

JCIA In vivo UVAPF - 10 subject



Test Conditions

Test Subjects

A minimum of 10 subjects are inducted for the study. According to statistical variability, additional test subjects may be included in the study.

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

Overview

JCIA adopted the ISO 24442 test method in 2012 and this will be official from 1st Jan 2013. There are now 4 categories (previously 3).

UVAPF	Protection Grade
2 to less than 4	PA+
4 to less than 8	PA++
8 to less than 16	PA+++
16 or more	PA++++

UVAPF is the Lowest ultraviolet A (UVA) dose that produces the first perceptible unambiguous persistent pigment darkening response with defined borders appearing over most of the field of UVA exposure, observed between 2 h and 24 h after the end of the UVA exposure.

The UVA - Protection factor (UVAPF) is calculated as ...

$$\frac{\text{MPPD (Seconds) - Protected Skin}}{\text{MPPD (Seconds) - Unprotected Skin}}$$

SPF must also be tested in accordance with JCIA SPF Measurement Standard (2011)

Experimental Design

Panel Composition Normal, healthy, adult volunteers who are above age of consent and up to 70 years.

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 with 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 .

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Method

The area of the back between the scapula line and the waste is utilised.

Light Source is a 150 watt Xenon Arc Solar Simulator 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).

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 persist for more than 2hrs 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.

Persistent pigmentation on each sub site is graded according to the following 4 point ordinal scale:

0 = No discernible pigment darkening +/- = Barely perceptible pigment.

+ = unequivocal pigment darkening, distinct borders, lasting more than 2 hours.

++ = pronounced pigment darkening, lasting more than 2 hours.

Reporting:

The mean UVA Protection factor (UVAPF) of the sample, when 10 subjects tested is reported.

Labelling

This must be in compliance with requirements of the JCIA. A reference can be made to "values based on ISO 24442"

References

Japan Cosmetic Industry Association Measurement Standards for UVA Protection Efficacy (2012 revised edition).

ISO 24442 Cosmetics - Sun Protection test Methods -In vivo determination of sunscreen UVA prtction.

Standard for the Fair Advertising Practices of Drugs, Quasi-drugs, Cosmetics and Medical Devices.

Dermatest DESOP - 027 Procedure for Conducting UVA Study - Persistent Pigment Darkening Method - JCIA Method