

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Winter 2022

Date: 12/06/2023

Course : B. Pharmacy

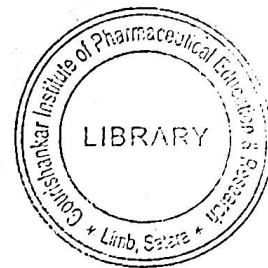
Sem : VII

Subject Name : Industrial Pharmacy-II

Subject Code : BP702T

Max Marks : 75

Duration : 3 Hr.



D. Pharma University Exam Papers | B. Pharma University Exam Papers | GPAT, NIPER, Pharmacist, Drug Inspector Exam Papers | Previous Year Exam Papers | Latest Pharma Job | Pharma Colleges | Pharma News | Pharma Quiz

Instructions:

1. All questions are compulsory Visit - pharmacyindia.co.in
2. Draw diagrams / figures wherever necessary
3. Figures to right indicate full marks

<https://pharmacyindia.co.in/>

Q. 1. Objective Type Questions (Answer all the questions) (10 x 2) = 20

- i) What is pilot plant? Write its objective.
- ii) What is Technology Transfer? Write about general idea of Technology Transfer.
- iii) Give contents of Investigator's Brochure.
- iv) What is Quality Management system and Quality certification?
- v) Describe IND. Give types of IND application.
- vi) Write the different phases of Human clinical trials.
- vii) Enlist various Regulatory authorities world wise.
- viii) What is ISO? What is its objective?
- ix) What are contents of COPP? <https://pharmacyindia.co.in/>
- x) Write the objective of GLP.

Q. 2. Long Answers (Answer 2 out of 3) (2 x 10) = 20

- i) Discuss general consideration and importance of pilot plant scale up. Explain in details about pilot plant scale up for solids.
- ii) What is NDA? Give its significance and describe process for NDA submission in USA and INDIA.
- iii) Explain about central drug standard control organization (CDSCO).

<https://pharmacyindia.co.in/>

Q. 3. Short Answers (Answer 7 out of 9) (7 x 5) = 35

- i) Enumerate the importance of TQM in pharma industry.
- ii) Summarize the biostatistics in pharmaceutical product development.
- iii) What do you mean by Platform Technology? List them. Discuss any four such platform technologies.
- iv) Explain QbD in pharmaceuticals.
- v) Elaborate Six Sigma concept in detail.
- vi) Explain role and responsibilities of Regulatory Affair Expert.
- vii) Write a note on SUPAC.
- viii) Discuss stepwise NABL accreditation.
- ix) Write a note on COPP.

<https://pharmacyindia.co.in/>

-----END OF THE PAPER-----

