UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

FOURTH B.PHARM PART I EXAMINATION – JUNE 2018

PH 4134 PHARMACEUTICAL TECHNOLOGY (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- There are **six (06)** questions in part A,B, C and D of SEQ paper.
- Answer each part in a separate booklet.
- Do not use any correction fluid.
- Marks will be deducted for illegible hand writing.

PART A

01. Answer all parts.

1.1. Discuss the functioning of air conditioners using a schematic diagram of an air conditioner.

(*25 marks*)

1.2.

    1.2.1. Draw a typical layout of pharmaceutical manufacturing plant. (*15 marks*)

    1.2.2. List **five** factors to be considered in the selection of a location for a pharmaceutical manufacturing plant. (*10 marks*)

PART B

1.3. Sunscreens are available in the form of lotion, gel, or spray or other topical product.

    1.3.1. List the main mechanisms by which sunscreens prevent sunburn. (*05 marks*)

    1.3.2. Define the term "Sun Protection Factor (SPF)" and state the meaning of SPF 4.

(*10 marks*)

    1.3.3. Mention the main types of UV filters use in Sunscreens by giving **two** examples for each category mentioned. (*15 marks*)

    1.3.4. The studies have shown that protection achieved by sunscreen is perhaps only one-half that is claimed by the product. Briefly explain the reasons for this ineffectiveness.

(*20 marks*)

PART C

02. Size reduction is one important unit operation in Pharmacy.

    2.1. There are **four** mechanisms of size reduction. Write a note on mechanisms of size reduction.

(*20 marks*)

    2.2. Using suitable diagrams describe how the milling efficiency of a ball mill changes with the velocity. (*20 marks*)

2.3. Deformation of a material upon applied stress happens as shown in the following graph.
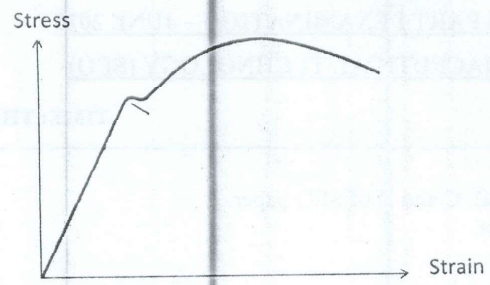
Identify key areas in this graph and describe how they are applied to the process of milling.

(*10 marks*)

2.4. Giving relevant examples, discuss the importance of size reduction in pharmaceutical industry.

(*20 marks*)

2.5. Draw a schematic diagram of a fine milling machine and describe its mechanism.

(*30 marks*)

03. Consider a situation where spherical shape particles of active ingredient and excipients are being mixed in a double cone mixer assuming that the size and density of the particles are same.

3.1. Distinguish between perfect mixing and random mixing. (*15 marks*)

3.2. If the proportion of the active ingredient (p) is one fourth and the total number of particles is 20 000, calculate the standard deviation of the mixed blend. (*20 marks*)

3.3. What methods that you would apply to calculate the standard deviation? (*15 marks*)

3.4. When manufacturing tablets from the blend, it is required to have normal distribution of 99.7% of all samples lies within ±3% from p.

3.4.1. Calculate the number of particles required in this blend. (*10 marks*)

3.4.2. If the strength of the tablet is 100 mg and tablet weight is 200 mg, what is the scale of scrutiny of the mixed blend? (*10 marks*)

3.5. Discuss the advantages of analyzing mixing index. (*15 marks*)

3.6. Write a short note on Rotary drum filtration. (*15 marks*)

04.

4.1. Compare between truck-tray dryer and fluidized bed dryer. (*20 marks*)

4.2. In static bed drying, different phases of drying can be identified.

4.2.1. Graphically represent the key areas in drying in a static bed. (*10 marks*)

4.2.2. Give brief description for each area you present in the graph. (*10 marks*)

4.3. 100 kg of water has been boiled in a steam jacketed pan with scaling and with a film of air. The table given below shows the conductance of heat through different layers in the steam jacketed pan.

	Thickness (mm)	K (W/m K)
Air film	0.2	0.05
Condensate film	0.1	0.60
Scale	0.2	1.00
Pan wall	3.0	17.0
Water boundary layer	0.4	0.60

4.3.1. Calculate the overall heat transfer coefficient (U). *(10 marks)*

4.3.2. What would happen to the overall conductivity U if:

4.3.2.1. scale has been removed *(10 marks)*

4.3.2.2. if air film has been removed and scale has been halved. *(10 marks)*

4.4. Write short notes on following.

4.4.1. Solute migration during drying *(15 marks)*

4.4.2. Equilibrium moisture content *(15 marks)*

PART D

05. Dry granulation in tablet manufacturing is a simple and low cost method.

5.1. List main steps involved in making powder ready to compression. *(15 marks)*

5.2. Briefly explain the dry granulation process by roller compactor. *(25 marks)*

5.3. Using appropriate diagrams, briefly describe the rotary tablet press cycle. *(25 marks)*

5.4. State the main steps of sugar coating process. *(10 marks)*

5.5. Briefly describe the film coating process of tablets. *(25 marks)*

06. Establishing specifications to ensure the quality of each of the components of an injection is essential.

6.1. Draw a schematic diagram for a typical process used to convert portable water to Water for Injection (WFI). *(20 marks)*

6.2. Briefly describe the operation process of vapor compression still used to prepare WFI. *(25 marks)*

6.3. State the storage conditions for WFI prepared by distillation. *(10 marks)*

6.4. Briefly describe how clean room grade A conditions are maintained in barrier isolators. *(25 marks)*

6.5. How would you assess the risk in a sterile manufacturing plant? *(20 marks)*

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