



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

DATE: 14TH MARCH 2023

TIME: 1.30 P. M. – 3.30 P.M.

Part B – 02 Short Answer Questions (20 Marks)

1.

1.1 Name four (04) authorized officers according to the National Medicines Regulatory Authority (NMRA). (04 marks)

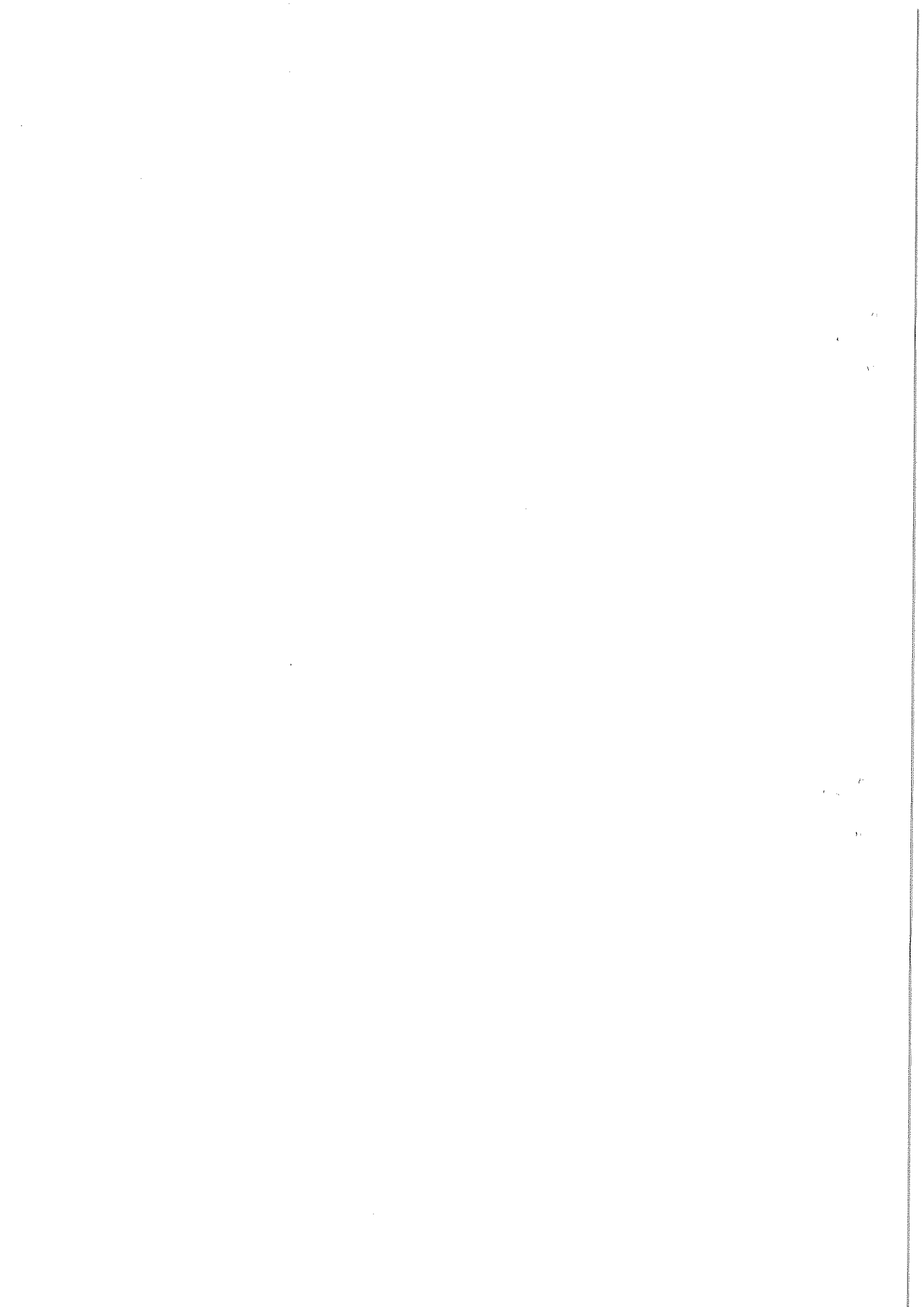
- I.
- II.
- III.
- IV.

1.2 List the four (04) categories of narcotic drugs? (04 marks)

- I.
- II.
- III.
- IV.

1.3 State two (02) objectives of the Sri Lankan National Drug Policy. (02 marks)

- I.
.....
- II.
.....



2.

2.1 State two (02) criteria that NMRA should consider before determining the introductory price of medicinal products. (02 marks)

- I.
.....
- II.
.....

2.2 Name two (02) main international organizations involved in making the global rules pertaining to patenting. (02 marks)

- I.
- II.

2.3 State four (04) inventions that are not patentable. (04 marks)

- I.
- II.
- III.
- IV.

2.4 Name two (02) stakeholders of a clinical trial. (02 marks)

- I.
- II.

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Part C – 02 Structured Essay Question (60 Marks)

1.

- 1.1 Write two (02) instances where the opium registration of a 'Vedarala' is cancelled. (04 marks)
- 1.2 State four (04) restrictions pertaining to the possession of dangerous drugs. (08 marks)
- 1.3 Briefly describe how poisonous substances should be stored in a dispensary. (08 marks)
- 1.4 Briefly explain restrictions pertaining to the import and export of raw and prepared opium. (10 marks)

2.

- 2.1 List the four (04) categories of narcotic drugs according to the World Health Organization (WHO). (08 marks)
- 2.2 Write four (04) tasks of the International Narcotics Control Board (INCB). (08 marks)
- 2.3 Write short notes on two (02) of the following topics. (14 marks)
- I. Labelling of extemporaneously prepared medicines
 - II. National Medicines Quality Assurance Laboratory
 - III. Schedule I medicines
 - IV. Starting a pharmaceutical manufacturing facility in Sri Lanka