(2 ½ hours) **Total marks: 60**

Note: i) All questions are compulsory

ii) Figures to the right indicate full marks

iii) Draw neat labelled diagrams wherever necessary

Q.1. Give an account of the national initiatives for regulation of ASU drugs. **[12]**

OR

Q.1. Comment on the WHO guidelines on the regulation of traditional drugs. **[12]**

Q.2. Discuss the guidelines for laboratories handling radioactive substances. **[12]**

OR

Q.2. Elaborate on the conservation and sustainable use of medicinal raw materials. **[12]**

Q.3. Describe the concept of electronic data management. **[12]**

OR

Q.3. Explain in detail the life cycle and disaster recovery of *e*-records. **[12]**

Q.4. Describe the constitution, scope and activities of *FSSAI.* **[12]**

OR

Q.4. What are OTC drugs? How are they regulated? **[12]**

TURN OVER

Q.5. Write short notes on (**any three**):

a) ISO 14001 **[4]**

b) CITES **[4]**

c) Electronic signature and its validation **[4]**

d) Significance of Carbon Credits in reducing carbon emissions **[4]**

e) Lab safety requirements in a bioanalytical lab **[4]**

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