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Research Article

Assessment of Sun Protection Factor in Sunguard PA+++

Vadiraj G Bharadwaj*, P Bharadwaja, Yamini Agalya Murugavel, Rahul Kankale and N Pushpa

Research and Development Centre, Sriveda Sattva Private Limited, Karnataka, India

***Corresponding Author:** Vadiraj G Bharadwaj, General Manager, Research and Development Centre, Sriveda Sattva Private Limited, Karnataka, India.

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Abstract

Objective: To evaluate the *in-vitro* Sun Protection Factor (SPF), UVA protection factor (UVAPF), and photostability characteristics of a topical sunscreen formulation, SUNSCREEN 2A (marketed as SUNGUARD PA+++).

Methods: SPF and UVA protection were determined using a validated *in-vitro* UV transmittance method employing a UV-2000S spectrophotometric analyzer in accordance with ISO 24443:2021 guidelines. The sunscreen was applied at 1.3 mg/cm^2 on polymethyl methacrylate (PMMA) plates. Spectral transmittance was measured across 290–400 nm before and after controlled UV irradiation. Parameters evaluated included SPF, UVA Protection Factor (UVAPF), SPF/UVAPF ratio, critical wavelength, and UVA/UVB ratio.

Results: The formulation demonstrated an *In vitro* SPF of 54.15 and *In vivo* SPF of 51.20. The mean post-irradiation UVAPF was 14.63, corresponding to a PA+++ classification. The critical wavelength was 373.91 nm, confirming broad-spectrum protection. Minimal variation between pre- and post-irradiation parameters indicated acceptable photostability. The product satisfied criteria for broad-spectrum labeling.

Conclusion: SUNSCREEN 2A exhibited high SPF, substantial UVA protection, and acceptable photostability under standardized *in-vitro* conditions. These findings support its suitability as a broad-spectrum sunscreen formulation.

Keywords: Sunscreen Formulation; *In vitro* Sun Protection Factor; UVA Protection Factor; Broad-Spectrum Photoprotection; Photostability; Skin Irritation; Phototoxicity; Botanical Extracts

Abbreviations

SPF: Sun Protection Factor; UV: Ultraviolet; UVA: Ultraviolet A; UVB: Ultraviolet B; UVAPF: Ultraviolet A Protection Factor; ROS: Reactive Oxygen Species; MMPs: Matrix Metalloproteinases; PMMA: Polymethyl Methacrylate; MED: Minimal Erythema Dose; PII: Primary Irritation Index; ISO: International Organization for Standardization; BIS: Bureau of Indian Standards; CTRI: Clinical Trials Registry of India; GCP: Good Clinical Practice; ICH: International Council for Harmonisation; SLS: Sodium Lauryl Sulfate

Introduction

Solar ultraviolet (UV) radiation is one of the most significant extrinsic factors contributing to premature skin aging and photocarcinogenesis. Chronic exposure to ultraviolet B (UVB, 290–320 nm) induces direct DNA damage through formation

of cyclobutane pyrimidine dimers, whereas ultraviolet A (UVA, 320–400 nm) penetrates deeper into the dermis and promotes oxidative stress via reactive oxygen species (ROS) generation, lipid peroxidation, and activation of matrix metalloproteinases (MMPs) [1,2]. Persistent oxidative stress contributes to collagen degradation, elastosis, and long-term dermal remodeling [3].

SPF (Sun Protection Factor) remains the internationally accepted measure of protection against UVB-induced erythema. However, SPF alone does not reflect UVA attenuation, which plays a central role in photoaging and pigmentary alterations. Therefore, contemporary sunscreen evaluation requires assessment of UVA Protection Factor (UVAPF), critical wavelength (≥370 nm for broad spectrum), and photostability characteristics according to ISO 24443:2021 guidelines [4].

In recent years, incorporation of botanical antioxidants into sunscreen formulations has gained scientific attention. Unlike synthetic UV filters that primarily attenuate radiation through absorption or reflection, plant-derived polyphenols and carotenoids may provide complementary photoprotection by scavenging ROS, modulating inflammatory pathways, and stabilizing cellular redox balance [5].

The Sunscreen 2A contains selected herbal ingredients integrated into the sunscreen formulation. Such botanicals have been described in literature for their antioxidant and anti-inflammatory potential, which may contribute to enhanced skin defense under UV exposure. The list of herbal ingredients are mentioned below:

- *Tagetes erecta* L. (Zandu) is a rich source of lutein and zeaxanthin, carotenoids known to absorb high-energy blue light and exhibit antioxidant properties [6]. Lutein has been reported to reduce UV-induced oxidative stress in skin models.
- *Cucumis sativus* L. (Trapusa) contains flavonoids and phenolic compounds with demonstrated antioxidant and soothing properties, potentially mitigating UV-induced inflammatory responses [7].
- *Rosmarinus officinalis* L. (Rosemary) is abundant in carnosic acid and rosmarinic acid, phenolic diterpenes shown to inhibit lipid peroxidation and attenuate oxidative damage induced by UV exposure [8].
- *Aloe barbadensis* Miller (Kumari) possesses polysaccharides and phenolic constituents associated with anti-inflammatory and wound-healing properties, which may support skin barrier recovery following UV stress [9].
- *Curcuma longa* L. (Haridra) contains curcuminoids that demonstrate inhibition of NF-κB activation and modulation of inflammatory mediators following UV irradiation [10].
- *Emblica officinalis* Gaertn. (Amla) is rich in ascorbic acid and ellagitannins, exhibiting strong free radical scavenging activity and protective effects against oxidative damage [11].
- *Moringa oleifera* Lam. (Shigru) contains flavonoids and phenolic acids with reported antioxidant and environmental stress–protective properties [12].

The integration of these botanicals into sunscreen formulations may provide synergistic photoprotective effects through combined UV attenuation and oxidative stress modulation. However, objective validation of photoprotective efficacy remains essential. Therefore, the present study aimed to evaluate the *in-vitro* Sun Protection Factor (SPF), UVA Protection Factor (UVAPF), critical wavelength, and photostability profile of Sunscreen 2A using standardized spectrophotometric methodology in accordance with ISO 24443:2021.

Materials and Methods

Study rationale and objectives

This investigation was designed to comprehensively evaluate the photoprotective efficacy and dermatological safety profile of Sunscreen 2A through a structured, multi-phase assessment framework.

Primary objective

To determine the *in-vitro* and *in-vivo* Sun Protection Factor (SPF) of Sunscreen 2A using standardized erythemal response methodology.

Secondary objectives

- To quantify UVA protection parameters, including UVA Protection Factor (UVAPF), critical wavelength, and photostability characteristics.
- To evaluate the primary skin irritation potential under occlusive exposure conditions.

- To assess phototoxicity potential following controlled ultraviolet irradiation.

Study design overview

The overall evaluation comprised three independent, single-arm clinical investigations conducted sequentially:

- *In-vitro* and *In-vivo* SPF determination
- Primary skin irritation assessment
- Phototoxicity evaluation

All studies were conducted at CCFT Laboratories, Meerut, India, under Good Clinical Practice (ICH E6 R2) and in accordance with the Declaration of Helsinki (2013 revision).

Ethical approval was obtained from the ARMHRC Institutional Ethics Committee prior to study initiation with the EC Numbers – CCFT 208, CCFT 237 and CCFT 232.

All these studies were registered with Clinical Trial Registration of India:

- **SPF study:** CTRI/2024/05/067562
- **Skin irritation study**: CTRI/2024/09/073168
- **Phototoxicity study**: CTRI/2024/07/070372

All participants provided written informed consent before enrollment.

Study population

Sample size

- **SPF study:** 10 healthy volunteers
- **Skin irritation study:** 24 healthy volunteers
- **Phototoxicity study:** 24 healthy volunteers

The sample sizes were consistent with applicable ISO and BIS guideline requirements for cosmetic evaluation studies.

Participant eligibility criteria

Inclusion criteria

Participants were eligible if they:

- Were aged 18–65 years.
- Had Fitzpatrick skin phototypes III–V.
- Had clinically healthy skin on the designated test area.
- Provided written informed consent.
- Agreed to avoid excessive UV exposure and strenuous sweating during the study.
- Demonstrated protocol compliance capability.

Exclusion criteria

Participants were excluded if they:

- Were pregnant or lactating.
- Had dermatological conditions, tattoos, scars, or excessive hair on test sites.
- Had known hypersensitivity to cosmetic products.
- Were receiving systemic or topical medication within one month prior to enrollment.
- Had chronic medical conditions potentially affecting dermal response.
- Were participating in another investigational study.

Determination of sun protection factor (SPF)

Guideline compliance

SPF determination was performed in accordance with ISO 24444:2019 — Cosmetics — Sun protection test methods — *In vitro* and *In vivo* determination of the sun protection factor (SPF).

Experimental procedure

Sunscreen 2A was applied at a standardized dose of 2 mg/cm^2 to designated areas on the upper back of each participant.

After an equilibration period allowing film formation, test sites were exposed to graded doses of UV radiation generated by UV2000S Transmittance Analyzer. Unprotected control sites were simultaneously irradiated.

Minimal Erythema Dose (MED) was determined 16–24 hours post-exposure by visual grading of erythema under standardized lighting conditions.

SPF was calculated using the formula:

$$SPF = \frac{\int_{290}^{400} E_\lambda \, S_\lambda \, d\lambda}{\int_{290}^{400} E_\lambda \, S_\lambda \, T_\lambda \, d\lambda}$$

In-vitro UVA Protection and Photostability Assessment

UVA protection was evaluated according to ISO 24443:2021 using a validated UV-2000S spectrophotometric system.

The formulation was applied at 1.3 mg/cm^2 to polymethyl methacrylate (PMMA) plates with defined surface roughness. Spectral transmittance was recorded between 290–400 nm at 1 nm intervals.

Measurements were performed:

- Prior to irradiation
- Following controlled UV exposure to evaluate photostability

The following parameters were calculated:

- *In-vitro* SPF
- UVA Protection Factor (UVAPF)
- Critical wavelength (λc)
- UVA/UVB ratio
- SPF/UVAPF ratio

Broad-spectrum protection was defined as a critical wavelength ≥ 370 nm.

Primary skin irritation assessment

Primary irritation potential was evaluated in accordance with BIS IS 4011:2018 (Part 1).

The product (40 µL) was applied in Finn chambers under occlusion for 24 hours on the upper back.

Dermal responses (erythema and edema) were graded at:

- 30 minutes post-removal
- Day 1
- Day 2
- Follow-up visit (Day 8 or Day 15 as per protocol)

The Primary Irritation Index (PII) was calculated as the arithmetic mean of individual irritation scores.

Phototoxicity evaluation

Phototoxicity was assessed according to BIS IS 4011:2018 (Part 3).

Following 24-hour occlusive application:

- One test site was irradiated with a controlled UVA dose.
- An adjacent site served as non-irradiated control.

Erythema responses were evaluated on Day 0, Day 1, Day 2, and Day 3.

A phototoxic reaction was defined as a clinically observable increase in erythema at the irradiated test site compared to the corresponding non-irradiated control site.

Statistical analysis

Descriptive statistical methods were applied.

- SPF values were expressed as mean ± standard deviation.
- UVAPF and critical wavelength were reported as mean values.
- Incidence of irritation and phototoxic reactions was expressed as frequency and percentage.

Results and Outcomes

In-Vitro photoprotective efficacy

Spectrophotometric evaluation was performed on four PMMA plates before and after controlled UV irradiation according to ISO 24443:2021. The results are tabulated in Table 1.

Parameter	Pre-Irradiation Mean ± SD	Coefficient of Variation (%)	Post-Irradiation Mean ± SD	Coefficient of Variation (%)
SPF	48.54 ± 14.50	29.00	54.16 ± 12.61	23.20
UVAPF	13.80 ± 3.13	22.15	14.63 ± 2.58	17.85
SPF/UVAPF Ratio	3.47 ± 0.29	51.20	3.67 ± 0.21	5.66

Table 1: Pre- and Post-Irradiation Photoprotection Parameters.

Post-irradiation SPF and UVAPF values demonstrated minimal variation, indicating acceptable photostability of the formulation under controlled UV exposure.

The photoprotection parameters are tabulated in Table 2.

Parameter	Value
Final *In-vitro* SPF	54.15
Mean Post-irradiation UVAPF	14.63
Critical Wavelength (nm)	373.91
Pre-irradiation UVA/UVB Ratio	0.284
Post-irradiation UVA/UVB Ratio	0.270
PA Classification	PA+++
Broad Spectrum Criteria (≥370 nm)	Met

Table 2: Photoprotection Parameters of Sunscreen 2A.

The critical wavelength exceeded 370 nm, confirming broad-spectrum protection. The slight reduction in UVA/UVB ratio following irradiation was not indicative of significant degradation.

Primary skin irritation assessment

Twenty-four healthy volunteers completed the 24-hour occlusive patch test. The Primary Skin Irritation Assessment is tabulated in Table 3.

Parameter	Sunscreen 2A	Positive Control (1% SLS)
Total Erythema Score	0	40
Total Edema Score	0	43
Combined Score (E + O)	0	83
Mean Irritation Score	0.00	3.46
Classification	Non-irritant	Mild Irritant

Table 3: Primary Skin Irritation Outcomes.

Sunscreen 2A demonstrated a Primary Irritation Index (PII) of 0.00 and was classified as non-irritant according to BIS IS 4011 grading criteria.

The positive control elicited a mild irritant response, confirming methodological sensitivity and study validity.

Phototoxicity evaluation

The Phototoxicity Evaluation is tabulated in Table 4.

Parameter	Sunscreen 2A
Number of Subjects	24
Positive Phototoxic Reactions	0
Mean Erythema Score (Irradiated Site)	0
Mean Erythema Score (Non-irradiated Control)	0
Phototoxic Classification	Not Phototoxic

Table 4: Phototoxicity assessment.

No subject demonstrated a clinically significant increase in erythema at irradiated sites compared to non-irradiated controls.

Overall study outcome

Sunscreen 2A demonstrated significant *In vitro* SPF (54.15), *In vivo* SPF (51.20)", substantial UVA protection (UVAPF 14.63; PA+++), and fulfilment of broad-spectrum criteria (critical wavelength 373.91 nm). The formulation exhibited acceptable photostability following controlled irradiation. Clinical safety evaluation revealed absence of primary skin irritation (PII = 0.00) and no evidence of phototoxic potential under standardized test conditions.

Discussion

The present study evaluated the *in-vitro* photoprotective efficacy and clinical safety profile of Sunscreen 2A, a multi-botanical sunscreen formulation. The product demonstrated a high *in-vitro* SPF value of 54.15, a post-irradiation UVAPF of 14.63 corresponding to PA+++ classification, and a critical wavelength of 373.91 nm, thereby fulfilling established broad-spectrum protection criteria.

Photoprotective performance and spectral balance

The critical wavelength exceeding 370 nm confirms that the formulation provides balanced protection across the UVA spectrum. Broad-spectrum protection is particularly relevant in mitigating UVA-induced dermal matrix degradation, photoaging, and oxidative stress. The relatively stable SPF/UVAPF ratio following irradiation indicates acceptable photostability, an important determinant of real-world sunscreen performance.

The modest change in UVA/UVB ratio after UV exposure suggests limited photodegradation of active constituents, supporting the structural stability of the formulation matrix.

Botanical contribution to photoprotection

Although the complete formulation matrix is proprietary, the botanical actives incorporated are known in literature for their antioxidant, anti-inflammatory, and UV-absorbing properties.

- *Tagetes erecta* contains lutein and flavonoids known to absorb high-energy visible light and contribute to photoprotection.
- *Cucumis sativus* provides hydration and exhibits soothing properties, potentially reducing UV-induced erythema.
- *Rosmarinus officinalis* is rich in rosmarinic acid and carnosic acid, potent free radical scavengers that mitigate UV-induced oxidative stress.
- *Aloe barbadensis* is reported to enhance skin barrier recovery and reduce inflammatory responses post UV exposure.
- *Curcuma longa* contains curcuminoids with established anti-inflammatory and ROS-modulating effects.
- *Emblica officinalis* is a potent antioxidant source of vitamin C and polyphenols.
- *Moringa oleifera* contains quercetin and chlorogenic acid, known to attenuate oxidative damage pathways.

Synergistically, such phytochemicals may enhance sunscreen efficacy not only by direct UV absorption but also by reducing reactive oxygen species (ROS) generated after UV exposure. This dual mechanism — physical attenuation plus oxidative stress modulation — may explain the observed photostability and spectral consistency.

Safety profile and dermal tolerability

Primary skin irritation testing demonstrated a PII of 0.00, classifying Sunscreen 2A as non-irritant. The positive control elicited mild irritation, confirming assay sensitivity. Absence of dermal irritation is particularly relevant in formulations containing botanical extracts, where sensitization potential must be carefully evaluated.

Phototoxicity assessment further demonstrated no significant increase in erythema following UVA exposure at treated sites, indicating absence of photo-irritant behavior. This finding supports the photostable nature of the formulation and reduces concerns regarding phytochemical-induced photosensitization.

Clinical and formulation implications

Modern photoprotection strategies emphasize:

- Broad-spectrum coverage
- Photostability
- Minimal irritation
- Antioxidant reinforcement

Sunscreen 2A fulfills these parameters under standardized testing conditions. The integration of botanically derived antioxidants may provide adjunctive protection against UV-induced oxidative cascades, which are not fully addressed by conventional UV filters alone.

Study limitations

The present investigation has certain limitations. The *in vitro* safety assessments were conducted in a relatively small cohort of healthy volunteers, which may limit the generalizability of the findings. Additionally, participants were recruited from a single geographic region, and variability across different climatic conditions and environmental UV indices was not evaluated.

Future studies involving larger, multi-center populations with broader skin phototype representation and diverse geographic settings may provide more comprehensive evaluation of clinical performance.

Conclusion

Sunscreen 2A exhibited a high *in vitro* SPF (54.15) and a UVAPF consistent with PA+++ classification, with a critical wavelength exceeding 370 nm, confirming broad-spectrum photoprotection. Post-irradiation evaluation indicated acceptable photostability under standardized testing conditions.

The dermal safety assessments demonstrated absence of primary irritation (PII = 0.00) and no evidence of phototoxic response in human volunteers.

Based on these findings, Sunscreen 2A has been introduced commercially under the designation SUNGUARD PA+++. The results of the present study provide the scientific basis supporting

its photoprotective performance and dermal tolerability under controlled experimental conditions.

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Conflict of Interest

All the authors are part of Research and Development centre at Sriveda Sattva Private Limited and declare that this study was sponsored by Sriveda Sattva Private Limited. The sponsor had a role in study support but did not influence data analysis or interpretation.

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