

## FDA Ruling and the SPF-290AS™

The FDA has recently published the document (21 CFR Parts 201 and 310 Labeling and Effective Testing: Sunscreen Drug Products for Over-the-Counter Human Use) to address effectiveness testing for over the counter (OTC) sunscreen products containing specified active ingredients. This FDA document contains specific sections that pertain to Sunscreen Protection Factor (SPF) testing and specifies criteria that relates to the use of the Solar Light SPF-290AS™ Sunscreen Protection Factor instrument.

The following points address specific technical issues called out by the FDA document and how they compare with or parallel the SPF-290AS™ instrument and its capability.

The above information indicates that the SPF-290AS™ is suitable for the testing as outlined in the FDA document (21 CFR Parts 201 and 310) for effectiveness testing for over the counter (OTC) sunscreen products.

### Measurements

The SPF-290AS™ is a recording UV spectrophotometer designed and optimized for the determination of SPF values on a variety of sunscreen and cosmetic products reducing the need for in-vivo testing.

Covering both the UVB and UVA spectral regions, the system automatically scans from 290nm to 400nm. Accumulating and storing data at intervals of 1, 2 or 5nm. The Monochromatic protection factor (MPF) is determined for each of the selected wavelengths and is used to calculate the SPF value, using solar irradiance and erythemal constants that are programmed into the software but which can be easily modified.

In addition to sunscreen products, the SPF-290AS™ also complies with the AATCC-183 Fabric Test. Method, enabling its use in a number of testing environments.

The SPF-290AS™ provides highly repeatable results, and has a Windows software interface, allowing for ease of use and high throughput. This results in faster formulation and lower development costs due to the reduction in the need for expensive and time consuming in-vivo panel studies.

For additional information, consult factory.

Parameter	FDA Ruling	SPF-290AS™
Plate	Use optical-grade polymethylmethacrylate (PMMA) plates suitable for UV transmittance measurements.	The SPF-290AS™ can be used with any UV transmissive substrate including PMMA plates.
Term Spectroradiometer	Spectrometer	The SPF-290AS™ can be classified as a Spectrometer.
Light Source	The light source should produce a continuous spectral distribution of UV radiation from 290nm to 400nm.	The xenon lamp in the SPF-290AS™ continuously emits radiation over the 290-400nm range specified.
Input Optics Bandwidth	The spectrometer input slits SHOULD BE set to a bandwidth that is less than or equal to 1 nm.	While the WinSPF™ software can measure in 1nm intervals the input optics of the SPF-290AS™ are limited to 1.6nm. Other commercially available machines operate at <4nm.
Dynamic Range of the Spectrometer	The dynamic range of the spectrometer should be sufficient to measure transmittance accurately through a highly absorbing sunscreen product at all terrestrial solar UV wavelengths (290nm to 400nm).	The dynamic range of the SPF-290AS™ is sufficient over the range of 290nm to 400nm and is assured by a system calibration test that can be performed prior to every use, if desired.
Application of Sunscreen	The product is applied at 0.75 mg per square centimeter.	This parameter is controlled by the operator.
Pre-Irradiation Dose	The irradiation dose should be 4 MEDs which is equivalent to an erythemal effective dose of 800 J/m <sup>2</sup> .	The pre-irradiation dose should be done with a calibrated solar simulator, not with the SPF-290AS™.
Calculation of 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 290nm to 400nm.	This is the criteria the SSPF-290AS™ uses to calculate critical wavelength.
Number of Transmittance Measurements	Values should be determined from at least 3 individual PMMA plates. This section requires at least 5 measurements per plate. There should be a total of at least 15 measurements.	The SPF-290AS™ can perform up to 12 measurements per plate.