2/7/22 M

Roll Number ---------- (Total Number of Questions 13) (Total number of Printed Pages 01)

| | |
|---|---|
| Programme | B. Pharmacy |
| Semester | 7th |
| Subject | Industrial Pharmacy-II |
| Subject Code | BP702T |
| Paper ID | 78388 |
| Time | 3Hours |
| Maximum Marks | 75 |

*Instructions to Candidates: No supplementary/continuation sheet will be issued to the candidates. Answer the questions precisely.*
**Section A consists of Ten parts of 2 marks each (Objective Type); Attempt ALL.*
***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any TWO.*
**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any SEVEN.*

**Section A** **(10 X2 = 20)**

1. Give very short answers to the followings (2 marks each):

| | |
|---|---|
| i. | What is Platform technology? |
| ii. | Define Granularity. |
| iii. | Enlist different phases of Clinical trials. |
| iv. | What is CDSCO? |
| v. | Define Quality Assurance. |
| vi. | What is SUPAC? |
| vii. | Define Quality by Design (QbD). |
| viii. | Define Technology Transfer. |
| ix. | What is COPP? |
| x. | Define Investigational New Drug (IND). |

**Section B** **(2 X 10 = 20)**

| | |
|---|---|
| 2. | What do you mean by "Pilot scale up"? Discuss various pilot plant scale up consideration for solids. |
| 3. | Discuss WHO Guideline on Transfer of Technology in Pharmaceutical Industry. |
| 4. | Describe role and importance of Good Laboratory Practices (GLP) in pharmaceutical industry. |

**Section C** **(7 X 5 = 35)**

| | |
|---|---|
| 5. | Describe the approach of QbD in quality management system. |
| 6. | Write a short note on quality control and analytical method transfer. |
| 7. | Discuss platform technology with its importance. |
| 8. | Discuss approval procedure of new drug in India. |
| 9. | Write a short note on Quality management system. |
| 10. | Write various functions of CDSCO. |
| 11. | Discuss the SUPAC with various change levels in brief. |
| 12. | Write a short note on prerequisites to establish a technology platform for early development. |
| 13. | Describe clinical research protocol. |

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Note: Disclosure of identity by writing mobile number or making request for passing on any page of answer-sheet will lead to UMC against the candidate.

26/11/21 M

**Roll Number ----------** **(Total Number of Questions 13)** **(Total number of Printed Pages 01)**

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***Section B consists of Three questions carrying 10 marks each (Long Answer); attempt any **TWO**.*
**** Section C consists of Nine questions carrying 5 marks each (Short Answer); attempt any **SEVEN**.*

## Section A (10 X2 = 20)

1. Give very short answers to the followings (2 marks each):

| | |
|---|---|
| i. | What are the recommended storage conditions for empty capsules shells in a pilot plant? |
| ii. | Enlist the different types of manufacturing changes with suitable examples. |
| iii. | Define Change Control. |
| iv. | Differentiate Qualification and Validation. |
| v. | Write down the full form and use of INDA and NDA. |
| vi. | Enlist the different teams with their prime work framed during drug development process. |
| vii. | What is the major difference between ISO9000 and ISO14000? |
| viii. | What is DMAIC in Six Sigma concept? |
| ix. | Write the full form of CDSCO. |
| x. | Why COPP is required by pharmaceutical industry? |

## Section B (2 X 10 = 20)

| | |
|---|---|
| 2. | What is the meaning and significance of pilot plant scale-up in Pharma industry? Strengthen your comments with suitable example. |
| 3. | Discuss the organization and function of CDSCO with special mention to its port offices. What are the requirement and various steps of approval of any drug in India? |
| 4. | Differentiate INDA with NDA. Describe the content and format of INDA with special mention to investigators brochure. |

## Section C (7 X 5 = 35)

| | |
|---|---|
| 5. | Discuss different types of Platform technology with their importance. |
| 6. | Give a brief account on SUPAC guidelines. |
| 7. | Discuss the role of Biostatistics in pharmaceutical development. |
| 8. | Write in brief about the various TT agencies in India. |
| 9. | Write the organization and functions of State Licensing Authority. |
| 10. | What are the major components of TQM? Discuss the significance of TQM in pharmaceutical industry |
| 11. | Describe the significance of technology transfer and quality risk management in Pharmaceutical industry. |
| 12. | What are the different elements and goals of Pharmaceutical QBD? |
| 13. | What are the requirements and various steps of approval of any drug in India? If, a drug is already approved in any other country, discuss the utility of COPP. |

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19 JAN 2021

Roll No. | | | | | | | | | | |

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.**