MANIPAL UNIVERSITY

FIRST YEAR M. PHARM. DEGREE EXAMINATION - MAY 2017
SUBJECT: ADVANCED INDUSTRIAL PHARMACY (PIP 601T)
(SPECIALIZATION: INDUSTRIAL PHARMACY)
(2014 REGULATION)
Saturday, May 20, 2017 (10.00 - 13.00 Hrs.)

Marks: 100 **Duration: 180 mins.**

Answer ALL the questions.

1)	Define "plant layout" and explain plant layout procedure.	(10)
2)	What is significance of 'Factory acceptance testing' (FAT) and 'Site acceptance testing' (SAT)? Explain the procedure for IQ.	(10)
3)	Mention different types and stages of process validation. Describe validation report and benefits of process validation.	(10)
4)	Explain vendor rating parameters with respect to pharmaceutical industry.	(10)
5)	Explain various critical process parameters to be controlled during drying of granules and tablet coating.	(10)
6)	What is GMP? Explain the procedure for handling regulatory audits.	(10)
7)	Discuss on "corrective or break down maintenance" in pharmaceutical industry.	(10)
8)	What is "On the job training"? Explain training, its evaluation and re-training.	(10)

Write short notes:

9A)	Requalification of equipment.	(5)
9B)	Applications of Steam in place (SIP) in pharmaceuticals.	(5)

Write briefly on the following:

10A)	Material flow pattern in pharmaceutical industry.	(5)
10B)	Various control levels in inventory system for replenish the materials.	(5)