

AUC and Bioequivalence Assessment

Experiment 9 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To analyse the assigned auc and bioequivalence assessment experiment or teaching dataset.

Principle

AUC measures exposure; bioequivalence assessment evaluates appropriate pharmacokinetic endpoints with a defined study design and statistical method. A simple mean ratio alone does not establish bioequivalence.

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. Review design

Record test/reference products, study design, sampling and the applicable regulatory/product-specific scope.

2. Calculate exposure

Apply the specified AUC integration and terminal rules consistently.

3. Read statistics

Use supplied log-scale analysis and the 90% confidence intervals for the applicable geometric mean ratios.

4. Conclude

For the standard applicable immediate-release systemic setting, compare the complete relevant intervals with 80.00–125.00%; use the assigned current product-specific criteria where they differ.

Observations and Record

Record component	Value
Products / applicable guidance	_____
AUC / Cmax	_____
Geometric mean ratio	_____
90% confidence interval	_____
Criterion and supported conclusion	_____

Biopharmaceutics and Pharmacokinetics

Worked Example

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

- Geometric mean ratio (%) = $\exp(\text{mean log}(\text{test}) - \text{mean log}(\text{reference})) \times 100$, under the assigned statistical model.
- Illustration: a ratio of 100% with a 90% interval of 92–109% is within an assigned 80–125% range; a mean ratio of 100% with an interval of 78–128% is not.

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](#)