Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2012

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

(SPECIALIZATION: PHARMACEUTICS/PHARMACOLOGY /PHARM. QUALITY ASSURANCE/ PHARM. BIOTECHNOLOGY)

Thursday, May 24, 2012

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

Answer ALL Questions.

1A. Explain the construction and working of photomultiplier tube in brief.
1B. Discuss the structural features essential for a molecule to exhibit the phosphorescence.
1C. Explain the factors affecting absorption spectra in brief.
1D. Explain the applications of ELISA in research.

(5×4 = 20 marks)

2A. Explain the paper electrophoresis techniques in details.
2B. Explain the sample handling in IR spectroscopy in detail.

(10+10 = 20 marks)

3A. Explain the theory of proton NMR spectroscopy.
3B. Write a note on COSY and 2-D NMR.
3C. With neat diagram, explain the working of a Quadrupole analyser.
3D. Explain the principle of chemical ionization spectrometry.

(5×4 = 20 marks)

4A. Discuss the advantages and applications of LC-MS/MS.
4B. Define following terminologies in chromatography with suitable equation and explain its importance. i) Distribution constant ii) Retention factor.
4C. Discuss how the efficiency of a column can be explained with the help of plate theory of chromatography. Write an equation for the determination of number of theoretical plates from a chromatogram.
4D. Explain the following procedures in HPTLC and explain its importance
i) Activation of the plate, ii) Chamber saturation.

(5×4 = 20 marks)

5A. What are the characteristics of an ideal GC detector? Explain the construction and working of flame ionization detector with the help of a neat diagram.
5B. Explain the working of a loop injection in HPLC with a neat diagram. What are its advantages over syringe injectors?
5C. Explain the principle and working of a refractive index detector used in HPLC. Discuss the characteristics and limitations of the same.
5D. Discuss the principle, advantages and applications of supercritical fluid chromatography.

(5×4 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2012

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Saturday, May 26, 2012

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

Answer ALL Questions.

1A. What is ISO 9000 and 14000? Explain in detail.

1B. Write a note on personnel training and hygiene for the pharmaceutical industry.

(15+5 = 20 marks)

2A. Explain in detail about master formula record and batch manufacturing record.

2B. Define labeling. Explain label issuance and line clearance in brief.

2C. Write a note on good warehouse practice.

(10+5+5 = 20 marks)

3A. Explain the term distribution and distribution record.

3B. Define product recall. Explain in detail about product recall classification and strategies for the same.

3C. Write in detail about the waste disposal procedure and records.

(5+10+5 = 20 marks)

4A. Write in detail about Statistic Quality Control Charts.

4B. Define 't' test. Enlist the situations in which the unpaired and paired 't' test are applied.

4C. Write a short note on equipment design qualification.

(10+5+5 = 20 marks)

5A. Explain the validation of moist heat sterilizer.

5B. Explain in detail about construction and working of HVAC system.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2012

SUBJECT: REGULATORY AFFAIRS (PQA 603)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Thursday, May 31, 2012

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

Answer All Questions.

1A. What is a Common Technical Document? Explain its content and format.

1B. Explain the tools used for process analytical technology. (PAT).

(10+10 = 20 marks)

2A. Enlist and explain the contents of European drug master file.

2B. Enlist the contents of abbreviated new drug application for a drug product.

(10+10 = 20 marks)

3A. Briefly classify impurities and explain the reporting, identification and qualification thresholds of impurities in new drug substances.

3B. Write the Analytical method validation parameters as per ICH Q2 (R1)

(10+10 = 20 marks)

4A. Explain the changes to an approved NDA or ANDA with respect to manufacturing sites, Manufacturing process, Specifications, Container closure systems and labeling.

4B. Define Patents. Distinguish between Patents, Copyrights and Trademarks.

4C. Explain the microbiological attributes of non-sterile drug products as per ICH Q6A.

(10+5+5 = 20 marks)

5A. Explain in detail patent filing procedure in India.

5B. Explain in detail the different methods to document bioavailability and bioequivalence studies for orally administered drugs.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2012

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Saturday, June 02, 2012

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

Answer ALL the questions.

1A. Discuss the instrumentation of power compensation DSC and heat flux DSC.

1B. What is the meaning of "Spiking"? Explain how 200 µl of blank plasma is spiked to get final concentration of 1.5 µg/ml of paracetamol in it?

1C. Explain in detail one level assay with standard curve method for the microbial assay of antibiotics.

(5+5+10 = 20 marks)

2A. What are *in situ* studies? Explain *in situ* studies for metabolic characterization of NCE.

2B. What is kinetic solubility? Explain its advantages and limitations.

2C. Design a sample protocol for stability testing of tablet dosage forms.

(5+5+10 = 20 marks)

3A. Define electrode potential. Explain the construction and working of silver/silver chloride reference electrode.

3B. Explain the different methods of detecting the end point and applications of potentiometric titrations.

3C. Describe the apparatus and procedure used for the determination of water by azeotropic distillation method.

3D. Explain the principle and reactions involved in the limit test for chloride. How 25 ppm chloride standard solution is prepared?

(5+5+5+5 = 20 marks)

4A. Discuss the "systemic injection test" (Test A) and "intracutaneous test" for evaluating rubber closures for injectable preparation, and provide acceptance limits.

4B. With the help of a neat diagram of the apparatus, describe the procedure and interpretation of results for carrying out dissolution testing of transdermal delivery systems using USP apparatus 6.

(10+10 = 20 marks)

5A. What is a Stability protocol? Design a sample protocol for stability testing of ointment formulations.

5B. Explore the relation between solubility and partition coefficient. Comment on the role BCS system in preformulation studies.

(10+10 = 20 marks)