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UNIVERSITY OF RUHUNA – FACULTY OF MEDICINE

ALLIED HEALTH SCIENCES DEGREE PROGRAMME

SECOND B PHARM PART II EXAMINATION- JUNE 2013

PH2223: PHARMACY LAW AND ETHICS

TIME: 9.00 a.m.- 12.00 noon

INSTRUCTIONS

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

1. Briefly explain the following with reference to Cosmetics, Devices and Drugs Act No.27 of 1980 and Regulations No.38 of 1984 and its amendments.

1.1 Obtaining a sample of Metformin Tablets from a retail pharmacy by an authorized officer for analysis. ***(40 marks)***

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1.2 Destruction of expired Amoxycillin capsules kept in a pharmacy. ***(30 marks)***

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1.3 On receipt of a 'new drug product' from the supplier. ***(30 marks)***

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2.0 With reference to the Cosmetics, Devices and Drugs Regulations,

2.1 Briefly describe the drug schedules including examples for each category. ***(40 marks)***

2.2

2.2.1 List the information that should be included on a label of a bulk pack of paracetamol tablets prepared for sale by a manufacturer. ***(40 marks)***

2.2.2 Indicate the importance of each item listed under 2.2.1 ***(20 marks)***

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3.0 Briefly describe the following.

3.1 Labeling requirements for cosmetics. ***(35 marks)***

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3.2. License to transport drugs. **(30 marks)**

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3.3. Explain the code of ethics for a pharmacist as a member of the healthcare delivery team.

(35 marks)

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4.0 With reference to the Medical Ordinance – Chapter 105, answer the following.

4.1 List the composition of Medical College Council/ College Council. ***(20 marks)***

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4.2 Briefly explain the qualifications required to register as a pharmacist in the Medical Ordinance. ***(50 marks)***

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4.3 The name of a pharmacist has been erased from the list of registration of pharmacists. Discuss the possible reasons with the aid of examples. ***(30 marks)***

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5.0

5.1 Give the Constitution and functions of National Dangerous Drug Control Board. ***(20 marks)***

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5.2 Write the duties of the Pharmacist in dispensing dangerous drugs. ***(20 marks)***

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5.3 Discuss labeling requirements needed for the dangerous drug containers as per the Poison, Opium and Dangerous Drugs ordinance (PODD). ***(20 marks)***

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5.4 Briefly explain the powers of authorized officers with respect to PODD. ***(20 marks)***

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5.5 Write short description on following headings.

5.5.1. Sale of Poisons ***(10 marks)***

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5.5.2. Opium officers ***(10 marks)***

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6.0 As per **Intellectual Property Act No. 52 of 1979,**

6.1. Who can apply for a patent? ***(10 marks)***

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6.2 What is an invention? ***(20 marks)***

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6.3. Briefly discuss the contents of the forms that to be included in the Application for a Patent. ***(30 marks)***

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6.4. Briefly describe the procedure of granting a patent. ***(40 marks)***

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