	Utech
Name:	
Roll No.:	To Opening State Confident
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:
 - $10 \times 1 = 10$
 - i) For drug products intended for storage in freezer, storage conditions are
 - a) $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 12 months
 - b) $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 6 months
 - c) 5° C $\pm 3^{\circ}$ C for 12 months
 - d) -5° C $\pm 2^{\circ}$ 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 %.

30814(M.Pharm)

[Turn over

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

b)

d)

- a) 1.4 million lux hours
- 1.8 million lux hours
- c) 1.2 million lux hours
- 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.

 $3 \times 5 = 15$

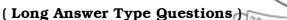
- 2. Write short notes on bracketing and matrixing designs for stability testing of a new drug substance.
- 3. Classify the clinical studies according to objective.
- 4. Briefly explain genotoxicty testing of pharmaceuticals.
- 5. Give a comparison of Indian Patent Acts and TRIPS.
- 6. Write short notes on lowest observed effect level, no observed effect level and permitted daily exposure.

30814(M.Pharm)

3

[Turn over

GROUP - C



Answer any three of the following.



- 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.

30814(M.Pharm)