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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY
FOURTH BPHARM PART II EXAMINATION – DECEMBER 2018
PH 4223 QUALITY CONTROL (SEQ)

TIME: TWO HOURS

INSTRUCTIONS

- There are four (04) questions in the SEQ paper.
- Answer **all** in booklet provided.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

01.

1.1 Mention **two** methods which are available to measure the uniformity of dosage units. (***10 marks***)

1.2. State **two** factors affecting the hardness of tablets. (***10 marks***)

1.3. The results of a hardness test carried out for a paracetamol batch was found to be higher than the specified limit. Assuming that you are the in-charge of quality control division, write the appropriate procedure for correcting this issue. (***20 marks***)

1.4. List **four** tests that should be performed to check the quality of the pharmaceutical syrup formulations. (***20 marks***)

1.5. Briefly describe the procedure of the friability test for uncoated conventional tablets. (***40 marks***)

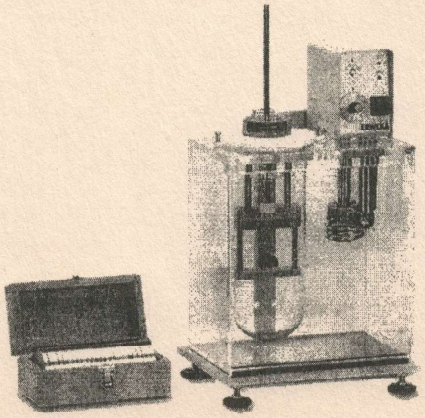
02.

2.1 Briefly describe the importance of performing package integrity tests for parenteral products. (***30 marks***)

2.2 Briefly describe the bubble test which is used to check the package integrity of parenteral dosage forms. (***30 marks***)

2.3

2.3.1 Identify the apparatus given below. (***10 marks***)



2.3.2. Write a brief description about the test performed by the apparatus mentioned in 2.3.1. (***30 marks***)

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03.

3.1 Briefly explain the purpose and the importance of Good Manufacturing Practices (GMPs) for pharmaceuticals. ***(30 marks)***

3.2 Briefly explain the general procedure of quality control of raw materials. ***(30 marks)***

3.3 Briefly describe the criteria which should be considered when selecting premises for establishing a pharmaceutical manufacturing plant. ***(30 marks)***

3.4. List **four** requirements to minimize contamination of pharmaceutical production area. ***(10 marks)***

04.

4.1 List **four** advantages of stainless steel and its alloy in the preparation of pharmaceutical fabrications. ***(20 marks)***

4.2. "Selection of materials for primary packages of medicines is very important aspect during the pharmaceutical manufacturing process". Justify the statement. ***(30 marks)***

4.4 List **four** quality control tests used to check quality of glass packaging materials. ***(20 marks)***

4.5 Briefly describe **one** of the tests mentioned in question 4.4. ***(30 marks)***

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