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UNIVERSITY OF RUHUNA – FACULTY OF ALLIED HEALTH SCIENCES
DEPARTMENT OF PHARMACY
SECOND BPHARM PART II EXAMINATION – AUGUST 2022
PH 2223 PHARMACY LAW AND ETHICS – SEQ

TIME: THREE HOURS

INSTRUCTIONS

- There are **six** questions in part **A, B, C** and **D** of this 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 Name two more parameters that are considered for regulating medicines in Sri Lanka in addition to the quality, safety, and efficacy of drugs. (***16 marks***)

1.2 Briefly describe three differences with respect to the provisions of Cosmetics, Devices and Drugs Act and National Medicines Regulatory Authority Act. (***24 marks***)

1.3 State five objectives of the National Medicines Regulatory Authority. (***30 marks***)

1.4 "Regulation and control of medicine advertisements are important" Justify the above statement. (***30 marks***)

02.

2.1 Define the term "borderline product". (***10 marks***)

2.2 State the principal function of the borderline products regulatory division. (***20 marks***)

2.3 "It is difficult to regulate borderline products". Explain this statement using a suitable example. (***30 marks***)

2.4 Briefly explain the criteria used for the evaluation of borderline products. (***40 marks***)

03.

3.1 Read the following sentences carefully and mark whether those statements are True (T) or False (F). (***50 marks***)

No.	Sentence	T/F
a	Prices of all medicines are controlled by the Sri Lankan government.	
b	A licensed local manufacturer/ an authorized importer of an overseas manufacturer who intends to register a medicine with the Authority shall submit an application to the Authority.	
c	Nutraceuticals and functional foods are regulated under the food act.	
d	Pictorials must be used in the patient information leaflet to demonstrate the correct usage of dosage forms.	
e	Any recall shall be enforced on part of a consignment, one or more batches, or on the entire product, depending on the extent of the defect.	
f	Every person who intends to open a pharmacy shall apply to the Authority for approval of the location.	

g	Any medicine imported for personal use shall only be for the exclusive personal use of such person.	
h	No person shall manufacture any medicine in Sri Lanka except under the license issued by the Authority.	
i	Over the counter medicines can be freely advertised.	
j	Promotion of safe and rational use of medicines by the health care professionals and consumers is one of the objectives of the NMRA Act.	

PART B

3.2

3.2.1 What is the aim of establishing the National Dangerous Drugs Control Board? (***10 marks***)

3.2.2 Briefly explain the functions of the National Dangerous Drugs Control Board. (***20 marks***)

3.2.3 List four members of the National Dangerous Drugs Control Board according to the constitution. (***20 marks***)

04. Answer the following questions with respect to 'Poison, Opium and Dangerous Drugs Ordinance' No.17 of 1929.

4.1 What is the purpose of establishing 'Poison, Opium and Dangerous Drugs Ordinance'? (***15 marks***)

4.2 List three authorized people who have the permission to handle poisons. (***20 marks***)

4.3 Assume that you have been appointed as an Opium Officer at the Government Opium Store. Briefly explain how you should carry out your duties there as a responsible government servant. (***30 marks***)

4.4 List two dangerous drugs included in group A and two dangerous drugs included in group B, in Part I of 3rd schedule. (***20 marks***)

4.5 List three authorized people who have the power to inspect the premises where poisons or dangerous drugs are stored. (***15 marks***)

PART C

05.

5.1 Define the term "patent". (***10 marks***)

5.2 List three criteria which is applicable in patenting. (***15 marks***)

5.3 Briefly explain the importance of following.

5.3.1 The patent law for a qualified pharmacist (***25 marks***)

5.3.2 Food Act No. 26 of 1980 (***25 marks***)

5.3.3 Consumer Affairs Authority Act No. 09 of 2003 (***25 marks***)

PART D

06.

6.1 Write three uses of the National Medicinal Drug Policy in Sri Lanka. (***15 marks***)

6.2 Write five qualifications that should satisfy to register as a pharmacist in Sri Lanka under the Medical Ordinance. (***25 marks***)

6.3 Write short notes on the following.

6.3.1 Three R concept in animal research (***30 marks***)

6.3.2 Importance of Good Clinical Practice (***30 marks***)

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