

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

**CLASS: M. PHARM
BRANCH: PHARMACY**

**SEMESTER: IST
SESSION: MO 2024**

SUBJECT: MQA104T PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

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. Discuss the various aspects of scale up in pilot plant for solid dosage form | [7] |
| 1b. Discuss the various aspects of scale up in pilot plant for liquid dosage form | [8] |
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| 2a. Discuss various aspects of drug discovery and development process in detail | [7] |
| 2b. Discuss the hatch Waxman act in detail | [8] |
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| 3a. "Solubility of weak acid increases with increase in pH of bulk solution". Justify your answer with suitable equation. | [7] |
| 3b. Enlist factors affecting dissolution rate. Discuss any two factors in detail. | [8] |
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| 4a. Discuss significance of supplemental new drug application in detail. | [7] |
| 4b. Discuss the significance and importance of clinical trials in detail. | [8] |
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| 5a. Discuss the importance of SUPAC in detail. | [7] |
| 5b. Enumerate in detail how supplemental new drug application may be helpful in improvement of drug formulation in the market. | [8] |
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| 6a. Discuss various aspects of technology transfer in detail. | [7] |
| 6b. Classify medical device packaging. Discuss any three types of medical device packaging in detail | [8] |
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| 7a. What is ideal requirement of pharmaceutical packaging. Discuss the evaluation test for plastic containers. | [7] |
| 7b. Discuss the various types of packaging material used for various purposes. | [8] |

:::12/12/2024:::M