

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

CLASS: M.PHARM
BRANCH: PHARMACY

SEMESTER : II
SESSION : SP/19

SUBJECT: MQA202T PHARMACEUTICAL VALIDATION

TIME: 3 HOURS

FULL MARKS: 75

INSTRUCTIONS:

1. The question paper contains 7 questions each of 15 marks and total 105 marks.
 2. Candidates may attempt any 5 questions maximum of 75 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.
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- Q.1(a) Describe briefly about calibration, qualification and validation. [7]
Q.1(b) What do you mean by FAT & SAT? Explain in detail about various aspects of FAT & SAT. [8]
- Q.2(a) Justify the role of intellectual property right in pharmaceutical industry. [7]
Q.2(b) Define Patent and discuss about significance of PCT in patent filing. [8]
- Q.3(a) Explain the qualification of Pharmaceutical water system. [7]
Q.3(b) Explain the qualification of Dissolution test apparatus [8]
- Q.4(a) Discuss the Computerized system validation with respect to Validation of Hardware. [7]
Q.4(b) Define and differentiate between digital signature, electronic signature and handwritten signature? [8]
- Q.5(a) Discuss the Validation of facilities in sterile plant. [7]
Q.5(b) Explain the validation of analytical method used in cleaning with a suitable example. [8]
- Q.6(a) Define and discuss the types of process validation with suitable examples. [7]
Q.6(b) Discuss the Validation of an analytical method as per ICH guidelines. [8]
- Q.7(a) Explain the qualification of UV-Visible spectrophotometer. [7]
Q.7(b) Explain the qualification of Tablet Compression Machine. [8]

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