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)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017
SUBJECT: CLINICAL TRIALS AND REGULATIONS (PRA 603T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Monday, July 24, 2017 (10.00 - 13.00 Hrs.)

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

Answer ALL the questions:

1)	Give the composition and functions of IRB.	(10)
2)	Discuss about: i) Minimum criteria for reporting of ADRs. ii) Drug-drug interaction studies in elderly population.	(10)
3)	Discuss the aspects that need to be considered for carrying out clinical evaluation of a medical device. Under what circumstances, a medical device must be reevaluated?	(10)
4)	Explain the use of dose-response information in choosing doses and regulatory requirement for archiving of clinical data.	(10)
5)	Explain the regulatory requirement in India with regard to bioequivalence study design and study population.	(10)
6)	What is the purpose of clinical investigator inspections?	(10)
7)	Discuss about: i) Role of IRB in volunteer recruitment. i) Data Retention upon the withdrawal of Subjects.	(10)
8)	Discuss the objectives of Phase II & III clinical trials.	(10)

9. **Write short notes on:**

9A)	Composition of clinical trial site management committee.	(5)
9B)	Level C and Level D correlations as per FDA guideline on IVIVC.	(5)

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

10A)	Advantages of a proper clinical trial design.	(5)
10B)	Compensation given to volunteers and investigators.	(5)

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FIRST YEAR M. PHARM. DEGREE EXAMINATION - JULY 2017
SUBJECT: QUALITY, SAFETY AND EFFICACY REGULATIONS (PRA 604T)
(SPECIALIZATION: DRUG REGULATORY AFFAIRS)
(2014 REGULATION)
Wednesday, July 26, 2017 (10.00 - 13.00 Hrs.)

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

Answer all the questions.

1)	Explain the factors to be considered while applying matrix design for drug stability studies.	(10)
2)	Write a note on 'Principle, data presentation and extrapolation' of stability testing as per ICH Q1E guidelines.	(10)
3)	Explain the consideration for implementation of test for particulate contamination as per ICH Q4B guidelines.	(10)
4)	Explain the strategy for process analytical technology implementation as recommended by USFDA.	(10)
5)	Explain the objectives and experimental design for safety pharmacological studies.	(10)
6)	What are the different approaches recommended for non-clinical studies to support exploratory clinical trials? Explain approach 1 and 3 in detail.	(10)
7)	Write approaches for setting dissolution specification for immediate release formulation as per FDA guidance document.	(10)
8)	Discuss the various evaluation process in harmonization and prepare a comparison chart using British Pharmacopoeia, US pharmacopoeia for any three drugs.	(10)

9. **Write short notes on:**

9A)	General quality risk management process as per ICH Q9.	(5)
9B)	Reproductive toxicity testing purpose.	(5)

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

10A)	Guidelines for GAMP.	(5)
10B)	ICH working groups.	(5)