MED Determination Using SLC Solar Simulators

Application Note 122

Introduction

Since 1966, Solar Light Company has produced solar simulators for biological research and SPF tests. Aptly named for the product line which focuses on biological effects of sunlight, Solar Light continues to set the standard for biologically significant ultraviolet light simulation and measurement. The U.S. Food and Drug Administration provides strict guidelines for the evaluation of the Sun Protection Factor (SPF) of over the counter, commercial sunscreens. An SPF value is determined utilizing data from MED measurements. MED (or minimal erythema dose) is the minimal amount of ultraviolet wavelength energy required to produce a well-defined reddening of human epidermal tissue. By comparing MED data of protected (e.g. applied topical sunscreen) versus MED measurements of unprotected skin, an SPF value can be applied to specific products and / or individuals. All of these procedures require the use of high quality equipment in order to facilitate the validity and repeatability of MED determination methodology and results. Due to their high standards of technical proficiency, the engineers at Solar Light Co. have developed state of the art equipment that has set the standard in the field of MED determination and SPF evaluation; so much so that approximately 90% of the field utilizes SLC technology.

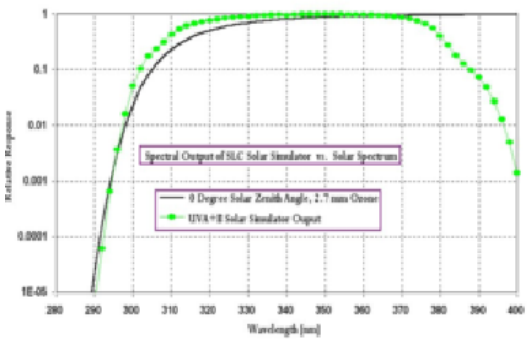
Application Guidelines

Current FDA regulations require a solar simulator utilized for MED / SPF testing to adhere to strict well-defined guidelines. These regulations have raised the quality benchmark for designers and manufacturers in the solar simulator production field. The following highlights each important FDA tenet concerning simulator use for MED determination. In each instance we have provided information why Solar Light Co. Solar Simulators fulfill the specified requirement.

"A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers similar to sunlight at sea level…"

All solar simulators produced by SLC effectively reproduce the solar, ultraviolet spectrum from 290 to 400 nm. Below is a graph of the typical output of a SLC Solar Simulator (data obtained from a 16S-300W Single Port Solar Simulator).

Typical Output of a Solar Light Company Solar Simulator

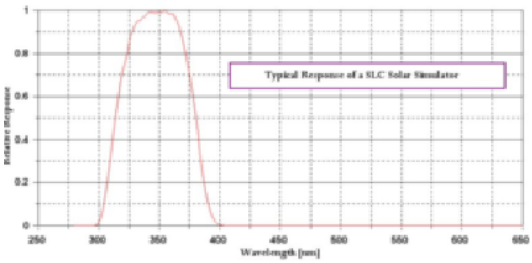


Evident from the preceeding graph, the spectral output of Solar Light Company Solar Simulators reproduces the sun's spectral profile accurately in the 290 to 400 nm range. This feature also acts to minimize the heat load that a subject must bear during exposure due to the absence of infrared bandwidth presence. This facilitates testing protocols which require prolonged exposure periods.

"… less than 1 percent of [the simulator's] total energy output contributed by nonsolar wavelengths [shall be] shorter than 290 nanometers; and it has not more than 5 percent of its total energy output contributed by wavelengths longer than 400 nanometers."

Below is a diagram that shows a typical SLC Solar Simulator response from 250 to 650 nm:

SLC Solar Simulator Response from 250 to 650 nm

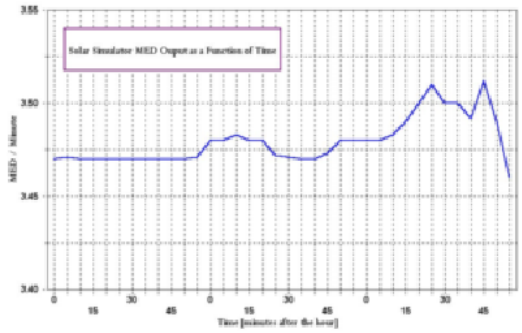


As seen from the above diagram, the typical response of a Solar Light Company Solar Simulator is predominately "flat" at wavelengths greater than 400 nm and less than 290 nm. This more than satisfies the FDA requirement limiting energy distributions of nonsolar wavelength radiation.

"… a solar simulator should have no significant time-related fluctuations in radiation emissions after an appropriate warmup time …"

In the following graph we show the typical MEDs per minute output of a SLC Solar Simulator over a period of three hours (data collected from a 601 series Multiport Solar Simulator):

MED / Min Output of Typical SLC Solar Simulator



Continued…

For the entire three hours of operation recorded above, the simulators output remained approximately within 3.44 and 3.52 MED / Minute. The average output of the simulator over this three hour of operation is 3.48 MED / Minute. Thus, output fluctuations over this period of time are +1.4% / -1.2%. Such a small deviation over an extended period of operation can be considered insignificant and more than qualifies the output of a SLC Solar Simulator as stable.

"... [a solar simulator used for MED determination] should have good beam uniformity (within 10 percent) in the exposure plane."

Perhaps the most difficult aspect of solar simulator engineering is radiation intensity uniformity across the exposure plane of a simulator. This problem becomes more demanding as the exposure area of simulator increases. Using new ideas and approaches to optical design, the engineers at Solar Light Company have successfully circumvented this obstacle. The data below displays the output of a LS-1000W SLC Solar Simulator with is configured to produce a 4" square beam:

The table to the bottom left is composed of intensity readings measured at specific intervals across the 4" x 4" exposure area. The field uniformity information is obtained from this data. What is refered to as "Beta Percent Difference" is a measure of uniformity defined as the ratio of the difference of the max and min intensities to the sum of the max and min intensities normalized to 100. Below is an energy histogram which conveys the information contained in the table above visually:

SOLAR® LIGHT

100 E.Glenside Ave, Glenside, PA 19038
Tel: 215-517-8700 | Fax: 215-517-8747
info@solarlight.com | www.solarlight.com