Drug Photostability Kit

Purpose

This kit has been designed to assist compliance with the requirement for drug photostability testing

imposed by the International Conference of Harmonisation's Q1B stability testing guidelines.

Quinine Sulfate is used as an Actinometry Standard.

Description and Discussion

In 1996, the ICH (International Conference On Harmonisation) issued its Q1B guideline stating that the photostability characteristics of new drug substances and products should be evaluated to demonstrate that exposure to light does not result in unacceptable change.

The substance under test is exposed to ultra-violet light under controlled conditions, using quinine as an actinometry standard, exposed under the same conditions.

The kit contains four special UV quartz cells, each with a PTFE screw cap, ensuring that samples only come into contact with inert materials. They are engraved and used as follows:

1. **Sample –** Test cuvette, to be filled with sample under evaluation for exposure to radiation.
2. **Control –** Test cuvette, to be filled with sample under evaluation, and then wrapped in aluminium foil to protect completely from light, and used as the control.
3. **Q Sam. –** Calibration cuvette, to be filled with quinine sulfate solution for exposure to radiation.
4. **Q Ref. –** Reference cuvette, to be filled with quinine sulfate solution, and then wrapped in aluminium foil to protect completely from light, and used as the standard.

Accreditation

Starna Scientific is accredited to both ISO 17034 as a Reference Material producer, and ISO/IEC 17025 as a Calibration Laboratory for optical reference measurements. Starna Scientific's manufacturing facility is accredited to the ISO 9001 Quality Management System with BSI. For details see www.starna.com/accreditations.

How to Order

	CATALOGUE NUMBER
Starna Drug Photostability Testing Kit	**RM-PHOTOSTABILITY**