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

CLASS: B. Pharm **SEMESTER: VII**
BRANCH: PHARMACY **SESSION: SP/2022**

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)

A. Enlist the three variables generally considered for film coating or other coating operation.

B. What do you mean by Hard Gelatin capsules?

C. What do you mean by clinical hold in Investigational New Drug Application?

D. Outline the physiological property of skin which affect the diffusion rate of semisolid preparation.

E. What do you mean by in silico studies?

F. ISO 9000 FAMILY stands for
   (i) Quality management
   (ii) Environment management
   (iii) Digital security
   (iv) Medical devices — Quality management systems

G. GLP Governs
   (i) Test and Control articles
   (ii) Raw material selection
   (iii) Approval of manufacturing process
   (iv) Environmental controls

H. Continuous improvement is part of TQM. Define.

I. What are criteria for market and business analysis?

J. What I.P are protected as patents?

PTO

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

(7 x 5 = 35 Marks)

Q2. Explain the role of channels in hydrophobic/lipid based system in sustained release formulation.
Q3. Based on the consideration of skin structure, Discuss the five formulation principles are followed to develop good transdermal formulation.
Q4. Discuss about phases of technology transfer and path of commercialization.
Q5. Elaborate documentation involved in technology transfer.
Q6. Describe in brief ICH guidelines.
Q7. Discuss about ISO family.
Q8. Describe about NABL in short.
Q9. Elaborate in detail export outside the bond.
Q10. Discuss basic elements in GLP.

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

(2 x 10 = 20 marks)

Q11. Discuss the salient features of pilot plant scale up studies for liquid products
Q12. Discuss the significance of investigational new drug application in detail.
Q13. Describe concept of QbD, aspects of QbD and implementation of TQM.

:::::22/11/2022:::::M