DOCTOR OF PHARMACY

5TH YEAR

SYLLABUS

RESEARCH DOCTOR PHARMA

5.1 CLINICAL RESEARCH (THEORY)

TOPICS –

I. **Drug development process:**

Introduction Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

II. **Clinical development of drug:**

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
    a. Sponsor
    b. Investigators
    c. Clinical research associate
    d. Auditors
    e. Contract research coordinators
    f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)

12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

TOPICS –

1. **Pharmacoepidemiology**:
   Definition and scope: Origin and evaluation of Pharmacoepidemiology need for Pharmacoepidemiology, aims and applications.
   Measurement of outcomes in Pharmacoepidemiology Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement
   Concept of risk in Pharmacoepidemiology Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio
   Pharmacoepidemiological methods Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.
   Sources of data for Pharmacoepidemiological studies
   Ad Hoc data sources and automated data systems.
   Selected special applications of Pharmacoepidemiology Studies of vaccine safety, hospital Pharmacoepidemiology, Pharmacoepidemiology and risk management, drug induced birth defects.
2. **Pharmacoeconomics:**
   Definition, history, needs of pharmacoeconomics evaluations
   Role in formulary management decisions

Pharmacoeconomic evaluation Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**
   Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

TOPICS –

1. Introduction to Clinical pharmacokinetics.
2. **Design of dosage regimens:** Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
3. **Pharmacokinetics of Drug Interaction**:
    a. Pharmacokinetic drug interactions
    b. Inhibition and Induction of Drug metabolism
    c. Inhibition of Biliary Excretion.
4. **Therapeutic Drug monitoring:**
    a. Introduction
    b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
    c. Indications for TDM. Protocol for TDM.
    d. pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
    e. TDM of drugs used in the following disease conditions:
        - cardiovascular disease
        - Seizure disorders
        - Psychiatric conditions
        - Organ transplantations
5. **Dosage adjustment in Renal and hepatic Disease**.
    a. Renal impairment
    b. Pharmacokinetic considerations
    c. General approach for dosage adjustment in Renal disease.

d. Measurement of Glomerular Filtration rate and creatinine clearance.

e. Dosage adjustment for uremic patients.

f. Extracorporeal removal of drugs.

g. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics**.

a. Introduction to Bayesian Theory.

b. Adaptive method or Dosing with feed back.

c. Analysis of Population pharmacokinetic Data.

7. **Pharmacogenetics**

a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.

b. Genetic Polymorphism in Drug Transport and Drug Targets.

c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

5.4 CLEARKSHIP (PRACTICAL)

TOPICS –

1. HOSPITAL POSTING
2. CASE ACTIVITY
3. CASE PRESENTATION
4. ARTICLE PRESENTATION

5.5 PROJECT WORK

1. HOSPITAL POSTING
2. CASE STUDY
3. CASE REPORT