Course Title: PHARMACOMETRICS AND METHODS OF BIOLOGICAL EVALUATION OF DRUGS

Course Code: CL212

Course Credit:
- Lecture: 05
- Practical: 04
- Tutorial: 00
- Total: 09

Course Objectives:
This course will provide a study of basic principles of bioassays, their importance and limitations. It will also give information regarding preclinical drug evaluation of its biological activity, potency and toxicity by various tests and microbiological assays of antibiotics and vitamins. The study will also provide basic information on pyrogens. It also elaborates about the cell line handling, maintenance and application with limitations. The course will include the biological evaluation methods for screening of drugs from several categories like drugs acting on CNS, ANS, CVS, GIT, endocrine and urogenital system along with that used in cataract, glaucoma, malaria.

Detailed Syllabus - Theory

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name of Chapter &amp; Details</th>
<th>Hours Allotted</th>
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<tbody>
<tr>
<td></td>
<td><strong>Section-I</strong></td>
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<tr>
<td>1</td>
<td>Biological evaluation of drugs—Screening and evaluation ( including principles of screening, development of models for diseases : In vivo models / In vitro models / cell line study ) techniques of the following: a. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmnic</td>
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<td>drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.</td>
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<td>b.</td>
<td>Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.</td>
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<td>c.</td>
<td>Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders and diuretics.</td>
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<td>d.</td>
<td>Various models for Cataract, glaucoma, inflammatory bowel disease.</td>
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<td>e.</td>
<td>Antimalarials</td>
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<td>f.</td>
<td>Dermatological and experimental models in skin pharmacology.</td>
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<td><strong>Section-II</strong></td>
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<td>2</td>
<td>Biological evaluation of drugs--Screening and evaluation ( including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study ) techniques of the following: General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson’s drugs, CNS Stimulants.</td>
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<td>Biological standardization, general principles, Scope and limitation of bioassay, bioassay of some official drugs.</td>
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<td>4</td>
<td>Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenicity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.</td>
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<td>5</td>
<td><strong>Pyrogens:</strong> Sources, Chemistry and properties of bacterial pyrogens and</td>
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### Pharmacometrics and Methods of Biological Evaluation of Drugs (Practical)

1. **Bioassays of Drugs**: Bioassay of agonists (Graphical, Matching, 3 Point, 4 point method) and Bioassay of antagonists using various isolated preparations.

2. **Toxicity Studies**

3. **Evaluation of Drugs Based on Theory Syllabus**

   **Illustrative Examples**

   1. Evaluation of the antiepileptic activity of drug using maximum electro convulsive shock seizures (M. E. S.) and chemical induced convulsions methods.

   2. Determination of the time required for induction and recovery from anesthesia for various volatile general anesthetics.

   3. Evaluation of the effect of pentobarbitone sodium and diazepam in mice.

   4. Evaluation of the effect of various tranquilizers and sedatives on motor co-ordination by rota rod test in mice.

   5. Evaluation of the effects of drugs on spontaneous motor activity and to evaluate their nature as CNS stimulants or depressants.

   6. Evaluation of the antiparkinsonian activity of drugs by pheno-thiazine induced catatonia.

   7. Evaluation of the effect of psychotropic drugs on condition avoidance response.

   8. Evaluation of the compulsive behavior (stereotypy) induced by apomorphine and its modification by chlorpromazine in mice.


   10. Study the effect of caffeine in human volunteers.

   11. Evaluation of the effect of cimetidine in drug induced gastric (peptic) and duodenal ulcers and hyper secretion of gastric acid in rats.

   12. Evaluation of the antisecretory and ulcer protective effect of cimetidine in...
pylorusligated rats.


15. Evaluation of the analgesic effect of drugs by acetic acid induced writhing method in mice.


   Evaluation of the effects of various drugs (diuretics) on the output of the urine in rats.

Instructional Method and Pedagogy:

- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each unit/topic and will be evaluated at regular interval.
- Surprise tests/Quizzes/Tutorials will be conducted.
- The course includes language practices such as Group Discussion, Interviews etc to develop the communication skills of the students.

Students Learning Outcomes:

At the completion of the course students should be able to:

1. Know various methods of bioassays with their advantages and limitations.
2. Know about the sources, properties and official tests for pyrogens.
3. Evaluate the drug preclinically for its toxicity and efficacy to find out ED50 and LD50.
4. Perform microbiological assays of antibiotics and vitamins.
5. Understand the applications and limitations of cell line in research.
6. Screen various drugs for their activity by standard methods of evaluation.
### Text Books:

1. Drug Discovery and Evaluation in Pharmacology assay: Vogel

### Reference Books:

1. Screening methods in pharmacology (vol I & II) – R.A. Turner
2. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
3. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
4. Pharmacology and Toxicology- Kale S.R.
5. Fundamentals of experimental Pharmacology- Ghosh M.N.

### Additional Resources

1. Various research journals, magazine and internet sources.