

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

**Paper PGPRAD – 102
General Pharmaceutical Laws and Guidelines**

Time allowed: Three hours

Maximum Marks: 100

SECTION – I

Marks

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

- i) Full form of FDCA
 - a) Food drug and cosmetic act.
 - b) Food drug and class act.
 - c) Feed drug and cosmetic action.
 - d) Food drug and cosmetic arc.

- ii) An Adulterated Drug is _____.
- iii) Import and Export of drug comes under section _____.
- iv) FPL stands for
 - a) Fast packaging and labeling Act
 - b) Fair packaging and lying Act
 - c) Fair packaging and labeling Act
 - d) None of the above.

- v) INDA stands for _____.
- vi) ANDA stands for _____.
- vii) Temper Resistant Packaging is _____.
- viii) OSHA stands for _____.
- ix) Environment Protectors Agency (EPA) provide _____ to citizen.
- x) PPA means
 - a) Population Promotion Act
 - b) Population Prevention Act
 - c) Population Program Act
 - d) Pollution Prevention Act

- xi) Validation is a _____.
- xii) Photo stability testing is done to _____.
- xiii) The objective of carcinogenicity study is to identify _____ potential in animals.
- xiv) Maximum feasible dose is _____ of diet.
- xv) IGCP were launched in the year _____.

- xvi) Full form of ICH _____.
- xvii) Counterfeit drugs are _____.
- xviii) ICDRA stands for _____.
- xix) Pharmacovigilance is the science and activity related to detection, assessment and prevention of _____ of drug.
- xx) Patent specifications are of two types 1.) _____, 2.) _____.

SECTION – II

Q2. Attempt any six questions in about 150 words

5X6=30

- i) Write about different types of patents that can be secured under Indian Patent Act.
- ii) What do you understand by patent infringement?
- iii) Write a note on PCT system.
- iv) Give various parameters for validation of an analytical Procedure as per ICH.
- v) Give various risk involved with Self Medication.
- vi) What is Computer Assisted Dry Registration?
- vii) What do you understand by Good Manufacturing Practices?
- viii) Write a short note on OSHA.

SECTION – III

Q3. Attempt any four questions in 500 words each

12.5X4=50

- i) Write in detail about patent filing process in India
- ii) Write in detail about carcinogenicity studies of medicines.
- iii) How new drug applications are filed and reviewed?
- iv) What is WHO certification scheme?
- v) Write about WHO program for International drug monitoring.
- vi) Write a note on effect of GATT on patent laws in India.
- vii) Discuss about one major environmental law.