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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

FOURTH BPHARM PART I EXAMINATION – OCTOBER/ NOVEMBER 2019

PH 4134 PHARMACEUTICAL TECHNOLOGY (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- Answer **all** questions in the booklets provided.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

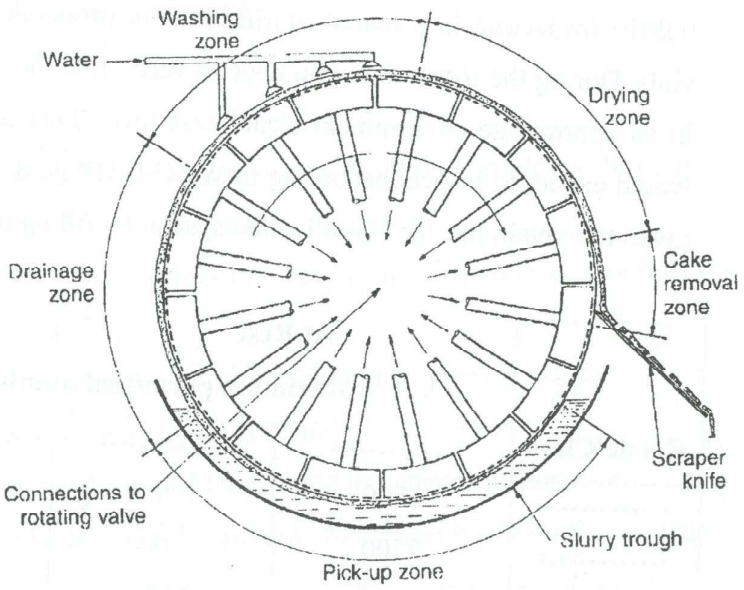
01.

1.1 State the **two** uses of the filtration process in pharmaceutical manufacturing.

(10 marks)

1.2 List the main classes of industrial filters available based on the method used to drive filtrate through the filter medium. ***(10 marks)***

1.3 Identify the filter shown below and briefly explain its operation in the preparation of products such as $CaCO_3$ and Starch. ***(30 marks)***



1.4 High efficiency particulate air filters (HEPA) are replaceable, extended media, dry type filters in a rigid frame having a particle collective efficiency of 99.97% to 99.99% for 0.3µm particles. Discuss the various mechanisms of particle retention by the HEPA filter.

(50 marks)

02.

2.1 Briefly explain following pharmaceutical modifications. ***(15 marks)***

2.1.1 Innovations in capsule shells

2.1.2 Innovations in capsule delivery system

2.2 Give reasons in brief for the need of modifications mentioned in 2.1. ***(20 marks)***

2.3 Briefly describe two types of non- animal origin capsule shells. ***(30 marks)***

2.4 Briefly explain the port capsule technology and hydrophilic sandwich capsules in relation with mechanism of drug release. ***(35 marks)***

03.

3.1 Define the following terms. ***(15 marks)***

3.1.1 Sterilization

3.1.2 Asepsis

3.1.3 Aseptic Technique

3.2 List terminal sterilization methods available for the use of pharmaceutical products. ***(15 marks)***

3.3 State factors to be considered in gaseous sterilization. ***(30 marks)***

3.4 Assume that you are requested to participate in a Good Manufacturing Practice (GMP) inspection in a manufacturing facility producing injections in ampoules and vials. During the inspection, you have to verify that the operations that are carried out in an appropriate environment cleanliness level. Discuss the typical rooms that you would expect to inspect according to WHO-GMP guidelines. (You may use the table given to explain the Air classification system by filling the blank spaces) ***(40 marks)***

	At Rest		**In operation**	
	Maximum permitted number of particles/m^3			
Grade/Class	.....	.....	.....	.....
.....	3500	0	3500	0
.....	3500	0	350000	2000
.....	350 000	2000	3500000	20000
.....	3500000	20000	-	-

04.

4.1

4.1.1 Define the term 'discipline cosmetic dermatology'. ***(05 marks)***

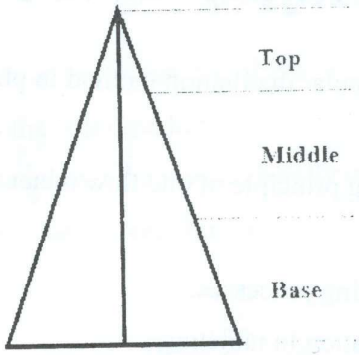
4.1.2 Briefly explain the purpose of such specialty. ***(10 marks)***

4.2 Briefly explain the dermatological uses of lasers. ***(15 marks)***

4.3 State the purpose of using cutaneous filler substances in cosmetology. Give **two** examples of cutaneous filler substances use in the industry. ***(20 marks)***

4.4 Differentiate cold cream from vanishing cream in terms of their properties. ***(20 marks)***

4.5 Briefly explain fragrance notes represented in the below fragrance pyramid. ***(30 marks)***



05.

5.1 Mixing is defined as randomization of dissimilar particles within a system. Giving an example state the meaning of 'scale of scrutiny'? ***(15 marks)***

5.2 Explain various mixture types that you would encounter in an industry using appropriate examples. ***(25 marks)***

5.3 Amphiphilic surfactants are characterized by the HLB values.

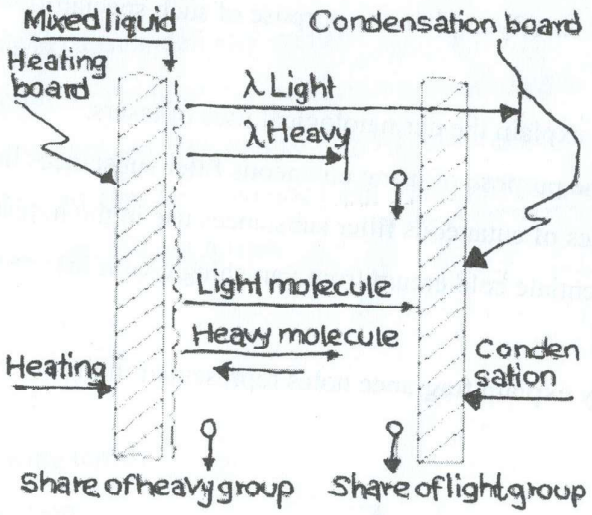
5.3.1 What is meant by HLB value?

5.3.2 Explain the use of HLB value in industry formulations. ***(20 marks)***

5.4 Briefly describe the classification of emulsifiers based on their action. ***(40 marks)***

06.

6.1 Explain briefly the principle of separation by molecular distillation using the diagram given below. ***(20 marks)***



6.2 List the advantages of molecular distillation method in pharmaceutical preparations. ***(20 marks)***

6.3 Briefly describe the working principle of one flow meter that you have studied. ***(20 marks)***

6.4 Write short notes on following processes. ***(40 marks)***

6.4.1 Pre-formulation in tableting

6.4.2 Wet granulation

6.4.3 Direct compression

6.4.4 Tyndall effect

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