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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY
FOURTH BPHARM PART I EXAMINATION – NOVEMBER/DECEMBER 2023
PH 4134 PHARMACEUTICAL TECHNOLOGY – SEQ PAPER

TIME: THREE HOURS

INSTRUCTIONS

- There are **six** questions in **Part A and B** of this SEQ paper.
- Answer **all** questions.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.

PART A

1.

1.1. State five examples for using evaporation in pharmaceutical industry. (*20 marks*)

1.2.

1.2.1. What is "fractional distillation"? (*05 marks*)

1.2.2. What is an "azeotropic mixture"? (*10 marks*)

1.2.3. Explain the use of an "entrainer" in separating an azeotropic mixture. (*10 marks*)

1.3. Write Darcy's equation and explain how you can increase the rate of filtration. (*25 marks*)

1.4.

1.4.1. What is the use of a "filter aid"? (*10 marks*)

1.4.2. List three characteristics of an ideal filter aid. (*20 marks*)

2.

2.1. What are the four main pathways of fluid mixing? (*10 marks*)

2.2. Explain the factors affecting solid-solid mixing. (*15 marks*)

2.3. Explain how the speed of rotation of a mixer affect powder mixing. (*10 marks*)

2.4. Describe the benefits of process validation in pharmaceutical manufacturing. (*25 marks*)

2.5.

2.5.1. Draw and explain the parts of a fluid bed dryer. (*20 marks*)

2.5.2. Discribe how wet granules are dried using a fluid bed dryer in tablet manufacturing. (*20 marks*)

3.

3.1. Explain mechanisms of emulsion breakdown. (*20 marks*)

3.2. Explain how you would select an emulsifier based on the HLB value. (*05 marks*)

3.3.

3.3.1. Explain "at rest" state and "in operation" state, with respect to a clean area. (*10 marks*)

3.3.2. List five important tests involved in performance validation of HEPA filers. (*20 marks*)

3.4. Explain the arrangement and precautions to be taken when preparing preparations containing micro-organisms in a sterile area. (*30 marks*)

3.5. Briefly explain the "isolator technology". (*15 marks*)

PART B

4. Fluidized Bed Processer (FBP) is one of the key versatile machineries used in pharmaceutical industry. Its adaptability and transformative impact make it an indispensable machinery, optimizing drug development and production processes with efficiency and precision.

4.1.

4.1.1. Briefly explain unit operations that could be performed using FBP. (*30 marks*)

4.1.2. Write three examples for the unit operations mentioned in 4.1.1. (*10 marks*)

4.2.

4.2.1. What is the main performance-based evaluation criterion for mixing in pharmaceutical manufacturing process? (*20 marks*)

4.2.2. Briefly explain the significance of evaluation criterion mentioned in 4.2.1. (*40 marks*)

5. Granulometry, a pivotal parameter in solid dosage form manufacturing, refers to the measurement and analysis of the particle size distribution within a pharmaceutical formulation.

5.1. What are the key particle properties of a powder material? (*30 marks*)

5.2. List the machineries used in pharma industry with their specialties to manage granulometry of a raw material. (*30 marks*)

5.3. Briefly explain the significance of granulometry in tablet manufacturing operation. (*40 marks*)

6. Heat transfer is the process by which thermal energy is exchanged between different regions of a system or between different systems. This exchange of thermal energy occurs in three main ways.

6.1. Briefly explain the three main mechanisms of heat transfer. (*30 marks*)

6.2. Explain two different types of heat exchangers, using drawings or diagrams to illustrate their respective designs and configurations. (*30 marks*)

6.3. How does the effectiveness of heat exchangers impact the overall efficiency of pharmaceutical manufacturing processes, and what specific strategies are employed in the pharmaceutical industry to enhance heat transfer in these devices? (*40 marks*)

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