Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.Pharm/SEM-2/MPT-215(2)/2013

2013
DRUG REGULATORY AFFAIRS

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

(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following : 10 × 1 = 10

   i) For drug products intended for storage in freezer, storage conditions are

      a) – 20°C ± 5°C for 12 months

      b) – 20°C ± 5°C for 6 months

      c) 5°C ± 3°C for 12 months

      d) –5°C ± 2°C for 6 months.

   ii) For conducting photo stability testing the light source is

      a) D55/D155 lamp b) D65/D165 lamp

      c) 165/I 165 lamp d) none of these.

   iii) Maximum daily does ≤ 1g, reporting threshold is

      a) 0·01% b) 0·05 %

      c) 0·1 % d) 0·5 %.

iv) IRS means

a) Integrated risk information system

b) International risk information system

c) Indian risk information system

d) None of these.

v) USEPA means

a) Unite State Environment Protection Agency

b) United State Economical Protection Agency

c) United State Evaluation Potency Agency.

d) None of these.

vi) For photo stability study UV fluorescent lamp spectral distribution is

a) 300 nm to 400 nm b) 320 nm to 400 nm

c) 350 nm to 400 nm d) 370 nm to 410 nm.

vii) For photo stability, sample is exposed to light, providing over all illumination of not less than

a) 1·4 million lux hours b) 1·8 million lux hours

c) 1·2 million lux hours d) 1·0 million lux hours.

viii) The Indian Patent Act was passed in the year of

a) 1911 b) 1970

c) 1972 d) 1994.

ix) What is the full form of WIPO ?

a) World Intellectual Property Organization

b) Wield Intellectual Property Organization

c) World Intellectual Potency Organization

d) None of these.

x) What is the full form of TRIPS ?

a) Trade Related aspect of Intellectual Property Rights

b) Trade relation aspect of Intellectual Property Rights

c) Technical relation aspect of Intellectual Property Rights

d) None of these.

xi) As per TRIPS the term of patent is

a) 20 years b) 14 years

c) 7 years d) 5 years.

xii) Invention related to drug and chemicals comes under

a) Product patent b) Process patent

c) Copyright patent d) Trademark patent.

GROUP – B

(Short Answer Type Questions)

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

2. Write short notes on bracketing and matrixing designs for stability testing of a new drug substance.

3. Classify the clinical studies according to objective.

4. Briefly explain genotoxicty testing of pharmaceuticals.

5. Give a comparison of Indian Patent Acts and TRIPS.

6. Write short notes on lowest observed effect level, no observed effect level and permitted daily exposure.

GROUP – C

(Long Answer Type Questions)

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

7. What are drug product and drug substance ? Describe in brief what are the storage conditions for drug product in general case, packaged in impermeable container, semi-permeable container, store in refrigerator and freezer container for stability study. Explain stability commitment for new drug product. 2 + 10 + 3

8. What are reporting threshold, identification threshold and qualification threshold for degradation products in new drug products explained as per ICH ? Describe Qualification of impurities in new drug substance. 5 + 10

9. What is residual solvent ? Classify residual solvent by risk assessment. Explain the method for establishing exposure limits. 1 + 2 + 12

10. What is intellectual property ? What is IPR ? Write in brief the feature of Indian Patent Acts ? What is the main objective of IPR ? Classify intellectual property and give a brief on it ?

1 + 7 + 2 + 5

11. What are the factors to be considered for carcinogenicity testing ? Describe the mechanistic studies for testing carcinogenicity of pharmaceuticals ? 8 + 7

12. Describe standard test battery for genotoxicity testing in pharmaceuticals.