**(2½Hrs)** **[Total Marks: 60]**

N.B:

1) **All** questions are **compulsory**
2) **Figures** to the **right** indicates **full** marks
3) Draw neat and labelled diagrams wherever necessary

| | | | |
|---|---|---|---|
| **Q1** | | Discuss in detail the various parameters to be followed for any analytical method validation | **12** |
| | | **OR** | |
| **Q1** | **(a)** | In context of GCP guidelines, explain reporting of adverse events. | **6** |
| | **(b)** | Write a note on the documentation of Good Manufacturing Practices. | **6** |
| **Q2** | | What is meant by Method Validation? Explain its significance with a note on the regulatory guideline on Method validation. | **12** |
| | | **OR** | |
| **Q2** | **(a)** | What is qualification? Explain Briefly. | **6** |
| | **(b)** | Explain Ruggedness and Robustness of an analytical method. | **6** |
| **Q3** | | Explain the term "BE" and its different BE parameters to evaluate drug. | **12** |
| | | **OR** | |
| **Q3** | **(a)** | Describe "Drug Dissolution Apparatus" | **6** |
| | **(b)** | Explain Factors affecting bioavailability | **6** |
| **Q4** | | With reference to clinical trials explain the following.<br>a. Ethics committee<br>b. Informed consent<br>c. Responsibilities of principal investigator | **12** |
| | | **OR** | |
| **Q4** | **(a)** | Explain audits of GMP compliance. | **6** |
| | **(b)** | What is the need to have SOP as a part of GLP? | **6** |

**Q5** Answer the following (any **three**) :- **12**

**i)** GMP audits
**ii)** IQ, OQ and PQ
**iii)** Ethics committee in GCP
**iv)** What is the difference between Document and Record in pharmaceutical industry?
**v)** LOD and LOQ of analytical Method
**vi)** Selectivity and specificity of an analytical method.

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