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

1. Describe in details about WHO patent IPR and its types.
2. Explain the need for patenting and discuss the types of patents.
3. Discuss the development and regulation of Biosimilars.
4. Describe about principle and elements of TQM.

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

5. Write a role of TRIPS in Regulatory Guidelines.
6. Write about the parts of patents.
7. Discuss briefly about USFDA.
8. Write a note on management tools of quality.
9. Write the role of CDSCO in Regulation Indian Pharmaceutical sector.
10. Write in brief on major regulatories bodies in Pharmaceutical sector.
11. Write a note on new qualities tools in TQM.
12. Define and write note on trademark protection in Regulatory guidelines.
13. Brief a role of TGA.
14. Write a note on EMEA.

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