Code No: F-7192/PCI

FACULTY OF PHARMACY

B. Pharmacy VII - Semester (PCI) (Main & Backlog) Examination, March 2024

Subject: Industrial Pharmacy

Time: 3 Hours **Max. Marks: 75**

PART - A

Note: Answer all the questions. **(10 x 2 = 20 Marks)**

1. Write a note on SUPAC guidelines.
2. What is pilot plant and scale-up?
3. Explain the importance of validation.
4. What is Technology transfer?
5. Write the role of regulatory affairs.
6. Mention five important data documents for ANDA.
7. Write a note on different stages of clinical trials.
8. What is informed consent?
9. Write a note on ISO 9000.
10. Write the role of CDL.

PART - B

Note: Answer any two questions. **(2 x 10 = 20 Marks)**

11. Write about pilot plant and scale up requirements for Tablets and Capsules.
12. (a) What is technology transfer? Write general principles of Technology Transfer.
    (b) Write the role and responsibility of regulatory affairs professionals.
13. (a) Explain the principles of QBD and applications of QbD.
    (b) Write a note on NABL and GLP.

PART - C

Note: Answer any seven questions. **(7 x 5 = 35 Marks)**

14. Write a note on pilot plant scale-up for liquid dosage forms.
15. Write a note on Technology Transfer procedure from R&D to production (Process, packaging and cleaning).
16. Write briefly on Investigational New Drug (IND) Application.
17. Write the role of biostatistics in pharmaceutical product development
18. What is QRM? Describe the principle and process of QRM.
19. Write a note on six sigma concept.
20. Write briefly on TQM.
21. Write a note on Indian Regulatory. Write CDSCO functions.
22. Write a note on COPP.

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