

**FINAL REPORT FOR THE BROAD SPECTRUM TEST; *IN VITRO* TEST METHOD:
CRITICAL WAVELENGTH**

Report Date: September 7, 2021	FSTI's Study #: 21-1166
Sponsor: [REDACTED]	FSTI 's Sample #'s: 21-1166-(1-3)
Formula Description: SPF 30	Sponsor's Formula #: [REDACTED] Sponsor's Lot #: 210134-13

Summary:

The Sponsor's test formula was tested, as per the attached Florida Suncare Testing (FSTI) test protocol, Appendix I. The test formula was prepared on 3 individual PMMA plates and scanned 5 times at different locations on each plate, resulting in a total of 15 measurements.


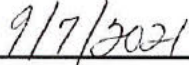
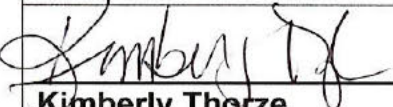
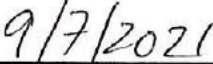
A graph depicting the mean scans of each plate is included in Appendix 2.

The results for the Critical Wavelength determination for the test formula are summarized in the following table.

FSTI's Study Number	Mean (Critical Wavelength)	Broad Spectrum Claim (Yes/No)
21-1166	371.53nm	Yes

This product **does meet** the requirement of a critical wavelength equal to or greater than 370 nm. Therefore a "Broad Spectrum" claim **can** be made for this product.

Approvals:

 Sherriel G. Wallace Clinical Director	 Date
 Kimberly Thorze Clinical Manager	 Date

FSTI STUDY NUMBER: 21-1166**SPONSOR:** [REDACTED]**SPONSOR'S FORMULA NUMBER:** [REDACTED]**SPONSOR'S LOT NUMBER:** 210134-13**SPONSOR'S FORMULA DESCRIPTION:** SPF 30**DATE RECEIVED:** September 7, 2021**DATE COMPLETED:** September 7, 2021**FSTI'S PROTOCOL NUMBER:** Attached (2011-06)**I. OBJECTIVE**

To measure the critical wavelength for a sunscreen formula, *in vitro*, in accordance with the "Broad Spectrum Test" of 21 FDA CFR Parts 201 and 310, Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule. Federal Register, Vol.76, No. 117, June 17, 2011. The test is performed utilizing an Optometrics LLC, Model SPF-290S UV spectrometer Analyzer System, equipped with the WinSPF Software version 4.5.

II. TEST FORMULA DESCRIPTION

FSTI's Study Number	Sponsor's Formula Number	Sponsor's Lot Number	Sponsor's Formula Description
21-1166	[REDACTED]	210134-13	SPF 30

III. TEST MATERIAL HANDLING

FSTI received the test formula described above from [REDACTED]
Table 1 below indicates the coding sequence of the test plates

Table 1

Plate ID	Sponsor's Formula Description
21-1166-1	SPF 30
21-1166-2	SPF 30
21-1166-3	SPF 30

IV. ARCHIVING

All original protocols, raw data sheets, and copies of final reports are maintained on the premises of Florida Suncare Testing, Inc., in limited access storage files in accordance with FSTI SOP# 2008-10. A duplicate copy of all final reports is kept on a secured, password-protected hard drive.

Appendix 1



PROTOCOL FOR THE BROAD SPECTRUM TEST; *IN VITRO* TEST METHOD: CRITICAL WAVELENGTH

Study 21-1166

I. OBJECTIVE

To measure the critical wavelength for a sunscreen formula, *in vitro*, in accordance with the "Broad Spectrum Test" of 21 FDA CFR Parts 201 and 310, Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. Final Rule. Federal Register, Vol.76, No. 117, June 17, 2011, and per Florida Suncare Testing, Inc. SOP 2011-06. The test is performed utilizing an Optometrics LLC, Model and a SPF-290S UV spectrometer Analyzer System, equipped with the WinSPF Software version 4.5.

II. STUDY TYPE

In vitro study, with the critical wavelength determined of the absorbance curve obtained by measuring the UV transmittance of the test formula.

III. TEST PRODUCT

FSTI's Study Number	Sponsor's Formula Number	Sponsor's Lot Number	Sponsor's Formula Description
21-1166	██████████	210134-13	SPF 30

TEST FORMULA DESCRIPTION

A. UV Spectrometry

- 1. Plate.** The plates to be used are constructed of optical grade polymethylmethacrylate (PMMA) suitable for UV transmittance measurements. The plates are roughened on one side to a three dimensional surface topography measure (Sa) between 2 and 7 micrometers. They are square with all sides being 5 cm.
- 2. Sample Holder.** The SPF-290S used in this test is equipped with a horizontal x-y stage that holds the PMMA plate in a horizontal position. It is mounted as close as possible to the input optics of the spectrometer to maximize capture of forward scattered irradiation.

It has a suitable aperture through which UV radiation can pass. The PMMA plate will be placed on the upper surface of the sample holder with the roughened side up.

3. *Light source.* The SPF-290S has a xenon light source that produces a continuous spectral distribution of UV radiation from 290 to 400 nanometers.
4. *Input optics.* The SPF-290S is equipped with an integrating sphere.
5. *Dynamic range of the spectrometer.* The dynamic range of the SPF-290S is sufficient to measure transmittance accurately at all terrestrial solar UV wavelengths (290 to 400 nm).

B. Test formula application to PMMA plate

The test formula will be applied to the PMMA plate on the roughened side at .75 mg per square centimeter. The test formula will be applied in a series of small dots over the entire plate and then spread evenly with a gloved finger (finger cot). Spreading will be done with a very light spreading action for approximately 30 seconds followed by spreading with greater pressure for approximately 30 seconds. The plate will then be allowed to equilibrate for 15 minutes in the dark before irradiation.

C. Test formula irradiation

The PMMA plates with the test formula will be irradiated with the Oriel as specified in section 352.70(b) of FDA, 21 CFR Part 352, Sunscreen Drug Products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph, Federal Register, Vol. 72, No. 165, August 27, 2007. The irradiation dose will be equivalent to an erythema effective dose of 800 J/m² (i.e., 800 J/m² – eff).

D. Calculation of mean transmittance values

After the irradiation, mean transmittance values will be determined for each wavelength over the UV spectrum (290 to 400 nanometers) using the SPF-290S. The transmittance values will be measured at 1 nanometer intervals. 5 measurements of spectral irradiance transmitted for each wavelength through a PMMA plate coated with 15 microliters of glycerin will be taken and stored in the computer's memory along with the mean of the 5 measurements using the SPF-290S, this is called the reference reading. Then this procedure is repeated for 5 measurements with the PMMA plate coated with the test product, again the mean is computed and stored. The computer can then ratio the mean reference reading at each wavelength with the mean test formula reading to compute the mean test formula transmittance.

E. Calculation of mean absorbance value

Mean transmittance values, are converted into mean absorbance values, at each wavelength by taking the negative logarithm of the mean transmittance value. The WinSPF's software makes this conversion.

F. Number of plates

3 individual PMMA plates will be utilized for this test. Each plate will be scanned 5 times at different locations, resulting in a total of 15 measurements.

G. Calculation of the critical wavelength

The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm. A mean critical wavelength of 370 nm or greater is classified as broad spectrum protection.

V. REPORTING

At the completion of the study, the Technician will provide the Sponsor with a final report.

VI. PRIVACY POLICY

Each study will be issued an individual study number. All final reports and any supporting documents will always be held in the strictest confidence and filed using the individual study number only. No one other than the Study Sponsor and the Staff of Florida Suncare Testing, Inc. will have access to the results from this study. Test products are identified by a study number. At no time will the Sponsor or Manufacturer's identity, product name, or any other information be shared unless requested by a regulatory government agency and then only on a need to know basis.

VII. PROTOCOL APPROVAL

For: [REDACTED]

Approved By: Sample Submission Form on File Date: September 7, 2021

For: Florida Suncare Testing, Inc.

Approved By: *Sherriel G. Wallace* Date: 9/7/2021
Sherriel G. Wallace, Clinical Director

Appendix 2

