Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2008

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

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

Friday, May 30, 2008

Time: 3 Hrs. Max. Marks: 100

✍ **Answer ALL the questions.**

1A. Discuss about radiation source in UV- Visible spectrometers.

1B. Explain Van-Deemter equation.

1C. Write about the stationary phases used in Gel permeation chromatography.

1D. Discuss in detail about ion-pair chromatography.

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

2A. Discuss about different types of capillary electrophoresis.

2B. Discuss about spin-spin coupling.

2C. Discuss about reference standards and solvents used in NMR spectroscopy.

(10+5+5 = 20 marks)

3A. Discuss in detail about sample handling for IR spectroscopic analysis.

3B. Write a note on:

i) Laser Spectroscopy.

ii) Raman Spectroscopy.

(10+10 = 20 marks)

4A. Explain the working of:

i) Prisms

ii) Gratings as dispersive devices in spectrophotometers.

4B. With a labelled diagram, explain the working of a photoemissive tube.

4C. Discuss about Electrospray Ionisation.

4D. Discuss the theories of chromatographic separation.

(6+4+5+5 = 20 marks)

5A. Write a note on solid supports used in GLC.

5B. Write about various types of sample injection in GC.

5C. Discuss about mobile phase selection in HPLC analysis.

5D. Compare and contrast HPLC and GC technique.

(7+3+5+5 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2008

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602)

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE

Saturday, May 31, 2008

Time: 3 Hrs. Max. Marks: 100

✍ **Answer ALL the questions.**

1A. Explain the importance of personnel training in Pharmaceutical industry.

1B. Write an ideal packing instruction for dry powder parentral preparation.

1C. Explain a short note on Vendor rating.

(6+6+8 = 20 marks)

2A. Write short note on handling and distruction of scrap materials.

2B. Write a short note on reconciliation of labels.

2C. List different inprocess Quality Control Tests for semisolid preparation and explain their significance.

(10+5+5 = 20 marks)

3A. Write about the premises requirement for pharmaceutical industry as per schedule M.

3B. Define the terms standard deviation, standard error and coefficient of variation. Explain its significance.

(13+7 = 20 marks)

4A. Explain in detail about equipment validation.

4B. Explain the validation of sterilization by filtration technique.

(10+10 = 20 marks)

5A. Write a note on water system validation.

5B. Explain about the ventilation system and non-ventilation system of air handling with its advantages and disadvantages of each.

(10+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2008

SUBJECT: REGULATORY AFFAIRS (PQA 603)

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE

Tuesday, June 03, 2008

Time: 3 Hrs. Max. Marks: 100

✍ **Answer ALL the questions.**

1A. Discuss about trade related intellectual property rights.

1B. Discuss the salient features of ICH-GMP guidelines.

(10+10 = 20 marks)

2A. Discuss the principles that should be followed for clinical trials as per ICHE 8 guidelines.

2B. Discuss about the FDA drug master file guidelines.

(10+10 = 20 marks)

3A. Discuss the implication of revised process patent and give its significance (Indian Patent Act 1970).

3B. Discuss the general principles of toxicokinetic studies.

(10+10 = 20 marks)

4A. Discuss about BCS classification of drugs and determination of drug substance permeability class.

4B. Discuss about the techniques and approaches for studies in vitro of drug metabolism and drug interaction.

((5+5)+10 = 20 marks)

5A. Discuss about the qualification of impurities and thresholds for degradation products in new drug substances as per ICH guidelines.

5B. Discuss about EUDRA guidelines on fixed combination products.

((5+5)+10 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2008

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604)

SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE

Wednesday, June 04, 2008

Time: 3 Hrs. Max. Marks: 100

✍ **Answer ALL the questions.**

1A. Write in detail about the methods involved in non-aqueous titrations as per Indian Pharmacopoeia.

1B. Explain the analysis of a weakly basic drug in plasma.

(10+10 = 20 marks)

2A. Discuss in detail about sterility testing.

2B. What are microsomal induction and inhibition assays? Explain the principle.

(10+10 = 20 marks)

3A. Write in detail about the test for particulate matter and endotoxins in injectable preparations.

3B. Write about the evaluation of Cartons and Shippers.

(10+10 = 20 marks)

4A. Explain the Colour and Clarity test as per Indian Pharmacopoeia.

4B. Explain about the importance and applications of dissolution testing.

(10+10 = 20 marks)

5A. Write elaborately about the invitro evaluation of transdermal delivery systems.

5B. Describe the various methods for determination of aqueous solubility of drug and explain the significance of pH solubility.

(10+10 = 20 marks)