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THE OPEN UNIVERSITY OF SRI LANKA  
15 SEP 2020  
EXAMINATION DIVISION

0062



THE OPEN UNIVERSITY OF SRI LANKA  
FACULTY OF HEALTH SCIENCES  
DEPARTMENT OF PHARMACY  
ACADEMIC YEAR 2019/2020 – SEMESTER I

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

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DATE: 15<sup>TH</sup> SEPTEMBER 2020

TIME: 9.30A.M. – 11.30 A. M.

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Index No.....

**Part B – Short Answer Question (20 marks)**

1.

1.1 What is meant by granting a “monopoly” by means of a patent? (04 marks)

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

i.....  
.....  
ii.....  
.....  
iii.....  
.....  
iv.....  
.....

1.3 Write the two (02) main international organizations that govern patent laws. (02 marks)

i.....  
ii.....

2.

2.1. State two (02) objectives of the National Medicinal Drug Policy (NMDP) of Sri Lanka.

(04 marks)

i.....

.....

ii.....

.....

2.2. List six (06) elements of the NMDP.

(03 marks)

i.....

ii.....

iii.....

iv.....

v.....

vi.....

2.3. According to the NMDP, state three (03) suggestions to improve the local pharmaceutical industry.

(03 marks)

i.....

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ii.....

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iii.....

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**Part C – 02 Structured Essay Questions- 60 marks**

1.

1.1 Differentiate between ‘laws’ and ‘ethics’. (06 marks)

1.2 Briefly explain the four (04) general principles of ethics as it relates to pharmacy practice. (08 marks)

1.3 Write a brief note on the ‘code of ethics for pharmacists’. (08 marks)

1.4 Briefly describe ‘conflict of interest’ with regards to the pharmacy profession using two (02) examples. (08 marks)

2.

2.1. Name the three (03) types of regulations made under the National Medicines Regulatory Authority (NMRA) Act No. 05 of 2015. (06 marks)

2.2. Briefly describe the process of registering medicines by the NMRA. (10 marks)

2.3. Write a brief note on regulations related to advertising medicines in Sri Lanka. (08 marks)

2.4. List four (04) responsibilities of an investigator of a clinical trial. (06 marks)