Total No. of Questions : 6]

SEAT No. :

P2009

[Total No. of Pages : 2

[5145]-707

Final Year B.Pharmacy

4.7.7 : PHARMACEUTICAL JURISPRUDENCE

(2013 Pattern) (Semester - VII)

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

Instructions to the candidates:

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

SECTION - I

Q1) Enlist different administrative bodies under Drugs and Cosmetics Act 1940. Discuss the qualifications, powers and duties of Drug Inspector. **[10]**

OR

Write in detail objectives and salinet features of Drugs and Magic Remedies Act 1954 and Rules 1955. **[10]**

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

a) What are the qualifications for entry of name in First Register as per the provisions of Pharmacy Act, 1948?

b) What does the Schedule J and Schedule H under D & C act 1940 prescribe?

c) Enumerate the main recommendations of Drug Enquiry Committee.

d) Write the provisions for the import of drugs for examination test or analysis.

e) Write in brief about Education Regulation.

f) What are the functions of Animal Welfare board of India.

g) What are the objectives of Central Consumer Protection Council established under Consumer Protection Act, 1986?

P.T.O.

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

a) Define "Illicit traffic". Discuss in detail control on certain operations by Central Government under Narcotic Drugs And Psychotropic Substances Act 1985.

b) Discuss the constitution, and functions of Central Drug Laboratory.

c) Define "Ceiling Price" under Drug Price Control Order 2013. Explain the general formula for calculation of ceiling price of a scheduled formulation.

d) Write a short note on registration of Pharmacist.

SECTION - II

Q4) What is IPR? Write its significance and elaborate different forms of IPR. **[10]**

OR

What is Patent? Discuss latest amendments in patent act 1970. **[10]**

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

a) What are product and process patents?

b) Write the significance of Hatch Waxman Act.

c) What is patent infringement?

d) What is "therapeutic good" as per the provisions of TGA.

e) Enlist different Standard Institutions and regulatory authorities.

f) Write in brief about Orange Book.

g) What are the documents required for patent filing?

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

a) What is Bioequivalence? Explain the contents of ANDA.

b) What are EMR and Compulsory Licensing?

c) Write a short note on opposition to grant of patent.

d) Write a short note on USFDA.