SOP # IJ-820-01-Y2K

STANDARD OPERATING PROCEDURES

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Actinometric procedures for monitoring exposure in photostability evaluations

1. PURPOSE

The purpose of this Standard Operating Procedure is to specify the Actinometric details and procedures for monitoring exposure to a near UV fluorescent lamp in photostability evaluations. These guidelines are based on June 1998 *draft* Guidance to Industry 'Stability testing of Drug Substances and Drug Products' based on work done by the FDA/National Institute of Standard and Technology studies.

2. Responsibility

Quality Control Unit personnel responsible for performing the testing.

3. Frequency

When a UV or alternative light source calibration is required .

4. Procedure

QUININE CHEMICAL ACTINOMETRY

4.1. The following provides details of an actinometric procedure for monitoring exposure to a near UV fluorescent lamp

4.2. Prepare a sufficient quantity of a 2 percent weight / volume aqueous solution of quinine monohydrochloride dihydrate (if necessary, dissolve by heating).

Option 1 - 20 mL ampoule method:

4.3. Put 10 milliliters (mL) of the solution into a 20 mL colorless ampoule (see ampoule drawing, below),

4.4. seal it hermetically, and use this as the sample.

4.5. Separately, put 10 mL of the solution into a 20 mL colorless ampoule seal it hermetically, wrap in aluminum foil to protect completely from light, and use this as the control.

4.6. Expose the sample and control to the light source for an appropriate number of hours.

4.7. After exposure, determine the absorbances of the sample (AT) and the control (AO) at 400 nm using a 1 centimeter (cm) path length.

4.8. Calculate the change in absorbance units as per formula;

- (AU): A = AT - AO.

The length of exposure should be sufficient to ensure a change in absorbance of at least 0.9 AU.

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Option 2 - Quartz Cell Method:

4.9. Fill a 1 cm quartz cell and use this as the sample.

4.10. Separately fill a 1 cm quartz cell, wrap in aluminum foil to protect completely from light, and use this as the control.

4.11. Expose the sample and control to the light source for an appropriate number of hours.

4.12. After exposure, determine the absorbances of the sample (AT) and the control (AO) at 400 nm.

4.13. Calculate the change in absorbance units as per formula;

- A = AT - AO.

4.14. The length of exposure should be sufficient to ensure a change in absorbance of at least 0.5.

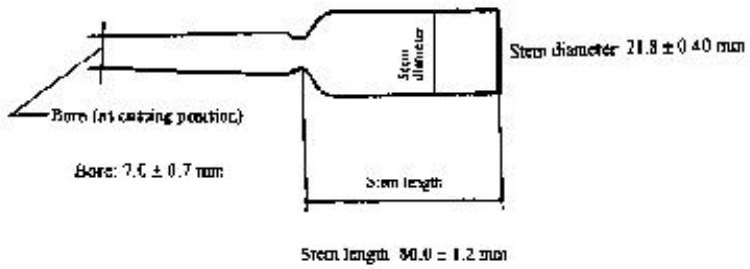
5. Limits and Limitations

The same approach as described above may be used for other light sources / actinometric systems, however each actinometric system should be calibrated for the actual light source used.

Alternative packaging configurations may be used if appropriately validated. Alternative validated chemical actinometers may be used.

6. Documentation

5.1 Note: Shape and Dimensions of 20 mL colorless glass ampoules.



REFERENCE

1. Yoshioka, S., "Quinine Actinometry as a Method for Calibrating Ultraviolet Radiation Intensity in Light- stability Testing of Pharmaceuticals," *Drug Development and Industrial Pharmacy*, 20(13):2049-2062, 1994
2. Japanese Industry Standard (JIS) R3512 (1974) for ampoule specifications.
3. ICH Q1B GUIDELINES

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