Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Define and classify Medical devices. Discuss the regulatory requirements for manufacture of Medical Devices in India. (2+4+4)
2. Explain regulatory requirements and its approval procedure for Nutraceuticals, Cosmetics and Biologics in India.
3. Write in detail Regulatory requirements for Fixed Dose Combination.
4. Describe ICMR-DBT guidelines for stem cell research.

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Write a note on relevant provisions of FPMBC?
6. Briefly describe drug product development in the pharmaceutical industry.
7. Discuss on BCS classification of Drugs.
8. Differentiate Nutraceuticals and Pharmaceuticals with an example.
9. Write a short note on BIS standards
10. Explain ISO standards.
11. Discuss the ICH and WHO stability requirements.
12. Explain ethical guidelines for human participant.
13. Define patent, trademark, copyright, industrial designs and geographical indications.
14. Explain the differences between IPR and Regulatory affairs.

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