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Photodegradation of Solid and Liquid Products

Practical 9 - Practical study

Aim

To assess photostability of solid and liquid preparations using exposure and protected-control records.

Principle

Light can cause chemical or physical change. A qualified photostability study controls the spectral distribution, measured exposure and temperature and compares exposed material with appropriate protected controls.

Materials and Requirements

- Approved stability protocol and product-specific specifications
- Qualified chamber records and container details
- Stability-indicating assay, impurity and physical-test data
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define solid and liquid preparations, container configurations and the applicable photostability protocol.
2. Record the qualified light source, calibrated exposure measurements, placement and temperature controls.
3. Expose preparations only through the approved equipment procedure; retain matched protected controls.
4. Test intact drug, degradants and relevant physical attributes after the required measured exposure.
5. Compare exposed and protected results and identify the evidence needed for protective packaging.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Interval / batch	Actual storage condition	Assay / degradants	Physical / performance result
Initial	Record	Record	Record
Intermediate	Record	Record	Record
Final available point	Record	Record	Record

Calculations

- Light-associated assay difference = protected-control assay - exposed assay, in percentage points

Worked Example

Illustrative protected assay 99.5% and exposed assay 95.0% differ by 4.5 percentage points. Compare degradants and control behaviour before attributing the change solely to light.

Exposure record

- Record visible and near-UV exposures as required by the adopted guideline; lamp time alone is not an adequate exposure measurement.

Result and Interpretation

• Report the actual data period, trends, excursions and limits of any extrapolation.

Precautions

• Use product- and market-appropriate conditions rather than a universal chamber schedule.
• Keep container and sampling traceability.
• Do not estimate shelf life from assay alone.

Viva Questions and Answers

What is stability indicating?

The method can distinguish the intended analyte from relevant degradation and matrix effects.

Why study the marketed pack?

The pack can influence moisture, light and gas exposure.

Can one accelerated result prove expiry?

A justified programme and complete evidence are required.

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