Polymorphism and Dissolution

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned polymorphism and dissolution experiment or teaching dataset.

Principle

Different crystal forms of the same substance can differ in dissolution and stability. A dissolved concentration curve does not by itself identify the crystal form.

Requirements

- Institution-assigned experimental method and coded in-vitro or supplied pharmacokinetic data.
- Calibrated analytical readings or supplied concentration table, calculator and plotting tools.

Procedure

1. Identify assigned forms

Read the supplied form identifiers and solid-state characterisation evidence.

2. Match the comparison

Check particle size, amount, method and other formulation variables that could confound the comparison.

3. Analyse profiles

Plot dissolution for the supplied forms using the same units and sampling corrections.

4. Assess

Relate the observation to the characterisation record without assuming the faster form is always the more stable form.

Observations and Record

Record component	Value
Form code / identity evidence	_____
Particle size / method basis	_____
Time-profile readings	_____
Observed difference	_____
Confounding / stability question	_____

Worked Example

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

- Use matched percentage-dissolved values or an assigned rate model; a fitted rate requires its stated validity range.
- Illustration: 40% versus 25% at the same assigned time is a 15 percentage-point difference, not a 15% relative increase.

Result

Dataset / method: ____. Calculated outcome and units: ____. Comparison: ____. Assumption or limitation: ____.

Precautions

- Record units, sampling times, dilution and the assumptions of the selected model.
- Use supplied human/animal data or the approved in-vitro teaching method; no new human/animal dosing or surgical preparation is prescribed.
- Keep an illustrative calculation separate from the actual result and do not use it as an individual patient dosing instruction.

Viva Questions and Answers

1. Why state model assumptions?

The derived parameter is valid only when the data and model satisfy them.

2. What accompanies a pharmacokinetic result?

Its units, dataset, calculation method and relevant limitation.

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