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Formulation and Evaluation of Cream Utilizing *Aloe vera* Extract and Goatmilk for Hyperpigmentation Treatment

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ABSTARCT

Hyperpigmentation is a common skin condition defined by the overproduction of melanin, which causes dark spots and uneven skin tone. The purpose of this study aimed to formulate and evaluate a cream using plant- loaded cream to treat hyperpigmentation. *Aloe vera* extract, goatmilk, Coconut oil, glycerol were used to prepare three formulations(F1,F2,F3).The creams were evaluated for their physical properties, pH, washability, anti-oxidant activity against the hyperpigmentation. The results showed that the combination formulation (F2) exhibited better anti-oxidant activity and synergistic effect compared to individual formulations. The cream formulations also demonstrated good homogeneity, satisfactory pH level, excellent spreadibility and ease of removal. This study suggests that the combination of *Aloe vera* extract, Goatmilk, Coconut oil, glycerol has potential in the management of hyperpigmentation.

Keywords: *Aloe vera*, Goatmilk, hyperpigmentation, skin care, Coconut oil, glycerol.

INTRODUCTION:

SKIN PIGMENTATION:

A person's ethnicity, genetics and physiology significantly influence human pigmentation. Patients with an alteration in the normal pigmentation of the skin due to a variety of skin diseases experience significant psychological and social impacts as a consequence of their physical appearance. The two types of pigmentary disorders consist of those that show up as hypopigmentation, or decreased pigment, and hyperpigmentation, or apparent excess pigment.[1]

Skin pigmentation, or the amount of melanin the body produces, is what gives skin its color.

The two primary forms of melanin produced by melanocytes in the skin's epidermal layer are phenomelanin and eumelanin. The pigments pheomelanin and eumelanin provide lighter and darker skin tones, respectively.[2]

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Table 1: Characteristics of different types of skin

Skin type	*Skin color*	*Characteristics*
I	very fair; white ; red or blond hair; blue eyes; freckles ;	Burns always, never tans
II	White; fair; red or blond hair; blue, green or hazel eyes	Usually burns, tans with difficulty
III	Creamy white; fair with any eye or hair color; very common	occasionally mild burn, gradually tans
IV	Brown color ; typically Mediterranean skin	Rarely burns, tans with easily
V	Dark brown skin color; Middle-Eastern skin types	Tans very easily, Very rarely burns
VI	Black color skin	Never burns, tans more easily

HYPERPIGMENTATION:

Increased melanin production and accumulation characterize several skin disorders such as acquired hyperpigmentation like melasma, post-inflammatory melanoderma, solar lentigo and others.[4] All skin types can experience hyperpigmentation, a common dermatological disease that is more noticeable in the becomes darker or more discolored.[3]

TYPES:

Hyperpigmentation is mainly of three types:

1. Post-inflammatory hyperpigmentation
2. Melasma
3. Solar Lentigines (or) Liverspots (or) Aka sunspots

POST-INFLAMMATORY HYPERPIGMENTATION:

An inflammation or injury to dark skin (Fitzpatrick classifications IV to VI) typically causes post-inflammatory hyperpigmentation, which can develop to lesions that last months or even years. For certain people, this might have severe psychological consequences.

Various pigmented skin lesions treated with laser therapy may also result in post-inflammatory hyperpigmentation. This condition may be temporary or chronic.[4]

From mosquito bites, psoriasis, hypersensitivity reactions from medicine, harm from irritants, and cosmetic activities can all cause it. However, atopic dermatitis, impetigo, and acne vulgaris are frequently associated with it.[5]

Figure 1: Post inflammatory hyperpigmentation

MELASMA:

Melasma is a progressive, macular, no scaling hyper melanosis of the skin in areas exposed to sunlight. Usually, the dorsal forearms and face are affected. Oral contraceptives, pregnancy, and anticonvulsants (such phenytoin [Dilantin]) may be linked to it, or it may have no apparent cause. Though it is mostly asymptomatic, the patient frequently experiences cosmetic stress. Three patterns of distribution are commonly observed in cases with melasma: mandibular (16%), malar (21%) and Centro facial(63%).Though not always, it is bilateral. The condition usually clears upon its own a few months after delivery or when the medicine is stopped.[4]

Figure 2 : Melasma

SOLAR LENTIGINES:

On sun-exposed skin surfaces, macular, hyperpigmented, well-circumscribed lesions of one to three centimeters are known as solar lentigines, also known as liver spots. Their color ranges from pale yellow to deep brown, and they frequently have a scattered look. The most common areas, which appear following either acute or chronic UV exposure, are the hands, face, chest, back, forearm and shins.[4]The aging patches on the skin are brownOn parts of the body that receive a lot of sunlight, like the face and the backs of the hands, grows there largely.[5]

Figure 3 : Solar lentigines

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ETIOLOGY OF HYPERPIGMENTATION:

Numerous factors can contribute to the common disease known as skin pigmentation. Genetics, sun exposure, and some drugs are the three primary factors that contribute to skin pigmentation. We can more readily manage and prevent skin pigmentation if we are aware of its primary causes.[1]

Figure 4: Etiology of hyperpigmentation

INTRODUCTION TO CREAMS :

Creams are useful for protecting, beautifying, improving appearance, and medicinal purposes. Creams are considered medical supplies since they are manufactured utilizing techniques used in the pharmaceutical industry.

TYPES OF CREAMS :

All the skin creams can be classified on different basis:

1. Based on the Nature of The Cream \ Type of Emulsion:

e.g. w/o emulsion creams ,o/w emulsion creams.

2.Based on the function:

e.g. foundation, cleansing, massage, etc.

3.Based on the characteristics properties:

e.g. vanishing creams, cold creams, etc.

Creams are classified based on their function, characteristics, and emulsion type:

1. O/W emulsion creams:

a) Make-up cream,

b) Vanishing creams,

c) Foundation creams.

2. W/O emulsion creams:

a) Cold cream or moisturizing creams.

b) Winter cream

c) Cleansing cream

3. All- purpose creams and general creams.

4. Night creams and massage creams.

5. Skin protective cream.

6. Hand and body creams.[5]

AIM:

The aim of the present work is to formulate and evaluate the cream utilizing *Aloe vera* and goat milk for the hyperpigmentation treatment.

OBJECTIVES:

The work will be carried out to attain the following objectives,

- To formulate Hyperpigmentation cream containing *Aloe Vera* Extract and goat milk.
- To evaluate the cream for its physiochemical properties.
- To evaluate the Hyperpigmentation cream for its Anti-oxidant activity.
- To ensure the efficacy of the formulated cream for its antioxidant activity.

METHODOLOGY:

List of materials and equipments:

Table 2 : List of materials used

S.NO	NAME OF THE CHEMICALS	SOURCE
1.	*Aloevera*	Bhaskara herbals and research centre
2.	Goat milk	Courtyard farms
3.	Stearic acid	Ennore India chemicals
4.	Cetyl alcohol	Tradeindia
5.	Almond oil	IndiaMart
6.	Glycerol	IndiaMart
7.	Methyl paraben	Chemico glass and scientific company
8.	Triethanolamine	Qualigens
9.	Ethanol	Chemico glass and scientific company
10.	KOH	Chemico glass and scientific company
11.	Phenolphthalein	Chemico glass and scientific company
12.	Methylene blue	Ennore India chemicals
13.	Petroleum ether	Tradeindia

APPARATUS:

Aloe vera powder is extracted using a solvent extraction technique in a Soxhlet apparatus. This unique Soxhlet device consists of a glass extractor sandwiched between a bulb condenser at the top and a round-bottom flask at the bottom. Aloe vera powder is placed in the glass thimble holder. The extracting solvent was initially placed in the round-bottom distillation flask, which was heated by an electrothermal heating mantle to a maximum temperature of 100°C and a volume of 1 liter. The solvent vapor condenses and collects inside the extractor as it ascends to the condenser. This is where the Aloe vera powder and solvent make contact. Here, the Aloe vera powder and solvent come into contact. Mass transfer occurs as the condensate travels through the powder. However, when the collected solvent rises solely due to the hydrostatic pressure head, a large amount of mass transfer of the extraction from the powder to the solvent occurs.[6]

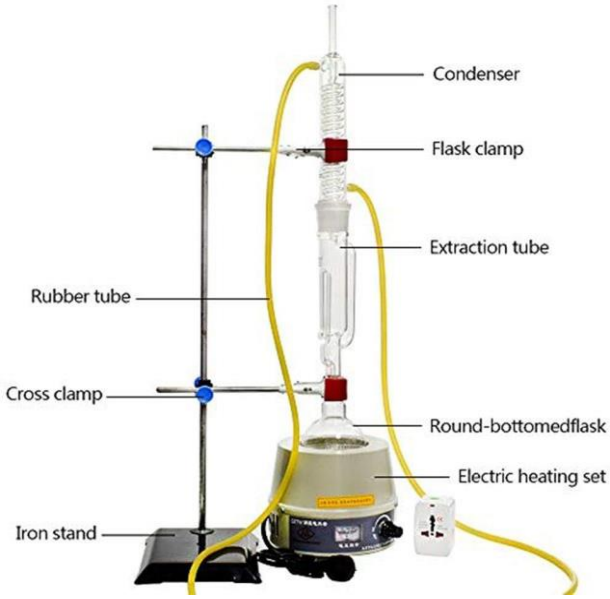

Figure 5: Soxhlet apparatus

PREPARATION OF ALOEVERA EXTRACT:

20 g of *Aloe vera* powder were weighed and transferred to a thimble. On top of a distillation flask containing 100 mL of the solvents petroleum ether and ethanol, it was set within the extraction chamber of a Soxhlet apparatus with a condenser. *Aloe vera* powder was then extracted under reflux with ethanol for 3 hours at a temperature of 70^0C. After the process of extraction, the extract was collected and it was stored in the refrigerator.[6]

Figure 6 : Extraction of aloe vera using Soxhlet apparatus

CREAM FORMULATION:

A semi-solid mixture known as an oil in water(O/W) emulsion is formed.

When stearic acid, coconut oil, cetyl alcohol are heated to 75°C, the oil dissolves in oil phase.Itis part A.Triethanolamine, methylp araben, aloe vera extract, and goat milk are among the watersoluble substances that are dissolved by the heated aqueous phase, wh ich reaches 75°C.It's part B.The oil phase was heated, and the aqueous phase was added gradually while being continuously agi tated until the emulsifier cooled. The table displays the cream's formula.[7]

TABLE 3: FORMULATION OF THE CREAM

S.NO	INGREDIENTS	FORMULATION		
		F1	F2	F3
1.	Ethanolic extract of *Aloe vera*(ml)	1.5	1	0.5
2.	Goat milk(ml)	0.5	1	1.5
3.	Stearic acid(gm)	4	4	4
4.	Cetyl alcohol(gm)	0.4	0.4	0.4
5.	Coconut oil(ml)	1	1	1
6.	Glycerol(ml)	1	1	1
7.	Methyl paraben(gm)	0.2	0.2	0.2
8.	Triethanolamine(ml)	1	1	1
9.	Water	q.s.	q.s.	q.s.

EVALUATION :

pH of the Cream:

Calibration of the pH meter was performed using a buffer solution. The pH was obtained by weighing and dissolving 0.5 g of cream in 50.0 ml of pure water with a digital pH meter.

Dye test:

Methylene Blue is mixed with the produced cream. Examine a drop of the cream under a microscope after placing it on a microscopic slide using a cover slip. The background is colorless when the globules appear as Blue. It's known as o/w type cream. The phrase "w/o type cream" describes a condition in which the scattered globules appear colorless but the background is blue.

Appearance:

When the formulation was kept for 40 days, there should be no change in the colour. The cream's appearance was rated based on its color, roughness, and pearlescence.

Homogeneity:

All prepared formulations produce uniformity of cream.It can be confirmed by appearance and by touch. So that the homogeneity of the cream was determined.

After feel:

The smoothness and emollient properties of the cream are important for its application in the skin. After application of the cream in the skin, the smoothness and emollient properties are examined.

Type of smear:

The cream was applied to the watch glass in order to do the examination. The properties of the film or smear that formed on the glass after application were investigated.[7]

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Washability test:

The ease of removal of the cream will be assessed by using tap water to wash the area where the cream is applied.

Irritancy test:

The left-hand frontal surface was marked with a precise area of 1 cm^2.Gentle application of the cream was used to ensure even coverage, and the application duration was carefully recorded for accurate assessment. At intervals of up to 24 hours, any signs of erythema, edema, or irritating effects were inspected carefully and recorded. The area on the left hand's dorsal surface should be marked. This test helps determine whether skin sensitivity or irritation may result in the cream formulation.

Viscosity:

The viscosity of the cream was measured using a Viscometer. Viscosity measurements were made using a viscometer. The formed sample was placed in the viscometer's adaptor, and the viscosity of the test sample was determined using the viscometer's standard operating methods. The spindle rotated at 0.5, 1, 5, 10, and 20 rpm, and the value closest to 100% torque was recorded. [8]

Anti- oxidant test:

The scavenging ability of the cream formulations was measured in this study using the ferric chloride assay, with formulation concentrations fixed at 25, 50, and 100 µL/mL. 2 grams of the formulated cream samples were combined with 2 ml of distilled water and vortexed for 30 minutes to create a clear solution, followed by 2 ml of FeCl3 solution. The mixtures were then incubated for 25 minutes at room temperature in the dark before being measured spectrophotometrically at 370 nm. [9]

RESULT AND DISCUSSION:

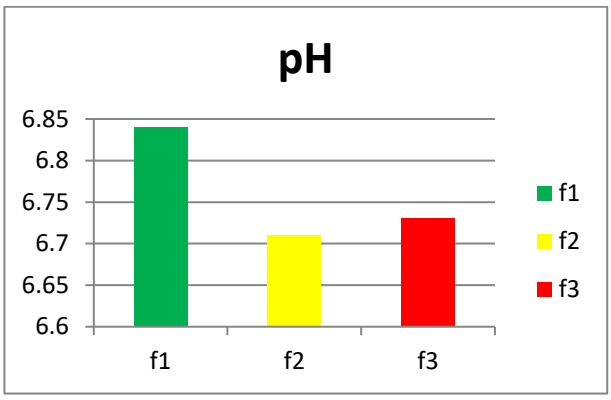
pH of the Cream:

The cream's pH has been found to be between 6.71 and 6.84, which is a good range for skin pH. Every cream formulation that has been created has a pH that is closer to that of skin.

Table 4 : pH of the cream

Parameter	Formulations								
	F1			F2			F3		
	1	2	3	1	2	3	1	2	3
Average pH value	6.93	6.85	6.74	6.81	6.62	6.71	6.83	6.72	6.64
	6.84			6.71			6.73		

GRAPHICAL REPRESENTATION :



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Dye test:

The o/w type emulsion cream composition was confirmed by methylene blue. Formulation F2, however, exhibits greater stability in o/w type emulsion.

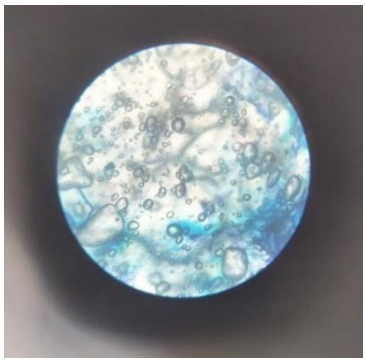


Figure 7 : Dye test

Homogeneity:

Every produced composition yields a uniform cream. Homogeneity was verified through touch and appearance.

Table 5 : Homogeneity of crem

Parameters	Formulations		
	F1	F2	F3
Homogeneity	Good	Good	Good

Appearance:

Long-term storage of the formulation revealed no change in the cream's color.

Table 6 : Appearance of cream

Parameters	Formulations		
	F1	F2	F3
Appearance	No change	No change	No change

After feel:

Following the application of a predetermined quantity of cream, slipperiness, emolliency, and residual amount were determined.

Table 7 : After feel of cream

Parameters	Formulations		
	F1	F2	F3
After peel	Emollient	Emollient	Emollient

Type of smear:

The smear type that developed on the skin after cream application was non-greasy.

Table 8 : Type of smear of cream

Parameters	Formulations		
	F1	F2	F3
Type of smear	Non greasy	Non greasy	Non greasy

Washability test:

Washing with tap water made it simple to remove the cream that had been applied.

Table 9 :Washability test of cream

Parameters	Formulations		
	F1	F2	F3
Removal	Good	Good	Good

Irritancy test:

The formulation did not cause edema, inflammation, redness, or irritation during irritancy tests. These formulas are safe for use.

Table 10 : Irritancy test of cream

Parameters	Formulations		
	F1	F2	F3
Irritancy	Nil	Nil	Nil

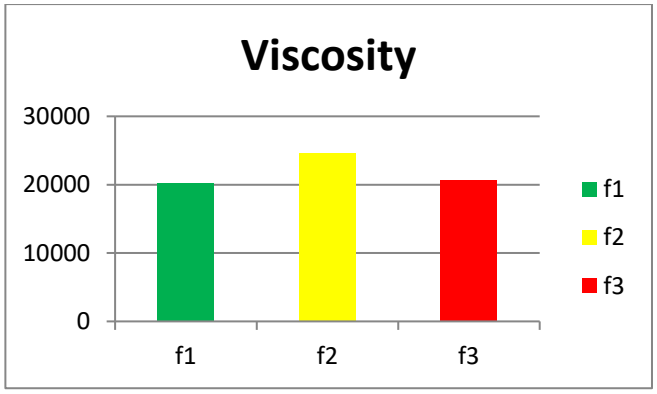
Viscosity test:

The formulation's viscosity was measured at 25°C and 100 rpm using a viscometer.

Table 11 : Viscosity test of cream

Parameters	Formulations		
	F1	F2	F3
Viscosity	20185	24679	20754

GRAPHICAL REPRESENTATION:



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Anti-oxidant test:

xThe results demonstrated significant antioxidant activity in the formulations, as measured by UV- Visible spectrophotometry, which confirmed the reduction of Ferric Chloride. The cream samples passed the test, exhibiting strong antioxidant potential highlighting the efficacy of the Aloe Vera extract-based creams.

F1:

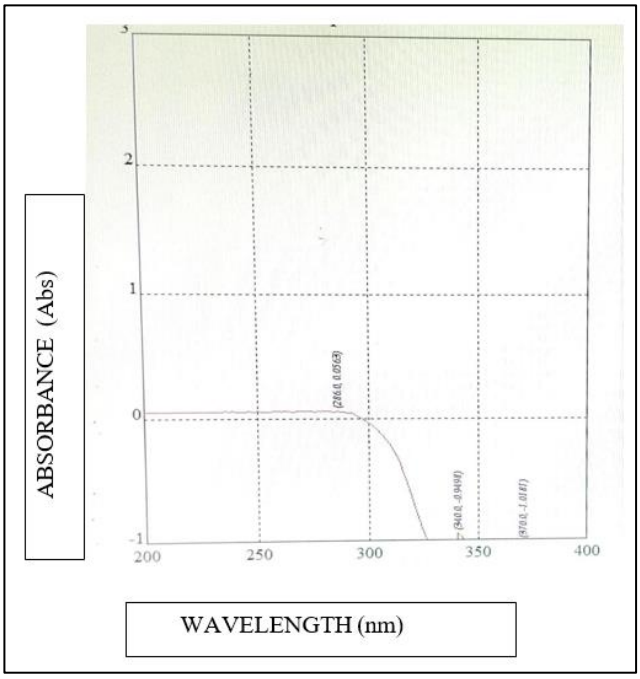


Figure 8: Graphical representation of anti-oxidant activity of F1

F2:

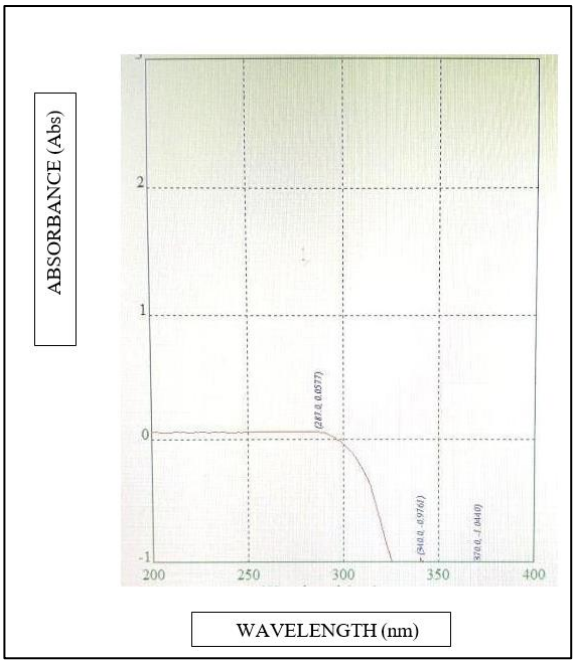


Figure 9: Graphical representation of anti-oxidant activity of F2

F3:

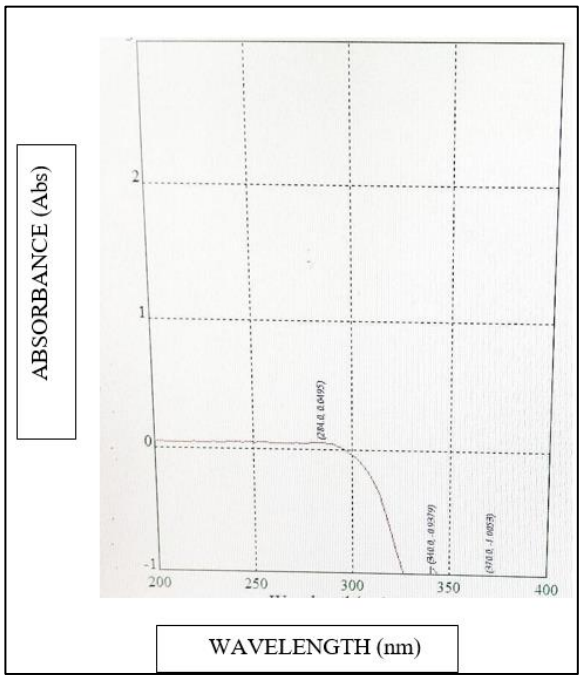
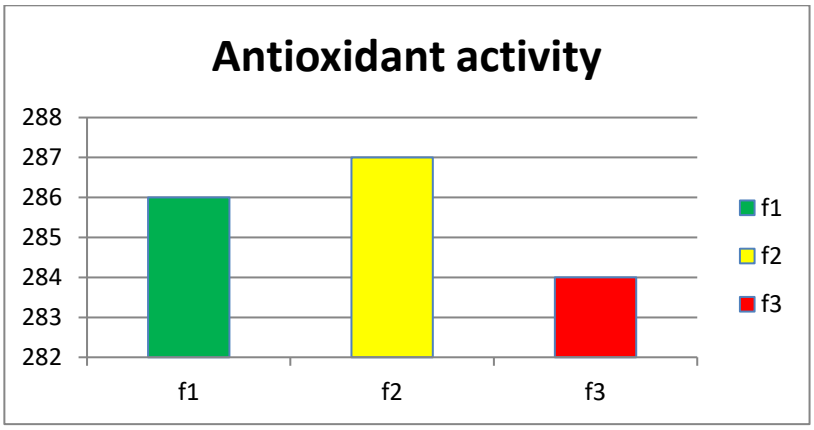


Figure 10: Graphical representation of anti-oxidant activity of F3

GRAPHICAL REPRESENTATION:



CONCLUSION:

The merits of the cream formulation shows better application property by topically. The addition of *Aloe vera* extract and Goatmilk shows synergistic effect on the exfoliation of skin. The combination has the better activity than that of individual formulations. The formulation of the cream fulfilled their needed characteristics of a potent management of the hyperpigmentation such as applicable viscosity and better efficacy in invitro studies. So, from this research work we concluded that the combination of *Aloe vera* extract and Goat milk has synergistic efficacy in the management of the hyperpigmentation.

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