Roll No……..

P. G. Diploma in Pharmaceutical Regulatory Affairs
Annual Examination – 2010
General Pharmaceutical Laws & Guidelines
PGPRAD – 102

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

Section – A

Attempt all the objective and short type questions. Each question carries one mark. : [1x10]

a) What is the function of SIAMED?
b) Name the three conditions which a patent must satisfy.
c) Fill in the blanks as directed
The WHO collaborating centre for international Drug monitoring is based at …… (Name the city), …… (Name the country).
d) State whether the following is patentable or not in India.
"Any process for medical, surgical, curative, prophylactic or other treatment of human beings, or any process for a similar treatment of animals or plants".
e) Expand ICDRA
f) Choose the best option out of the four options available to you.
CIOMS-1 and CIOMS-2 are the working groups on expedited alert reports and periodic safety update reporting under.
i) FDA ii) ICH iii) EMEA iv) WHO
g) Fill in the blanks
The long term Safety study should cover a minimum of …….. months duration on at least ……. primary batches at the time of submission and should be continued for a period of time sufficient to cover the proposed …… period
h) Define Counterfeit drugs.
i) Fill in the blank.
The books are protected by ……..
j) Fill in the blanks
The PCT stands for ……..

Section – B

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

1. What are the different types of patents that can be secured under the Indian Patent Act?
2. Classify different types of impurities in New Drug Substances.
3. What do you understand by the FDA Recall system?
4. What are the legal protections given to employees in OSHA?
5. What is NDA? How it is filed and reviewed.
6. Briefly explain tamper resistant packaging.
7. What do you understand by the work "Trade Mark"? How they are protected?
8. What are the functions of WHO International Drug Monitoring Committee?

P.T.O

Section – C

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

1. Discuss the salient features of the Patent (Amendment) ordinance, 2004 and the Patent Amendment Rules, 2005.
2. Describe the Environmental Protection Agency. What are the objectives and functions of SARA?
3. Discuss the regulatory assessment of medicinal products for use in self medication.
4. Discuss the measures to combat counterfeit medicines.
5. Describe validation of analytical procedures as per ICH guidelines.