

Course Code: PHL 454
Course Name: BIOLOGICAL STANDARDIZATION
Pre-requisite: PHL 451

Course Description:

The course deals with methods of biological detection and quantitative measurements as applied to the bioassay of hormones, sera, vaccines, toxins, anti-toxins and their mathematical and statistical calculations.

Course contents: Hours

- | | |
|---|---|
| I. Biostatistics for Bioassay measurements: | |
| * Revision of some basic principles | 1 |
| * Application of statistical methods to the comparison of treatment groups: | 4 |
| - Student's t-test (Paired, unpaired) | |
| - Wilcoxon Rank Test (signed & sum) | |
| - Contingency tables and Chi-Square Test | |
| * Analysis of the Dose-response data: | 3 |
| - Linear regression of graded responses and test for parallelism between two lines. | |
| - Quantal response data (probit analysis of Miller & Tainter; and method of Karber). | |
| II. Measurement of Biological Responses: | 7 |
| - Uses of bioassay | |
| - Dose-response relationships and determination of relative potency. | |
| - Determination of affinity constant and efficacy of agonists. | |
| - Determination of dissociation constant and efficacy of partial agonists. | |
| - PA ₂ , Dose ratio and affinity constants of competitive antagonists. | |
| - PD' ₂ of irreversible competitive or reversible non-competitive antagonists. | |

III. Specialized Bioassay and Pharmacopeal limit tests: 6

- Bioassay of glucagon
- Bioassay of Erythropoeitin.
- Chorionic Gonadotropin
- Somatotropins
- Heparin
- Protamine sulfate
- Bioassay of immunological products:
 - antitoxins by protection against toxin lethality (B.P, U.S.P.)
 - Assay of snake or scorpion antivenom (B.P., U.S.P., N.F.)
 - Radioimmunoassay and ELISA for protein hormones.
 - Test for abnormal toxicity (B.P.)
 - Test for depressor substance (B.P.)
 - Test for Histamine (B.P.)

IV. Measurement of pharmacological activity of drugs: 5

1. Analgesic activity
2. Anti-inflammatory activity
3. Antipyretic activity
4. Anti-convulsant activity
5. Antidysrhythmic activity.

EXAMINATION: 2

Total Hours: 28

PHL 454 PRACTICAL

- Lab 1 Bioassay of histamine on the guinea pig ileum using the 4-point assay design.
- Lab 2 Bioassay of d-tubocurarine on the rat-phrenic hemidiaphragm or frog rectus abdominis muscle using 4 or 6 point assay.
- Lab 3 Determination of PA_2 for an antagonist (e.g. parasympatholytic or antihistamine).
- Lab 4 Determination of the LD_{50} for a C.N.S. depressant drug.
- Lab 5 Bioassay of vasopressin in rats.
- Lab 6 Bioassay of insulin injection and select oral hypoglycemic agents in rabbits.
- Lab 7 Measurement of analgesic activity using 2 x 2 method.
- Lab 8 Bioassay of oxytocin on rat uterus.
- Lab 9 Measurements of anti-inflammatory activity.
- Lab 10 Measurements of anticonvulsant activity.
- Lab 11 Radioimmunoassay of T_3 or T_4 , Demonstration (Radioisotope lab.).
- Lab 12 Tests for abnormal toxicity. IP in mice.
- Lab 13 Tests for depressor substances and for histamine.
- Lab 14 Examination and/or Revision.