



PAPER ID-310135

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B PHARM
(SEM VII) THEORY EXAMINATION 2020-21
INDUSTRIAL PHARMACY-II

Time: 3 Hours

Total Marks: 75

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt all questions in brief.

10 x 2 = 20

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| a. | Enlist the GMP consideration required for pilot plant studies. |
| b. | What is the purpose conduction of pilot-plant scale up studies? |
| c. | Define technology transfer. Enlist the names of Indian agencies which are involved in technology transfer process. |
| d. | What is process validation? |
| e. | What is meant by regulatory affairs? Why regulatory affairs are essential for pharmaceutical industry? |
| f. | Expand the terms: INDA, NDA, ANDA, IB. |
| g. | Write the names of the laboratories which are governed by CDSCO. |
| h. | What is COPP? Why is it required? |
| i. | Explain the terms: TQM and QbD. Write the benefits of QbD. |
| j. | What is the role of six-sigma in pharmaceuticals. |

SECTION B

2. Attempt any two parts of the following:

2 x 10 = 20

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| a. | Who is the Drug Controller General of India? Describe the organization and functions of CDSCO. Write the functions of the laboratories governed by CDSCO. |
| b. | Explain in detail about NDA. How ANDA is different from NDA? |
| c. | What is the importance of technology transfer in pharmaceutical industry? Write a note on NRDC. |

SECTION C

3. Attempt any five parts of the following:

7 x 5 = 35

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| a. | Explain in detail about SUPAC guidelines. |
| b. | What is QRM? What are the principles involved in QRM? Explain the process of QRM. |
| c. | What are the functions of different TOT related documents in industrial pharmacy? |
| d. | Explain in detail about INDA. |
| e. | What is the methodology involved in six-sigma process? Explain the different levels. |
| f. | What is ISO 9000? How does ISO 9000 series of quality systems standards differ from ISO 14000? |
| g. | Write a brief note on NABL and OOS. |