Ex/PG/PHAR/T/115A/29/2017
Ex/PG/CLP/T/115A/189/2017

MASTER OF PHARMACY & CLINICAL PHARMACY
EXAMINATION, 2017
(1st Semester)

Pharmaceutical Quality Control & Assurance

Time: Three hours Full Marks: 100

Use separate Answer-Script from each group.

Answer any **Five** questions taking at least **Two** from Group A

GROUP - A

1. (a) Define HTS and its importance in drug discovery and development; Explain different steps involved in HTS

   b) State the importance of the following instrument in quality control and quality assurance:

   i) LC-MS

   ii) DSC

   iii) AAS

   iv) Zetasizer

   12+8 = 20

2. (a) State various enzyme inhibition studies. How an inhibitor can help in drug development explain with example

   b) State the importance of the followings in quality assurance of Drugs :

   i) Scanning Densitometry

   ii) Fluorescence Detector

   iii) P - value

   iv) NMR Spectroscopy

   8+12 = 20

3. (a) Classify different 'Omic' techniques used in drug discovery and development. What is metabolomics? How it helps in drug development.

   (b) Explain with example various techniques for validation of instruments .

   12+8 = 20

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M. PHARM 1st YEAR 1ST SEMESTER EXAMINATION, 2017
&
M. PPHARM IN CLINICAL PHARMACY AND PHARMACY PRACTICE 1ST YEAR 1ST SEMESTER 2017

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) Classify raw materials with regards to control of quality variation 5

(b) Discuss quality assurance in the finished product 10

(c) Give reasons why sampling plays a crucial role from Pharmaceutical standpoint. Write the various sampling plans. 2+3

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PHARMACEUTICAL QUALITY CONTROL & ASSURANCE

GROUP - C

6. a) What is the difference between 'QA' and 'QC'?
   b) Who should be responsible for 'QA' and 'QC' activities?
   c) Discuss in brief the ten steps of total quality management.
   d) What are the principles of TQM?

2+6+6+6= 20

7. a) Why do we need GLPs?
   b) What are GLPs principles?
   c) What are SOP writing guidelines?
   d) Who must comply with GLPs?
   e) Why were the GLPs mandated?
   f) What GLPs SOPs can't do?
   g) Distinguish 'verification', 'calibration' and 'standardization'.
   h) What are FDA GLP compliance?

2.5×8= 20