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Drug Solubility in Different pH and Buffer Systems

Experiment 10 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To measure equilibrium solubility at controlled pH and temperature.

Principle

For ionisable compounds, total aqueous solubility can change with pH because ionised forms contribute to the dissolved concentration. The ideal relationship assumes an appropriate solid form and controlled conditions; salt formation, degradation and activity effects can cause departures.

Requirements

- Assigned teaching drug, validated buffers and concentration-assay method.
- Temperature-controlled mixing, calibrated pH meter, suitable separation method and standards.

Procedure

1. Prepare buffers

Use the assigned pH range and controlled buffer/ionic-strength conditions. Measure actual pH and temperature.

2. Add excess solid

Add sufficient drug to leave visible undissolved solid at equilibrium. Prepare replicates and a drug-free buffer blank.

3. Equilibrate

Mix for the validated period. Confirm equilibrium with consistent concentrations at successive time points rather than assuming any fixed short time is sufficient.

4. Separate

Remove undissolved material using the validated centrifugation/filtration method without cooling, adsorption loss or pH change.

5. Assay

Dilute the clear phase as needed and measure concentration against matrix-appropriate standards. Confirm that the result represents intact drug.

6. Report

Record final pH, temperature, residual solid and concentration with units. Compare marketed material only with its excipient and solid-form differences stated.

Observations and Record

Initial / final pH	Temperature / equilibration check	Solubility and units
_____	_____	_____
_____	_____	_____
_____	_____	_____

Worked Example

The numbers below are illustrative; enter your own observations in the record.

- Ideal monoprotic weak acid: $S = S_0[1 + 10^{(pH-pK_a)}]$. Weak base: $S = S_0[1 + 10^{(pK_a-pH)}]$.
- For a weak acid with $S_0 = 0.10$ mg/mL, $pK_a = 4.0$ and $pH = 5.0$, ideal $S = 1.10$ mg/mL.
- A measured 15.0 mg dissolved in 50.0 mL corresponds to 0.300 mg/mL; experimental results need not equal the ideal estimate.

Result

Record the observed outcome and calculated value, with units. State whether the stated laboratory specification was met; do not copy the worked example as your result.

Precautions

- Use the instructor's assigned material and apparatus; record actual temperature and units with every measured property.
- Check instrument calibration and use repeat readings rather than a single convenient result.
- Compare a marketed teaching formulation only under the same method and conditions; its excipients can change the property.

Viva Questions and Answers

1. Why require excess solid?

It helps ensure the measured solution is saturated rather than merely the amount added.

2. Why measure final pH?

Drug dissolution can change the buffer pH.

3. Why validate filtration?

The filter may adsorb drug or allow fine solids through.

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