

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

**CLASS: M. Pharm.
BRANCH: PHARMACY**

**SEMESTER: IInd
SESSION: SP25**

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.

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| 1a. | Describe the qualification process and protocols for a fluidized bed dryer. | [7] |
| 1b. | Discuss the stages of process validation. | [8] |
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| 2a. | Discuss the calibration process of weights and measures. | [7] |
| 2b. | Describe the cleaning validation protocol and report. | [8] |
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| 3a. | Define Calibration, validation and qualification. Compare calibration and validation. | [7] |
| 3b. | Elaborate on the qualification process of the dissolution test apparatus. | [8] |
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| 4a. | Discuss the validation master plan. | [7] |
| 4b. | Explain all the components of the qualification. | [8] |
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| 5a. | Explain the prospective, concurrent and retrospective validation. | [7] |
| 5b. | Describe the qualification process of the Disintegration test apparatus. | [8] |
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| 6a. | Enumerate the scope, frequency and importance of calibration. | [7] |
| 6b. | Discuss the qualification and validation protocols. | [8] |
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| 7a. | Discuss in brief about the concepts of Intellectual Property Protection (IPP) and Intellectual Property Rights (IPR). | [7] |
| 7b. | Describe the process of filing a patent application in detail. | [8] |

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