Your Roll No.....

P.G Diploma in Pharmaceutical Regulatory Affairs (PGDPRA)
Examinations 2017

Paper – PGPRAD- 101
An introduction to Pharmaceutical Drug Regulatory Affairs

Time: 3 Hrs

Maximum Marks: 100

(Write your Roll No. on the top immediately on receipt of this question paper)

SECTION- A

Answer all the objective and short type questions. Each question carries one mark. (1x20)

1. sNDA stands for.....
2. Define documentation?
3. The first drug price control order (DPCO) was passed in .....
4. What do you understand by NRx and XRx?
5. BGA is drug controlling authority in .....
6. CFR stands for.....
7. DMF means .....
8. The explanation of FID is .....
9. IND stands for.....
10. PSUR means.....
11. Define flanking strategies for growth markets.
12. CRO stands for.....
13. Name the two types of sales organizations.
14. Name the two type of NMR spectrometer designs are.....
15. The source for the UV covers a range of .....nm.
16. The Patent Act was passed in the year .....
17. Write names of the two ionization methods used in mass spectroscopy.
18. NCE stands for.....
19. Define trade mark.
20. Externally used drugs have to be labeled with the words in.....

SECTION- B

Attempt any six questions in about 150 words. All questions carry equal marks (6x5=30)

1. What are the methodologies used for literature search in regulatory affairs?
2. What are the professional qualifications needed for the regulatory affairs manager?
3. Write about the regulatory affairs department in pharmaceutical industry.
4. Discuss the number of ways by which ethics can be analyzed?
5. What do you understand from Guerilla warfare strategies for growth markets?
6. What do you mean by pharmaceutical dossier?
7. Describe three IND types?
8. Write a note on copyright.

SECTION- C

Attempt any four questions in about 500 words. All questions carry equal marks (12.5x4=50)

1. What is Pharmacovigilance? Write in details about the plans used for Pharmacovigilance.
2. Give requirements for labeling of drugs?
3. Discuss pharmaceutical marketing setup in an organization.
4. What are the marketing strategies of pharmaceutical companies? What are their objectives?
5. What is the marketing authorization process for generic medicines in European Union?
6. How molecular structure of an alkaloid is elucidated?
7. What is chromatography? Write in brief about chromatographic methods?

P.G. Diploma in Pharmaceutical Regulatory Affairs (PGDPRA)
Paper –PGPRAD 102
General Pharmaceutical Laws and Guidelines

Time: Three Hours **Maximum Marks:** 100

(Write your Roll No. on the top immediately on receipt of this question paper)

Section A

Answer all objective and short type questions. Each question carries one mark (1x20)=20

1. Elaborate CBER ----------
2. Fair Packaging and Labeling (FPL) Act came in the year ----------.
3. If a drug bears a false or misleading label, it is considered misbranded drug. Yes/No
4. The full form of MAC is ----------.
5. Name any two workplace hazards for which safety standards are being issued by OSHA.
6. ACCSH is an acronym for ----------.
7. The major objective of EPA is ----------.
8. What is the full form of FIFRA.
9. NEPA stands for ----------
10. Define precision.
11. Write down the examples of inorganic impurities.
12. Elaborate MEDDRA----------
13. Counterfeit drug is defined as ----------
14. The three general objectives of national drug policy are to ensure access, quality and ---
    ----------.
15. World Health Assembly- the conglomerate of -------- countries helps in the global implementation of various programmes formulated by WHO.
16. ICDRA stands for ----------.
17. The first federal Copyright Act was enacted in ----------.
18. Give two examples of trademarks.
19. IPR is elaborated as ----------
20. Define ADR.

Section B

Answer any six questions in about 150 words. All questions carry equal marks. (6x5=30)

1. Write a short note on FDA recall system.
2. Describe the Reproductive toxicity studies of Pharmaceuticals.
3. What are the major factors that encourage the counterfeiting of drugs?
4. Enlist the various validation parameters. Explain any two.
5. Write a detailed note on the ICH guidelines for stability study of New drug substance and product.
6. Describe in detail trademarks and trade secrets.
7. Briefly describe about the various certificates given by WHO and other drug regulatory authorities in the exporting countries.
8. Write a note on the information which is to be provided in IND application.

Section C

Answer any four questions in about 500 words. All questions carry equal marks. (12.5x4=30)

1. Write a detailed note on regulations of current Good Manufacturing Practices (cGMP) as imposed by FDA for preparation of drug products for administration to humans or animals.
2. Enlist the major environmental laws governed by EPA. Write a brief note on any four.
3. Briefly discuss the preclinical safety evaluation of biotechnology-derived pharmaceuticals with special mention to GCP guidelines.
4. Define Pharmacovigilance. Give the purpose and need of pharmacovigilance. Also discuss the role of pharmacovigilance in national drug policy, regulation of medicines, clinical practice and health programmes.
5. What do you understand by PCT? Give the history and principal objectives of PCT along with its benefits. Also explain the Indian patent grant procedure.
6. What are the objectives and activities of OSHA. Discuss the rights and responsibilities of an employer and employee under the Occupational Safety and Health Act.

P.G. Diploma in Pharmaceutical Regulatory Affairs (PGDPRA)
Paper -PGPRAD 103
Drug Regulatory Affairs in India

Annual Examination, 2017

Time : Three Hours **Maximum Marks** : 100

(Write your Roll No. on the top immediately on receipt of the question paper)

Section A

Answer all in objective and short type questions. Each question carries one mark (1x20)

1. ----------is the full form of WTO.
2. DPCO is elaborated as----------
3. Drug policy in India was modified in the year---------- .
4. Mention one major objective of Drug policy of India?
5. Full form of NPPA is ----------.
6. DPCO proposed two categories of drugs namely ---------- and ----------.
7. Operation of Blood bank is conducted as per form----------
8. An ---------- is an important requirement for conducting plasmapheresis on a blood donor.
9. ------ ------ and ---------- are the two important offices set under the Food and Drug Adminstration,Maharshtra.
10. GMP Sub part B deals with ----------and Sub part C deals with----------.
11. Define cosmetics.
12. Define drug.
13. What is a patent?
14. DTAB is elaborated as ----------.
15. DCC is an acronym for ----------.
16. The prevention of Food Adulteration Act was passed in the year ----------
17. Novelty ,---------- and commercial viability are the three features necessary for grant of patent.
18. --------- is an example of spurious drug.

Section B

Answer any six questions in about 150 words. All questions carry equal marks. (6x5=30)

1. Write a brief about the punishments as handed out for contravention in relation to opium and cannabis .
2. Write a short note on Insecticide Act 1968.Also discuss about insecticide inspectors.
3. Give a snapshot of the drugs and cosmetics which are prohibited for import.
4. Write a brief on Central drugs laboratory.
5. Discuss the details of Indian Patent Act, 1970. What are the amendments associated with it.
6. Write detailed notes on Phases of clinical trials and five a brief on Clinical Trial auditing.

7. Discuss the types of licences for sale of drugs
8. Write a brief account of the Narcotic drugs and psychotropic substances Act 1985.

Section C

Answer any four questions in about 500 words. All questions carry equal marks. (12.5x4=50)

1. FDA , Maharashtra, India has been a success story. Discuss its genesis and important functions.

2. Discuss the summary of the products characteristics(SPCs)

3. Give details of the guidelines on requirements of the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials.

4. What are the components of preclinical data? Discuss the toxicological and pharmacological documentation.

5. What are counterfeit drugs ? Also define adulterated and spurious drugs as per AYUSH system of medicine. Discuss the Prevention of Food Adulteration act 1954.

6.Drugs and cosmetics Act , 1940 is the backbone of the Pharma sector and practice of pharmacy in India. Share the various salient features of the same to have an insight of its working .

7. Who are Inspectors as stated in Drugs and Cosmetics Act 1940?What are the minimum eligibility for the position? What are his primary roles and functions.

Roll No.....

PG Diploma in Pharmaceutical Regulatory Affairs Examination 2017
Information & Quality Management
PGPRAD 104

Time : 3hrs **Max. Marks : 100**

Section-A

Attempt all objective Questions. Each carries 01 mark. **1x20=20**

1. What is a database?
2. Define network.
3. What is internet?
4. Give Full Form of ICH.
5. Define Archive.
6. What is a product recall?
7. Write full form of PCET and PCI?
8. Describe auditing.
9. Give full form of GCP & GMP.
10. Define ADME studies.
11. What is ESTRI?
12. Topology is .....
13. CDER is .....
14. Partition coefficient is.....
15. Sterility is.....
16. Blinding is also known as .....
17. MedRA is .....
18. Pharmacogenetic is a term suggested by .....
19. Raw data is .....
20. CRO is .....

Section-B **6x5=30**

Attempt any six questions. All carry equal marks.

1. Describe in detail objectives of Quality control.
2. Write down duties and functions of a QC Manager
3. What is ICH?
4. What is common Technical Document?
5. What are quality audits?
6. What is the importance of Quality management system?
7. Give essential features of preformulation studies.
8. Write down importance of Good practices in production.

Section-C

10x5=50

Attempt any five questions. All carry equal marks.

1. Write in detail about Pre approval Inspection.
2. Discuss in details good practices in QC.
3. Write in details about the process design.
4. What are sterile and non sterile preparation?
5. Write down the salient features of a corrective action system.
6. Write down note on product recall and give some examples.
7. Write down four techniques for the measurement of melting point.

Roll No.....

P. G. Diploma in Pharmaceutical Regulatory Affairs (PGDPRA)

Annual Examination – 2017

Chemical, Pharmaceutical and Biological Aspects of Regulatory Documentation

PGPRAD – 201

Time allowed: 3 Hours **Max Marks: 100**

Section – A

Attempt all the objective and short type questions. Each question carries one mark. [1x20]

1. Define Bioavailability
2. Define Polymorphism
3. Climatic Zone II for the purpose of stability testing is: .....
4. What is difference between repeatability and reproducibility?
5. Define LOD and LOQ.
6. Define toxicokinetics.
7. What is chemical reference substance?
8. Define C_{max} in relation to plasma data.
9. PTAC stands for .....
10. Define 'Total clearance'.
11. SOP stands for .....
12. Define 'Pharmaceutical equivalents'.
13. What is Expiry date?
14. What is toxicity treatability evaluation?
15. What is genotoxicity?
16. The pre-clinical testing of an investigational compound takes.....years prior to submission of IND.
17. SIS stands for .....
18. NDA stands for .....
19. Is 80/20 rule is the rule of acceptance of bioequivalence. State 'True' or 'False'.
20. Define acute toxicity.

Section – B

Attempt <u>any six</u> questions in about 150 words. All questions carry equal marks. [6x5]

1. Explain the essential components of batch packaging records.
2. What problems are encountered during BA-BE studies?
3. Discuss various climatic zones in regard to stability testing.
4. Describe the methods of accessing bioavailability.
5. What are the main objectives of toxicokinetics studies in preclinical testing?
6. Describe 5 factors affecting bioavailability.
7. Describe various ways to represent toxicity data of new drug substance.
8. Discuss the different stages of clinical trial for drug development.

Section – C

Attempt <u>any four</u> questions in about 500 words. Each question carries equal mark. [12.5 x4]

1. Discuss documentation of ADR during clinical trial stage IV.
2. Describe various validation parameters required for Analytical Process development.
3. Describe in detail various mechanisms of drug absorption
4. Explain general guidelines for PK/PD studies.
5. Write note on Good Laboratory Practices.
6. Classify toxicity and write note on acute toxicity testing.
7. Discuss the aspects of preclinical safety evaluation of biotechnology derived pharmaceuticals.

Your Roll No.....

P.G. Diploma in Pharmaceutical Regulatory Affairs (PGDPRA)
Annual Examination -2017

Paper No: PGDPRA-202

Clinical Trials and Health Care Policies

Time: Three hours ***Maximum Marks: 100***

(Write your roll no at the top immediately on receipt of this question paper)

Section-A

Answer all the objective and short type questions. Each question carries one mark (1x20)

1. Define protocol.
2. What is GCP?
3. ICD_____
4. CDSCO_____
5. SOP_____
6. ANDA_____
7. ADME means_____
8. What is PLA?
9. CIOMS_____
10. What is dossier?
11. PK studies are carried out_____
12. PV stands for_____
13. Phases of CT_____
14. HTA_____
15. ADR means_____
16. ICF_____
17. The purpose of randomization_____
18. What is GCP?
19. What is pacebo effect?
20. What is ICH?

Section –B

Answer any six questions in about 150 words. All questions carry equal marks. (6x5=30)

1. Describe objectives of clinical trials in details.
2. Discuss GCP documentation and compliance.
3. Explain different types of Pharmacokinetic trials.
4. Write detailed note on organization of NDA dossiers.
5. Discuss current scenario of health care policies in India.
6. Give a detailed account on Pharmacogenetics.
7. Describe the safety assesment of subjects participating in clinical trials.
8. Discuss importance and need of pharmacovigilance studies.

Section –C

Attempt any four questions in about 500 words. All the questions carry equal marks. (12.5x4=50)

1. Describe the design and requirement of clinical trial.
2. Describe the composition, working and responsibilities of IRB.
3. Discuss the design and conduct of bioavailability and bioequivalnce studies.
4. Explain the ADR reporting procedures.
5. Write basic principles of GCP.
6. Discuss Pharmacovigilance for tradional and homeopathic medicines.
7. Write clinical trial guidelines for vaccines and immunoglubulins.

P.G. Diploma in Pharmaceutical Regulatory Affairs
Annual Examination -2017
Paper No. PGPRAD-203
International Licensing

Time: Three Hours **Maximum Marks : 100**

(Write your Roll No. on the top immediately on receipt of this question paper)

Section-I

Attempt all the objective and short type questions. Each question carries one mark. (1x20 = 20)

Q.1 A. Define the following

i) Orphan Drugs
ii) Generic Drugs
iii) Bioavailability
iv) FDA Modernization Act (1997)
v) Validation
vi) Parent drug
vii) Clinical Trials

B. Give the full form of the following

i) EMEA
ii) CPMP
iii) GCP
iv) ICH
v) IND
vi) ANDA
vii) TGA

C. Fill in the blanks

i) Module-3 of CTD is related to_____
ii) A sponsor is required to submit IND annual reports within_____
iii) BLA refers to_____
iv) _____ is drug regulatory agency in New Zealand
v) Drug regulatory authority of Nigeria is _____
vi) Application form FDA 356h is application form and contain basic information about_____ and _____

Section –II

Answer any six questions in about 150 words. All questions carry equal marks. (6x5=30)

1. Name the drug licensing authority of Australia. What are the objectives of Therapeutics Goods Act?
2. Discuss briefly the role of the TGA in drug supply in Australia.
3. Give the information about wholesale dealing or distribution in South Africa.
4. Write a note on Kefauver-Harris drug amendments act.
5. What is IND safety report?
6. What is emergency use of an IND. Discuss briefly the procedure for withdrawal of an IND?
7. Explain the way of organizing documents in CTD format.
8. Discuss briefly the procedure followed for product recall?

Section –III

Answer any four questions in about 500 words. All questions carry equal marks. (12.5x4=50)

1. Give detail account of Module-2 and Module-3 of CTD formats.
2. Describe various types of IND and discuss their regulation in USA.
3. Discuss the procedure for registration of medicinal products for export in Nigeria.
4. How generic drugs can be filed in European countries?
5. What is the regulations for orphan drug in European countries?
6. Explain fast review and accelerated review process of drug registration in China.
7. Explain drug evaluation and registration in Ethiopia.

P.G. DIPLOMA IN PHARMACEUTICAL DRUG REGULATORY AFFAIRS
(PGDPRA)
ANNUAL EXAMINATION-2017
PAPER-PGPRAD-204
Regulatory considerations in controlled drug delivery and future aspects of biopharmaceuticals

Time: 3 hours **Maximum Marks: 100**

SECTION-A

1. Fill in the blanks. Each question carries one mark. (1×5=5)
   (i) _____ provides resources to assist drug sponsors with submitting applications for approval to begin new drug experiments on human subjects.
   (ii) _____ provides a hypothetical tool in investigating biological properties and the rate and extent of gastrointestinal absorption of drug substances.
   (iii) Noyes-Whitney equation is _____.
   (iv) _____ and _____ are the methods to determine bioavailability.
   (v) _____ refers to protein or nucleic acid based pharmaceutical substances used for therapeutic or in-vivo diagnostic purposes which are produced by direct extraction from natural biological sources.

2. Define the following terms. Each question carries one mark. (1×5=5)
   (i) New Drug Application
   (ii) Bioavailability
   (iii) Extended release products
   (iv) Vaccines
   (v) Drug substance as per FDA

3. Give the full form of the following abbreviations. Each question carries one mark. (1×5=5)
   (i) IVIVC
   (ii) FDA
   (iii) tPA
   (iv) PAGE
   (v) PLA

4. Give the therapeutic uses of the following products. (1×5=5)
   (i) HAS
   (ii) Trypsin
   (iii) Procrit
   (iv) Catecholamine
   (v) Insulin

SECTION-B

Answer any six questions in about 150 words. All question carry equal marks.

(6×5=30)

Q1. Discuss the types and applications of investigational new drug application (IND).

Q2. Give the advantages and classification of controlled release products.

Q3. How will you assess bioavailability by using blood level studies?

Q4. Give the detailed account of applications of IVIVC.

Q5. Describe the biological origin based biopharmaceuticals with suitable examples.

Q6. Differentiate between

(i) Extended and delayed release
(ii) Immediate and modified release

Q7. Write a short note on parenteral drug delivery system.

Q8. Describe the study design of bioequivalence briefly.

SECTION-C

Answer any four questions in about 500 words. All questions carry equal marks.

(12.5×4=50)

Q1. Discuss the characterization of drug entity by various aspects.

Q2. What are the various specific standards for animal and microbial origin based biopharmaceuticals?

Q3. How will you prepare vaccines? Write a note on DNA vaccine.

Q4. Describe stability testing methods as per ICH Guidelines.

Q5. Give a detailed account of the following:

(i) Recombinant DNA Technology
(ii) Hybridoma Technique

Q6. Write a detailed note on IND Submission.

Q7. Describe about abbreviated new drug application (ANDA) and requirements to meet safety and efficacy of controlled release products.

Q8. What are the various methods for assessment of bioequivalence? Explain in detail.