NE-02010311 Seat No. _____

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

January – 2017

Pharmaceutical Quality Assurance : Paper - II

Good Manufacturing & Good Laboratory Practice (Theory)

(CORE - III)

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 out of given ten questions : **2×7=14**

(a) What is the difference between GMP and cGMP?

(b) What is the difference between GLP and GCP?

(c) Give the content of monograph.

(d) What is quality audit?

(e) Give the importance of purchase specifications.

(f) What is the role of pharmaceutical packaging?

(g) What is IPQC testing?

(h) Give the importance of good warehousing practice.

(i) Give in brief about waste disposal procedure and record.

(j) What is distribution records?

2 Answer the following :

(a) Discuss the GMP requirement for design, construction and layout of plant. **7**

(b) How GMP is helpful to maintain the quality of drug product? Discuss the personnel and hygiene requirement. **6**

3 Answer the following :

(a) How would you decide purchase specification of any instrument? Discuss with example. **7**

(b) What is CIP? Discuss the importance of cleaning in place technology in pharma industry. **6**

4 Answer the following :

(a) Explain the term: Loan Licensing, Quality audit, IPQC and BMR. **7**

(b) Enlist IPQC of sterile dosage form and discuss any two in detail. **6**

SECTION - II

5 Answer any two out of three questions : **7×2=14**

(a) What is the role of GLP in industry? Discuss the concept of quality assurance.

(b) Write a note on a concept and advantage of audit.

(c) What are the raw materials? Discuss the purchase specifications of raw material.

6 Answer the following :

(a) What is master formula record? Discuss its role in manufacturing and control of pharmaceutical dosage form. **7**

(b) What is SOP? Prepare a SOP for cleaning of common laboratory glass ware. **6**

7 Answer the following :

(a) What is the difference between quality control and quality assurance? Give the list and advantages of IPQC testing for tablet compression. **7**

(b) Classify the pharmaceutical packaging materials and discuss common labeling requirement according to type of dosage form. **6**

8 Answer the following :

(a) Discuss the GMP requirement for environmental control for maintenance of sterile area with diagram. **7**

(b) Write a short note on recall procedures. **6**