MANIKGAD-V: SUMMER - 2015
SUBJECT: CLINICAL RESEARCH

Day: Monday
Date: 6-4-2015

Time: 10.00 A.M To 1.00 P.M
Max. Marks: 70

N.B:

1) **Q. No.1** and **Q. No. 5** are **COMPULSORY.** Out of remaining questions attempt **ANY TWO** questions from each section.
2) Answer to both the sections should be written in the **SEPARATE** answer books.
3) Figures to the right indicate **FULL** marks.

SECTION-I

Q.1 **A)** Answer **ANY FOUR** of the following: **(08)**

i) What are different types of INDs?
ii) What is Hatch-Waxman Act?
iii) Mention in brief activities of EMEA.
iv) What are the objectives of Phase-II trial?
v) Expand the following abbreviations ICMR and CDSCO.
vi) Define Protocol.

B) Write the significance of blinding and randomization in clinical trial. **(03)**

Q.2 Explain in detail different phases of clinical trial. **(12)**

Q.3 **a)** Discuss abbreviated new drug application process. How does it differ from NDA? **(07)**

b) Explain the steps involved in Pre-clinical drug development. **(05)**

Q.4 Write short notes on **ANY THREE** of the following: **(12)**

a) Helsinki declaration
b) Criteria for subject selection in clinical trial
c) Drug characterization
d) Regulatory environment in US with respect to drug application.

SECTION-II

Q.5 **A)** Answer **ANY FOUR** of the following: **(08)**

i) Expand following abbreviations DSMB and USFDA.
ii) Who are vulnerable subjects?
iii) What is the need for informed consent?
iv) Define SAE.
v) What is Nuremberg trial?
vi) How many members constitute independent ethics committee?

B) What is the role of Monitor in efficient conduct of clinical trial? **(03)**

Q.6 Explain the roles responsibility of sponsor in clinical trial. Enlist the members of sponsor's team. **(12)**

Q.7 **a)** Discuss safety monitoring and reporting in clinical trial. **(07)**

b) Define audit and audit trial as per ICH-GCP. **(05)**

Q.8 Write short notes on **ANY THREE** of the following: **(12)**

MANIKGAD- V: SUMMER - 2015

SUBJECT: PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Day: Wednesday Time: 10.00 A.M. To 1.00 P.M.

Date: 8.4.2015 Max. Marks: 70

N.B.:

1) **Q. No. 1** and **Q.No.5** are **COMPULSORY**. Out of remaining questions attempt **ANY TWO** from each section.
2) Figures to the right indicate **FULL** marks.
3) Answer to both sections should be written in the **SEPARATE** answer book.

SECTION-I

Q.1 **a)** Answer **ANY FOUR** of the following: **[08]**

i) Write advantages and disadvantages of prescription event monitoring.
ii) Enumerate different types of record linkage systems.
iii) Enumerate various automated data base systems.
iv) Explain use of case repots in Pharmacoepidemiology.
v) Outline the strengths of spontaneous ADR reporting.
vi) Applications of Pharmacoepidemiology.

b) Brief note on Ad Hoc data sources. **[03]**

Q.2 Classify different types of study designs used in pharmacoepidemiological research. Explain any two in detail. **[12]**

Q.3 **a)** Explain the role and significance of registries in pharmacoepidemiology. **[07]**

b) Compare the drug policy objectives in developing and developed countries. **[05]**

Q.4 Write short notes on **ANY THREE** of the following: **[12]**

i) Medical record data base system
ii) Relative risk
iii) Role of 'Signal' in adverse drug reaction monitoring
iv) Time-risk relationship
v) Data mining in ADR reporting.

SECTION-II

Q.5 **a)** Answer **ANY FOUR** of the following: **[08]**

i) Enumerate the objectives of Pharmacoeconomics
ii) Define Adverse Event, Serious Adverse Event with suitable example.
iii) Write a note on "patient perspective" with respect to cost.
iv) Enlist any four applications of Patient Reported Outcome (PRO).
v) Write the formulae for Incremental Cost-Effectiveness Ratio (ICER).
vi) Define cost-utility analysis

b) Define and give various applications of Pharmacoeconomics Research. **[03]**

Q.6 Explain Risk Management in detail with respect to Pharmacoepidemiology. **[12]**

Q.7 **a)** Describe cost-minimization analysis with their application giving suitable example. **[07]**

b) Explain various health care cost categories with suitable example. **[05]**

Q.8 Write short notes on **ANY THREE** of the following: **[12]**

i) Outcome analysis
ii) HRQOL

MANIKGAD - V : SUMMER - 2015

SUBJECT: CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING

Day: Friday
Date: 10-4-2015

Time: 10.00 A.M. To 1.00 P.M.
Max Marks. 70

N.B.

1) Q. No. 1 and Q. No. 5 are **COMPULSORY**.
2) From the remaining answer any other **TWO** questions from Section - I and **TWO** questions from Section - II.
3) Answer Section - I and Section - II on **SEPARATE** answer books.
4) Figures to the right indicate **FULL** marks.

SECTION - I

Q.1 **a)** Answer any **FOUR** of the following **(08)**

i) Define loading dose.

ii) What is half life?

iii) Define volume of distribution

iv) Name two hepatic enzyme inducers

v) Mention two methods for determining serum drug level

vi) Define clinical pharmacokinetics

b) Explain with suitable examples pharmacokinetic drug interactions related to drug absorption. **(03)**

Q.2 Define therapeutic drug monitoring (TDM). Explain the indications and applications of TDM in details. **(12)**

Q.3 **a)** Describe the intravenous to oral conversion. **(07)**

b) Explain drug dosing in elderly patients. **(05)**

Q.4 Write short notes on TDM of any **THREE** of the following, drugs. **(12)**

a) Theophylline

b) Phenytoin

c) Methotrexate

d) Aminoglycosides

P.T.O.

SECTION - II

Q.5 a) Answer any **FOUR** of the following **(08)**

i) Pharmacogenetics

ii) Single nucleotide polymorphism (SNP)

iii) Give examples of drugs which inhibit liver enzymes

iv) Creatinine clearance

v) What is genotype?

vi) Define adverse drug reaction.

b) Describe drug dosign in renal important. **(03)**

Q.6 What are the advantages of population pharmacokinetics over traditional pharmacokinetic? Explain documentation of popular pharmacokinetics. **(12)**

Q.7 a) Explain genetic polymorphism in drug transport. **(07)**

b) Explain how response is affected due to individual patient variations? **(05)**

Q.8 Write short notes of **THREE** of the following. **(12)**

a) Nomogram

b) Drug metabolism in hepatic diseases

c) Extracorporeal removal of drugs

d) Genetic polymorphism in drug target

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