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A Comprehensive Review of Sunscreen: Formulation Approaches, Active Ingredients, Skin-Type-Based Selection, Nanotechnology, and Regulatory Considerations

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A B S T R A C T

Excessive exposure to ultraviolet (UV) radiation is a major contributor to acute and chronic skin damage, including Sun burn, premature aging, immune suppression, ocular damage, heat-related illnesses, and the development of melanoma and non-melanoma skin cancers. Sunscreens play a critical role in photoprotection by minimizing UV-induced harm through absorption, reflection, and scattering of radiation. This review comprehensively examines the classification of sunscreens into organic, inorganic, and systemic agents, along with their mechanisms of photoprotection and ideal physicochemical characteristics. Special emphasis is placed on skin-type-based selection of sunscreen formulations, highlighting suitable products for oily, acne-prone, dry, sensitive, post-procedure, pediatric, and pregnant populations. Various dosage forms, including creams, lotions, gels, sprays, and sticks, are discussed with respect to their advantages and limitations. The role of excipients in enhancing stability, safety, spreadability, and user acceptability is critically reviewed. Emerging strategies such as oral and injectable photoprotective agents, including Polypodiumleucotomos extract, nicotinamide, and afamelanotide, are explored for their adjunctive benefits in UV protection and skin cancer prevention. Advances in nanotechnology, particularly the use of nanosized titanium dioxide and zinc oxide, are discussed with respect to formulation improvement, safety, and regulatory concerns. The review also outlines global and Indian regulatory frameworks governing sunscreen products, along with evaluation parameters such as SPF determination, stability testing, and quality assessment. Overall, this review provides an integrated scientific perspective to support evidence-based sunscreen formulation, selection, and regulatory compliance for effective photoprotection.

Keywords: Ultraviolet radiation (UVA/UVB), Sun-induced skin damage, Excipients in sunscreen formulations, Sunscreen regulatory guidelines, Nanotechnology in sunscreens, Sunscreen formulation.

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INTRODUCTION

Repeated exposure of the skin to sunlight can produce both immediate and long-lasting alterations in skin structure. In the short term, continuous sun exposure leads to erythema, commonly known as Sun burn. This redness is followed by stimulation of melanocytes, which increases melanin synthesis, resulting in darkening of the skin, a process referred to as tanning. Prolonged and repeated exposure over time causes permanent loss of skin elasticity and significantly increases the risk of developing skin cancers, including both melanoma and non-melanoma types. The severity of sun-induced skin damage is influenced by multiple factors such as duration of exposure, seasonal variation in solar intensity, geographic location, and individual characteristics including age, skin type, immune status, and behaviouralhabits.In recent decades, the use of sunscreens or sun-protective products has increased substantially, likely due to growing awareness of the harmful effects associated with chronic sun exposure. Continuous exposure to ultraviolet radiation elevates the risk of three major forms of skin cancer: melanoma, basal cell carcinoma, and squamous cell carcinoma. Among these, melanoma is associated with higher mortality, whereas non-melanoma skin cancers contribute more significantly to morbidity and cosmetic skin damage. Several clinical studies have demonstrated that regular sunscreen application can reduce the incidence of skin cancers, particularly melanoma and squamous cell carcinoma.Cosmetics are products applied to the human body for cleansing, beautifying, or enhancing appearance, with sunscreens being among the most commonly used. Sunscreens are formulated to protect the skin from harmful ultraviolet (UV) radiation. Sunlight consists of electromagnetic waves with varying energies, of which high-energy cosmic, gamma, and X-rays are blocked by the Earth's atmosphere, while UV radiation can reach the skin. Lower-energy waves such as microwaves and radio waves are not associated with skin damage.UV radiation spans wavelengths from 100 to 400 nm and is classified into UVC, UVB, and UVA. UVC is completely absorbed by the ozone layer and poses no medical concern. UVB stimulates melanin production, causes epidermal thickening, and is the primary cause of Sun burn and long-lasting tanning. UVA radiation penetrates deeply into the skin, leading to quick tanning, and significantly contributes to long-term skin damage, premature aging, and wrinkle formation. It also generates free radicals that may cause DNA damage and increase cancer risk. People with lighter skin are more vulnerable to UV-related damage because ultraviolet rays can penetrate more easily into the deeper layers of their skin. [1]

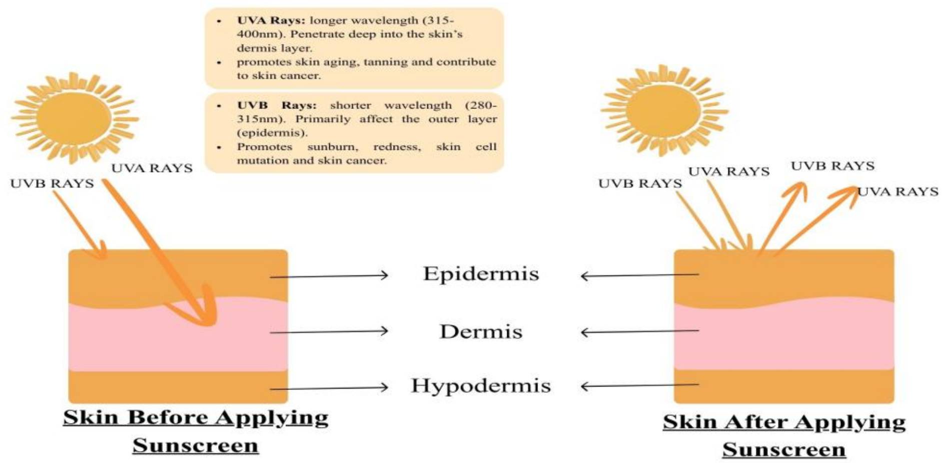


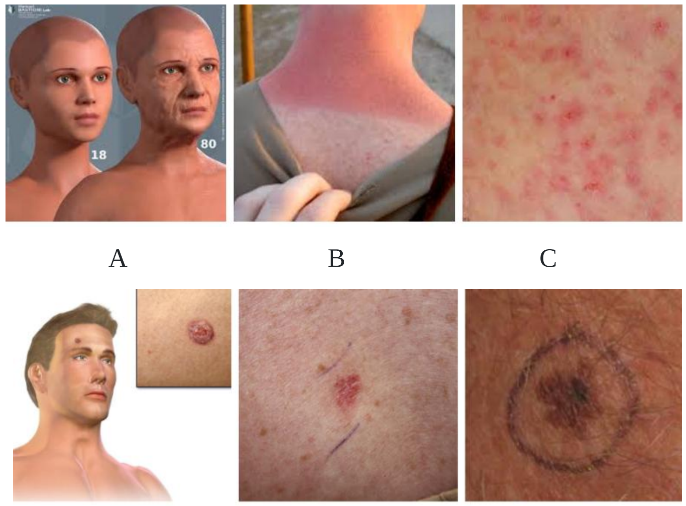
Figure 1: Effects of UVA and UVB radiation on skin layer

Health Effects of Excessive Sun Exposure:

1. Early aging of the skin: Continuous exposure to sunlight speeds up the aging process of the skin. This early aging leads to the formation of wrinkles, freckles, uneven skin color, visible blood vessels, and reduced skin firmness. Sun rays damage collagen and elastic fibres, causing the skin to sag and become fragile. Long-term sun exposure may also result in light or dark patches, small cyst-like bumps, and blackheads, especially on the facial area.(Fig no.2-A)
2. Weakening of the immune system:Too much ultraviolet radiation can disturb the normal functioning of the immune system. As a result, the body becomes less capable of defending itself against infections, and skin-related vaccines may not work as effectively.
3. Eye damage and vision problems:Extended exposure to UV rays increases the chances of developing cataracts and other eye disorders. UV radiation can harm the retina and may cause Sun burn of the cornea, leading to blurred vision and cloudy areas on the eye surface.
4. Heat exhaustion:People exposed to high temperatures for long periods, especially outdoor workers, are at risk of heat exhaustion. This condition occurs due to excessive loss of fluids and electrolytes and presents with symptoms such as dizziness, headache, fatigue, nausea, thirst, elevated body temperature, and reduced urination.
5. Heat stroke:If heat exhaustion is not managed properly, it can progress to heat stroke, which is a medical emergency. Symptoms include confusion, aggressive behavior, difficulty speaking, seizures, fainting, and extremely hot skin. Heat stroke is a serious condition that can cause lasting damage to vital organs and may even be fatal.
6. Sun burn: Sun burn occurs when the skin is exposed to sunlight for extended durations. It causes redness, swelling, pain, blister formation, fever, chills, headache, and sometimes nausea.(Fig no.2-B)
7. Heat rash:Heat rash develops when sweat becomes trapped under the skin due to blocked sweat glands. It appears as clusters of red bumps or small blisters, commonly seen on the neck, chest, elbow folds, and areas where skin rubs together.(Fig no.2-C)
8. Skin cancer:One of the most serious consequences of prolonged sun exposure is skin cancer, which affects millions of people worldwide each year. Sunlight exposure is strongly linked to three major types of skin cancer:
    a) Squamous cell carcinoma:This cancer arises due to long-term sun damage, old burn scars, or non-healing skin wounds. It has the potential to spread to lymph nodes and other parts of the body.(Fig no.2-D)

b) Basal cell carcinoma:Basal cell carcinoma usually develops on areas of skin that receive frequent sun exposure. It often appears as a smooth, shiny, pink lesion that is fragile and easily damaged. It is commonly seen in shaved facial areas in men and gradually grows deeper if untreated.(Fig no.2-E)

c) Malignant melanoma:Malignant melanoma is the most severe and life-threatening type of skin cancer. It originates from pigment-producing cells and can occur anywhere on the body. This condition is most commonly found in young adults, especially women aged 18 to 29.[2].(Fig no.2-F)



D E F

Figure 2: Representative images showing skin damage and different forms of skin cancer associated with prolonged sun exposure (A–F).

Classification of sunscreens and the mechanism of photoprotection :

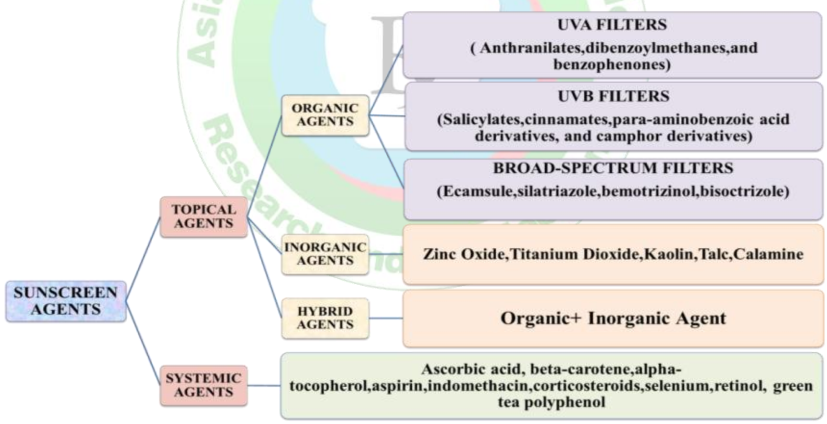


Figure 2: Classification of Sunscreens. [1]

Broadly, sunscreens can be grouped into topical and systemic types, depending on how they are administered. Topical sunscreens are further categorized into organic and inorganic agents, based on how they protect the skin from sunlight.

Organic sunscreens: These agents are mainly aromatic compounds that contain a carbonyl group. They are generally classified into three groups according to the wavelength range they protect against: UVB (290–320 nm), UVA (320–400 nm), and broad-spectrum sunscreens that provide coverage across the full UV range (290–400 nm). Organic UVB filters include para-aminobenzoic acid (PABA) and its derivative padimate O; salicylates such as octisalate and homosalate; cinnamates like octinoxate and cinoxate; as well as octocrylate, benzylidene and dibenzoylmethanes. UVA protection is provided by compounds such as benzophenones (including oxybenzone and sulisobenzone), avobenzone,meradimate, methyl anthranilate, and ecamsule. Some organic filters, including bisoctrizole and silatriazole, offer broad-spectrum protection by covering both UVA and UVB radiation.

Inorganic sunscreens: These sunscreens consist of particles that reflect and scatter ultraviolet radiation away from the skin, forming a physical barrier against UV light. The most commonly used particulate agents are titanium dioxide and zinc oxide. Because they provide protection across the full ultraviolet range, they are classified as broad-spectrum sunscreens. Inorganic sunscreens are also known as sunblocks, a term that reflects their mode of action in blocking UV radiation.

Systemic sunscreens: These sunscreens work by being absorbed into the body and accumulating in the skin, where they help protect against ultraviolet radiation. Common examples include ascorbic acid, retinol, and green tea polyphenols. However, systemic sunscreens are not commonly used as part of daily sun-protection routines. [1]

Oral and Subcutaneous Agents for Photoprotection and Skin Cancer Prevention:-There is growing interest in oral and injectable agents as supportive methods for protecting the skin from ultraviolet radiation (UVR).Unlike topical sunscreens, these agents work through internal biological mechanisms.They may help reduce Sun burn severity, decrease photosensitivity, and limit long-term skin damage linked to aging and skin cancer.Although early studies show promising results, larger clinical trials are still needed to confirm their safety and effectiveness.

Polypodiumleucotomos extract: Polypodium leucotomos is a tropical fern native to Central and South America, traditionally used for medicinal purposes. Today, it is available worldwide as oral supplements and topical products. Studies show that oral extracts provide photoprotective effects, particularly against UVB radiation and psoralen-UVA damage. It may also help reduce certain photosensitivity disorders such as polymorphous light eruption and possibly solar urticaria. The extract increases the skin's tolerance to ultraviolet exposure, reducing redness, pigmentation, and phototoxic reactions. In one clinical study, taking 240 mg twice daily for two months significantly reduced UVB-induced skin redness. Its benefits mainly come from antioxidant and anti-inflammatory properties, although its direct sun-blocking ability is limited, providing protection roughly equivalent to SPF 3–8.

Nicotinamide: Nicotinamide, the amide form of vitamin B3, is commonly used as an oral supplement. It is a precursor of NAD, an essential molecule involved in cellular energy production, immune function, and DNA repair. Unlike niacin, nicotinamide does not lead to the flushing effect on the skin.. Nicotinamide helps protect skin cells from UV-induced energy depletion, improves DNA repair, and reduces UV-related immune suppression. Clinical studies have shown that taking 500 mg once or twice daily can significantly reduce actinic keratoses. A large randomized trial also reported a 23% reduction in new non-melanoma skin cancers and an 11% decrease in actinic keratosis after 12 months of supplementation. The protective effect occurs only during regular use, but the supplement is generally well tolerated with minimal side effects.

Afamelanotide: Afamelanotide is a synthetic analogue of α-melanocyte-stimulating hormone that enhances photoprotection by stimulating eumelanin production, a pigment that naturally protects the skin from ultraviolet radiation and provides antioxidant effects. It is administered as a controlled-release subcutaneous implant that releases the drug over about two weeks, with increased melanin production occurring within two days and protective effects lasting up to two months. Clinical trials in Europe and the United States showed that patients with erythropoietic protoporphyria (EPP) receiving 16 mg implants every 60 days experienced longer pain-free sun exposure and improved quality of life. Side effects were generally mild, including headache, nausea, and back pain. Afamelanotide has also shown potential benefits in solar urticaria and is being studied for other photosensitivity conditions. These findings emphasize the need for broader photoprotection strategies beyond UV radiation alone.

Mechanism of photoprotection: Sunscreens protect the skin from the harmful effects of ultraviolet (UV) rays after sun exposure by increasing the skin's tolerance to UV radiation. They work mainly through two mechanisms. First, inorganic (mineral) sunscreens protect the skin by scattering and reflecting UV rays from the skin surface, forming a protective layer that prevents the rays from penetrating the skin. Second, organic (chemical) sunscreens absorb UV radiation and convert it into heat energy, which reduces its harmful effects and limits its penetration into the skin. Chemical sunscreens usually contain a combination of organic compounds to provide protection across different regions of the UV spectrum. In contrast, inorganic particulate sunscreens scatter microscopic particles within the upper skin layers, increasing the distance travelled by UV photons and enhancing their absorption. This mechanism improves the overall sun protection factor (SPF) and provides effective protection.

Ideal Characteristics of Sunscreen Agents: An ideal sunscreen agent should provide broad-spectrum protection against both UVA and UVB rays while remaining non-volatile and thermally stable to maintain effectiveness under heat and sun exposure. It must be chemically and physically stable when exposed to air, moisture, and sunlight, and should not form toxic by-products if degradation occurs. The agent should spread easily on the skin, ensure uniform coverage, and be safe for topical use without causing irritation or sensitization. Additionally, it should be neutral in nature, compatible with formulation bases, and have low water solubility so that it is not easily washed off by sweat or water, ensuring long-lasting protection.

Selection of Sunscreen Formulations Based on Skin Type:

Choosing the right sunscreen formulation should be tailored to individual skin characteristics to achieve maximum protection while maintaining skin safety and comfort.

1.Oily and acne-prone skin:Skin that produces excess oil or is prone to acne responds best to lightweight, non-comedogenic sunscreen formulations. Products such as gels, water-based lotions, and silicone-based "dry-touch" sunscreens help control shine and prevent blockage of pores. When combined with a suitable moisturizer, sunscreen use can also support the skin barrier and improve tolerance during acne treatment.

2.Combination skin:Combination skin, which is oily in the T-zone and dry on the cheeks, benefits from balanced formulations like gel-cream textures or oil-free lotions. These products provide adequate hydration while limiting excess oil production. The inclusion of advanced emulsifiers and silicones such as dimethicone, improves spreadability and overall skin feel.

3.Dry skin:Individuals with dry skin require richer sunscreen formulations, typically in cream form. These should contain moisturizing agents such as glycerin or panthenol to reduce water loss from the skin and strengthen the protective barrier. Such formulations are particularly beneficial for aged or severely dry (xerotic) skin.

4.Sensitive skin:Sensitive skin is more likely to experience irritation or allergic reactions. Performing a patch test before regular use is recommended to identify potential sensitivities. When testing is not possible, mineral-based sunscreens containing zinc oxide or titanium dioxide are preferred due to their low reactivity. Fragrance-free formulations further reduce the risk of irritation.

5.Post-procedure or compromised skin: Skin that has undergone procedures like laser therapy or microneedling requires gentle protection. Mineral sunscreens are ideal in these cases as they remain on the skin surface and cause minimal irritation. Newer micronized mineral formulations improve cosmetic appearance while offering effective broad-spectrum protection without disturbing the healing process. [2]

Market-Available Sunscreen Based on Skin Types

(Fig no. 3) presents the classification of commonly available commercial sunscreens based on different skin types: acne-prone, oily, dry, and sensitive skin. It shows how specific sunscreen brands are suited to particular skin needs depending on their formulation. Lightweight, non-comedogenic sunscreens are generally preferred for acne-prone and oily skin to avoid pore blockage and excess shine. For dry skin, sunscreens often contain moisturizing ingredients to help maintain hydration while providing sun protection. Products designed for sensitive skin focus on gentle formulations that reduce the risk of irritation. Overall, the chart highlights the importance of choosing sunscreens according to individual skin type to support better daily sun protection and skincare practices.

Figure 3: Market-Available Sunscreen Based on Skin Types. [3-7]

Table: 1 Sunscreen Ingredients Selected According to Skin Type

Ingredients Used in Sunscreen	Used in Acne-prone skin	Used in Oily skin	Used in Dry skin	Used in Sensitive skin
Zinc Oxide	✅	✅	✅	✅
Titanium Dioxide	✅	❌	✅	✅
Avobenzone	✅	✅	✅	❌
Octocrylene	✅	✅	✅	❌
Homosalate	✅	✅	✅	❌
Ensulizole	✅	✅	❌	❌
Disodium EDTA	✅	✅	✅	❌
Butylated hydroxytoluene	✅	✅	✅	❌
Oxybenzone	❌	❌	✅	❌
Octinoxate	✅	✅	✅	❌

Various formulations of sunscreens and their advantages:

1. **Lotions and Creams:** These are the most commonly used sunscreen types. They are usually made as oil-in-water emulsions, which help protect the skin from the sun at a lower cost. They can easily include moisturizers, softening agents, and anti-aging ingredients. This type spreads smoothly on the skin, forming an even, lightweight layer that doesn't look visible. Because of this, they are ideal for everyday use.

2. **Gels:** Gel sunscreens are light and feel fresh on the skin. Water-based gels are easy to wash off, while alcohol-based gels dry fast and give a cooling feel. However, alcohol gels can dry or irritate the skin and may protect unevenly. Microemulsion gels give strong and even sun protection but cost more and can sometimes irritate sensitive skin.

3. **Sprays:** Spray sunscreens are easy to use, especially in hard-to-reach areas. However, they still need to be rubbed in properly to ensure even and effective coverage.

4. **Sticks:** Stick sunscreens are small, light, and easy to carry. They work well for small areas and quick touch-ups, but their waxy formula can feel greasy on the skin.[2]

Sunscreens in Special Populations:

Children: Teaching sun protection early helps children develop lifelong healthy habits.Children's skin is more delicate, making it more vulnerable to sun damage, which can increase the risk of skin problems, including skin cancer, later in life.For children, sunscreens with physical filters such as zinc oxide and titanium dioxide are usually recommended because they are gentle and remain on the skin surface.However, babies under 6 months should be kept out of direct sunlight, and sunscreen is generally not recommended for them.

During Pregnancy: During pregnancy, hormonal changes can make the skin more sensitive and prone to conditions such as melasma, making regular sunscreen use important. However, some chemical UV filters may enter the bloodstream and raise safety concerns for the developing baby. Ingredients like oxybenzone have shown the ability to cross the placenta. Therefore, sunscreens containing physical filters such as zinc oxide and titanium dioxide are generally considered safer during pregnancy, and consulting a dermatologist can help in selecting an appropriate product.[2]

Recommended Sunscreens for Pregnant Women: For pregnant women, sunscreens made with physical ingredients like zinc oxide or titanium dioxide are the safest choice. These ingredients stay on the surface of the skin and do not get absorbed into the body. It is also advised that expecting mothers talk to a dermatologist to help choose a sunscreen that is safe for pregnancy and free from UV filters that could be harmful.

Practical Recommendations:

1. Sun protection should start early in life. For babies and young children, gentle physical sunscreens are the safest option.

2. During pregnancy, women should carefully choose sunscreens and prefer physical UV filters to reduce any possible risk to the baby.[2]

Excipients Used in Sunscreen Cream Formulations: Excipients are inactive yet indispensable constituents of sunscreen cream formulations. While they do not directly participate in the absorption or reflection of ultraviolet (UV) radiation, excipients strongly influence the formulation's stability, safety, effectiveness, and user acceptability. Proper selection and optimization of excipients ensure uniform distribution of sunscreen agents, desirable texture and spreadability, enhanced shelf life, and maintenance of optimal physicochemical characteristics throughout the product's lifespan.[9,18]

1. **Emulsifiers and Co-emulsifiers:** Sunscreen creams are commonly formulated as oil-in-water (O/W) or water-in-oil (W/O) emulsions. Emulsifiers such as

cetyl alcohol, cetostearyl alcohol, glyceryl monostearate, and emulsifying waxes play a vital role in maintaining emulsion stability by lowering interfacial tension between the oil and aqueous phases. Co-emulsifiers, including stearic acid, further reinforce the emulsion system and contribute to improved viscosity and consistency of the cream. [11,13]

2. **Emollients and Oils:** Emollients are incorporated to enhance skin smoothness and counteract dryness caused by prolonged sun exposure. Commonly used emollients include liquid paraffin, isopropyl palmitate, glycerine, coconut oil, and various herbal oils such as Moringa oleifera seed oil. These ingredients promote easy application, improve spreadability, and form a thin protective film on the skin surface, thereby enhancing moisturization .[9,10,18]
3. **Gelling and Thickening Agents:**To obtain the desired viscosity and physical stability, thickening and gelling agents are essential components of sunscreen creams. Polymers such as Carbopol, hydroxypropyl methylcellulose (HPMC), and xanthan gum are widely used. These agents help prevent phase separation, improve structural integrity, and ensure even application of the formulation on the skin.[11,13]
4. **Humectants:** Humectants play a crucial role in maintaining skin hydration during sun exposure. Substances like glycerine and propylene glycol attract moisture from the environment and retain water within the stratum corneum. In addition to preventing skin dehydration, humectants enhance product feel and minimize irritation caused by environmental stressors. [9,10,16]
5. **Preservative:**Preservatives are necessary to safeguard sunscreen creams against microbial contamination during storage and use. Common preservatives include methyl paraben, propyl paraben, sodium methyl paraben, and sodium propyl paraben. These agents inhibit the growth of bacteria, fungi, and molds, thereby ensuring product safety and extending shelf life.[18]
6. **Chelating Agents:**Chelating agents such as disodium EDTA are incorporated in low concentrations to bind trace metal ions that may trigger oxidative or degradation reactions. Their inclusion improves the chemical stability of both active ingredients and excipients, contributing to overall formulation robustness.[12]
7. **pH Adjusters and Neutralizing Agents:**Maintaining a suitable pH is essential for skin compatibility and product stability. Neutralizing agents like triethanolamine are used to adjust the pH of acidic polymers, such as Carbopol, bringing the final formulation within the skin-friendly pH range of approximately 5.5 to 7. [16,18]
8. **Solvents and Vehicles:**Purified or distilled water acts as the primary solvent and vehicle in most sunscreen cream formulations. It facilitates the dissolution of hydrophilic components and ensures uniform dispersion of all ingredients throughout the formulation. [11,18]
9. **Antioxidants and Stabilizers:**Antioxidants are incorporated to protect oils and sunscreen agents from oxidative degradation. Compounds such as vitamin E (tocopherol) and butylated hydroxytoluene (BHT) enhance formulation stability and provide additional skin benefits by neutralizing free radicals generated upon UV exposure. [14,17]
10. **Herbal and Natural Additives as Functional Excipients:**Herbal and cosmeceutical sunscreens often include natural ingredients like aloe vera, turmeric, rosemary, tomato extract, manjistha, propolis, and lutein esters. While some offer mild UV protection, most act as supportive excipients by boosting antioxidant activity, calming the skin, and enhancing the product's therapeutic and aesthetic value. [14,15,17]

Introduction to nanotechnology

Nanotechnology focuses on the precise design and control of materials at the nanoscale,a dimension measured in billionths of a meter. By working at this extremely small size range, scientists are able to create materials with distinctive characteristics that differ from their conventional counterparts. These advances have significantly influenced multiple sectors, including healthcare, engineering, manufacturing, information technology, and environmental sciences. Nanomaterials, generally defined as particles smaller than 100 nanometers, exhibit unique physical and chemical properties due to their reduced size, making them especially useful for a wide range of modern technological applications.[32]

The use of nanosized particles in sunscreens

Prior to the use of nanotechnology, conventional sunscreen formulations were often dense, greasy, and challenging to spread uniformly on the skin. These products commonly left a noticeable white residue, which reduced user acceptance and cosmetic appeal. This effect was largely attributed to the use of mineral UV filters such as titanium dioxide (TiO_2) and zinc oxide (ZnO), which have long been recognized for their ability to effectively protect the skin against both UVA and UVB radiation. In recent years, the introduction of nanosized forms of these minerals has allowed manufacturers to retain their broad-spectrum protective efficacy while significantly enhancing product texture, transparency, and overall aesthetic performance. [32]

How common are nanosized particles in sunscreens?

The use of nanoscale materials in sunscreen formulations is already well established and represents current industry practice rather than a developing concept. Regulatory assessments in Australia suggest that nearly 70% of titanium dioxide–based sunscreens and about 30% of zinc oxide–based products incorporate these ingredients in nanosized form. In contrast, sunscreen labelling regulations in the United States do not mandate disclosure of nanoparticle content. Consequently, reliable data on the prevalence of nano-enabled ingredients in U.S. sunscreen products are not publicly available. [32]

Potential risks of nanosized particles

Toxicological evidence suggests that the greatest health concerns related to nanoparticle exposure are associated with inhalation, such as contact with airborne pollutants, candle emissions, or particles generated during food heating. Once inhaled, these ultrafine particles can deposit within the respiratory tract and potentially trigger inflammatory responses. Nevertheless, the safety of nanoparticles applied directly to the skin—particularly through sunscreen formulations—also warrants careful evaluation. The primary concerns surrounding nanoscale ingredients in sunscreens stem from their minute size and the possibility that they may evade the body's natural immune barriers. [32]

Methodology for the Preparation of Nanoparticles for Sunscreen: Nanoparticles are commonly produced using traditional techniques such as sol–gel, solvothermal, hydrothermal, electrochemical, and precipitation methods. Despite their widespread use, these methods present several drawbacks. The sol–gel process, for example, is time-consuming and may take several hours or even days to complete. Hydrothermal synthesis depends on chemically intensive reactions and requires controlled experimental conditions. Likewise, precipitation techniques often struggle with regulating particle size, as rapid nucleation can result in the formation of larger or uneven particles. In comparison, microbial-assisted nanoparticle synthesis represents a greener and more economical alternative.[19,20]

Preparation of Titanium dioxide nanoparticles:TiO_2 nanoparticles have been synthesized using a solvothermal approach based on the hydrolysis of titanium isopropoxide in the presence of benzyl alcohol and acetic acid at 180 °C, resulting in nanoparticles with varying sizes and morphologies . Another widely used technique is the hydrothermal method, which follows a similar principle to solvothermal synthesis but employs water as the reaction medium instead of organic solvents .Zhang and co-workers reported the preparation of TiO_2 nanoparticles by heating titanium sulfate as the titanium source along with ammonium hydrogen fluoride as a morphology-directing agent.This method produced relatively pure TiO_2 nanoparticles and showed enhanced photocatalytic performance.Preparation of TiO2 nanoparticles TiO2 NPs were synthesized by hydrolyzing titanium isopropoxide [Ti{OCH(CH3)2}4] in a mixture of ethanol and water. The so obtained gel was dried at 80◦C for 4 h. Finally, the white powder was calcined at 500 ◦C.[20,21]

Preparation of Zinc oxide nanoparticles: Zinc oxide nanoparticles were synthesized using a hydrothermal-assisted approach. In this process, zinc acetate dihydrate was used as the zinc precursor, while sodium hydroxide was dissolved in methanol and gradually introduced under continuous stirring. The pH of the reaction mixture was maintained in the range of 8–11 to facilitate nanoparticle formation. The resulting suspension was then subjected to thermal treatment in a Teflon-lined stainless steel autoclave at 120 °C for 6–12 hours. After the reaction was completed, the product was thoroughly washed with distilled water and methanol to remove impurities. Finally, the purified suspension was freeze-dried to obtain a powder of zinc oxide nanoparticles.Preparation of ZnO nanoparticles. In a common synthesis procedure, zinc acetate [$Zn(CH_3COO)_2 \cdot 2H_2O$] and citric acid were mixed in a 1:1 molar ratio and dissolved in deionized water. The mixture was heated and stirred at 100 °C for one hour until it formed a gel. The gel was first heated to 200 °C and then annealed at 450 °C for 1 hour to produce crystalline ZnO nanoparticles.[19,20]

Safety of Nanoparticles: Many sunscreens contain inorganic UV filters such as zinc oxide (ZnO) and titanium dioxide (TiO_2), often used in nanoparticle form to improve transparency and spreadability. Although concerns have been raised about possible skin penetration and cellular damage, scientific reviews, including a 2017 assessment by Australian health authorities, indicate that these nanoparticles mostly remain on the skin surface and do not significantly penetrate the outer skin layer. Current evidence therefore suggests that they are unlikely to pose a risk of systemic toxicity.[22]

Toxicity of ZnO and TiO2 : ZnO NPs in sunscreens are their toxic potential in viable human keratinocytes and their ability to penetrate the skin, resulting in possible local and systemic distribution.TiO2 and ZnO include their poor dispersive properties and thus their skin-occlusive effects. The toxicity of these NPs is due to the generation of ROS thereby causing oxidative stress. [20]

Regulatory Framework and Guidelines for Sunscreen Products: Sunscreen regulations have been updated worldwide to prevent misleading label claims and to help consumers choose products that provide proper protection from harmful sun exposure and skin damage. Different countries regulate sunscreens through authorities such as the United States Food and Drug Administration, European Commission, Health Canada, and the Therapeutic Goods Administration in Australia.In Canada, sunscreens with inorganic filters like titanium dioxide or zinc oxide are regulated as Natural Health Products, while those containing organic UV filters are treated as OTC drugs and must display either an NPN or DIN number on the label. In New Zealand, sunscreens are considered cosmetic products and follow the AS/NZS 2604 testing standard used in Australia, although compliance with this standard is voluntary.

United States Food and Drug Administration (FDA) guideline: The United States Food and Drug Administration (FDA) regulates sunscreen products in the United States as over-the-counter (OTC) drugs. Earlier regulations mainly focused on protecting the skin from UVB radiation, which causes Sun burn, and gave less importance to protection against UVA radiation and long-term skin damage. Because some products used unclear labels and unsupported marketing claims, the FDA introduced stricter and clearer sunscreen guidelines.According to the updated rules, sunscreen products must undergo specific tests to prove their effectiveness against both UVA and UVB radiation before they can claim broad-spectrum protection. The FDA also standardized labeling through the Drug Facts label, which clearly explains the product's ingredients, directions for use, and warnings. Terms such as waterproof, sweat-proof, and sun-proof are no longer allowed, while water-resistant claims are permitted only if supported by proper testing.Additionally, only sunscreens with an SPF of 15 or higher can claim that they help reduce the risk of skin cancer and premature skin aging when used as directed. Products with SPF between 2 and 14 may provide protection from Sun burn but are not allowed to make these health-related claims.

Indian Guideline: In India, there are currently no standardized industry guidelines specifically governing sunscreen agents, nor is there a comprehensive public list of approved sunscreen products. The official website of the national regulatory authority identifies only two combination products as approved drugs, while many other sunscreens are categorized as cosmetic products and therefore do not appear in this listing. In addition to commonly used ingredients such as benzophenone-3 (BZ-3), zinc oxide (ZnO), and titanium dioxide (TiO_2), several other UV-protective agents are widely used in the Indian market. These include camphor benzalkonium methosulfate (6%), octyl salicylate (5%), camphor derivatives, and broad-spectrum UV filters such as bis-ethylhexyloxyphenol methoxyphenyl triazine (10%) and methylene bis-benzotriazolyl tetramethylbutylphenol (10%). Most sunscreens on the market contain combinations of multiple active ingredients rather than a single agent.

European Guideline: Europe regulates sunscreens as cosmetic products under the European Commission cosmetic legislation. In contrast, Australia classifies sunscreens as either cosmetic or therapeutic depending on their purpose and SPF level. Therapeutic sunscreens are regulated by the Therapeutic Goods Administration, while cosmetic sunscreens must follow rules set by the Australian Competition and Consumer Commission and use ingredients approved by the Australian Industrial Chemicals Introduction Scheme.According to European guidelines, sunscreens must provide adequate UVA protection, where the UVA protection factor should be at least one-third of the SPF value. Products can display SPF values such as 6, 10, 15, 20, 25, 30, 50, or 50+, which are grouped into low, medium, high, and very high protection categories. Sunscreens should also protect against UV radiation up to a critical wavelength of 370 nm. Products that meet these standards can show the UVA seal, and UVA protection is often indicated using a 1-to-5 star rating system developed by the Boots UK.[22,23]

Evaluation:

Determination of *In Vitro* SPF of Sunscreen Cream: The sun protection factor (SPF) of the samples was evaluated using a spectrophotometric method. For this purpose, 0.5 g of each sample was diluted with distilled water to achieve a final concentration of 0.2×10^{-4} g/mL. Each sample was initially dispersed in 100 mL of distilled water and homogenized by ultrasonication for 5 minutes to ensure uniform mixing. The resulting dispersion was then filtered through filter paper, and the first 10 mL of the filtrate was discarded to eliminate any impurities. Subsequently, 2 mL of the filtered solution was diluted to a final volume of 50 mL using distilled water.

The absorbance of the prepared samples was measured using a UV–visible spectrophotometer over the wavelength range of 290–320 nm, corresponding to the UVB region, at 5 nm intervals. Distilled water was used as the blank. A freshly prepared sunscreen sample, which had not been exposed to temperature variations, served as the control to determine the initial SPF value. All measurements were conducted in triplicate. The SPF values were calculated based on the absorbance data obtained from the spectrophotometric analysis using the Mansur equation.

$$SPF = CF \times 290 \sum 320 [EE(\lambda) \times I(\lambda) \times Abs(\lambda)]$$

Where:

CF = Correction factor (usually 10)

$EE(\lambda)$ = Erythemal effect spectrum

$I(\lambda)$ = Solar intensity spectrum

$Abs(\lambda)$ = Absorbance of sunscreen at wavelength λ. [22]

Stability Tests: Stability evaluations were conducted to assess the impact of different storage environments on the physical stability of the formulated sunscreen emulsions. The prepared formulations were kept at three different temperature settings: refrigerated conditions (8 ± 2 °C), ambient room temperature (25 ± 2 °C), and higher temperature conditions (40 ± 2 °C). These conditions were selected to simulate normal, cold, and accelerated storage environments. Over a period of 28 days, the samples were periodically examined for any visible changes. Parameters such as color variation, phase separation, and signs of liquefaction were carefully observed at predetermined time intervals. These observations were used to assess the physical stability of the emulsions and to determine their suitability for storage under different environmental conditions.[22]

PH Determination: The pH of the sunscreen formulations was measured using a digital pH meter. For this analysis, 1 g of each formulation was dissolved in 100 mL of freshly prepared distilled water and allowed to stand for two hours before measurement. The purpose of the study was to confirm that the pH of the sunscreens remained close to that of human skin after prolonged daily use. Each measurement was performed in triplicate to ensure accuracy, and the standard deviation (S.D.) was calculated from the obtained values. [24]

Spreadability: The spreadability of a sunscreen indicates how easily it can be applied to the skin, which affects its effectiveness. To measure this, a small amount of sunscreen was placed between two glass slides. A specified weight was applied on top, and the time taken for the top slide to move or slide off the bottom slide was recorded in seconds. Spreadability is considered better when the slides separate in a shorter amount of time.

S=M×L/T

Where, M= Weight applied

L=Length of slide movement

T= Time taken for the slides to separate. [24]

Viscosity: The viscosity of the sunscreen was assessed using a Brookfield viscometer fitted with the suitable spindle. About 50 grams of the formulation were placed in a 50 ml beaker, and the spindle was carefully immersed once the rotational speed (rpm) was set. Measurements were taken at various speeds: 5, 10, 20, 50, and 100 rpm. The readings obtained were then multiplied by the instrument-specific factor to calculate the final viscosity of the preparation. [24]

Accredited Laboratories in India

Table no.2 highlights accredited laboratories in India that are actively involved in testing and evaluating sunscreen and cosmetic products. These facilities contribute to regulatory compliance by conducting key assessments, including SPF and UVA/UVB performance testing, microbiological and preservative effectiveness studies, stability and shelf-life evaluations, safety and toxicity analyses, and chemical testing. Together, these laboratories form an essential part of the quality assurance framework, helping to confirm sunscreen efficacy, ensure consumer safety, and support reliable product claims in accordance with both Indian and international cosmetic regulations.

Table 2: Accredited Laboratories in India [25-30]

Laboratory Name	Test performed
MS Clinical Research Pvt. Ltd (Bengaluru)	SPF Testing, UVA-PF testing, Water resistance testing
CCFT-Centre for Cruelty Free Testing (Meerut)	SPF Testing, UVA/UVB Protection testing, Phototoxicity testing
Qualitek Labs (Pune)	Chemical Testing, Microbiological Testing
TNTH-Tamilnadu Test House (Chennai)	Allergen testing, Shelf life testing, Preservative efficacy study, SPF Testing.
METS Laboratories - Middle East Testing Services (Haryana)	Safety and toxicity studies ,Microbiological testing, Stability and shelf-life testing , Packaging compatibility testing, Heavy metal analysis, Chemical safety testing.
Shriram Food and Research (UttarPradesh)	Stability testing, Performance testing, Microbiological testing.
Qaaf Healthcare- Partner Lab Network (New Delhi)	SPF testing, Microbiological analysis.

CONCLUSION

This review brings together current scientific knowledge on sunscreen use by examining the effects of ultraviolet radiation on the skin, the underlying principles of photoprotection, advances in formulation science, emerging internal photoprotective strategies, and global regulatory perspectives. Special attention is given to the careful selection of UV filters, excipients, and formulation types to create sunscreens tailored for different skin conditions, including oily, acne-prone, dry, sensitive, and medically compromised skin. By emphasizing formulation optimization, safety assessment, stability considerations, and regulatory adherence, this review seeks to support evidence-based decision-making among researchers, product developers, healthcare professionals, and consumers, thereby enhancing effective protection against UV-related skin damage and long-term dermatological disorders.

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