Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2009

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

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

Wednesday, May 27, 2009

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

✍ **Answer ALL questions.**

✍ **Draw neatly labelled diagrams wherever necessary.**

1A. Explain various factors affecting absorption spectra with suitable examples.

1B. Explain the quantitative applications of IR spectroscopy with examples.

1C. Explain the usefulness of IR spectroscopy in structural elucidation with suitable examples.

(10+5+5 = 20 marks)

2A. Explain the derivatization in fluorimetry with two examples.

2B. List the differences and limitations between IR and Raman spectroscopy.

2C. List seven capillary electrophoresis modes. Explain each mode in brief.

(5+5+10 = 20 marks)

3A. Explain the applications of ELISA in diagnosis.

3B. Explain the construction, working, advantages and disadvantages of thermal conductivity detector.

3C. Write a note on solvent selection in HPLC.

3D. What is in-situ densitometry in HPTLC? Explain the calibration curve method of quantitative estimation using HPTLC.

(5×4 = 20 marks)

4A. Explain the principle, advantages and working of supercritical fluid chromatography.

4B. Write the theory of NMR spectroscopy.

4C. What is chemical shift? Explain the factors affecting chemical shift with examples. How many NMR signals will arise from acetaldehyde?

(5+5+10 = 20 marks)

5A. Classify the mass spectrometer. Explain the construction and working of double focusing mass spectrometer.

5B. What is metastable ion? Explain with example and give its significance.

5C. Explain the hyphenated techniques in brief.

(10+5+5 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2009

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602)

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE

Thursday, May 28, 2009

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

✍ **Answer ALL the questions.**

1A. Write in detail about the importance of GLP in Pharmaceutical industry.

1B. Write in detail about the packing and labelling controls.

(10+10 = 20 marks)

2A. Write in short about the significance of preventive maintenance.

2B. Explain the precautions to be taken against Contamination.

2C. Discuss about the calibration of Dissolution test apparatus.

(5+10+5 = 20 marks)

3A. Explain the guideline for product recall.

3B. Write a short note on good warehousing practices.

3C. Explain in detail about personnel validation.

(5+7+8 = 20 marks)

4A. Explain in detail about the process validation for solid dosage form.

4B. Explain the principle of Computer System Validation.

(13+7 = 20 marks)

5A. Write in detail about filteration validation.

5B. Define the terms mean, median and explain their significance.

(15+5 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2009

SUBJECT: REGULATORY AFFAIRS (PQA 603)

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE

Saturday, May 30, 2009

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

✍ **Answer all questions.**

1A. Explain Hatch-Waxman act and 180 days exclusivity of generic drugs.

1B. Outline the contents of IND and NDA.

(10+10 = 20 marks)

2A. Write in detail about accelerated FDA approvals.

2B. Discuss the quality management principles of ICH GMP guidelines.

(10+10 = 20 marks)

3A. Discuss about the waivers of bioavailability and bioequivalence studies for immediate release solid oral – dosage forms.

3B. Write in detail about the editing of PIC documents on SOP.

(10+10 = 20 marks)

4A. Discuss about the decision tree for identification and quantification of impurities in new drug substances.

4B. Discuss about techniques and approaches for studies of in-vitro of metabolism and drug interaction as per FDA guidelines.

(10+10 = 20 marks)

5A. Discuss in detail about EUDRA guidelines on Pharmacokinetics and metabolic studies in animals for new medicinal products.

5B. Discuss the SUPAC – IR guidelines with respect to changes in batch size and site.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2009

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604)

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE

Monday, June 01, 2009

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

✍ **Answer all the questions.**

1A. Explain the different types of polarography.

1B. Discuss in detail about the applications of hyphenated techniques in the analysis of drugs in biological fluids.

(10+10 = 20 marks)

2A. Explain the principle and procedures involved in the evaluation of antimicrobial agents in injectables.

2B. Write in detail about the types, principles and methodology employed in immunoblotting.

(10+10 = 20 marks)

3A. Enumerate the difference between qualitative and quantitative analysis. What is semiquantitative analysis? Explain any one semiquantitative assay method.

3B. Write about the evaluation of plastic containers used for injectable preparations.

(10+10 = 20 marks)

4A. Explain the prediction of shelf life of semisolid dosage forms.

4B. What do you mean by IVIVC? How the dissolution testing devices have relevance to IVIVC? Explain in detail.

(10+10 = 20 marks)

5A. Write a short note on in-vitro evaluation of liposomes.

5B. Describe the various methods used for the determination of partition coefficient.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – NOVEMBER 2009

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

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

Monday, November 02, 2009

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

✍ **Answer all questions. Draw neat and labeled diagrams where ever necessary.**

1A. Explain the working of

i) Prisms

ii) Gratings as dispersive devices in spectrophotometers.

1B. With a labelled diagram, explain the working of photoemissive tubes.

1C. Discuss about sample handling for IR spectroscopic analysis.

(6+4+10 = 20 marks)

2A. Write in detail about fluorescence quenching.

2B. Write a note on Laser spectroscopy.

2C. Discuss the basic principle of NMR phenomenon.

2D. What is NOE? Explain the principle and its applications.

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

3A. Discuss about detection strategies in HPTLC analysis.

3B. Write a note on the structural types of HPLC column packing.

3C. Discuss the mechanism of separation by Ion-pair chromatography.

3D. Enlist the applications of HPLC technique.

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

4A. Discuss about σ bond dissociation and α-cleavage.

4B. Explain the working of a double focusing magnitude sector analyser with a diagram.

4C. Enlist the applications of MS/MS technique.

4D. How do you distinguish primary, secondary and tertiary alcohols by IR spectroscopy?

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

5A. Write a note on Gel electrophoresis technique.

5B. Discuss the principle of i) ELISA ii) RIA.

5C. Write the expected NMR pattern for the following with justification

(10+5+5 = 20 marks)