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Effect of pH on Drug Solubility

Practical 21 - Practical study

Aim

To construct and interpret a pH-solubility profile for a selected ionisable compound.

Principle

For an ideal monoprotic weak acid S = S0(1 + 10^(pH - pKa)); for a weak base S = S0(1 + 10^(pKa - pH)). These equations assume the appropriate solid phase and equilibrium; salts, complexes and degradation can cause deviations.

Materials and Requirements

- Selected weak acid or base and defined buffer series
- Calibrated pH meter and temperature-controlled equilibration
- Validated concentration assay and phase-separation method
- 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. Choose a justified pH range and document buffer composition and ionic strength.
3. Equilibrate excess solid at each pH, recording actual pH before and after equilibration.
4. Separate particles without disturbing the equilibrium and assay intact drug with appropriate blanks.
5. Plot solubility against pH and compare the observations with the ionisation model and possible solid-phase changes.
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.

Buffer / actual pH	Temperature / time	Measured solubility	Model prediction
Below pKa	Record	Record mg/mL	Calculate
Near pKa	Record	Record mg/mL	Calculate
Above pKa	Record	Record mg/mL	Calculate

Calculations

- Weak acid: S/S0 = 1 + 10^(pH - pKa)
- Weak base: S/S0 = 1 + 10^(pKa - pH)

Worked Example

Illustrative weak acid: S0 = 0.010 mg/mL and pKa = 4.0. At pH 5.0, predicted S = 0.110 mg/mL.
The prediction is conditional; compare it with measured intact-drug content and final pH.

Result and Interpretation

• Report the observed profile and limitations rather than assigning an ideal curve as experimental evidence.

Precautions

• Recheck pH after adding drug.
• Assess chemical stability and filter recovery.
• Do not extend the simple equation to multiprotic systems without a suitable model.

Viva Questions and Answers

What is S0?

Intrinsic solubility of the un-ionised form under the defined conditions.

Why measure final pH?

Drug addition or equilibration can shift pH.

Why can data depart from the equation?

Solid-phase changes, nonideality, complexation or degradation may occur.

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