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REVIEW ON HERBAL COSMETICS - PREPARATION AND EVALUATION

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ABSTRACT

The man used colours for the decoration in ancient times 3000BC to charm the creatures he needed to hunt and even the man escaped the rival's assault by colouring his skin and decorating his body for defence to evoke fear in an opponent (whether man or animal). For the skin and hair appearance of individuals, hygiene, habits, everyday work, climatic conditions and maintenance were responsible. The skin can dehydrate during summer due to prolonged heat exposure and cause wrinkles, freckles, blemishes, pigmentation, and sunburns. In the shape of breaks, burns, maceration, infections and hair drops, the harsh winter does damage to the skin and hair. Skin disorders are widespread in all age groups and could be attributable to exposure to pathogens, toxic chemicals, environmental biological pollutants, and even due to deprivation to certain degree. Cosmetics are designed to decrease wrinkles, combat acne and to regulate the secretion of oil. Formulations such as skin protective, sunscreen, antiacne, ant wrinkle, and antiaging are formulated for different forms of skin disorders using varieties of ingredients, including natural or synthetic. The great thing about herbal makeup is that the herbs and shrubs are exclusively made from them. There are no reactions to the human body from the normal material in the herbs; instead, supplements and other beneficial minerals strengthen the body. The market for herbal cosmetics is now rising day by day. Because of their high-quality properties and less side effects, herbal formulations obtain more public concentration. In addition, it also provides the skin with the nutrients required.

INTRODUCTION:

The idea of makeup and appearance is as old as humanity and culture. Indian herbs and their importance are recognised worldwide. Deep in the *Rigveda*, *Yajurveda*, *Ayurveda*, Unani and Homeopathic method of medicine, the fundamental concept of skin care cosmetics lies. These herbs should have variations of properties such as antioxidant, anti-inflammatory, antiseptic, emollient, anti-seborrheic, antikerolytic action and antibacterial, etc⁽¹⁾ ⁽²⁾. In the history of man as they evolved, the birth of cosmetics forms a continuous tale. Man used colours for decoration in ancient times 3000BC to charm the creatures he needed to hunt, even the man escaped the rival's assault by colouring his skin and decorating his body for defence to evoke fear in an opponent (whether man or animal). Hunting, battle, confidence and credulity were associated with the roots of cosmetics and later associated with medicine⁽³⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁶⁾ ⁽⁷⁾.

For the skin and hair appearance of individuals, hygiene, habits, everyday work, climatic conditions and maintenance were responsible. The skin can dehydrate during summer due to prolonged heat exposure and cause wrinkles, freckles, blemishes, pigmentation, and sunburns. In the shape of breaks, burns, maceration, infections and hair drops, the harsh winter does damage to the skin and hair. Skin disorders are widespread in all age groups and could be attributable to exposure to pathogens, toxic chemicals, environmental biological pollutants, and even due to deprivation to certain degree. ⁽¹⁾ ⁽⁴⁾ ⁽⁷⁾ ⁽⁸⁾

Cosmetics are designed to decrease wrinkles, combat acne and to regulate the secretion of oil. Formulations such as skin protective, sunscreen, antiacne, ant wrinkle, and antiaging are formulated for different forms of skin disorders using varieties of ingredients, including natural or synthetic ⁽¹⁾.

Cosmetics are chemicals meant to be used to cleanse, beautify, enhance beauty and improve the appearance of the human body without altering the composition or functions of the body. Use of synthetic chemicals is damaging to young people and our climate. Various synthetic compounds, hormones, colorants and their derivatives have been shown to cause several side effects of various skin diseases. Thus, we use natural cosmetic as much as we can⁽¹⁾. The great thing about herbal cosmetic is that the herbs and shrubs are main ingredients. There are no reactions to the human body from the active constituents of the herbs; instead, supplements and other beneficial minerals strengthen the body. The market for herbal cosmetics is now rising day by day. Because of their high-quality properties and less side effects, herbal formulations obtain more public concentration. In addition, it also provides the skin with the nutrients required⁽¹⁾ ⁽⁹⁾ ⁽¹⁰⁾ ⁽¹¹⁾.

WHAT IS COSMETICS?







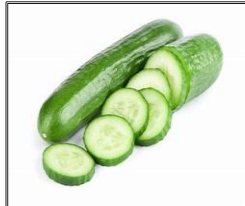
The term cosmetic was derived from the Greek word "*kosmtikos*" meaning that it has the ability to decorate, organise, order, abilities ^(8, 10, 12,11, 13, 14, 2, 7). Under the Drug and Cosmetics Act 1940, cosmetics are described as articles intended to be rubbed, spilled, brushed or sprayed over, introduced into or otherwise applied to the human body or any part of the body to cleanse, beautify, encourage beauty or modify appearance. ^(1,8, 12 5, 6).








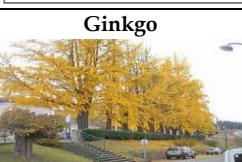
ADVANTAGES OF HERBAL COSMETICS OVER SYNTHETIC

The modern trend in the world of beauty and fashion is herbal cosmetic. Herbal cosmetics are gaining more popularity as most women nowadays choose natural ingredients for their personal care over chemicals to boost their appearance as these products supply the body with nutrients and boost health and provide pleasure as they are free from a potential human carcinogen.

- **Compatible with all skin types:** For all types of skin, natural cosmetics are appropriate. You will find natural cosmetic preparations such as mascara, eye shadow, and lipstick that are suitable regardless of your skin colour, no matter whether you are dark or fair. They can also be used for women with dry or allergic skin and they never have to think about deteriorating their skin condition. Coal tar-derived colours are commonly used in cosmetics, Coal tar is known as a human carcinogen, and a colour (whether made from coal tar or synthetically) can cause cancer is the key issue for individual coal tar. Yet natural colours are safer, and are derived from herbs^(8, 15, 16, 17).
- **Wide selection to choose from:** In the cosmetic industry, natural cosmetic might still be a new form, but they already sell a range of beauty items for all make-up insane women to pick from. A number of foundations, eye shadow, gloss, blush, mascara, concealer, and several more are all naturally formulated, one can find. In addition, one can find natural cosmetics made locally or those made worldwide by prominent designers. A wide range of herbal extracts exist, to name a few: *Andrographispaniculata* (Kalmegh), *Asparagus racemosus* (Shatawari), *Boswelliaserrata* (SalaiGuggal), Asphalt (Shilajit), etc^(8, 15, 18, 17).
- **Fits your budget:** Natural cosmetics aren't that costly. Any of these are actually more economical than synthetic ones. A WHO report indicates that about 80% of the world's population relies on natural goods for their health care, owing to the side effects of industrial medicine and rising prices. Currently, through natural health care initiatives, the World Health Organisation promotes traditional herbal treatments since these medications are widely available at low cost and are relatively safe^(8, 11, 15, 19, 17).
- **Not tested on animals:** Initially, certain cosmetics may be checked on animals to ensure that they are safe for human use. Natural cosmetics should not be checked on primates, though. These natural formulations are tested in laboratories by professionals using state of the art equipment that does not include animals^(1, 8, 15, 20, 17, 21).
- **No side effects:** Synthetic cosmetic products can irritate and cause pimples to irritate your skin. They will block your pores and make your skin oily or dry. The natural ingredients used do not have any side effects; they can be used whenever. Herbal products, for example, are free of parabens, which are the most commonly used preservatives in cosmetics and can enter the skin. And accused of interference with the role of hormones (endocrine disruption)^(8, 15, 20, 22, 17).

DIFFERENT HERBS AND SPICES USED IN SKIN CARE^(8, 11,13)

Drug	BIOLOGICAL SOURCE	USES
Coconut Oil 	Dried solid part of endosperm of <i>Cocos nucifera</i> (Arecaceae)	Excellent skin moisturizer, used in skin itching & rashes, skin infection. Used as an emollient and protect skin from bacteria.
Sunflower Oil 	Seeds of <i>Helianthus annuus</i> (Asteraceae)	Used as an emollient, excellent noncomedogenic property, regenerating damaged skin cells and getting rid of acne causing bacteria.
Olive Oil 	Fruits of <i>Olea europaea</i> (Oleaceae)	Used to moisturize dry skin, as an anti-inflammatory, to treat skin damage, as antioxidant and to treat psoriasis and eczema.
Aloe Vera 	Dried latex of leaves of <i>Aloe barbadensis</i> Miller (Liliaceae)	-Heal, moisturize & soften skin, prevent aging, regenerate growth of cells, prevent skin irritation and used in case of sunburn
Neem 	Leaves of <i>Azadirachta indica</i> (Meliaceae)	Effective in Skin infection, rashes, pimples, to treat dry skin & wrinkles, acne.
Turmeric 	Dried rhizomes of <i>Curcuma longa</i> (Zingiberaceae)	Used as wound healing, anti-inflammatory, anti-oxidant, antipsoriasis, acne, wounds, burns, eczema, premature aging
Cucumber 	Fruits of <i>Cucumis sativa</i> (Cucurbitaceae)	Has cooling, soothing, healing, anti-wrinkle, anti-inflammatory agent. Protect skin from sunburns, soothes irritation and reduce swelling & puffiness

Green Tea 	Leaves of <i>Camellia sinensis</i> (Theaceae)	has anti-oxidant, anti-inflammatory, anti-carcinogenic agent. -Effective in acne & oily skin by reducing sebum secretion, improve skin elasticity, reduce puffiness and swelling
Lemon 	Fruit of <i>Citrus limon</i> (Rutaceae)	Reduce skin itching, acne breakouts, nourishes damaged skin & hydrates the skin, has strong anti-bacterial and anti-oxidant activity. used to exfoliate, brighten & lighten skin
Garlic 	Rhizomes of <i>Allium sativum</i> (Alliaceae)	has anti-bacterial, anti-anti-septic properties, reduce swelling and inflammation and increase blood circulation, prevent psoriasis and skin cancer.
Papaya 	Fruit of <i>Carica papaya</i> (Caricaceae)	act as anti-oxidant, anti-inflammatory & anti-acne, helps in lighten & soften the skin, remove dead skin cells & inactive proteins, thus rejuvenating skin
Tulsi 	Leaves of <i>Ocimum sanctum</i> (Lamiaceae)	Reduce skin infection, Prevent blackheads, acne & stimulate blood circulation, has healing, anti-bacterial, anti-fungal & anti-inflammatory and rejuvenating activity.
Fenugreek 	Seeds of <i>Trigonella foenum-graceum</i> (Fabaceae)	Act as Emollient, Used for wound healing, skin irritation, itching, & dermal cancer.
Orange 	Fruit of <i>Citrus sinensis</i> (Rutaceae)	act as anti-oxidant, have high content of citric acid which aids in exfoliation & dry out acne. The peel has anti-bacterial & anti-microbial properties which treat acne & oily skin. Works as a natural cleanser, astringent, scrub, moisturizer, & toner.
Ginkgo 	Leaves of <i>Ginkgo biloba</i> (Ginkgoaceae)	Has anti-bacterial property, thus it can fight against acne, psoriasis, dermatitis or eczema.

Almond oil 	Fruit of <i>Prunus dulcis</i> (Rosaceae)	Reduces puffiness & swelling, thus act as an anti-inflammatory, Act as Emollient & improve skin tone & complexion, Treats dry skin, eczema, & psoriasis, Reduces appearance of scars & stretch marks.
Amla 	Fruit of <i>Embilicaofficinalis</i> (Phyllanthaceae)	Reduces pigmentation & dark spots & restores natural glow, Keep skin smooth & young, Treat acne & remove dead skin cells.
Carrot 	Root of <i>Daucus carota</i> (Apiaceae)	has anti-aging property, Rejuvenating akin, act as a natural toner, promotes formation of new cells, Keeps the skin fresh & free of toxins.
Walnut 	Seeds of <i>Juglansnigra</i> (Juglandaceae)	Rich source of vitamin E Sooths dry skin & keep moisturize it, Reduce skin inflammation, delay skin aging.
Saffron 	Dried stigma & styletops of <i>Crocus sativus</i> (Iridaceae)	reduce pigmentation, brown spots & other skin blemishes, treat acne and blemishes, lighten the skin tone.
Sandalwood 	Dried wood of <i>Santalum album</i> (Santalaceae)	Has an astringent, anti-septic, anti-acne, anti-inflammatory activity, mainly used in face-packs & scrubs.

ANATOMY OF SKIN

The skin is the human body's most available organ. Its most fundamental role is clearly a defensive one. Through holding moisture in and bacteria out the skin prevents desiccation and disease as a barrier. Nevertheless a gross underestimation of the anatomical and physiological complexities of this essential system is the depiction of the skin as a simple "plastic wrap." End-organ malfunction or deficiency is not a criterion for the diagnosis of skin disease, unlike parenchymal organs, since

all skin disorders can be detected clinically, regardless of their functional consequences. Some elicit only insignificant aberrations of skin structure or function within the spectacular collection of neoplastic, allergic, viral, and hereditary cutaneous diseases, while others contribute to profound and morbid effects.

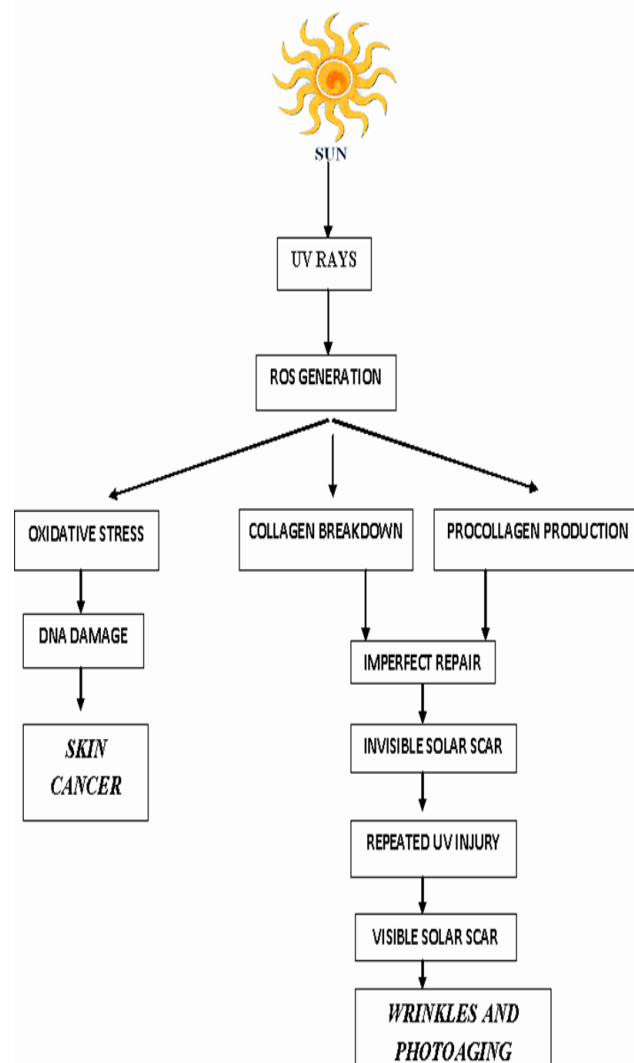
Functions of Skin:

The skin performs a number of main roles as the largest organ of the body, arising from numerous chemical and physical processes

taking place within it. The skin is a membrane that protects the body from components, destruction, and oxidation. By making the body respond to varying environmental temperatures and atmospheric environments through the control of moisture loss, it helps sustain a stable body temperature. It absorbs sensory input and plays an active, disease-protective function in the immune system. The skin must preserve its own repair capacities and functional integrity in order to fulfil any of these roles, such as defensive, biochemical, sensory and immunological.

Cosmetics are very important ingredients for the defensive role of the skin. Sunscreen protects against UV radiation and thereby against premature skin acquisition and cancer of the skin. Bactericidal creams and lotions suppress and/or regulate the unnecessary growth of skin bacteria, a concern especially associated with oily skin and one of the major causes of the development of acne. And by building an invisible layer on the surface of the skin, unique moisturising components can help mitigate the lack of moisture that occurs in dehydration of the skin. The skin also protects internal organs from oxygen exposure ⁽²³⁾.

HARMFUL ASPECTS OF UVB RADIATION⁽²⁴⁾



UVB radiation, including wrinkles, ageing skin conditions, and cancer, can cause skin damage. Collagen degradation, the development of free radicals, interfering with the DNA repair process and inhibiting the immune system against infection are some of the potential pathways for UVB skin injury. UVB light promotes the development of reactive oxygen (ROS) molecules, creating adverse skin effects ^(25, 23). The key cause of sunburn is ultraviolet B (UVB) rays, which differ with time and season. A leading risk factor for melanoma and non-

melanoma skin cancers is sunburned skin. A mixture of different techniques, such as the use of broad-spectrum sunscreen formulations, will achieve protection from damage to UVB rays. Harmful compounds called free radicals or reactive oxygen species (ROS), which can cause skin cancer and premature ageing, can be formed by UV radiation (UVR) absorbed by the skin surface. Reactive oxygen species (ROS) produced by UVB radiation are capable of causing oxidative decomposition, leading to the development of toxic components and lipid peroxidation^(26, 27).

Protein injury, lipid peroxidation and skin lesions can also be caused by UVB rays. Lipid peroxidation is the mechanism in which electrons from the lipids in cell membranes are obtained by free radicals, resulting in cell destruction. Species of reactive oxygen (ROS) dissolve unsaturated lipids and form malondialdehyde (MDA), which is called a lipid peroxidation marker enzyme. Superoxide dismutase (SOD), decreased glutathione (GSH), catalase (CAT), ascorbic acid (ASC) and total protein (TP) levels allow for the estimate of skin tissue antioxidant enzyme levels. ROS produced by UVB radiation, in addition to biochemical changes, can also cause major structural changes, such as epidermal erosion, altered epidermal surface thickness, fibrinoid and oedema, uneven epidermal layers, and unorganised collagen fibrils. De-oxy Ribose nucleic acid (DNA) readily absorbs UVB radiation, which often alters the molecule's structure^(28, 27, 29). Thus, it is essential to make skin protected from harmful effects of UVB radiation.

The major harmful aspects of UVB radiation include the followings-

1. **Sunburn (Erythema):** Sunburn (or erythema) is a skin redness disease that is caused by elevated blood supply to the skin due to exposure to UV radiation

caused by dilatation of the superficial blood vessels of the dermis. UVB radiation, since it is more erythmogenic by a factor of 1,000, is considered to be mostly responsible for sunburn. For people with fair skin, it takes just 15-30 minutes to cause erythema in the midday heat. The chest, neck and trunk are two or four times more vulnerable than the limbs with respect to regions of the body that are more susceptible to sunburn⁽³⁰⁾.

2. **Tanning:** Tanning refers to delayed skin pigmentation, or pigmentation of melanin. Usually, it becomes visible one or two days after exposure to the Sun and steadily rises for weeks or months to last for several days. Tanning results from an increase in the amount of melanocyte (pigment cell) functions, resulting in increased enzyme tyrosinase production. This leads to new melanin production and a rise in the number of granules of melanin throughout the epidermis⁽³¹⁾.
3. **Premature Aging of the Skin:** Premature ageing of the skin, which involves a variety of clinical symptoms that indicate systemic changes in the epidermis and dermis, is one of the persistent effects arising from prolonged UVB radiation exposure. Dryness, wrinkles, accentuated skin furrows, sagging, loss of elasticity and mottled pigmentation are among these clinical signs, and are the result of degenerative elastin and collagen changes. In spite of the induction of sunburn and nonmelanoma skin cancer, UVB is 1,000 to 10,000 times more effective than UVA, with premature skin ageing⁽³²⁾.
4. **Skin Cancer:** Like non-melanoma skin tumours, basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and melanoma, there are numerous forms of skin cancer. In each of these cancers,

exposure to UVB radiation is thought to be an important factor because it induces DNA damage, but the types of exposure needed to cause different types of skin cancer may vary. Cumulative sun exposure is thought to be important for non-melanoma skin cancers, whereas the intermittent exposure hypothesis has been postulated for melanoma ⁽³³⁾.

5. **Damage to the Eyes:**As more than 99 per cent of UV radiation is absorbed in front of the eyes, UV rays can also affect the eyes. Both potential chronic consequences of UV exposure are corneal damage, cataracts, which macular degeneration and may eventually contribute to blindness. Melanoma may also form inside the eye, a form of skin cancer. Intraocular melanomas are 8 times more likely to arise in whites than in blacks⁽³¹⁾.
6. **Suppression of the Immune System:**A significant contributor to the growth of nonmelanoma skin cancers is suspected to be the repression of the immune system arising from exposure to UV radiation. A condition of relative immunosuppression that inhibits tumour rejection is caused by UV radiation⁽³⁴⁾. This is primarily done by interfering with the regular control role of Langerhans antigen-presenting cells in the epidermis, which are responsible for the activation of T-lymphocytes in response to foreign antigens. Exposure to UV radiation changes the number of Langerhans cells and their characteristics, whereas related cells responsible for the selective activation of suppressor lymphocyte pathways are immune to UV injury. This causes an imbalance in the activity of the local T-cell and a change from helper to suppressor pathways, eventually favouring tumorigenesis and development ⁽³⁵⁾.

In one of the studies carried out it was concluded that the prevention of UVB-induced green tea polyphenol (-)-epigallocatechin-3-gallate

immunosuppression in mice could be associated with alterations in the development of interleukin IL-10 and interleukin IL-12. If UV radiation is present, the metalloproteinase matrix (MMP). The amount of fibroblast is raised, which results in the lack of collagen. It was stated earlier that the leaves of *Terminaliacatappa* L. (Combretaceae) improves Type I procollagen production by inhibiting the activity of MMP-1, -3 and -9 and is also used in cosmetic anti-aging products ⁽³⁶⁾.

7. **Cell Death:**The immune system's last line of defence is a mechanism called apoptosis. Apoptosis is a cell-suicide mechanism that destroys cells that are badly compromised so that they cannot become cancerous. By enhancing free radical production, activating apoptotic cell death pathways and depolarizing mitochondrial membrane potential, UVB induces cell death. There are some factors that inhibit this cell death that cause cells to begin to differentiate and potentially become cancerous, like UVB exposure. The investigator concluded that the p53 gene encodes signalling molecules responsible for causing cell cycle arrest and contributing to cell death ⁽³⁷⁾.
8. **Collagen Breakdown:**UVB radiation in the dermis allows collagen to break down at a greater rate compared for only chronological ageing. Sunshine harms collagen fibres which cause abnormal elastin to collect. Enzymes called metalloproteinase are created in vast amounts as this Sun-induced elastin accumulates.

Metalloproteinase remodelling Sun typically injures the skin by generating and transforming collagen. However this procedure does not necessarily perform well and some of the collagen is actually broken down by metalloproteinase. This results in the formation of solar scars known as disorganised collagen fibres. When the skin repeats this incomplete process of reconstruction over and over again, wrinkles are formed ⁽³⁸⁾.

9. **Free Radicals:** Oxygenated compounds are the most damaging agents for the skin, also referred to as free radicals." One of the main creators of free radicals is UV radiation. Unstable oxygen molecules that only have one electron instead of two are free radicals. The molecule must scavenge other molecules for another electron, since electrons are contained in pairs. When the second molecule loses its electron to the first molecule, the process must then be replicated with another electron. This process will harm the role of cells and modify genetic material. By activating metalloproteinase, which breaks down collagen, free radical damage induces wrinkles. They cause cancer by modifying the cell's genetic content, RNA and DNA. Researchers advocate using sunscreen to shield the skin from dangerous UVB radiation and minimise the production and damage of ROS. The area of photo safety possibilities can require the creation of sunscreens that stay on the skin surface for a longer period of time and may contain antioxidants that may neutralise ROS. Antioxidants can help the photo protection effect by trapping free radicals. This research therefore focuses on the safety of images from UVB radiation and the assessment of changes in biochemical

parameters and histological changes in skin tissues ⁽³⁹⁾.

Advantages of Herbal Sunscreens^(40, 41):

- (1) Easily available.
- (2) No side effect.
- (3) No special equipment needed for preparation.
- (4) Renewable resources.
- (5) Botanical ingredients are easily available.
- (6) They are inexpensive

Topical sunscreen agents

Topical sunscreens can be roughly categorised into two classes, chemical absorbers and actual blockers, depending on their mode of action. By absorbing ultraviolet (UV) radiation, chemical absorbers function and can be further distinguished by the form of radiation they receive, either UVA or UVB, or both UVA and UVB. By reflecting or scattering UV radiation, physical blockers work.

a) Chemical absorbers

A mixture of additives are often present in chemical absorbing sunscreens to achieve shielding against both UVB and UVA radiation. Some are mixed with actual blockers as well. When exposed to sunlight, some organic formulations may degrade; they may therefore not perform as well as expected.

b) Physical blockers

In protecting against both UVA and UVB radiation, physical blockers are effective. Titanium dioxide and zinc oxide are the two most common physical blockers. As they are chemically inert, stable, and defend against the full UV spectrum, these agents are the near perfect sunscreen. Their biggest downside when added to the skin is their poor cosmetic look. Micro-sized or ultra-fine grades were formed by decreasing the particle size, hence reducing the appearance of whitening. Bright neon colours have been applied to some items⁽⁴²⁻⁴⁵⁾.

PREPARATION OF SUNSCREEN CREAM:**Theory**

Sun screen is a vanishing type cream. It is W/O type emulsion, which when applied to skin; it vanishes and leaves an almost invisible layer on it. The layer left behind after application; act as a base or foundation, for facial makeup. Since water is an external phase, it will be quickly washed off with water.

The main ingredients of sunscreen creams are stearic acid, alkali and water. Stearic acid gives a pearly white shining appearance to the cream, which on application gives a thin white film of free stearic acid. Soap is prepared in-situ by the chemical reaction between alkali and stearic acid, which is used as emulsifying agent.

For preparation of sunscreen creams, various types of alkalis are used such as potassium hydroxide, sodium hydroxide, aqueous ammonia, Potassium carbonate, Sodium carbonate, Borax and Triethanolamine.

- Out of these alkalis potassium hydroxide is most widely used, because it makes a cream of fine texture and excellent consistency. Otherwise, Borax can be used in combination with potassium hydroxide or triethanolamine, to get smooth and white cream.
- If sodium hydroxide is used alone, it makes the cream hard. Hence it should be used in combination with potassium hydroxide.
- Carbonates are generally not used, because they liberate carbon dioxide and make the cream spongy.
- Aqueous ammonia is also used as effective alkali, but due to its objectionable odor and volatility, it is difficult to handle. Ammonia creams also tend to turn yellow in color, with age (during storage).

Sun screen creams are W/O type emulsions, there is a possibility of evaporation of water from external phase of emulsion.

Therefore, Glycerin, polyethylene glycol or alcohol are incorporated as humectants, to prevent the drying out of cream, since external phase of sunscreen is aqueous, it should be protected from the contamination, from microorganisms by adding suitable preservatives, like methyl paraben or propyl paraben. These creams also be scented pleasantly, using suitable perfumes in small quantities.

Procedure: (By emulsification method)⁽⁴⁵⁾

Since there will be little wastage during weighing and preparing, to manipulate these practical losses, calculate the ingredients for at least one or two grams extra, than prescribed.

1. Melt stearic in china dish on a water bath up to 70 °C.
2. In a breaker, dissolve potassium hydroxide and methyl paraben in water, add glycerin to it. Heat this aqueous solution up to 70 °C.
3. When both aqueous and oily phases reach the same temperature, add aqueous on phase to the melted stearic acid, with continuous stirring.
4. Remove the dish from heat and continue the stirring. When the temperature reaches 40 °C, add perfume and mix uniformly until it becomes cool and a homogenous cream is obtained.

EVALUATION OF CREAM:

Physical Properties- Cream was observed for colour, odour and appearance.

Test for Thermal Stability -Thermal stability of the formulation was determined by the humidity chamber controlled at 60- 70% RH and 37 ± 1 °C.

Determination of pH - 5 ± 0.01 g of the Cream was weighed accurately in a 100ml beaker. 45ml of water was added & dispersed the Cream in it. The pH of the suspension was determined at 27°C using the pH meter.

Viscosity: Viscosity of the formulation was determined by Brookfield Viscometer at 100 rpm, using spindle no 7.

Homogeneity: The formulations were tested for the homogeneity by visual appearance and by touch.

Dye test: The scarlet red dye is mixed with the cream. Place a drop of the cream on a microscopic slide covers it with a cover slip, and examines it under a microscope. 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 in the red ground.

Stability studies- Stability testing of drug products begins as a part of drug discovery and ends with the demise of the compound or commercial product. To assess the drug and formulation stability, stability studies were done according to ICH guidelines. The stability studies were carried out as per ICH guidelines. The cream filled in bottle and kept in humidity chamber maintained at $30 \pm 2^\circ\text{C}$ / $65 \pm 5\%$ RH and $40 \pm 2^\circ\text{C}$ / $75 \pm 5\%$ RH for two months. At the end of studies, samples were analysed for the physical properties and viscosity.

Patch Test - About 1-3gm of material to be tested was placed on a piece of fabric or funnel and applied to the sensitive part of the skin e.g. skin behind ears. The cosmetic to be tested was applied to an area of 1sq.m. of the skin. Control patches were also applied. The site of patch is inspected after 24 hrs.

Spreadability studies - An important criterion for semisolids is that it possesses good spreadability. Spread ability is a term expressed to denote the extent of area to which the cream readily spreads on application to the skin. The therapeutic efficacy of a formulation also depends on its spreading value. A special apparatus has been designed to study the spreadability of the formulations. Spreadability

is expressed in terms of time in seconds taken by two slides to slip off from the formulation, placed between, under the application of a certain load. Lesser the time taken for the separation of the two, better the spreadability. Two glass slides of standard dimensions were selected. The formulation whose spreadability had to be determined was placed over one of the slides. The other slide was placed on top of the formulations was sandwiched between the two slides across the length of 5 cm along the slide. 100 g weight was placed up on the upper slide so that the formulation 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. One of the slides was fixed on which the formulation was placed. The second movable slide was placed over it, with one end tied to a string to which load could be applied by the help of a simple pulley and a pan. A 30g weight was put on the pan and the time taken for the upper slide to travel the distance of 5.0cm and separate away from the lower slide under the direction of the weight was noted ⁽⁴⁶⁾.

Acid value: Take 10 gm of substance dissolved in accurately weighed, in 50 ml mixture of equal volume of alcohol and solvent ether, the flask was connected to reflux condenser and slowly heated, until sample was dissolved completely, to this 1 ml of phenolphthalein added and titrated with 0.1N NaOH, until faintly pink colour appears after shaking for 30 seconds.

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

- n = the number of ml of NaOH required.
- w = the weight of substance

Saponification value: Introduce about 2 gm of substance refluxed with 25 ml of 0.5 N alcoholic KOH for 30 minutes, to this 1 ml of phenolphthalein added and titrated immediately, with 0.5 N HCl.

Saponification value = $(b-a) \times 28.05/w$

- The volume in ml of titrant = a
- The volume in ml of titrant = b
- The weight of substance in gm = w

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.

Rheological studies: The formulated cream was found to be non-Newtonian. Take a fixed quantity 10gms of cream in a 10 ml beaker. Keep it impact for 1 hr. The beaker was inclined to one side see whether the cream is liquefied or not. Beaker is shaken to and fro for continuous 5 min and checked whether consistency has changed or not. The beaker was again tilted and checked for pour ability of the cream.

Test for microbial growth in formulated creams- The formulated creams were inoculated on the plates of agar media by streak plate method and a control was prepared by omitting the cream. The plates were placed in to the incubator and are incubated at 37 °C for 24 hours. After the incubation period, plates were taken out and check the microbial growth by comparing it with the control ^(45, 47-49).

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