



UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

FOURTH BPHARM PART I EXAMINATION – JUNE 2022

PH 4134 PHARMACEUTICAL TECHNOLOGY – SEQ

TIME: THREE HOURS

INSTRUCTIONS

- There are **six** questions in part A, B, and C of the paper.
- Answer all questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

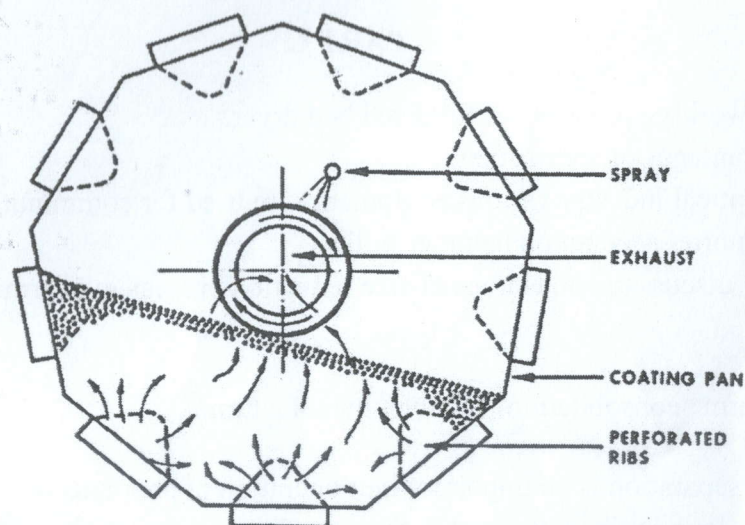
PART A

01:

- 1.1 Define the term ‘preformulation studies’ in the development of dosage forms. *(15 marks)*
- 1.2 Briefly discuss the important areas of preformulation research. *(25 marks)*
- 1.3 List 5 classes of excipients use in tablet formulation giving examples for each category. *(25 marks)*
- 1.4 “Consideration of biopharmaceutical parameters are extremely important in pharmaceutical formulation”. Justify the above statement. *(35 marks)*

02.

- 2.1 Define the term ‘accommodation schedule’ in relation to pharmaceutical manufacturing plant design. *(15 marks)*
- 2.2 List four important outcomes expected from a HVAC system in environmental control of a pharmaceutical production site. *(25 marks)*
- 2.3 A cross sectional image of a Driacoater pan is given below. Briefly describe its mechanism of operation. *(20 marks)*



- 2.4 The drying efficiency of a standard coating pan can be improved using various new techniques. Briefly describe two such improvements using illustrations. *(40 marks)*

03.

- 3.1 Define the term 'aseptic technique'. (10 marks)
- 3.2 List five terminal sterilization methods available for the use of pharmaceutical products. (20 marks)
- 3.3 'Sterilization by gases is considered when the other methods are not suitable'. Explain this statement. (30 marks)
- 3.4 Discuss the typical room conditions that you would expect for a sterile product manufacturing plant as per the WHO-GMP guidelines. (40 marks)

PART B

04.

- 4.1 Define the term "heat exchanger". (10 marks)
- 4.2 Briefly discuss three major heat exchangers according to their flow arrangement. (30 marks)
- 4.3 Write a short note on the following.
- 4.3.1 Heat insulators (25 marks)
 - 4.3.2 Fluid dynamics (25 marks)
- 4.4 Name two distillation methods that are related to pharmaceutical industry. (10 marks)

05.

- 5.1 List four factors that affect the process of evaporation. (20 marks)
- 5.2 Briefly explain how filter media affect the process of filtration. (30 marks)
- 5.3 Write a brief note on "molecular/ air filtration". (20 marks)
- 5.4 In an industrial process of mixing a liquid dosage form, it encounters a vortex formation. Briefly explain the following.
- 5.4.1 The effect of vortex formation in this product. (15 marks)
 - 5.4.2 If the vortex formation is not desirable for the product, how would you resolve it. (15 marks)

PART C

06.

- 6.1 Explain the working principle of fluidized bed dryer. (15 marks)
- 6.2 List five advantages of spray dryer. (15 marks)
- 6.3 In pharmaceutical industry various equipments are used for comminution process.
- 6.3.1 Write a brief account on hammer mill. (15 marks)
 - 6.3.2 Briefly discuss the objectives of size reduction process in pharmaceutical industry. (20 marks)
- 6.4 Define the term "consolidation" in tablet manufacturing. (10 marks)
- 6.5 Particle size separation is an important unit operation in pharmaceutical manufacturing.
- 6.5.1 Write four equipments used in the particle size separation process. (10 marks)
 - 6.5.2 Briefly explain the working process of one equipment you mentioned on 6.5.1 (15 marks)

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