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

CLASS: M.PHARM **SEMESTER: II**
BRANCH: PHARMACY **SESSION: SP 2023**

SUBJECT: MQA202T PHARMACEUTICAL VALIDATION

TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:

1. The missing data, if any, may be assumed suitably.
2. Before attempting the question paper, be sure that you have got the correct question paper.
3. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.
5. Answer any five questions.

1a.	Define & differentiate between calibration, qualification & validation. Explain about various aspects of qualification.	[7]	CO1 & CO2
1b.	Discuss about different types of validation. Give a not on VMP.	[8]	CO1 & CO3
2a.	What is URS? Justify the role of FAT & SAT in quality management of pharmaceutical products.	[7]	CO1 & CO3
2b.	Explain about the calibration of HPLC with suitable examples.	[8]	CO3
3a.	Justify the role of qualification of instruments in pharmaceutical preparations. Elaborate the qualification of disintegration tester.	[7]	CO2 & CO3
3b.	Discuss the qualification of hot air oven & FBD	[8]	CO2
4a.	Explain about qualification of HVAC system used in pharmaceutical industry as well as in laboratories.	[7]	CO2
4b.	Define validation and components of validation for cleaning validation.	[8]	CO1 & CO2
5a.	Describe process validation and types of process validation. Enlist documentation of process validation	[7]	CO1 & CO2
5b.	Explain through a case study of process validation of any quality control parameter of tablet formulation	[8]	CO3
6a.	Discuss in short(any two): (i) Cleaning validation and its components (ii) Checklist for cleaning validation of analytical instrument (any) (iii) CIP	[7]	CO2
6b.	Elaborate intellectual property rights including different modes of protection.	[8]	CO3
7a.	Discuss the patent infringement with a case study on it.	[7]	CO3
7b.	Elaborate analytical method development as per ICH.	[8]	CO2
	Describe process validation and types of process validation. Enlist documentation of process validation		

::::::25/04/2023::::::E