



UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

FOURTH BPHARM PART II EXAMINATION – JUNE 2017

PH 4223 QUALITY CONTROL (SEQ)

TIME: TWO HOURS

INSTRUCTIONS

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

1. Answer **all** parts.

- 1.1. Define the term “quality”. (10 marks)
- 1.2. Briefly describe the following costs of quality giving **three** activities associated with each.
- 1.2.1. Prevention costs (15 marks)
- 1.2.2. External failure costs (15 marks)
- 1.3. Differentiate quality control and quality assurance. (15 marks)
- 1.4. State **five** determinants of the quality of medicine. (10 marks)
- 1.5. Briefly describe how the quality of medicine is assured. (25 marks)
- 1.6. List **five** common quality control tests for suspensions. (10 marks)

2. Answer **all** parts.

2.1.

- 2.1.1. State the main steps involved in the implementation and certification of Good Manufacturing Practices (GMP). (10 marks)
- 2.1.2. According to GMP guidelines state the information available in a ‘master formula record’. (15 marks)

2.2.

- 2.2.1. List chemical reactions occur between ‘fabricating materials and active ingredient’ giving examples. (10 marks)
- 2.2.2. Briefly describe ideal qualities of rubber as a closure used in pharmaceuticals. (15 marks)

2.3.

- 2.3.1. Explain the term In Process Quality Control (IPQC). (10 marks)
- 2.3.2. Name **five** IPQC problems that are uncounted in tablets. (10 marks)
- 2.3.3. Explain **two** of problems mentioned in 2.3.2. (30 marks)

3. Answer **all** parts.

3.1. Name **five** IPQC tests for injectable preparations. (10 marks)

3.2. Leakage test is employed to test the package integrity of parenteral products. The test can be performed in terms of **four** tests.

3.2.1. List all the **four** tests. (10 marks)

3.2.2. Explain **two** of above tests mentioned in 3.2.1. (30 marks)

3.3. Viscosity and consistency directly relates with stability of solutions; measurement of viscosity is very important quality control test.

3.3.1. List **four** different types of viscosities. (10 marks)

3.3.2. Define **three** different types of viscosities mentioned in 3.3.1. (30 marks)

3.4. State **five** compulsory necessities for parenteral preparations. (10 marks)

4. Answer **all** parts.

4.1. Define the term pharmaceutical packaging. (10 marks)

4.2. Briefly describe requirements of pharmaceutical packaging. (40 marks)

4.3. Write **five** advantages of glass as a pharmaceutical packaging material. (10 marks)

4.4. Describe limitations of use of plastic material for packaging pharmaceutical dosage forms. (40 marks)

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