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

**CLASS: M. Pharm.** **SEMESTER: 1st**
**BRANCH: PHARMACY** **SESSION: SP/2022**

**SUBJECT: MQA104T PRODUCT DEVELOPMENT & 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. | What do you mean by drug discovery? Discuss the various aspects need to be considered for designing clinical trials. (CO1) | [7] |
| 1b. | Describe the composition and role of investigation new drug (IND) application review team. (CO1) | [8] |
| 2a. | What are various ingredients present in content and format of IND application. Discuss any three ingredients in detail. (CO1) | [7] |
| 2b. | What do you mean by preformulation studies? Discuss any three aspects of preformulation studies in detail. (CO2) | [8] |
| 3a. | Describe how solubility of weak base is affected by pH using suitable equation. (CO3) | [7] |
| 3b. | Describe how solubility of weak acid is affected by pH using suitable equation. (CO3) | [8] |
| 4a. | Discuss in detail technology transfer checklist. (CO2) | [7] |
| 4b. | Elaborate on importance of technology contract and terms associated with contract. (CO2) | [8] |
| 5a. | Discuss briefly steps in pilot plant scale up. (CO1) | [7] |
| 5b. | Explain in short and draw layout for pilot plant scale up for solid dosage formulations as per GMP. (CO3) | [8] |
| 6a. | Discuss about significance and path of pilot plant scale up. (CO1) | [7] |
| 6b. | Describe about technology transfer documentation using a case study. (CO2) | [8] |
| 7a. | Elaborate on analytical method transfer in technology transfer. (CO2) | [7] |
| 7b. | Explain in detail SUPAC. (CO3) | [8] |

**:::::24/11/2022:::::E**