MANIKGAD – V : SUMMER- 2017
SUBJECT : CLINICAL RESEARCH

Day : Thursday
Date : 06/04/2017

Time : 10.00 A.M. TO 01.00 PM
Max. Marks : 70

N. B. :

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

SECTION - I

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

i) Institutional Ethics Committee
ii) Ethical guidelines in Clinical Research
iii) High throughput Screening methods in drug discovery and development
iv) Why healthy volunteers are enrolled in Phase – I studies
v) Regulatory authority responsible for clinical trials in USA
vi) Application of bioisosters in drug discover

B) Toxicity studies in preclinical research. **(03)**

Q. 2 Explain in detail the different stages of drug discovery and development process. **(12)**

Q. 3 **a)** Discuss the various drug characteristics techniques during drug development process. **(07)**

b) Write the ethical principles of ICH-GCP in Clinical Research. **(05)**

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

a) IND Application
b) Investigational product
c) Design of clinical research
d) Challenges in implementing ethical guidelines in Clinical Research

P. T. O.

SECTION - II

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

i) Assent in Clinical Research

ii) Essential documents in Clinical Research

iii) Selection and withdrawal of subjects in clinical trials

iv) Regulatory authority responsibility in safety

v) Who are sponsors in clinical trial?

vi) PMS Studies

B) Differentiate between NDA and ANDA. **(03)**

Q. 6 Discuss in detail clinical research and the various phases of clinical trials. **(12)**

Q. 7 a) Explain the role of clinical investigator in clinical trials as per ICH-GCP. **(07)**

b) Discuss safety monitoring in clinical trials. **(05)**

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

a) Data Management Process

b) Design and development of Protocol

c) Differentiate eCRF v/s paper CRF

d) CDSCO Guidelines

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MANIKGAD-V : SUMMER- 2017

SUBJECT : PHARMACOEPIDEMIOLOGY AND PHARMACOEOCONOMICS

Day : Saturday
Date : 08/04/2017

Time : 10.00 A.M. TO 01.00 PM
Max. Marks : 70.

N.B.:

1) Q. No. 1 and Q. No. 5 are **COMPULSORY**. Out of remaining attempt any **TWO** questions from Section-I and any **TWO** questions from Section-II
2) Section-I and Section-II should be written in **SEPARATE** answer book.
3) Figures to the right indicate **FULL** marks.

SECTION-I

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

i) Enlist various methods used for outcome analysis.
ii) Explain intangible medical costs.
iii) Define Pharmacoeconomics.
iv) Mention the use of case reports in Pharmacoepidemiology
v) Define prevalence with suitable examples.
vi) Define prescribed daily doses with suitable example.

B) Write a short note on PSUR. **(03)**

Q.2 Explain the steps involved in establishing a drug utilization review (DUR) program in a hospital set up. **(12)**

Q.3 a) Describe the important considerations while performing a meta-analysis? **(07)**

b) Enumerate the various methods of measuring risk. Explain any two in deail. **(05)**

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

a) Strengths and limitations of case-control surveillance.
b) Strengths of spontaneous reporting system.
c) Various methods for measuring medication adherence.
d) Various clinical and methodological problems in of hospital pharmacoepidemiology studies.
e) Various clinical problems in of drug-induced birth defect studies.

SECTION-II

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

i) How Cost Benefit Analysis is different from cost utility and cost effectiveness analysis?
ii) Expand WTP and briefly define it.
iii) Expand ICER and briefly explain the application of ICER.
iv) What do you understand by one-way sensitivity analysis?
v) Differentiate between effectiveness and efficacy.
vi) What is opportunity cost?

B) What are the two ways of collecting costs? **(03)**

P.T.O.

Q.6 Explain Cost Effectiveness Analysis (CEA) with suitable example. State its advantages in economic analysis. **(12)**

Q.7 **a)** Explain Standard Gamble Method for utility valuation. **(07)**

b) Differentiate between Direct and Indirect costs. **(05)**

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

a) Quality Adjusted Life Year
b) Cost of Illness
c) Time-Trade-off (TTO)
d) Willingness to pay
e) Various clinical problems in risk management research.

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Pharm - D
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MANIKGAD - V: SUMMER- 2017

SUBJECT: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

Day : Tuesday
Date : 11/04/2017

Time : 10.00 A.M. TO 01.00 PM
Max. Marks : **70**

N. B. :

1) **Q. No. 1** and **Q. No. 5** are **COMPULSORY**. Out of remaining **Any TWO** questions from **Section - I** and **Any TWO** questions from **Section – II.**
2) Both the sections should be written in the **SEPARATE** answer book.
3) Figures to the right indicate **FULL** marks.

SECTION – I

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

i)) Name two inhibitors of drug metabolism.

ii) What are the main kinds of drug dosage?

iii) Define loading dose.

iv) Define therapeutic index.

v) Enlist factors affecting drug absorption.

vi) Enlist the advantages of compartmental model.

b) Describe drug dosing in obese patients. **(03)**

Q.2 Discuss the applications of pharmacokinetic/ pharmacodynamic correlation in drug therapy. **(12)**

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

b) Describe Nomograms and tabulation in designing dosage regimen. **(05)**

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

a) Aminoglycosides

b) TDM of digitalis

c) First pass metabolism

d) Inhibition of biliary excretion and its effect on pharmacokinetics

P.T.O.

SECTION - II

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

i)) Enumerate four causes of renal dysfunction.

ii) What is meant by dosing with feedback?

iii) Enumerate the methods used to determine GFR.

iv) Explain the various liver function tests and their significance.

v) Write the significance of pharmacokinetic-pharmacodynamic correlation.

vi) Calculate the creatinine clearance for a child (8 years, body length 122 cm) whose serum creatinine value is 0.9 mg/dl.

b) The maintenance dose of Gentamicin is 80 mg every 6 hours in a patient with normal renal function (normal creatinine clearance of 100 ml/min). calculate the dose for a uremic patient with creatinine clearance of 20ml/min (given ku/KN=0.2) **(03)**

Q.6 Explain Bayesian theory with a suitable example and briefly the concept of dosing with feedback. **(12)**

Q.7 **a)** Explain in detail Hemodialysis. **(07)**

b) Explain pharmacokinetic considerations during renal impairment. **(05)**

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

a) Approaches for dose adjustment during renal disease.

b) Role of liver enzymes in drug interaction with suitable examples.

c) Determination of creatinine clearance?

d) Pharmacokinetic-pharmacodynamic correlations in drug therapy.

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