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FORMULATION AND EVALUATION OF CALAMINE LOTION WITH ALOVERA AND VITAMIN-E

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ABSTRACT
The present study focuses on the formulation and evaluation of a calamine lotion enhanced with natural and therapeutic additives – Aloe vera and Vitamin E – to improve its skin- soothing, moisturizing, and healing properties. Calamine, a zinc-based compound, is widely used for its antipruritic and astringent effects in the treatment of minor skin irritations. The addition of Aloe vera, known for its anti-inflammatory and hydrating effects, and Vitamin E, a potent antioxidant, aims to enhance the overall efficacy of the lotion. The formulation was prepared using standard emulsification techniques and evaluated for key parameters including pH, viscosity, spreadability, stability, skin irritation potential, and antimicrobial activity. Results indicated that the prepared lotion possessed optimal physicochemical properties, remained stable over time, and was well-tolerated on the skin without adverse effects. The synergistic combination of calamine with Aloe vera and Vitamin E suggests a promising topical formulation for soothing irritated skin and promoting skin health

INTRODUCTION
The concept of beauty and cosmetics dates to ancient mankind's civilization. Generally, herbal cosmetics are also referred to as herbal cosmetics. Herbal cosmetics are formulated, using different cosmetic ingredients to form the base in which one or more herbal ingredients are used to cure the various type of skin ailments. The name itself suggests that herbal cosmetics are natural and free from all harmful synthetic chemicals. Instead of traditional synthetic products, different plant parts and plant extracts are used in these products, e.g. *Aloe vera* gel and vitamin E. There are a rising number of consumers concerned about ingredients such as synthetic chemicals, mineral oils who demand more natural ingredients, free from harmful chemicals and with an emphasis on the properties of botanicals.

Calamine is basic zinc carbonate coloured with ferric oxide. Calamine had mild astringent and antipruritic actions and is used as a dusting powder, cream, lotion, and ointment in a variety of skin conditions. Diphenhydramine is an H1 antihistaminic that is used in allergic conditions, known to cause skin hypersensitivity. Contact dermatitis is an acute or chronic skin inflammation, which is occurring due to contact with an irritant or allergic substances. Topical antibiotics and topical anaesthetics are usually implicated in contact dermatitis. Contact dermatitis due to calamine lotion is not reported in the literature. There are rare reports of contact dermatitis due to diphenhydramine.

BACKGROUND OF CALAMINE LOTION
Calamine lotion is a widely used topical formulation known for its ability to treat minor skin irritations. It is typically composed of calamine (a mixture of zinc oxide and ferric oxide) suspended in water or a solution of glycerine. The primary function of calamine lotion is to soothe and protect the skin from itching and irritation caused by conditions such as insect bites, sunburn, chickenpox, and allergic rashes.

The soothing effects of calamine are due to its astringent properties, which help to reduce inflammation and dryness in affected areas. It also forms a protective barrier on the skin, preventing further irritation. Over the years, calamine lotion has been a trusted remedy for mild skin conditions, making it a staple in first aid kits and household medicine cabinets.

Despite its effectiveness, traditional calamine lotion can sometimes feel drying or leave a chalky residue on the skin. This project aims to improve the formulation by combining calamine with ingredients known for their skin-healing and moisturizing properties, namely **Aloe Vera** and **Vitamin E**.

IMPORTANCE OF ALOE VERA AND VITAMIN E IN SKINCARE
- **ALOE VERA**: Aloe Vera is a well-known natural ingredient with a rich history in traditional medicine. The gel extracted from the Aloe Vera plant is widely regarded for its healing, soothing, and moisturizing properties. It is commonly used in skincare for treating sunburns, wounds, and skin irritations. Aloe Vera is rich in vitamins, antioxidants, and anti-inflammatory compounds, which make it an excellent addition to any skin care product.
- **Soothing s Anti-Inflammatory**: Aloe Vera has a cooling effect on the skin, which helps to reduce redness, swelling, and irritation.
- **Hydration**: Aloe Vera has high water content, which can help hydrate the skin and prevent dryness, a common side effect of calamine lotion.
- **Promotes Skin Repair**: Aloe Vera accelerates the healing of minor wounds and cuts by stimulating collagen production, which can be beneficial for treating skin damaged by rashes or burns.

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VITAMIN E: Vitamin E is a potent antioxidant that helps protect the skin from damage caused by free radicals, which are harmful molecules that can accelerate aging and cause skin damage. It is also known for its moisturizing and skin-healing properties. In addition, Vitamin E is often used to reduce the appearance of scars and stretch marks, making it a valuable ingredient for improving skin texture.

- **Antioxidant Protection**: Vitamin E helps protect the skin from environmental stressors such as UV radiation and pollution.
- **Moisturization**: Vitamin E is highly emollient, meaning it helps retain moisture in the skin, keeping it soft and supple.
- **Wound Healing**: Vitamin E is believed to enhance the skin's natural healing processes, which can be helpful in reducing irritation and redness caused by various skin conditions.

LITERATURE SURVEY

Calamine lotion is a widely used topical preparation known for its soothing, anti-itching, and protective properties. It primarily contains zinc oxide and ferric oxide, which provide astringent, antiseptic, and mild anti-inflammatory effects. Traditionally, it has been used to relieve skin irritations

1.Kulkarni et al., 2012)

Aloe vera (Aloe barbadensis Miller), a natural plant extract, is extensively recognized for its skin-beneficial properties. It contains polysaccharides, vitamins, enzymes, and amino acids that exhibit moisturizing, anti-inflammatory, wound-healing, andantibacterial effects. Its use in dermatology has been well documented for accelerating healing and reducing skin inflammation

2.(Surjushe et al., 2008).

Vitamin E (tocopherol) is a lipid-soluble antioxidant that plays a crucial role in protecting skin cells from oxidative stress. It helps in reducing UV-induced skin damage, promotes wound healing, and improves skin hydration and elasticity. Its topical application has shown promising results in

3.(**Thiele et al., 1999).**

The incorporation of Aloe vera and vitamin E into calamine lotion enhances its therapeutic value, especially in terms of skin hydration, healing, and protection. This combination is particularly useful in treating dry, irritated, or damaged skin. Studies have shown that herbal additions to conventional formulations improve both efficacy and patient stability. Evaluation of such formulations includes tests for pH, viscosity, spreadability, homogeneity, stabilityand skin irritation potential. These parameters ensure product safety, consistency, and shelf life. Formulations enriched with natural components like Aloe vera and vitamin E are gaining attention in modern cosmeceuticals for their enhanced skin care benefits

4. (Patil et al., 2016).

In conclusion, combining calamine with Aloe vera and vitamin E offers a novel and effective formulation for topical use, particularly for sensitive and irritated skin. The literature supports the formulation's multifunctional properties and its potential for further development and commercialization

AIM & OBJECTIVE

AIM

"Formulation And Evaluation Calamine Lotion with Aloevera and Vitamin E."

OBJECTIVES OF THE PROJECT

This project seeks to formulate a new variant of calamine lotion that combines the soothing and protective benefits of calamine with the hydrating and healing properties of **Aloe Vera** and **Vitamin E**. The key objectives of this project are:

1. **Formulation Development**: To create a stable and effective calamine lotion that incorporates Aloe Vera and Vitamin E.
2. **Enhanced Skin Benefits**: To evaluate whether the combination of these ingredients improves the skin's healing, reduces irritation, and enhances moisturization compared to traditional calamine lotion.
3. **Improved Sensory Experience**: To develop a lotion with a pleasant texture and fragrance that can be easily applied without leaving a greasy or chalky residue.
4. **Evaluation of Effectiveness**: To test the new formulation for its ability to heal minor skin irritations and provide hydration, while reducing the discomfort typically associated with the use of calamine lotion.
5. **Safety and Stability**: To ensure that the lotion is safe for use on the skin and remains stable over time without separating or degrading

PLAN OF WORK

METHOD USED: MORTAR & PESTLE PROCEDURE

1. All glassware was washed and dried.
2. Required quantity of chemicals were taken and weighed.
3. Weigh and mix the calamine, zinc oxide, and bentonite in a mortar so that the bentonite is well distributed.
4. Dissolve sodium citrate in ml rosewater, and gradually add to the mixture in the mortar so that a smooth paste is produced.
5. Add the liquefied phenol and glycerine and mix well.
6. Add the aloe vera gel then stir and mix well.
7. The preparation was then transferred to a light-resistant container.
8. Container was labelled.

PLANT PROFILE

1. ALOE VERA

Botanical Name: Aloe barbadensis miller
Family: Asphodelaceae.
Common names: Aloe vera and Ghritkumari.
Cultivation: It mainly grows in the dry regions of Africa, Asia, Europe, and America. In India, it is found mainly in Rajasthan, Andhra Pradesh, Gujrat, Maharashtra, and Tamil Nadu.
Active constituents: Vitamins (vitamin A, vitamin C, vitamin E, and vitamin B12), enzymes, minerals, sugars, lignin, saponins, salicylic acids, amino acids, folic acids, and choline.

Chemical Formula - C16H13NO3
Drug Category – Antiseptic & Anti – inflammatory
Description - Green or completely transparent in colour.

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Properties

- Moisturises dry skin
- Fights acne
- Removes dark circles
- Soothes irritated skin
- Treats sunburn
- Eliminates dead skin cells
- Relieves eczema and psoriasis

FIGURE NO. 1 – ALOE VERA

MATERIALS AND METHODS

MATERIALS

1. CALAMINE

Calamine powder is a composition of zinc oxide combined with some amounts of ferric oxide. The presence of iron (in the form of ferric oxide) in Calamine powder.

2. ALOE GEL + VIT E

I. PREPARE THE ALOE LEAVES-

To use a fresh aloe leaf from a plant, first cut off one of the outer leaves from the base of the plant.
We can also use a store-bought leaf.

After washing it well, removing any dirt, and then stand it upright in a cup or bowl for 10–15 minutes. This allows the yellow-tinted resin to drain out of the leaf.
The resin contains latex, which can irritate our skin, so completing this step is important.
After the resin has drained completely, wash off any remains on the leaf and peel off the thick skin using a small knife or vegetable peeler.

II. MAKE THE GEL

Once the leaf has been peeled, we can see the natural *Aloe vera* gel.
Using a small spoon, scoop it into your blender. We should be careful not to include any pieces of the *Aloe vera* skin.
Blend the gel until it's frothy and liquefied, which should only take a few seconds.
At this point, our gel is ready to use. However, if we plan on keeping it for more than 1 week, we should add preservatives.

3. BENTONITE

It is an absorbent swelling clay consisting mostly of montmorillonite. It usually forms from weathering of volcanic ash in seawater, which converts the volcanic glass present in the ash to clay minerals.

4. ZINC OXIDE

Zinc oxide is a *zinc* molecular entity. ChEBI. *Zinc oxide* is an inorganic compound used in several manufacturing processes. It can be found in rubbers, plastics, ceramics, glass, cement, lubricants, paints, ointments, adhesives, sealants, pigments, foods, batteries, ferrites, fire retardants, and first-aid tapes.

5. SODIUM CITRATE

Sodium citrate is the sodium salt of citric acid. It is white, crystalline powder or white, granular crystals, slightly deliquescent in moist air, freely soluble in water, practically insoluble in alcohol. Like citric acid, it has a sour taste.

6. LIQUID PHENOL

A colourless liquid when pure, otherwise pink or red. Combustible. Flash point 175°F. Must be heated before ignition may occur easily. Vapors are heavier than air. Corrosive to the skin but because of anaesthetic qualities will numb rather than burn. Upon contact, the skin may turn white. May be lethal by skin absorption. Do not react with water. Stable in normal transportation. Reactive with various chemicals and may be corrosive to lead, aluminium and its alloys, certain plastics, and rubber. The freezing point is about 105°F. Density 8.9 lb/gal. Used to make plastics, adhesives, and other chemicals.

7. INSTRUMENTS

Beaker, test tube, weighing machine, mortar & pestle, funnel, burette, pipette, ring stand, watch glass, glass slide, pH meter, hot air oven.

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FORMULATION & EVALUATION

Table: Formulation Calamine lotion with Aloe vera gel for (50ml)

Ingredients	Quantity
Calamine Powder	7.5 gm
Aloe gel & Vit E	0.75 gm
Zinc Oxide	2.5 gm
Bentonite	1.5 gm
Sodium Citrate	0.25 gm
Liquid Phenol	0.25 gm
Glycerine	2.5 ml
Water	Q.S for (50 ml)

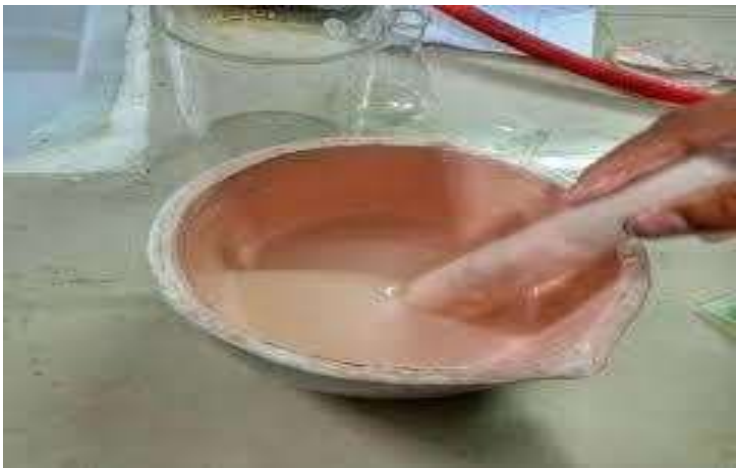

Figure: Preparation Of Calamine Lotion

IDENTIFICATION TESTS

I. IDENTIFICATION TESTS FOR CALAMINE

A. To 2 ml add 2ml of periodic acid reagent, shake, centrifuge, and add 0.5 ml of the supernatant liquid to 2 ml of ammoniacal silver nitrate solution in a test tube; a silver mirror is produced on the walls of the tube.

B. Mix 2 ml with 50 ml of water, centrifuge and decant the supernatant liquid. Suspend the residue in 20 ml of water, add 1ml of hydrochloric acid, mix, and filter. 5 ml of the filtrate, after neutralization by dropwise addition of 2 M sodium hydroxide, gives the reactions of zinc salts.

II. IDENTIFICATION TESTS FOR ALOE GEL

- **BORAX TEST:** Take 10 ml of aloe solution and to it add 0.5 gm of borax and heat; a green-coloured fluorescence is produced indicating the presence of aloe-emodin anthranol.
- **BROMINE TEST:** To 5 ml of aloe solution, add an equal volume of bromine solution; a bulky yellow precipitate is formed due to the presence of tetrabromaloin.

SOLUBILITY TEST

A. CALAMINE: Practically insoluble in water; soluble with effervescence in mineral acids.

B. ALOE GEL: Aloe vera is a desert plant that contains some 95% water that, without a proper water-tight container, would evaporate in a jiffy. The gel is where aloe vera stores its 95% water and its water-soluble nutrients (e.g. water-soluble vitamins). The rind is the barrier that stops the Aloe vera gel (water) from evaporating, so obviously, the rind is not water-soluble but lipid-based. So that is where its lipid-soluble nutrients (e.g. fat-soluble nutrients) reside.

EVALUATION STUDY

➢ pH

5 ± 0.01 gm of the lotion was weighted accurately in a 100 ml beaker. 45 ml of water was added and dispersed the lotion in it. The pH of the suspension was determined at 27o c using the pH meter.

➢ VISCOSITY

Viscosity is a measure of fluid's resistance to flow. It is to drive a spindle (which is immersed in the test fluid) through a calibrated spring. The viscous drag of the fluid against the spindle is measured by the spring deflection. Spring deflection is measured with a rotary transduce.

➢ PHYSICAL APPEARANCE

The visual appearance of the formulation at each stability test condition was assessed by comparing the colour of the lotion to the initial colour and appearance of the C. niloticus oil lotion. Photos were taken of each formulation, placed at the same location in the laboratory each time that appearance was evaluated. A digital camera was placed approximately 15 cm away from the formulations.

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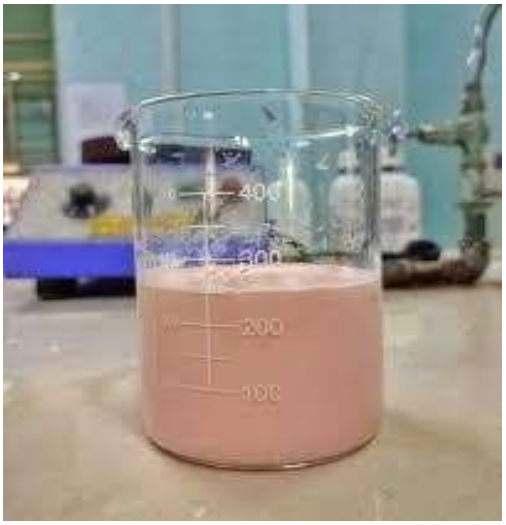

Figure: Physical Appearance

- **STABILITY TEST**

The thermal stability of the formulation was determined by the humidity chamber controlled at 40oC for 7 days.

- **SPREADABILITY TEST**

The Spreadability test has been done and the result has been found.

- **SKIN IRRITATION TEST**

2 ml of the formulation was taken, applied to the skin of the hand first then to the backside of the ear. It produces no skin irritation after 30 min.

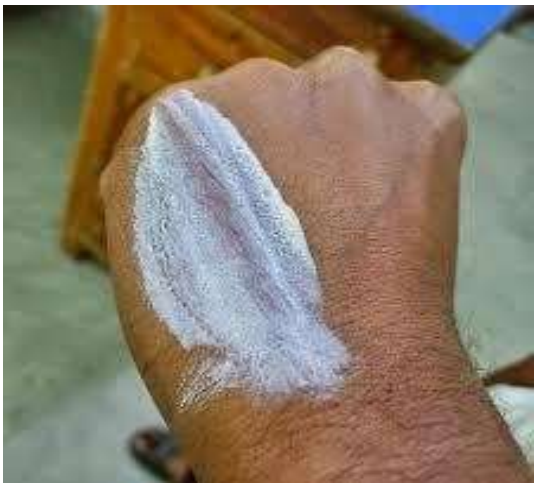

Figure: Skin Irritation and Spedability Test

ADVANTAGES & DISADVANTAGES

❖ **ADVANTAGES OF CALAMINE LOTION**

- It can relieve itchiness.
- When applied to the skin, the aqueous component of calamine lotion evaporates. The heat required for evaporation is taken from the body which gives a cooling effect at the site of application. This provides the lotion its soothing and antipruritic effect.
- The powder added to the lotion increases the surface area of evaporation. As a result, the lotion effectively dries and cools wet and weeping skin
- It is suitable for application to large surface areas due to its ability to spread easily and uniformly.
- Calamine lotion allows passage of some amount of secretion and exudation.
- It is often the favourite preparation in treating children and considered safe in infants. However, phenol containing preparation is to be avoided in infants.

❖ **DISADVANTAGES OF CALAMINE LOTION**

- A drying effect on skin.
- Some patients and some body areas (calamine lotion becomes gritty in moist, intertriginous areas) do not tolerate the lotion.
- The powder component may clump together and become abrasive after evaporation of water, and hence, patients should be instructed to remove the residual particles before reapplication.
- The pink colour may be cosmetically unacceptable for daytime use, especially on exposed skin.
- Calamine lotion produces only a superficial effect since it does not penetrate to deeper layers of skin, which makes it less effective as a treatment modality.

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RESULT & CONCLUSION

RESULT

Add to about 1.5 g, accurately weighed, 50 mL of sulfuric acid (0.5 mol/l) VS, heat gently until no further precipitation occurs, and filter. Wash the residue with hot water until the last washing is neutral to litmus paper R. Combine the wash liquid and the filtrate, add 2.5 g of ammonium chloride R, cool, and back-titrate with sodium hydroxide (1 mol/l) VS using methyl orange/ethanol TS as an indicator.

Each mL of sulfuric acid (0.5 mol/l) VS is equivalent to 40.69 mg of ZnO.

Titre value = 12 ml;

Specific Gravity = 3.05; **Equivalent weight** = 40.69mg;

Weight of Sample Taken =1.5gm; **Calculation-**

$$\frac{12\times 3.05\times 40.69\times 100}{1.5\times 1000}$$

=99.2836 %w/v

CONCLUSION

Here in the work done it has been concluded that calamine lotion can be prepared from herbal natural extract like *Aloe vera*. The formulation showed the best results when compared with other formulations. It showed the pH like skin pH and no skin sensitivity with greater stability.

Calamine/diphenhydramine is commonly prescribed as systemic antihistaminic which is available as an over-the-counter medication in many countries for countless conditions including nasal allergy and the common cold. We should be aware of its particular adverse reactions and as far as the possible combination of calamine and diphenhydramine is to be avoided.

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