Total No. of Questions : 6]

SEAT No. :

[Total No. of Pages : 2

P2922

[5049] - 707

Fourth Year B.Pharmacy (Semester - VII)

4.7.7 : PHARMACEUTICAL JURISPRUDENCE

(2013 Pattern)

Time : 3 Hours] *[Max. Marks : 70*

Instructions to the candidates :

1) ***Answers to the two sections should be written in separate answer book.***
2) ***All questions are compulsory.***
3) ***Figures to right indicate full marks.***

SECTION - I

Q1) Define "illicit traffic". Discuss in detail the powers of central Government to permit, control and regulate certain operations under NDPS Act 1985.**[10]**

OR

What are different administrative bodies under Drugs and Cosmetics Act 1940. Discuss the qualifications, duties and working procedure of Government Analyst.

Q2) Attempt any five (3 marks each) **[15]**

a) Write the functions of PCI.

b) What are the objectives of Industrial Development and Regulation Act 1951.

c) Define Displaced Person and Repatriate under Pharmacy Act 1948.

d) What are the provisions for experimentation on animals under the Prevention of cruelty to Animals Act, 1960.

e) Explain objectives of DPCO 2013. Give the general formula for calculation of ceiling price of the scheduled formulation.

f) Specify Schedule D and Schedule G under Drugs and Cosmetics Act 1940.

g) Write the classes of certain drugs and cosmetics prohibited for manufacture and sale under drugs and cosmetics Act 1940.

P.T.O.

Q3) Attempt any two (5 marks each) **[10]**

a) Define Magic Remedy. Discuss the classes of advertisements prohibited and exempted under Drugs and Magic Remedies Act 1954.

b) Write the conditions of Loan Licence and Repacking licence.

c) Discuss the constitution and functions of State and Joint State pharmacy councils.

d) Write a short note on DTAB.

SECTION - II

Q4) Define Patent. Write in detail about filling and processing of patent. **[10]**

OR

Elaborate trademark, copyright, industrial design and geographical indications under IPR.

Q5) Attempt any five (3 marks each) : **[15]**

a) What are product and process patents?

b) What is patent infringement?

c) What is EMR?

d) Discuss in brief about "opposition to grant of patent".

e) Write in brief criteria to obtain patent.

f) What are Provisional and Complete specifications.

Q6) Attempt any two (5 marks each) **[10]**

a) Write a short note on Therapeutic Goods Administration.

b) Write in brief ANDA and Bioequivalence.

c) Explain Patent Certification.

d) Discuss in brief salient features of Hatch Waxman Act with reference to generic drugs.