NE-02010309 Seat No._____

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

January – 2017

Industrial Pharmacy (Pharmaceutics)

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

Instructions : (1) Answer and tie up both the section separately.
(2) Answer to the right indicates marks.
(3) Answer three (03) questions from each section.
(4) Question One (1) and Question Five (5) are compulsory.

SECTION - I

1 Answer any seven out of ten : **14**

a. Comment with reasons that the humidity has to be controlled for manufacturing of Soft gelatin capsules.

b. Briefly describe the objectives of validation master plan.

c. Describe the contents of SOP.

d. Enlist various IPQC parameters for tablet manufacturing.

e. What is class 100 clean area?

f. Explain the difference between GMP and cGMP.

g. Enlist the various equipment required for manufacturing liposomes.

h. What is master formula record?

i. Justify the importance of validation protocol.

j. Explain the objective of SUPAC guidelines.

2 a. Describe HVAC as utility service in pharmaceutical manufacturing. **7**

b. Explain qualitative and quantitative departmental layout for Transdermal Drug delivery systems. **6**

3	a.	Describe the factors affecting the location of a pharmaceutical industry.	**7**
	b.	What is pilot plant? Describe pilot plant operation.	**6**
4	a.	Describe the equipments required in the manufacture of solid dosage forms as per Schedule-M.	**7**
	b.	Enlist the equipments required for semisolid dosage forms. Describe Colloidal mill.	**6**

SECTION - II

5 Answer any two out of three : (07 × 02) **14**

a. Discuss personnel facilities required in pharmaceutical industry.

b. Describe departmental layout for oral liquid dosage forms.

c. Describe the preparation of SOP for sterile manufacturing.

6	a.	What is SUPAC SS? Describe different levels of changes in MR formulations.	**7**
	b.	Discuss the scale up for tablet coating process.	**6**
7	a.	Explain routing and scheduling with respect to production planning.	**7**
	b.	Discuss qualitative and quantitative departmental layout for Aerosols.	**6**
8	a.	What is documentation? Describe Batch Packaging Record.	**7**
	b.	What is the significance of GMP in pharmaceutical manufacturing.	**6**