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

Paper PGPRAD – 204
Regulatory Considerations in controlled drug delivery and future aspects of Biopharmaceuticals

Time allowed: Three hours | Maximum Marks: 100

SECTION – I | Marks

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

i) The full form of IND is :
a) International New Drug
b) Investigational New Drug
c) Indian New Drug
d) Investigational Novel Drug

ii) Generic drug product is comparable to innovator drug product in :
a) Dosage form and strength
b) Route of Administration
c) Quality
d) All of the above

iii) Angle of Repose is measured using formula :
a) Tan θ = H/R
b) Tan θ = R/H
c) Tan 2θ = H/R
d) Tan 2θ = R/H

iv) The gastric transit time during fasted state for a solid dosage form is
a) 0-30 minutes
b) 0-60 minutes
c) 0-90 minutes
d) 0-120 minutes

v) Normal human volunteers are involved in which phase of Clinical Trials
a) Phase I
b) Phase II
c) Phase III
d) Phase IV

vi) IND application is submitted after completion of

a) Preclinical Studies b) Phase I Clinical trials

c) Phase II Clinical trials

d) Phase IV clinical trials

vii) SUPAC stands for :

a) Scale up processing and control
b) Scale up and pre approval changes
c) Scale up production and control
d) Scale up and post approval changes

viii) FDA guidelines state that two formulations are bio equivalent if their rate and extent of absorption differ by:

a) -25% / +25%

b) -20% / +25%

c) -25% / + 30%

d) -30% / + 30%

ix) The active pharmaceutical ingredient in catapress – TTS

a) Pilocarpine

b) Diclofenac

c) Scopolamine

d) Insulin

x) Erythropoeitin is used for the treatment of :

a) Anaemia

b) Rheumatoid Arthritis

c) Leukemia

d) Gout

xi) Types of dissolution apparatus described in USP are :

a) Two

b) Three

c) Five

d) Seven

xii) For marketing of New biological products, filing of following licenses are required:

a) PLA/ELA

b) IND/NDA

c) PLA/NDA

d) ELA/ NDA

xiii) Novolog is used in the treatment of :

a) Hypertension

b) Urticaria

c) Depression

d) Diabetes Mellitus

xiv) For highly lipophilic drugs log p should be

a) <2

b) 2-4

c) >5

d) 4-5

xv) Mean pH of saliva is

a) 4

b) 6

c) 8

d) 10

xvi) Ideal value of angle of repose for good flow characteristic of the product is _____.

xvii) _____ is a bio pharmaceutical product of microbiological origin.

xviii) Surface or contact blood clotting factor is also called as_____.

xix) Phase IV clinical trials are termed as _____.

xx) With increase in particle size, the bio availability of water soluble drug _____.

SECTION – II

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

i) Enumerate various methods for assessment of bioavailability. Give detail account of anyone of them.

ii) What are important parameters for selection of drug candidate for transdermal product?

iii) Give an account on "invitro –invivo correlation".

iv) Describe Peptide based biopharmaceuticals with suitable examples.

v) Explain the role of Preformulation in drug designing.

vi) How the GI tract pH affects the drug absorption?

vii) Differentiate between:
   a) NDA and ANDA
   b) Relative and absolute bioavailability

viii) Discuss regulatory consideration for veterinary products.