Roll No. | | | | | | | | | | | | Total No. of Pages : 02

Total No. of Questions : 13

B.Pharma. (Sem.-7)

INDUSTRIAL PHARMACY – II (THEORY)

Subject Code : BP-702T

M.Code : 78388

Date of Examination : 14-12-22

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. Write briefly :

a. IND

b. NABL

c. CDSCO

d. APCTD

e. NRDC

f. TIFAC

g. BCIL

h. TBSE

i. SIDBI

j. OOS.

SECTION-B

2. Discuss the pilot plant scale up considerationS for solids.

3. Discuss the ICH guidelines on quality risk management.

4. Discuss the technology transfer Process related to APl and excipients.

SECTION-C

5. What are the responsibilities Regulatory Affairs Professionals?

6. Discuss about Clinical Research Protocols.

7. How the Data Presentation is done for FDA Submissions?

8. Discuss the concept of Six Sigma concept.

9. Write a note on organization and responsibilities of Central Drug Standard Control Organization.

l0. Discuss the role of leadership in TQM.

11. Write a note on ISO 9000 series.

12. Briefly discuss GLP.

13. What are the regulatory requirements and approval procedures for New Drugs?

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.