QUESTION BANK

UNIT-1 PILOT PLANT SCALE UP TECHNIQUE

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 orals.
4. Explain the procedure for pilot plant scale-up for semisolid dosage form.
5. Explain the procedure for pilot plant scale-up for liquid dosage form.
6. What do you mean SUPAC?
7. Write a short note on pilot plant scale-up for solid dosage form.

UNIT-2 TECHNOLOGY DEVELOPMENT AND TRANSFER

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 the information required for technology transfer of starting materials from SU to RU?
4. Write briefly on the information required for process and finished product.
5. Write a note on analytical method transfer and basic responsibilities of SU and RU.
6. Which agencies are working for Technology Transfer in India? Write about any two agencies.
7. What is QRM? Describe the principle and process of QRM.

UNIT-3 REGULATORY AFFAIRS & REGULATORY REQUIREMENTS FOR DRUG APPROVAL

1. What is an NDA? Discuss the requirements of data while filing a NDA. Give examples where a NDA can be filed.
2. Comment on the bioequivalence requirements according to ICH guidelines.
3. Discuss the Intellectual Property protection laws in India in brief.
4. What is PCT? Discuss the content of PCT and its applications.
5. Write a note on Drug Master Files.
6. Briefly discuss Master Formula Record and its importance.

7. What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial.
8. Write short notes on Pharmacovigilance.
9. Write short notes on Investigator Brochure.
10. Discuss the NDA regulatory approval process with suitable example.
11. Write a note on outsourcing BA-BE studies to CRO.
12. Write short notes on the Post marketing surveillance.

UNIT- 4 QUALITY MANAGEMENT SYSTEMS

1. Write a note on ICH guidelines.
2. Explain the principles of TQM and QBD.
3. Write about the six sigma concepts.
4. Define OOS. How will you find out the possible OOS in the results? Explain.
5. Write the basic principles of ISO 9000. Explain ISO 9000 series in detail. Write a note on requirements of ISO 9000 Series.
6. What is EMS? Write the basic working principle of ISO 14000 series. What are the advantages of it?
7. Write a short note on GLP and NABL.

UNIT- 5 INDIAN REGULATORY REQUIREMENTS

1. Explain the details of CDSCO and give its functions.
2. Write about various Drug Regulatory agencies.
3. Write details about different Central Drugs Testing Laboratories available in India.
4. Write short note on State Licensing authorities.
5. Explain about Central Drugs Laboratory and its function.
6. What is RDTL and its function?
7. What is COPP and its importance?
8. What are general requirements for submission of application for issue of COPP?
9. What is the procedure for accepting the application for issue of COPP?
10. What are the documents required for applying grating on revalidation of COPP?
11. What are the regulatory requirements and approval procedures for new drugs?