MANIKGAD - V: APRIL / MAY 2013
SUBJECT : CLINICAL RESEARCH

Day : Saturday
Date : 13-04-2013
Time : 10:00AM 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) 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) Define clinical trials.
ii) Enlist various steps of drug development process.
iii) Expand the following terms: ANDA, IND.
iv) What is the duration of preclinical studies in whole drug development process?
v) What do you mean by phase '0' trial?
vi) How to file an IND application?

B) What is the need of carrying out post marketing surveillance studies? **[03]**

Q.2 Describe the principles of ICH-GCP guidelines. Explain some of the key issues in efficient conduct of clinical trials. **[12]**

Q.3 a) Explain the drug discovery process. Elaborate the concept of pharmacological screening in drug development. **[07]**

b) Highlight some of the important requirements of CDSCO. **[05]**

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

a) Toxicological screening
b) Clinical research V/s academic research
c) Drug safety monitoring
d) PSUR
e) Clinical trial phases

SECTION - II

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

i) Describe the role of clinical research coordinator in clinical trials.
ii) What do you mean by informed consent discussion?
iii) Name two regulatory bodies from where permission is sought before conducting clinical trial.
iv) Enlist two vulnerable populations in clinical trials.
v) Write two main principles of good clinical practice guidelines.
vi What is investigator's brochure?

B) What are the important ethical issues in clinical research? **[03]**

Q.6 Explain the composition, responsibilities and procedures of IEC in clinical trials. **[12]**

Q.7 a) Describe the requirements of informed consent. Explain regarding informed consent procedure and documentation in clinical trials. **[07]**

b) What are the different steps to be followed in safety monitoring of clinical trials? Which bodies play an important role in safety monitoring of clinical trials? **[05]**

MANIKGAD - V: APRIL / MAY - 2013

SUBJECT: PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Day: Tuesday
Date: 16-04-2013

Time: 10:00AM-TO1:00P.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 difference
ii) Define prescribed daily doses with suitable examples
iii) Explain time-risk relationship
iv) What is case-cohort study?
v) Define incidence and incidence rate
vi) What is automated data system?

B) Enlist various applications of pharmacoepidemiological research. **(03)**

Q.2 Define the term meta-analysis. Describe the important consideration while performing a meta-analysis. **(12)**

Q.3 **a)** Explain the methodological problems in drug- induced birth defect studies. **(07)**
b) Explain the applications of drug use utilization review. **(05)**

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

a) Odds ratio
b) Prevalence
c) Case report and case series
d) Spontaneous reporting
e) Prescription event monitoring

SECTION-II

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

i) Mention few needs of pharmacoeconomic evaluation.
ii) What is cost of illness?
iii) Merits and demerits of cost minimization studies.
iv) What is direct medical cost with suitable examples?
v) Enlist various applications of patient reported outcomes measures.
vi) Explain use of case reports in pharmacoeconomics.

B) Write a short note on Health Related Quality of Life. **(03)**

Q.6 Define pharmacoeconomics and explain cost-benefit and cost utility analysis with suitable examples. **(12)**

Q.7 **a)** Explain different steps involved in development of patient reported outcome instrument. **(07)**
b) Explain cost -effectiveness analysis with suitable examples. **(05)**

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

a) Steps employed for conducting pharmacoeconomic evaluation

MANIKGAD - V : APRIL / MAY - 2013
SUBJECT : CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

Day : Thursday
Date : 18-04-2013

Time : 10:00AM TO 1:00 PM
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 Volume of Distribution (Vd).

ii) Fixed dose.

iii) Explain the meaning of ADME.

iv) Define Therapeutic Drug Monitoring (TDM).

v) Enlist the necessity of TDM.

vi) Mention two inducers of liver microsomal drug metabolizing enzymes.

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

Q. 2 **a)** Explain drug clearance. **(07)**

b) Explain the protocol for TDM. **(05)**

Q. 3 **a)** Explain the necessity for individualization of drug dosage regimen. **(07)**

b) Explain pharmacokinetic drug interactions with suitable examples. **(05)**

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

a) PK / PD model in pharmacokinetic

b) TDM of aspirin

c) TDM of carbamazepine

d) TDM of theophylline

SECTION - II

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

i) Define polymorphism.

ii) Define pharmacogenetics.

iii) Define pharmcogenomics.

iv) Name two drugs cleared by hemodialysis.

v) Give examples of synthetic biotransformation reactions.

vi) Define adverse drug reaction.

b) Describe dosage adjustment in renal disease. **(03)**

Q. 6 a) Explain population pharmacokinetics. How it differs from traditional pharmacokinetics? **(07)**

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

Q. 7 a) Describe extracorporeal removal of drugs. **(07)**

b) Describe the role of cytochrome P 450 enzymes in adverse drug reactions. **(05)**

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

a) Genetic polymorphism in drug targets

b) Variation in drug effect due to genetic defect

c) Liver microsomal drug metabolizing enzymes

d) Measurement of glomerular filtration rate and creatinine clearance.

SUPPLEMENTARY : JULY – 2013

MANIKGAD - IV:
SUBJECT: CLINICAL TOXICOLOGY

Day: Saturday
Date: 06-07-2013

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 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) What are different types of poisons?
ii) Define toxicokinetics.
iii) What are the harmful effects of alcohol withdrawal?
iv) Enlist symptoms of salicylate poisoning.
v) Mention signs and symptoms of overdose of opiates.
vi) Give an account of constituents of bee venom.

B) Writ a note on Therapeutic application of antidotes. **(03)**

Q.2 Describe in detail organic mercury poisoning. **(12)**

Q.3 **a)** Describe general principles in management of poisoning. **(07)**
b) Discuss the signs and symptoms of alcohol poisoning. **(05)**

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

a) Copper poisoning
b) Acute poisoning due to NSAIDs
c) Gastric lavage
d) Radiation poisoning

SECTION-II

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

i) Give an account on poisoning due to scorpion bite.
ii) Write a note on tobacco poisoning.
iii) Mention clinical effects of snake venoms.
iv) Give an account of toxicity of sulphanic acid.
v) Examples of CNS depressants causing dependence.
vi) Define food poisoning.

B) Describe the elimination of poison (decontrainationn) **(03)**

Q.6 Describe in detail sources, sign and symptoms, management of arsenic poisoning. **(12)**

Q.7 **a)** Comment on mycotoxins. **(07)**
b) Give an account of spider bites. **(05)**

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

a) Chronic poisoning
b) Lead poisoning