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Solubility Improvement by Co-Solvency

Practical 25 - Practical study

Aim

To determine how a selected cosolvent changes equilibrium solubility.

Principle

Changing solvent composition changes solvent-solute interactions. An empirical log-linear model may fit part of a composition range, but it is not a universal law and does not establish route-specific suitability.

Materials and Requirements

- Model drug, water and approved cosolvent
- Composition records and controlled equilibration
- Matrix-matched assay and separation controls
- 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. Prepare a series with explicitly stated mass or volume fractions; account for mixing contraction when relevant.
3. Equilibrate excess drug in each composition at the same temperature.
4. Separate the solid phase, verify recovery and assay with standards prepared in compatible matrices.
5. Plot log solubility versus cosolvent fraction and discuss the supported range and potential precipitation on dilution.
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.

Cosolvent fraction	Equilibration condition	Solubility	Log solubility
0.00	Record	Record	Calculate
0.20	Record	Record	Calculate
0.40	Record	Record	Calculate

Calculations

- Empirical fit: log10 S = log10 S_water + sigma x cosolvent fraction

Worked Example

Illustrative S_water = 0.010 mg/mL and sigma = 3.0. At fraction 0.20, predicted S = 0.010 x 10^0.6 = 0.0398 mg/mL.

Verify the model with measured data; do not assume the formulation remains soluble after dilution.

Result and Interpretation

• Report composition basis, fit limitations and dilution behaviour.

Precautions

• Use approved solvent handling and waste controls.
• Keep temperature constant.
• Assess volatility and actual mixture composition.

Viva Questions and Answers

Why specify fraction basis?

Mass and volume fractions differ.

What does sigma describe?

An empirical sensitivity of log solubility to cosolvent fraction.

What can happen on dilution?

Loss of solvent capacity can cause precipitation.

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