Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: PHARMACEUTICAL REGULATIONS (PRA 601)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Saturday, May 24, 2014

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

Answer ALL questions.

1A. Briefly discuss various stages of new drug development.

1B. Discuss the animal pharmacology and toxicology information of an Investigational New Drug application.

(10+10 = 20 marks)

2A. Write a note on electronic submission. Discuss the format of Common Technical Document.

2B. Discuss the review process of Abbreviated New Drug Application.

2C. Discuss the marketing exclusivity provisions as per Hatch-Waxman Act .

(10+5+5 = 20 marks)

3A. Discuss the fast track initiative in drug approval and the "rolling New Drug Application" .

3B. Discuss the important provisions of process development of biologic drugs.

3C. What are the orphan drug designation requirements and its incentives programme in the US.

(5+5+10 = 20 marks)

4A. Discuss the general reporting requirements of "Post Marketing Surveillance" programme.

4B. What are generic drugs and medical devices? Explain its regulations in India.

(10+10 = 20 marks)

5A. What are drugs? Explain its import licensing procedure and post approval regulations of drug products in India.

5B. Discuss mutual recognition procedure for registration of drug in EU .

(10+10 = 20 marks)

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M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

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

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Wednesday, May 28, 2014

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

✍ **Answer ALL questions.**

1A. Explain Patent Administration in India and the US.

1B. What are the steps involved in filing for a patent in India. Explain each step.

(10+10 = 20 marks)

2A. What is meant by Trade Secret? How does a Trade Secret benefit business entity? Discuss with relevant examples.

2B. What is non-disclosure agreement (NDA)? Explain the provisions of NDA.

(10+10 = 20 marks)

3A. Discuss any four cases of Trademark infringement in India.

3B. Explain Patent Cooperation Treaty (PCT) and discuss patenting provisions under Chapter I and Chapter II of PCT.

(10+10 = 20 marks)

4A. What benefits Small and Medium Enterprises (SMEs) derive from patent system? Describe in detail.

4B. Describe various provisions under which a patent can be revoked in India.

(10+10 = 20 marks)

5A. What are various types of patent infringement? Enlist and explain each in detail.

5B. What is patent drafting dilemma? What points are important while drafting a patent claim? Explain whether claim should be broad or narrow and Why?

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

SUBJECT: CLINICAL TRIALS AND REGULATIONS (PRA 603)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Friday, May 30, 2014

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

Answer ALL the questions.

1A. What are clinical trials? Write the risks and benefits of the same.

1B. Classify observational clinical studies. Discuss in detail the cross sectional clinical studies.

1C. Compare GCP guidelines of ICH and WHO.

(5+5+10 = 20 marks)

2A. Write the composition of Institutional ethics committee.

2B. Discuss the audit process in clinical research organization.

2C. Discuss BA/BE guidelines of CDSCO.

2D. Write a note on biowaivers as per FDA guidelines.

(5 marks × 4 = 20 marks)

3A. Explain the process of clinical documentation.

3B. Design an ADR report format for glibenclamide in Phase-I study.

3C. Explain importance of clinical trials in special population.

3D. Explain the roles and responsibilities of a principal investigator in clinical trial management.

(5 marks × 4 = 20 marks)

4A. Discuss the bridging studies.

4B. Write a note on parameters to be analysed in Pharmacokinetic studies.

4C. Explain IVIVC models.

(5+5+10 = 20 marks)

5A. Explain the initial biological evaluation tests on medical devices in detail.

5B. Write the animal welfare requirements for biological evaluation of medical devices in brief.

5C. Explain the importance of site management in clinical trials.

(10+5+5 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2014

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

Monday, June 02, 2014

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

Answer ALL questions.

1A. What are the scope and objectives of ICH Q1A (R2)?

1B. What is "significant change" as defined by ICH Q1A (R2)?

1C. Explain the selection of high dose for general toxicity studies with the help of a flow chart.

(5+5+10 = 20 marks)

2A. Write notes on 'bracketing design stability studies' and "matrixing design stability studies".

2B. Explain the selection of batches for stability testing of biotechnological/biological products as per ICH Q5C guidelines.

(10+10 = 20 marks)

3A. Write a note on generally agreed principles of ICH E1 guidelines.

3B. Explain the dose levels and core battery tests for safety pharmacology studies for human Pharmaceuticals.

(10+10 = 20 marks)

4A. Define intrinsic dissolution, test preparation and procedure as per USP.

4B. Write about potential application for quality risk management as per ICH Q9.

(10+10 = 20 marks)

5A. Define general quality risk management process as per ICH Q9.

5B. What is the purpose of reproductive toxicity testing?

5C. Define the role of an expert working group of ICH harmonisation process.

(10+5+5 = 20 marks)