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

**CLASS: B.PHARM** **SEMESTER: VIII**
**BRANCH: PHARMACY** **SESSION: SP/2025**

**SUBJECT: BP805ET PHARMACOVIGILANCE**

**TIME: 3.00 Hours** **FULL MARKS: 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. Enumerate the basic minimum required criteria to identify a valid case with respect. to pharmacovigilance. CO3

B. Define adverse event (AE) and serious adverse event (SAE). CO1

C. What is ICH? What are the main goals of ICH guidelines. CO2

D. Write a note on CDL CO1

E. Give three purposes of Schedule Y CO2

F. Give full form of CDSCO CO1

G. What is drugs consultative committee. CO2

H. What is DDD and its application by WHO CO3

I. What is Drug Dictionary by WHO CO2

J. What is ICD and its application by WHO CO2

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

(7 x 5 = 35 Marks)

Q2. Describe the different sources of Individual Case Safety Reports (ICSR). CO2

Q3. Enumerate the principles of ICH E6 Good Clinical Practice. CO2

Q4. What are periodic safety reports? Why are periodic safety reports required? Outline the main components of PSUR. CO2

Q5. Define & classify Vaccines CO1

Q6. What is vaccine safety & vaccine failure CO3

Q7. Enumerate pharmacovigilance methods. What is passive surveillance method CO2

Q8. What type of members constitute Drugs technical advisory board CO3

Q9. What is MedDRA ? Explain significant function of MedDRA in Medical field CO2

Q10. . Explain function and role of Eudra-vigilance information system in Medical vigilance field. CO3

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

(2 x 10 = 20 marks)

Q11. Explain the components of ICH E2A guideline. CO2

Q12. Define pharmacovigilance. Define & classify Adverse drug reactions & it's management CO3

Q13. Explain five different levels & structure of ATC code classification by WHO with suitable examples. CO3

**::::::29/04/2025::::::E**