HU-M2011117 Seat No. _____

M. Pharm. (Sem. II) (CBCS) Examination

June / July - 2017

Modern Pharmaceutical Analysis : Specialization Paper - III

(Quality Assurance)

(Core Subject-IV) (Theory)

Time : **3** Hours] [Total Marks : **80**

Instructions : (1) Answer and tie up both the sections separately.
(2) Figure to the right indicates marks.
(3) Answer the three (03) questions from each section.
(4) Question one (01) and question Five (05) are compulsory.
(5) Draw neat and clean diagrams as required.

SECTION - I

1 Answer any seven of the following questions : **14**

a. How calibration is different from validation ?

b. What is isoelectric point ? Give example.

c. Explain the term "Genetic engineering".

d. What is fl and f2 stands for in dissolution study ?

e. What is sequence analysis in amino acid ?

f. What is Edman's reaction ?

g. How do you calibrate UV- visible spectrophotometer ?

h. Enlist IPQC test for parenterals.

i. Give two pharmaceutical applications of automated analysis.

j. Give the application of basket type and paddle type dissolution apparatus.

2 Answer the following questions.

a. What do you mean by modern pharmaceutical analysis ? Discuss techniques for amino acid analysis. **8**

b. Give an informative note on cosmetic analysis. **5**

3 Answer the following questions :

a. Discuss objectives and importance of dissolution study. Enlist commonly preferred dissolution media required for tablet dosage form. 8

b. Discus In-vivo and In- vitro Co-relation. 5

4 Answer the following questions :

a. What is the difference between crude drug and herbal drug ? Discuss compendial methods for their evaluation. 8

b. Give the advantages and disadvantages of automated analysis. 5

SECTION - II

5 Answer any two of the following questions : 14

a. Discuss different types of dissolution test apparatus used in pharmaceutical science.

b. How do you analyse the presence of drug and its metabolite in urine ?

c. Discuss. Discuss IPQC testing for pharmaceutical packaging and labelling.

6 Answer the following questions :

a. Explain the term IPQC. Discuss IPQC tests for liquid oral formulation. 8

b. Write a short note on: Different regulatory guidelines for pharmaceutical analysis. 5

7 Answer the following questions :

a. How do you analyse presence of amino acid in amino acid supplement ? Discuss tryptic mapping method in detail. 8

b. Discuss with example: How calibration, validation and quality control are important to maintain the quality of drug product ? 5

8 Answer the following questions :

a. Discuss the applications of UV, IR, NMR and Mass in preformulation study. 8

b. Discuss: similarity and dissimilarity factor. 5