Dissolution Comparison of Two Dosage Forms

Experiment 2 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned dissolution comparison of two dosage forms experiment or teaching dataset.

Principle

Two dissolution curves must use a common suitable method, amount basis and sampling corrections. A visual difference is not automatically an in-vivo bioavailability difference.

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 products

Record formulation, strength, batch and labelled drug amount.

2. Run or review matched tests

Use the assigned apparatus and medium; preserve replicate measurements rather than averaging prematurely.

3. Correct concentrations

Apply dilution and cumulative removed-drug corrections where samples are replaced.

4. Plot and interpret

Compare time profiles and the assigned comparison metric; discuss method applicability.

Observations and Record

Record component	Value
Product / amount basis	_____
Test conditions / replicates	_____
Concentration and correction	_____
Percent dissolved by time	_____
Comparison metric	_____

Worked Example

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

- With equal-volume withdrawal v replaced by blank medium: cumulative mass at time n = Cn V + v × sum of earlier measured concentrations; V is constant vessel volume.
- Example: V = 900 mL, v = 5 mL, C1 = 0.01 and C2 = 0.02 mg/mL. At time 2, mass = 0.02 × 900 + 5 × 0.01 = 18.05 mg.

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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