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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY

FOURTH BPHARM PART I EXAMINATION – MARCH/APRIL 2021

PH 4134 PHARMACEUTICAL TECHNOLOGY – SEQ

TIME: THREE HOURS

INSTRUCTIONS

- There are **six** questions in parts **A, B** and **C** in this SEQ paper.
- Answer each part in a separate booklet.
- 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 following terms giving two examples for each. ***(18 marks)***

1.1.1 Cosmetic

1.1.2 Cosmeceutical

1.1.3 Cosmetic Dermatology

1.2 Classify the following cosmetics according to their major function. ***(12 marks)***

1.2.1 Antiperspirant

1.2.2 Sunscreen

1.2.3 Face powder

1.2.4 Lipstick

1.2.5 Toothpaste

1.2.6 Baby soap

1.3 "*Sometimes cosmetics are considered as drugs*". Justify the statement with relevant regulations and suitable examples. ***(30 marks)***

1.4 Briefly describe factors to be considered in the development of a new face cream. ***(40 marks)***

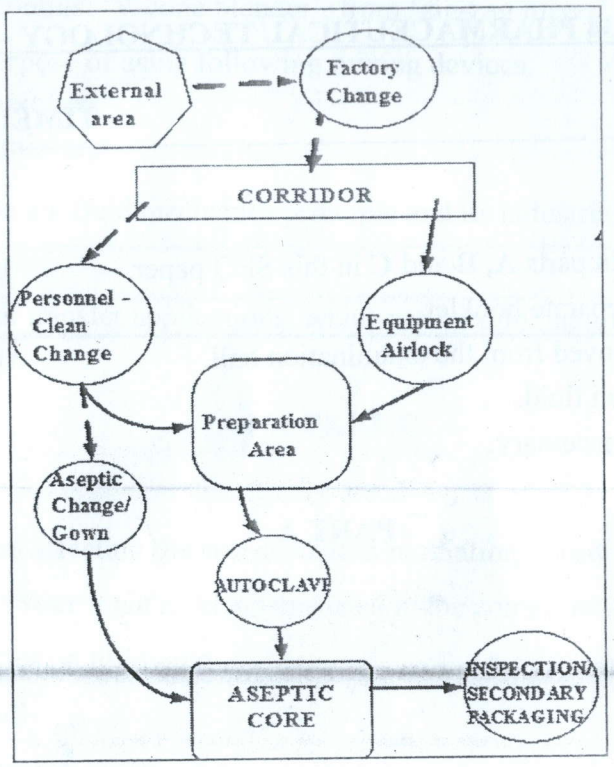
02.

2.1 Define the term 'cross-contamination' and state the possible points of cross-contamination in a manufacturing setting. ***(20 marks)***

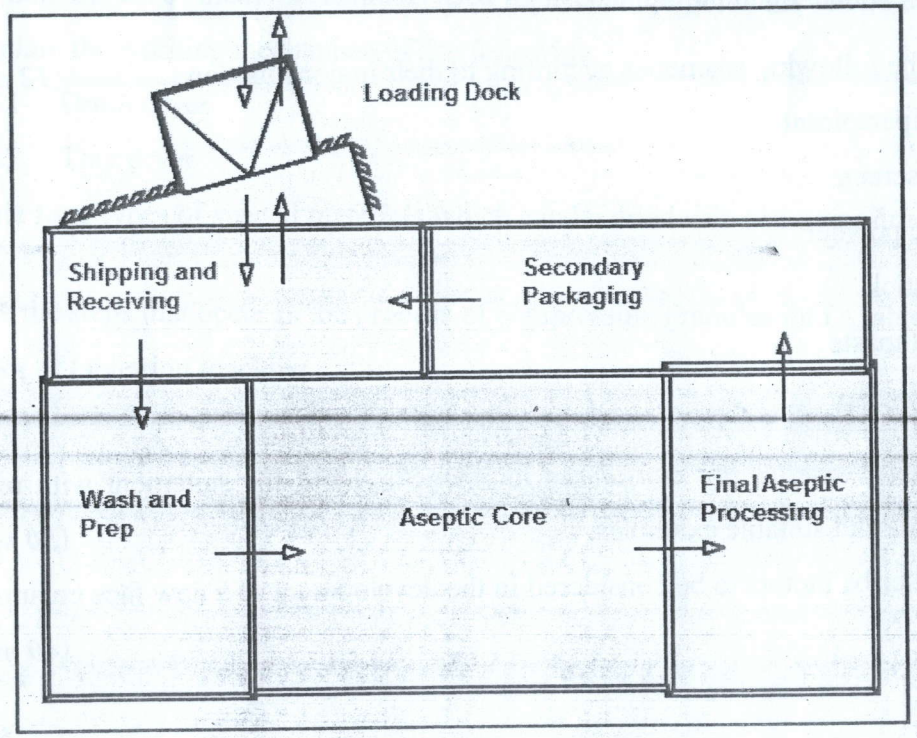
2.2 The needs of the manufacturing facility are defined during the facility programming stage. What are the basic criteria that should be satisfied by a proper facility layout? ***(15 marks)***

2.3 The following image shows a bubble diagram developed during the first stage of layout design. Explain its importance in pharmaceutical plant construction.

(*30 marks*)



2.4 Examine the plant layout given below, where material flow is shown by arrows.



2.4.1 Comment on the desirability of the above layout for pharmaceutical manufacturing.

(*15 marks*)

2.4.2 Redraw the layout incorporating your suggestions to improve it further.

(*20 marks*)

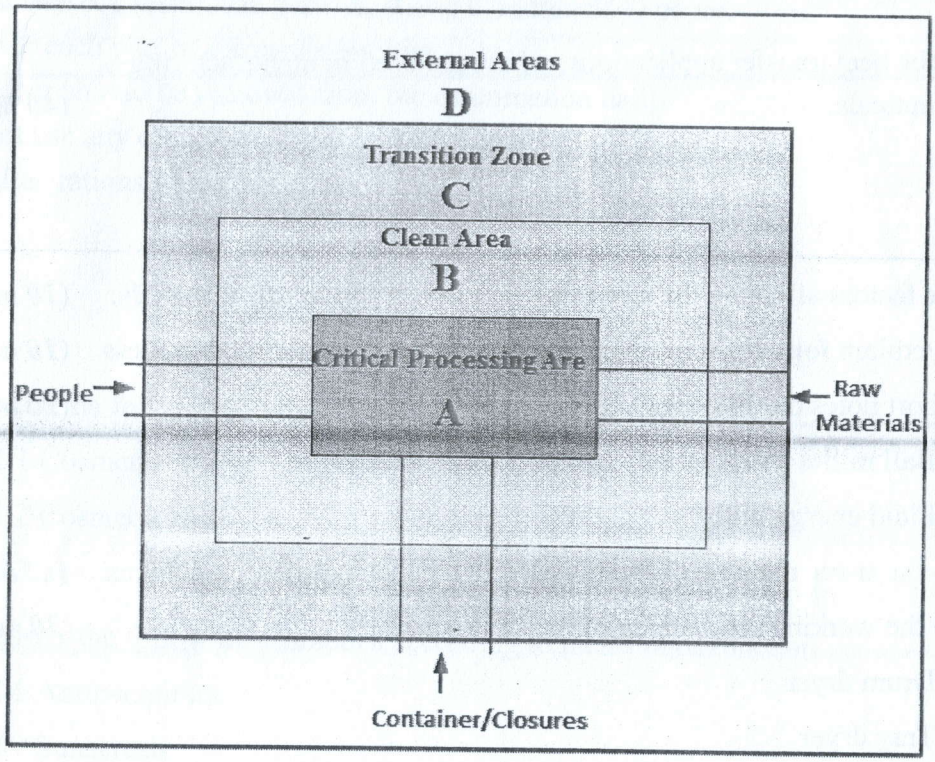
(9)

03.

3.1 Define the term 'bloom value' *(10 marks)*

3.2 Briefly explain the steps that are involved in making empty hard gelatin capsules. *(25 marks)*

3.3 The following design concept is used to minimize challenges faced in the aseptic processing of pharmaceutical products. Briefly explain the possible activities that can be carried out in each area (A-D). *(20 marks)*



3.4 Write short notes on the following.

3.4.1 The components of HVAC system. *(15 marks)*

3.4.2 Industrial hazard and risk. *(15 marks)*

3.4.3 Tablet coating process. *(15 marks)*

PART B

04.

4.1 Write the simplest form of a natural circulation evaporator. *(06 marks)*

4.2 State **two** differences between 'tubular bowl centrifuge' and 'conical disc centrifuge'. *(10 marks)*

4.3 List **four** factors affecting evaporation. *(12 marks)*

4.4 Briefly discuss the material and energy balance applicable to a pharmaceutical industry. *(30 marks)*

4.5 Explain the distillation methods, which are used in pharmaceutical industry to synthesize and isolate the pure ingredients. *(42 marks)*

05.

5.1 State how you would correct the de-mixing of powders. (*10 marks*)

5.2 Compare and contrast 'V-cone blender', from 'zig-zag mixer'. (*10 marks*)

5.3 Mention the purpose of using following mixing devices. (*10 marks*)

5.3.1. Baffle mixtures

5.3.2. Turbine mixtures

5.4 Briefly describe the fluid mechanics principle and its industrial applications. (*30 marks*)

5.5 Discuss the heat transfer applications, which are used in manufacturing of pharmaceuticals. (*40 marks*)

PART C

06.

6.1 List **five** factors affecting the size reduction in relation to raw materials. (*10 marks*)

6.2 Briefly explain **four** main mechanisms used in the comminution process. (*10 marks*)

6.3 Write short notes on following. (*20 marks*)

6.3.1 Ball mill

6.3.2 Fluid energy mill

6.4 Explain the **three** main mechanisms used in mechanical sieving devices. (*12 marks*)

6.5 Explain the working mechanism of the following. (*30 marks*)

6.5.1 Drum dryer

6.5.2 Tray dryer

6.6 State **four** types of special materials which can be dried using vacuum dryer. (*08 marks*)

6.7 State the steps that occur in the process of compressing granules into a tablet in a die cavity of tabletting machine. (*10 marks*)

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