DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Winter 2022

Date: 05.01.2023

Course	:	B. Pharmacy	Semester:		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) Describe IND. Give types of IND application.
ii) Enlist the steps involved in clinical research process.
iii) Enlist Technology Transfer Team members with their role.
iv) Discuss reasons behind creation of GLP.
v) Differentiate between ISO 9001 & ISO 14001 Series.
vi) Compile objectives of pilot plant scale up in Pharmaceutical Industry.
vii) Enlist the responsibilities of CDSCO.
viii) Highlight benefits of QMS implementation at Pharma space.
ix) Enlist the contents of IB.
x) Define Technology Transfer (TT). Illustrate in brief the need of TT in pharmaceuticals?

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

i) Discuss general/GMP considerations and importance of pilot plant scale up. Elaborate pilot plant scale up for Tablet manufacturing with CQAs.
ii) Explain the need and objectives of regulatory requirements for drug approvals. Discuss NDA & ANDA application process in detail.
iii) Elaborate the concept of Total Quality Management in Pharma Industry with historical background and benefits of implementation at Pharma space.

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

i) Summarize organization and responsibilities of CDSCO.
ii) Comment on QRM in Pharmaceuticals with its process.
iii) Elaborate Six Sigma concept in detail.
iv) Summarize clinical research protocol in short.
v) Explain QbD in pharmaceuticals.
vi) Illustrate the significance of personnel requirements, space requirements and raw materials in Pilot plant scale up techniques.
vii) Illustrate scope, significance, content and procedure for issuance of CoPP.
viii) Explain role & responsibilities of Regulatory Affair Expert.
ix) Enlist and explain Tech Transfer agencies in India.

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