P.G. Diploma in Pharmaceutical Regulatory Affairs
Annual Examinations – 2006

Paper PGPRAD – 202
Clinical Trials and HealthCare Policies

Time allowed: Three hours | Maximum Marks: 100

SECTION – I | Marks

Q1. Attempt all the objective type questions given below | 1X20=20

i) Fill in the blank

_____ trials are conducted to detect presence and amount of medicine at various times in different tissues and compartments.

ii) Expand IRB and CRO

iii) Which pharmacokinetic parameters characterizes rate and extent of absorption?

iv) Subsequent treatments should be separated by periods long enough to eliminate the previous dose before the next one. Such periods are called (Tick the appropriate answer)

a) Clean Period
b) Separated Period
c) Washout Period
d) Wash in Period

v) Fill in the blanks

_____ are used to assess permeability through biological membranes and _____ is used to assess plasma protein binding.

vi) Define Placebo.

vii) Fill in the blank

The phase IV of the clinical trials is known as _____.

viii) Define GCP.

ix) Fill in the blank

India has developed its own set of guidelines that are specified for Good Clinical Practice by _____.

x) Tick the correct answer

SOP is known as

a) Standardized Operating Procedure.
b) Standard Operating Procedure.

c) Standard Operation Procedure.
d) Subsidized Operation Procedure.

xi) Fill in the blank
The type 4 FDA classified clinical type and therapeutic potential of commercially sponsored IND and NDAs deals with _____.

xii) Fill in the blank
The _____ approach can be used to estimate population parameters of a response surface model in Phase I and late Phase IIb of clinical drug development.

xiii) Fill in the blank
About 1 in 1500 persons has plasma _____ deficiency, which decreases succinylcholine inactivation.

xiv) To which module of the common technical document the clinical trial report is the part
xv) Define Health Technology Assessment (HTA).
xvi) How Cost-effectiveness ratio is calculated?
xvii) Define Pharmacovigilance.
xviii) Why in 1964 'Declaration of Helsinki was made?
xix) Tick the correct option
In some clinical trial design, patients are randomized to one of the two treatment groups and usually receive the assigned treatment during the entire trial. Such trials are called
a) Crossover Design
b) Parallel Design
c) Latin Square Design
d) Concurrent Design

xx) Define Pharmacogenetics.

SECTION – II

Q2. Attempt any six questions in about 150 words 5X6=30

i) Distinguish between single – blind and double – blind clinical trials. Briefly give an account on combination of blinds.
ii) What do you know understand by the term absolute and relative bio-availability? How are these calculated?
iii) How Biopharmaceutical validation of the retard release form carried out?
iv) Briefly explain Good Pharmacovigilance Practice.
v) What are the Pharmacoeconomic fundamentals?
vi) Briefly discuss classification of clinical trials.
vii) Give Ethical approval process for clinical studies.

viii) Give Clinical summary prerequisite in Module 2 of common technical document.

SECTION – III

Q3. Attempt any four questions in 500 words each 12.5X4=50

i) Discuss various Phases of clinical trials.
ii) Explain Good Clinical Practice Documentation and Compliance.
iii) Describe design and conduct of bioavailability or bioequivalence studies.
iv) Discuss the clinical studies performed to support the licensure of combination vaccines.
v) Discuss application dossier for clinical trial documentation.
vi) Discuss type and number of control groups of patients being evaluated in any clinical trials.
vii) Explain the important steps which are taken to ensure safety in clinical trials.