



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.*

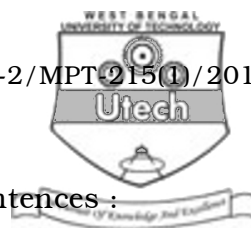
GROUP – A

(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. $3 \times 5 = 15$

- 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. $3 \times 15 = 45$

- 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. $3 + 12$

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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
