THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
THE ACADEMIC YEAR 2020/2021 – SEMESTER II

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

DATE: 06TH OCTOBER 2022 TIME: 1.30 P.M. – 3.30 P.M.

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Part B - Short Answer Question (20 Marks)

1.

1.1 Define the following. (04 marks)

I. Limit test

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II. Quantitation Limit

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1.2 Name the following apparatus. (02 marks)

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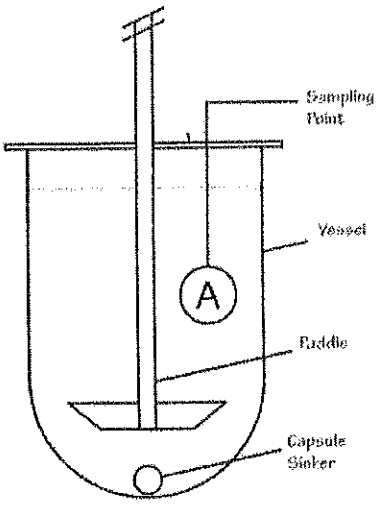

Figure 01

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1.3 State the standard test procedure that use the above apparatus (Figure 01). (02 marks)

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1.4 State two (02) tests used to confirm the uniformity of dosage units during quality testing of tablets. (02 marks)

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2

2.1 Sate three (03) factors that affect the hardness of tablets. (03 marks)

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2.2 State one (01) method to detect total viable aerobic count in liquid dosage forms.

(02 marks)

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2.3 Mention three (03) components of Quality Management System (QMS).

(03 marks)

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2.4 State the main aim of conducting quality assurance in pharmaceutical manufacturing.

(02 marks)

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Part C - Structured Essay Questions (60 Marks)

1.

1.1 Name four (04) quality tests conducted for semi-solid dosage forms. (04 marks)

1.2 State three (03) ways to overcome impurity-related problems in pharmaceutical dosage forms. (06 marks)

1.3 Briefly explain the followings. (10 marks)

I. Minimum fill test

II. Spreadability test

1.4 Briefly describe the softening time test for suppositories. (10 marks)

2.

2.1 Briefly explain the "Re-dispersibility test" (10 marks)

2.2 State four (04) criteria for analytical test validation. (04 marks)

2.3 Discuss the types of pharmaceutical impurities according to ICH classification. (14 marks)

2.4 State two (02) devices used to measure the tablets hardness . (02 marks)