**INDUSTRIAL PHARMACY-II**

**VII Sem B Pharm**

**Long Essays**

1. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.

OR

Write a note on WHO guidelines for Technology Transfer (TT).

1. Discuss Regulatory requirement of NDA approval process.
2. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.

OR

What is validation? Write a detailed note on validation and calibration of analytical equipment.

1. Explain the significance of documentation in BA-BE studies and add a note on outsourcing BA and BE to CRO.
2. Explain how master formula records and batch manufacturing records are developed in pilot plant scale up studies.

OR

Discuss Quality risk management studies as per ICHQ9 Guideline.

1. Discuss the Role of Regulatory affairs department in pharma industry.
2. Explain the protocol for pilot plant scale up for tablets production.

OR

Discuss the Granularity of TT Process for Active Pharmaceutical Ingredients (API) and excipients.

1. What are the data’s to be submitted during New Drug Application (NDA) filing
2. Explain the requirements for pilot plant scale up of Liquid Orals.

OR

What are the contents of Technology transfer protocol?

1. Explain the Different Phases of drug development.
2. Explain the requirements for pilot plant scale up of Semisolids.

OR

Define technology transfer? Explain the different stages of technology transfer.

1. Explain the functioning of various Drug Development Teams.
2. What is a pilot plant? Explain the factors to be considered in the organization of a pharmaceutical pilot plant.

OR

Discuss the TT Process for finished products and packaging materials.

1. Describe in detail the process of Investigational New Drug Application.
2. Give Regulatory Requirements for INDA approval process.

OR

Explain the concepts of Total Quality Management and Quality by Design (QbD).

1. Explain the CDSCO and COPP.
2. Explain in detail Pilot plant scale up considerations for Liquid orals. Write a note on platform technology.

OR

What is technology transfer? Discuss the TT protocol, process, packaging and cleaning.

1. Discuss regulatory requirement of NDA approval process, modules of CTD.
2. Write a note on platform technology.

OR

Name the various Approved regulatory bodies and agencies in TT. Explain any two.

1. Explain in detail the process of transfer from R and D to Production.

**Short Essays**

1. Write a note on Platform Technology.

OR

Write a note on process validation.

1. Write a note on Technology transfer protocol.

OR

Explain the protocol for conduct of Non-clinical testing.

1. Explain the responsibilities of regulatory affairs professionals.
2. Explain six sigma concepts for Quality Improvement.
3. Define TQM? Discuss in detail the principles of TQM.
4. Explain the CTD triangles and its modules.
5. What is CDSCO? What are the different functions of CDSCO?
6. Explain the requirements for pilot plant scale up of Liquid Orals.

OR

What are the different reasons of Technology Transfer?

1. Discuss Granularity of TT Process for API.

OR

Explain the historical overview of regulatory affairs.

1. Write a note on investigators brochure.
2. Write a note on QbD concept as per ICH Q8 Guidelines.
3. Discuss the objectives and scope of GLP in Pharmaceutical industry.
4. Discuss how OSS results are handled in pharmaceutical industry.
5. Explain in detail certification of pharmaceutical product.
6. What is a pilot plant? What is the significance of Pilot Plant scale up techniques?

OR

What are the Barriers of Technology Transfer.

1. Discuss the TT Process of packaging materials.

OR

Explain the Different Phases of drug development.

1. Describe the key elements in managing clinical programs.
2. What are the advantages of Implementing TQM.
3. What are the Benefits of NABL accreditations?
4. Write a note on Central Drugs Testing Laboratories (CDTL).
5. Describe the Organization of CDSCO with flow diagram.
6. Discus the Significance of personnel requirements in pilot Plant scale up.

OR

Discuss the Documentation process involved in TT.

1. Differentiate between qualification and validation with suitable examples.

OR

Discuss the Types of studies involved in Pre-clinical Drug Development.

1. Write a note on ICH E6 (R2) Good Clinical Practice guidelines.
2. Write a note on QbD concept as per ICH Q8 Guidelines.
3. Write a note ISO 14000 Guidelines.
4. Write a note on Drug Technical Advisory Board (DTAB) and its functions.
5. Write a note on Drug Approval of New Drugs in India.
6. Discus the space requirements in pilot Plant scale up.

OR

What is qualification? Explain the different types of qualification in validation with suitable examples.

1. What are the various steps involved in Transfer of analytical methods.

OR

What are the Contents of the Investigator’s Brochure?

1. Explain the Responsibility of the Regulatory Affairs Professionals.
2. What are the conditions under which laboratories can be disqualified according to GLP?
3. Explain the procedure of NABL accreditation.
4. Describe the WHO Certification Scheme for a Certificate of Pharmaceutical Product (COPP).
5. Functions of State Drug Regulatory Authorities (SDRAs).
6. Define clinical trials? Why are the clinical trials required?

OR

Write a note on Platform Technology.

1. List out Risk management methodology.

OR

What are the Equipment requirements during TT?

1. Discuss the Scope and objectives of Regulatory Affairs.
2. What does ICH stands for? Describe the composition of ICH.
3. Discuss the approval and implementation of Change control management System in Pharmaceutical Industry.
4. Write the Functions of Drugs Controller General of India (DCGI).
5. Describe the Process to apply for a COPP.
6. Discuss change in Equipment and process as per SUPAC Guidelines

OR

Write on information’s required in Process Technology Transfer.

1. Organization of technology transfer

OR

Describe the principle and procedure involved in BE Studies.

1. Applications of Biostatistics in Pharmaceutical Product Development.
2. Explain the concepts of six sigma for Quality Improvement.
3. Explain briefly the protocol for conducting Non-clinical lab studies.
4. Describe the Types of COPP and Contents.
5. Describe the Organization of CDSCO with flow diagram.
6. Write a note on scale up process approval changes.

OR

Give the details about Quality Risk Management.

1. Discuss the Technology Transfer agencies in India.

OR

Explain the significance of documentation in BA – BE studies.

1. Write in detail about Pilot plant scale up considerations for solids.
2. Write a note on documentation of finished products, packaging materials.
3. What is clinical research protocols and data presentation?
4. Write the elements of ISO14000.
5. Discuss the GLP and discuss the same.
6. Write about USFDA guideline for Good laboratory Practices.

OR

Write a note on different phases of Clinical trials.

1. Write the CDSCO guidelines for BA and BE studies.

OR

Write a note on Total quality management and Quality by design.

1. Discuss the SUPAC guidelines.
2. Explain briefly the handling of out of specification (OOS).
3. Write a note on Certificate of Pharmaceutical Product.
4. Define Documentation, APCTD, FDA, CTD and QbD.
5. Write the general considerations of Pilot plant.
6. Write a note SUPAC Guidelines.

OR

List out the responsibilities of Sending Unit in technology transfer.

1. What are information’s required in Process Technology Transfer.

OR

Write a note on management of clinical studies.

1. Explain Investigator’s Brochure.
2. Write a note on different philosophies of TQM.
3. Explain the steps involved in ISO 9000 registration.
4. How to obtain COPP.
5. Write a note on Drug Approval of New Drugs in India.

**Short Answer**

1. What is master formula records?
2. Write the principles of quality risk management.
3. Enumerate the objectives of TIFAC.
4. Name the different types of drug applications that can be submitted to FDA.
5. What are the objectives of ICH guidelines?
6. What are the benefits of ISO 9000?
7. List out the significance of NABL accreditation
8. Define medical device. Give two examples.
9. Give two applications of biostatistics in pharmaceutical product development.
10. How equipment’s are categorized as per SUPAC guideline.
11. What are the significance pilot plant?
12. Differentiate qualification and calibration of equipment.
13. Write the primary functions of APCTD.
14. What is the purpose of confidential agreement?
15. What are the advantages of implementing TQM.
16. Mention the advantages of QbD.
17. Define clinical trials and write its importance.
18. Define biostatistics.
19. What are the objectives of OOS.
20. Name the technology transfer agencies in India.
21. Enlist the significances of batch formula record.
22. How equipment are categorized as per SUPAC guideline
23. Write the two importance of Technology Transfer in Pharmaceutical Industry.
24. Write the primary objectives NRDC.
25. Write two key elements in managing clinical programs.
26. Write the significance BE study.
27. What is zero-defect product?
28. What are the objectives of GLP.
29. Two functions of Port Offices of CDSCO
30. Write the types of drugs for which COPPs may be issued.
31. What are the different parts of batch manufacturing record?
32. What is platform technology?
33. Write the two reasons for technology transfer in Pharmaceutical Industry.
34. Write the functions of BCIL.
35. List out various Regulatory Authorities.
36. Name the two key elements in managing clinical programs.
37. Write the four reasons for disqualification of testing facilities.
38. Classify Changes and give examples.
39. What is CTD.
40. Difference between assignable and non-assignable causes as per OOS.
41. Significance of Raw material requirements**.**
42. Write the benefits of pilot plant scale up studies
43. Write the two reasons for technology transfer in Pharmaceutical Industry.
44. Write the two functions of TIFAC.
45. Name the two significance of New Drug Application (NDA).
46. List the two key responsibilities of Regulatory Affairs.
47. What are the elements of QbD.
48. Classify Changes and give examples.
49. What are the significances of CTD?
50. What are the Types of COPP.
51. Name the contents of batch manufacturing record.
52. Name any four general requirements for pilot plant construction
53. What are the Steps involved technology transfer
54. Write features of TBSE.
55. Write the two significances of BE Study.
56. What is ADR reporting
57. Define TQM? What are the key elements of TQM.
58. Enlist the benefits of ISO 14000.
59. List out places of Zonal offices and Sub-zonal offices of CDSO.
60. What is the scope of COPP.
61. Write the benefits of pilot plant scale up studies
62. Name any four general requirements for pilot plant construction
63. Enlist the significances of batch formula record
64. Write the primary objectives of NRDC.
65. Write the two reasons for technology transfer in Pharmaceutical Industry.
66. Define validation and qualification.
67. Name types of studies involved in Pre-clinical Drug Development.
68. Name the five ICH efficacy guidelines with number and title.
69. What are the personnel requirements as per GLP.
70. What is zero-defect product?
71. Write the significance of personnel requirements.
72. Write the guidelines for technology transfer (TT).
73. Write the functions of clinical studies.
74. What is State licensing authority?
75. What are the objectives of NRDC.
76. What are MoUs and legal issues?
77. Define qualification and validation.
78. Discuss the Role of Regulatory affairs department.
79. What is six sigma concept and OOS.
80. Salient features of ISO 9000.
81. Elements of TQM.
82. Define clinical research protocol.
83. What is innovation and collaboration?
84. Quality control in Technology transfer.
85. What is CMC and preclinical testing?
86. Prospective validation.
87. Detection limit and Quantitation limit.
88. What is investigators brochure.
89. Write about similarity factors and its significance.
90. Write the principles of total quality management.
91. Write the primary objectives of pilot plant.
92. Enlist the significances of batch formula record.
93. Write two responsibilities the Receiving Unit in technology transfer
94. What are the legal issues in TT.
95. Write two functions of Drug Development Team.
96. Define Bioavailability and bioequivalence.
97. Write two objectives of GLP.
98. Define standard deviation.
99. Write two advantages of the COPP scheme.
100. Write two functions of State Drug Regulatory Authorities (SDRAs)