Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – NOVEMBER 2013

SUBJECT: PHARMACEUTICAL REGULATIONS (PRA 601)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Monday, November 04, 2013

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

1A. Discuss the accelerated development programs of US FDA. Differentiate between "Fast track", "Accelerated approval", and "priority review". Add a note on rolling NDA.

1B. What are combination products? Give examples. Discuss the role of Office of combination products (OCP) and the Request for designation (RFD) approval process.

(10+10 = 20 marks)

2A. What is Bioresearch monitoring programme (BIMO) of US FDA? Discuss the investigator oriented inspection program. What are the post inspectional US FDA actions?

2B. Discuss briefly on various advertisement regulations and its enforcement actions.

(10+10 = 20 marks)

3A. Discuss the NDA review process and US FDA actions on NDA.

3B. What is CTD? Discuss the organization of CTD.

(10+10 = 20 marks)

4A. What are the basic requirements for an ANDA designation? Elaborate on bioequivalence requirement.

4B. What are drugs? Explain its import licensing procedure and post approval regulations in India.

(10+10 = 20 marks)

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

5B. What are medical devices? Classify with examples and explain tracking system in USA.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2013

SUBJECT: PHARMACEUTICAL PATENT, IPR AND REGULATIONS (PRA 602)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Wednesday, May 29, 2013

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

1. Define Patents. Discuss criteria for granting patents. What inventions are patentable and non-patentable according to Indian Patents Act 1970?

2. Discuss Copyrights and Trademarks with relevant examples.

3. What is Non-Disclosure Agreement (NDA)? Explain provisions of NDA.

4. What is Patent Cooperation Treaty (PCT)? What are the objectives and advantages of PCT? Schematically explain filing patent through PCT.

5. Under what circumstances a patent can be revoked in India? List provisions according to Indian Patents Act 1970.

6. What is patent infringement? Discuss various types of Patent Infringement.

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

8. What is technology transfer? Explain importance and ways of technology transfer with relevant examples.

9. What are various types of patent claims? Discuss in detail.

10. Write a detailed note on research collaboration agreements.

(10×10 = 100 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – NOVEMBER 2013

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

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Wednesday, November 06, 2013

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

1A. Schematically explain patent filing procedure in India.

1B. Discuss any four cases of Trademark infringement in India in detail.

(10+10 = 20 marks)

2A. Explain with examples how patent system can benefit Small and Medium Enterprises.

2B. 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)

3A. Elaborate on types of patents and types of patents filed with Patent Offices.

3B. What are Complete and Provisional specifications? Briefly Explain.

3C. What is license in intellectual property agreements? Explain various types of licenses that are possible as a part of license agreement.

(5+5+10 = 20 marks)

4A. What is technology transfer? Explain importance and methods of technology transfer with relevant examples.

4B. What are various types of patent claims? Discuss in detail.

(10+10 = 20 marks)

5A. Write a detailed note on research collaboration agreements.

5B. What is Compulsory Licensing? Explain various provisions under which Compulsory Licensing can be issued?

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2013

SUBJECT: CLINICAL TRIALS AND REGULATIONS (PRA 603)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Friday, May 31, 2013

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

Answer ALL the questions.

1A. Classify clinical trials. Discuss the constitution of IRB.

1B. What are descriptive clinical studies? Discuss control clinical studies in detail.

1C. Compare GCP guidelines of USFDA and ICMR.

(5+5+10 = 20 marks)

2A. Write the review procedure and exemption from review in clinical trials in brief.

2B. Prepare a checklist for auditing the clinical trial facility.

2C. Discuss impact of BCS based biowaivers.

(5+10+5 = 20 marks)

3A. Explain the hurdles encountered in the management of clinical trials.

3B. Discuss the timelines for reporting ADR and role of principal investigator in addressing the same as per FDA.

3C. Why it is necessary to perform the clinical trials in special population? Explain with examples.

3D. With the help of flow chart discuss clinical trial management.

(5×4 = 20 marks)

4A. Write ethnic issues in clinical trials in detail.

4B. Write a note on importance of pharmacodynamics studies.

4C. Explain IVIVC with respect to modified release dosage forms.

4D. Write the benefits of virtual clinical trials.

(5×4 = 20 marks)

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

5B. Write the flow chart for systematic approach to biological evaluation of medical devices.

5C. List the pre-trial site management activities.

(10+5+5 = 20 marks)

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M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2013

SUBJECT: QUALITY, SAFETY AND EFFICACY REGULATIONS (PRA 604)

(SPECIALIZATION: DRUG REGULATORY AFFAIRS)

Monday, June 03, 2013

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

Answer ALL questions.

1A. Explain ICH Q1A (R2) guidelines under the following headings for both drug substances and drug products:

i) Stress testing

ii) Selection of batches

1B. Write a note on qualification of degradation products as per ICH Q3B guidelines.

(10+10 = 20 marks)

2A. Write a note on stability indicating profile of biotechnological/biological products as per ICH Q5 guidelines.

2B. Explain the objectives of ICH E1 guideline – assessment of clinical safety of long-term treatment drugs.

(10+10 = 20 marks)

3A. Write a note on test system for safety pharmacology studies for human pharmaceuticals.

3B. Explain Q4B evaluation process in detail.

(10+10 = 20 marks)

4A. Define 'Q' point, its significance and acceptance criteria for immediate release, extended release and delayed release formulation as per USP.

4B. Write a note on organization structure of International Conference on Harmonization.

(10+10 = 20 marks)

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

5B. List the types of toxicity studies as per ICH.

5C. Write in detail about recommended analytical methods for arsenic and radioactive contaminants as per WHO guideline for herbal medicine.

(10+5+5 = 20 marks)