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

CLASS: BPHARM **SEMESTER: VII**
BRANCH: PHARMACY **SESSION: MO 2024**

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)

J. Define the terms 'quality' and 'quality management system'. (CO1)
K. Enlist the names of various models of total quality management. (CO)
L. Mention different quality management tools adopted by an organization. (CO1)
M. What is total quality management (TQM)? Enlist its benefits in an organization. (CO1)
N. Define NABL. Outline its objectives. (CO2)
O. What is Hatch Waxman act? (CO3)
P. State any FOUR the functions of CDSCO. (CO5)
Q. Differentiate "complete clinical hold" and "partial clinical hold" upon submission of investigational new drug application. (CO4)
R. State the basic pharmacokinetic parameters used to compare two pharmaceutical products during bioequivalence study. (CO3)
S. Differentiate new drug application (NDA) and abbreviated new drug application (ANDA). (CO4)

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

(7 x 5 = 35 Marks)

Q2. Discuss the process of NABL accreditation. (CO2)
Q3. Explain the primary elements of TQM. (CO1)
Q4. What are the basic steps needed to implement QMS? Outline the management responsibilities to implement QMS. (CO1)
Q5. Differentiate generic and brand drugs. How does FDA ensure generic medicines work the same as brand-name medicines? (CO2)
Q6. Schematically present the new drug application (NDA) review process. (CO4)
Q7. Write short notes of investigator's brochure and its importance. (CO3)
Q8. Describe the key aspects if the technology transfer of analytical methods. (CO3)
Q9. Write short notes on good laboratory practices. (CO2)
Q10. Define standard operating procedure and discuss its importance in pharmaceutical industries. (CO2)

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

(2 x 10 = 20 marks)

Q11. Discuss six sigma concept along its methodologies and principles. (CO1)
Q12. Briefly discuss different phases of clinical trial. State the components of clinical trial protocol for conducting clinical trial in India. (CO2)
Q13. Discuss the responsibilities of regulatory affair professionals. (CO5)

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