Draw neat, labeled diagrams wherever necessary.

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

1. Regulatory approval process for Investigational New Drug (IND).
2. Write in detail about Eudralex directives for human medicines.
3. Elaborate in detail about drug regulatory approval process in Japan.
4. Enumerate the regulatory requirements for drug and post approval requirements in ASEAN country.

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

5. Explain the approval process of IMPD.
6. Write a note on Hatch Waxman Act.
7. Differentiate between NDA and ANDA.
8. Explain in brief content and approval process of IMPD.
9. Write a note on post marketing surveillance in Japan.
10. Qualified Person (QP) in EU.
11. Write a note on regulatory requirements for orphan drugs.
12. Regulatory requirements for Registration of drug in China.
13. Write about National and mutual recognition procedures in EU.
14. Registration Procedures of drug in South Asia.

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