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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

FOURTH BPHARM PART I EXAMINATION – DECEMBER 2017

PH 4134 PHARMACEUTICAL TECHNOLOGY (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- There are **six (06)** questions in parts A and B in the SEQ paper.
- Answer **each part** in a separate booklet provided.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

PART A

1.

1.1 Explain the difference between monotropic polymorphs and enantriotropic polymorphs. ***(20 marks)***

1.2 Discuss briefly the suitability of amorphous solids in pharmaceutical manufacturing. ***(20 marks)***

1.3 What is the difference between dynamic viscosity and kinematic viscosity? ***(10 marks)***

1.4 The intrinsic viscosity (η) and Huggins constants (K_H) determined for two different polymers are shown in the table below. (Note: each polymer has three different grades)

Polymer	Polymer Grade	[η](dl/g)	K_H(g/dl)
Polymer A	A1	0.56	0.41
	A2	0.96	0.44
	A3	1.23	0.41
Polymer B	B1	0.51	0.32
	B2	0.8	0.31
	B3	1.76	0.29

1.4.1 By considering the data given in the table above, if you plot reduced viscosity against concentration for different grades of polymers (A and B), sketch the expected shapes of the graphs. (Show intrinsic viscosities and Huggins constants on your graphs). ***(20 marks)***

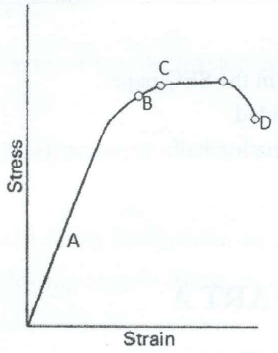
1.4.2 Describe briefly the solubility of two polymers (**A** and **B**) in ethanol using Huggins constants. ***(15 marks)***

1.4.3 Explain briefly suitability of this polymer-solvent mixture as a coating solution when polymer-solvent interactions are strong. ***(15 marks)***

2.

2.1 Using an appropriate diagram, explain the construction and working principle of a ball mill. ***(20 marks)***

2.2 Following graph shows the behavior of a material upon a force/stress.



2.2.1 Identify the areas or points shown in the graph. ***(08 marks)***

2.2.2 Explain briefly the effect of persistent stress on the material. ***(12 marks)***

2.3 Discuss briefly the advantages of size reduction with respective to pharmaceutical preparations. ***(20 marks)***

2.4 Explain briefly the principle of centrifugation. ***(20 marks)***

2.5 Discuss briefly the methods of improving efficacy of filtration process. ***(20 marks)***

3.

3.1 Discuss briefly the importance of the following particle properties during transitional rearrangement of granules in die cavity.

3.1.1 Particle size ***(10 marks)***

3.1.2 Particle shape ***(10 marks)***

3.2 Assume that you are provided with a powder blend with following properties. After mixing, powder bed shows a normal distribution of 99.7% of samples lies within three standard deviations. The accepted content deviation for this product is 2.5%. If the amount of active ingredient is $2x10^{-3}$:

3.2.1 Calculate the number of particles required in each sample to comply with these specifications. ***(12 marks)***

3.2.2 If tablet target weight is 60 mg, calculate the weight of one particle in kilograms. ***(08 marks)***

3.3 Define the terms "sensible heat" and "latent heat". ***(10 marks)***

3.4 Calculate the amount of heat required to convert 15 kg of water in room temperature (25 ^{0}C) into saturated steam at a pressure of $2.0X10^5$ Pa. (Latent heat of vaporization is ~~2.20 J/kg~~ 2260 kJ/kg. The saturation temperature at 2x105 Pa is 120.4 °C. Specific heat capacity of water is 4.21 kJ/kgK) ***(15 marks)***

3.5 Assume that the steam produced in question 3.4 has been used to boil water in a steam jacketed pan with an area of 1.5 m^2, and the following obstacles:

	Thickness (mm)	K (W/mK)
Air film	0.2	0.03
Condensate film	0.1	0.6
Scale	0.2	1.00
Pan wall	3.0	17
Water boundary layer	0.4	0.6

3.5.1 Calculate the overall heat transfer coefficient. ***(15 marks)***

3.5.2 Calculate the temperature of the water in the steam jacketed pan after 10 minutes of heating. ***(20 marks)***

PART B

4. Safety is violated by accidents in pharmaceutical industry.To minimize such incidental hazards and risks must be identified and remedial actions must be taken.

4.1 Define the terms "hazards and risks". ***(15 marks)***

4.2 Briefly explain the basic steps of Hazard and Operability Study (HAZOP) designed to identify hazards. ***(30 marks)***

4.3 State the **five** main components of dust explosion. ***(10 marks)***

4.4 List **five** fire safety policies that you would apply in to a pharmaceutical production plant. ***(15 marks)***

4.5 Sketch the cross section of a flame arrester and briefly describe how the propagation of gas flames through pipelines is prevented by the internal arrangement. ***(30 marks)***

5. The preparation of emulsion for parenteral drug delivery requires proper mixing of two phases with the emulsifier and sterility of the product should also be maintained.

5.1 What are the uses of baffles in mechanically stirred mixing tanks? ***(10 marks)***

5.2 If the total liquid volume of a "standard" cylindrical stirred tank is 8 m^3 calculate the following dimensions of the tank. ***(20 marks)***

5.2.1 Internal diameter of the tank

5.2.2 Liquid height

5.2.3 Baffle width

5.2.4 Impeller diameter

5.2.5 Gap between tank and the baffle

5.3 Briefly describe the working principal of rotor and stators in mixing. ***(30 marks)***

5.4 Differentiate terminal sterilization and aseptic processing. ***(15 marks)***

5.5 Manufacturers of sterile products use extensive measures to control the environment. Briefly describe the tests that can be used to determine the control level of environment. ***(25 marks)***

6. Solid dosage formulations are the most important dosage form for pharmaceuticals which include tablets, capsules, and powders.

6.1 Write down the steps to prepare powder mixture ready to compress using wet granulation method. ***(20 marks)***

6.2 Briefly describe the working principle of fluid-bed granulator in granulation. Use appropriate diagrams. ***(30 marks)***

6.3 List the **four** main steps in filling hard gelatin capsules. ***(10 marks)***

6.4 Write short notes on following capsule filling methods.

6.4.1 The plate method ***(20 marks)***

6.4.2 Vacuum filling ***(20 marks)***

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