BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: BPHARM **SEMESTER: 7th**
BRANCH: PHARMACY **SESSION: MO/23**

SUBJECT: BP702T INDUSTRIAL PHARMACY-II

TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:

1. **The missing data, if any, may be assumed suitably.**
2. **Before attempting the question paper, be sure that you have got the correct question paper.**
3. **Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.**
4. **This question paper consists of (03) three parts. Read the part wise instructions before attempting the questions.**

PART-I
Objective types questions (Instruction: Answer all questions)

Q1. (10 x 2 = 20 Marks)

L. Define Technology Transfer [CO1]
M. Discuss Critical Control Point (CCP) [CO1]
N. Define Drug Master File (DMF) [CO1]
O. Define Performance Qualification and Operational Qualification [CO1]
P. What is Process Validation? [CO1]
Q. Differentiate between Quality Assurance and Quality Control [CO1]
R. What do you understand by Receiving unit and Sending Unit? [CO1]
S. Identify the uses of Standard Operating Procedure [CO1]
T. State true or false: [CO1]
   iii. Slugs ranging in diameter from 1 inch are more easily slugged than materials of 3/4rth Inch in diameter.
   iv. Multi-station Presses are termed rotary because the head that hold the upper punch, dies and lower punches in place rotates

U. Cosolvency is a technique _____ [CO1]
V. What do you mean by Validation Protocol and Validation Report? [CO1]

PART-II
Short Answers
(Instruction: Answer seven out of nine questions)

(7 x 5 = 35 Marks)

Q2. Discuss the steps of Regulation of Drug approval Process with a flow chart. [CO2]
Q3. Discuss Quality Risk management [CO2]
Q4. Write a note on Preclinical drug Development [CO3]
Q5. Discuss in detail the process of New Drug Application (NDA) [CO3]
Q6. Discuss in brief QbD approach? [CO4]
Q7. Explain principle and concept of TQM. Elaborate components of TQM. [CO4]
Q8. Describe in brief GLP principles. [CO4]
Q9. Discuss about ISO 9000 family. [CO4]
Q10. Describe about NABL in short. [CO4]

PART-III
Long Answers
(Instruction: Answer two out of three questions)

(2 x 10 = 20 marks)

Q11. Discuss in details on Transfer from R& D to Production including Process , Packaging and Cleaning **[CO2]**
Q12. Discuss about CDSCO and its function. Elaborate process of new drug approval. [CO5]
Q13. Elaborate about implementation of ICH Q8, Q9, Q10 guidelines throughout the product life cycle [CO4]

::::::22/11/2023::::::M