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Quality Assurance Audit Statement

Clinical Study Number: 2019-0006
Date of Test: February 18, 2019
Sponsor: [redacted]
Study Type: Critical Wavelength (FDA Broad Spectrum)
Product Code: Sonrei Sea Clearly SPF 50+
[redacted]

The clinical study listed above was conducted in accordance with the clinical study protocol, CRLS, LLC Standard Operating Procedures (SOPs), which incorporate the principles of applicable Good Clinical Practice (GCP) defined by applicable guidelines and regulations established by the International Council for Harmonization (ICH) and U.S. Regulatory Agencies. The clinical study master file was reviewed for compliance with the clinical study protocol, CRLS SOPs, and applicable guidelines and regulations by the Lab Manager and the Quality Assurance.

[redacted]

Signature **Date**

ECRLNC2019-0006: In Vitro Evaluation of the Critical Wavelength of Sunscreen Products
Final Report
February 22, 2019

Objective: To evaluate the critical wavelength of sunscreen products after irradiation with a full spectrum UV dose of 4 MEDs (800 effective J/m^2), according to the FDA Final Rule of June 17, 2011.

Test Date: February 18, 2019

Test Product: Sonrei Sea Clearly SPF 50+ [redacted]

Results: The test product, Sonrei Sea Clearly SPF 50+ [redacted] had a mean Critical Wavelength of 374 nm after a full spectrum UV dose of 4 MEDs (800 effective J/m^2), indicating that the formula meets the requirements for labeling as "Broad Spectrum". [1]

Sponsor: [redacted]

Investigator: Kacie Murdoch

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Introduction:

In 1993, Diffey [2] proposed a spectroscopic method for broad spectrum classification of sunscreens, based on the absorbance spectrum. The broad spectrum rating was determined by measuring the absorbance spectrum and integrating the area under the spectral curve from 290 nm to the wavelength at which the area reached 90 percent of the total area under the absorbance curve from 290 to 400 nm.

In June of 2011, the US Food and Drug Administration defined a broad spectrum sunscreen as one that has an SPF of at least 15 and a critical wavelength of at least 370 nm, after irradiation with a UV dose of 4 MEDs (800 effective J/m^2), to account for any lack of photostability. [1]

Objective:

To evaluate the critical wavelength of sunscreen test products after irradiation with a full spectrum UV dose of 4 MEDs (800 effective J/m^2), according to the FDA Final Rule of June 17, 2011.

Procedure:

Application

The test product was applied at 0.75 mg/cm^2 to the entire roughened surface of each of 3 PMMA plates with a roughness value (S_a) of 5 µm (Helioplate PMMA plates SB6, HelioScreen, Criel, Lot 222UK), in a series of small dots, and spread evenly using a gloved finger, with a very light spreading action for approximately 30 seconds, followed by spreading with greater pressure for approximately 30 seconds. The plates were then allowed to equilibrate for 15 minutes in the dark. After equilibration the plates were irradiated with a full spectrum UV dose of 4 MEDs (800 effective J/m^2). Irradiation Source is described in Table 1.

Irradiation:
After equilibration the plates were irradiated with a full spectrum UV dose of 4 MEDs (800 effective J/m^2) using a 150 watt multi-port xenon arc solar simulator (Model 601, Solar Light Co., Philadelphia). The Irradiation Source met the requirements as described in Table 1.

Table 1. Requirements for Irradiation Source

1. Continuous emission spectrum from 290 to 400 nm
2. Emission spectrum measured at least annually and after replacement of lamp bulb or any change in optical components, using a spectroradiometer system that is calibrated to a NIST traceable source
3. Daily radiation intensity monitored before and after each phototest, or at least at the beginning and end of each test day using an erythemally-weighted radiometer with a calibration consistent with the spectroradiometer system.
4. No significant time-related fluctuations in the exposure plane (±20%)
5. Good beam uniformity (±20%)
6. UVAII (320-340 nm): ≥ 20% of Total UV Irradiance
7. UVAI (340-400 nm): ≥ 60% of Total UV Irradiance
8. Total Irradiance from 250 to 1,400 nm ≤1,500 W/M^2
9. Percent erythemal dose contributions as shown below:

Wavelength Range	Percent Erythemal Dose Contribution
<290	**<0.1**
290-300	**1.0-8.0**
290-310	**49.0-65.0**
290-320	**85.0-90.0**
290-330	**91.5-95.5**
290-340	**94.0-97.0**
290-400	**99.9-100.0**

Measurements

After irradiation of the plates, the UV transmission at wavelengths, λ, from 290 to 400 nm at 1 nm intervals were measured for 5 locations on the reference plate coated with 15 µl of glycerin **[C1(λ), C2(λ), C3(λ), C4(λ)** and **C5(λ)]** and each of the irradiated plates **[P1(λ), P2(λ), P3(λ), P4(λ)** and **P5(λ)]**.

The UV transmission was measured by irradiating the reference plate and test product-treated plates with a lamp that provided continuous full spectrum radiation from 290 to 400 nm and measuring the transmitted spectral irradiance with an Optronic Laboratories OL756 Spectro-radiometer equipped with an integrating sphere (Gooch & Housego, Orlando, FL). The UV dose during one measurement cycle did not exceed 0.2 J/cm^2 and a total area of at least 2 cm^2 was measured on each plate. The mean transmittance for each wavelength, **T(λ)**, was computed as follows:

$$\overline{\mathbf{T}(\lambda)} = \frac{\sum_{1}^{5} \mathbf{P}(\lambda)/5}{\sum_{1}^{5} \mathbf{C}(\lambda)/5}$$

Then

$$\overline{\mathbf{A}(\lambda)} = -\log \overline{\mathbf{T}(\lambda)}$$

Where $\overline{\mathbf{A}(\lambda)}$ is the mean absorbance at each wavelength.

The critical wavelength for each plate was then calculated as follows:

$$\int_{290}^{\lambda c} \overline{A(\lambda)}\,d\lambda = 0.9 \int_{290}^{400} \overline{A(\lambda)}\,d\lambda$$

Where λ_c = Critical wavelength

$\overline{A(\lambda)}$ = mean absorbance at each wavelength

$d\lambda$ = wavelength interval between measurements

Results are shown in Figures 1 through 3.

Figure 1. Mean Absorbance and Mean Critical Wavelength before Irradiation and after a Full-Spectrum UV Dose of 4 MEDs (800 effective J/m^2)

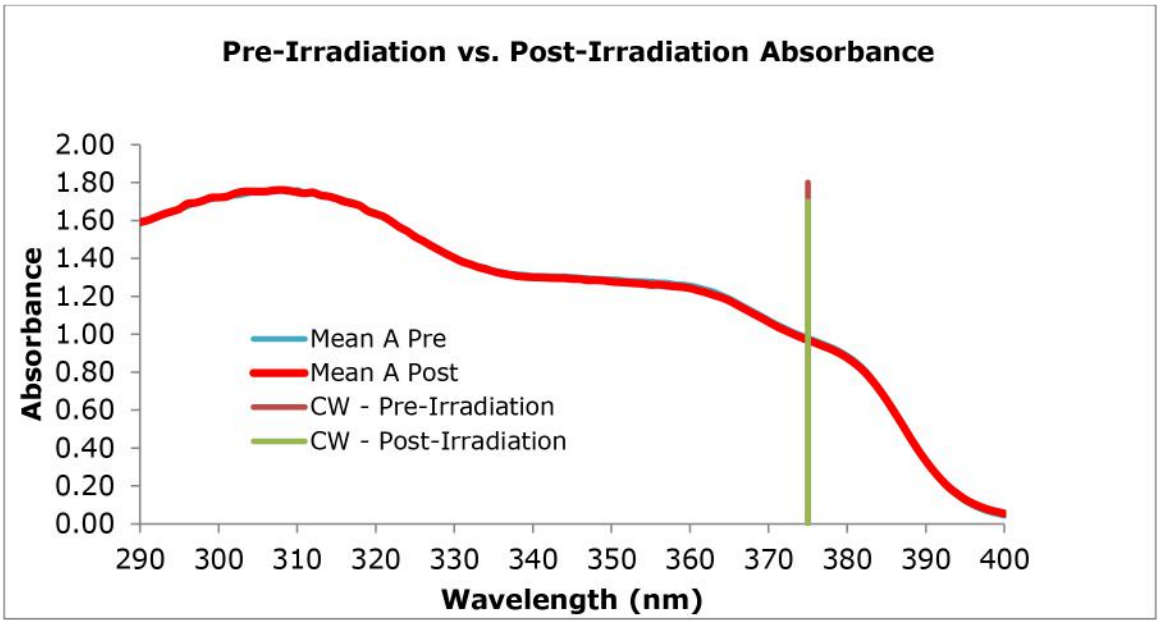


Figure 2. Mean Percent Area under the Absorbance Curve between 290 and 400 nm after a Full-Spectrum UV Dose of 4 MEDs (800 effective J/m^2)

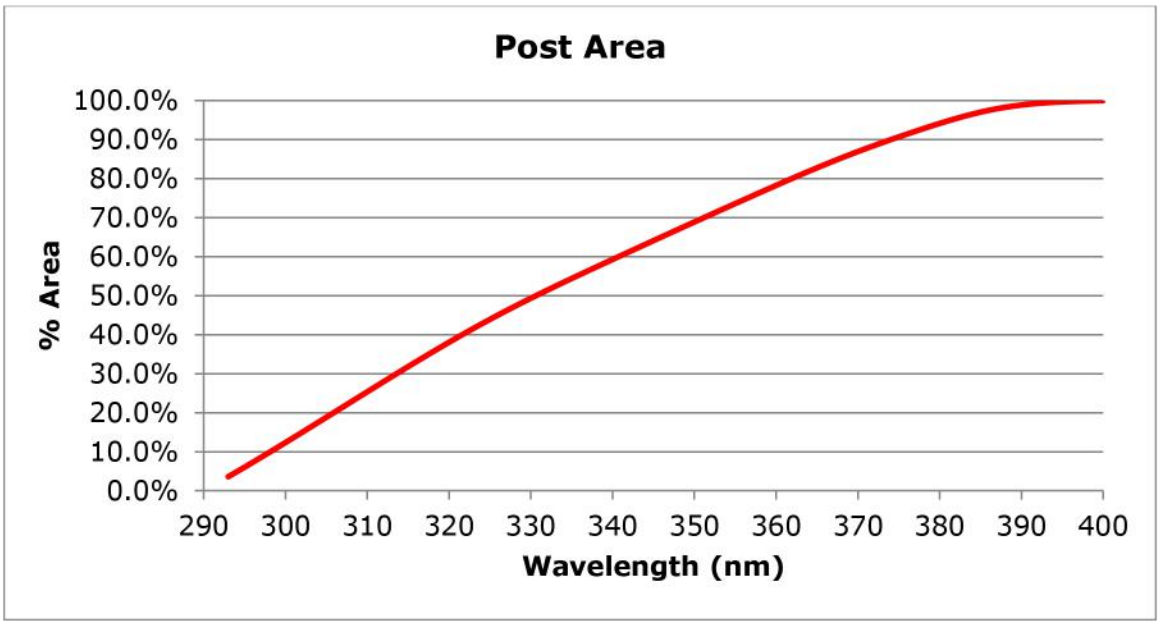
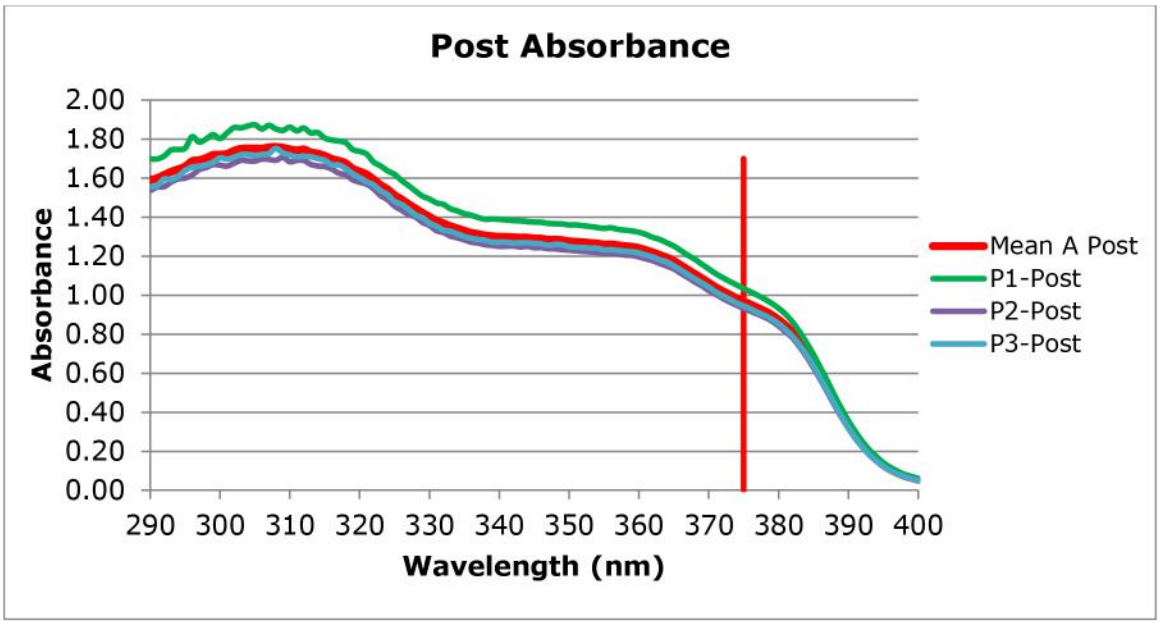


Figure 3. Absorbance Spectra, the Mean Absorbance Spectrum and the Critical Wavelength for Each Plate after a Full-Spectrum UV Dose of 4 MEDs (800 effective J/m^2)



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Conclusion:

The mean Critical Wavelength was 374 nm (SD=0.58, CV%=0.15%) after a full-spectrum UV dose of 4 MEDs (800 effective J/m^2). The test product meets the requirements for labeling as "Broad Spectrum". [1]

[redacted] [redacted]

Kacie Murdoch – Investigator Date

References:

1. Broad Spectrum Test Procedure, U.S. Food and Drug Administration, 21 CFR Parts 201 and 310, Federal Register, Vol. 76, No. 117, Friday, June 17, 2011, pp. 35620-35665
2. Diffey BL. A method for broad spectrum classification of sunscreens. Int J Cosmet Sci 1994; 16:47-52.