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Long-Term and Accelerated Stability Study

Practical 10 - Practical study

Aim

To evaluate long-term or accelerated stability data and prepare a justified stability conclusion.

Principle

Stability assesses time-dependent chemical, physical, microbiological and performance attributes in the proposed container system. Accelerated conditions support an assessment but do not by themselves establish a universal expiry period.

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 the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define batches, pack orientation, storage conditions, intervals, tests and statistical plan in the protocol.
3. Verify chamber qualification and retain actual monitoring, excursions and sample-pull records.
4. Review content, degradants, physical attributes and performance at each interval using qualified methods.
5. Plot each relevant attribute against time; investigate atypical results without deleting them and assess the supported storage period.
6. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

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

- For a justified first-order model: ln(Ct/C0) = -kt; t90 = -ln(0.90)/k
- Do not extrapolate a shelf life without the applicable stability and statistical justification.

Worked Example

Illustrative first-order k = 0.0020 month^-1 gives t90 = 52.7 months mathematically.

This is a model calculation, not a product expiry claim. Real assignment requires the complete attribute, packaging and stability evidence.

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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