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Review Article

**AN OVERVIEW - FORMULATION AND EVALUATION OF
COLD CREAM INCORPORATED WITH CITRUS SINENSIS AND
ALOE BARBADENSIS MILLER****Ms. Hashima Asim Khan^{*1}, Ms. Najuma Shajahan^{*1}, Ms. Nandini O B^{*1}, Ms. Reeba Roy^{*1},
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Thiruvananthapuram, Kerala, India**Article Received:** March 2024**Accepted:** March 2024**Published:** April 2024**Abstract:**

A cosmetic product is defined as any substance or preparation intended to be placed in contact with the various external part of human body. Cosmetics are the preparations used to beautify and enhancing the human appearances. The cold cream is prepared by using the orange peel oil and aloe vera gel. The aim of this study was to prepare a cold cream for the purpose of moisturizing, brightening and for treating tan. Various ingredients such as aloe barbadensis miller (aloe vera gel), and citrus sinensis (orange peel oil) are used to make the cream. The choice of ingredients is based on the various medicinal properties of these agents. The cream is tested on different evaluation parameters.

Keywords: Cosmetics, Cold Cream, Aloe vera gel, orange peel oil.

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INTRODUCTION:

The cosmetics are the word derived from Greek word – ‘kosmesticos’ which means to adorn. From that time the materials which are used to promoting appearances or to beautify the skin are called as cosmetics. Cosmetics are the external preparations, which are applied to skin, hairs, nails for various purposes like protecting, covering, coloring, beautifying, cleansing, and nourishing. Cosmetic production and formula development has evolved over the years from the days of Galen (150AD) to the present era of automation and computerization¹. The demand for cosmetic products, particularly in urban population, is steadily rising owing to various reasons. The use of cosmetics as substances to enhance or protect the beauty of the human body.

Certain cosmetics have transcended the barriers of age and gender and have assumed the role of protectants as they are now being used in form of cold cream, sunscreen, lip gels. The cosmetics are now finding greater distribution among all the economic sections of our society. The acceptance of cosmetics as appearance enhancers by the people from lower strata to the upper privileged has created a congenial environment for the growth of cosmetic industry.

CATEGORIES OF COSMETICS

Cosmetics may be categorized according to the body part over which they are applied. All cosmetics are typically intended to be applied externally to the face (on the skin, lips, eyebrows, and eyes), to the body (on the skin, in particular the hands and nails), and to the hair. The cosmetics have been categorized into,

1. Cosmetics for Hair
2. Cosmetics for Nails
3. Decoration of Dental care
4. Cosmetics for Skin

HAIR COSMETICS

Hair is an important component of the overall appeal of the human body. Hair follicle originates from an interaction between epidermal and dermal layers of the skin. The hair follicle is a sheath of epidermal cells and connective tissue that encloses the route of the hair. The average human head has about 100,000 hair follicles². The diameter of human hair ranges from 17 to 181 μm . Black or brown color of hair is due to pigment melanin. Melanin is formed in epithelium cells of the matrix. Due to change in metabolism, melanin is not formed and therefore not carried with the cells and hair becomes grey.

The study of hair, mane, locks, curls, or tresses and its related science is known as Trichology. Hair contains

97% protein and 3% moisture. This strong fibrous protein is called keratin. Each hair comes out of the scalp through the hair follicle. The angle at which the hair comes out of the skin is directly related to the shape of the hair. Straight hair is round in cross section and shoots straight out from the scalp³. Wavy hair is oval and comes out of the scalp at a straight angle, curly hair is flattened and comes out of the scalp at an extreme angle. Nourishment to hair is gained by the capillaries of sebaceous gland surrounding hair bulb.

NAIL COSMETICS

Nails are transparent protective coverings on the fingertips and toes of feet. They grow out of cuticle or horny layer of the skin in the nail matrix. These cells consist of granular layers, which possess the powder of constantly increasing or growing. The nail does not have a direct blood supply but is connected to blood vessels through the nail bed. Nail growth rates varies from person to person and season to season of the year⁴. The care of the nail is referred to as manicuring. They comprise of nail lacquer or enamel, enamel remover, powder polish, paste, nail cream. The care of the toenails is termed as pedicure. Nail lacquers/paint/enamels/varnish are viscous preparation intended to decorate nails of fingers and toes.

DENTAL CARE COSMETICS

Maintenance of teeth clean and in good health is essential and important for everyone. This can be achieved by using various dental care preparations or dentifrices are the preparation used for cleaning the surfaces of teeth and keep them shiny and to preserve the health of the teeth and gums. These preparations may also be expected to help inhibit the formulation of unpleasant odor and freshen the breath. Regular use of dentifrices helps to prevent occurrence of tooth decay⁵. A good dental health increases the possibility of a good general health.

SKIN COSMETICS

The purposes, functions, and roles of skin care cosmetics such as face cleansing cosmetics, lotions, milky lotions, creams, gels, essences (beauty lotions), packs and masks, shaving cosmetics and several other products (for example, powder and cleansing oil). The functions of skin care cosmetics include cleaning the skin, preserve the skin's moisture balance, stimulate skin metabolism, and protect the skin from harmful ultraviolet radiation. Skin care cosmetics contain substances which enable the skin to function properly⁶. They support its homeostasis function so that it is maintain in a beautiful and healthy condition or regains such a state if it is not.

ANATOMY AND PHYSIOLOGY OF SKIN

The skin (word derived from Greek derma, and Latin cutis) completely covers the body and is continues with the membranes lining the body orifices. And it accounts for 16% of total body weight of approximately 17.5 square feet and weighs about 2100gm in adult and contains glands, hair, and nails. Skin is more merely the largest organ (integumentary system) of the body, but it also receives the largest number of assaults and insults from the environment. Skin is the outer protective layer and most complex organ of the human body. It prevents loss of several internal body fluids and restricts penetration of foreign materials, radiations, etc. from outside. The skin is constantly being renewed and every 28-50days there is a new skin in healthy well-nourished person. The renewal takes place by shedding of skin's outermost layer. The skin normally is very smooth but due to aging, exposure to sunlight, cold, dust, abrasions, microbial infections etc., its smoothness is lost, and it becomes rough and thicker⁷. Skin is constantly exposed to several types of chemicals as various formulations are applied on it. Skin contains several chemicals like keratin, lipids, fatty acids, etc.

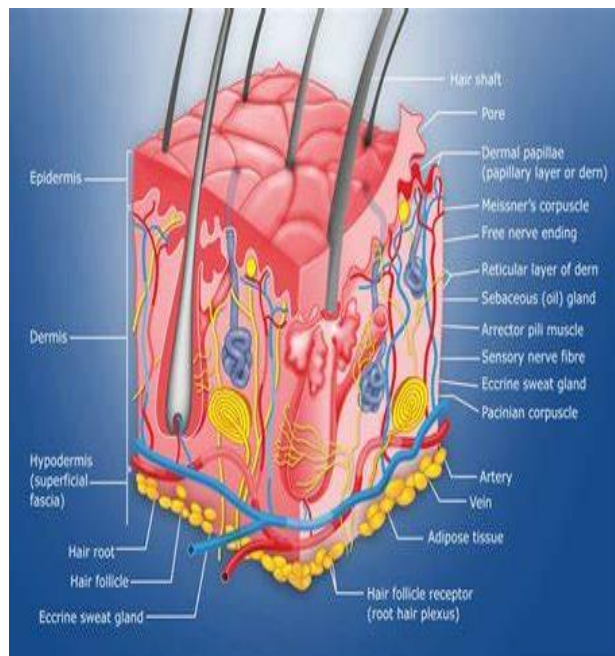


Fig 1 Structure of Skin

LAYERS OF SKIN

To understand the structure of skin, one may broadly segregate it into three basic layers, viz.

- Epidermis
- Dermis
- Hypodermis

EPIDERMIS

Epidermis is the most superficial layer of skin and is composed of stratified epithelium. It is the main target of most skin problems. It is itself made up of several layers. The outermost portion of this layer is casting off regularly. New cells from lower layer continuously replace, it protects the skin from bacterial and fungal attacks as well as from mechanical injury. The cells in the epidermis include keratinocyte, Langerhans, melanocytes, Merkel cells, hair and secretion from sebaceous and sweat glands.

Layers of Epidermis

Stratum corneum – It is the outermost layer of the cornified (or horny) cells which provide mechanical protection to the skin and a barrier to water loss. It is composed of dead cells that lack nuclei.

Stratum lucidum – It is the clear layer of the skin found below stratum corneum on palms and soles.

Stratum granulosum – It is composed of granular cells containing keratohyalin granules. It reduces water loss from the skin. It is more prominent in palms and soles.

Stratum spinosum – It contains spinous cells which have a spine-like appearance. They contain keratin filaments. It is also called transitional layer.

Stratum germinativum – It contains basically situated mitotically active keratocytes that attach to the basement membrane zone and give rise to cells of the more superficial epidermal layers⁸. The innermost layer of polyhedral cells divides to form new cells. All the glands and keratin structures are derived from this layer.

DERMIS

The dermis is tough and elastic and is composed of connective tissue containing collagen and elastin fibers. Blood vessels, nerve glands and hair follicles are embedded in the dermis. Also, there are fibroblast and mast cells in the dermis. The combination of collagen and elastic fibers in the reticular region provides the skin with strength, extensibility, and elasticity. The dermis also contains certain masses of specialized sensory nerve tissue receptors including Ruffini's corpuscle, Meissner's corpuscle, Krause corpuscle and Pacinian corpuscle.

HYPODERMIS

The reticular region is attached to underlying organs, such as bone and muscle, by the subcutaneous layer called the hypodermis or superficial fascia. In addition to areolar connective tissue adipose tissue the subcutaneous layer also contains nerve endings called lamellated or Pacinian corpuscles, that are sensitive to pressure.

COSMETIC CREAMS

Cosmetic creams are usually marketed based on their broad claims made on their packaging. Cream is a topical preparation usually for application to the mucous membranes. Creams are semi-solid emulsions that are mixtures of oil and water. They are divided into two types: oil in water (o/w) creams which are composed of small droplets of dispersed in a continuous aqueous phase, and water in oil (w/o) creams which are composed of small droplets of water dispersed in a continuous oily phase. Oil-in-water creams are more comfortable and cosmetically acceptable as they are less greasy and, more easily washed off using water. Water-in-oil creams are more difficult to handle but many drugs which are incorporated into creams are hydrophobic and will be released more readily from a water-in-oil cream than an oil-in-water cream⁹. Water-in-oil creams are also more moisturizing as they provide an oily barrier which reduces water loss from the stratum corneum, the outermost layer of the skin.

Depending upon the main ingredients and the purpose of these formulations, they can be broadly classified as

- a. Make up creams (o/w emulsions)
 - Vanishing creams
 - Foundation creams
- b. cleansing creams (w/o emulsions)
- c. Creams for winter (w/o emulsion)
 - Cold cream
- d. Creams for Dry skin
 - Moisturizing creams (and lotions)
- e. All Purpose creams.
- f. Night creams.
- g. Skin Protective and Hand creams.

CREAMS FOR WINTER

COLD CREAM

The term 'cold' is possibly due to the cooling sensation caused by evaporation of the water in the cream after it is applied to the skin. Cold creams are an emulsion of water and certain fats that is used to smooth skin and remove makeup. In the cosmetic industry, called creams consist of water-in-oil emulsions that are made by using beeswax and alkali, usually borax, as the emulsifying agent.

The emulsifying agent used in the cold cream type is really a soap formed in-situ by the interaction of borax with the free acid of the beeswax. Borax or sodium tetra borate is usually marketed as a decahydrate. Borax is hydrolyzed by water and the solution has marked alkaline reaction. It is a cosmetic that calms and cleanses the skin; it often has an oily and heavy consistency¹⁰. It fits the description of a cleansing cream.



Fig 2 Cold cream.

ALOE BARBADENSIS MILLER (ALOE VERA GEL)

Family: Liliaceae

Biological source: Dried latex of leaves of aloe vera

Biological name: Aloe barbadensis miller

Chemical constituents: The most important constituents of Aloes are the three isomers of Aloins, Barbaloin, β -barbaloin and Isobarbaloin, which constitute the so-called 'crystalline' Aloin, present in the drug at from 10 to 30%. Other constituents are amorphous Aloin, resin, emodin and Aloe-emodin. Barbaloin is present in all the varieties; it is slightly yellow colored, bitter, water soluble, crystalline glycoside. Isobarbaloin is a crystalline substance, present in Curacao aloe and in trace amount in Cape aloe and absent in Socotrine and Zanzibar aloe. The chief constituents of Socotrine and Zanzibar aloe are Barbaloin and β -Barbaloin.

Therapeutic uses: Several beneficial effects of aloe vera including immunomodulatory, wound and burn healing, hypoglycemic, anticancer, gastro-intestinal antifungal, and anti-inflammatory property. These polyphenols, along with some of the other compounds in aloe vera, help prevent the growth of certain bacteria that can cause disease in humans. Aloe vera is known for its antibacterial, antifungal, and antiviral properties.

This is one reason why it helps to heal wounds and cure skin problems. Aloe vera is often referred to as a cosmetic used to treat sunburn. Additionally, it may provide other health benefits, mainly due to its antioxidant properties. Preliminary research suggests that aloe vera may benefit your skin, teeth, mouth, and digestive health.



Fig 3 Aloe vera gel

CITRUS SINENSIS (ORANGE PEEL OIL)

Family: Rutaceae

Biological source: oil extracted from dried peels of *Citrus sinensis*

Biological name: *Citrus sinensis*

Chemical constituents: Orange peel contains several chemical constituents, including D-Limonene, monoterpene alkenes, oxygenated monoterpenes, alcohol aldehydes and esters, sesquiterpenes, linear alkanes, and aldehydes. It also contains cellulose, hemicellulose, lignin, pectin, chlorophyll pigments, and other low-molecular weight compounds. It is also rich in polyphenolic compounds, including phenolic acids, flavonoids, and their derivatives.

Therapeutic uses: Essential oil components have insecticidal activities against various insect species and have been found to be advantageous against numerous diseases. Orange peel oil can be used for cleaning supplies, beauty treatments, and aromatherapy. It can be used to strengthen and thicken the outer layer of the skin, smooth out fine lines and wrinkles, and minimize dryness and flakiness of the skin. It also helps boost protein regeneration, as well as collagen and elastin synthesis



Fig 4 Orange Peel Oil

VARIOUS CHEMICALS USED

Table 1 Role of Ingredients

SR.NO	INGREDIENTS	ROLES
01	White beeswax	Emulsifier, thickening agent
02	Liquid paraffin	Lubricating agent, alkaline agent
03	Borax	Stability
04	Orange peel oil	Anti tanning agent, skin whitening
05	Aloe vera gel	Moisturizer
06	Cinnamon oil	Preservative and Fragrance
07	Distilled water	Hydrate and refresh the skin

METHOD OF PREPARATION

The cold cream was prepared by using cream base that is white beeswax, liquid paraffin, borax, orange peel oil, aloe vera gel, cinnamon oil, distilled water. The cold cream is prepared by using extemporaneous method for geometric and homogenous mixing of all the excipients, orange peel oil and aloe extracts¹¹. By extemporaneous method, we have developed five batches of cold cream. All the five batches were evaluated for safety, quality and efficacy.

FORMULATION OF COLD CREAM: INCORPORATED WITH CITRUS SINENSIS MILLER AND ALOE BARBADENSIS

Melt beeswax in a China dish followed by liquid paraffin in a hot plate at 75°C. To this, add orange peel oil and stir it well. Also in a 100 ml beaker, borax was dissolved in water and was heated on other hot plate at 75°C. Both the unctuous and waterless phases are heated at the same temperature i.e. 75°C. Now borax result is added gradationally to the melted beeswax-oil mixture, drop by drop with constant stirring with the help of heat. Continue this process for 5 minutes. Then remove from heat. Then add a measured amount of aloe vera gel and stir vigorously until it forms a smooth cream¹². Then add a few drops of rose water for fragrance and stir it until it becomes cold and a semi solid mass was gain.

EVALUATION STUDIES

1) Physical Properties

The Cream was observed for color, odor and appearance.

2) Spread ability

The Spread ability was expressed in terms of time in seconds taken by two slides to slip off from the cream, placed in between the slides, under certain load. Lesser the time taken for separation of the two slides, better the Spread ability. Two sets of glass slides of standard dimensions were taken. The herbal cream formulation was placed over one of the slides. The other slide was placed on the top of the formulation, such that the cream was sandwiched between the two slides weight was placed upon the upper slides so that the cream between the two slides was pressed uniformly to form a thin layer. The weight was removed and the excess of formulation adhering to the slides was scrapped off. The upper slide allowed slipping off freely by the force of weight tied to it. The time taken for the upper slide was noted.

$$\text{Spreadability} = m \times l / t$$

Where,

m = weight tied to the upper slide l =length of glass slide

t =time taken in seconds

3) Homogeneity

Container by applying of normal force at 27±20 °C. In addition, bulk of contents shall extrude from the crimp of container and then rolled it gradually.

4) Irritancy Test

Mark an area (1sq.cm) on the lefthand dorsal surface. The cream was applied to the specified area and time was noted. Irritancy, erythema, oedema, was checked if any for regular intervals up to 24 hours and reported.

5) Washability

A small amount of cream applied on hand & washed under running tap water.

6) Viscosity

Viscosity of formulated cream was determined by book field viscometer at 100 rpm using Spindle number S-64 at 20 rpm was used at a temperature of 25°C and was determined by taking an average of three readings.

7) pH of the cream

The pH of various formulations was determined by using digital pH meter. About 1 g of the cream was weighed and dissolved in 100 ml of distilled water and stored for two hours. The measurement of pH of each formulation was done in triplicate and average values were calculated.

8) Stability

The cream shall be stable, but not to be deteriorating, ferment and segregate during normal storage conditions and usage. Stability of cream can be tested when it exposes to 45±20°C for a period of 28 days. After storage, no phase separation, fermentation and gassing can be observed. Also exposed to cool conditions such as 50°C for 1 hour, no obstruction of extrudable form from the container is observed agar disc diffusion method.

9) Dye test

The scarlet red dye is mixed with the cream. Place a drop of the cream on a microscopic slide then covers it with a cover slip, and examines it under a microscopic. 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.

10) Test for microbial growth

Agar media was prepared then the formulated cream was inoculated on the plate's agar media by steak plate method and a controlled is prepared by omitting the cream. The plates were placed in the incubator and are incubated in 37°C for 24 hours. After the incubation period, the plates were taken out and the microbial growth were checked and compared with

the control.

11) Determination of type of smear

This test was conducted by the application of cream on the skin surface of a human volunteer for its greasiness. After application, the type of smear was observed.

12) Dilution test

In this test type of emulsion is determined by diluting the emulsion either with water or oil. The emulsion is completely miscible with water if it is o/w type, as the dispersion medium is water and separates out if it is w/o type of emulsion. Similarly, w/o type of emulsion is miscible, if the emulsion is dissolved in oil but o/w type of emulsion is immiscible in oily liquid.

13) Saponification value

Take 2 gm of the substance and reflux it with the 25 ml of 0.5 N alcoholic KOH for 30 minutes. Then add 0.1 ml of phenolphthalein as an indicator and titrate it with the 0.5 N HCL.

$$\text{Saponification value} = (b-a) * 28.05/W$$

Where,

a = volume of titrate b = volume of titrate

w = weight of substances in gram

14) Acid value

Take 10 gm of the cream is dissolved in accurately weighed in 50 ml mixture of the equal volume of alcohol and solvent ether. Then attached the flask with the condenser and reflux it with the slow heating until the sample gets completely dissolve then add 1 ml of phenolphthalein and titrate it with 0.1 N NaOH until it gets faint pink colour appears after shaking in 20 seconds.

$$\text{Acid value} = n * 5.61/w$$

Where,

w = weight of the substances

n = number of ml in NaOH required.

CONCLUSION:

Creams are semisolid formulations widely acceptable by the society. The purpose of cold cream is to moisturize dry skin and cool the body while also removing waste from pores and pores. By using orange peel oil, aloe vera gel cream showed anti-tanning with moisturizing effect. The main principle of cold cream involves slow evaporation of water phase which leads to cooling sensation. Cosmeceutical has been extensively improved in personal care system and there is a great demand for cosmetics nowadays. Topical application of creams

provides great photoprotective effect and could be useful in human skin care. Creams can be modified with drugs and can be used as optimal delivery system for different skin diseases. The new approaches include incorporating bioactive ingredients with clinically proven therapeutic benefits into dermo cosmetics emollient.

The skin receives additional conservation from water phase with the use of cold creams. The skin is the most accessible part of the body and as such is also highly vulnerable to injuries. Research and development for the formulation of pharmaceutical cold creams for moisturizing and make up removal purpose has grown in recent decades owing to its obvious benefits. With the progress in the pharmaceutical field and industry, it is assured that pharmaceutical cold creams will still \ be an interesting and appealing area of research for years to come. More advanced technologies and methods will be used for preparation, formulation and evaluation of cold creams in coming years.

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