



Your answers should be specific to the questions asked.
Draw neat labeled diagrams wherever necessary.

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. Enumerate various validation processes of mixing and granulation?
2. Write in detail about types of cosmetic preparations and their general requirement as per D&C act and add a note on hygiene products?
3. Enumerate various validation procedures for UV spectrophotometer and pH meter?

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Write about the formulation and evaluation of Chewable tablet?
5. Describe installation qualification and performance qualification for equipments.
6. Explain the different approaches in the formulation of transdermal drug delivery systems
7. Write about shelf life and its determination?
8. How will you enhance the solubility of drug by Hydrotropy and dielectric constant methods?
9. Describe different types of containers and closures for pharmaceuticals.

SHORT NOTES

2 X 5 = 10 Marks

10. Write a note on Evaluation of suppositories.
11. Write about validation of analytical procedures?

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Draw neat labeled diagrams wherever necessary. Answer all questions

LONG ESSAY (Answer any TWO)

2 X 20 = 40 Marks

1. Explain the concept of ISO 9000. Outline the Procedure for dealing with recovered materials and reprocessing.
2. What do you mean by patent? What are the procedures to be followed while obtaining a patent? Write a note on patent Regime.
3. Write a detailed note on WHO Certification and Globalization of Drug Industry.

SHORT ESSAY (Answer any FIVE)

5 X 10 = 50 Marks

4. Explain the concept and philosophy of TQM.
5. Write a note on In-process quality control aspects of Sterile dosage Forms.
6. Write a note on packaging and labeling controls.
7. Explain in detail good warehousing practice.
8. Write a note on loan licensing concepts.
9. Write a note on the scope objectives of Consumer Protection Act.

SHORT NOTES

2 X 5 = 10 Marks

10. Write a brief note on **EXIM policy**
11. Present Status of Pharmaceutical industry in India.

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Draw neat labeled diagrams wherever necessary. Answer all questions

LONG ESSAY (Answer any TWO)**2 X 20 = 40 Marks**

1. Write a note on analysis of Crude drugs. Explain in detail about heavy metal determination and Pesticides residue determination.
2. Explain the principle and procedure involved in the Biological assay of Pertussis vaccine.
3. What is microbiological assay? Explain in detail. Write a note on principle and procedure involved in the microbiological assay of any one antibiotic of your choice.

SHORT ESSAY (Answer any FIVE)**5 X 10 = 50 Marks**

4. Write a detailed note on Differential Thermal Analysis (DTA).
5. Explain Radioimmunoassay (RIA)
6. Enumerate the applications of Mass spectrometry in drug quantification.
7. Write a note on biological assay of Tetanus antitoxin.
8. Write a note on Validation parameters of GC method.
9. Write the principle and procedure involved in the testing of pyrogens as per I.P

SHORT NOTES**2 X 5 = 10 Marks**

10. Explain the biological assay of Oxytocin.
11. Write a note on Thermo Gravimetric Analysis.

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