



* D K - M - 2 0 1 1 1 1 7 *

DK-M-2011117 Seat No. _____
M. Pharm. (Sem. II) (CBCS) Examination
April / May – 2015
Modern Pharmaceutical Analysis
(Core Subject - IV) (Speci. Paper - III)
(Quality Assurance)

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 (1) and question Five (05) are compulsory.
 - (5) Draw neat and clean diagrams as required.

SECTION - I

- 1** What do you mean by modern pharmaceutical analysis? **14**
Enlist the different analytical technique used in pharmaceutical sciences with its application.

- 2** (a) What do you mean by quality control and In-process quality control? Discuss the significance of in-process quality control for safety and efficacy of drug product. **8**
 (b) Give the objective and importance of dissolution study for a solid dosage form. **5**

- 3** (a) What is Genetic engineering? Discuss the principle of tryptic mapping method. **8**
 (b) Explain in detail amino acid sequence analysis. **5**

- 4** (a) Write a history, role and content of ICH guideline. **8**
 (b) Write an informative note different extraction technique used in bio-analytical method development. **5**

SECTION – II

- 5 How will you develop a new analytical method? Give its basic steps. What are the different parameters to be included for validation of analytical methods? Discuss briefly. 14
- 6 (a) Enlist the different analytical techniques used in preformulation study and give application of each method. 8
- (b) Discuss quality control test for tablet dosage form. 5
- 7 (a) Enlist the different IPQC test for parenteral dosage form and discuss any three in detail 8
- (b) Write a note on: Importance of calibration in pharmaceutical sciences. 5
- 8 (a) How will you select the proper dissolution media? Discuss various conditions used in dissolution study. 8
- (b) Write a short note on: In-vivo and In- vitro Co-relation (IVIVC). 5
-