Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601T)

(SPECIALIZATION: PHARMACEUTICS/INDUSTRIAL PHARMACY/PHARM. QUALITY ASSURANCE/ PHARM. BIOTECHNOLOGY)

(2014 REGULATION)

Wednesday, May 18, 2016

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

✍ **Answer ALL questions.**

1. Write the quantitative applications of double beam UV-Visible spectroscopy with examples. (10 marks)

2A. Explain with suitable example the Fermi resonance.

2B. Explain the solid sampling techniques in IR spectroscopy and their limitations. (5+5 = 10 marks)

3A. Explain with suitable example spin - spin splitting.

3B. Explain the importance of double resonance and Lanthanide shift reagents in NMR spectroscopy. (5+5 = 10 marks)

4A. Explain the construction and working of quadruple mass spectrometer.

4B. Explain isotopic ion peak and metastable ion peak in mass spectrum. (5+5 = 10 marks)

5A. What is a chromatogram? What are the information obtained from the chromatogram?

5B. What is rate theory of chromatography? Explain how band broadening is explained using this theory? (5+5 = 10 marks)

6A. Write briefly about the flow controls and importance of ideal flow rate in GC.

6B. Explain the principle, instrumentation and working of electron capture detector. (5+5 = 10 marks)

7A. Explain the sample injection systems used in HPLC. What are the desirable characteristics? Explain the working of loop injection.

7B. Explain the principle, process and applications of size-exclusion chromatography. (5+5 = 10 marks)

8. Explain the paper electrophoresis techniques in details.

(10 marks)

9. **Write short notes:**

9A. Structural features essential for a molecule to exhibit the phosphorescence.

9B. Retention parameters in HPTLC.

(5 marks × 2 = 10 marks)

10. **Write briefly on the following:**

10A. Applications of ELISA in research.

10B. Advantages and applications of LC-MS.

(5 marks × 2 = 10 marks)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602T)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE / DRUG REGULATORY AFFAIRS)

(2014 REGULATION)

Friday, May 20, 2016

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

- **Answer ALL questions.**
- **Use of scientific calculator is allowed.**
- **Draw neatly labeled diagram wherever necessary.**

1. Write a brief note on ISO 9000.

(10 marks)

2. Define the term "Raw materials". Explain in detail purchase specifications, inventory methods and control on raw materials.

(10 marks)

3. What is Quality Audit? What are its objectives? Explain different types of quality audit in details.

(10 marks)

4. Write in detail about objective and scope of documentation in pharmaceutical industry. Enlist the components of master formula record and batch formula record.

(10 marks)

5. Explain in detail about the cleaning validation in pharmaceutical industry.

(10 marks)

6. Define and classify drug product recall and explain in detail about the recall strategy.

(10 marks)

7. Systolic blood pressure (SBP) of 9 normal individuals, who had been recumbent for 5 minutes was taken. Then 2 ml of 0.5% solution of hypotensive drug was given and blood pressure was recorded again. Did the injection of drug lower the blood pressure? Justify.

BP before injection	BP after injection
122	120
121	118
120	115
115	110
126	122
130	130
120	116
125	124
128	125

(10 marks)

8. Write in detail about analytical method validation as per ICH guideline.

(10 marks)

9A. Write a note on reserved sample and reference standard in quality control laboratory.

9B. Write a note on reprocessing of the recovered material in pharmaceutical industry.

(5+5 = 10 marks)

10A. Write a note on location and construction of pharmaceutical plant.

10B. Explain the importance of training in pharmaceutical manufacturing unit.

(5+5 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

SUBJECT: REGULATORY AFFAIRS (PQA 603T)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)
(2014 REGULATION)

Wednesday, May 25, 2016

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

✍ **Answer ALL questions.**

1. Write a note on special consideration as per FDA bioavailability, bioequivalence guidance document.

(10 marks)

2. Explain, with relevant examples, process and product patent. Enlist inventions that can and cannot be granted patents according to Indian Patents Act 1970 (as amended).

(10 marks)

3. A new HPLC method for quantitative testing of impurities is developed. Explain the validation of the same as per ICH Q2A(R1).

(10 marks)

4. Explain in detail PAT and its applications in current pharmaceutical development, manufacturing and quality assurance requirements of a pharmaceutical industry.

(10 marks)

5. Write a note on stress testing and photostability testing.

(10 marks)

6. Explain different parameters considered in BCS classification system for IR solid dosage forms.

(10 marks)

7. Write a note on changes to an approved NDA or ANDA with respect to specifications and container closure system.

(10 marks)

8. Briefly explain the criteria to grant a patent. Explain Patent filing process in India.

(10 marks)

9. **Write short notes on:**

9A. What are the responsibilities of management in Pharmaceutical Quality System?

9B. Write a note on copyrights.

(5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Write a note on model independent approach using a similarity factor and model dependent approach in dissolution profile comparison of IR formulation.

10B. Explain intrinsic dissolution.

(5+5 = 10 marks)

Reg. No.										

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION – MAY 2016

SUBJECT: PHARMACEUTICAL ANALYSIS & PRODUCT DEVELOPMENT (PQA 604T)

(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)

(2014 REGULATION)

Friday, May 27, 2016

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

✍ **Answer ALL the questions.**

1A. Explain various protein precipitation techniques and list their limitations.

1B. What is "kinetic solubility"? Explain its advantages over equilibrium solubility.

(5+5 = 10 marks)

2. How the test for endotoxin is carried out as per IP? Explain in detail.

(10 marks)

3. Describe various methods used for the determination of partition coefficient in detail.

(10 marks)

4A. Explain the determination of Refractive index by Abbe refractometer as per IP.

4B. Explain the construction of disintegration apparatus IP and the procedure for disintegration test.

(5+5 = 10 marks)

5A. Explain in detail about suspended-level viscometer.

5B. Explain ICH Q1D guidelines in detail.

(5+5 = 10 marks)

6. Write the principle and detailed procedure for the determination of volatile oils in herbal drugs.

(10 marks)

7. Discuss bracketing and matrixing designs for stability testing of new drug products with suitable examples.

(10 marks)

8A. Explain the construction and any two advantages and disadvantages of dissolution apparatus 3 USP (Reciprocating cylinder).

8B. Explain the procedure and acceptance criteria for dissolution testing of delayed release dosage forms.

(5+5 = 10 marks)

9. **Write short notes:**

9A. Liquid membrane electrode

9B. Differential Scanning Calorimetry

(5+5 = 10 marks)

10. **Write briefly on the following:**

10A. Importance of metabolic profiling in drug discovery

10B. Test for metal particles for evaluation of metal containers for eye ointments

(5+5 = 10 marks)