Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.Pharm/SEM-2/MPT-215(1)/2011

2011
DRUG REGULATIONS

Time Allotted : 3 Hours *Full Marks :* 70

The figures in the margin indicate full marks.

Candidates are required to give their answers in their own words as far as practicable.

GROUP – A

(Objective Type Questions)

1. Answer any *ten* of the following : 10 × 1 = 10

A. Choose the correct alternatives for the following :

i) According to Drugs and Cosmetics Act, what do you mean by "import licence" ?

a) a licence in Form 10 to import drugs

b) a licence in Form 10A to import drugs

c) a licence in Form 10B to import drugs

d) a licence in Form 9A to import drugs.

ii) What is the period of validity of an import licence before it is suspended or cancelled ?

a) One year from the date of its issue

b) Four years from the date of its issue

c) Five years from the date of its issue

d) Three years from the date of its issue.

iii) In which court shall an offence punishable under the Chapter IV of Drugs and Cosmetics Act shall be tried ?

a) No court inferior to that of a Metropolitan Magistrate or of a first class Judicial Magistrate

b) No court inferior to that of a District Session Judge

c) Any court

d) None of these.

iv) The area of the quality control laboratory may be divided into

a) Chemical, Instrumentation, Microbiological and Biological testing

b) Chemical, Microbiological and Biological testing

c) Chemical, Instrumentation and Biological testing

d) None of these.

v) Who shall prepare and endorse the Master Formula records relating to all manufacturing procedures ?

a) Plant head of the industry

b) Vice President of the company

c) Competent technical staff *i.e.* head of production and quality control

d) none of them.

vi) What is maximum number of permitted particles of 0·5 μ size per cubic metre equal to or above for an area of Grade *A* ?

a) 35200 b) 3520

c) 352 d) 352000.

vii) Unless there are product specific requirements, what are the temperature and humidity in the aseptic areas ?

a) Shall not exceed 17 degree centigrade and relative humidity 55%, respectively

b) Shall not exceed 20 degree centigrade and relative humidity 45%, respectively

c) Shall not exceed 20 degree centigrade and relative humidity 55%, respectively

d) Shall not exceed 27 degree centigrade and relative humidity 55%, respectively.

B) Answer in *one* or *two* sentences :

viii) What do you mean by TRIPS ?

ix) What is the full form of GATT ?

x) What is PDUFA ?

xi) How many categories of intellectual property rights are recognized under the TRIPS agreement of the WTO (World Trade Organization) ?

xii) Write the full form of WIPO.

GROUP – B

(Short Answer Type Questions)

Answer any *three* of the following. 3 × 5 = 15

2. For the purpose of Chapter III of the Drugs and Cosmetics Act 1940, define Misbranded and Adulterated drugs.

3. Describe "Power of Inspectors".

4. Write in brief about Building and Premises requirement according to revised schedule M.

5. Describe the terms "apheresis", "autologous blood" and "blood bank" according to Part XII-B and Part XII-C of Schedule *F* of Drugs and Cosmetics Rule, 1945.

6. Write a note on Indian Patents Act, 2005.

GROUP – C

(Long Answer Type Questions)

Answer any *three* of the following. 3 × 15 = 45

7. a) Write in detail about "Penalty for manufacture, sale, etc., of cosmetics in contravention of Chapter IV of The Drugs and Cosmetics Act, 1948.

   b) Describe the qualification required for competent technical staff for the grant or renewal of a licence in Form 25. 9 + 6

8. What do you mean by Orphan drug ? Describe in detail about clinical trial design for rare disease. 2 + 13

9. Describe in detail about general considerations for revised schedule M.

10. Describe conditions of granting licence in Form 28-C, Form 28-E, Form 26-G or Form 26-I shall be subject to the special conditions set out in Schedule *F*, Part XII-B and Part XII-C, for setting up a blood bank.

11. Write notes on the following :

    a) Requirements for Quality control section for manufacture of Unani system of medicine as per Schedule T.

    b) Pharmaceutical Industries in India after Post GATT scenario.