Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

SUBJECT: PHARMACEUTICAL REGULATIONS (PRA 601T)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Wednesday, May 18, 2016

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

✍ **Answer ALL questions.**

1. Discuss the provisions of Good Laboratory Practices (GLP) and explain GLP inspection. (10 marks)

2. Briefly discuss the content and format of a New Drug Application as per USFDA. (10 marks)

3. What is Abbreviated new Drug Application? Enlist the contents of the same and elaborate on the bioequivalence requirement. (10 marks)

4. Define biologics as per the USFDA. List the contents of Biologic Licence Application. (10 marks)

5. Discuss the provisions of orphan drug development programme. (10 marks)

6. Explain the "bioresearch monitoring programme" of USFDA. (10 marks)

7. Explain the conditions of import license as per the rule 26 of Drugs and Cosmetic act and explain post approval regulations of drug products in India. (10 marks)

8. Explain the decentralized procedure for marketing authorization of medicinal products in the EU. (10 marks)

9. **Write short notes:**

9A. Generic drug regulations in India
9B. Medical devices regulations in India

(5 marks × 2 = 10 marks)

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

10A. Fair Balance requirement and off label promotion requirements under advertisement regulations as per USFDA.
10B. Phase-4 commitments.

(5 marks × 2 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

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

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Monday, May 23, 2016

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

Answer ALL the questions.

1. Write a note on criteria to grant a patent. Discuss about process and product patent with an example. What is meant by provisional application and complete specification in a patent process?

(10 marks)

2. Discuss importance of "Protection of undisclosed information" for a business organization citing example and add a note on Confidentiality Agreement.

(10 marks)

3. What is meant by an act of infringement? Explain various types of patent infringement with one example of each type.

(10 marks)

4. Enlist various objectives of carrying out a patent search. How a patent search is beneficial to an inventor? Explain different types of patent search.

(10 marks)

5. What steps an inventor need to follow while filing a patent application in India?

(10 marks)

6. Enlist various treaties governing IPR. Explain Budapest Treaty and Paris Convention.

(10 marks)

7. What are the conditions specified under Indian Patents Act 1970 to revoke a patent? Under what circumstances a compulsory licensing can be used by the government?

(10 marks)

8. What is the importance of claims in a patent document? Discuss types of patent claims.

(10 marks)

9. **Write short notes on:**

9A. Licensing

9B. Technology Transfer

(5 marks × 2 = 10 marks)

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

10A. Data Protection

10B. TRIPS and pharmaceutical industry

(5 marks × 2 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

SUBJECT: CLINICAL TRIALS AND REGULATIONS (PRA 603T)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Wednesday, May 25, 2016

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

Answer ALL the questions.

1. Discuss the principles of ICH, GCP guidelines.

(10 marks)

2. Discuss regulatory requirements for:

2A. Pharmacokinetic studies in renally impaired patients

2B. Reporting time frame for ADRs

(10 marks)

3. Discuss the important toxicity studies for medical devices.

(10 marks)

4. Explain the purpose of dose-response studies and regulatory requirement for clinical trial data backup and storage.

(10 marks)

5. Enlist the objectives of ICH guidelines on Ethnic factors in the acceptability of foreign clinical data. Explain BCS classification of drugs.

(10 marks)

6. Under what circumstances in-vitro dissolution testing is sufficient to establish bioequivalence as per Indian guideline?

(10 marks)

7. When clinical investigator inspections are conducted by FDA? Explain.

(10 marks)

8. Explain the objectives of Phase I and II clinical trials.

(10 marks)

9. **Write short notes on:**

9A. Applications of IVIVC

9B. Responsibilities of site management organization

(5 marks × 2 = 10 marks)

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

10A. Surrogate end points in a clinical trial

10B. Handling of Investigational product

(5 marks × 2 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

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

Friday, May 27, 2016

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

Answer ALL questions.

1. What is bracketing as per ICH Q1D guidelines? Explain the design factors and design considerations for the same with the help of an example.

(10 marks)

2. Write a note on stability testing for post approval changes as per USFDA guidelines.

(10 marks)

3. Explain the standards for expedited reporting as per ICH E2D guidelines.

(10 marks)

4. How does industry and regulators use Q4B annex?

(10 marks)

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

(10 marks)

6. Discuss Potentially hazardous contaminants and residues in herbal medicine.

(10 marks)

7. Write a note on process analytical technology tools.

(10 marks)

8. Explain the methods of exploratory clinical trials.

(10 marks)

9. **Write short notes on:**

9A. Potential application for quality risk management as per ICH Q9

9B. Sources of Post Approval Safety data management

(5 marks × 2 = 10 marks)

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

10A. The general principle of photo safety evaluation

10B. Global cooperation group of ICH

(5 marks × 2 = 10 marks)