer	Coslab Pvt.Ltd.India

Drug and excipient profile:

NEEM

Synonyms :

Azadirachta indica

Biological Source :

Neem consists of almost all the part of the plant which are used as drug of Azadirachta indica.

It is belong to family Meliaceae.

Geographical source :

India is native of Azadirachta.

It is also cultivated in Nepal Pakistan Bangladesh and Sri-Lanka.

Neem is a fast growing tree that can reach a height of 15-20 m, rarely to 35-40m. It is evergreen.

Chemical constituents :

Leaf: quercetin, nimbosterol, nimbin

Seeds: Azadirachtin, Azadiradione, nimbin, vepinin

Azadirachtin : Provide repellent, anti-hormonal and anti-microbial properties.

Nimbin : Provide anti-inflammatory, anti-pyretic, anti-histamine, and anti-fungal properties.

Nimbidin : Provide anti-bacterial, anti-ulcer and anti-fungal properties.

Nimbidol : Provide anti tubercular, anti protozoa and anti pyretic properties.

HONEY

Synonyms :

Madhu, Madh, Mel, Purified Honey

Biological Source :

Honey is a viscid and sweet secretion stored in the honey comb by various species of bees, such as *Apis mellifera*, *Apis dorsata*, *Apis florea*, *Apis indica* and other species of *Apis*, belonging to family Apidae (Order: Hymenoptera).

Geographical Source :

Honey is available in abundance in Africa, India, Jamaica, Australia, California, Chili.

Chemical Constituents:

Moisture 14–24%, Dextrose 23–36%, Levulose (Fructose) 30–47%, Sucrose 0.4–6%, Dextrin and Gums 0–7% and Ash 0.1–0.8%. Besides.

It is found to contain small amounts of essential oil, beeswax, pollen grains, formic acid, acetic acid, succinic acid, maltose, dextrin, coloring pigments, vitamins and an admixture of enzymes.

Uses:

Honey shows good antimicrobial, anti-inflammatory, anti-pyretic activity and gives the soothing effect to the skin.

OLIVE OIL

Synonyms :

Salad oil, sweet oil, oleum oil.

Biological Source :

Olive oil is a fixed oil obtained by expression of the ripe fruits of *Olea europaea* Linn. or Indianolive (*O. ferruginea*), belonging to family Oleaceae.

Geographical Source :

Olive is a native of Palestine and produced extensively in the countries adjoining the Mediterranean Sea. Spain being the largest producer. It is also grown in the south western United States and many other subtropical localities.

Uses:

Olive oil are rich source of vitamin E which enhance the skin glow, and gives soothing effect to skin.

BEE SWAX

Synonyms :

Cera Flaba. Cera Alba. Yellow Wax, White Wax

Biological Source :

Obtained from the honey comb of the bees *Apis mellifera* and other species of *Apis* belonging to the family Apidae.

Chemical Constituents:

Beeswax consists of about 80 percent of myristyl palmitate, about 15 percent of free cerotic acid and small quantities of an aromatic substance, cerolein.

Uses :

Beeswax is used as a Pharmaceutical necessity in ointment and as a base for cerates and plasters.

ROSE WATER

We can use it directly or mix rose water in cream as a flouring agent. Add extra dose of miniaturization to the skin. It gives healthy glow to the skin.

BORAX

Physical Properties :

It is a colorless crystalline solid, that dissolves in water to make a basic solution. It is commonly available in powder or granular form.

Uses :

Borax is used in cosmetic industry to prevent bacterial growth. It is also used to eradicate skin bacteria and remove dead skin cells. emulsifier created by the chemical reaction made the oil and water parts of cold cream less likely to separate on standing borax were so cold creams made with borax were more stable.

LIQUID PARAFFIN

Physical Properties :

Liquid paraffin is an oily, transparent, colorless liquid. It does not dissolve in water, glycerol. It dissolves in ether, benzene, ethanol.

Uses :

It relieves dry skin conditions such as eczema, ichthyosis and pruritus of the elderly. Liquid paraffin is an emollient (substance that softens or soothes the skin). It works by preventing water loss from the outer layer of skin.

EXPERIMENTAL WORK

Method of preparation :

- Melt beeswax in a china dish on hot plate.
- Liquid paraffin is added and then heat on a hot plate at 70°C.
- Borax was dissolved and heated along with olive oil in beaker.
- Neem oil and honey was added in the beaker and borax solution is added at 70°C.
- Few drops of rose oil is added to give fragrance.

Table : Optimized batch

Ingredient	Quantity
Neem oil	50 ml
Honey	10 ml
Olive oil	5 ml
Bees wax	15 gm
Borax	10 gm
Rose water	8.5 ml
Liquid paraffin	1.5 ml

Evaluation tests :

Appearance :

The color, Oduor and homogeneity of the cream were visually determined.

pH :

Cream pH was measured with a digital pH meter. A total of 10 % solution of cream was prepared in distilled water and the solution was immersed in the pH meter.

Washability :

A portion of cream was applied over the skin of the hand and allowed to flow under the force of flowing tap water for 10 min. The time when the cream completely removed was noted.

Spreadability :

The spread ability of cream was determined by the parallel plate method. Two glass slides of 20/20 cm were selected. About one gm of the cream formulation was placed over one of the slides. The other slide was placed upon the top of the cream such that the cream was sandwiched between the slides and 125 gm weight was placed upon the upper slide so that cream between the two slides was pressed uniformly to form a thin layer. The weight was removed and the spread diameter was measured.

Irritancy test :

Mark an area on left hand dorsal substance up to (1 Sq cm) The cream was applied to the specified area And time was noted. Irritancy was checked if any up to 24 hrs. For regular intervals.

Phase Separation :

We Prepared cream in 5 batches and the cream was kept in a closed container at a temperature of 25-100 °C away from light. Then phase separation was checked for 24 h .for 100gm formulation.

Viscosity :

Viscosity was evaluated in Brookfield viscometer using the LV-3 spindle. The rotation rate was adjusted to 50 rpm. The formulated cream was directly immersed into the spindle and the viscosity was measured

Antimicrobial studies :

The antimicrobial activity of the gel was determined by using the modified agar well diffusion method against Gram-positive (*Staphylococcus aureus* NCIM 2654) and Gram-negative (*Pseudomonas aeruginosa* NCIM 2200) bacterial pathogens with slight modifications. For further study, the respective test pathogen suspension was prepared in sterile saline then pathogens were spread on the surface of nutrient agar plates using a sterile spreader for the antimicrobial activity test. After that, an agar well was created using a 0.7 cm diameter sterilized cork borer. Then a desired amount of the formulations was weighed on an analytical balance and placed aseptically into the respective well. Then plates were placed at 34°C for 10 min for sample diffusion in a culture medium and transferred to an incubator at 37 °C for 24 h. Furthermore, The diameter of the inhibition zone was measured in mm and the results were recorded

III. RESULTS & DISCUSSION

Morphology :

Table : Physical test for antiseptic cream

Sr. No	Parameters	Observation
1	Nature	Semi-solid
2	Colour	Yellowish
3	Odour	Pleasant
4	Texture	Cream- Smooth

pH :

Using pH meter, the pH of the formulation was found to be 7.

Washability :

The time taken for the completely removal of cream is 5 min.

Spreadability :

Spreadability investigations revealed that formulation have greater spreadability. It was found to be 6.29

Irritancy test :

No skin irritation was present.

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Phase Separation :

Table : Phase Separation of Antiseptic cream

Sr. No	Formulation	Phase Separation
1	F1	Phase separation
2	F2	Phase separation
3	F3	Phase separation
4	F4	No Phase separation
5	F5	No Phase separation

Viscosity :

The viscosity of the formulation was measured using a Brookfield viscometer

Table : viscosity value of formulation

Sr. No	RPM	Cps
1	50	11570

Antimicrobial activity :

Obtained results state that the gel shows good antimicrobial activity against test

Sr.no	Test organisms	Zone of inhibition of respective compounds in mm		
		cream	Ethanol	
1.	<i>S.aureus</i>	19	00	26
2.	<i>P. aeruginosa</i>	18	00	21



Fig : Antimicrobial activity against *Staphylococcus aureus*



Fig : Antimicrobial activity against *Pseudomonas aeruginosa*

IV. SUMMARY AND CONCLUSION

A topical antiseptic cream was prepared in this research. The formulation was optimized and important parameters like pH, viscosity, irritancy, washability and spread ability were also evaluated. All the parameters were found within the acceptable range.

The formulated cream was studied for antimicrobial activity against *Staphylococcus aureus*, *Pseudomonas aeruginosa* there is no sign of microbial growth was visible.

From the above results it is concluded that the formulated cream showed good consistency and spread ability, viscosity, pH, washability and there is no phase separation during study period and it is safe to use and they did not show any signs of irritancy and redness. The formulated cream showed good antimicrobial activity against skin infections. As the cream was made from herbal ingredients such as neem oil & honey and it is safe, effective, showing less side effects.