Fifth Year - Pharm D - 2016.

MANIKGAD – V : SUMMER - 2016
SUBJECT : CLINICAL RESEARCH

Day : Monday
Date : 04-04-2016

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

N.B.

1) Q.1 and Q.5 are **COMPULSORY.**
2) Out of the remaining attempt any **TWO** questions from each section.
3) Figures to the right indicate **FULL** marks.
4) Answers to both the sections should be written in **SEPARATE** answer book.

SECTION – I

Q.1 **A)** Answer any **FOUR** of the following: **(08)**
a) What do you mean by Preclinical Studies?
b) Lipinski's Rule of 5.
c) Expand : IND, ANDA, NDA.
d) Preformulation Studies
e) Toxicity studies in clinical research.
f) Target identification and validation.

B) High throughput screening in drug development. **(03)**

Q.2 Write down in detail the drug discovery and development process. **(12)**

Q.3 **a)** Process of filling an IND application in drug discovery. **(07)**
b) Pharmacological studies in preclinical development. **(05)**

Q.4 Write short note on any **THREE** of the following: **(12)**
a) Ethical guidelines in clinical research
b) Introduction to clinical trials
c) Over view of regulatory requirement in Europe
d) Drug characterization in clinical research development

SECTION – II

Q.5 **A)** Answer any **FOUR** of the following: **(08)**
a) Roles and responsibilities of clinical research associate.
b) SAE in clinical trials.
c) Expand CRF and ICF in clinical research.
d) Methods of post marketing surveillance
e) Contract research organization
f) Composition of IRB.

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

Q.6 Give a detail account of various phases of clinical research. **(12)**

Q.7 **a)** Challenges in implementation of guidelines. **(07)**
b) Write down about Informed consent process. **(05)**

Q.8 Write short note on any **THREE** of the following: **(12)**
a) Data management and its components
b) Regulatory authority
c) ICH-GCP guidelines
d) Selection criteria for selection of subjects in clinical trial

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MANIKGAD – V : SUMMER - 2016

SUBJECT : PHARMACOEPIDEMINOLOGY & PHARMACOECONOMICS

Day : Wednesday
Date : 06-04-2016

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

N.B.

1) Q.1 and Q.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 **SEPARATE** answer book.

SECTION – I

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

i) Define odds ratio.
ii) Enlist positive outcome of pharmcoepidemiological study.
iii) Write in brief about defined daily dose.
iv) Differentiate prevalence and incidence.
v) Explain the term medication adherence.
vi) Write about the benefits of metanalysis.

B) Write about drug induced birth defect with example. **(03)**

Q.2 Explain the ad-hoc data source and automated data system for pharmacoepidemiology. **(12)**

Q.3 **a)** Explain the need of pharmacy-epidemiology. **(07)**
b) Define drug utilization review and mention steps involved in it. **(05)**

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

a) Cross sectional study
b) Cohort studies
c) Randomized controlled studies
d) Attributed risk and relative risk

SECTION – II

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

i) Explain the importance of registries.
ii) Enumerate different types of costs involved in pharmacoeconomic studies.
iii) Expand PEM and state its advantages.
iv) What do you mean by primary triage and secondary triage?
v) Write in brief the pharmacovigilance process steps.
vi) What do you mean by outcome research?

B) Write in detail about the ECHO model. **(03)**

Q.6 Define and explain ~~elaborately~~ Cost Effectiveness Analysis (CEA) with a suitable example. Mention its advantages in pharmacoeconomic study. **(12)**

Q.7 **a)** Compare cost utility and cost benefits analysis. **(07)**
b) Explain the Cost Minimization Analysis (CMA) and state its importance. **(05)**

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

a) Adverse Event Reporting System (AERS)
b) Hospital Pharmacoepidemiology
c) ATC classification system
d) Micro and Macro applications of Pharmacoeconomics

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MANIKGAD – V: SUMMER - 2016

SUBJECT : CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING

Day : Saturday
Date : 09-04-2016

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) Answers to both the sections should be written in **SEPARATE** answer books.
3) Figures to the right indicate **FULL** marks.

SECTION – I

Q.1 **a)** Attempt **ANY FOUR** of the following: **[08]**
- **i)** Give two example of metabolism interaction.
- **ii)** Define Continuous Renal Replacement therapy.
- **iii)** Name the mutant alleles of CYP 2D6.
- **iv)** Name the analytical method for quantification of amiodarone.
- **v)** Mention the formula to calculate dosing body weight in obese patients.

b) Define TDM and mention its objectives. **[03]**

Q.2 Describe the following methods of population pharmacokinetic data analysis: **[12]**
- **i)** Naïve Pooled approach
- **ii)** Iterative two stage approach
- **iii)** Non-linear Mixed effect Model approach

Q.3 **a)** Explain the genetic polymorphisms of the following CYP enzymes: **[07]**
i) 2D6 **ii)** 2C9.

b) Explain the interactions of drugs that occur during distribution phase. **[12]**

Q.4 Write short notes on **ANY THREE** of the following: **[12]**
- **a)** Describe various extracorporeal elimination techniques.
- **b)** Mention all the formula used in dosage calculation for pediatrics.
- **c)** Explain the differences between conventional and population pharmacokinetics.
- **d)** Mention the significance of age and weight of the patient in dosage adjustment.

SECTION – II

Q.5 **a)** Attempt **ANY FOUR** of the following: **[08]**
- **i)** Mention the therapeutic range of lithium and lamotrigine.
- **ii)** Mention two drugs interactions due to alteration of protein binding.
- **iii)** Mention two drugs removed by dialysis.
- **iv)** Mention the formula to calculate BMI and classify overweight and obesity.
- **v)** Mention the formulae to calculate loading and maintenance doses.

b) Explain any two mechanisms of enzyme induction. **[03]**

Q.6 Explain the criteria and methods of IV to Oral conversion procedure. **[12]**

Q.7 **a)** Explain direct and indirect link model for PK – PD correlation. **[07]**
b) Explain factors governing dosage adjustment in obese patients. **[05]**

Q.8 Write short notes on **ANY THREE** of the following:
- **a)** TDM of Lithium and Cyclosporine
- **b)** Glomerular filtration rate and creatinine clearance
- **c)** Child – Pugh classification for classification of hepatic disease severity
- **d)** Genetic polymorphism in drug transporters

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