JHARKHAND Rai University
RANCHI

End Semester/Reappear (Semester VIII) Examination May 2025

Programme: B. Pharm
Course: Pharmacovigilance **Full Marks: 75**
Course Code: BP805ET **Time: 3 Hrs.**
Enrolment no. _____

Q.No.	Questions	CO	Bloom Taxonomy Category	Marks
	Section I			
1	**Objective Type Questions**			
	i. What is the primary goal of the Pharmacovigilance Programme of India (PvPI)? a. Drug development b. Cost reduction in drug production c. Monitor and ensure drug safety d. Promotion of generic drugs ii. Management of ADRs includes all except: a. Discontinuation of the drug b. Switching to a safer alternative c. Ignoring mild symptoms d. Symptomatic treatment iii. What does ATC classification stand for? a. Advanced Therapeutic Classification b. Anatomical Therapeutic Chemical classification c. Anatomical Technical Compound classification d. Authorized Therapeutic Control iv.What is the purpose of Defined Daily Dose (DDD)? a. Estimating overdose risk b. Comparing drug usage between populations c. Determining therapeutic effectiveness d. Classifying drug side effects v.The purpose of Eudravigilance database is to: a. Store drug manufacturing data b. Monitor adverse drug reactions in the EU c. Record pharmaceutical profits d. Register new generic drugs vi.Spontaneous reporting is an example of: a. Active surveillance b. Comparative study c. Passive surveillance d. Laboratory-based monitoring vii.Which of the following study designs compares individuals with a disease to those without it? a. Case-control study b. Cohort study c. Sentinel surveillance d. Case series viii.Post-Marketing Surveillance (PMS) occurs during which phase? a. Preclinical b. Phase I c. Phase II d. Post-approval ix.Expedited reporting is required for: a. Non-serious ADRs b. Delayed effects c. Unexpected serious ADRs d. Administrative issues x. Genetic polymorphisms affecting pharmacokinetics may alter: a. Drug color b. Drug metabolism c. Tablet size d. Injection site xi.During pregnancy, drug safety evaluation is crucial due to: a. High compliance b. Teratogenic risks c. Low bioavailability d. Reduced ADRs xii.The CIOMS Form is used for: a. Applying for drug patents b. Expedited ADR reporting c. Drug pricing applications d. Pharmacokinetic analysis xiii.Targeted clinical investigations are usually done to: a. Detect rare ADRs in the general population b. Establish drug pricing c. Investigate specific safety concerns d. Study market competition xiv.INN ensures: a. Patented drug naming b. Consistent and universal drug naming c. Confidential drug identification d. Pricing regulations xv.Seriousness of an ADR refers to: a. The intensity of the symptom b. Whether it leads to hospitalization, disability, or death c. The predictability of the ADR d. Patient's opinion about the drug xvi.What is the main focus of vaccine pharmacovigilance? a. Improving vaccine pricing b. Detecting and assessing adverse events following immunization c. Enhancing vaccine marketing strategies d. Monitoring manufacturing process only xvii.Which phase is primarily used to test a drug's efficacy and monitor adverse reactions in a larger patient group? a. Phase I b. Phase II c. Phase III d. Phase IV xviii.Pharmacovigilance planning is essential during: a. Product recall b. Drug development and approval c. Drug import d. Post-approval only xix.CIOMS Working Groups focus on: a. Medical education b. Global pharmacovigilance practices c. Hospital safety procedures d. Drug branding xx.Predictability of ADRs helps in: a. Marketing the drug b. Managing dosage schedules c. Preventing future occurrences d. Reducing drug cost	CO1	Remember	**1 x 20 = 20**

Section II				
2. Short Answer type questions.				
a	What are the minimal set of information should be provided for the proper assessment of ADR case report?	CO1	Understand	
b	Explain ATC with example. What are the general principles for ATC classification. Write the coding of drugs on their anatomical groups.	CO2	Remember	
c	Enlist the Vaccine provide by Govt. of India. Explain the Basic Calculation of Vaccine Evaluation.	CO3	Remember	
d	Explain Drug Utilization Study and Pharmacovigilance Practice	CO4	Understand	
e	Explain Genetic Polymorphism of Drug Transporters and Genetic Polymorphism and Mutation of Drug Metabolizers.	CO5	Understand	**7 x 5 = 35**
f	Explain AEFI. Which AEFIs should be reported and also classify AEFI.	CO3	Remember	
	or			
	What are the different types of vaccine reactions? Draw the chart of Serious AEFI cases (formats and timelines).	CO3	Understand	
g	Explain Eudravigilance. Explain EVMPD, what it offers and write its purpose	CO2	Understand	
	or			
	What are the methods of post marketing surveillance (PMS) used by the pharmaceutical industry?	CO2	Remember	
Section III				
Long Answer Type questions				
3	Highlight the structure and importance of Individual Case Safety Reports (ICSRs) in pharmacovigilance. What are the major sources of ICSRs and how do reporting requirements vary depending on the source and nature of the case?	CO4	Evaluate	
	or			
	Describe the methods used to generate safety data during the pre-clinical phase of drug development. How do these methods help in predicting human risk, and what are the limitations?	CO4	Evaluate	**2 x 10 = 20**
4	Comment on the risks and considerations involved in drug safety evaluation during pregnancy and lactation. How do physiological changes in these stages affect drug pharmacokinetics and pharmacodynamics?	CO5	Evaluate	
	or			
	Discuss the function of CIOMS in global drug safety and ethics. How do the CIOMS working groups contribute to international pharmacovigilance and ethical research practices?	CO5	Evaluate	

Course Outcomes (CO):

On the successful completion of the Course, students will be able to:-

- CO 1. To know about pharmacovigilance, adverse drug reactions
- CO 2: To know about drug and disease classification, drug dictionaries and coding in pharmacovigilance.
- CO 3: To know about vaccine safety surveillance, pharmacovigilance methods.
- CO 4: To know about safety data generation, ICH Guidelines for pharmacovigilance.
- CO 5: To know about pharmacogenomics of adverse drug reactions, drug safety evaluation in special population, CDSCO and CIOMS.