

Pharmaceutical Preparation and Evaluation of Cold Cream

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Abstract:- Since the beginning of time, creams have been valued as essential topical preparations in cosmetic products because of how simple it is to apply and remove them from the skin. Pharmaceutical creams are used for a number of aesthetic purposes, including cleansing, beautifying, modifying look, moisturising, etc. They also protect the skin from bacterial and fungal infections and can be used to treat skin injuries including burns, cuts, and wounds. The general population and society can safely employ these semi-solid preparations. The products used to enhance and beautify human appearances are known as herbal cosmetics. The current study's objective was to design and assess herbal cold creams that contained plant extracts made utilising the water in oil method for the goal of moisturising and nourishing the skin. Neem oil and turmeric extract are used to make the cold cream. Utilising several evaluation techniques, the created product's quality was evaluated. The physical characteristics of the cream formulation did not alter. During the research study period, the cream formulation demonstrated good consistency and spreadability, homogeneity, pH, non-greasy properties, and no signs of phase separation. There was no discernible change in the created cream's viscosity, aroma, or visual appearance during the research period, according to stability measures. As the water in the emulsion slowly evaporates, the cooling and calming effects of the herbal extract with cold cream are produced. Cold creams are more moisturising because they create an oily barrier to stop the loss of water from the stratum corneum, the outermost layer of the skin. They are water-in-oil emulsion and intended for application on skin or accessible mucous membrane to provide localized and sometimes systemic effect at the site of application.

Keywords:- Beeswax, Parrafin.

I. INTRODUCTION

Cosmetics are the products which are generally used to beautify the skin and also to purify the skin. 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 cosmetic. From ancient time till now people are still using polyherbal or herbal cosmetics for the

beautification of skin. Cold cream is the water in oil emulsion. Cold cream gives the prolonged contact time in the site of application as compared to the other semisolid dosage form or formulation.

They give elegance to the skin and it is not that much greasy. Due to the oil phase, it gives an emollience to the skin. The function of the cold cream is for restoring moisture to dry skin, it allows to eliminate the waste materials from the pores and also cools the body. It is easily watered washable and easy to wash away. They are non-irritating when applied on the skin. The water phase provides the skin with additional protection. At body temperature, it becomes liquefiable. It enters the skin through the pores of the skin's epidermis. Galen, a Greek physician who created the cold cream formulation in the second century, is credited with developing it. He made a mixture of water, beeswax, and rose petals. These were the main moisturiser components he used to create the cold cream. Galen's cream was the common name for this skin lotion. Cold creams can be used to remove temporary tattoo marks and then removed with a cotton ball in addition to moisturising the skin. Uses of cold creams are also related to the creation of children's face paint.[1]

II. TOPICAL DRUG DELIVERY

The administration of medications to the human body through a variety of routes, including oral, sublingual, rectal, parental, topical, inhalation, etc., has been used to treat illnesses during the past few decades. Topical delivery is the application of a drug-containing formulation to the skin to treat a cutaneous disorder or the cutaneous manifestations of a general disease (such as psoriasis) directly with the goal of containing the pharmacological or the effect of the drug to the surface of the skin or within the skin. Semisolid formulations in all their variety dominate the system for topical delivery, but foams, spray, medicated lotions, and other forms of topical administration are also used.[1, 2]

III. ADVANTAGE OF TOPICAL DRUG DELIVERY

- Preventing of first pass metabolism.
- Convenient and simple to use.
- Prevention of risk.
- The drawbacks of intravenous therapy and the various conditions of absorption, such as PH changes, the presence of enzymes, the rate at which the stomach empties, etc
- Continuous drug input can achieve efficacy with a lower total daily dose of medication
- Prevent intra- and inter-patient fluctuations in medication levels
- The medicine or its excipients may cause skin irritation or dermatitis
- Because they are poorly fat soluble and have a large molecular weight, most medications are not absorbed through the skin or mucous membranes.
- Very low absorption.
- It can only be used for medications whose plasma concentrations must be extremely low to work.
- May only be used for medications whose action depends on very low plasma concentrations.
- The potential for allergic responses.
- Larger-particle drugs are more difficult to absorb via the skin.[3]

IV. PHYSIOLOGY OF HUMAN SKIN

➤ Epidermis:

The thickness of the stratified, keratinized squamous epithelium that makes up the epidermis, the skin's outermost layer, varies depending on where on the body it is located. The palms of the hands and the bottoms of the feet have the thickest layer. There is no blood present. The dermis' interstitial fluid, which supplies oxygen and nutrients and drains away as lymph, bathes the deeper layers of the epidermis but does not reach the veins or nerve terminals of the epidermis.

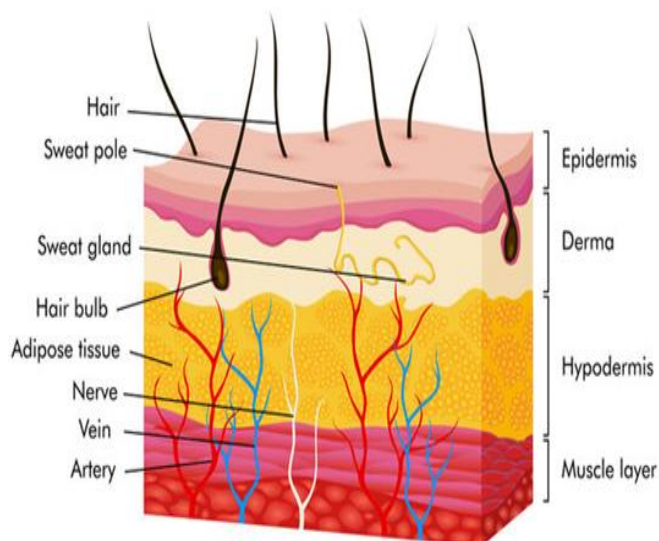


Fig 1 Structure of Skin

➤ Dermis:

The dermis is elastic and resilient. It is made of connective tissue, and the matrix contains elastic and collagen fibres woven together. Stretch marks, also known as permanent striae, are a result of the skin's elastic fibres rupturing when it is overstretched during pregnancy and obesity. Water is held together by collagen fibres, which also give the skin its tensile strength. As collagen fibres age, wrinkles start to appear. The primary cells in the dermis are mast cells, macrophages, and fibroblasts. Areolar tissue and various levels of adipose (fat) tissue are found under the skin's lowest layer.

➤ Subcutaneous Gland:

Another crucial location for the processing and regulation of androgen is the sebaceous gland. The skin contains all the required enzymes for converting cholesterol to steroid precursors or adrenal hormones, such as dehydroepiandrosterone. Using an enzyme that is present as early as 16 weeks of foetal life, hydroxysteroid dehydrogenase, the sebaceous gland can also inactivate androgens. In the sebaceous glands, particularly those on the face and scalp, the type-1 isoform of 5-alpha-reductase, which is responsible for converting testosterone into its most potent form, is also abundantly generated. Hormones play a significant role in controlling the sebaceous gland. By attaching to nuclear androgen receptors (AR), androgens control the activity of the sebaceous gland. Numerous skin components include ARs, with the sebaceous gland—where androgens are found—having a special affinity.[4]

V. FUNCTIONS OF SKIN

➤ Skin Performs the following Functions:

- Langerhans cells: which are a component of the adaptive immune system, are an anatomical barrier that protects the body from pathogens and damage between the internal and exterior environments.
- Sensation: Consists of a range of nerve endings that respond to touch, pressure, vibration, and tissue injury. For more information, see the somatosensory system and haptics
- Heat regulation: The skin's blood supply is far more than what it needs, allowing for fine control of energy loss by radiation, convection, and conduction. Constricted blood vessels significantly restrict cutaneous blood flow and maintain body heat whereas dilated blood vessels promote perfusion and heat loss.
- Controlling evaporation: The skin acts as a semi-permeable, relatively dry barrier against fluid loss. The significant fluid loss in burns is a result of the loss of this function.
- Others can judge our emotions, physical condition, and beauty based on the appearance of our skin.
- Storage and synthesis: By the action of UV rays on specific areas of the skin, it serves as a storage site for lipids and water as well as a method for vitamin D production.

- Water resistance: The skin serves as a water-resistant barrier to prevent the body's vital nutrients from being rinsed away. [5]

➤ Diseases of Skin

- Vitiligo.
- Scabies.
- Rosacea.
- Psoriasis.
- Melanoma.
- Eczema.

➤ Cold Creams:

- Cold cream is an emulsion of water and certain fats that is used to smooth skin and remove makeup. It typically contains beeswax and other fragrances.
- The European Pharmacopoeia refers to it as Fatty Cream.
- Water and oil are combined in every type of cold cream. The water in the cream evaporates as you apply it to your skin, giving you a cooling sensation. Most likely, the name came from this chilling effect.
- Moisturiser or moisturising cream are other names for cold cream. Cold cream needs to behave emolliently. When used, it should feel cool to the touch and leave no occlusive oil film on the skin.
- Although it is an emulsion with a high proportion of fatty and oily content, it has a cooling effect when applied to the skin because the water in the emulsion slowly evaporates. An illustration of a water-in-oil (W/O) emulsion is cold cream
- In cold cream, the major portion is the oil phase. Simply, the cold cream is an oil-based semisolid preparation. Cold cream is also known as Unguentum or Ceratum Refrigerans. Generally, it contains mineral oil, beeswax, borax, and water .
- It is a cosmetic that calms and cleanses the skin; it often has an oily and heavy consistency. It fits the description of a cleansing cream. [6]

VI. HISTORY OF COLD CREAM PREPARATION

Prior to the first century, numerous druggists would prepare rosewater cream and keep it chilled on ice so that it would be suitable for use as a skin cream. Since the water in cold cream evaporates when applied, it produces a cooling sensation, thus the Latin word "refrigeran" (meaning "making cold").

Galen, a renowned Greek physician and chemist who worked in Rome during the First Century AD's Roman Empire, is credited with creating the first cold cream. Over many centuries, the proportions and preparation procedure of the Galen cold cream formula have seldom changed.

It is ideal for treating dry skin on the knees, feet, and elbows as well as for using as a natural makeup remover and preventing eczema in dry areas of the body. The cream gets

its name from the fact that it feels cold to the touch. People use it to soften their skin, calm sunburns, and protect their faces from cold weather, among other things. The combination of fats and water in this product helps moisturise. Unlike the "oil in water" type emulsion of vanishing cream, which is so-called because it appears to vanish when applied to skin, the emulsion is of the "water in oil" kind. An example of a cold cream is a lubricating cream, often known as a night cream or massage cream, which contains lanolin and its derivatives.

The term "cold cream" refers to the numbing sensation the cream left behind on the skin. Water in oil (w/o) emulsions were typically used to create cold creams. Much of the water in the creams evaporates after they are applied to the skin, leaving the residual oil to function as a solvent, clearing the skin of makeup and other impurities. Additionally, surfactant activity might exist. According to some chemists, the cooling effect of the water evaporation on the skin is the reason why these creams are referred to as "cold creams." An other argument is that the creams required to be stored in a cool environment to prevent them from growing rancid in the days before mineral oil or Petrolatum were utilised. They acquired their moniker because of how frigid they felt to the touch. Galen, a Roman physician who lived around 150 CE, is credited with creating the first cold cream by blending water with molten beeswax and olive oil. It took a lot of mixing to make it, and when it stood, it tended to split. The recipe, which typically uses rosewater and/or oil of roses as a perfume, continued nonetheless, and was included in the first edition of the "pharmacopoeia Londinensis" in 1618.

Early versions were not durable because vegetable oils, including almond oil, are susceptible to deterioration when combined with water. Cold creams were typically prepared at home or bought in small quantities freshly prepared by a neighbourhood pharmacy, chemist or druggist because of their limited shelf life.

Cold creams with a high concentration of mineral oil (liquid paraffin) or petroleum jelly were generally used as cleansers, applied thickly, and then removed with a cloth or tissues. They were frequently marketed as beauty creams or night creams, although depending on the formulation, they might be used for a range of things.[7, 4]

VII. GENERAL INGREDIENTS USED IN COLD CREAM

Table 1 Ingredients Used In Cold Cream

Ingredients	Quantity taken(20gm)	Use of ingredients
Bees wax	3.2gm	Emulsifying agent
Borax	0.16gm	Emollient
Methyl paraben	0.02gm	Preservative
Liquid paraffin	10ml	Laxative
Water	6ml	Diluent
Perfume	0.62ml	Fragrance

➤ *Apparatus Used:*

- Measuring cylinder
- Spatula
- Pipette
- Water bath
- China disc
- Glass rod
- Thermometer

➤ *Raw Materials Used:*

Mineral and vegetable oils, together with fatty alcohols, fatty acids, and fatty esters, emulsifying agents, preservatives, and filtered water, can all be used to create cold creams. There should be the following four main components:

- Oil
- Water
- Emulsifier
- Thickening Agent

➤ *Procedure of Making Cold Cream:*

- To start, we weighed each ingredient.
- Next, we add the 3.2 grammes of weighed beeswax to the china disc, which serves as the basis in this case.
- The 10ml of liquid paraffin is then added to the china disc.



Fig 2 Bees Wax

- After melting the beeswax and making it miscible with the liquid paraffin, we combined the two materials using a glass rod and heated the mixture in a water bath at 70°C.



Fig 3 Hot Water Bath

- The china disc was taken out of the water bath and set aside.
- We should keep in mind that the temperature of the combined solution should be up to 70°C and that it should be in a liquid state before adding the remaining ingredients to it.
- Next, using a glass rod to stir, we combined the borax and water.
- To get borax to dissolve in water, we boil the mixture in a water bath until it does. We dropped the boric acid solution into the first solution after the borax had completely dissolved.
- Dropwise add the boric acid solution while stirring the mixture continually with a glass rod.
- The following stage was adding the previously weighed 0.02 gm of methyl paraffin and mixing the solution with a glass rod until all of the paraffin's particles were fully dissolved.
- As a final touch, we added a drop or two of rose oil, which we utilised to smell the recipe.
- After that, we continually stirred the entire mixture using a glass rod until it took on a semi-solid form.



Fig 4 Prepared Cold Cream

- Lastly we got our Final Product (cold cream).

VIII. USES OF COLD CREAM

The contents of a cream determine the uses of cold cream, i.e., functional ingredients determine the uses of cold cream. These are the primary applications for cold cream: In order to maintain the skin's moisture balance and prevent dry skin diseases, medicated cold cream is primarily utilised as a topical pharmaceutical dosage form for the treatment of skin. It is one of the basic applications for non-medicated cold cream.

- As a makeup removal and cleansing preparation.
- In order to provide an emollient effect
- To give the skin an oiled barrier of protection.
- As with sunscreen components, additionally offer a chemical barrier.
- As a vehicle for pharmaceutical ingredients such diflucortolone valerate in ointments.
- To eliminate skin contaminants that are soluble in oil

IX. FUNCTIONS AND USES OF THE INGREDIENTS USED IN THE PREPARATION

➤ *Bees Wax:*

- It functions as an antioxidant. Beeswax is frequently included in the development of skin moisturisers and body creams since it supports moisturising and softening as well as encourages cell repair, making it a fantastic ingredient to employ when creating products specifically for dry and rough skin types
- Beeswax serves as an emollient (skin softening) and humectant (attracts water and aids in absorbing it in the skin) in this form of body care.
- which works here as a stiffening agent, which increases the viscosity cold cream beside this, beeswax also shows healing property and this is a good source of vit. A. It is a common ingredient of most of the cosmetic products
- Like – skin moisturizer, body creams, lip gloss, lip balm, eye shadow, lipstick.
- Beeswax also as medicinal benefits to its use in body products as well.
- Beeswax as anti-inflammatory, antiviral, and antibacterial properties. These 3 properties make beeswax very helpful for the healing of shaller wounds and injuries and can also be used for slight skin irritations too.
- Beeswax also has therapeutic properties and is a strong source of vitamin A, and it acts here as a stiffening agent, increasing the viscosity of the cold cream.
- The majority of cosmetic goods often contain it as an ingredient.
- For example, lip gloss, lip balm, eye shadow, lipstick, body creams, and moisturisers for the skin.
- The usage of beeswax in cosmetic and personal care products has health benefits.

➤ *Liquid Paraffin:*

- Liquid paraffin, a mineral oil that is essential for skin care since it keeps the skin moisturised.
- It serves as a barrier to the skin, preventing moisture loss.
- Liquid paraffin is also used in the cosmetics business.
- The ingredient can be found in a variety of beauty products, such as detergent creams, cold creams, moistened creams, oils, and cosmetics. As an emollient lotion, it can be used to treat dry skin
- To aid in the skin's ability to retain moisture, liquid paraffin is frequently used in cream formulations for skin care.
- The skin has a built-in barrier that protects against moisture loss and keeps the skin healthy.
- Skin disease symptoms may be lessened with liquid paraffin.

➤ *Borax:*

- The main component of borax is boric acid salt. This serves as an emulsifying agent by reacting with the beeswax's free acids.
- A chemical called an emulsifying agent makes water and other substances miscible.
- Borax keeps the preparation's pH stable and inhibits bacterial development.
- It is known as sodium tetra borate in scientific jargon, and it is a mixture that is combined from the depths of the earth and also found as deposits in lake bottoms and mountain runoffs.
- Wax and borax are both common ingredients in creams, gels, and lotions for cosmetic usage.
- Borax's alkaline nature makes it the ideal ingredient in cleaner products, where it is famously used to help wash off the oil or grease from the hands.
- However, some of these properties might irritate the skin and lead to rashes
- Boric acid and sodium borate both inhibit or stop bacterial development, preventing spoiling of cosmetics and personal care items.

➤ *Methyl Paraben:*

- In this circumstance, the methyl paraben functions as a preservative to stop the growth of dangerous microorganisms.
- Methyl paraben is a form of paraben. Parabens are chemicals that are frequently employed as preservatives to extend the shelf life of items.
- In order to stop the growth of mould and other dangerous bacteria, they are added to food or cosmetics.
- Many products that contain methyl paraben also contain one or two other types of parabens in their ingredients.
- Foods, medications, and a wide range of cosmetic products all contain parabens.
- Parabens may be present in a variety of cosmetics, including makeup, moisturiser, hair care, and shaving products.[8]

X. COLD CREAM FOR COLD WEATHER

For good reason—its hydrating benefits—cold cream has had a modern renaissance. Dry skin is a result of the cold weather, and cold creams are fantastic for dry skin.

Water and oil are emulsified to create cold cream. The difference between water and oil is significant to the formulation of the cold cream recipe since it causes the skin to feel cold when applied, hence the name. This is due to the fact that cold cream absorbs more slowly into the skin than oil in water products do. The four main components of cold cream are typically water, oil, an emulsifier, and a thickening agent.

The cream can reach the outer layer of skin without being absorbed as deeply into your skin as water-based treatments because water and oil are mixed in roughly equal

amounts. As a result, when used as a nocturnal skin treatment, it feels more like an overnight mask than a moisturiser.[9]

➤ *Ideal Characteristics of Cold Cream*

- Normally, it shouldn't be diluted.
- The cold cream's pH should ideally range from 4.6 to 6.0.
- It should have the ideal consistency to allow for easy application and removal from the container.
- Following external application, the skin should experience a cooling effect.
- To prevent water from evaporating from the skin's surface, it must create a thin, waxy protective coating on the skin.
- Should have a quicker emollient action so that extremely dry skin can quickly expand and soften.
- Ointments tend to be more oily.
- Creams often have a white to off-white colour, although they can also have other colours, such yellow (Nystatin Cream USP).
- Easily applied to skin.
- Free of dusty components.

XI. EVALUATION OF COLD CREAM

➤ *The following several test may perform to evaluate the quality of cold cream.*

- *Morphological Evaluation:* This refers to the manual evaluation of an ice cream's physical characteristics based on its colour, flavour, and texture.
- *pH:* In order to calibrate the pH metre, standard buffer solution was used. With the aid of a digital pH metre, weigh 0.5 g of cream and dissolve it in 50.0 ml of purified water.
- *Test for Spreadability:* The cream sample was placed in between the two glass slides and compacted to a uniform thickness by applying weight for five minutes before adding more weight to the weighing pan. The spreadability was measured by the amount of time the upper glass slide travelled across the lower slide.
- *Stability Test:* A month-long stability test was conducted on the developed formulation by storing it at various temperatures. While being maintained at various temperatures, including room temperature and 40°C, the packed glass vials of formulation were examined for physical traits such as colour, aroma, pH, consistency, and feel.
- *To Test for Irritability,* mark a 1-square-centimeter region on the left dorsal surface. The cream was applied to the designated region, and the duration was recorded. The presence of irritation was monitored for up to 24 hours at regular intervals.
- *Homogeneity:* The homogeneity was examined visually and tested. [10]

XII. RESULT

• *Morphological Evaluation:*

A morphological evaluation of cold cream is shown in the Table. Formulation was a white. The produced formulations' pleasant and well-acceptable flavour makes them ideal for cosmetic formulations. Smoothness and texture was suitable for cosmetic formulation requirements.

Table 2 Data of Morphological Evaluation

Morphological parameter	Results
Color	White
Odour	Pleasant
Texture	Fine

- *pH :* The pH is found to be neutral and shown in table as

Table 3 pH Test

pH	7.3

• *Stability:*

The stability results were displayed in Table. No change in colour, smell, texture, or smoothness was noticed under the stability parameters stated. The stability research indicated that at normal temperature.

Table 4 Stability Testing

Stability parameter	Result
Color	No change
Odour	No change
Texture	No change
pH	No change

• *Irritancy Test:*

The table below displays the results of the irritancy test. During irritancy trials, the formulation displayed absence of irritation, redness, and edema. This formulation is skin safe for usage.

Table 5 Result of Irritancy Test

Irritancy test	Result
Irritation	No
Edema	No
Redness	No
Swelling	No

- *Spreadability:* The Spreadability of cold cream was shown in table and found to be

Table 6 Result of Spreadability Test

Formula	Average spreadability
FI	6.5

- *Homogeneity:* The homogeneity of cold cream was quite good enough.

XIII. CONCLUSION

The created cream demonstrated good consistency and spreadability, homogeneity, pH, non-greasiness, and there was no phase separation during the research period, according to the aforementioned data. The purpose of cold cream is to moisturise dry skin and cool the body while also removing waste from pores and pores. It is simple to wet, wash, and put away. When used on the skin, they do not irritate. The skin receives additional conservation from the water phase.

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