A Review on Formulation and Evaluation of Sunscreen

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ABSTRACT:
Excessive exposure to ultraviolet (UV) radiation from the sun has been linked to various skin disorders, including skin cancer, premature aging, and sunburn. The development of effective sunscreens is crucial to mitigate these risks. This review aims to provide a comprehensive overview of the formulation and evaluation of sunscreens, focusing on the importance of UV protection, types of UV radiation, and the classification of sunscreens. The review discusses the various ingredients used in sunscreen formulations, including organic and inorganic UV filters, and their mechanisms of action. Additionally, it highlights the importance of evaluating sunscreens using standardized methods, including in vitro and in vivo tests, to ensure their efficacy and safety. The review also explores the challenges and limitations in sunscreen development, including the need for improved photostability, water resistance, and skin tolerance. This comprehensive review provides valuable insights for researchers, formulators, and manufacturers working towards the development of effective and safe sunscreens.

INTRODUCTION:
The three types of solar radiation that reach the Earth's surface are visible light, infrared (IR), and ultraviolet (UV) rays. All electromagnetic radiation has spectra between 100 nm and 1 mm, with UV radiation having the shortest wavelength from 200 to 400 nm, followed by visible light (400 to 740 nm) and infrared (760 to 1,000,000 nm). UV radiation makes up around 10% of the sun's total light output. UVA, UVB, and UVC are the three suggested ranges into which the broad spectrum of UV radiation is separated. In this case, UVA photons have the longest wavelength (320–400 nm) but the lowest energy, UVB photons have the medium wavelength (280–320 nm), and UVC photons have the shortest wavelength (100–280 nm) but the highest energy. Moderate sun exposure has been shown to have several positive impacts, such as increased cardiovascular health, antibacterial activity, and vitamin D generation. Nonetheless, prolonged exposure to UV radiation is thought to increase the risk of both acute and chronic eye damage as well as skin cancer (Figure 1).

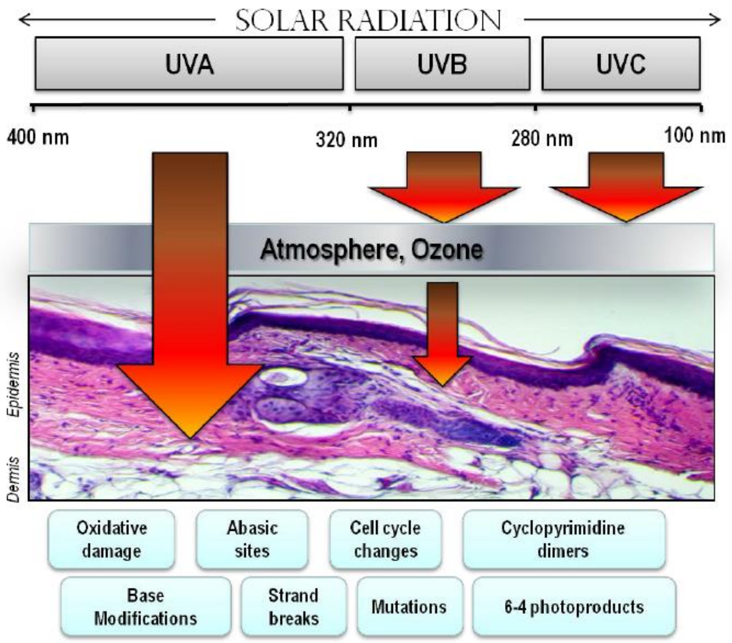

Fig-1: Electromagnetic spectra solar ultraviolet (UV) rays and their biological effects on the skin[1]

One of the most prevalent issues worldwide is UV-induced skin damage. Undoubtedly, UVA poses a risk for skin cancer, dryness, photosensitivity in the dermatology, and aging of the skin. By producing reactive oxygen species (ROS), which lead to oxidative DNA base alterations and DNA strand breakage, it damages DNA and causes mutations in mammalian cells. However, UVB rays can directly harm DNA by forming pyrimidine dimers, which can then result in apoptosis or mistakes in DNA replication, which can cause mutation and cancer. Despite having the shortest and strongest wavelength, UVC is the most harmful kind of UV radiation since it can have a number of negative consequences, including mutagenic and carcinogenic ones. However, the atmospheric layer is impervious to UVC radiation.

It has been demonstrated that photoprotectors, particularly sunscreen, are essential in lowering the prevalence of UV-induced skin problems in humans, such as pigmentation signs and skin aging. Since its initial commercialization in the United States in 1928, sunscreen has become a crucial component of photoprotection strategies all over the world. Because of its capacity to absorb, reflect, and disperse solar rays, it has been discovered to prevent and reduce the harmful effects of UV light. As photoprotective compounds have been developed throughout the decades, sunscreens have also been gradually enhanced. Undoubtedly, modern sunscreens are proven to shield the skin against various dangers (such as infrared, blue light, and pollution) in addition to UV rays. It is important to recognize the possible participation of these significant detrimental effects, even though UV radiation is most frequently linked to the development of skin disorders. According to some theories, these elements may exacerbate dyspigmentation conditions, hasten aging, and cause genetic abnormalities.

Additionally, sun protection factor (SPF) and protection grade of UVA (PA) measurements are used to assess the photoprotective effectiveness of sunscreen. The Food and Drug Administration (FDA) mandates that commercial goods have SPF numbers on the label that illustrate the efficiency of protection and how long the product will shield the user from UV rays. Undoubtedly, the SPF ranges from 6 to 10, 15 to 25, 30 to 50, and 50+, which stand for low, medium, high, and very high protection, respectively. However, there are several basic misconceptions about the SPF. An SPF 15 sunscreen is said to be able to absorb 93% of erythemogenic UV rays, whilst an SPF 30 product is able to block 96% of them, which is just over

3%. (Figure 2). The argument is insufficient to determine the amount of UV radiation that enters the skin, but it might be accurate when measuring sun protection capacity. This means that when you apply an SPF 30 product, half as much UV radiation will reach your skin as when you use an SPF 15 product. This is further demonstrated by contrasting sunscreens with SPF 10 and SPF 50. It is estimated that a differential factor of five will occur when applying SPF 10 and SPF 50 products, respectively, as ten and two photons transmit (%) through the sunscreen film and penetrate the skin. However, the Japan Cosmetic Industry Association (JCIA) created an in vivo persistent pigment darkening (PPD) technique in 1996 to assess sunscreen's UVA effectiveness. The labels PA+, PA++, PA+++, and PA++++ are applied to sunscreens in accordance with the UVA (PA) protection grade determined by the PPD test. The limited protection of sunscreens with the PA+ designation is mostly caused by two to four UVA filters. Sunscreens with four to eight ingredients are referred to be PA++ since they exhibit considerable UVA blocking. The PA+++ and PA++++ designations, on the other hand, stand for goods with a high level of sunscreen efficacy and made up of more than eight UVA filters.[2]

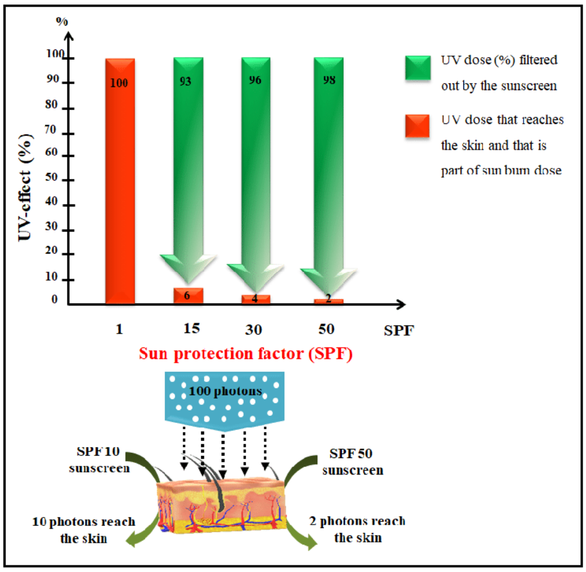

Fig-2:Illustration of the sun protection factor (SPF) definitions, including filtered and transmitted UV radiation

2.1: INTERACTION BETWEEN SKIN AND UV RADIATION

The skin: Two bands of distinct tissue, separated by a thin membrane, make up the skin. It is the inner band or dermis. Stratum basale, stratum spinosum, stratum granulosum, and stratum corneum are the four layers that make up the outer band, or epidermis.

As the outermost layer of the epidermis, the stratum corneum is visible to the unaided eye. It has no living cells and no blood supply, and it is around 20 layers thick. Known as the acid mantle or horny layer, the stratum corneum acts as a barrier to keep moisture out of the environment and within the body. Some UV protection is offered by the stratum corneum, which may also change its composition to offer more defense.

UV radiation: UV radiation is made up of three wavelengths: UVA (320–400 nm), UVB (290–320 nm), and UVC (200–290 nm). Since UVC is blocked by our atmosphere, only UVB and UVA light may reach the earth's surface. UVA rays can reach the dermis, but UVB rays often only reach the epidermis. Both UVA and UVB may alter the skin, however UVB is 50–100 times more potent than UVA at such effects.

UVB radiation is more potent than UVA radiation at causing squamous cell cancer, DNA damage, melanogenesis, and erythema.

Interaction between UV and skin: UV rays that strike the skin's surface can either be absorbed by materials on the stratum corneum's surface, reflected back toward the environment, or penetrate deeper into the skin. A review of UV radiation physics can be found elsewhere. One In order to absorb more UV, the stratum corneum thickens as it adjusts to UV exposure.

Interaction between UV and sunscreen actives:There are three possible ways that sunscreen active ingredients might theoretically lessen or stop UV-induced blistering. To stop the UV rays from harming living tissue, one method (chemical) would be to absorb them. Reflecting the UV rays would be a second (physical) method. The third (biological) method would be to lessen inflammation by either improving biological repair or inhibiting the biological inflammatory response. Some sunscreen active ingredients may have many modes of action.

A biological sunscreen active would need to reach the living tissues in order to be effective, but a chemical or physical sunscreen active would need to remain on the stratum corneum.

It is thought that a chemical sunscreen active shields the living tissues by absorbing UV rays and converting them into less harmful radiation, like light or heat. In reaction to UV light, chemical sunscreen active ingredients may also produce free radicals. Chemical sunscreen actives, regardless of the method, should absorb UV rays before they can reach living tissues. In order for this to happen, the sunscreen active ingredient has to be concentrated in the stratum corneum for a number of hours.[3]

2.2 HARMFUL EFFECT OF SUNLIGHT

1. **Premature aging:** Sunlight exposure results in photoaging, a premature aging of the skin that is characterized by fine wrinkles, freckles, capillary dilatation, uneven pigmentation, and loss of elasticity. Sun exposure is a major contributor to the early onset of wrinkles becauser ays weaken the skin's collagen and elastic tissues, making it drooping and brittle and unable to regain its original shape.In addition, sun exposure results in dark white spots on the skin and white cysts and blackheads on the cheeks.
2. **Suppression of Immune system:** Excessive exposure to UV radiation changes the immune system's functioning, making it harder for the body to fight off some illnesses and making skin-based vaccinations less effective.
3. **Cataract and eye disorder:** Overexposure to UV rays raises the risk of cataract development and other eye conditions. The cataract. In addition to causing damage to the retinal tissue and the formation of hazy bumps along the cornea, corneal sunburn can also develop over the cornea and impair eyesight.
4. **Heat exhaustion:** Employees who work in hot environments run the danger of developing heat exhaustion, which is linked to excessive loss of water and salt and manifests as symptoms such as headache, weakness, nausea, thirst, increased body temperature, and decreased urine production
5. **Heat stroke:** Irritability, slurred speech, loss of consciousness, seizures, and hot, dry skin with excessive perspiration are all signs of heat stroke, which can result from untreated heat exhaustion and cause death or lifelong disability.
6. **Sunburn:** This condition is brought on by prolonged exposure to sunlight and manifests as skin redness, blisters, swelling, pain, nausea, fever, chills, and headache..
7. **Heat rash**: Caused by sweat ducts trapping perspiration beneath the skin, heat rashes appear as red clusters of pimples or tiny blisters and appear around elbow creases, skin folds, on the neck, and on the upper chest.

8. **Skin cancer:** Non-melanoma skin cancer affects over a million people annually throughout the world. The worst result of too much sun exposure is the development of skin cancer. Three forms of skin cancer are frequently brought on by exposure to the sun. exposure 1) squamous cell carcinoma 2) basal cell carcinoma and 3) malignant melanoma.
1. **Squamous cell carcinoma**: this type of skin cancer develops as a result of burn scars, prolonged sun exposure, or persistent skin ulcers. which can spread to other organs and lymph nodes.
2. **Basal cell carcinoma**: This type of cancer always develops on sun-damaged skin, which is typically pink and glossy. It becomes extremely delicate and is prone to injury. It is particularly common in men's beard areas where they have shaved, and it grows deeper and larger over time
3. **Malignant melanoma:** This extremely deadly condition affects any part of the skin that has pigment-producing cells, and it can affect the entire skin. It primarily affects young women between the ages of 18 and 29.[4]

2.3 IDEAL PROPERTIES OF SUNSCREEN AGENTS:

1. Sunscreen must shield the skin from a wide spectrum of ultraviolet radiation
2. To avoid evaporating at high temperatures, it must be non-volatile in nature.
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4. It must be stable whether exposed to moisture, air, or light.
5. It shouldn't release any harmful substances if it decomposes.
6. should be absorbed by the skin with ease.
7. It needs to be neutral or almost neutral in order to neutralize the effects of bases and acids
8. It must not cause irritation or harm
9. .In an ointment base or vehicle, it should be well soluble.
10. Low water solubility is necessary to prevent sweat from removing.

3. CLASSIFICATION OF SUNSCREEN AGENTS:

Two methods are used by sunscreens to protect against UV radiation:

a. by blocking the production of free radicals (using UV filters) and
b. by scavenging free radicals (using antioxidants).[6]

Sunscreen agent classification is displayed in (Figure 3)

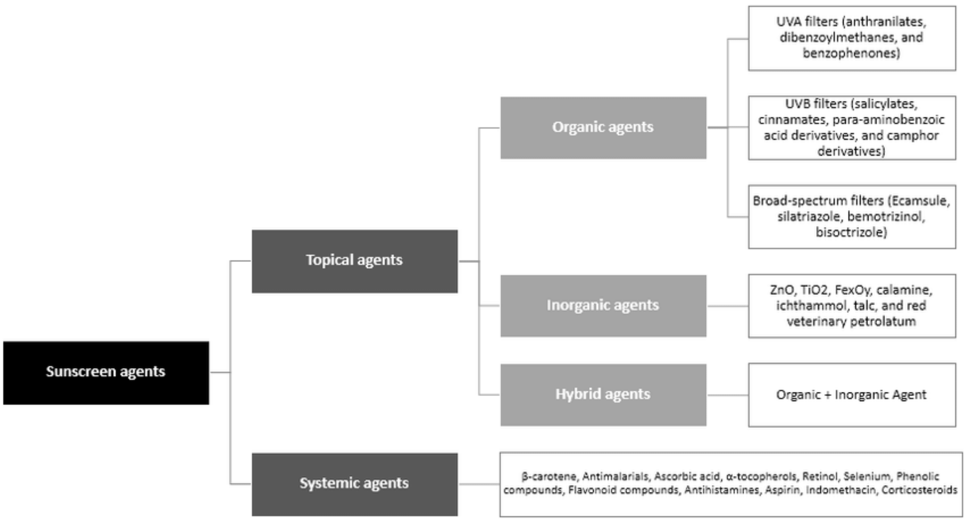

Fig-3: CLASSIFICATION OF SUNSCREEN AGENTS [7]

A. ORGANIC SUNSCREEN AGENTS

Depending on their chemical makeup, organic UV filters' active components can absorb UV light in a certain wavelength range. The UV filter changes from a low-energy ground state to a high-energy excited state after energy absorption. Any one of the three subsequent processes could emerge from this excited state, contingent on the filter's capacity to process the energy it has absorbed:

Photostable filter: This kind of filter returns to its ground state after releasing its absorbed energy into the atmosphere as heat. After that, it can fully absorb UV light once more.

Photounstable filter: After absorbing UV light, the filter degrades or changes chemically. It cannot re-absorb UV radiation.

Photoreactive filter: When the filter is stimulated, it interacts with molecules in the environment, such as oxygen, other sunscreen chemicals, and the proteins and lipids in the skin. Reactive species are created as a result, and they could have undesirable biological impacts.

Organic sunscreens are further divided into UVB and UVA filters:

1. UVB filters

a. PABA derivatives – Padimate O
b. Cinnamates – Octinoxate, Cinoxate
c. Salicylates – Octisalate, Homosalate, Trolamine salicylate
d. Octocrylene
e. Ensulizole

2. UVA filters

a. Benzophenones, Oxybenzone, Sulisobenzone, Dioxybenzone
b. Avobenzone or Parsol 1789
c. Meradimate

3. Newer generation broad spectrum (UVA + UVB) filters –

Bisoctrizole (Tinosorb M), Bemotrizinol (Tinosorb S), Silatriazole (Mexoryl XL), and Ecamsule (Mexoryl SX) L'Oréal owns the patent for Ecamsule, which is primarily a UVA filter; L'Oréal and its brands are the only ones that can use sunscreens that contain Ecamsule. Tinosorb M is the first of a new type of UV filter that combines the characteristics of both organic and inorganic traditional UV filters. It absorbs, reflects, and scatters UV radiation.

B. INORGANIC SUNSCREENS AGENTS

Inorganic substances work by absorbing, dispersing, or reflecting ultraviolet light. Using micronized or ultrafine particles can help reduce their natural drawbacks of being opaque and having a "whitening effect."

1. Zinc oxide
2. Titanium dioxide
3. Others - iron oxide, red veterinary petrolatum, kaolin,

C.SYSTEMIC PHOTOPROTECTIVE AGENTS

Furthermore, there are a number of substances that provide systemic photoprotection; they are frequently called "systemic sunscreens."

β-carotene, antimalarials, ascorbic acid, α-tocopherols (i.e., vitamins A, C, and E), retinol, selenium, green tea polyphenols, PABA, antihistamines, aspirin, indomethacin, corticosteroids.[8]

4. SUN PROTECTION FACTOR:

The sun protection factor, or SPF, indicates how effectively a sunscreen protects against sunburn. A sunscreen with a higher SPF value provides better protection against sunburn and UVA radiation damage than similar products with lower SPF values, especially when used correctly. Broad-spectrum coverage adds to its effectiveness by guarding against both UVA and UVB rays.[9]

According to the FDA, the use of a sunscreen with an SPF of 15 or above, combined with other measures, such as wearing sunglasses and avoiding the midday sun,can help prevent the skin cancer,

In some places, protection levels are expressed as follows:[10]

- **Low protection**: SPF is below 15
- **Medium protection**: SPF is 15 to 29
- **High protection**: SPF is 30 to 49
- **Very high protection**: SPF is over 50

Sunscreens have an specific sun protection factor (SPF), defined as the ratio of the minimal erythemal dose on sunscreen-protected skin (MEDp) to the minimal erythemal dose on unprotected skin (MEDu), as shown in Figure-4[11]

$$SPF = \frac{Minimal\ erythemal\ dose\ in\ sunscreen\ protected\ skin\ (MEDp)}{Minimal\ erythemal\ dose\ in\ unprotected\ skin\ (MEDu)}$$

Fig 4: formula of sun protection factor[11]

5. FORMULATION

Four pivotal processes are involved in sunscreen expression choosing the target product design, active constituents, and delivery system, also optimizing the final product, as seen in Figure 5. The expression expert's main thing is to produce a product that leaves a nonstop subcaste on the skin. Minimize the quantum of organic factors that access the skin. Organic sunscreens come in the form of light ointments and creams. They give UV protection by forming a thin subcaste on the skin's face when applied. Canvases, gels, mixes, aerosols, sticks, maquillages, scums(fluid mixes), and other phrasings are also available. Because inorganic sunscreens are flyspeck, they're further grueling to formulate. In history, they were created as unctuous, sticky, and unwelcome creams. Spray phrasings that produce a translucent subcaste on the skin that protects while conserving the product's appearance have been made possible by nanomization. Because these nanoparticles can be ingested and produce system venom, no nanomized sunscreen spray phrasings have been approved for enrollment as of yet. The phrasings of inorganic sunscreens include pastes, ointments, sprays, and mixes. To ameliorate the products' visual appeal, flyspeck engineering ways similar to micronization and nanomization of the patches are used. The expression fashion is guided by stoner convenience and safety. You should stay down from anything that can irritate your skin or beget disinclinations. Bonds to encourage skin adsorption and a suitable vehicle to distribute the active component are necessary for expression, just like in other skin care products. Patents are pivotal to the development process, therefore before starting a product development design, significant study must be given to them.

Among the difficulties and worries related to topical sunscreen, phrasings are the photostability of organic pollutants, expanding the parameters and diapason of efficacity, adding active substances, enhancing the aesthetics and sensitive rudiments, and customizing vehicles. Effectiveness for the intended purpose, UVA and UVB protection diapason, topical safety and tolerability, stability, no apparel staining, applicable cosmetics, affable scent, water resistance, spreadability, high extermination measure, and cost-effectiveness are all factors that should be taken into account when creating the perfect sunscreen expression. The primary sunscreen constituents are included in sunscreen phrasings, along with expression-specific excipients such as the right detergent or vehicle systems. The physicochemical makeup of the accouterments and their intended operation mandate the selection of the contents. Rear osmosis and other tried-and-true ways for artificial water sanctification are employed to give the purified water needed in product creation

Titanium dioxide, zinc oxide, avobenzone, benzophenone 8, octocrylene, and oxybenzone are the most extensively used active constituents in sunscreens. The volume of the active element is changed to change the quantum of sun protection. Lademan and his platoon set up that organic and inorganic sunscreens work well together, and they showed that products that combine the two are more effective than those that solely include organic or inorganic sunscreens. The FDA specifies the contamination content and the loftiest permitted attention of each substance. To give value, sunscreen is constantly co-formulated with other skin care products. A result that has been courteously created and manufactured improves stoner compliance while furnishing the essential defense against UV-convince skin damage. The top nonsupervisory bodies have pushed for the perpetration of the Quality by Design(QbD) conception for the once 20 times. Espousing this strategy entails strictly designing the product using wisdom, choosing accouterments precisely, and conforming process parameters to guarantee that a destined product quality profile is satisfied. A Quality Target Product Profile(QTTP), which outlines the intended physicochemical and performance characteristics of the sunscreen, is created by the deviser. They also go ahead and specify the process parameters and Critical Material Attributes(CMAs) demanded to reach the QTTP as specified. Areas that can hamper the accomplishment of the intended product quality are penciled through threat assessment, and suitable conduct is performed to alleviate these possible hazards. Design of trial(DoE) tools might be a useful aid in perfecting the required rates of the sunscreens to help reach the target product quality.[12]

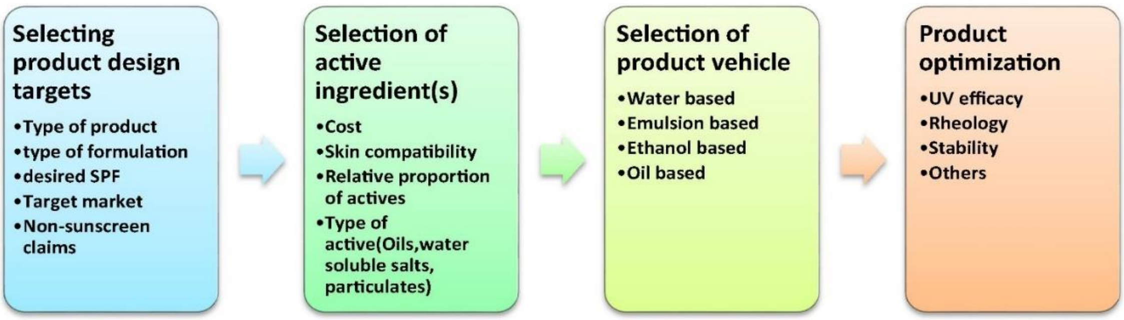

Fig-5: The procedure for creating sunscreen formulations[12]

6. EFFICACY OF THE SUNSCREEN:

Healthcare professionals generally recommend using sunscreen products to reduce skin damage from sunlight's UV rays. Sun Protection Factor (SPF), a helpful indicator for evaluating protection against UVB rays, is the main way that sunscreen efficacy is evaluated. However, it does not accurately represent the full photoprotective profile against UVA radiation.[13]

Sunscreens, when used at the prescribed levels, can dramatically lower the risk of skin malignancies, such as squamous cell carcinoma and melanoma.[14]

When compared to organic sunscreens, products with mineral filters such as zinc oxide (ZnO) and titanium dioxide (TiO_2) typically offer superior UVA protection and are more likely to maintain their stated SPF levels. Since sunscreen must be applied correctly and frequently to maintain its protective properties, this is very important. That wearing sunscreen every day can slow down the photoaging process and significantly lower the number of skin cancer incidences.[15]

7.SUNSCREEN SAFETY

In order to shield your skin from the sun, sunscreen is essential. Using a broad-spectrum sunscreen that is water resistant and has an SPF of 30 or higher can

- Lower your chance osafetyf getting skin cancer
- Avoid getting sunburned.

Reduce the appearance of wrinkles, age spots, and sagging skin, which are indicators of early aging. Stop existing melasma from darkening and new patches from appearing Reduce the risk of dark spots appearing when acne, psoriasis, or another skin condition clears.[16]

The FDA regulates sunscreens to protect customers.Assessing the quality, safety, and efficacy of sunscreens is one of the FDA's duties. The FDA has very strict regulations for over-the-counter (OTC) sunscreen products in order to protect individuals. The FDA bases its recommendations on the most recent scientific data, which does not indicate that any of the ingredients in sunscreens currently marketed in the United States are hazardous to human health.

OTC medications must be monitored by the FDA. Finding chemicals that are generally regarded as safe and effective (GRASE) is one of the FDA's responsibilities. If the FDA deems components in a sunscreen as GRASE, then the product can be made without going through an FDA approval process.

The FDA is requesting additional information on the following 12 ingredients before deciding whether to keep them in the GRASE category:

Ingredients commonly used in the U.S.: Ensulizole, octisalate, homosalate, octocrylene, octinoxate, oxybenzone, avobenzone.

Ingredients not frequently used in the U.S.: Cinoxate, dioxybenzone, meradimate, padimate O, sulisobenzone.

Despite its request for additional information, the FDA does not declare the ingredients dangerous. It makes no recommendations for people to avoid using sunscreens that contain any of these substances.

A recent study conducted by the FDA examined four sunscreen ingredients and concluded that their absorption into the body indicates a need for further research to assess any potential health effects. The researchers emphasized that the mere fact an ingredient is absorbed into the bloodstream does not necessarily mean it is harmful or unsafe.

The most prevalent type of cancer in the United States is skin cancer, and one of the main risk factors for skin cancer is unprotected exposure to the sun's damaging UV radiation. The AAD is still dedicated to improving and assisting with patient care. Consult a board-certified dermatologist to create a sun protection strategy that suits you if you have concerns about the safety of the ingredients in your sunscreen.[17]

8. EVALUATION OF SUNSCREEN

1. Physical characteristics:

Color: The formulation's color was manually examined and noted.

Odor: By using the available preparation and inhaling the scent, the formulation's smell was assessed.
Appearance: The formulation's appearance was examined visually

2. pH de.termination

A digital pH meter was used to measure the pH of sunscreens. After dissolving 1 g of the formulation in 100 ml of freshly made distilled water for two hours, the pH was determined. The goal of this study was to ensure that, after a full day of use, the pH of the herbal sunscreens created would be comparable to the pH of the skin. S.D. was noted after the results were verified three times.

3. Viscosity determination

The appropriate number of spindles was chosen, and viscosity was tested using the Brookfield viscometer. 50 g of preparation was kept in a 50 ml beaker until the spindle groove was dipped and the rpm was adjusted. The viscosity of the sunscreen was measured at 5, 10, 20, 50, and 100 speeds. The factor derived from the reading was used to calculate the viscosity.

4. Spreadability:

The therapeutic efficacy of sunscreens was assessed based on their capacity to spread. After applying the proper quantity of sunscreen between two slides and following the load instructions, the two sides took the allotted number of seconds to slide off. Spreadability was defined as the speed at which two slides may be separated.

The formula for calculating it is:

$S = M \times L$ /t

Where, M = weight tied to the upper slide

L = length of glass slide

T = time taken to separate the slides

5. Washability

To do this test, just rinse the sunscreen off with water.

6. Homogeneity:

Touch and visual appearance were used to verify the formulation's homogeneity.

7. Irritancy Test:

On the left-hand dorsal surface, mark a one-square-centimeter region. Time was recorded while the lotion was administered to the designated region. At regular intervals up to 24 hours, irritability, erythema, and edema were assessed and reported if present.

8. Stability Testing:

After seven days of study, the resulting formulation's stability was tested at room temperature. After that, the formulation was examined for 20 days at 45 ±1°C. The formulation was observed on days five, ten, fifteen, and twenty for all assessment parameters while being maintained at room temperature and at a higher temperature

9. Determination of In vitro Antioxidant Activity:

One milliliter of sunscreens in various concentrations and ascorbic acid as a standard were taken in separate vials. After adding 5 mL of DPP methanolic solution and giving it a good shake, it was incubated for 20 minutes at 370C. Methanol was used as a blank to determine the absorbance at 516 nm. As a control, the DPP absorbance was employed. The percentage of antiradical activity was calculated using the formula below:[18]

$\% Anti-radical\ activity =$

$Control\ absorbance - Sample\ absorbance \times$ 100 Control Absorbance

9. CONCLUSION:

Sunscreen formulation continues to evolve, driven by the increasing understanding of the damaging effects of UV radiation and the demand for effective, safe, and cosmetically appealing sunscreens. Advancements in active ingredients, delivery systems, safety assessments, and emerging innovations are paving the way for the development of next-generation sunscreens. As research in this field progresses, sunscreen products are poised to offer enhanced protection, better skin compatibility, and sustainable solutions for the growing concerns of sun-induced skin damage and skin cancer.

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