

Semester Examination- FH2022 (Academic Year 2021-2022)

M. Pharm Sem II (Choice based R2019)-Branch- Pharmacology

Subject: MPL 204 T-Clinical Research and Pharmacovigilance

Paper Code: 69543 – Set II

Duration: 3 Hours

Total Marks: 80

Q. 1 Attempt all Multiple-Choice Questions (MCQ)

20M

Sr No	Questions		Options
1	The elements of Informed Consent are described in _____ of Schedule Y 2014.	a	Appendix V
		b	Appendix IV
		c	Appendix VII
		d	Annexure III
2	A compilation of the clinical and nonclinical data on the investigational products related to the clinical study is called as:	a	Informed Consent Form
		b	Investigator's Brochure
		c	Drug Dossier
		d	Protocol Amendment
3	A printed, optical, or electronic document designed to record all of the protocol required information on each Trial Subject:	a	Source Documents
		b	Monitoring Report

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		c	Case Report Form
		d	Protocol Amendment
4	Hypersensitivity Reactions caused by Antibiotics are _____ type of Adverse Drug Reaction.	a	Type B
		b	Type F
		c	Type A
		d	Type C
5.	Which One of the following is ICH Efficacy Guideline?	a	Safety Pharmacology Studies
		b	Good Laboratory Practices
		c	Bioanalytical Method Validation
		d	Good Clinical Practices
6	The Periodic Safety Update Report is:	a	Report of Completed Clinical Trial
		b	The Systematic Review of Safety Data of Marketed Drug
		c	Monitoring Report of Clinical Study

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		d	Compilation of the Clinical Data of the Investigational Product
7	According to ICH-GCP “An organization contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions” is called as:	a	Contract Research Organization
		b	Trial Management Centre
		c	Clinical Study Centre
		d	Site Management Organization
8	One of the following is a function of Independent Ethics Committee:	a	Conduct the Clinical Study as per the Protocol
		b	Submit Progress Report of the ongoing Trial
		c	Safe-guard the Rights, Safety and Well-being of all Trial Subjects
		d	Implement a Quality Management System
9	Which one of the following is Drug Regulatory Authority in India?	a	Central Drugs Standard Control Organization

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		b	National Institute of Health Research
		c	Indian Drug Manufacturer's Association
		d	Drug Price Control Order
10	Naranjo's Scale method is used for:	a	Safety Monitoring of Clinical Trials
		b	Data Collection of Adverse Drug Reaction
		c	Causality Assessment of Adverse Drug Events
		d	Spontaneous Reporting of Drug Safety
11	The Science and Activities related to Detection of Adverse Effects following Immunization is called as:	a	Materiovigilance
		b	Hemovigilance
		c	Causality Assessment
		d	Vaccine Safety Surveillance
12	Which of the Following is a type of Pharmaco-epidemiology Study?	a	Cost-benefit Analysis

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		b	Drug Utilization Study
		c	Pre-clinical Drug Development
		d	Drug Safety Monitoring
13	The Process of assigning Trial Subjects to treatment or control groups using an element of chance is called as:	a	Blinding
		b	First in Human Study
		c	Randomization
		d	Subject Identification
14	The Serious Adverse Event:	a	Results in Persistent Disability
		b	Have Mild Symptoms
		c	Can be managed by Out Patient Department
		d	Can be reported till next Seven Days
15	Which of the following is the Method for Reporting of Adverse Drug Reactions?	a	Translational Research
		b	Case Control Studies

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		c	Micro dosing
		d	BA-BE Studies
16	Pharmaco-economics is associated with:	a	Description and Analysis of Cost of Drug Therapy
		b	Study of Evaluation of Health Care System
		c	Patient Demographic Data Analysis
		d	Drug Utilization Studies
17	The ability of a Drug to cause Malformation in the fetus is called as:	a	Genotoxicity
		b	Mutagenicity
		c	Teratogenicity
		d	Myelosuppression
18	Schedule Y is a Part of one of the following Act:	a	Indian Patent Law
		b	Drugs & Cosmetic Act
		c	Drug Price Control Order
		d	The Pharmacy Act

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19	The software used as a core element of an Integrated Pharmacovigilance and Risk Management System is:	a	Vigibase
		b	PV Net
		c	Aris G
		d	Med watch
20	Which one of the following ICH Guideline describes the Structure and Content of Clinical Study Report?	a	E 3
		b	E 10
		c	S 7
		d	M 11

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Q 2. Attempt Any One question

12 M

1. Write a note on Structure and Content of Clinical Study Report.
2. Give a detailed account on: Vaccine Safety Surveillance.

Q 3. Attempt Any Four questions.

48 M

1. Elaborate on Schedule Y 2014.
2. Define the Terms: Sponsor and Monitor in Clinical Trials. Add a note on the Responsibilities of the Monitor.
3. Define Adverse Drug Reactions. Classify ADR with suitable examples.
4. Elaborate on the Pharmacovigilance Programme of India.
5. Discuss the various types of Pharmaco-epidemiology Studies. Write a note on Applications of Pharmaco-epidemiology.