Sun Protection Factor Final Report

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Report Date: 11/28/2022	**FSTI Study / Sample #: 22-1516**
Sponsor Formula #: [redacted]	**Sponsor Lot #: p.01-AP-132**
Sponsor: Sonrei Skin [redacted] **Santa Barbara, CA 93105**	**Sample Description: Sonrei SPF 30 Spray Organic**

Summary:

The sponsor test product sample, Formula # 20-SP-010, was tested under FSTI (Florida Suncare Testing, Inc.) SOP # 2021-02 80 Minute Water Resistant SPF testing as set forth by the FDA, Over the counter monograph M020:Sunscreen Drug Products for Over-the-counter Human use (posted September 24, 2021) as part of the Final Administrative order (OTC000006) effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136 on March 27, 2020. Part D - Testing Procedure. M020.80 Sun Protection Factor (SPF) test procedure.

The ten (10) subject test panel study yielded a mean 80 Minute Water Resistant SPF value of **36.63, Label SPF 34**. See Page 9 (Table 1) of this report for a summary of all test results obtained in this study.

The FDA Standard Sunscreen Product tested concurrently with the experimental test sample yielded a mean Static SPF value of 17.79, within the allowable guidelines of 16.3 ± 3.43.

Approvals:

[redacted] **FSTI Clinical Research Director**	11/28/2022 **Date**
[redacted] **Board Certified Dermatologist**	11/29/22 **Date**

FSTI SAMPLE NUMBER: 22-1516

SPONSOR: Sonrei Skin
[redacted]
Santa Barbara, CA 93105

SPONSOR FORMULA #: [redacted] **SPONSOR LOT #:** p.01-AP-132

STUDY START DATE: October 24, 2022 **DATE COMPLETED:** November 22, 2022

I. OBJECTIVE

To measure the Sun Protection Factor (SPF) value for the sponsor test sample following 80 Minutes water immersion and the static SPF value for the FDA standard sunscreen product under the guidelines of FSTI (Florida Suncare Testing, Inc.) SOP # 2021-02 using Over the counter monograph M020:Sunscreen Drug Products for Over-the-counter Human use (posted September 24, 2021) as part of the Final Administrative order (OTC000006) effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136 on March 27, 2020. Part D - Testing Procedure. M020.80 Sun Protection Factor (SPF) test procedure.

II. STUDY TYPE

Ten (10) subject 80 Minute Water Resistant SPF study, with a final report furnished to the sponsor, which includes subject demographics, individual, mean SPF and Label SPF values of the sponsor's test sample.

III. SAMPLE DESCRIPTION

Sonrei SPF 30 Spray Organic, Formula # [redacted], Lot # p.01-AP-132, FSTI Sample # 22-1516.

IV. TEST MATERIAL HANDLING

The Sonrei Skin test sample, labeled Formula # [redacted], Lot # p.01-AP-132, was assigned Florida Suncare Testing, Inc. sample number 22-1516 and entered into the SPF test submission log. The FDA standard 16.3 SPF sunscreen, as described in M020.80 Sun Protection Factor (SPF) test procedure (b) SPF standard, was used concomitantly as the control test product for this study.

V. 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, Florida Suncare Testing, Inc. computer hard drive and also backed up offsite.

VI. PANEL DESIGN

Number of Subjects enrolled 10

Number of Subjects completing study 10

Age Range .....26 – 63

Male .....4 Female 6

Skin Types: I (3) II (4) III (3)

VII. PANEL COMPOSITION

A. Fair-skinned subjects, male and female, eighteen years of age or older, of skin types I, II, or III as defined in M020.80 Sun Protection Factor (SPF) test procedure (c) Test subjects (2) Medical History (i).

Type I - Always burns easily; never tans (sensitive)

Type II - Always burns easily; tans minimally (sensitive)

Type III - Burns moderately; tans gradually (normal)

B. The test panelists were selected based on the following criteria:

a. Inclusion Criteria

1. Individuals eighteen years of age or older.

2. Individuals with fair, uniformly-colored skin on the lower area of the back which would allow a discernable erythema.

3. Individuals free of any dermatological or systemic disorder which, in the opinion of the testing personnel, would interfere with the results of the study.

4. Individuals in good health who have completed a preliminary medical history.

5. Individuals who have read, understood and signed a consent document in compliance with 21 CFR 50.

b. Exclusion Criteria

1. Individuals with any visible skin disease at the study site, which in the opinion of the investigative personnel would, interfere with the study results.

2. Individuals taking medications which might affect study results, e.g.,.photosensitizers, antihistimines, analgesics or anti-inflammatory drugs.

3. Females who are pregnant, planning a pregnancy or nursing a child

4. Individuals with a history of skin cancer.

5. Individuals with a history of hepatitis or other blood disease.

6. Individuals with a known sensitivity to cosmetics, skin care products or topical drugs as related to product(s) being evaluated.

7. Individuals with recent sun exposure on the areas to be tested.

VIII. INFORMED CONSENT

An informed consent was signed by each volunteer prior to initiating the study describing the purpose of the study, the test procedure, potential risks and benefits of participating, as well as the limits of liability. Each subject completed an extensive medical history form and was assigned a subject identification number. These forms are available for inspection on the premises of Florida Suncare Testing, Inc. only.

IX. LIGHT SOURCE

SPF testing conducted under the test guidelines of FDA 2021 will be performed utilizing Solar Light Company Model 16S Single-Port Solar Simulators, with a 150 watt xenon arc solar simulator lamp which provides a continuous light spectrum from 290-400 nanometers with a limit of 1500 watts per square meter (W/m2) of total irradiance for all wavelengths between 250-EPC 0905-01500 nanometers. The spectral output of the solar simulators, with a dichroic mirror and WG320 and UG11 filtering which meet the spectral output requirements for testing Sunscreen Drug Products for over-the-counter human use as directed in M020.80, Part D, Testing Procedures, (a) UV Source (solar simulator), Section 1, Emission Spectrum, posted September 24, 2021. The UV doses are constantly monitored and accurately delivered using a Model DCS-2 Dose Control System equipped with a Model 2105 UVB detector.

X. GENERAL TESTING PROCEDURE

Day 1

Subject Enrollment

The test subjects reported to the testing laboratory and received a complete explanation of the study procedures. Those who participated signed a written, witnessed consent form, and a permission to release personal health information form and provided a brief medical history. The technician did a final examination of the subject's back, between the belt-line and shoulder blades and determined their suitability to participate in this study.

MEDu UV Dose Administration

1. A series of 5 UV radiation doses expressed as Joules/square meter, increasing in 25% increments, was administered to two unprotected separate locations on the test subject's back, just below the shoulder blades and above the belt-line, to determine the initial unprotected MED (MEDu).
2. The test subjects were instructed to avoid additional UV exposure, and to avoid taking any photosensitizing medications until the conclusion of the study.
3. The MEDu was administered in the following 5 dose series, with X representing the amount of UV energy projected to produce the test subject's MEDu:

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.64X	0.80X	1.00X	1.25X	1.56X

Day 2

MEDu Determination

1. Subjects returned to the testing laboratory within 16 to 24 hours following completion of the MEDu doses for evaluation of their responses, and to determine each subject's unprotected MED (MEDu).
2. The subject's Minimal Erythemal Dose (MED) was the quantity of erythema effective energy, or dose corresponding to the first site that produced the first unambiguous erythema reaction with clearly defined borders. Table A below shows the grading scale used in this study for determining a MED (+) response.

Table A

-	No perceptible erythemal response
?	Barely perceptible erythemal response
+	Unambiguous erythema reaction with clearly defined borders (MEDu)
++	Moderate erythema with sharp borders
+++	Dark red erythema with sharp borders

Application of Product for SPF Determination

Two test areas (10 cm x 5 cm), 50 square centimeter rectangles, were drawn in the designated locations on the subject's back, (between the beltline and the shoulder blade) using a template and an indelible marker. The technician applied the test formula in one of the test areas and the FDA standard sunscreen in the adjacent test area. The sunscreens were applied by "spotting" the product across the test area and gently spreading, using a finger cot (as specified in M020.80 Sun Protection Factor (SPF) test procedure (d) Sunscreen Application), until a uniform film was applied to the entire test area. A product density of 2 mg/cm2 was delivered to the test area. To accomplish this, the technician weighed an amount in excess of 100 mg, to allow for the residual amount left on the finger cot (approximately 10%). The test products were permitted to dry a minimum of 15 minutes prior to the Static UV exposures.

80 Minute Water Immersion Sequence

1. An indoor fresh water Jacuzzi maintained at 23 to 32 deg. Celsius was used in this testing procedure. Fresh water is clean drinking water that meets the standards in 40 CFR part 141.
2. The pool and air temperature, as well as the relative humidity was recorded prior to testing.
3. The SPF values for the test product submitted by the sponsor was determined after 80 Minutes of water immersion using the following procedure as specified in in M020.80 Sun Protection Factor (SPF) test procedure (d) Sunscreen Application (g), Determination of Water Resistance:

   a. Apply sunscreen product. (Followed by a minimum 15 minute waiting period after application).
   b. Twenty minutes of moderate activity in the water.
   c. Fifteen minute rest period. (Do not towel test sites)

d. Repeat steps b. and c. until a total of 80 Minutes of water immersion is achieved.
e. Conclude water test. (Air dry test sites completely without toweling)

4. Begin light source exposures to the 80 Minute water resistant test site areas in accordance with M020.80 Sun Protection Factor (SPF) test procedure (e) UV Exposure.

MEDp UV Dose Administration

The technician administered a series of 5 UV radiation doses expressed as Joules/square meter, as specified in M020.80 Sun Protection Factor (SPF) test procedure (e) UV Exposure, progressively increasing in increments of 15 percent, determined by the previously established MEDu (unprotected MED) from Day 1 and the expected SPF range of the test product. The MEDp was administered in the following 5 dose series with X representing the expected amount of UV energy required to produce a MEDp:

Expected SPF 16.3 (FDA Standard Static)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.76X	0.87X	1.00X	1.15X	1.32X

Expected SPF 30.00 (Test Product following 80 min Water Immersion)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.76X	0.87X	1.00X	1.15X	1.32X

MEDu Repeat UV Dose Determination

On Day 2, the technician administered a second timed series of 5 UV doses, increasing in 25% increments to an unprotected area of the subject's back to determine the subject's second day MEDu. The series of 5 doses included the original MEDu from Day 1 in the center as follows:

Multiple of Original MEDu (X)

Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
0.64X	0.80X	1.00X	1.25X	1.56X

Day 3

Evaluation of Responses to UV Doses Static & 80 min WR SPF and Repeat MEDu

1. Subjects returned 16 to 24 hours following completion of the UV doses from Day 2. The MED for all sites that received UV doses, both protected and unprotected areas was evaluated.
2. The study was conducted in a double-blinded manner. Neither the test subjects nor the designated staff member who evaluated the MED responses knew which sunscreen formulation was applied to which site or what doses of UV radiation were

administered, as he was not the technician who applied the sunscreen test products or administered the doses of UV radiation.

3. The grader evaluated and recorded the MED responses on both the unprotected and protected test sites under the following conditions:
   a. The source of illumination was a warm white fluorescent light bulb that provides a level of illumination of at least 450 lux at the test site.
   b. The test subject was seated when evaluated, the same as when the test sites were irradiated.

XI. CALCULATION OF SPF VALUES

SPF values were calculated for both the test product and the FDA standard using M020.80 Sun Protection Factor (SPF) test procedure (f) Determination of SPF, by calculating the ratio of the MEDp value produced in the sunscreen protected sites to the MEDu produced in the unprotected test area, for each individual using the following calculation:

$$MEDip / MEDiu = SPFi \text{ value}$$

Data from ten (10) subjects was used for calculating the test product's 80 Min Water Resistant Label SPF value. The mean SPF value (x) and the Standard Deviation (s) for these subjects was computed. The upper 5-percent point from the student distribution table (denoted by t) with n-1 degrees of freedom was obtained. The quantity A was computed using the formula A = ts/Square root n (with n representing the number of test subjects (10) in a full study). A label SPF value was calculated by determining the largest whole number less than X – A. Any test product with a label SPF less than 2 is not a sunscreen drug product and will not display an SPF value.

XII. REJECTION OF STUDY DATA

There are three (3) primary reasons for rejection of study data as noted in M020.80 Sun Protection Factor (SPF) test procedure (e) UV Exposure (5) Invalid Test data. The exposure series fails to elicit an MED response on either the protected or unprotected test sites; an MED response was noted on all the protected test sites, or the test subject was non-compliant (failed to follow instructions or withdrew from the study).

XIII. RESULTS

A total of ten (10) healthy subjects who fulfilled the test panel participation criteria were inducted into this investigation. The demographic data is shown in Section V., Panel Design. The individual, mean and label SPF values of the Sonrei Skin test sample, Sonrei SPF 30 Spray Organic, Formula # 20-SP-010, Lot# p.01-AP-132, FSTI Sample # 22-1516, are shown in Table 1, page 9.

XIV. ADVERSE EXPERIENCES

No adverse experiences were reported during this study.

XV. CONCLUSIONS

The Sun Protection Factor (SPF) of the above sample described herein; tested under 80 Minute "Water Resistant" conditions, yielded the following SPF values:

Sponsor Formula Number	FSTI Sample Number	Mean 80 min WR SPF	Label SPF
20-SP-010	22-1516	36.63	**34**

The FDA standard for this study had a mean static SPF value of 17.79 and satisfied all statistical criteria as specified in M020.80 Sun Protection Factor (SPF) test procedure (f) Determination of SPF.

References:

U.S. Food and Drug Administration, Over the counter monograph M020:Sunscreen Drug Products for Over-the-counter Human use (posted September 24, 2021) as part of the Final Administrative order (OTC000006) effective upon enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136 on March 27, 2020. Part D - Testing Procedure. M020.80 Sun Protection Factor (SPF) test procedure.

FLORIDA SUNCARE TESTING, INC.

FDA 2021 80 Min Water Resistant SPF

TABLE 1

Study No.: 22-1516

Date: November 28, 2022

Sponsor: Sonrei Skin

Sponsor Formula No.: [redacted]

Florida Suncare Testing, Inc.
QA Reviewed
By [redacted] Date: 11/28/2022

Sample Description: Sonrei SPF 30 Spray Organic

FSTI Sample No.: 22-1516

Subject Tested: 10

Subject ID Number	Sex	Age	Skin Type	Base MEDu Joules/M2	1902Z FDA Std. SPF Static	22-1516 20-SP-010 SPF 80 Min WR
3304	F	63	II	79.33/79.33	16.25	39.63
3258	M	59	I	59.50/59.50	18.83	39.67
2908	F	28	I	59.50/59.50	18.83	39.67
1831	M	42	III	79.33/79.33	18.75	39.63
2945	F	26	II	59.50/59.50	18.83	34.50
3120	M	42	III	79.33/79.33	18.75	30.00
2976	F	40	III	79.33/79.33	16.25	34.50
2748	M	26	I	59.50/59.50	16.33	39.67
3295	F	57	II	79.33/79.33	16.25	34.50
3330	F	39	II	59.50/59.50	18.83	34.50
		MEAN:			17.79	36.63
		STD DEVIATION:			1.31	3.46
		A = ts / sq root n			0.76	2.01
		X - A			17.03	34.62
		LABEL SPF			17	**34**