Reg. No.: _____

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601T)
(SPECIALIZATION: PHARMACEUTICS/INDUSTRIAL PHARMACY/PHARM. QUALITY ASSURANCE/PHARM. BIOTECHNOLOGY)
(2014 REGULATION)
Thursday, May 18, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1A)	Name and explain the different regions of electromagnetic spectrum.	(5)
1B)	Define laws of photometry. Explain the deviations of Beer's laws in brief.	(5)
2A)	List the applications of LASER and Raman spectroscopy.	(5)
2B)	Why C=O vibrational frequency shifts from its normal value in IR spectrum? Explain with suitable example.	(5)
3A)	What is the scope of 'decoupling methods' in ^{13}C NMR spectroscopy? Explain.	(5)
3B)	Explain the significance of the reference standard used in PNMR spectroscopy.	(5)
4A)	Explain desorption methods of ionization techniques in mass spectroscopy and its applications.	(7)
4B)	What is metastable ion? Explain.	(3)
5A)	What are the factors responsible for band broadening in chromatography? How can they be minimized?	(5)
5B)	Explain the following terms in chromatography (i) Chromatogram, (ii) Resolution, (iii) Retention time, (iv) Peak asymmetry.	(5)
6A)	Explain briefly on "carrier gas" and "injection port" used in GC.	(5)
6B)	Explain the qualitative and quantitative analysis in GC. List any four applications of GC.	(5)
7A)	Explain the working of a "refractive index detector" used in HPLC. List any two advantages and disadvantages.	(5)
7B)	Explain the principle, process and applications of UPLC.	(5)
8A)	Explain the principle and working of horizontal paper electrophoresis.	(5)
8B)	Explain the capillary electrophoresis methods in brief.	(5)

Write short notes:

9A)	In-situ densitometry in HPTLC.	(5)
9B)	Applications of ELISA in diagnosis.	(5)

Write briefly on the following:

10A)	Derivatization in fluorimetry with two examples.	(5)
10B)	Applications of LC-MS.	(5)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602T)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE / DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Saturday, May 20, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

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

1) Write in detail about location, design, plant layout, and construction of a pharmaceutical manufacturing facility. (10)

2) What is ISO 9000? Explain in detail. (10)

3) Write in brief about personnel responsibility, training and hygiene in the pharmaceutical industry. (10)

4) Define product recall. Explain in detail about product recall classification and strategies for the same. (10)

5) Explain in detail about importance of In Process Quality Control (IPQC) tests. Enlist the IPQC tests with its significance for semisolid dosage form. (10)

6) Explain analytical method validation as per ICH guideline. (10)

7) Systolic blood pressure values (X) of four occupations are given. Determine if there is significant difference in mean blood pressure of four groups in order to access the role of occupation in causation of BP. Justify (10)

Officers (X1)	Clerks (X2)	Lab technicians (X3)	Attendants (X4)
125	120	120	118
130	122	115	120
135	115	115	118
120	110	130	120
115	125	120	120
120	122	125	115
130	120	122	125
135	120	115	125
140	126	126	120
135	120	118	115

8) Explain the importance of cleaning validation and explain in detail about the different methods of sampling. (10)

9A) Enlist the components of master formula record. (5)

9B) Define SOP. Enlist the components of SOP. (5)

10A) Explain the terms distribution and distribution record. (5)

10B) Explain Phase I testing of water system. (5)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: REGULATORY AFFAIRS (PQA 603T)
(SPECIALIZATION: PHARMACEUTICAL QUALITY ASSURANCE)
(2014 REGULATION)
Thursday, May 25, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1)	Enlist the various components of Intellectual Property Rights.	(10)
2)	Explain Copyrights and Trademarks with relevant examples.	(10)
3)	Explain the monograph development process for BP.	(10)
4)	Write a note on content of site master file as per European commission.	(10)
5)	Write a note on bracketing design of stability testing.	(10)
6)	What are the criteria to grant a patent? Enlist inventions that are patentable and non patentable according to Indian Patents Act 1970.	(10)
7)	Write in detail about data required to support a request for biowavier for IR solid oral dosage form based on biopharmaceutics classification system.	(10)
8)	What are the different options for describing limits of class 2 solvents as per ICH Q3C (R5) guidelines?	(10)

Write short notes on:

9A)	Write a note on machine readable bar code label requirements for blood and blood components.	(5)
9B)	Write a note on data analysis and labeling as per FDA fed, fasted bioavailability and bioequivalence guidance document.	(5)

Write briefly on the following:

10A)	Explain QBR-quality overall summary to be completed by ANDA sponsor for pharmaceutical product quality to office of generic drugs.	(5)
10B)	Write a note on quantification of degradant impurities in drug products.	(5)