



**UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY**

FOURTH BPHARM PART II EXAMINATION – JUNE 2018

PH 4223 Quality Control (SEQ)

TIME: TWO HOURS

INSTRUCTIONS

- There are four (04) questions in Parts A and B of the SEQ paper.
- Answer each part in separate booklet provided.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

Part A

01.

- 1.1 What is cross contamination of pharmaceuticals? (10 marks)
- 1.2 Briefly explain how you would prevent the cross contamination of pharmaceuticals during the manufacturing process. (50 marks)
- 1.3 Briefly describe the importance of pharmaceutical standardization. (40 marks)

02.

- 2.1 Briefly describe three physical factors influencing the selection of materials for pharmaceutical equipment fabrication. (25 marks)
- 2.2 Briefly describe the qualities of good closures. (25 marks)

Part B

2.3

- 2.3.1 Briefly describe the term “parenteral preparations”. (10 marks)
- 2.3.2 List five necessities of parenterals. (10 marks)

2.4 Leakage test is employed to test the package integrity of parenteral products.

- 2.4.1 List all four tests those can be used to test the package integrity of parenteral products. (10 marks)
- 2.4.2 Explain briefly two tests listed in 2.4.1. (20 marks)

2

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03.

- 3.1 Define the term "In-process quality control" (IPQC). (10 marks)
- 3.2 Briefly explain the purpose and importance of "IPQC". (30 marks)
- 3.3 Briefly explain six types of IPQC physical tests. (30 marks)
- 3.4 Name five IPQC problems that are encountered in capsules. (10 marks)
- 3.5 "Hardness" and "Friability" are two important IPQC parameters of tablets manufacturing. Explain the terms "Hardness" and "Friability"? (20 marks)

04.

- 4.1 Briefly explain four types of viscosities of liquid preparations. (50 marks)
- 4.2 Name five quality control tests for suppositories. (20 marks)
- 4.4 Explain one of the quality control test named in 4.2. (20 marks)
- 4.5 Name five IPQC tests for emulsions. (10 marks)

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