Reg. No.										

MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2011

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601)

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

Tuesday, May 24, 2011

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

Answer all questions.

1A. Define Beer-Lambert's law and derive an expression for the same.

1B. Explain the principle and applications of chemilumniscence.

1C. Name LASER sources and their applications.

1D. Explain the applications of ELISA in diagnosis and write the advantages of ELISA over RIA.

(5×4 = 20 marks)

2A. Write a note on papers, electrodes and source of current used in paper and gel electrophoresis.

2B. List applications of micellar electrokinetic chromatography.

2C. Describe the component parts of a mass spectrometer.

2D. Explain M+2 ion peak.

(5×4 = 20 marks)

3A. What is Fermi Resonance? Explain the factors affecting the absorption position in IR spectroscopy.

3B. What is chemical shift? What are the factors affecting chemical shift? Give examples.

(10+10 = 20 marks)

4A. Discuss the advantages and applications of LC-MS/MS.

4B. What are the methods of quantitative analysis by HPTLC? Enumerate the applications of HPTLC.

4C. Explain in brief the 'single point direct comparison method' for quantitative analysis using an internal standard in GC. A chromatographic injection containing 2000µg/ml of toluene (IS) and 1000 µg/ml of benzene (analyte) gave a peak area of 1,20,000 and 67,000 respectively. Now inject a sample containing 2000µg/ml of tolune and an unknown amount of benzene using the same chromatographic conditions. The resulting areas are 1,22,000 for tolune and 43,000 for unknown sample of benzene. Calculate the amount of benzene present.

4D. Write a short note on temperature programming in GC.

(5×4 = 20 marks)

5A. Compare the advantages of HPLC over column chromatography.

5B. What are the requirements for an ideal sample injection system in HPLC? Explain the working of a loop injection system.

5C. What are the ideal characteristics for a HPLC detector? Explain the principle and working of a UV-Visible spectrophotometric detector with a schematic representation.

5D. Discuss the principle, advantages and applications of supercritical fluid chromatography.

(5×4 = 20 marks)

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M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2011

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Thursday, May 26, 2011

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

- **Answer ALL Questions.**
- **Scientific calculators are allowed.**

1A. Write in detail about personnel responsibility, training and hygiene for the pharmaceutical industry.

1B. Name and explain about the types of

i) Cleaning methods ii) Cleaning evaluation

(10+10 = 20 marks)

2A. Explain the calibration of fluorimeter and high performance liquid chromatography.

2B. Explain analyst validation.

2C. Write a note on master formula record.

(10+5+5 = 20 marks)

3A. What is ISO 9000 quality standards? Explain its principle and implementation in details.

3B. A study was conducted with 300 patients who were admitted with Typhoid fever in a hospital in one year. 150 cases were given ciprofloxacin and another 150 cases were given chloramphenicol. Results of the patients cured completely after 10 days treatment is given below. Is there any difference in the effect of two drugs? Justify with suitable statistical hypothesis.

Drug	Cured	Not Cured
Ciprofloxacin	143	7
Chloramphenicol	137	13

(10+10 = 20 marks)

4A. Write in detail about reprocessing of recovered material.

4B. Enlist the components of distribution and warehouse records.

4C. Define and classify product recall. Explain the levels of product recall effectiveness.

4D. Write note on good warehouse practice.

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

5A. What is quality audit? Explain types of quality audit in detail.

5B. Explain the validation life cycle of water.

(10+10 = 20 marks)

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M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2011

SUBJECT: REGULATORY AFFAIRS (PQA 603)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Tuesday, May 31, 2011

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

✍ **Answer All Questions.**

1A. What is "clinical hold"? Explain the types, process and monitoring of "clinical hold" as per USFDA policy.

1B. Explain the validation of electronic common technical document (eCTD).

(10+10 = 20 marks)

2A. Enlist the contents of a typical 'quality overall summary' of a immediate release tablet.

2B. Explain the submission requirements of ANVISA.

(10+10 = 20 marks)

3A. Explain BCS classification system with approaches for setting dissolution specifications for a NCE and generic products.

3B. Write the component, manufacturing process, container closure system, microbiological attributes and compatibility of a drug product in pharmaceutical development.

(10+10 = 20 marks)

4A. Briefly classify impurities and explain the reporting, identification and qualification thresholds of impurities in new drug substances.

4B. Explain the methods to document BA and BE studies for orally administered drug products.

(10+10 = 20 marks)

5A. Schematically explain various stages of patent cooperation treaty and discuss its advantages.

5B. Write short notes on:

i) Continuation Patent Application

ii) Divisional Patent Application

5C. Write a note on continual improvement of pharmaceutical quality system as per ICH Q10.

(10+5+5 = 20 marks)

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MANIPAL UNIVERSITY

M. PHARM. PART–I DEGREE EXAMINATION – MAY/JUNE 2011

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

Thursday, June 02, 2011

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

✍ **Answer ALL the questions.**

1A. Describe various methods used for the determination of dissociation constant.

1B. What is "Internal standard"? Explain the role of internal standard in analysis of drugs in biological fluids.

1C. Explain the principle and procedure involved in evaluation of antimicrobial agents in injectable preparations.

(5+5+10 = 20 marks)

2A. Explain the construction and working of a glass electrode for measuring pH. Discuss the principle of potentiometric titration and methods of detecting the end point.

2B. With the help of a neat diagram, explain the construction of USP dissolution apparatus 2 Paddle apparatus. Describe the procedure and interpretation of results for carrying out the dissolution test of "immediate release dosage form".

(10+10 = 20 marks)

3A. Explain in detail stability indicating assay. Comment on various validation parameters of stability indicating assay.

3B. Explain in detail the stability testing of phytopharmaceuticals with suitable examples.

(10+10 = 20 marks)

4A. Define particulate contamination. Explain the procedure for microscopic particle count test and discuss the acceptance limits as per IP.

4B Explain the importance of IVIVC. Name various ways of achieving correlation. How is a level A correlation developed?

4C. Describe the parameters for evaluating the rubber closures for injectable preparations. Give the acceptance limits wherever necessary.

(5+5+10 = 20 marks)

5A. Explain the principle, procedure and applications of differential thermal analysis.

5B. Enlist various methods for the determination of solubility. Explain high-throughput screening methods for the determination of aqueous drug solubility and its applications.

5C. What is herbal standardization? Name the quality control tests for herbal drugs as per WHO guidelines. Explain any three tests in detail.

(5+5+10 = 20 marks)