**ARKA JAIN University, Jharkhand**

8th Semester 1st Internal Examination – 2022-2023



**Subject: Pharmacovigilance (Theory)**

**Course: B. Pharm** **Full Marks: 30**

**Time: 1hr**

* **All Questions are compulsory**.
1. **Multiple Choice Questions**$\left(10×1=10\right)$

**1. A harm that Occurs When a patient is taking a drug, irrespective of whether the drug is suspected to be the cause is also Known as\_\_\_\_.**

A. Adverse effect B. Adverse event

C. Serious adverse effect D. Toxic effect

**2. The aim of Clinical Trail Phase zero is \_\_\_\_.**

A. Micro dosing Phase B. Safety check

C. Therapeutic Confirmation D. Therapeutic Exploration

**3. Yellow Card Scheme was Introduced to UK in \_\_\_\_\_.**

A. 1964 B. 1962 C. 1969 D. 1968

**4. The reactions Which are idiosyncratic and not predictable on the basis of the pharmacology is known as\_\_\_\_\_.**

A. Augmented reactions B. Bizarre Reactions

C. chronic reactions D. Delayed effects

**5. In which year WHO Organized a Programme for International Drug Monitoring?**

A. 1964 B. 1968 C. 1962 D. 1969

**6. Why Pharmacovigilance is needed for our products?**

A. Protection of patients

B. Minimizing risks and taking appropriate measures.

C. Fulfil regulatory requirement of DGDA and/or PV Agreements with business partner.

D. All of the above

**7. CDSCO stands For \_\_\_\_.**

A. The Control Drugs Standard Central Organization

B. The Central Drugs Standard Control Organization

C. The Central Drugs Specific Control Organization

D. The Central Drugs Systemic Control Organization

**8. ATC Classification stands For**

A. Alphabetical, therapeutic and chemical classification of drugs.

B. Anatomical, technical and chemical classification of drugs.

C. Anatomical, therapeutic and chemical classification of drugs.

D. Anatomical, therapeutic and Constitutional classification of drugs.

**9. In Which Year, Florescence Nightingale, made 1st model of systemic collection of hospital data?**

A. 1860 B. 1862 C. 1894 D. 1893

**10. Phase 03 of Clinical Trails is Conducted For \_\_\_\_\_.**

A. Micro dosing Phase B. Safety check

C. Therapeutic Confirmation D. Therapeutic Exploration

1. **Long Answers (Answer 1 out of 2)** $\left(1×10=10\right)$

1. What is MedDRA? Explain the Governing Bodies of MedDRA and Objective of MedDRA.

2. Brief Explain About Anatomical, therapeutic and chemical classification of drugs.

1. **Short Answers (Answer 2 out of 3)**$ (2×5=10)$

1. Give a Short note on Pharmacovigilance Program of India (PvPI).

2. Discuss some Basic terminologies used in pharmacovigilance.

3. Give A Short Note on Contract Research Organizations.