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Effect of Surfactants on Drug Solubility

Practical 7 - Practical study

Aim

To measure the influence of surfactant concentration on apparent equilibrium solubility.

Principle

Micelles and other surfactant assemblies can increase apparent drug solubility. The change depends on surfactant identity, concentration, medium and temperature; an analytical signal must distinguish dissolved material from suspended particles.

Materials and Requirements

- Model drug and approved surfactant levels including zero
- Controlled equilibration and phase-separation equipment
- Matrix-matched assay, blanks and recovery check
- 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 matched media with fixed pH and temperature, varying only surfactant concentration.
3. Equilibrate excess solid by the adopted method and confirm equilibration with time-point evidence.
4. Separate undissolved particles using a method checked for drug loss or micelle disruption.
5. Assay the clarified phases with matching blanks and compare solubility against surfactant concentration.
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.

Surfactant level	Equilibration time	Drug concentration	Relative solubility
Zero	Record	Record mg/mL	Baseline
Low	Record	Record mg/mL	Calculate
High	Record	Record mg/mL	Calculate

Calculations

- Solubility enhancement ratio = apparent solubility in test medium / solubility in matched surfactant-free medium

Worked Example

Illustrative concentrations 0.020 and 0.120 mg/mL give a sixfold enhancement.

This does not prove that unbound drug concentration or absorption increases sixfold.

Result and Interpretation

• Plot the measured concentrations and describe uncertainty, equilibration evidence and filtration controls.

Precautions

• Control pH and temperature.
• Use matrix-matched calibration when surfactant affects response.
• Do not treat a cloudy dispersion as a true dissolved phase.

Viva Questions and Answers

Why use excess solid?

A persistent solid phase helps establish saturation.

What is apparent solubility?

The method-measured dissolved amount, potentially including micelle-associated drug.

Does solubilisation prove bioavailability?

Further release, permeability and in-vivo evidence is needed.

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