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Formulation and Evaluation of Herbal Antibacterial Cream of Jamun Leaf Powder

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Abstract: *The aim of present study was to formulate antibacterial herbal cream comprising extracts of natural products such as Syzygiumcumini leaves. In this research work we prepared oil in water (O/W) herbal cream. The antimicrobial activity of the Syzygiumcumini leaves hydroalcoholic extract may be due to tannins and other phenolic constituents. Syzygiumcumini is known to be very rich in gallic and ellagic acid polyphenol derivatives. Also, acylated flavonol glycosides, kaempferol, myricetin, and other polyphenols were isolated from Syzygiumcumini leaves. The evaluations of all formulations (F1 to F2) were done on different parameters like pH, viscosity, spreadibilty and stability were examined. Formulations F1 and F2 showed good spreadibilty, good consistency, homogeneity, appearance, pH, spreadibilty, no evidence of phase separation and ease of removal. hence, formulations are safe for skin. These studies suggest that composition of extracts and base of cream of F1 and F2 are more stable and safe, it may produce synergistic action..*

Keywords: *Syzygiumcumini* leaves, Almond oil, Excipient profile, Herbal cream, Evaluation parameters

I. INTRODUCTION

Skin diseases are due to poor hygiene, overcrowding, malnourishment, non-availability of potable water, high temperature and humidity. Further, drugs used to treat them are antibiotics, steroids and sulfonamides, which are not only out of reach of local population in remote areas but also associated with adverse effects like atrophy, telangiectasia, hirsutism and sensitizing dermatitis which are far more troublesome. Indigenous medicinal plants have been a readily available source of drugs since ancient times and even today almost 50% new drugs have been patterned after phytochemicals. Majority of the population in developing countries and approximately 25% people in developed regions use herbal medicine for prevention and treatment of diseases. Recognizing the medicinal significance of indigenous plants, World Health Organization (WHO) in its 1997-guideline states that ‘‘effective locally available plants be used as substitutes for drugs. Research work on medicinal plants and exchange of informations obtained will go a long way in scientific exploration of medicinal plants for the benefit of man and is likely to decrease dependence on imported drugs’’[1].

Creams are semisolid dosage forms containing more than 20% water or volatile components and typically less than 50% hydrocarbons, waxes, or polyols as vehicles.[2] They may also contain one or more drug substances dissolved or dispersed in a suitable cream base. This term has traditionally been applied to semisolids that possess a relatively fluid consistency formulated as either water-in-oil (e.g., cold cream) or oil-in-water (e.g., fluocinoloneacetonide cream) emulsions. However, more recently the term has been restricted to products consisting of oil-in-water emulsions or aqueous microcrystalline dispersions of long-chain fatty acids or alcohols that are water washable and more cosmetically and aesthetically acceptable. Creams can be used for administering drugs via the vaginal route (e.g., Triple Sulfa vaginal cream). Creams are also used to treat sun burns.[2]

The antimicrobial activity of the *Syzygiumcumini* leaves hydroalcoholic extract may be due to tannins and other phenolic constituents. *Syzygiumcumini* is known to be very rich in gallic and ellagic acid polyphenol derivatives [3]. Also, acylatedflavonol glycosides, kaempferol, myricetin, and other polyphenols were isolated from *Syzygiumcumini* leaves. The extract of Syzygiumcumini leaves showed different activity against the selected bacteria at all concentration levels.Methanol extracts from Syzygiumcumini (S. jambos) leaves were tested f o r antimicrobial activity and toxicity. S. jambos leaf extract inhibited the growth of bacteria. Both gram-positive and gram

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negative bacterial growth were inhibited by S. jambos leaf extract, although gram positive bacteria appeared more susceptible.

Fig No.1: Jamun leaf powder [4]

Fig No.2: Jamunleaves[5]

Advantages of Herbal Cream :

- They do not provoke allergic reaction & do not have negative side effects.
- They are easily incorporated with skin and hair.
- With small quantity they are very effective as compared to synthetic cosmetics.
- Extracts of plant decreases the bulk property of cosmetics and gives appropriate pharmacological effects.
- Easily available & found in large variety & quantity.
- Easy to manufactures and chief in cost.

Excipient profile :

Excipient is a substance formulated alongside the active ingredient of a medication. Excipients serve various purposes, including long-term stabilization, bulking up solid formulations containing potent active ingredients in small amounts (often referred to as "bulking agents", "fillers", or "diluents"), or enhancing the therapeutic properties of the active ingredient in the final dosage form. They can facilitate drug absorption, reduce viscosity, or enhance solubility [6,7].Excipients can also aid in the manufacturing process by improving the handling of active substances, facilitating powder flowability, or preventing denaturation and aggregation during the expected shelf life. The selection of excipients depends on factors such as the route of administration, dosage form, and active ingredient.

Steric acid: Stearic acid is a saturated fatty acid that finds extensive application in various industries, including pharmaceuticals. It is a versatile compound widely utilized as an excipient in the formulation of drugs and as a lubricant in the manufacturing of pharmaceutical tablets and capsules.

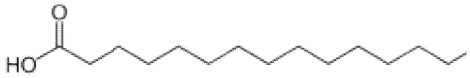

Fig no.3:Chemical structure of steric acid

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Sources and Manufacturing Process:

Stearic acid is a naturally occurring fatty acid commonly found in animal and vegetable fats. It is present in high concentrations in fats like beef tallow, cocoa butter, and shea butter. The pharmaceutical industry primarily relies on two sources to obtain stearic acid: animal-derived and vegetable-derived.Animal-derived stearic acid is typically obtained from the fat of animals, such as cows or pigs, through a process called saponification. In this process, the fat is hydrolyzed using a strong alkali, leading to the formation of soap.[14]

Molecular Formula: $C_{18}H_{36}O_2$

Synonyms: Stearic acid, Octadecanoic acid

Molecular Weight: 284.5 g/mol

Physical Description: Stearic acid is a white solid with a mild odor. Floats on water.

Color: White or slightly yellow

Boiling Point: 721 °F at 760

Melting Point: 156.7 °F

Solubility: Insoluble in water, Slightly soluble in ethanol, benzene; soluble in acetone, chloroform, carbon disulfide.

Cetyl alcohol:

Cetyl alcohol, also known as 1-hexadecanol or n-hexadecyl alcohol, is a 16-C fatty alcohol with the chemical formula CH3(CH2)15OH. It can be produced from the reduction of palmitic acid. Cetyl alcohol is present in a waxy white powder or flake form at room temperature, and is insoluble in water and soluble in alcohols and oils. Discovered by Chevrenl in 1913, cetyl alcohol is one of the oldest known long-chain alcohol. It may be contained in cosmetic and personal care products such as shampoos, creams and lotions.

Fig.no.4:Chemical structure of cetyl alcohol

Molecular Formula: $C_{16}H_{34}O$

Synonyms: 1-Hexadecanol,cetyl alcohol,Hexadecan-1-ol

Molecular Weight: 242.44 g/mol

Physical Description: Pellets or Large Crystals; Liquid; Pellets or Large Crystals, Liquid; Other Solid; Dry Powder; Liquid, Other Solid

Boiling Point: 334 °C at 760 mm Hg

Melting Point: 49.3 °C

Solubility: Slightly soluble in alcohol; soluble in acetone; very soluble in ether, benzene, chloroform[15]

Triethanolamine:

Triethanolamine is a tertiary amino compound that is ammonia in which each of the hydrogens is substituted by a 2-hydroxyethyl group. It has a role as a buffer and a surfactant. It is a tertiary amino compound, a triol and an amino alcohol. It is functionally related to a triethylamine. It is a conjugate base of a triethanolammonium. It is a bifunctional compound that exhibits both properties of alcohols and amines. Trolamine contains small amounts of diethanolamine and ethanolamine and may also act as an antioxidant against the auto-oxidation of animal and vegetable fats. It is commonly used as a pH adjuster and surfactant in industrial and cosmetic products such as skin and hair conditioning products.

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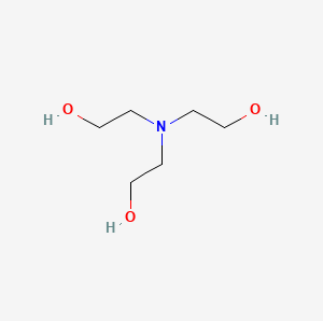

Fig no.5: chemical structure of Triethanolamine

Molecular Formula: $C_6H_{15}NO_3$
Synonyms: TRIETHANOLAMINE, Trolamine
Molecular Weight: 149.19 g/mol
Physical Description: Triethanolamine is an oily liquid with a mild ammonia odor. Denser than water.
Boiling Point: 635.7 °F at 760 mmHg
Melting Point: 70.9 °F
Solubility: Miscible with water, methanol, acetone; soluble in benzene [16]

Glycerin :

Glycerol is a triol with a structure of propane substituted at positions 1, 2 and 3 by hydroxy groups. It has a role as an osmolyte, a solvent, a detergent, a human metabolite, an algal metabolite, a Saccharomyces cerevisiae metabolite, an Escherichia coli metabolite, a mouse metabolite and a geroprotector. It is an alditol and a triol.

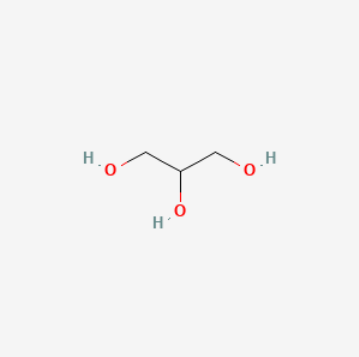

Fig no. 6: Chemical structure of glycerin

Molecular Formula: $C_3H_8O_3$, $CH_2OH\text{-}CHOH\text{-}CH_2OH$
Synonyms: glycerol, glycerin
Molecular Weight: 92.09 g/mol
Physical Description: Glycerine appears as a colorless to brown colored liquid. Combustible but may require some effort to ignite.
Boiling Point: 554 °F at 760 mmHg
Melting Point: 64 °F
Solubility: Miscible with ethanol; slightly soluble in ethyl ether; insoluble in benzene, carbon tetrachloride, chloroform, carbon disulfide, petroleum ether
Density: 1.261 at 68 °F[17]

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Methylparaben:

Methylparaben is a 4-hydroxybenzoate ester resulting from the formal condensation of the carboxy group of 4-hydroxybenzoic acid with methanol. It is the most frequently used antimicrobial preservative in cosmetics. It occurs naturally in several fruits, particularly in blueberries. It has a role as a plant metabolite, an antimicrobial food preservative, a neuroprotective agent and an antifungal agent.The physiologic effect of methylparaben is by means of Increased Histamine Release, and Cell-mediated Immunity.

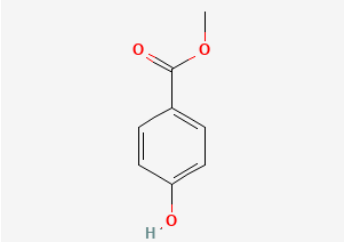

Fig no.7: chemical structure of Methylparaben

Molecular Formula: $C_8H_8O_3$
Synonyms: Methyl 4-hydroxybenzoate
Molecular Weight: 152.15 g/mol
Physical Description: Colorless or white solid
Boiling Point: 270.5 °C
Melting Point: 125.2 °C
Solubility:lightyl soluble in water; very soluble in ethanol, ether, acetone; soluble in trfluoroacetic acid[18]

EXTRACTION OF PLANT EXTRACT:

Extraction is the first step to separate the desired natural products from the raw materials. Extraction methods include solvent extraction, distillation method, pressing and sublimation according to the extraction principle. Solvent extraction is the most widely used method. The extraction of natural products progresses through the following stages:
(1) the solvent penetrates into the solid matrix
(2) the solute dissolves in the solvents
(3) the solute is diffused out of the solid matrix
(4) the extracted solutes are collected.
Any factor enhancing the diffusivity and solubility in the above steps will facilitate the extraction. The properties of the extraction solvent, the particle size of the raw materials, the solvent-to-solid ration, the extraction temperature and the extraction duration will affect the extraction efficiency [11,12,13].

Fig no.8: Extraction process

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Chemical tests:

Test	Procedure	Observation	Result
Test for alkoloids	Mayer's test :3ml filtrate was taken in test tube and add few drops of mayer's reagent.	cream precipitate was observed ,indicates presence of alkoloids.	
Test for tannins	To the extract, a few drops of dilute solution of ferric chloride was added.	Color of the solution changed to the dark blue shows the presence of tannins.	
Test for flavonoids	Ferric chloride test: to the small quantity of alcoholic solution of extract, few drops of neutral ferric chloride was added.	Color changed to blakish red colur indicates the presence of flavonoids.	
Test for carbohydrates	Fehling;stes: small portion of the extract was treated with fehling's solution and then heated on water bath.	brick red color precipited was not found and blue colur is obtained indicating absence of carbohydrate.	
Test for Terpenoids.	Salkowski test: extract was mixed with chloroform and concentrated sulphuric acid was carefully added to form a layer.	Reddish brown coloration indicates the presence of terpenoids.	

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Formulation table:

Oil phase:

Ingredients		Batches		Role of Ingredient
		B1	B2	
Steric acid		2.2gm	5.4 gm	Emulsifier
Cetyl alcohol		0.8 gm	2.0 gm	Thickening agent and emulsifier
Almond oil		0.8 ml	2.0 ml	Moisturiser and an emollient.

Aqueous phase:

Ingredients		Batches		Role of Ingredient
		B1	B2	
Jamun leaf powder extract		1 gm	5 gm	Active ingredient

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Triethanolamine		**0.3 ml**	**0.75 ml**	**Maintain stability**
Glycerin		**1.0 ml**	**2.5 ml**	**Humectant**
Methylparaben		**0.2 gm**	**0.5 gm**	**Preservative**
Water		**14.7 ml**	**36.85 ml**	**Vehicle**

Method of preparation :

Oil in water (O/W) emulsion-based cream (semisolid formulation) was formulated.

↓

he emulsifier (stearic acid) and other oil soluble components (Cetyl alcohol, almond oil) were dissolved in the oil phase (Part A) and heated to 75° C.

↓

The preservatives and other water soluble components such as methyl paraban, triethanolamine, glycerin extract of *Syzygiumcumini* Linnwere dissolved in the aqueous phase (Part B) and heated to 75° C.

↓

After heating, the aqueous phase was added in portions to the oil phase with continuous stirring until cooling of emulsifier took place.

↓

Then the product is filled in closed container.

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Fig no.9: Formulation of Herbal cream

Evaluation parameters:

pH of the Cream:

The pH meter was calibrated using standard buffer solution. About 0.5 g of the cream was weighed and dissolved in 50.0 ml of distilled water and its pH was measured.

RESULT: The pH of the cream was found to be in range of 6.5 – 6.8 which is good for skin pH. All the formulations were shown pH nearer to skin required

Table 1: pH of cream base

Formulation	pH
F1	6.8
F2	6.5

Viscosity:

Viscosity of the formulation was determined by Brookfield
Viscometer at 100 rpm, using spindle no 7.

RESULT: The viscosity of was cream was in the range of 27019 – 27023 cps which indicates that the cream is easily spreadable by small amounts of shear. But F1 and F2 shows good spreadable property than other formulations.

Table 2: Viscosity of Cream

Formulation	Viscosity (in cps)
F1	27019
F2	27023

Dye test:

The scarlet red dye is mixed with the cream. Place a drop of the cream on a microscopic slide covers it with a cover slip, and examines it under a microscope. If the disperse globules appear red the ground colourless. The cream is o/w type. The reverse condition occurs in w/o type cream i.e. the disperse globules appear colourless in the red ground.

Result: This dye confirm that all formulation were O/W type emulsion cream.

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Homogeneity:
The formulations were tested for the homogeneity by visual appearance and by touch.
Result: All formulations produce uniform distribution of extracts in cream. This was confirmed by visual appearance and by touch.

Appearance:
The appearance of the cream was judged by its color, pearlscence and roughness and graded.
Result: When formulation were kept for long time, it found that no change in colour of cream

After feel:
Emolliency, slipperiness and amount of residue left after the application of fixed amount of cream was checked.
Result: Emolliency, slipperiness and amount of residue left after the application of fixed amount of cream was found.

Type of smear:
After application of cream, the type of film or smear formed on the skin were checked.
Result: After application of cream, the type of smear formed on the skin were non greasy

Removal:
The ease of removal of the cream applied was examined by washing the applied part with tap water.
Result**:** The cream applied on skin was easily removed by washing with tap water .

Irritancy test:
Mark an area (1sq.cm) on the left hand dorsal surface. The cream was applied to the specified area and time was noted. Irritancy, erythema, edema, was checked if any for regular intervals up to 24 hrs and reported.
Result: The formulation F1, F2 and F3 shows no redness, edema, Inflammation and irritation during irritancy studies. These formulations are safe to use for skin.

Table 3: Type of adverse effect of formulations

Formulation	Irritant	Erythema	Edema
F1	NIL	NIL	NIL
F2	NIL	NIL	NIL

Conclusion: In this project work, the selected active ingredients are jamun leaf powder. The ingredient is collected from dry leaves of jamun. Along with this the selected excipients almond oil, stearic acid, as base material: cetyl alcohol as emollient and surfactant for formulation. The formulation secure to use for skin application. These study indicates that the extract and cream is more stable and healthy.

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