Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: PHARMACEUTICAL REGULATIONS (PRA 601T)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Monday, May 18, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

Answer ALL Questions.

1. Discuss the organization of Common Technical Document

(10 marks)

2. Enlist the post marketing requirements of USFDA. Discuss the adverse event reporting requirements.

(10 marks)

3. What are the requirements of USFDA on advertisement of prescription drugs?

(10 marks)

4. What are the provisions of pediatric drugs initiative of USFDA

(10 marks)

5. Explain the format of labeling for human prescription drug and biological products.

(10 marks)

6. What are medical devices? Classify with examples and explain tracking system in USA

(10 marks)

7. Describe procedure for drug registration process in EU

(10 marks)

8. Discuss various toxicity studies used for non-clinical testing of a new chemical entity

(10 marks)

9. **Write short notes:**

9A. Process development and manufacturing regulations of biologics

9B. Fast track initiative of USFDA

(5 marks × 2 = 10 marks)

10. **Write briefly on the following**

10A. New drug registration process in India

10B. Procedure for fixing MRP of formulation in India

(5 marks × 2 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: PHARMACEUTICAL PATENT, IPR AND REGULATIONS (PRA 602T)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Friday, May 22, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ Answer ALL the questions.

1. Define Patent. Enlist components covered as a part of Intellectual Property Rights. What things are patentable and non-patentable according to Indian Patents Act 1970 as amended?

(10 marks)

2. Discuss objectives of patent search. What are various types of patent search? Explain thoroughly.

(10 marks)

3. Write a detail note on various stages involved in filing a patent application in India.

(10 marks)

4. Discuss the concepts of Licensing and Technology Transfer with relevant pharmaceutical examples.

(10 marks)

5. Describe importance of patent as a business tool.

(10 marks)

6. Write a detail note on Copyrights, Trademarks and Tradesecrets.

(10 marks)

7. What is meant by Compulsory Licensing? Briefly explain. Under what circumstances a patent can be revoked in India?

(10 marks)

8. What impact TRIPs agreement has made on pharmaceutical industry? Explain in detail.

(10 marks)

9. **Write short notes on:**

9A. Data Protection

9B. Budapest Treaty

(5 marks × 2 = 10 marks)

10. **Write briefly on the following:**

10A. Historical development of patent system in India

10B. Patent Administration in India

(5 marks × 2 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: CLINICAL TRIALS AND REGULATIONS (PRA 603T)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Monday, May 25, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

✍ **Answer ALL the questions.**

1. What are the responsibilities of a monitor as per ICH GCP guideline?

(10 marks)

2. **Discuss about:**

2A. Formal pharmacokinetic studies in geriatrics

2B. Reporting time frame for ADRs

(10 marks)

3. Explain the purpose of dose-response information and write in detail about clinical trial co-ordinating centre.

(10 marks)

4. Explain the regulatory requirement in India with regard to bioequivalence of modified release products.

(10 marks)

5. With a flow chart, explain biological evaluation of medical devices as a part of risk management.

(10 marks)

6. Describe the steps to be followed for closing a clinical trial.

(10 marks)

7. How clinical investigator inspections are conducted by FDA?

(10 marks)

8. Explain the objectives of clinical trial.

(10 marks)

9. **Write short notes on:**

9A. Role of site management organisation

9B. Blinding in clinical trials

(5 marks × 2 = 10 marks)

10. **Write briefly on the following:**

10A. BCS classification of Drugs

10B. Purpose of clinical trial monitoring

(5 marks × 2 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2015

SUBJECT: QUALITY, SAFETY AND EFFICACY REGULATIONS (PRA 604T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)

Wednesday, May 27, 2015

Time: 10:00 – 13:00 Hrs. Max. Marks: 100

1. Explain the stability study for any five specific dosage forms as per USFDA stability testing guidelines.

2. Explain the evaluation of retest period or shelf life estimation for drug substance intended to be stored below room temperature.

3. Classify the clinical safety events as agreed upon by WHO collaborative centre.

4. List the harmonized pharmacopoeial text topics.

5. Explain the Q4B outcome and consideration for implementation of microbiological examination of non-sterile products.

6. Write a note on use of near infrared radiation in process analytical technology.

7. Define general quality risk management process as per ICH Q9.

8. Write in detail steps taken to develop a dissolution method for BCS class IV compounds.

9. **Write short notes on:**

9A. Potentially hazardous contaminants and residues in herbal medicine.
9B. Objectives of GAMP.

10. **Write briefly on the following:**

10A. The circumstances under which repeated dose tissue distribution study needs to be conducted.
10B. The need to have quality, safety and efficacy regulation guidelines.

(10 marks × 10 = 100 marks)