

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

**Paper PGPRAD – 101**  
**Introduction to Pharmaceutical Drug Regulatory Affairs**

Time allowed: Three hours

Maximum Marks: 100

**SECTION – I**

Marks

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

- i) FDA stands for \_\_\_\_\_.
- ii) DPCO is :
  - a) Drug product control order
  - b) Drug price control order
  - c) Drug product careful order
  - d) Drug price careful order
- iii) If the drug is included in schedule H and it also is a narcotic drug, then it has to be labeled with the symbol \_\_\_\_\_.
- iv) Warning label of schedule X drug states \_\_\_\_\_.
- v) Patent act was passed in the year \_\_\_\_\_.
- vi) The New York based giant \_\_\_\_\_ sells four of the ten best selling medicines.
- vii) GMP stands for
  - a) Good Manufacturing practices
  - b) Great Manufacturing parameters
  - c) Good Manufacturing Procedures
  - d) Good Making Procedures.
- viii) DMF stands for \_\_\_\_\_.
- ix) UV and visible spectroscopy methods are used for identification of structural groups. ( True/False)
- x) FT- NMR stands for \_\_\_\_\_.
- xi) Chromatography is a separation method that depends on \_\_\_\_\_.
- xii) Commonly used detectors on gas chromatograph are \_\_\_\_\_ and \_\_\_\_\_.
- xiii) For the drugs falling under schedule \_\_\_\_\_ of the Drugs and Cosmetic act, manufacturing date and expiry date should be mentioned.
- xiv) There are \_\_\_\_\_ phases of Clinical trials.
- xv) \_\_\_\_\_ is the legal and regulatory centre responsible for providing information to the medical department, health care practioners etc.

xvi) CFR means

- a) Code of finance regulation.
- b) Codex of federal regulations.
- c) Code of federal regulations.
- d) Code of federal rights.

xvii) Advertisement of Epilepsy is not prohibited. (True/False)

xviii) Drugs intended for free distribution as sample to physician shall bear on their label the words “\_\_\_\_\_”.

xix) The government agency which controls pharmaceutical industry compliance with regulated standards is \_\_\_\_\_ in USA.

xx) Essential Commodities Act was passed in the year

- a) 1954
- b) 1955
- c) 1956
- d) 1957

### SECTION – II

Q2. Attempt any six questions in about 150 words each

5X6=30

- a) Define “Pharmacovigilance”. Why is it gaining importance? What are the elements of a pharmacovigilance plan?
- b) Describe the professional qualification of a DRA manager.
- c) What are marketing ethics? Enumerate the rules for Ethical marketing.
- d) Explain the marketing authorization process followed for generic medicines in European Union.
- e) What is a Drug Master file? What are its different types and what categories of information it contains?
- f) Explain the four phases of drug discovery.
- g) Define “Intellectual Property”. What are the different kinds of intellectual property which can be protected under law? What all legislations are covering IPR's in India?
- h) How does a regulatory affairs department functions in pharmaceutical industry?

### SECTION – III

Q3. Attempt any four questions in about 500 words each.

(12.5X4=50)

- a) Why the advertisements of prescription drugs are regulated? Enumerate the list of prohibited advertisement and misleading advertisement relating to drugs and magical remedies.
- b) Discuss in detail the different kinds of marketing set-up seen in different organizations.

- c) What are marketing strategies? What are their objectives? What are the different types of strategies followed?
- d) What all information needs to be incorporated in a Dossier? Write in Detail.
- e) What are the different kinds of Chromatographic technique used for separation of substances? Explain any one of them in detail.
- f) What is IND and its different types and categories? Describe in detail the contents of an IND application.
- g) What all steps are followed for elucidating the structure of common chemical groups?