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**UNIVERSITY OF JAFFNA, SRI LANKA**  
**BACHELOR OF PHARMACY**  
~~THIRD YEAR FIRST SEMESTER EXAMINATION~~ <sup>Second</sup> ~~SEMESTER~~ <sup>Second</sup> EXAMINATION – AUGUST 2016  
**PHAJE 2253 Pharmaceutical Jurisprudence and Ethics**

**ANSWER ALL EIGHT QUESTIONS.**

**Date: 15.08.2016**

**Time: 03 Hours**

- 01.** 1.1 Define the followings:
- 1.1.1. Medicine. (10 Marks)
  - 1.1.2. Biowaiver. (10 Marks)
  - 1.1.3. Bioequivalence. (10 Marks)
- 1.2 Explain how the drugs are scheduled in Sri Lanka. (70 Marks)
- 02.** Answer the following with the reference to the poison and Opium and dangerous drug act and their Amendments.
- 2.1 What is a 'Poison'? (10 Marks)
  - 2.2 Briefly explain 'Sign Order'. (20 Marks)
  - 2.3 What are the functions of 'Opium Board'? (20 Marks)
  - 2.4 What precautionary measures have to be taken by a pharmacist while dispensing a prescription containing Dangerous Drugs? (50 Marks)
- 03.**
- 3.1 Describe the requirements to register as a Pharmacist under Medical ordinance. (40 Marks)
  - 3.2 List 15 functions of a state pharmacist. (60 Marks)
- 04.**
- 4.1 What is meant by 'pharmaceutical ethics'. (15 Marks)
  - 4.2 Briefly explain the principles of pharmaceutical ethics. (85 Marks)
- 05.**
- 5.1 How does the Sri Lanka Medical Council maintain professional standards? (50 Marks)
  - 5.2 List the members of the Ceylon Medical College Council. (30 Marks)
  - 5.3 Name ten (10) certificates issued by Ceylon Medical College Council. (20 Marks)
- 06.** Write an account on:
- 6.1 Forensic pharmacy. (50 Marks)
  - 6.2 International Pharmaceutical federation (FIP). (50 Marks)

- 07.** With reference to the National Medicines Regulatory Authority Act No. 05 of 2015 (NMRAA).
- 7.1 Name the chapters of National Medicines Regulatory Authority Act. (20 Marks)
  - 7.2 List the powers and functions of National Medicines Regulatory Authority. (80 Marks)
- 08.** With reference to National Medicines Regulatory Authority Act No. 05 of 2015 (NMRAA).
- 8.1 How does National Medicines Regulatory Authority Act promote the generic medicine dispensing? (30 Marks)
  - 8.2 What are the regulations of National Medicines Regulatory Authority which regulate the pharmacies? (35 Marks)
  - 8.3 Write the powers of Authorized officers of National Medicines Regulatory Authority. (35 Marks)