FIFTH YEAR PHARM. D : SUMMER - 2018

SUBJECT: CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING

Day : **Tuesday**
Date : **10/04/2018**

S-2018-4047

Time : **10.00 AM 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 hepatic enzyme inducers.

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

iii) Give formula for calculation of pediatric doses.

iv) Define clinical pharmacokinetics.

v) Define volume of distribution.

vi) What is therapeutic index?

b) Describe pharmacokinetic drug interactions with examples. **(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 dosing conversion. **(07)**

b) Describe the inhibition of biliary excretion and its effect on pharmacokinetics. **(05)**

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

a) TDM of lithium

b) Methotrexate

c) Nomograms

d) Drug dosing in obese patients

P.T.O.

SECTION - II

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

i)) How do you adjust dose of a drug in a renal impairment with a constant dosing interval.

ii) Calculate creatinine clearance in an 85 year old female weighing 190 Ibs, with serum creatinine concentration of 1.5 mg/100ml.

iii) Give examples of hepatic makers and their importance.

iv) Define genetic polymorphism and give examples.

v) Define pharmacogenetics.

vi) Explain the intrinsic clearance of drug.

B) Describe genetic polymorphism in CYP2D6. **(03)**

Q.6 What is population pharmacokinetic data? Explain in detail the methods adopted in analysis of such data. **(12)**

Q.7 **a)** What is Bayesian theory? Explain with suitable example. **(07)**

b) What is extracorporeal removal of drugs? Explain. **(05)**

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

a) Effect of hepatic diseases on pharmacokinetics

b) Role of genetic polymorphism in drug metabolism

c) Effect of renal and hepatic diseases on protein binding

d) Methods of determining creatinine clearance in adults

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FIFTH YEAR PHARM. D : SUMMER - 2018
SUBJECT : CLINICAL RESEARCH

Day : **Thursday** Time : **10.00 AM to 01.00 PM**
Date : **05/04/2018** **S-2018-4045** Max. Marks : 70

N.B.:

1) **Q.N0.1** and **Q.No.5** are **COMPULSORY**. Out of the remaining questions attempt **ANY TWO** questions from each sections.
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)** Answer **ANY FOUR** of the following: **[08]**
- **i)** Define IND and ANDA.
- **ii)** What are pre-formulation studies?
- **iii)** Explain HTS application in drug development.
- **iv)** Drug characterization in Clinical Research.
- **v)** Application of Bioisosters in drug design and development.
- **vi)** Regulatory Authority of India for Clinical Research.

B) Various approaches in drug design and development. **[03]**

Q.2 Explain in detail Toxicity studies in preclinical stage. **[12]**

Q.3 **a)** Process of filing an IND application in US. **[07]**
b) Target Identification and Validation. **[05]**

Q.4 Write a short note on **ANY THREE** of the following: **[12]**
- **a)** CDSCO guidelines for Clinical Research
- **b)** Various methods of PMS
- **c)** Introduction to Clinical Research
- **d)** Lead Identification and Development

SECTION – II

Q.5 **A)** Answer **ANY FOUR** of the following: **[08]**
- **i)** Roles and responsibilities of a CRA in Clinical Research.
- **ii)** Differentiate between NDA vs. ANDA
- **iii)** PIS – ICF in Clinical Research.
- **iv)** Composition of Ethics Committee as per Indian Guidelines.
- **v)** What is data-lock?
- **vi)** Define SAE.

B) Roles and responsibilities of Auditors in Clinical Research. **[03]**

Q.6 Explain Informed Consent Process in detail. **[12]**

Q.7 **a)** Roles and responsibilities of Sponsor in clinical research. **[07]**
b) Roles and responsibilities of Ethics Committee in clinical research. **[05]**

Q.8 Write short note on **ANY THREE** of the following: **[12]**
- **a)** Data management and its components in Clinical Research
- **b)** Safety monitoring in Clinical Research
- **c)** Designing of CRF in Clinical Research
- **d)** Ethical issues in implementation of guidelines

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FIFTH YEAR PHARM. D : SUMMER - 2018

SUBJECT : PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Day : **Saturday** Time : **10.00 AM to 01.00 PM**

Date : **07/04/2018** **S-2018-4046** 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) 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)** Answer **ANY FOUR** of the following: **[08]**

i) Classify drug utilization review on timeline basis.
ii) What is confounder?
iii) State advantages of case report.
iv) Define meta-analysis.
v) Define incidence rate with example.
vi) State the application of odds ratio.

B) State any three advantages of case-control studies. **[03]**

Q.2 What do you mean by pharmacoepidemiology? State the various reasons to perform pharmacoepidemiology studies. **[12]**

Q.3 **a)** Discuss the strengths and weaknesses of Prescription Event Monitoring (PEM). **[07]**

b) Write and briefly explain the events for which follow up information is sought from general practitioner in PEM. **[05]**

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

a) Cohort studies
b) Analysis of secular trends
c) Attributatble risk
d) Defined Daily Dose

SECTION – II

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

i) Explain WTP with suitable example.
ii) What is the purpose for conducting meta-analysis?
iii) Explain the term 'moral hazard'.
iv) What are the limitations of effectiveness measure?
v) What do you mean by person trade-off?
vi) Expand ICER and state its use in pharmacoeconomics research.

B) Why hospital drug monitoring is suitable for pharmacoepidemiological studies? **[03]**

Q.6 State the benefits of Cost Identification Analysis. Elaborate the various types of costs evaluated in pharmacoeconomic research. **[12]**

Q.7 **a)** Compare between the cost effectiveness analysis and cost benefit analysis. **[07]**

b) Explain the cost effectiveness plain with a suitable diagram. **[05]**

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

a) Quality Adjusted Life Years (QALY)
b) Discounting
c) WHO Drug use Indicators
d) Clinical issues in vaccine safety

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