BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI
Quality Assurance and Regulatory Affairs (PHA G532)
Mid Semester examination-2022(Closed Book)

Weightage: 30% **Duration: 90Mins** **Date: 01/11/2022**

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. Write the applicability of following guidelines. **4M**
    a. S8
    b. S4
    c. S7A- S7B
    d. S3A and S3B
    e. E6
    f. S1A-S1C
    g. S2
    h. S5

2. Explain the goals of the New Drug Application and write the classification of NDA. **6M**

3. Explain the two important meets with FDA during the process of drug discovery. Write the time line required for following activity. **2M + 4M**
    a. IND Approval/Hold
    b. NDA filing
    c. CMC section submission
    d. NDA review
    e. Meeting of NDA applicant with FDA reviewer after NDA submission to discuss the status of application
    f. IND Safety Reports
    g. Annual Reports
    h. Safety Update Report

4. To decrease the uncertainty in decision making owing to misinterpretation of data, explain the different aspects needs to be incorporated in secondary pharmacology study reports from regulatory review perspective. **4M**

5. Considering you as one of the sponsor and want to conduct a non-clinical laboratory study for the BITS123 compound having an antihypertensive activity. In this regard, what will be the role of testing facility management in carrying out this study? **6M**

6. Explain the organization of ICH Common Technical Documents-M4 (R3). **4M**