Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.PHARM/SEM-2/MPT-215(1)/2012

2012
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 Choice Type Questions)

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

A. Choose the correct alternatives for the following :

i) Effective fumigation of aseptic areas requires a temperature and humidity as

a) 25° and relative humidity 40 — 45%

b) 25° C and relative humidity 50%

c) 20°C and relative humidity 40—45%.

ii) Operators should not enter into fumigated areas after cessation of the operation until the level of formaldehyde vapours is reduced to less than the threshold limit value (TLV) of

a) 5 parts per million (ppm)

b) 3 parts per million (ppm)

c) 2 parts per million (ppm).

iii) Sterilization of linen to be used in sterile manufacturing area is be done at

a) 115°C for 30 minutes

b) 110°C for 60 minutes

c) 121°C for 30 minutes.

iv) Rubber gloves to be used in sterile area, should be sterilized at

a) 110° C for 15 minutes

b) 110°C for 30 minutes

c) 121°C for 30 minutes.

v) An "import licence" in Drugs and Cosmetics Act means

a) a licence in Form 10 to import drugs

b) a licence in Form 10 A to import drugs

c) a licence in Form 10B to import drugs

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

vi) The court where an offence punishable under the Chapter IV of the Act shall be trialed is

a) No court inferior to that of a First class judicial magistrate

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

c) Any court

d) None of these.

vii) What is the maximum number of particles of 0·5 μ size per cubic metre allowed for Grade A area ?

a) 35200 b) 3520

c) 352 d) 352000.

B. Answer the following in *one* or *two* sentences :

viii) What is PDUFA ?

ix) Explain Schedule T.

x) What are generally temperature and humidity requirements in the aseptic area ?

xi) How may the area of QC lab be divided ?

xii) Write down the full form of UATT.

GROUP – B

(Short Answer Type Questions)

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

2. Give the requirements for establishing a Blood Bank as per Drug Rules with amendments to date.
3. Give the basic difference underlying in Part XB, Part XIIB and Part XIIC of Schedule F of Drugs and Cosmetics Rules with amendments to date.
4. What is WTO ? Discuss the duties and responsibilities of WTO.
5. Describe the required qualification of Drugs Inspector.
6. Write a note on reports of Government Analysts.

GROUP – C

(Long Answer Type Questions)

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

7. What are the uses of whole human blood ? Write in brief about its source, collection, storage and other requirements to be fulfilled as per Drugs and Cosmetic Rules, with amendments to date. 3 + 12

8. What are the advantages of dried human plasma over whole human blood ? Write in brief about the preparation of dried human plasma for clinical use. 7 + 8

9. Describe in general about the considerations of Indian GMP.

10. Describe orphan drug. What are the facilities provided to encourage research on orphan drug ? Describe the penalty for manufacture, sale etc. of drugs in contravention of the Chapter III of Drugs and Cosmetics Act, 1970. 3 + 5 + 7

11. Write notes on the following : 6 + 9

    a) Power of Inspectors

    b) GMP requirements of Parenteral section in brief.

12. a) Design a clinical trial for the treatment of rare disease.

    b) What are the sources and uses of whole human blood ?

10 + 5