



**UNIVERSITY OF JAFFNA, SRI LANKA**  
**BACHELOR OF PHARMACY**  
**SECOND YEAR SECOND SEMESTER EXAMINATION – April 2020**  
**PHAJE 2253 Pharmaceutical Jurisprudence and Ethics**

**ANSWER ALL EIGHT (08) QUESTIONS.**

**Date: 25.09.2020**

**Time: 03 Hours**

- 01.** With reference to National Medicines Regulatory Authority Act No. 05 of 2015, Explain the offences pertaining to medicine. (100 Marks)
- 02.**
- 2.1 Explain the professional standard which is regulated by Sri Lanka Medical council. (50 Marks)
- 2.2 List the members of the Sri Lanka Medical council. (30 Marks)
- 2.3 Name the certificates that are issued by Ceylon Medical College Council. (20 Marks)
- 03.**
- 3.1 Briefly explain the:
- 3.1.1. biowaiver in the medicine registration. (30 Marks)
- 3.1.2. registration of medicine. (40 Marks)
- 3.2 Name the licenses, that are required to handle the medicine. (30 Marks)
- 04.** Answer the following with the reference to the poison and Opium and dangerous drug act and their Amendments.
- 4.1 Briefly explain 'Sign Order'. (40 Marks)
- 4.2 What are the functions of 'Opium Board'? (20 Marks)
- 4.3 Write an account on storage of poison. (40 Marks)
- 05.** With reference to the National Medicines Regulatory Authority Act No. 05 of 2015, Answer the questions.
- 5.1 Explain the:
- 5.1.1 "Boarderline products". (35 Marks)
- 5.1.2 "Medical Device". (15 Marks)
- 5.2 Write an account on medical devices evaluation. (50Marks)

- 06.** Explain the followings.
- 6.1 6.1.1. Address of the registered person under medical ordinance is important. (30 Marks)
  - 6.1.2 Dentists are exempted from serving on jury. (20 Marks)
  - 6.2 List the functions of a state pharmacist. (50 Marks)
- 07.**
- 7.1 Define the following with 03 example for each.
    - 7.1.1 Poisons. (10 Marks)
    - 7.1.2 Poisonous substances. (10 Marks)
  - 7.2 Write the condition of sale of arsenic. (30 Marks)
  - 7.3 Give the procedure that are to be followed by pharmacist while dispensing prescription with controlled drug. (50 Marks)
- 08.** Write an account on.
- 8.1 Pricing of pharmaceuticals. (30 Marks)
  - 8.2 Drug schedule. (70 Marks)