Industry Pharmacy-II

Unit test-1

1. What do you mean by pilot plant scale-up? Give examples
2. What is the significance of pilot plant scale-up with routine production procedure?
3. Explain the procedure for pilot plant scale-up for liquid dosage form.
4. Write a short note on SUPAC guidelines.
5. Write a short note on pilot plant scale-up for solid dosage form.

Unit test-2

1. Define technology transfer. What is sending unit and receiving Unit? Write the principles of technology transfer.
2. Define the following terms:
   (a) API
   (b) Excipients
   (c) DQ, IQ, OQ and PQ
3. What is QRM? Describe the principle and process of QRM.
4. Write briefly on the information required for process and finished product.
5. Which agencies are working for Technology Transfer in India? Write about any two agencies.

Unit test-3

1. What is an NDA? Discuss the requirements of data while filing a NDA. Give examples where a NDA can be filed.
2. Write a note on Drug Master Files.
3. What is PCT? Discuss the content of PCT and its applications.

4. What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial.
5. Write short notes on Investigator Brochure.

Unit test-4

1. Write a note on ICH guidelines.
2. Explain the principles of TQM and QBD.
3. Write about the six sigma concepts.
4. Write a short note on GLP and NABL.
5. Write the basic principles of ISO 9000. Explain ISO 9000 series in detail. Write a note on requirements of ISO 9000 Series.

Unit test-5

1. Explain the details of CDSCO and give its functions.
2. Write about various Drug Regulatory agencies.
3. Write short note on State Licensing authorities.
4. What are general requirements for submission of application for issue of COPP?
5. What are the regulatory requirements and approval procedures for new drugs?

Unit test-6

1. Write details about different Central Drugs Testing Laboratories available in India.
2. What are COPP and its importance?
3. What are RDTL and its function?

4. What is EMS? Write the basic working principle of ISO 14000 series. What are the advantages of it?
5. Define OOS. How will you find out the possible OOS in the results? Explain.

Unit test-7

1. Write a note on outsourcing BA-BE studies to CRO.
2. Write short notes on the Post marketing surveillance.
3. Write short notes on Pharmacovigilance.
4. Briefly discuss Master Formula Record and its importance.
5. Discuss the Intellectual Property protection laws in India in brief.