Roll No……..

P. G. Diploma in Pharmaceutical Regulatory Affairs
Annual Examination – 2010
Information and Quality Management
PGPRAD – 104

Time allowed : 2½ Hours **Max Marks:70**

Section – A

Attempt all questions given below. Each question carries one mark. : [1x10]

a) When computers are connected in a small geographical area of about 10kms, it is called as ……,
b) CDER is elaborated as ……..
c) …… Is a method for measuring melting point of an API.
d) The packaging system which comes directly into contact of the product is called as ……
e) …… is a climatic test done on packaging material.
f) …….. is a sugar based oral preparation.
g) Penetration studies are a quality control method for ……..
h) The pharmaceutical operation carried out on the site is recorded in …… file.
i) ICH is elaborated as ……..
j) Accepted value of angle of repose is ……..

Section – B

Answer any **six** questions. All questions carry equal marks. [6 x 5 = 30]

1. What is GMP? Write in short its applicability to pharmaceutical industries.
2. What do you understand by Clinical trials? Elaborate on each of its phases and highlight their significance.
3. Give technical details of the different methods employed for finding the melting point of a drug.
4. Write in detail about caps and closures used to pack pharmaceutical products.
5. What do you understand by the term SIAM? Explain the various new and stringent ICH requirements to establish quality of drug and products.
6. Give a short write-up on document management in a pharmaceutical setup.
7. Enumerate the various objectives of PAI. Highlight the specific areas for which PAI is carried out.
8. Write a short note on product recall system.

Section – C

Answer any **Three** questions of long answer types. All questions carry equal marks. [3 x 10 = 30]

1. What are the various types of plastic packages? Elaborate upon the various product-plastic compatibility studies?
2. What do you understand by the terminology BUD in context with compounded sterile preparations? Mention the factors critical in establishing BUD. Also discuss the role of Process validation in establishing BUD and CSP sterility.
3. Give a detailed account of Quality control of non sterile solid dosage forms.
4. Discuss the quality control measures to be undertaken for evaluation of suspensions.
5. Enumerate the various aims and objectives of Quality Auditing. Classify its types.