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

Paper PGPRAD – 104
Information and Quality Management

Time allowed: Three hours | Maximum Marks: 100

SECTION – I | Marks

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

i) Expand the following 5X1=5

a) ALU b) CPU c) CU d) LAN e) PDF

ii) A ledger sheet consisting of rows, columns and cells prepared on computer is called as a _____.

iii) A facility of being able to connect onto a network from a distant computer is called as _____.

iv) State whether the following statements are true or false 3X1=3

a) Document identification numbers are compulsorily alphanumeric. (T/F)
b) MT SOPs are the standard operating procedure for maintenance. (T/F)
c) Product recall becomes mandatory if a report from market surveillance proves it to be defective. (T/F)

v) What do you mean by : 2X1=2

a) TQM b) GMP

vi) Name four techniques for measuring the melting point. 4X1=4

vii) _____ is an accepted value of angle of repose and ensures good flow properties.

viii) _____ and _____ are the two major types of packaging systems. 2X1=2

ix) What is one major objective of GAP analysis in a company?

SECTION – II

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

a) Write a short note on ISO (International Organisation of Standardization)
b) Explain how a good documentation practice helps in establishing a good manufacturing setup.
c) Enumerate the various objectives of a Pre-Approval Inspection (PAI)
d) Give the specifications of the following

i) Child Resistant Packaging requirements.
ii) Tamper Resistant Packaging

e) Give the various quality test controls applicable to tablet dosage forms.
f) Give the general types of primary and secondary packaging materials and their uses.
g) Enlist the various product characterization parameters needed to assess the performance or manufacturability of the drug product.
h) What do you mean by excipients compatibility? Name the techniques used to assess the same.

SECTION – III

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

Q3. Discuss the requirements of supervisory authorities for quality assurance systems.
Q4. Write short notes on the following
a) Package integrity and performance test methods.
b) Validation of sterile package integrity.
Q5. Give the quality control of emulsions, suspensions and ointments
Q6. What do you understand by quality audits? What are the various objectives of auditing? Also explain the mechanism of auditing.
Q7. Highlight the various legislature requirements in quality of the products. Name the different laboratories being run by the central government throughout the country.
Q8. Write short notes on:
(i) Product –Plastic compatibility studies.
(ii) Composition and manufacture of glass.
(iii) Product –glass compatibility
Q9. What are the different types of quality audits? How does auditing helps in building a brand strength of a company.