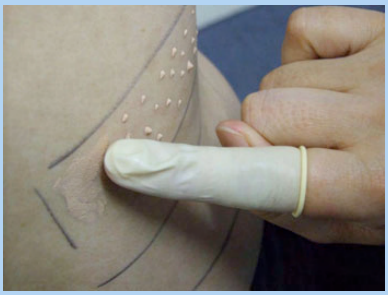
eurofins | Dermatest

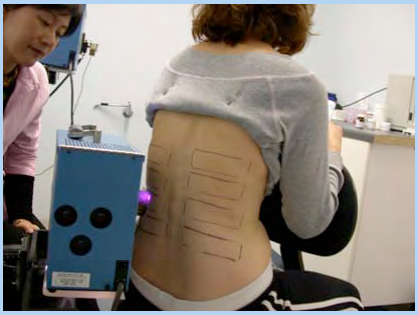
SPF FDA Protocol

STEPS

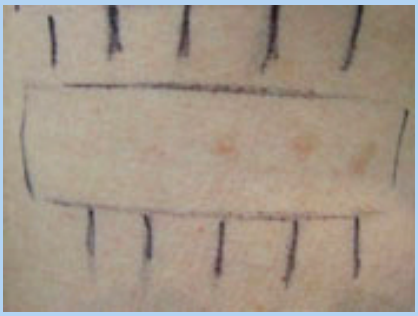


1.Product Application

2. Water Resistance Challenge



3. Solar Simulator



4. Reading of Results

Compliance with this protocol is a mandatory requirement for FDA and is either Static (No swim) or Water Resistance testing according to client requirements. If water resistance is claimed, the SPF value must be the post swim result at 40 min or 80 minutes as tested. Broad Spectrum claims require compliance with the in-vitro Critical Wavelength test (separately described) and applies for sunscreens with SPF 15 and above where claims related to aging are skin cancer are to be made.

Solar Simulation
The light source employed is a 150 watt Xenon Arc Solar Simulator compliant with FDA requirements. Exposures are taken at a position within 8 mm from the surface of the skin. The field of irradiation is not less than 0.5 cm square.

Determination of the Static Sun Protection Factor (Where conducted)
The procedure for this study is outlined in FDA Final Monograph. One test site area served to determine each subject's Minimal Erythema Dose (MED). The individual subject's MED is the shortest time of exposure that produces minimally perceptible erythema at 16 to 24 hours post irradiation.
The Reference Sunscreen Product is delivered to the test site through plastic volumetric syringes. The material is evenly applied to a rectangular area for a final covering of 2.0 mg/cm2. The test area is air dried prior to exposure from the solar simulator using designated 12.5% or 25% increments. The exact series of exposures given is determined by the control MED and the expected SPF of the product.

Determination of Water Resistance (Where Conducted)
This test is employed to determine the substantivity of a test product and its ability to resist water immersion.
The procedure is as outlined at page 35648 of the Federal Register and consists of cycles of 20 min immersion followed by 15 minutes drying time.

Panel Composition 10 to 13 Normal, healthy, adult volunteers who are above 18 years of age.
Individuals are selected form skin types I, II, or III. Informed consent will be obtained.
Individuals free of any dermatological or systemic disorder which would interfere with the results.
Individuals who have completed a preliminary medical history evaluation.
Individuals who have read, understood and signed an informed consent document relating to the specific study to which they are subscribing.
Individuals with no known abnormal response to sunlight.

Standard for Exclusion of a Panelist from a Study Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
Individuals with chronic skin allergies.
Individuals with suntan or sunburn.
Individuals with abnormal reaction to the sun.
Pregnant or lactating females.

FDA Final Monograph Federal Register /Vol 76 No. 117/ Friday June 17, 2011 Rules and Regulations
Dermatest Standard Operating Procedures Manual

Eurofins Dermatest Pty Ltd
20 - 22 King St
Rockdale NSW Australia
ph 61 2 9556 2601
info@dermatest.com.au