THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
THE DEPARTMENT OF PHARMACY
THE ACADEMIC YEAR 2024/2025 – SEMESTER I

BACHELOR OF PHARMACY HONOURS
FMU5205 – PHARMACEUTICAL ANALYSIS II – LEVEL 5
FINAL EXAMINATION
DURATION: TWO (02) HOURS

DATE: 23RD APRIL 2025 TIME: 01.30 P.M. – 03.30 P.M.

Part B – Short Answer Questions (20 Marks)
Answer all the questions.

1.

1.1 List two (02) key regulatory requirements for quality control in pharmaceutical products. (04 marks)

I.....

II.....

1.2 State three (03) reasons why compliance with pharmacopeia standards is important for pharmaceutical products. (06 marks)

I.....

II.....

III.....

2.

2.1 List two (02) quality control tests specific to emulsions. (04 marks)

I.....

II.....

2.2 Given the following data for a pharmaceutical suspension:
Total volume of suspension (V_o) = 100 mL
Volume of sediment (V_u) = 80 mL

a. Calculate the sedimentation volume (F). (02 marks)
$F = V_O / Vo$

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b. What does the calculated value of F indicate about the suspension? (04 marks)

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Index No:.....

Part C – Structured Essay Questions (60 Marks)
Answer all the questions.

1.

1.1 List two (02) analytical procedures that require validation before evaluating the quality of pharmaceutical products. (04 marks)

1.2 Giving an example, explain the difference between the accuracy and precision of an analytical method. (06 marks)

1.3 Explain the concepts of Detection Limit (DL) and Quantitation Limit (QL) in analytical procedures, including their significance and methods of determination. (20 marks)

2.

2.1 State why residual solvents are considered undesirable in pharmaceutical products. (04 marks)

2.2 Explain the reasons why the International Conference on Harmonisation (ICH) guidelines set threshold limits for organic impurities. (06 marks)

2.3 According to the ICH guidelines, solvents are classified into four (04) classes.
If a pharmaceutical manufacturer seeks a solvent with minimal toxicity for a new drug formulation, which solvent class should they select? Give two (02) examples and briefly describe this class. (10 marks)

2.4 Write a short note on methods used to overcome impurity-related problems during the manufacturing of pharmaceuticals. (10 marks)