Reg. No.: _____

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017
SUBJECT: MODERN PHARMACEUTICAL ANALYSIS (PQA 601T)
(SPECIALIZATION: PHARMACEUTICS/INDUSTRIAL PHARMACY/PHARM. QUALITY ASSURANCE/PHARM.BIOTHECHNOLOGY)
(2014 REGULATIONS)
Monday, July 17, 2017 (10.00 - 13.00 Hrs.)

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

Answer ALL the questions:

1A)	Explain the effect of solvent and crossed conjugation on absorption spectra with example.	(5)
1B)	Explain the Woodward-Fieser rules for Dienes.	(5)
2A)	Explain the instrumentation of Raman spectroscopy.	(5)
2B)	Why the vibrational frequency of C=0 shifts from its normal value in IR spectrum? Explain.	(5)
3A)	What is the scope of 'decoupling methods' in ^{13}C NMR spectroscopy? Explain.	(5)
3B)	Explain the causes for deshielding of aldehyde protons in ^{1}H NMR spectroscopy.	(5)
4A)	Explain the gas phase ionization techniques in mass spectroscopy and their applications.	(7)
4B)	What are M+1 ion peak, M+2 ion peak and metastable ion?	(3)
5A)	Explain any four mechanisms responsible for separation in chromatography.	(5)
5B)	Explain the variables that affects the column efficiency in a chromatographic separation.	(5)
6A)	Explain the columns and stationary phases in GC.	(5)
6B)	Explain the working of Electron capture detector.	(5)
7A)	Explain the theory and instrumentation of HPLC.	(5)
7B)	Explain the theory, process and applications of Ion-exchange HPLC.	(5)
8)	Explain the principle and applications of micellar electrokinetic chromatography in brief.	(10)

Write short notes:

9A)	Detection techniques in HPTLC.	(5)
9B)	Applications of Hyphenated techniques.	(5)

Write briefly on the following:

10A)	Merits and demerits of phosphorimetry over fluorimetry.	(5)

10B) Principle and experimental requirements for ELISA. (5)

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017
SUBJECT: QUALITY ASSURANCE AND MANAGEMENT (PQA 602T)
(SPECIALIZATION: PHARM. QUALITY ASSURANCE / DRUG REG. AFFAIRS)
Wednesday, July 19, 2017 (10.00 - 13.00 Hrs.)

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

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

1) What is the importance of personnel training, responsibility and hygiene in pharmaceutical industry? (10)

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

3) Write a brief note on "Total Quality Management". (10)

4) Explain about labelling operation and issuance in packaging as per US FDA. (10)

5) Explain master formula record and batch manufacturing record in detail. (10)

6) Explain in detail in process quality control test for tablets and capsules. (10)

7) In a nutritional study 13 children were given a usual diet plus vitamins A and D tablets while the second comparable group of 12 children was taking the usual diet. After 12 months the gain in weight in pounds was noted as given in the table below. Can we say that vitamins A and D were responsible for this difference? Justify. (10)

Children on vitamins (group A)	Children on usual diet (Group B)
5	1
3	3
4	2
3	4
2	2
6	1
3	3
2	4
3	3
6	2
7	2
5	3
3	-

8)	Explain in detail water system validation in pharmaceutical industry.	(10)
9A)	What is the importance of control on reserve samples? Explain.	(5)
9B)	Explain about different training methods as a part of personnel validation.	(5)
10A)	Write a note on accuracy, LOD and LOQ of analytical method validation.	(5)
10B)	What is manufacturing process qualification?	(5)

MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017
SUBJECT: BIOPHARMACEUTICS AND PHARMACOKINETICS (PCE 602T)
(SPECIALIZATION: PHARMACEUTICS / INDUSTRIAL PHARMACY / PHARM. QUALITY ASSURANCE)
(2014 REGULATION)
Friday, July 21, 2017 (10.00 - 13.00 Hrs.)

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

Answer ALL the questions:

1)	Explain the pharmacokinetics of a drug following two compartment open model when administered as an IV bolus.	(10)
2)	Explain the application of the sigma - minus method to determine the pharmacokinetics of drugs in urine administered by IV bolus assuming that it follows one compartment open model.	(10)
3)	Explain the determination of absorption rate constant of drug in blood by the method of residuals when administered by extravascular route assuming that it follows one compartment open model.	(10)
4)	Explain with examples the applications of pharmacokinetics on therapeutic drug monitoring.	(10)
5)	Discuss the evaluation of in vivo bioavailability data for modified release drug products.	(10)
6)	Describe the phase-1 oxidative reactions in biotransformation of drugs with examples.	(10)
7)	How pharmacokinetics and pharmacodynamics can be related? Explain	(10)
8)	How Vmax and Km are determined? Discuss at least two methods.	(10)

9. **Write short notes:**

9A)	Time-dependent pharmacokinetics.	(5)
9B)	Drug accumulation index 'R'.	(5)

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

10A)	Solubility and permeability criteria as per the BCS.	(5)
10B)	Importance of Ka and Tmax and AUC in Bioavailability.	(5)