BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: M.PHARM **SEMESTER : II**
BRANCH: PHARMACY **SESSION : SP/18**

SUBJECT: MPH2027 PHARMACEUTICAL MANUFACTURING TECHNOLOGY

TIME: 3 HOURS **FULL MARKS: 60**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 12 marks and total 84 marks.
2. Candidates may attempt any 5 questions maximum of 60 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a)	Describe the steps for getting Drug license for setting up of Drug Formulation industry.	[6]
Q.1(b)	Discuss the cGMP requirements in brief in Drug Formulation industry.	[6]
Q.2(a)	What do you mean by Production Planning & Control in Drug Formulation industry?	[6]
Q.2(b)	Draw a layout for sterile Manufacturing unit.	[6]
Q.3(a)	Draw flow chart for tablet, Liquid oral and Injectable preparation.	[6]
Q.3(b)	What do you mean by Inprocess control? Specify it for tablet, Liquid oral and Injectable preparation.	[6]
Q.4(a)	Discuss automation in non sterile manufacturing tablet and Liquid oral product.	[6]
Q.4(b)	Describe the use of equipments for coating process and fluidized bed coating.	[6]
Q.5(a)	Define QbDand its goals and explain the importance of the following in QbD a) QTTP b) PAT c) Process capability.	[6]
Q.5(b)	Write the typical material attributes, process parameters and quality attributes of six pharmaceutical unit operations.	[6]
Q.6(a)	How product and process understanding is essential in QbD? Illustrate with an example?	[6]
Q.6(b)	Explain the importance of the following i) Control strategy ii) Continual Improvement iii) Risk assessment.	[6]
Q.7(a)	What are the nine elements of packing design and Explain them in detail?	[6]
Q.7(b)	Discuss various packing material used in pharmaceutical industry and its quality control.	[6]

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