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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

SECOND BPHARM PART II EXAMINATION – DECEMBER 2017/ JANUARY 2018

PH 2223 PHARMACY LAW AND EHICS (SEQ)

TIME: THREE HOURS

INSTRUCTIONS

- There are six **(06)** questions in Parts A and B in the SEQ paper.
- Answer each question in separate booklets provided.
- No paper should be removed from the examination hall.
- Do not use any correction fluid.
- Use illustrations where necessary.

PART A

1. The following are related to National Medicines Regulatory Authority (NMRA) Act No. 05 of 2015.

1.1. List **ten** members of the National Advisory committee of National Medicines Regulatory Authority. ***(50 marks)***

1.2. Interpret the "borderlinc product" and list the considerations in deciding any product as a borderline product according to NMRA. ***(20 marks)***

1.3. Briefly discuss the objectives of the Authority of NMRA Act No. 05 of 2015. ***(30 marks)***

2. The followings are related to the Poisons, Opium and Dangerous Drugs Ordinance Act No. 13 of 1984.

2.1. Name **three** poisons which may be sold by retail only upon a prescription. ***(15 marks)***

2.2. List **five** contents of the sale of poisons book. ***(10 marks)***

2.3. Briefly describe the procedure for labeling of poisons. ***(40 marks)***

2.4. Briefly explain the procedure in issuing a certificate of registration to a registered consumer according to poisons, opium and dangerous drugs ordinance. ***(20 marks)***

2.5. Explain the followings. ***(15 marks)***

2.5.1. Signal

2.5.2. Vehicle

2.5.3. Person in charge

3. With reference to regulations of Cosmetics, Devices and Drugs Act No. 27 of 1980, write explanatory notes on following topics.

3.1. Processing fee for the registration of a drug. ***(20 marks)***

3.2. Conditions for importing the drugs for

3.2.1 testing ***(10 marks)***

3.2.2 distribution as samples. ***(10 marks)***

3.3 Advertising of drugs. ***(20 marks)***

3.4. Information required for registration of a drug. ***(20 marks)***

3.5. Conditions to transport the drugs specified in schedule II and III. ***(20 marks)***

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4.

4.1. List **seven** *ex-officio* members of the Food Advisory Committee. (***35 marks***)

4.2. Name **two** duties of the Food Advisory Committee. (***15 marks***)

4.3. List **three** objectives of the Consumer Affairs Authority. (***15 marks***)

4.4. Write **four** items which are in a receipt by a trader. (***20 marks***)

4.5. State **three** offences in storing of goods by a tradcr. (***15 marks***)

5.

5.1. List **eight** elements which are addressed by Sri Lanka National Medicinal Drug Policy (NMDP). (***32 marks***)

5.2. What is an "invention"? (***08 marks***)

5.3. Briefly describe the term " patent". (***30 marks***)

5.4. Name **two** factors affecting the revolution of the nutraceuticals. (***10 marks***)

5.5. Briefly discuss the classification of nutraceuticals. (***20 marks***)

PART B

6.

6.1. State **three** characteristics of a profession. (***10 marks***)

6.2. Briefly describe **one** characteristic mentioned in 6.1. relating to pharmacy profession. (***20 marks***)

6.3. Write a short account on activities or functions of Sri Lanka Medical Council. (***40 marks***)

6.4. State the disciplinary inquiry procedure adopted by the SLMC upon receipt of a complaint against a pharmacist. (***20 marks***)

6.5. List **five** reasons for the removal of a pharmacist's name from the SLMC register. (***10 marks***)

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