



UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES

DEPARTMENT OF PHARMACY

SECOND BPHARM PART II EXAMINATION – SEPTEMBER 2020

PH 2223 PHARMACY LAW AND ETHICS (SEQ)

**TIME: THREE HOURS**

**INSTRUCTIONS**

- There are **six** questions in the parts **A** and **B** in the SEQ paper.
- Answer **all** questions.
- 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 term “borderline product” (10 marks)

1.2 Explain the criteria that you will consider in evaluating borderline products for registration. (40 marks)

1.3 Read through the following incidences carefully. Name the respective legislation/s governing each of them. (50 marks)

- I. Maximum selling price of rice
- II. Trading beverages containing alcohol more than 1% by volume to persons under 21 years of age
- III. Importation of veterinary medicines
- IV. Donation of cord blood
- V. Labeling of a schedule II pharmaceutical product
- VI. Cultivation, conservation and propagation of medicinal plants
- VII. Authorization to use the title “Vaidyacarya”
- VIII. Employment of persons under eighteen
- IX. Promotion of competition and consumer interest
- X. Maternity leave for office workers

**02.** Describe the purpose/objectives of below mentioned legislations.

2.1 National Medicines Regulatory Authority Act No. 05 of 2015 (15 marks)

2.2 Food Act No. 26 of 1980 (15 marks)

2.3 National Authority on Tobacco and Alcohol Act No. 27 of 2006 (20 marks)

- 2.4 The Consumer Affairs Authority Act No, 09 of 2003 (20 marks)
- 2.5 Ayurveda Act No. 31 of 1961 (30 marks)

03.

- 3.1 List three items which are regulated under the Control of Pesticides Act no. 33 of 1980. (20 marks)
- 3.2 Name the licensing authority for pesticides. (10 marks)
- 3.3 Answer below questions in relation to the office of the licensing authority for pesticides.
- 3.3.1 State the main function of this office. (10 marks)
- 3.3.2 Briefly describe the major focus areas in implementation of control of pesticides act. (35 marks)
- 3.4 "A nominee from the National Medicines Regulatory Authority (NMRA) should be a member of the Pesticide Formulary Committee" comment on this statement. (25 marks)

04.

- 4.1 List four main legislations approved for the prevention and control of drug abuse in Sri Lanka. (20 marks)
- 4.2 Briefly explain the objectives of two authorities established under the legislations mentioned in 4.1. (40 marks)
- 4.3 Assume you are a patent owner. Describe your rights regarding handling your patent (20 marks)
- 4.4 "Intellectual property protection has several positive impacts". Justify the above statement. (20 marks)

05.

- 5.1 Industrial safety division is one of the key segments of the Labour Department of Sri Lanka. Answer below questions.
- 5.1.1 State the main objective of the industrial safety division. (10 marks)
- 5.1.2 Briefly explain the main functions of the industrial safety division. (40 marks)
- 5.2 Read the following sentences carefully and mark whether true or false. (50 marks)

No.	Sentence	T/F
I.	The shop and office employees act is applicable to all employees working in a shop, office or a factory.	

II.	NATA recommend measures in consultation with the national dangerous drugs control board, for the elimination or minimization of illicit drug use.	
III.	Any person above the age of eighteen years, may consent to the donation, to take effect upon his death, of his body or any part thereof.	
IV.	Atropine, its salts & their preparations are part 1 poisons according to Poisons opium and dangerous drugs ordinance.	
V.	Containers for poison & poisonous substances should not be different from ordinary containers.	
VI.	License is not required to collect the seeds, pods, leaves and flowers of poppy, coca or hemp plants.	
VII.	Provision of services for the treatment of disease, preservation and promotion of the health, according to Ayurveda is one of the key objectives of Department of Ayurveda.	
VIII.	No trader is allowed to eliminate or substantially damage a competitor in that market.	
IX.	The customs ordinance has nothing to do with provisions in the Food Act.	
X.	Every vendor of food shall if so required by an authorized officer, disclose the name, address and such other particulars required of the person from whom that vendor purchased that food.	

## PART B

06.

6.1 Assume that you are requested to carry out a survey on a selected community to find the factors associated with the poor medication adherence by elderly people.

6.1.1 Write four ethical principles you should consider in conducting your survey?

(10 marks)

6.1.2 Briefly describe three principles you mentioned in 6.1.1.

(30 marks)

6.2 List **five** uses of having a National Medicinal Drug Policy for Sri Lanka.

(10 marks)

6.3 Write short notes on following.\*

6.3.1 The Ceylon Medical Council.

(25 marks)

6.3.2 Importance of code of ethics for pharmacists.

(25 marks)