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# BP 805 ET

Roll No. of candidate | | | | | | | | | | |

**2021**

**B. Pharm. 8th Semester (Regular) End-Term Examination**

**PHARMACOVIGILANCE (THEORY)**

**New Regulation (W.e.f. 2017-18)**

Full Marks – 75 Time – Three hours

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The figures in the margin indicate full marks for the questions.

Answer All Questions.

I. Multiple choice questions (MCQ) $(20 \times 1 = 20)$

1. The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.

   (a) Clinical research (b) Clinical data management

   (c) Pharmacovigilance (d) Project management

2. Pharmacovigilance continue throughout

   (a) Post marketing surveillance

   (b) Pre and post marketing surveillance

   (c) Pre marketing surveillance

   (d) None of the above

3. Process of pharmacovigilance is

   (a) Case processing-signal management-risk management -submission to umc

   (b) Case processing-risk management -signal management-submission to umc

   (c) Submission to umc- case processing-signal management-risk management

   (d) Risk management- submission to umc- case processing-signal management

**[Turn over**

4. Adverse event is due to
   (a) Life threatening
   (b) Due to drug/treatment
   (c) May or may not have casual relationship with treatment
   (d) None of above

5. Serious adverse event
   (a) Result in death
   (b) Life threatening
   (c) Both (a) and (b)
   (d) None of the above

6. Pharmacovigilance
   (a) Increase economic burden on healthcare system
   (b) Improve public health
   (c) Neglects patient safety
   (d) Discourage effective drug use

7. Sulphanilamide disaster occurred in
   (a) 1937
   (b) 1948
   (c) 1958
   (d) 1948

8. NDA stands for
   (a) New drug applicant
   (b) Novel drug application
   (c) New device application
   (d) New drug application

9. Pharmacovigilance programme of India
   (a) 2009
   (b) 2010
   (c) 2005
   (d) 2012

10. Observational studies include all except
   (a) Cross sectional study
   (b) Case control study
   (c) Cohort study
   (d) Spontaneous report study

11. What is the first steps of vaccine Pharmacovigilance?
   (a) Develop hypothesis
   (b) Immunization
   (c) Detect signal
   (d) Test hypothesis

12. What are primary resources of ADR?
   (a) Academic journals
   (b) Laboratory experiments
   (c) Books
   (d) All of the above

13. Teratogenicity falls under which type of ADR?

(a) Type A (b) Type B

(c) Type C (d) Type D

14. Which is not a requirement for establishing national pharmacovigilance system?

(a) A national pharmacovigilance center

(b) A national spontaneous reporting system

(c) A national database or system

(d) A regulatory body

15. Which is not specialized resource of ADR?

(a) Case report (b) Comprehensive Monitoring

(c) Population Monitoring (d) Spontaneous Reporting

16. Which country started "YELLOW CARDS" system.

(a) UK (b) USA

(c) Sweden (d) Canada

17. The laboratory work using computers and associated with web-based analysis generally online is referred to as

(a) In silico (b) Dry lab

(c) Wet lab (d) All of the above

18. Adverse drug reactions in elderly is

(a) Greater than young people (b) Lesser than young people

(c) Equal to young people (d) None of the above

19. National Coordination Centre (NCC) for pharmacovigilance is

(a) PGI Chandigarh

(b) CDRI Lucknow

(c) Indian Pharmacopoeia Commission (IPC), Ghaziabad

(d) CMC Vellore

20. Which of the following terms does not describe an Adverse Drug Reaction?

(a) diosyncrasy (b) Anaphylaxis

(c) eratogenic effect (d) lacebo effect

II. Short answers (Answer 7 out of 9) $(7 \times 5 = 35)$

1. Describe specialized resources for ADRs with examples?
2. Explain how an effective communication in pharmacovigilance is established?
3. Differentiate between passive surveillance and active surveillance?
4. Explain the protocol for establishing a stabilized pharmacovigilance in a hospital?
5. Write a note on adverse events following immunization?
6. What are observational studies? Explain cross sectional study with an example?
7. Discuss the role of regulatory agencies in pharmacovigilance?
8. Write a detail note on WHO international drug monitoring Programme?
9. Describe the organization and objectives of International Conference on Harmonization.

III. Long answers (Answer 2 out of 3) $(2 \times 10 = 20)$

1. Describe different factors affecting placental transfer of drugs. What are the various quality measures of drug prescribing in geriatric patients? Write in brief the drug safety evaluation in pediatric patients. 5+5
2. What do you mean by MedDRA? Explain in detail with its scope? Write different criteria of Post marketing surveillance (PMS). Mention different types of test available for safety pharmacology. 1+4+5
3. Discuss in detail about the history and development of Pharmacovigilance with the help of Thalidomide and Sulphanilamide tragedy?