



[Time: 3 Hours]

[Max. Marks: 75]

International Pharmaceutical Regulations-II

Q.P. CODE: 5147

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three)

3 X 10 = 30 Marks

1. What do understand by emerging market? What led to the genesis of SADC and who are the member countries? Write briefly about regulatory requirements for registration of drugs in one of the SADC countries?
2. Explain in detail about WHO Prequalification program. Add a note on regulatory requirements for registration of drugs in Egypt.
3. Explain in detail the ACTD? Name the countries in ASEAN and write about regulatory requirements for registration of drugs in China.
4. Prepare the check list of documents required for marketing pharmaceutical products in Russia.

SHORT ESSAY (Answer any Nine)

9 X 5 = 45 Marks

5. Write a note on APEC region.
6. Explain briefly the countries under PANDRH? Which are the regulatory agencies of those countries?
7. Explain the process of obtaining CoPP in South Africa.
8. What are market authorization requirements for drugs in Vietnam?
9. What are the different countries which are under ASEAN Market and their regulatory authorities?
10. Explain the regulatory requirements for registration of drugs in South Korea.
11. Write a short note on Post approval requirements in CIS countries.
12. What are the market authorization requirements for Kazakhstan?
13. Regulatory pre-requisites for market authorization of drugs in UAE.
14. What are the stability requirements for finished products to be marketed in GCC countries?

* * * * *