BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI
Quality Assurance and Regulatory Affairs (PHA G532)
Mid Semester examination-2023 (Closed Book)

Weightage: 30% **Duration: 90Mins** **Date: 11/10/2023**

Instructions:

- ✓ **Write correct and precise answer. No spelling mistakes.**
- ✓ **Marks will only be given to correct and well explained answer and not to partial answers.**
- ✓ **Write in clear and legible handwriting. Do not write short forms.**
- ✓ **Answer the questions in same sequence. Write the each question on a separate sheet.**

1. What do you mean by preclinical studies and explain its objectives? How these studies help in the process of drug discovery and development? [3M+2M]

2. Explain the term "Secondary Pharmacological Data". Comment on regulatory assessment of *in vitro* secondary pharmacology data. [1M+4M]

3. Explain the expedited development and review pathways used by the USFDA in the process of drug approval. [4M]

4. As per part 58, explain what all should be included in the protocol for and conduct of a nonclinical laboratory study? [4.5M]

5. Explain the different types of amendments as per the CFR 312. [4M]

6. Explain the principles of ICH E6 (R1) guidelines. [5.5M]

7. Explain the following terms. [2M]
    a) S -Standard review
    b) P -Priority review
    c) Initial review cycle
    d) NDA Rewrite