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

CLASS: MPHARMA **SEMESTER : II**
BRANCH: PHARMACY **SESSION : SP/18**

SUBJECT: MPH2023 PHARMACEUTICAL VALIDATION

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)	Define and differentiate between calibration, qualification, and validation. Write the significance of calibration	[6]
Q.1(b)	What do you mean by URS? Write short notes on FAT and SAT	[6]
Q.2(a)	Write the qualification of dry powder mixers and its significance in manufacturing process	[6]
Q.2(b)	Why calibration is required in instruments? How do you calibrate UV-Vis spectrophotometer and HPLC	[6]
Q.3(a)	What is HVAC? How it is validated in various utility system?	[6]
Q.3(b)	Justify the qualification of hardness tester and dissolution test apparatus	[6]
Q.4(a)	Write a note on types of validation and their significance	[6]
Q.4(b)	Discuss the role of electronic records and digital signature in an industry.	[6]
Q.5(a)	What do you mean by Prospective, Concurrent and Retrospective validation? Explain with suitable examples.	[6]
Q.5(b)	What are the criteria to be considered for validation of an analytical method as per ICH guidelines?	[6]
Q.6(a)	Explain the significance and importance of cleaning validation policy for a pharmaceutical industry.	[6]
Q.6(b)	Discuss the importance of computer system validation with emphasizing on electronic records and digital signature.	[6]
Q.7(a)	What is the process to file a patent application in India? Explain	[6]
Q.7(b)	What are the rights and responsibilities of a patentee? Discuss in context to patent infringement.	[6]

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