Test Protocol Outline

UVA PF by Persistent Pigment Darkening - 10 subjects

To determine UVA protection afforded by a sunscreen product using the Persistent Pigment Darkening (PPD) response.

Experimental Design
Panel Composition Normal, healthy, adult volunteers who are above 18 years of age.

Individuals must..
... exhibit good general health, who are not currently under a physician’s care for any medical condition
... have a self-reported Fitzpatrick Skin Types II, III, IV
... have no uneven skin tones, pigmentation, scars or other irregularities within the treatment area.
... refrain from using other topical products or anti-inflammatory drugs during the study.
... not be pregnant or lactating.
... not present a history of skin cancer(s), toxic or allergic responses to sun exposure or photosensitive skin disease(s).
... not have atopy, psoriasis, eczema, or other chronic skin diseases.

Informed consent will be obtained.

Method
Light Source is a 150 watt Xenon Arc Solar Simulator (Solar Light Co, Philadelphia, Pennsylvania Model 12S, 14S or Model 600.) equipped with an Ultraviolet (UV) reflecting dichroic mirror, 3mm thick Schott WG-335 filter together with a 1mm thick Schott UG-11 filter to produce simulation of the UVA solar spectrum.

UVA radiation is monitored continuously during exposure using a Model DCS-1 Sunburn UV Meter/Dose Controller System (Solar Light Co.), formerly known as the Robertson-Berger Sunburn meter (R-B meter).

The mid to lower untanned back, lateral to the midline, is used for the treatment and exposure areas.

MPPD Determination
The threshold dose for PPD in unprotected skin is determined over the mid to lowed back by administering a series of exposures in 25% dose increments of UVA radiation in geometric progression. The minimum PPD dose (MPPD) is the smallest UVA dose required to produce PPD 2 to 4 hours after exposure. A minimum of 5 exposures are made. The MPPD of unprotected skin is determined under standardized lighting conditions 2 to 4 hours after exposures. The threshold response is taken as an unequivocal pigment darkening with distinct borders which persisted for at least 2 to 4 hours.

Persistent pigmentation on each sub site is graded according to the following 4 point ordinal scale:
0 = No discernible pigment darkening +/- = Barely perceptible pigment
1 = unequivocal pigment darkening, distinct borders, lasting more than 2 to 4 hours
2 = pronounced pigment darkening, lasting more than 2 to 4 hours.

Test Material Application and UVA Exposure
2.0mg/cm2 or 2 ul/cm2. Fifteen minutes after application, a series of UVA light exposures were administered at 25% increments. The threshold PPD within each site is determined.

The UVA - Protection factor (UVA-PF) is calculated as  UVA-PF = MPPD (Seconds) - Protected Skin
                      MPPD (Seconds) - Unprotected Skin

Reporting:
The mean UVA Protection factor (UVA-PF) of the sample when tested with a WG-335 filter is reported.

References
Japan Cosmetic Industry Association - J.C.I.A. - measurement standards for UVA protection efficacy