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

CLASS: B. PHARM **SEMESTER: VIII**
BRANCH: PHARMACY **SESSION: SP/2024**

SUBJECT: BP805T 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

Q1. (10 x 2 = 20 Marks)

Objective types questions (Instruction: Answer all questions)

K. Define adverse drug reactions with an example. CO1
L. What are the special populations concerning clinical research and drug safety? CO1
M. Name all the levels in ATC. CO1
N. Explain Boolean logic? CO2
O. What is schedule Y? CO1
P. Define pharmacovigilance? Why drug safety monitoring is important? CO1
Q. Enumerate the basic minimum required criteria to identify a valid case with respect to pharmacovigilance. CO3

R. Define serious adverse event (SAE). CO1
S. What is ICH? What are the main guidelines of ICH. CO2
T. Enlist the different levels in severity assessment. CO4

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

(7 x 5 = 35 Marks)

Q2. Describe different types of search engines. What are the primary, secondary, and tertiary information resources? CO3

Q3. Define the Medical Dictionary for Regulatory Activities (MedDRA). Describe MedDRA structure or hierarchy with an example of any disease. CO2

Q4. A health centre provided 80000 metronidazole tablets to 250 people in 2 years. The active substance in each tablet is 500 mg and the defined daily dose (DDD) of metronidazole is 2g. Find the total number of DDD for 1000 people per day. CO5

Q5. Briefly describe the steps to establish a pharmacovigilance programme in a hospital. CO4

Q6. Describe causality assessment. CO4

Q7. Classify vaccination failure. CO3

Q8. Summarize the main components of Individual Case Safety Report (ICSR). CO2

Q9. Explain Periodic Safety Update Report (PSUR). CO2

Q10. Case Study

INFORMATION HAS BEEN RECEIVED FROM THE CONSUMER VIA PV HOTLINE (110 123XXXXX), THE CONSUMER CALLED THE HOTLINE AND REPORTED THAT HIS SON TOOK XYZ SYRUP AT 18 O'CLOCK ON 14 FEB 2024 AND 10 O' CLOCK ON 15 FEB 2024 (INDICATION WAS UNKNOWN). BUT HE THOUGHT THE DRUG DID NOT RELIEVE HIS SON'S SYMPTOM. NO FURTHER INFORMATION WAS EXPECTED TO GET FROM THE CONSUMER.

Based on the above case study answer the following questions (01X05=05) (CO5)

a) Is the case valid? (Yes/ No)
b) If yes, then please write name of the drug responsible for AE.
c) What is AE in the above case?
d) Is the case serious? (Yes/No)
e) What is the source of the above case?

P.T.O

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

(2 x 10 = 20 marks)

Q11. Explain the pharmacogenomics of adverse drug reactions and the major components of pharmacogenomics machinery with examples of genes. Elaborate on the types and functions of non-coding RNAs (ncRNAs) with sketches. How can pharmacogenomics studies minimize drug-induced toxicity in patients? CO3 and CO4

Q12. Outline and explain different events involved in the history and development of Pharmacovigilance. CO1

Q13. Explain the various surveillance methods used in Pharmacovigilance. CO5

::::::26/04/2024::::::E