MANIKGAD - V: APRIL / MAY - 2014

SUBJECT: PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Day: Tuesday
Date: 15-04-2014

Time: 2.00 P.M. To 5.00 P.M
Max. Marks: 70

N.B.:

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

SECTION-I

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

i) Define risk ratio
ii) Explain meta analysis
iii) What is defined daily dose (DDD)
iv) Define drug utilization research
v) Define prevalence with a suitable example
vi) Explain case series analysis with a suitable example

B) Write the advantages and disadvantages of prescription event monitoring. **(03)**

Q.2 Discuss cross-sectional studies and case control studies with suitable examples. **(12)**

Q.3 **a)** Explain medical record data base system with its applications. **(07)**
b) Outline strength and limitations of spontaneous ADR reporting system. **(05)**

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

a) Medication adherence
b) Monetary units
c) Incidence rate
d) Pharmacoepidemiology
e) Ad Hoc data source

SECTION-II

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

i) Define cost benefit analysis.
ii) What is Health Related Quality of Life (HRQOL)?
iii) Write a short note on patient reported outcomes.
iv) Explain indirect medical cost with suitable examples.
v) Enlist various applications of pharmacoeconomics.
vi) Enlist the role of software in pharmacoeconomics.

B) Explain cost -effectiveness analysis with suitable examples. **(03)**

Q.6 Explain any two methods widely employed for conducting pharmacoeconomic evaluation. **(12)**

Q.7 **a)** Explain role of pharmacoeconomics in formulary management decisions. **(07)**
b) Outline advantages and disadvantages of cost utility analysis. **(05)**

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

a) ECHO model
b) ACER and ICER
c) Intangible cost
d) Define pharmacoeconomics

MANIKGAD - V : APRIL / MAY - 2014
SUBJECT : CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

Day : Friday
Date : 11.04.2014

Time : 2.00 P.M. To 5.00 P.M.
Max. Marks : 70

N. B. :

1) **Q. No. 1** and **Q. No. 5** are **COMPULOSRY**. Out of remaining attempt **ANY TWO** questions from each section.
2) Section I & Section II 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) Define clinical pharmacokinetics.

ii) Give examples of drugs for which TDM is not required.

iii) Name two inhibitors of drug metabolism.

iv) Give formula for calculation of pediatric doses.

v) What are the main kinds of drug dosage?

vi) Define half life ($t1/2$).

b) Describe pharmacokinetic drug interactions with examples. **(03)**

Q. 2 **a)** Define therapeutic drug monitoring. Describe the indications and applications of TDM. **(07)**

b) Describe the pharmacokinetic / pharmacodynamic correlation in drug therapy. **(05)**

Q. 3 **a)** Explain the causes of inter-subject pharmacokinetic variability. **(07)**

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

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

a) First pass (presystemic) metabolism

b) TDM of theophylline

c) TDM of digitalis

d) TDM of lithium

P. T. O.

SECTION - II

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

i) Define hysteriesis.

ii) Define biomarkers.

iii) Name two conditions (other than drugs) which may induce cytochrome P enzymes.

iv) Define pharmacogenomics.

v) Define population pharmacokinetics.

vi) Which physiochemical properties are required for hemodialysis?

b) Explain drug disposition in liver disease. **(03)**

Q. 6 **a)** Describe the extracorporeal clearance of drugs. **(07)**

b) Explain cytochrome P 450 enzymes and adverse of drugs reactions. **(05)**

Q. 7 **a)** Explain the consequences and uses of induction of liver microsomal drug metabolizing enzymes. **(07)**

b) Explain genetic polymorphism in drug transport. **(05)**

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

a) Drug disposition in liver disease

b) Nomograms

c) Conversion of i.v. to oral dosage

d) Dose adjustment in renal disease

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MANIKGAD - V: APRIL / MAY - 2014

SUBJECT : CLINICAL RESEARCH

Day : Monday
Date : 07.04.2014

Time : 2:00 P.M. To 5:00 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) Answers 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 is EMEA.
ii) Describe the functioning of CDSCO.
iii) Name any two screening tests for preclinical studies.
iv) Expand the following terms : ICH-GCP, ANDA.
v) Explain in brief about microdosing studies.
vi) Why phase-II trials are also called as 'Exploratory Trials'?

B) How post marketing surveillance is performed? Describe various steps involved in it. **[03]**

Q.2 Define clinical trials. Explain the different phases of clinical trials with respect to objectives, patient population, duration and outcome. **[12]**

Q.3 a) Explain the process of IND application. What are the specifications required to file IND application? **[07]**

b) Write in brief about the principles of ICH-GCP. **[05]**

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

a) Drug dosage formulation in drug development process
b) Confidentiality of trial participants
c) Pharmacovigilance
d) Vulnerable population in clinical trials
e) Fraud and misconduct in clinical trials

SECTION - II

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

i) What is the role of an auditor?
ii) Name regulatory authorities in USA and Europe.
iii) Why study coordinator act as a link between principal investigator and monitor?
iv) How the rights and well-being of participants are preserved?
v) Write two exceptions where informed consent can be waived off.
vi) What is phase '0' trial?

B) Write in brief about the constitution of independent ethics committee. **[03]**

Q.6 What are the important ethical issues in clinical trials? Why informed consent is a mandatory requirement in case of children? **[12]**

Q.7 a) Which all documents are considered as 'Essential documents'? Describe the components of CRF which places high priority as far as documentation is concerned. **[07]**

b) Explain the process of conduct of a clinical trial in India. **[05]**

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

a) Roles and responsibilities of sponsor
b) Trial master file
c) Investigator's brochure