

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

**Paper PGPRAD – 201
Chemical, Pharm & Biological aspects of Regulatory documentation**

Time allowed: Three hours

Maximum Marks: 100

SECTION – I

Marks

Q1. Attempt all the objective type questions given below

1X20=20

- i) Raw materials are
 - a) Inactives
 - b) Actives
 - c) Inactive and active
 - d) None

- ii) Reference Standard is
 - a) Active Substance
 - b) A standard specification
 - c) A pure and tested sample of substance
 - d) None

- iii) Specifications are _____.
- iv) Batch Process is a
 - a) Single Step Process
 - b) Multi Step Process
 - c) Both a & b
 - d) Long Process

- v) GLP stands for _____.
- vi) Pharmacokinetic is _____.
- vii) Physico Chemical properties of drug affects its _____.
- viii) Toxicity studies are _____.
- ix) Pharmacopoeial methods are
 - a) Methods given in regulatory documents
 - b) Methods given in Pharmacopeias
 - c) Methods given by ICH
 - d) None

- x) Analytical reports are signed by
- Production Manager
 - QA Manager
 - QC Manager
 - None
- xi) In-house test mean
- Test of house
 - Test other than pharmacopial test
 - QC – Test
 - None
- xii) Closuses are
- Container Seal
 - Container Cap
 - Both a & b
 - None
- xiii) Technology transfer is
- Transfer of know how
 - Transfer of machines
 - Transfer of production
 - None
- xiv) Pre formation studies are
- Studies conducted by marketing
 - Studies conducted on marketed products
 - Studies conducted on actives alone and in combination with inactives
 - None
- xv) Stability studies are conducted
- To find out the activity of products
 - To calculate the shelf life of a product
 - To calculate the life of a product
 - None
- xvi) Product release specifications are _____.
- xvii) SOP mean
- Specific operating Procedure
 - Standard operating Procedure
 - Specific operator Procedure
 - Standard Operator Procedure

- xviii) STP stands for _____.
- xix) GCP means _____.
- xx) Bioequivalence studies uses

- a) Comparative Plasma drug profile
- b) Comparative dissolution profile
- c) Comparative stability profile
- d) None

SECTION – II

Q2. Attempt any six questions in about 150 words

5X6=30

- i) What are Pre-Clinical documents?
- ii) Write a note on acute and chronic toxicity studies.
- iii) What do you understand by absorption distribution and metabolism of drugs?
- iv) Discuss the safety evaluation of medicinal products.
- v) Give different objective of pharmacological documentation.
- vi) What are pre formation studies?
- vii) Discuss the role of SOP and STP in quality control.
- viii) Write a note on stability documentation?

SECTION – III

Q3. Attempt any four questions in 500 words each

12.5X4=50

- i) How potential adverse effects are documented?
- ii) Give objectives and significance of repeated dose tissue distribution studies.
- iii) What is safety pharmacology as per ICH guidelines?
- iv) Write a note on Animal Ethics and welfare.
- v) Write in detail about Production documentation.
- vi) Discuss the documentation of a bio-equivalence study.
- vii) Discuss the significance of preclinical studies