GALGOTIAS UNIVERSITY

| ADMISSION NUMBER |
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# School of Biomedical Science

**Master of Science Clinical Research**
**Semester End Examination - Jun 2024**

**Duration : 180 Minutes**
**Max Marks : 100**

## Sem II - Q1PN204T - Global Regulation

*General Instructions*
*Answer to the specific question asked*
*Draw neat, labelled diagrams wherever necessary*
*Approved data hand books are allowed subject to verification by the Invigilator*

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| 1) | Define the Decentralized process. | K1(2) |
| 2) | Explain ICMR and indian GCP. | K2(4) |
| 3) | Explain the bioavailability (BA) Trials. | K2(6) |
| 4) | Illustrate the history and structure of of ICH. | K3(9) |
| 5) | Illustrate the importance of (ICMR) Indian Council of Medical Research. | K3(9) |
| 6) | Examine the Drug - Development for Orphan diseases . | K5(10) |
| 7) | Analyze the Post marketing Clinical Studies. | K4(12) |
| 8) | Examine the essential documents during the trial in clinical trials. | K5(15) |
| 9) | Examine the market authorization process in United States (US). | K5(15) |
| 10) | Elaborate the Drug approval process in USA. | K6(18) |