

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

CLASS: B.PHARM
BRANCH: PHARMACY

SEMESTER: VIII
SESSION: SP/2023

SUBJECT: BP805ET PHARMACIVIGILANCE

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.
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PART-I

Objective type questions (Instruction: Answer all questions)

- Q1. (10 x 2 = 20 Marks)
- A. What are the challenges of PV in India.
 - B. Define Vigibase.
 - C. Define the concept of DESI drugs.
 - D. Differentiate ICD 11 from ICD 10.
 - E. Write the WHO definition of DDD.
 - F. Write note on CDL.
 - G. Write note on DCC.
 - H. Give full form of DILI & CIOMS.
 - I. Give full forms of CDSCO & HLA.
 - J. What does Schedule Y define.

PART-II

Short Answers

(Instruction: Answer seven out of nine questions)

- (7 x 5 = 35 Marks)
- Q2. Write short notes on Thalidomide tragedy and Sulphanilamide tragedy.
 - Q3. Describe the INN of drugs. How it is different from Trade marks.
 - Q4. Explain the WHO International Drug monitoring program.
 - Q5. Describe the ATC classification system of drugs.
 - Q6. How to manage Adverse Drug Reactions.
 - Q7. Define & classify Vaccines.
 - Q8. Explain the differences in Indian & global Pharmacovigilance requirements.
 - Q9. Give programs & activities of CIOMS. Name & elaborate Groups added in 2017.
 - Q10. Discuss different phases of Human trials.

PART-III

Long Answers

(Instruction: Answer two out of three questions)

- (2 x 10 = 20 marks)
- Q11. Describe the International classification of diseases in detail.
 - Q12. Describe the Pharmacovigilance program of India along with its programming pathway.
 - Q13. Give Schedule Y guidelines on clinical trials with regards to nature & permission. How we carry our tests for Acute & long term toxicities.

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