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# A REVIEW ON FORMULATION AND EVALUATION OF CALAMINE LOTION

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## ABSTRACT

Herbal cosmetics are formulated, using different cosmetic ingredients to form the base in which one or more herbal ingredients are used to cure various skin ailments. The name itself suggests that herbal cosmetics are natural and free from all the harmful synthetic chemicals which otherwise may prove to be toxic to the skin. Compared to other beauty products, natural cosmetics are safe to use. Cosmeceuticals are cosmetic-pharmaceutical hybrid products intended to improve the health and beauty of the skin by providing a specific result, ranging from acne-control and anti-wrinkle effects, to sun protection. Calamine lotion is widely used as an antiseptic and protective for its cooling and soothing effect in various skin disorders. Instead of traditional synthetic products different plant parts and plant extracts are used in this study to procure calamine lotion having natural humectants, e.g. aloe-vera gel and honey. Herbal cosmetics are the preparations used to enhance the human appearance. The purpose of this study is to compare the semi synthetic activity of glycerin with other humectants in terms of their emollient properties to ensure whether calamine lotion can be formulated using natural humectants or not.

**Keywords:** Humectants, Emollient, Antiseptic, Calamine Lotion.

## I. INRODUCTION

Calamine lotion comes under the category of shake lotions and contains calamine and zinc oxide as active ingredients. In addition, it also contains bentonite, glycerine, sodium citrate, and liquified phenol. This article focuses on calamine lotion and preparations that contain calamine lotion. The topical preparations that contain zinc oxide or calamine alone (instead of calamine lotion as a whole) are not discussed here. Simple suspensions or solutions of medication in water, alcohol, or other liquids are called lotions. When left on the skin, the lotion will leave a film of medication on skin surface, as the liquid portion evaporates. Shake lotion is an aqueous suspension of powders. Hence, such lotions require shaking before each application. The United States of America Food and Drug Administration (US FDA) has approved calamine lotion as an over-the-counter medication that can serve as a skin protectant. Calamine lotion is included as an anti-inflammatory and antipruritic medicine in the World Health Organization's list of essential medicines, under the category of dermatological medicines (topical). It is recommended that all shake lotions should be dispensed in wide neck bottles so that a small paint or varnish brush (with which the lotion is applied to the skin) can be directly inserted into the bottle. There are some differences in the ingredients of calamine lotion as mentioned in British Pharmacopoeia (BP) and the United States Pharmacopoeia (USP). The difference starts from the constituents of calamine itself. As per BP, calamine is basic zinc carbonate coloured with ferric oxide. Calamine according to the USP is zinc oxide coloured with ferric oxide.

### 1.1 PROJECT AIM AND OBJECTIVES

**Aim**: To prepare and submit of 30 ml of calamine lotion

**OBJECTIVES**

1. The objective of the study was to formulate the Calamine lotion which do not any side-effect or adverse reaction.
2. To evaluate the prepared calamine lotion for moisturising the skin
3. Calamine lotion is used for rejuvenate the skin, remove wrinkles on skin, provide soothing effect to the skin.

**BENEFITS OF CALAMINE LOTION**

1. It helps in treating acne.
2. It helps in drying oozing or weeping from minor skin irritations that are caused by chickenpox, insect bites, measles, eczema, sunburn and poison ivy etc.
3. Calamine lotions are used as antiseptic and protective for its cooling and soothing effect in various skin disorders.
4. Calamine lotion can produce small densities on mammographic examination simulating micro calcifications.
5. The skin lesions are also treated symptomatically with the calamine lotion.
6. It can be used to treat pruritus and urticaria along with topical corticosteroids or oral.

**TYPES OF LOTION**

From youthful skin to anti-tanning, anti-wrinkles to cellulite reduction, lotions come for a wide variety of purposes. Broadly speaking, the classification of body lotions can be done as:

**Skin maintaining:** These lotions are aimed at keeping your skin soft, healthy and glowing. They may be further classified under lotions for dry, normal and oily skins.

**Damage repairing:** For very dry, highly sensitised or problem skin types.

**Cellulite-reduction:** Targets cellulite, helping smooth that orange-peel skin out.

**Anti-wrinkle or anti-ageing:** Specially for mature skin, they often contain retinol, vitamin E and other anti-oxidants.

**Anti-tan and fairness:** Some target already tanned skin, while others proclaim to internally activate fairer skin by blocking melanin (the skin's natural darkening pigment) production.

**Anti-stretch marks:** These are bestsellers with pregnant women (for obvious reasons and are available for two stages -the preventive stage and the repair stage.

**EXCIPIENT USED IN LOTION**

**Oily compounds:** In topical cream formulations, oily compounds act as active substance carriers. They also serve as skin penetration enhancers and consistency or viscosity modifiers. The oily excipients may influence cream viscosity, drug solubility, physical stability, drug release performance, and transport into the skin. Oily compounds commonly used in cream formulations include saturated and unsaturated fatty acids/fatty acid esters, hydrocarbons, and polyols.

**Thickeners and Emulsifying agents:** Topical cream formulations consist of the oily phase and water phase. As the two phases are immiscible, in the absence of thickeners and emulsifying agents, molecules in the topical cream formulation will form droplets. Rapid aggregation of droplets within each phase will eventually lead to phase separation. Physical stability is determined by the mitigation ability to these physical instability phenomena. Thickeners increase cream viscosity and thus reduce dispersed droplets' mobility. They hinder the separation of phases, thereby increases the physical stability of the cream. For example, the inclusion of methylcellulose and paraffin reduces dispersed droplets' mobility in an oil-in-water emulsion and water-in-oil emulsion respectively. Emulsifying agents can reduce the interfacial tension between the two phases, thus retards phase separation. Ionic surfactants are used in oil-in-water emulsions, whereas nonionic surfactants are used in both oil-in-water and water-in-oil formulations.

**Preservatives and Antioxidants**

Oils and fats used in topical cream formulations are susceptible to oxidation by atmospheric oxygen or microorganism action. The stability against oxidation can be enhanced by the introduction of antioxidants. The selection of antioxidants and their concentration can only be determined by testing their effectiveness on the final product, according to pharmacopoeial information. The efficiency of antioxidants depends on their compatibility with other excipients and oil/water partition coefficient. Oxidations from microbiological source influence the physicochemical properties of the emulsion, resulting in colour and odour changes, fat and oil hydrolysis, pH changes in the aqueous phase, or phase separation of the cream. Oil-in-water creams are more susceptible to microbial contamination. Therefore, preservatives are included to prevent any microorganism growth. Preservatives suitable for topical cream formulations must present a broad spectrum of bactericidal activity, low logP, compatibility with other excipients, stability, and effectiveness over a wide range of pH and temperatures.

**Buffer agents**

By buffering any potential pH change, buffer agents can provide chemical stability and ensure the physical compatibility of the topical cream formulation. They ensure that the formulation can deliver the correct amount of drug to the therapeutic application site, is free from microbial contamination, and physically unchanged since the manufacturing day. Nonetheless, buffer agents need to be carefully added to avoid undesirable effects on physical stability. For example, buffer agents may influence the rheological behaviour.

## USES

Lotions maintain skin's hydration levels by locking in the moisture, keeping the skin healthy, soft, and supple. Unlike a cream, the lotions are less greasy and have more water content Here are some of their additional benefits: Reduce the skin dryness and flaky spots.

## II. FORMULATION OF CALAMINE LOTION

| Sr. NO. | Ingredients | For 30ml |
|---|---|---|
| 1 | Calamine | 4.5 gm |
| 2 | Zinc Oxide | 1.5 gm |
| 3 | Bentonite | 0.9 gm |
| 4 | Glycerine | 0.15 ml |
| 5 | Aqu. Ad | 0.15 ml |

**Calamine:** It may be either zinc carbonate or zinc oxide (98%), coloured pale pink with ferric oxide (2%), and has bland, soothing, and antipruritic properties.

**Zinc oxide:** It is an inorganic powder with cooling and slightly astringent properties. It has soothing and protective properties. It can block broad-spectrum sunlight (ultraviolet B and A and visible light). Hence, it is preferred as an inexpensive physical sunscreen. Ann et al. reported that zinc oxide exhibited bactericidal action on Staphylococcus aureus and Pseudomonas aeruginosa. The antibacterial property was attributed to the structural morphology of zinc oxide that induced toxicity and a killing effect on bacteria.

**Bentonite:** Bentonite is colloidal hydrated aluminium silicate. Bentonite serves as a stabiliser in shake lotions.

**Glycerine:** Glycerine is a humectant, emollient, and stabiliser.

**Sodium citrate:** Sodium citrate controls the pH of the lotion.

Liquified phenol: It acts as a preservative, alleviates itching(through its anaesthetic effect), and acts as an antiseptic.

**Ingredients used in preparation of calamine lotion and their respective uses.**

| Sr.No. | Ingredients | Uses |
|---|---|---|
| **1** | Calamine | Astringent |
| **2** | Zinc Oxide | Protective |
| **3** | Bentonite | Suspending agent |
| **4** | Glycerine | Soothing agent |
| **5** | Purified water | Vehicle |
| **6** | Aloe vera Gel | Moisturization |
| **7** | Vitamin E | Antioxidant |

**PLANT PROFILE**

**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 cholin.

It belongs to Asphodelaceae (Liliaceae) family, and is a shrubby or arborescent, perennial, xerophytic, succulent, pea- green colour plant. It grows mainly in the dry regions of Africa, Asia, Europe and America

**Fig.2.1 Aloe Vera**

**Anatomy:** The plant has triangular, fleshy leaves with serrated edges, yellow tubular flowers and fruits that contain numerous seeds. Each leaf is composed of three layers: 1) An inner clear gel that contains 99% water and rest is made of glucomannans, amino acids, lipids, sterols and vitamins. 2) The middle layer of latex which is the bitter yellow sap and contains anthraquinones and glycosides. 3) The outer thick layer of 15–20 cells called as rind which has protective function and synthesizes carbohydrates and proteins. Inside the rind are vascular bundles responsible for transportation of substances such as water (xylem) and starch (phloem).

## III. METHODOLOGY

## MATERIALS AND METHODS

## MATERIALS:

**3.1Calamine Powder:** 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.

**Fig.3.1 Calamine Powder**

**3.2. Aloe gel + Vit E:** 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 gelOnce 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.

**Fig.3.2 Vitamin E (Evion)**

**3.3.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 clay minerals.

**Fig.3.3 Bentonite**

**3.4. 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.

**Fig.3.4 Zinc Oxide**

**3.5. 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.

**Fig.3.5 Sodium Citrate**

**3.6. Liquid Phenol:** A colourless liquid when pure, otherwise pink or red. Combustible. Flash point 175°F. Must be heated before ignition may occur easily. Vapours 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.


**Fig.3.6 Liquid Phenol**


**Fig.3.7 Glycerine**

## Instruments:

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

## METHODS:

**1.PHYSICAL APPEARANCE:**

**I. Calamine:**
**Colour-** Peachy pink
**Odour-** Characteristics
**Texture-** Powder

**II. Aloe gel:**
**Colour:** Light greenish
**Odour:** Characteristics
**Texture:** Viscous liquid

**2. pH:** Normally pH of aloe is 4.50

**3. IDENTIFICATION TESTS:**

I. Identification tests for calamine lotion:

A. To 1 ml add 1ml of periodic acid reagent, centrifuge, shake, and add 0.25 ml of the supernatant liquid to 1 ml of ammonical silver nitrate solution in a test tube; a silver mirror is produced on the walls of the tube.

B. Mix 1ml with 30 ml of water, centrifuge and decant the supernatant liquid. Suspend the residue in 30 ml of water, add 0.5ml of hydrochloric acid, mix, and filter. 2.5 ml of the filtrate, after neutralization by drop-wise addition of 1 M sodium hydroxide, gives the reactions of zinc salts.

| Sr. No. | Ingredients | Company | Category |
|---|---|---|---|
| 1 | Calamine (extra pure confirming to B.P.) | Loba chemie | Astringent |
| 2 | Zinc oxide (confirming to LP) | Loba chemie | Protective |
| 3 | Bentonite (Aluminium silicate hydrate) | CDH Laboratory reagent | Suspending agent |
| 4 | Tri sodium citrate (Dihudrate extra pure) | Loba chemie reagent and pure chemicals | Chelating agent |
| 5 | Liguefied phenol (Carbolic acidcrystals) | CDH Laboratory regent | Antiseptic/Preservation |
| 6 | Glycerin | Purified CDH | Soothing effect |
| 7 | Purified water | - | Vehicle |

**Procedure:**

1) Weight all the ingredients like calamine, zinc oxide and bentonite placed in mortar.
2) Triturates it to make uniform size by size reduction
3) The mixture was grinded to make them fine particles
4) 0.15ml of glycerin and 30 ml of water was added and a fine paste was made out of them
5) Now carefully make dilution of this paste using water
6) Now make this paste pourable by dilution
7) Use water for dilution
8) Transfer it in a measuring cylinder
9) Now adjust the final volume up to 30 ml using water
10) Transfer it in a suitable container

**Fig.3.8 Mortar and Pestle**

## IV. RESULT AND DISCUSSION

**EVALUATION:**

**Organoleptic Evaluation:** the organoleptic parameter include it's colour, odour, nature, texture, appearance evaluated. It's manually physical properties.

| Sr.NO | Parameter | Observation |
|---|---|---|
| 1 | Colour | Slightly yellow |
| 2 | Odour | Odourless |
| 3 | Texture | non-greasy, light texture |
| 4 | Appearance | Semi-Solid |
| 5 | Nature of calamine lotion after applied to skin | Provide soothing and nourishing to the skin |

**Physicochemical Evaluation:**

| Sr. No. | Parameter | Observation |
|---|---|---|
| 1 | Homogenisity | homogenous |
| 2 | Viscosity test | 66.1% |
| 3 | Thermal stability | Stable |
| 4 | Spread ability | 6.3 |
| 5 | Water content | 90% |

**Irritancy Test:** the prepared calamine lotion was subjected for irritancy test and the result shown as follows.

| Sr. No. | Parameter | Observation |
|---|---|---|
| 1 | Irritation | Nil |
| 2 | Redness | Nil |
| 3 | Swelling | Nil |

**Observation:** Irritancy test showed negative for irritancy, redness, swelling, as the calamine in their natural form with addition additional chemical were found to be compatible with the skin.


**Fig.4.1 Calamine Lotion** **Fig.4.2 Semi-Solid Lotion of Calamine**

Label - Calamine lotion I.P……30 ml

Calamine lotion IP……..30 m|

Rx
Calamine ……..……4.5gm
zine oxide……..……1.5gm
Bentennoite……..…..…0.9gm
Sodium citrate….……0.15gm
Liquid Phenol.……0.15ml
Glycerine……..……0.15ml
Rose water……..……0.3ml

Mfg Date. Apr 2023
Exp. Date. Oct 2025
Mfg Lic NO : 30/04/23
Batch No. E/92

**Category- As protective**

SHAKE WELL BEFORE USE
FOR EXTERNAL USE ONLY

Lotion should be applied with a cotton ball moistened with the lotion.
Then the medication should be allowed to dry on the skin.

**Storage: Keep air tight bottle in the cool page**
**Mfg By- Ojas College Of Pharmacy,Jalna.**

## 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 similar to 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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