

Bioequivalence Review of Marketed Products

Experiment 11 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned bioequivalence review of marketed products experiment or teaching dataset.

Principle

A marketed-product comparison must distinguish dissolution, a pharmacokinetic comparison and a formal bioequivalence conclusion. The evidence needed depends on the product and permitted study pathway.

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 dosage form, strength, batch and comparator status from the assigned records.

2. Map evidence

Separate pharmaceutical quality, dissolution and supplied pharmacokinetic/statistical evidence.

3. Evaluate the comparison

Check method suitability, design and current product-specific criteria; do not infer BE from a similar dissolution graph alone.

4. Report

State what the supplied evidence supports and which required evidence is missing.

Observations and Record

Record component	Value
Product / comparator	_____
Quality and dissolution evidence	_____
PK/statistical evidence	_____
Applicable criterion	_____
Supported claim / gap	_____

Biopharmaceutics and Pharmacokinetics

Worked Example

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

- If an assigned dissolution comparison uses f_2 , apply its validity conditions and prescribed sampling basis before calculating it.
- Illustration: two similar curves may support the assigned in-vitro comparison, while a formal in-vivo BE claim still needs its applicable evidence.

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.

Continue Learning with FirstHope

Complete Notes on the FirstHope App

Complete subject and semesters are available on FirstHope app only.

- Get complete subject and semester notes in the FirstHope app.
- Available for B.Pharm, D.Pharm, M.Pharm and Pharm.D students.

[Click here to get the FirstHope app](#)

Join the FirstHope Telegram Channel

Join FirstHope Notes and keep up with channel updates.

[Click here to join Telegram](#)

Instagram

@firsthope.official

[Click here to follow Instagram](#)

YouTube Channel

FirstHope-Pharmacy / Live streams

[Click here to watch the YouTube channel](#)

WhatsApp Channel

Follow FirstHope on WhatsApp.

[Click here to join the WhatsApp channel](#)

FirstHope Website

firsthopenotes.com

[Click here to visit the website](#)