DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy **Sem: VIII**

Subject Name: Pharmacovigilance **Subject Code: BP805ET**

Max. Marks: 75 **Date: 18/07/2022** **Duration: 3.45 Hrs.**

Instructions –

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

i) Naranjo's scale method of causality assessment is

a) Algorithmic method b) probabilistic method c) Global introspection d) Algebraic Method

ii) The most commonly adopted method for reporting of ADR is –

a) Expedited reporting b) Suspected reporting

c) Spontaneous reporting d) Longitudinal electronic patient records

iii) Aims of spontaneous reporting are

a) To keep watch on even b) Adverse drug event c) Benefit risk analysis d) Case studies

iv) PV tools not used by UMC are –

a) VigiFlow b) VigiSearch c) VigiMine d) VigiPass

v) International Conference on Harmonisation (ICH) was created in 1990 as an agreement between the _____to harmonize different regional requirements for registration of pharmaceutical drug products.

a) China, USA and EU b) Russia, EU, Australia

c) EU, Japan and the USA d) Australia, USA, Brazil

vi) ICH guidelines E6 is for--

a) Studies in support of special population b) General considerations for clinical trials.

c) Good Clinical Practice d) The extent of Population

vii) What is informed consent in a clinical trial?

a) The subjects do not know which study treatment they receive

b) Patients injected with placebo and active doses

c) Fake treatment

d) Signed document of the recruited patient for the clinical trial procedures

viii) This is the type of registry

a) Disease registry b) Case registry c) Case series d) ADR registry

ix) The WHO International Drug Monitoring Programme was established in the year

a) 1986 b) 1990 c) 1996 d) 1968

x) Which one of the following is the last step of a clinical trial process?

a) Investigator selection b) Patient recruitment
c) Statistical Analysis d) Data filed and registration

xi) GCP are seen in all of the following except
a) Phase I trial b) Phase II trial c) Phase IV trial d) Preclinical trials

xii) This is the type of registry
a) Disease registry b) Case registry c) Case series d) ADR registry

xiii) How many people will be selected for phase I trial?
a) The whole market will be under surveillance b) 300-3000 people
c) 20-300 people d) 20-50 people

xiv) What is meant by the therapeutic ratio or index?
a) The ratio of LD50 to ED99 b) The ratio of LD50 to ED50
c) The ratio of LD1 to LD50 d) The ratio of ED99 to ED50

xv) ICH stands for –
a) The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
b) International council on harmonization
c) Internal conference on harmonization
d) Indian committee on harmonization

xvi) Signal Detection is
a) The act of looking for and/or identifying signals using data from any source
b) To identify information regarding drug
c) To identify information about any vaccine
d) detection of bioavailability of drug

xvii) Who is responsible for WHO International Drug Monitoring Program?
a) Upshala drug monitoring centre
b) WHO drug dictionary
c) PVPI
d) CRO

xviii) Which of the following define Cohort studies?
a) The act of looking for and/or identifying signals using data from any source
b) Studies that identify defined populations and follow them forward in time, examining their rates of disease.
c) Studies that identify defined sample and follow them forward in time, examining their rates of ADR.
d) Detection of bioavailability of drug

xix) Sentinel meaning:
a) Adverse drug reaction b) To keep watch for an event
c)Adverse drug event d) Sponsor reporting

xx) What is full form of MedDRA
a) Medical Dictionary for Regulatory activities b) Medical Directory for Regulatory Affairs
c) Medical Dictionary for Regulations and Actions d) Medical Directory for Regulations of Affairs

Q. 2. Long Answers) = 2 x 10 = 20 (Answer 2 out of 3)

i) Enumerate the different method of causality and severity assessment of ADR and explain the WHO scale

ii) Describe organization and objective of ICH with Guideline for Individual case safety reports.

iii) Explain in details Clinical trials and add a note on safety data generation for it.

Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)

i) Discuss in details clinical trials for drug safety data generation

ii) Write down about Effective communication in Pharmacovigilance

iii) Scope of MedDRA and Clinical research organization.

iv) Explain international classification of disease.

v) Write a note on pharmacovigilance of India (PvPI)

vi) Discuss in detail post approval phase of drug safety data generation

vii) Write a note on GCP guidelines in pharmacovigilance

viii) Role of Pharmacist in management of ADRs

ix) Functions of CDSCO in pharmacovigilance.

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