

THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
ACADEMIC YEAR 2020/2021 – SEMESTER I



BACHELOR OF PHARMACY HONOURS
FMU5202 - LAWS AND ETHICS FOR PHARMACY - LEVEL 5
FINAL EXAMINATION
DURATION: TWO (02) HOURS

DATE: 18TH MARCH 2022

TIME: 2.00 P.M. – 4.00 P.M.

Part B - Short Answer Questions (20 marks)

1. Answer the questions given below with regard to the Poison Opium and Dangerous Drug Ordinance (PODDO).

1.1. State two (02) persons who are eligible to dispense and sell poisons.

(04 marks)

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.....

1.2. Mention four (04) requirements of a prescription for a dangerous drug that ensures the validity of the prescription.

(04 marks)

I.
.....

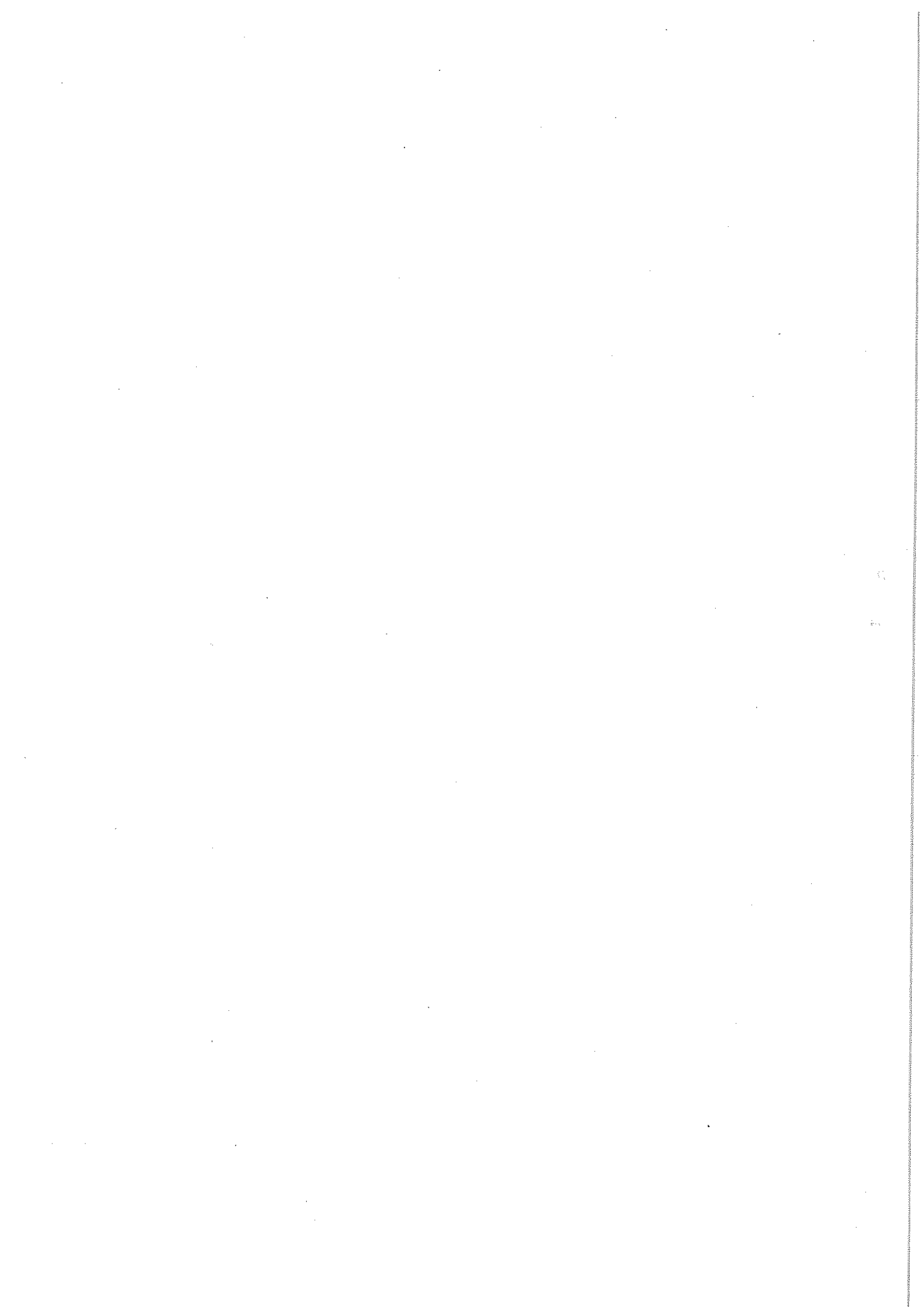
II.
.....

III.
.....

IV.
.....

1.3 Name a person authorized to import “raw and prepared opium” to Sri Lanka.

(02 marks)



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2. Answer the questions given below with respect to the National Medicine Regulatory Authority Act (NMRA Act) No. 05 of 2015.

2.1. State an authorized officer according to the NMRA Act. (02 marks)

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2.2. Write the main responsibility of following divisions. (04 marks)

I. Clinical Trial Regulatory Division

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II. Pharmacovigilance Division

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.....

2.3 State two (02) functions of the National Advisory Committee. (04 marks)

I.
.....

II.
.....

Index No

Part C - Structured Essay Questions (60 marks)

1.

- 1.1 Name the division of the Nation Medicine Regulatory Authority (NMRA) responsible for the registration of the medicines. (04 marks)
- 1.2 State five (05) functions of the Manufacturing Regulatory Division. (10 marks)
- 1.3 According to the NMRA Act, state four (04) procedures that should be followed when prescribing and dispensing a medicine related to its generic and brand names. (12 marks)
- 1.4 List two (02) offences with respect to manufacturing of medicines according to NMRA Act. (04 marks)

2.

2.1 Answer the following questions with respect to Medical Ordinance.

- i. State two (02) functions conducted by the Ceylon Medical College Council. (CMCC) (05 marks)
- ii. Outline the procedure for obtaining the "Certificate of efficiency as a pharmacist". (10 marks)

2.2

- i. State the government body which is responsible for granting patents in Sri Lanka. (05 marks)
- ii. Write a short note on "Withdrawal of medicines from use" with respect to the NMRA Act. (10 marks)