THEORY: (3 hours per week)

1. (a) Microbial Limit Tests, Sterility Tests.
   (b) Biological standardization, General Principles, Scope and limitation of bioassays, Bioassays of some official drugs.
2. Preclinical Drug Evaluation for its biological activity, potency and toxicity -Toxicity animals including acute, subacute and chronic toxicity, ED_{50} and LD_{50} determination, special toxicity tests like teratogenicity and mutagenicity. Animal experiments for assessing safety of packaging materials.
3. Pyrogens: Sources, chemistry and properties of bacterial pyrogens and endotoxins, official pyrogen tests
4. Microbiological assays of antibiotics and vitamins.
5. Biological Evaluation of Drugs- Principles and practice as illustrated by the analysis of the following class of drugs: Analgesics, Anti-inflammatory agents, Antiepileptic, Antiaxiety and Antipsychotic drugs, local anesthetics, C.N.S. stimulants, Drugs acting on A.N.S., Drugs acting on C.V.S., Antihistaminics, Bronchodilators, Skeletal muscle relaxants, Hypoglycemic, Antifertility agents and other hormones, Anti tumor agents, Anthelmentic and antiparasitic drugs.
6. Introduction to Bioequivalence studies: USP.

BOOKS RECOMMENDED:

3. Animal and Clinical Pharmacologic Techniques in Drug evaluation -- Nodine and Siegler.
6. Basic Laboratory Procedure in Clinical Buteriology; WHO.