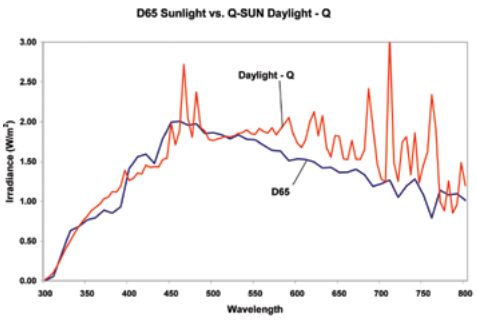
PRODUCT SUMMARY LX-5014

Photostability Testing for Cosmetics & Pharmaceuticals (ICH Guidelines)

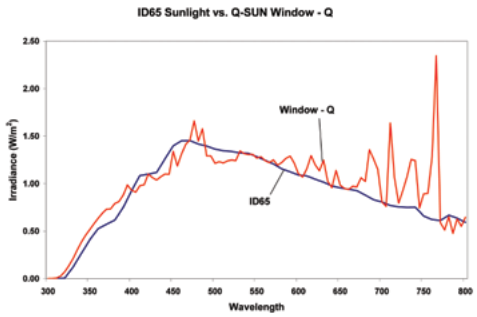
The Q-SUN® xenon test chamber from Q-Lab offers state-of-the-art, full-spectrum photostability test exposures for pharmaceutical and cosmetics applications. Q-SUN testers are available in two sizes with options that meet ICH *Guidelines for Photostability Testing of New Drug Substances and Products*, including simulation of direct sunlight or sunlight through window glass. Accurate control of light intensity and temperature ensures repeatable and reproducible results. These features enable the Q-SUN chamber to perform photostability tests according to in-vitro test procedures for sunscreens.

Key Features: Simplicity & Accuracy

- Simple operation and lamp replacement so you can concentrate on what's most important: your tests!
- Full spectrum xenon arc lamp and optical filter system creates D65 and ID65 sunlight simulations that enable you to test your products against outdoor or indoor daylight.
- SOLAR EYE® Irradiance Control monitors and controls the light intensity to ensure your tests are repeatable and reproducible.
- Precise control of chamber air or black panel temperature gives you flexibility to determine the effects of different temperature environments on photodegradation.
- Optional chiller unit enables tests to be run at room temperature or as low as 15 °C so you can determine the synergistic effects of light and heat on your materials and products.



This chart shows the Q-SUN chamber's Daylight-Q filter compared to D65 outdoor sunlight.



This chart shows the Q-SUN chamber's Window-Q filter compared to ID65 indoor daylight.

Two Sizes - All the Critical Features

The Q-SUN tester comes in two sizes with all the critical features for pharmaceutical and cosmetics applications. The Xe-1 is available in a convenient tabletop size and offers an optional chiller. For labs that need high throughput, the Xe-3 is a free-standing unit with triple the capacity. The Xe-3 also provides precise control of relative humidity.

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ICH Guidelines

Photostability testing of drug substances and products can be done several ways according to the ICH Guidelines. The exposure requirements are defined as ***minimum*** values within the visible and ultraviolet ranges:

- Visible Light: 1.2 million lux-hours.
- Ultraviolet Light: 200 W-hr/m² of integrated UV energy (spectral range of 300-400 nm)

Under the ICH Guidelines, it is perfectly acceptable to expose specimens to higher dosages in either range. In fact, light sources that meet the D65 or ID65 definition will achieve the ultraviolet energy dosage well before the visible light energy dosage. Therefore, a D65 or ID65 light source will create an "overexposure" of UV energy upon completion of the test.

Bottles and other oddly-shaped samples can be easily tested in a Q-SUN chamber due to its flat specimen tray and variety of mounting options.

Using the Q-SUN Test Chamber to Meet ICH Guidelines. The Q-SUN tester can be an ideal solution for ICH Guidelines (Option 1, for xenon arc testers) because of its excellent simulation of sunlight. Because the light intensity is not specified in ICH, a variety of test settings can be run in the Q-SUN unit to meet the minimum exposure requirements.

The ICH Guidelines do not specify whether the spectrum should match D65 or ID65. Commonly, the ID65 spectrum is simulated using a Window-Q filter in the Q-SUN because it represents sunlight entering a building interior. However, a Daylight filter is appropriate for outdoor applications such as hair dyes and sunscreens.

The table below gives some examples of Q-SUN chamber set points using a single-step exposure with a Window-Q filter and a 420 nm control point. These exposures meet the visible light (illuminance) requirements and provide much more than the required UV energy. Other control points and filters may be used - contact Q-Lab for details.

Set Point (420 nm)	UV Irradiance (300-400 nm)	Visible Light (Illuminance)	Test Duration	UV Energy	Visible Light Energy
0.60 W/m²	29.1 W/m²	45.0 klx	26.7 hours	775 W·hr/m²	1.20 Mlx·hr
1.10 W/m²*	53.4 W/m²	82.4 klx	14.6 hours	775 W·hr/m²	1.20 Mlx·hr
1.50 W/m²	72.8 W/m²	112.5 klx	10.7 hours	775 W·hr/m²	1.20 Mlx·hr

* 1.10 W/m² is a common set point in photostability tests.

The table below gives an example of a two-step exposure that meets both the visible light (illuminance) and UV energy requirements. This can be performed in a Q-SUN chamber using a 420 control point; one step uses Window-Q filters while the second adds a UV Blocking filter. Other control points and filters may be used - contact Q-Lab for details.

Step	Optical Filter	Set Point (420 nm)	UV Irradiance (300-400nm)	Visible Light (Illuminance)	Test Duration	UV Energy	Visible Light Energy
1	Window-Q	1.10 W/m²*	53.4 W/m²	82.4 klx	3.7 hours	197 W·hr/m²	0.30 Mlx·hr
2	UV Blocking	0.75 W/m²	0.4 W/m²	82.4 klx	11.0 hours	3 W·hr/m²	0.90 Mlx·hr
Total						**200 W·hr/m²**	**1.20 Mlx·hr**

Temperature and Relative Humidity Control

ICH Guidelines do not include temperature or relative humidity requirements. Tests are commonly performed in a variety of temperature environments, including normal room temperatures. Adding the optional chiller to the Q-SUN unit is recommended to achieve common room temperature conditions in the test chamber.

Although chamber relative humidity may not be critical for testing drug substances enclosed in packaging or test bottles, the Q-SUN Xe-3 provides precise control of RH for testing materials exposed to indoor or outdoor environments that may benefit from RH control.

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Q-Lab.com/support

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