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.**

Instructions:

1. *All questions are compulsory*
2. *Draw diagrams / figures wherever necessary*
3. *Figures to right indicate full marks*

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?
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).

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.

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