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Total No. of Pages : 02

Total No. of Questions : 22

B.Pharma (Sem.-7)
INDUSTRIAL PHARMACY-II THEORY
Subject Code : BP-702T
M.Code : 78388

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A** is **COMPULSORY** consisting of **TEN** questions carrying **TWO** marks each.
2. **SECTION-B** contains **THREE** questions carrying **TEN** marks each and student has to attempt any **TWO** questions.
3. **SECTION-C** contains **NINE** questions carrying **FIVE** marks each and student has to attempt any **SEVEN** questions.

SECTION-A

- 1) Mention the name of general consideration for the pilot plant scale-up technique.
- 2) Elaborate the term six sigma.
- 3) Mention the name of different TT agencies in India.
- 4) a) What is Six Sigma Concept?
b) Define the concept of OOS.
- 5) Define Regulatory Affairs & Regulatory authorities.
- 6) What do you mean by NDA?
- 7) Mention the steps in the technology transfer process.
- 8) What is Certificate of Pharmaceutical Product?
- 9) Write the importance of Quality by Design.
- 10) Briefly explain platform technology.

SECTION-B

- 11) Explain in brief Pilot plant scale-up techniques General considerations - including the significance of personnel requirements, space requirements, and raw materials?
- 12) Write in detail about Regulatory requirements and approval procedures for New Drugs.
- 13) Write a detailed note on clinical research and BE studies.

SECTION-C

- 14) Describe the technology transfer protocol.
- 15) Give an elaborate detail on Quality Risk Management (QRM).
- 16) Discuss about Responsibility of Regulatory Affairs Professionals.
- 17) Discuss about Investigator's Brouchure.
- 18) Discuss about quality management and certification.
- 19) Write briefly about ISO and its series.
- 20) Write a short note on GLP.
- 21) Discuss the responsibilities of State Licensing Authority.
- 22) Write a short note on qualification, validation and reasons for technology transfer.

NOTE : Disclosure of Identity by writing Mobile No. or Marking of passing request on any paper of Answer Sheet will lead to UMC against the Student.