Name : .....

Roll No. : .....

Invigilator's Signature : .....

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

2012

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) Maximum daily dose ≤ 2 gm. Reporting threshold in new drug substances is

a) 0·01% b) 0·03%

c) 0·05% d) 0·08%.

ii) Maximum daily dose < 10 mg. Qualification threshold in new drug products is

a) 0·5% or 50 μg TDI, whichever is lower

b) 0·3% or 30 μg TDI, whichever is lower

c) 0·7% or 35 μg TDI, whichever is lower

d) 1·0% or 50 μg TDI, whichever is lower.

iii) Maximum daily dose < 1 mg. Identification of threshold in new drug products is

a) 1·0% of 5 μg TDI, whichever is lower

b) 2·0% of 15 μg TDI, whichever is lower

c) 0·5% of 2·5 μg TDI, whichever is lower

d) 1·0% of 20 μg TDI, whichever is lower

iv) IPCS means

a) International program on chemical safety

b) Indian program on chemical safety

c) International program on commercial safety

d) None of these.

v) Benzene is classified as which class of residual solvent ?

a) Class 1 b) Class 2

c) Class 3 d) None of these.

vi) The changes made in Q1A (R) of ICH guidelines for climatic zone III are that the intermediate storage condition has been changed from 30°C ± 2°C/60%RH± 5% RH to the

a) 35°C ± 2°C/65% RH ± 5% RH

b) 30°C ± 2°C/65% RH ± 5% RH

c) 35°C ± 2°C/70% RH ± 5% RH

d) 32°C ± 2°C/65% RH ± 5% RH

vii) Dedicated production area is used to produce

a) Anti-inflammatory agents

b) cephalosporins

c) Antacids

d) Beata-blockers.

viii) US and EU regulators consider that the DSUR, submitted annually. What is DSUR ?

a) Detailed Safety Update Report

b) Development Surveillance Update Report

c) Drug Safety Update Report

d) Development Safety Update Report.

ix) A measureable DNA and/or RNA characteristic that is an indicator of normal biologic processes, pathogenic processes and / or response to therapeutic or other interventions is known as

a) a genomic biomarker

b) a cytotoxin biomarker

c) single nucleotide polymorphism.

x) A genomic biomarker can consist of

a) one or more deoxyribonucleic acid (DNA) characteristics

b) one or more deoxyribonucleic acid (DNA) and /or ribonucleic acid (RNA) characteristics

c) one or more ribonucleic acid (RNA) characteristics

d) one deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) characteristics.

xi) DIBD is the

a) sponsor's first authorization to conduct a clinical trial in any country worldwide

b) investigator's first conduct of a clinical trial in any country worldwide

c) sponsor's first authorization to conduct a clinical trial in USA

d) sponsor's first authorization to conduct a clinical trial in India.

GROUP – B

(Short Answer Type Questions)

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

2. Describe the analytical procedures for detection of impurity in new drug substances.
3. What do you mean by intellectual property rights ? Give your answer with due justifications.
4. What is a Patent ? What are the types of patent known to you ? Write in brief about them.
5. Describe accelerated stability testing of new pharmaceutical products.
6. Explain the need for carcinogenicity studies of pharmaceuticals.

GROUP – C

(Long Answer Type Questions)

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

7. a) Define impurity and degradation products.
   b) Classify impurites as per ICH.
   c) Describe listing of impurities in specifications for new drug substances according to ICH.
   d) Write a note on qualification of degradation products in new drug products according to ICH. 2 + 3 + 5 + 5
8. a) Define PDE, LOEL and NOEL.
   b) Classify residual solvents by risk assessment.
   c) Describe the methods for establishing exposure limits. 3 + 5 + 7
9. Give the essential pre-requisites for filing a patent application. Write in detail the steps necessary to be taken for fulfilling the criteria stipulated for filing patent application in India as well as globally. 6 + 9
10. Describe different climatic zone according to ICH. Mention the storage condition and frequency of stability testing guidelines of ICH in case of new drug products for both normal drug products and drug products indented to be stored at freezer. Describe about light source used for photo-stability testing of drug prudcuts. 6 + 6 + 3
11. Describe ICH GCP guidelines for protocol writing in clinical trial.