Total No. of Questions : 14]

BP 702 T

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IV/IV B. PHARMACY (Regular) EXAMINATIONS, NOV / DEC - 2022

Seventh Semester

INDUSTRIAL PHARMACY - THEORY

Time : **Three Hours**

Maximum : 75 Marks

SECTION - A

Answer any FIVE Questions. **5x10 = 50 M**

1. Write in detail about Pilot plant scale up considerations for liquid orals & semisolids & add a note on documentation related to scale up process of liquid orals & semisolids.
2. Discuss Granularity of technology transfer process for Active pharmaceutical ingredients, excipients, finished products & packaging materials ?
3. Describe the roles & responsibilities of the following technology transfer agencies
   (a) APCTD (b) NRDC.
4. Write a note on following
   a) Investigational New drug application.
   b) Investigator's brochure.
5. Enlight about clinical research protocols & Biostatistics in pharmaceutical product development ?
6. Write a detail account on concept of quailty by Design & its applications.
7. Discuss in detail about approval procedure for new drugs & write a note on certificate of pharmaceutical product ?

SECTION - B

Answer any FIVE Questions. **5x5 = 25 M**

8. Describe the responsibilities of CDSCO & State licensing authorities ?

P.T.O.

9. Discuss the process of change control & write significance of change control.

10. Enumerate ISO 9000 series standards of Quality system ?

11. What is plate form technology & explain it ?

12. List out the different documents needed for technology transfer ?

13. Write a note on clinical research protocol in drug development process ?

14. Discuss about Analytical method transfer process.

Total No. of Questions : 14]

BP 702 T

[Total No.of Pages : 01

IV/IV B. PHARMACY DEGREE EXAMINATIONS, JUNE / JULY -2022

Seventh Semester

INDUSTRIAL PHARMACY - THEORY

Time : **Three Hours**

Maximum : **75** Marks

SECTION - A

Answer any FIVE Questions. **5x10 = 50 M**

1. Discuss in detail about personal & space requirements and considerations of pilot plant scale up techniques ?
2. Explain the process of technology transfer from R&D to production and add a note on quality risk management ?
3. Explain the Work Plan & Regulations given by Technology Transfer Agencies like TIFAC& BCIL ?
4. Discuss about the significance of drug development teams and studies of Pharmacology, Drug Metabolism and Toxicology in order to meet the regulatory requirements for drug approval.
5. Give a note on following :
   a) New drug application.
   b) Data presentation for FDA submission.
6. Discuss in detail about Six sigma concept with suitable examples.
7. Enumerate Regulatory requirements in India as per Central Drug Standard Control Organisation and add a note on structure & responsibilities of CDSCO ?

SECTION - B

Answer any FIVE Questions. **5x5 = 25 M**

8. Enlight about organisation of State Licensing Authority.
9. Give a note on out of specifications of Quality Management System.
10. Enumerate Good laboratory practices & role of GLP in maintaining quality ?
11. Discuss about SUPAC guidelines for scale up process.
12. Write significance of Biostatistics tools in pharmaceutical product development.
13. Enlight the responsibilities of regulatory affairs professionals.
14. List out TT agencies in India & add a note on TBSE ?