MASTER OF PHARMACY EXAMINATION, 2018
(1st year, 1st Semester)

Pharmaceutical Quality Assurance

Time: Three hours Full Marks: 100

Answer any ***five*** questions taking atleast ***one*** from each group.

GROUP - A

1. (a) Differentiate between reductionist and synergistic approaches for drug development from natural resources with example in each case.

   (b) Describe the importance of HTS and HRS in drug discovery and development with suitable example. How can you differentiate between the two methods explain different steps involved with schematic diagrams.

   (c) Describe the sample application and development and detection techniques in RPHPLC with example 5+8+7 = 20

2. Describe the following and their importance in development of drugs and pharmaceuticals: 8x 2.5 = 20

   (a) AChE enzyme inhibition study

   (b) Microtitre Bio assay

   (c) Metabolomic study

   (d) Receptor binding assays

   (e) Reverse Pharmacology

   (f) Drug interaction study through CYP450

   (g) Biochemical Assay

   (h) SGOT and SGPT

3. Explain the following techniques and their importance in quality assurance of drugs and pharmaceuticals with example wherever applicable : 5x4 = 20

   (a) LC-MS/MS

   (b) Scanning Densitometry

   (c) AAS

   (d) Detectors in HPLC

   (e) Chi-square test

M. PHARM 1st YEAR 1ST SEMESTER EXAMINATION, 2018

SUBJECT: PHARMACEUTICAL QUALITY ASSURANCE
GROUP – B

4. **(a)** What do you understand by Quality Assurance? What role does it play in maintaining the quality standards of pharmaceutical products? **5+5**

(b) Provide a schematic chart for PET. **10**

5. **(a)** Elaborate the various parameters of quality analysis **10**

(b) Why sampling plan forms an integral part of quality analysis? Explain with a suitable graph "Ouality Chart by Variables" **5+5**

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Pharmaceutical Quality Assurance

GROUP - C

6. i. a. Why were the GLP mandated?

b. What were the regulatory processes before GLP?

c. What role do GLP play?

d. What are the regulatory processes after GLP?

e. Who must comply with GLP?

f. Mention the GLP regulations, rules and tools.

g. Define the term Verification/Testing, Calibration and Standardization.

h. What is the relevance of using logbook?

i. How do you know what expiration date to use?

j. Documentation is important in all sorts of situations!! Explain.

k. What are the cases where GLP compliances are not required?

l. What are GLP principles?

m. Why do we need GLP?

n. What are the SOP writing guidelines?

o. Why are SOPs required?

15×1= 15

ii. In cGMP Process must be managed and improved! Explain.

7. What are the difference between QA and QC? Who should be responsible for the QA and QC activities? How can TQM be compared to ISO 9001? Mention the foundation, steps and principles of Total Quality Management.

8+2+10= 20