PHOTOSTABILITY

Drug applications for a new molecular entity or associated products must include data to demonstrate that light exposure does not result in an unacceptable change. The International Conference on Harmonization developed recommendations for the photostability of new drug substances and products (ICH Q1B).

Photostability studies are performed in a sequential manner starting with irradiating the drug substance, the fully exposed product then progressing, as necessary, to the product in the immediate package and then in the marketing package. Testing progresses until the results demonstrate that the drug product is adequately protected from exposure to light.

Forced degradation studies involve a deliberate attempt to cause light degradation of the pharmaceutical materials. These studies are a valuable tool for elucidation of a degradation pathway. For the development of stability indicating methods, forced degradation ensure that potential photodegradants are adequately resolved and detected. Confirmatory studies are used to establish the photosensitivity of products under standardized conditions. This information is used to identify precautionary measures that may be required for the manufacturing and storage of drugs. Photolabile materials may require light resistant packaging and special labeling to prevent degradation during normal handling and the product shelf-life.

The ICH guideline allows for selection of several light sources. Guidelines for confirmatory studies require samples be exposed to an overall illumination of not less than 1.2 million lux-hr and an integrated near ultraviolet energy not less than 200 watt hr/m^2. ICH Q1B Option 1 designates light sources including fluorescent sources, metal halide or xenon lamps emitting both visible and UV. These light sources may lead to overexposure and the metal halide and xenon lamps often produce excessive amounts of heat that may result in thermal degradation. ICH Q1B Option 2 utilizes two separate lamps including: 1) cool white fluorescent and; 2) near UV fluorescent lamp. Using two fluorescent sources allows independent control of the illuminance and UVA irradiance mitigating potential issues with overexposure and excessive heat.

R. D. Laboratories, Inc. is ready to assist you by performing photostability testing to ensure product quality and regulatory compliance. We utilize a Caron 6545-1 photostability chamber that is specifically designed to meet ICH, FDA, EMEA and Health Canada requirements for photostability testing according to ICH Q1B Option2.

We are able to provide uniform light intensity (typically UVA at 30 W•m^2 and visible at 30 klux) and temperature control (10°C to 35°C ±2.5°C) with continual monitoring to ensure compliance with each photostability protocol. The independent control of the near UV and cool white lamps allow programming to shut-off lamps based on an exposure level. Exposures are monitored with two light detectors with an integral radiometer to provide precise and accurate light intensity measurement. The light detectors are cosine corrected and calibrated with NIST traceable standards. The chamber is designed with specular aluminum surfaces to ensure uniform light reflection. Typical integrated near-UV and overall illumination exposure times are 6 hours and 40 hours to meet ICH recommendations. Please contact us for your photostability needs.

204 Lange Drive
Washington, Missouri 63090 USA
www.rdlaboratories.com

T636 390. 2622
F636 390. 2722