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FORMULATION AND EVALUATION OF ANTIMICROBIAL CREAM OF AZADIRACHTA INDICA

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INTRODUCTION

In the pharmaceutical market, various dosage forms are designed and introduced to cater to patient needs, improve compliance, and offer faster relief. While each dosage form possesses unique advantages, they also come with certain limitations.

Historically, drugs have been administered to the human body through numerous routes, including oral, sublingual, rectal, parenteral, topical, inhalation, and others. Among these, topical delivery, particularly through creams, is considered superior for skin-related conditions.

Topical delivery involves applying a drug-containing formulation directly to the skin to treat cutaneous disorders or systemic diseases that manifest on the skin (e.g., psoriasis). The goal is to localize the drug's effect to the skin's surface or deeper layers. Although creams are the predominant topical delivery system, other formulations such as medicated sprays, powders, solutions, and adhesive systems are also commonly used.

Cosmetics and Cold Cream

Cosmetics are the products that which are formulated to enhance or change the appearance of the human body. The term "cosmetic" is obtain from the Greek word "kosmetikos," which means "adornment."

Cold cream is a specific type of cosmetic, a water-in-oil (w/o) type of emulsion. It offers several advantages over other semi-solid formulations.

Increased contact time: Cold cream stays on the skin longer, allowing for better

absorption of active ingredients.
Moisturizing: The oil phase provides moisture to the skin.

Cleansing: It helps to remove the impurities and dirt off the skin. Soothing: Cold cream can soothe irritated skin.

Non-irritating: It is gentle on the skin. Herbal Cosmetics.

Herbal cosmetics are beauty products that utilize plant-based ingredients. They have gained significant popularity due to their potential benefits and reduced risk of side effects compared to synthetic products.

Key advantages of herbal cosmetics include.

Natural ingredients: They are derived from plants, often considered safer and more environmentally friendly.

Multiple benefits: Herbal ingredients can offer various properties, such as antioxidant, anti-inflammatory, and antimicrobial effects.

Reduced side effects: They are less likely to cause skin irritation or allergic reactions.

As consumers become more aware of the potential risks related with synthetic chemical products, there is growing demand of herbal cosmetics. These products are formulated to label a variety of skin concerns, including acne, dryness and aging.

Note: While herbal cosmetics can be beneficial, it's important to choose reputable brands and consult with a dermatologist if you have specific skin concerns. Skin, Our Body's Shield

Our skin, the body's largest organ, is constantly exposed to environmental stressors and internal imbalances. These factors can disrupt its delicate balance, leading to a range of skin issues like dryness, acne, irritation, and premature aging.

The Power of Herbal Creams
Herbal creams offer a natural and effective solution to these skin concerns. By utilizeing the power of plants, these creams can.

Hydrate and Nourish: Replenish lost moisture, leaving skin soft and flexible.

Soothe and Calm: Reduce inflammation and irritation, alleviating conditions like eczema and psoriasis. Clear and Purify: Combat acne and blemishes, promoting a clear complexion.

Protect and Shield: Form a protective barrier against environmental damage.

Revitalize and Rejuvenate: Reduce the appearance of wrinkles and fine lines, promoting a youthful glow. A Natural Alternative.

Unlike many conventional creams that rely on synthetic chemicals, herbal creams offer a safer and more sustainable option. By avoiding harsh additives, these creams minimize the risk of skin irritation and allergic reactions.

The Science Behind Herbal Creams

Creams are semi-solid formulations that can be applied topically to the skin. They are designed to deliver active ingredients into the skin, where they can work and show their pharmacological action. By understanding the science behind creams, we can appreciate the benefits of herbal formulations.

Let's work together to develop a versatile herbal cream that addresses a wide range of skin concerns and promotes overall skin health.

The term has been restricted to products consisting of oil-in-water (o/w) type of emulsions or aqueous microcrystalline dispersions of long-chain fatty acids or alcohols that are water cleansable and more cosmetically and aesthetically acceptable. Creams are used for the multiple causes like to enhancing beauty, to get therapeutic effect, to relieve sun burn, and moisturized skin, as a makeup base, etc. Medicated creams are used for treating various skin related conditions such as psoriasis, dermatitis, burns, vaginal infections (e.g. Triple Sulfa Vaginal Cream), dry skin, etc. Galen, a Greek doctor, he discovered the cold cream in second century, he composed the formulation of cold cream which was popularly known as ‘Galen's cream’. He prepared the formulation by using an emulsion of water & beeswax along with rose petals as the essential moisturizer agent of the cold cream. Cold creams are not only hydrate the skin but also used for removing makeup and temporary tattoo marks. The cream is rubbed on tattoo marks and then erased with help of a cotton ball. Cold cream used are also related with preparation of facial paints for young one.

Advantages

1) Creams are slighter glossy and easy to applied on skin.
2) Cream make cool effect proper to vanishing of water and causes soothing effect on inflamed cream.
3) Creams are less interfere with skin function and have more exposure with skin than ointment.
4) Creams are physically more stable.
5) They more stable as compare to liquid dosage form.

Disadvantage

1) They are large than solid dosage form.
2) When an application of an exact quantity of ointment to the affected area is required, it is difficult to discover the same.
3) The allergic reactions, in addition to increased bacterial resistance.

APPLICATION OF CREAM

In order to formulate an effective and efficient cream preparation, deliberation must be given to the intended purpose. This is directly concerned with the site of action and the desired effect of preparation.Cream preparations may be used for.

1) Surface Effects: - Cleansing (removal of dirt and germs), Cosmetics (enhance appearance), Protective (prevention of moisture loss, sunscreen), Antimicrobial (reduction of infection).

2) Stratum Corneum Effects: - Protective (e.g. sunscreens that penetrate this layer), 1 (a sloughing of the skin, useful in the treatment of psoriasis), protective (moisturizing)

3) Viable Epidermal and Dermal Effects: Several classes of drugs may pierce to these layers (anti- inflammatory, anesthetic, and antipruritic, antihistamine). Although it is difficult for drugs to penetrate the stratum corneum, once they get in the dermis, they can diffuse into the general circulation. It is very difficult to formulate a drug with only a local effect without subsequent uptake by the blood.

4) Appendage Effects: - Some classes of drugs are intended to exert their action in these portions of the skin (depilatory, antimicrobial, and antiperspirant).[8]

The plant product or natural products show an important role in diseases prevention and treatment through the enhancement of antioxidant activity, inhibition of bacterial growth, and modulation of genetic pathways. The therapeutics role of number of plants in diseases

management is still being enthusiastically researched due to their less side effect and affordable properties. It has been accepted that drugs based on allopathy are expensive and also exhibit toxic effect on normal tissues and on various biological activities. It is a largely accepted fact that numerous pharmacologically active drugs are derived from natural resources including medicinal plants. Various religious documents such as Bible and Quran also supported the herbs role in health care and prevention. Islamic perspective also confirms the herbs role in diseases management and Prophet Mohammed (PBUH)recommended various plants/fruits in the diseases cure .Neem ingredients are applied in Ayurveda, Unani, Homeopathy, and modern medicine for the treatment of many infectious, metabolic, or cancer diseases. Different types of preparation based on plants or their constituents are very popular in many countries in diseases management. In this vista, Neem (Azadirachta Indica), a member of the Meliaceae family, commonly found in India, Pakistan, Bangladesh, and Nepal, has therapeutics implication in diseases cure and formulation based on the fact that Neem is also used to treat various diseases. Azadirachta Indica has complex of various constituents including nimbin, nimbidin, nimbolide, and limonoids and such types of ingredients play role in diseases management through modulation of various genetic pathways and other activities. Quercetin and ß-sitosterol were first polyphenolic flavonoids purified from fresh leaves of Neem and were known to have antifungal and antibacterial activities.[9]

Azadirachta Indica A. Juss, traditionally named Neem (Meliaceae), has been widely known for centuries as a source of active ingredients to develop products for health providers in remote areas. Thus, primary healthcare in developing countries has included treatments with this tree or its parts. For instance, Indian traditional medicine reported cases of success that were not always scientifically tested.

A. Indica is considered a multipurpose medicinal tree. Outstanding for its wide distribution in nature, as well as its low toxicity, Neem can be considered a natural source of cosmetic raw material for large-scale production. This tree is biologically close to Mahogany and all its parts (root, gum, leaves, flowers and fruits) can be used in agriculture, medicine and cosmetology since the seeds and leaves have a higher concentration of secondary metabolites, which are more accessible through different extraction processes. Therefore, its beneficial effects can be attributed to one or more phytochemicals, including flavonoids, for instance. In general, it has a better effect through the synergism of its constituents.[10]

Neem tree (Azadirachta indica) is a local, evergreen, tropical tree to India. Neem is a versatile, multifarious tree with a great capacity to own the most beneficial non-wooden products. Neem has various medicinal properties, including anti-cancer properties. In India, Neem is called the village of pharmacy due to its recovery versatility, and it's been utilized in Ayurvedic medication for extra than 4,000 years because of its medicinal properties. Azadirachtin is the principal compound of the neem oil with insecticidal activity. Neem extracts were also reported to possess inhibitory effects on several cancer cell lines such as breast, gynecological, gastrointestinal, haematological, prostate, and skin cancers. Several active chemical compounds were discovered in neems, such as Nimbin, Saladin, azadirachtin (AZA), glycosides, and dihydrochalcone polyphenolics, coumarin, and tannins. Pharmacological activities have been reported, including anti-bacterial, anti-inflammatory, anti-fungal, anti-arthritic, anti- pyretic, anti-gastric ulcer, hypoglycemic, and anti-tumor activities.[11]

2] Literature Survey

2.1. André Rolim Baby, et.al (2022)[10]

Azadirachta indica (Neem) is a large tree that is native to India and is traditionally used due to its several properties, mainly to treat skin diseases, as well as its “herbicidal” activity. Its bark, leaves, seeds, fruits and flowers are widely used in medicinal treatment due to the presence of active secondary metabolites with biological effects, mainly limonoids and tetranortriterpenoids, such as azadirachtin. Thus, A. indica was studied in a variety of conditions, such as anticancer, antiseptic, anti-inflammatory and chemopreventive agents, as well as a bio pesticide.

2.2. Imrana siddiqua et.al (2022)[18]

To formulate and evaluate herbal cream cold cream using Turmeric to give glowing & cooling effect. Methods: The cream was prepared by using the cream base that is bee’s wax, liquid paraffin, borax, distilled water, rose oil. The cream was prepared by using the slab technique/extemporaneous method for geometric and homogenous mixing of all the excipients and the herbal extracts. Cream was prepared & was evaluated for different parameters like appearance, PH, viscosity, stability test, patch test, test for homogeneity, spread ability, smear test, evaluation of Emolliency & Test for microbial growth.

2.3. Puja Saha, et.al (2021)[11]

Assuming that herbal preparation is better with fewer side effects than synthetics, natural

treatments are more effective than allopathy in terms of side effects for better human body healing. Herbal products have a growing demand in the world market, and the plants have been reported in the literature as having various pharmacological activities such as anti-microbial, anti-oxidant, anti- inflammatory activity, [UdMO4] anti-cancer, anti-diabetic. The purpose of this study was to develop anti-aging poly-herbal cream by mixing the extract of Punica leaf, Neem Oil, Jamun powder, Carrot powder as the main ingredient, and then creams were developed based on the anti-oxidant ability of herbal extracts and performed their evaluation study.

2.4. Tejswini Devidas Navgire, et.al (2021)[2]

In this study creams were formulated based on the anti-oxidant potential of herbal extracts and its evaluation. Selected plant parts are dried and extracted using 70% alcohol by maceration. The extract was tested for antioxidant activity by superoxide scavenging activity. Quality evaluation of the product was assessed by using different evaluation methods. No change of the physical properties was observed; the pH was in aproper range (approximately pH6). The marker Curcumin was present in the extract, formulation and the peak was comparable with standard Curcumin obtained by HPLC. The formulations showed good spreadability, no evidence of phase separation and good consistency during this study period.

2.5. Mayuri Gadhave et.al (2021)[8]

A cream is a topical preparation usually for application to the skin. Creams for application to mucus membranes such as those of the rectum or vagina are also used. Creams may be considered pharmaceutical products as even cosmetic creams are based on techniques developed by pharmacy and unmedicated creams are highly used in a variety of skin situation (dermatoses). The use of the inger tip unit concept may be helpful in guiding how much topical cream is necessary to cover different areas. 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 oil dispersed in a continuous 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 suitable as they are less greasy and more easily washed off using water.

2.6. Nikhil Nitin Navindgikar, et al (2020)[5]

The cream was prepared by using the cream base that is bee's wax, liquid paraffin, borax, methyl paraben, distilled water, rose oil, Aloe Vera gel, dimethyl sulphoxide extracts of Neem

and Tulsi. The cream was prepared by using the slab technique/extemporaneous method for geometric and homogenous mixing of all the excipients and the herbal extracts. By using slab technique, we have developed three batches of our herbal cream, namely F1H, F2H, and F3H. All three batches were evaluated for different parameters like appearance, pH, viscosity, phase separation.

2.7. Varsha Barethiya, et.al (2020)[1]

The aim of the present study is to formulate and evaluate cold cream enriched with vitamin E and almond oil providing moisturizing effect. The cold cream was prepared by incorporating beeswax, borax, sweet almond oil, vitamin E and all other excipients. Fusion method is used for the formulation of the cold cream. Five different formulations are prepared and evaluated for the compliance with the pharmacopoeial parameters. All the prepared formulations are evaluated for the various parameters like pH, color, homogeneity test, viscosity, rheological studies, stability studies, etc.

2.8. Vijaya Sadashiv Rabade, et.al (2020)[3]

The aim of the present research was to formulate and evaluate the herbal cold containing plant extracts prepared by using water in oil method for the purpose of nourishing and moistening the skin. The cold cream is prepared by using the neem oil and extract of turmeric. Quality evaluation of the formulated product was assessed by using different evaluation methods. No change of the physical properties was observed in formulated cream. The formulated cream showed good consistency and spread ability, homogeneity, pH, non-greasy, no evidence of phase separation during study period of research. Stability parameters like visual appearance, nature, viscosity and fragrance of the formulated cream showed that there was no significant variation during the study period of research.

2.9. Manish Kamble, et.al (2020)[17]

In day to day practice the medicinal plants or herbs are widely used by the traditional practitioners for curing various diseases. There is an increase in demand for plant based medicines, cosmetics, health products, food supplements and various pharmaceutical products. The aim of present study is to formulate and evaluate cold cream using Bombax ceiba fruit pulp. Traditionally, Bombax ceiba is a well-known plant used in treatment of many diseases, with its therapeutic activity partly due to the presence of flavonoids, phenolics, sesquiterpenoids, shamimicin, bombamalosides, bombamalones, bombasin, bombasin 4-o-glucoside, and bombalin. The literature stated the plant having various

pharmacological activities such as antioxidant, antimicrobial, anticarcinogenic, anti-inflammatory, immunemodulatory, hypotensive, hypolipidemic, antihyperglycemic, and analgesic.

2.10. Neha Shivastava, et.al (2020)[23]

The aim of the present research work was to formulate and evaluate polyherbal face cream using ethanolic extracts of Aloe Vera gel, Neem, Turmeric and Mint.Extraction was done by the cold maceration technique. The cream was prepared by using the slab technique for homogeneous mixing of all the excipients and the herbal extracts. Three formulations of Oil in Water (O/W) type herbal cream were developed, namely F1, F2, and F3.

2.11. R. Chandrasekar, et.al(2018)[14]

Neem and Tulsi called as holy tree and herb has been used since ancient times for the treatment of various skin diseases. In this study Neem leaves Azadirachta indica and Tulsi leaves Ocimum sanctum was incorporated with various ingredients and a poly herbal cream was prepared. Neem leaves and Tulsi leaves were collected from Tirupati Local Area. Both these plants were shade dried for 4 days and size reduced using mixer grinder converted into coarse powder and passed through sieve number 22. The coarse powder was stored for further studies. Both Neem and Tulsi leaf were defatted using pet ether 60-40 and then extracted using ethanol in a soxhlet aapparatus.

3. AIM AND OBJECTIVE

3.1 AIM

Formulation and Evaluation of Antimicrobial Cream of Azadirachta Indica.

3.2 OBJECTIVE

1. To formulate herbal cold cream.
2. To study anti-microbial property in herbal cold cream.
3. To prepare nontoxic, cost effective and sterile cream.
4. To moisturize the dry skin.

4. PLAN OF WORK

The present proposed research work is planned as follows.

1) Literature Review.
2) Selection of plant material for preparation of herbal cold cream.

3) Collection of material from plant parts.
4) Extraction of plant material.
5) Formulation of anti-microbial cream.
6) Evaluation of herbal cold cream.
7) Reference.

5. DRUG PROFILE

Neem

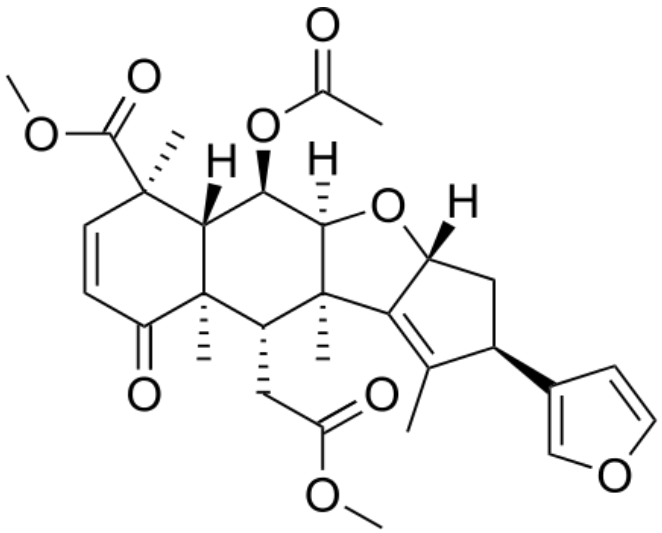
Azadirachta Indica A. Juss, traditionally named Neem (Meliaceae), has been widely known for centuries as a source of active ingredients to develop products for health providers in remote areas. Azadirachta Indica has complex of various constituents including nimbin, nimbidin, nimbolide, and limonoids and such types of ingredients play role in diseases management through modulation of various genetic pathways and other activities. Quercetin and ß-sitosterol were first polyphenolic flavonoids purified from fresh leaves of Neem and were known to have antifungal and antibacterial activities.

Kingdom: Plantae **Order**: Rutales **Suborder**: Rutinae **Family**: Meliaceae **Subfamily**: Melioideae **Tribe -** Melieae **Genus**: Azadirachta **Specie**: Indica **Latin**: Azadirachta indica **Indian**: Holy tree, Indian lilac tree **Hindi**: Neem, Nim **Sanskrit**: Nimba

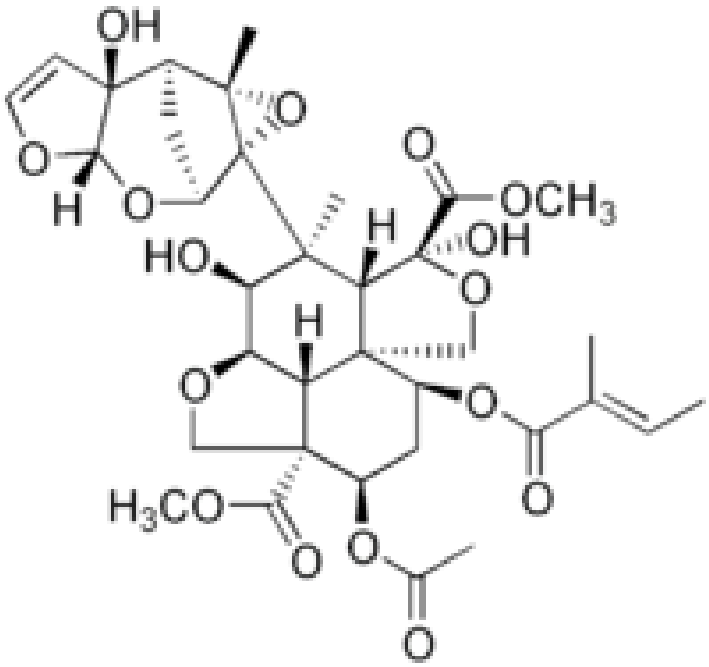
Chemical constituents: Nimbin, Nimbidin, Azadirachtin, salannin.

Uses: Neem contains fatty acids, antioxidants, and antimicrobial compounds, and these can benefit the skin in a range of ways. Research shows that these compounds may help fight skin infections, promote wound healing, and combat signs of skin aging, treat dry skin and wrinkles, stimulate collagen production, reduce scars, treat acne, minimize warts and moles.

Structure of Nimbin



Structure of Azadirachtin



MATERIAL AND METHOD

5.1 Material

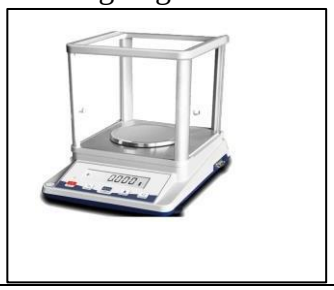
Role of ingredients

Ingrained	Role
Neem	Promote wound healing, relieves skin dryness, itching and redness.
Bees wax	Emulsifying agent, stabilizer and gives thickness to the cream
Liquid paraffin	Lubricating agent
Borax	Alkaline agent which reacts with emulsifying agent to form soap
Methyl paraben	Preservative
Rose oil	Fragrance

Ingredients

Ingredients	Quantity	Supplier
Liquid paraffin	15 ml	Research lab fine chem indudtries, mumbai
Bees wax	3 gm	Research lab fine chem indudtries, mumbai
Borax	0.4 gm	Research lab fine chem indudtries, mumbai
Methyl paraben	0.04 gm	Research lab fine chem indudtries, mumbai
Neem extract	1 ml	Campus surrounding
Distilled water	Q.S	Campus surrounding
Rose oil	Q.S	Khadi herbal

EQUIPMENT

Sr no	Equipment	Supplier
1	Weighing balancea 	Tacson's
2	Heating Mantle 	Acculab lab instruments

5.2 Method

5.2.1. Collection of plant material

Neem (Azadirachta Indica) leaves were collected from the college campus, Shri Sai Institute Of Pharmacy and research. The plants were identified by Assistant professor, Shri Sai Institute Of Pharmacy and Research Aurangabad.

5.2.2. Chemicals and Reagents

Liquid paraffin, Beeswax, Borax, Methyl paraben, Ethanol was obtained from the college laboratory. Rose oil was obtained from Himalaya herbals Pvt Ltd.

5.2.3. Extraction of plant material

Neem leaves were shade dried for 4 days and size reduced using mixer grinder converted into coarse powder and passes through sieve number 22. The coarse powder was stored for

further studies. The shade dried and coarsely powdered (50 g) Azadirachta Indica was placed in Soxhlet extractor, using petroleum ether and then successively extracted with 250 ml of 90% ethanol for 4 hrs. And the Neem extract was obtained.

Preparation of Cold Cream

1. Accurately weigh all the chemicals in the given quantities.
2. Heat liquid paraffin and beeswax in a borosilicate glass beaker at 75 ℃ and maintain that heating temperature (Oil phase).
3. In another beaker, dissolve borax, methyl paraben in distilled water and heat this beaker to 75 ℃
   to dissolve borax and methyl paraben and to get a clear solution (Aqueous phase).
4. Then slowly add this aqueous phase to heated oily phase.
5. Then add a measured amount of Neem extract and stir vigorously until it forms a smooth cream.
6. Then add few drops of rose oil as a fragrance.[12]
7. Pour the cream in a suitable container.

6. EVALUATION METHOD

6.1 Physical properties

The cream was observed for the color, odor and appearance.

6.2 Wash ability

The cream was applied on the hand and observed under the running water.

6.3 pH

The pH meter was calibrated with the help of standard buffer solution. Weigh 0.5 gm of cream dissolved it in 50 ml of distilled water and its pH was measured with the help of digital pH meter.

6.4 Irritancy test

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

6.5 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.

6.6 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 a indicator and titrate it with the 0.5 N HCl.

6.7 Acid value

Take 10 gm of the cream 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 color appears after shaking in 20 seconds.

6.8 Phase separation

Prepared cream was kept in a closed container at a temperature of 25-100 ℃ away from light. Then phase separation was checked for 24 h for 30 d. Any change in the phase separation was observed.

6.9 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 spreadability. Two sets of glass slides of standard dimension were taken. Then one slide of suitable dimension was taken and the cream formulation was placed on that slide. Then other slide was placed on the top of the formulation. Then a weight or certain load was placed on the upper slide so that the cream between the two slides was pressed uniformly to form a thin layer. Then the weight was removed and excess of formulation adhering to the slides was scrapped off. The upper slide was allowed to slip off freely by the force of weight tied to it. The time taken by the upper slide to slip off was noted.

Spread ability= m × l/t Where, m= Standard weight which is tied to or placed over the upper slide (30g) l= length of a glass slide (5 cm) t= time taken in seconds.

6.10 Greasiness

Here the cream was applied on the skin surface in the form of smear and checked if the smear was oily or grease-like.

6.11 Homogeneity

The formulated cold cream was tested for the homogeneity by visual appearance and by touch.

6.12 After feel

Emolliency, slipperiness and amount of residue left after the application of fixed amount of cream was checked.

6.13 Type of smear

After application of cream, the type of film or smear formed on the skin were checked.

7.13 Removal

The ease of removal of the cream applied was examined by washing the applied part with tap water.

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