Roll No……..

P. G. Diploma in Pharmaceutical Regulatory Affairs
Annual Examination – 2010
An Introduction to Pharmaceutical Drug Regulatory Affairs
PGPRAD – 101

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

Section – A

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

1. What is DRA?
2. CFR stands for ……..
3. Name of Pfizer's cholesterol lowering pill ……
4. Marketing Authorization was previously known as ……
5. PSUR stands for ……..
6. Name of three kinds of toxicity studies……..
7. What is DMF?
8. Molar absorptivity (e) is defined as ……..
9. …….. spectroscopy involves the absorption of radio – frequency radiation by a nucleus in a strong magnetic field.
10. …… chromatography is used for the separation of volatile organic compound.

Section – B

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

1. Describe the various phases involved in Drug Development.
2. Why is it necessary to control the prices of the drugs? What order is taking care of pricing policies and how it is controlled?
3. What attributes should be possessed by a Regulatory affairs manager.
4. What are ethical conflicts? How do they arise? Explain with examples.
5. Enumerate the various objectives of marketing strategies.
6. What are the major components of a UV-visible spectrophotometer? Also write the various applications of UV and visible spectroscopy.
7. Describe the marketing authorization process followed for generic medicines in European Union.
8. What is "product positioning"? Explain with reference to various strategies followed for product positioning.

Section – C

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

1. What is labeling of drugs? Why is it done? What are the various essential information that should be present on the label of various categories of drugs?
2. Explain the various steps involved in the elucidation of molecular structure of a common substance.
3. What is gas chromatography? Explain with reference to the instrumentation, detectors and application of gas chromatography.
4. Describe the role of GRP after registration of pharmaceuticals and GRP with regard to Licensing Authorities and supervision bodies.
5. Enumerate the various responsibilities of a DRA manager.