

Pre- PhD Syllabus

Pre-PhD Papers

1. PS801: PHARMACEUTICAL LEGISLATIONS-I (General)
2. PS802: PHARMACEUTICAL LEGISLATIONS-II (D & C Act & Rules)
3. PS803: NANOPHARMACEUTICALS
4. PS804: PHYTOCHEMICAL METHODS
5. PS805: CHEMICAL AND BIOLOGICAL METHODS OF EVALUATION
6. PS806: ADVANCED PHARMACEUTICAL MICROBIOLOGY
7. PS807: ONCOLOGY — FUNDAMENTALS
8. DBT102: TECHNIQUES IN MOLECULAR BIOLOGY & GENETIC ENGG.
9. DBT205: IMMUNOLOGY & MEDICAL BIOTECHNOLOGY

PS801: PHARMACEUTICAL LEGISLATIONS-I (General)

1. Pharmacy Act

- 1.1 Objectives & Definitions of the terms involved in the Act:
 - 1. Register, Registered Pharmacist, Medical Practitioner, State & Central Councils
- 1.2 Constitution and Composition of Central & State Pharmacy Councils
- 1.3 Approval and Withdrawal of Courses of Study
- 1.4 Inspection of Institutions
- 1.5 Powers of Central & State Governments to make Rules
- 1.6 Composition of Joint -state Council and Inter-state Agreement
- 1.7 Inspection by State Council
- 1.8 Central Register, Preparation of first Register, Qualifications for entry in first Register & subsequent Registration, Removal from Register
- 1.9 Offences & Penalties

2. Pharmaceutical Ethics

- 2.1 Pharmacist Oath
- 2.2 Pharmacist in Relation to his Profession & Medical Professionals
- 2.3 Role of Pharmacist in Community Pharmacy, as Counselor & in connection to Preventive Diseases

3. History of Drug Legislation

- 3.1 Pharmaceutical Scenario in Post first World War period
- 3.2 Drug & Pharmaceutical Enquiry Committees
- 3.3 Import of Drug Bill & Introduction of Drug Act
- 3.4 Hathi & Mashelkar Committees
- 3.5 Drug Policy 1984 & 1996

4. Drug & Pharmaceutical Industry in India

- 4.1 Status of Pharmaceutical industry in Pre-Independence Era
- 4.2 Development of Bulk Drug & Formulation Production
- 4.3 Import & Export of Pharmaceuticals
- 4.4 Contribution of Multination Companies & Organized-Sector in Pharmaceutical Production
- 4.5 Status of Small-Scale Sector
- 4.6 Effect of -
 - 4.6.1 Tax-Free Zone on Pharmaceutical Industry
 - 4.6.2 Drug Price Control order on Pharmaceutical Industry
 - 4.6.3 Patent Acts and Rules on Pharmaceutical Industry

5. Factories Act (relevant to Pharmaceutical Industry)

- 5.1 Objectives & Definitions of terms involved in the Act:
 - Adult, Adolescent, Young Person, Manufacturing Process, Machinery Factory Workers, Calendar Year, Relay-shift
- 5.2 Requirement of Health & Safety
- 5.3 Disposal of Waste & Effluents
- 5.4 Provisions for Ventilation, Temperature Control & Artificial Humidification
- 5.5 Safety & Occupational Health Survey
- 5.6 Provisions of Occupier
- 5.7 Offence & Penalties

6. State-Shops & Establishments Act & Rules

- 6.1 Objectives
- 6.2 Registration of Establishment
- 6.3 Hours & Timings for Work
- 6.4 Wages & Leaves
- 6.5 Offences & Penalties

PS802: PHARMACEUTICAL LEGISLATIONS-II (D & C Act & Rules)

1. Definitions of Terms involved in the Act & Rules
Drugs, Ayurvedic, Shiddha & Unani Drugs, Patent & Proprietary Medicines, Homeopathic Medicines, New Drugs, Quality/Standards of Drugs, Misbranded & Spurious Drugs & Cosmetics, Adulterated Drugs, Manufacture, Import, Board, Inspector, Government Analyst, Registered Medical Practitioner, Whole-Sale, Retail-Sale, Cosmetics, etc.
2. Statutory Committees Under D & C Act & Rules
 - 2.1 Drug Technical Advisory Board-
 - 2.1.1 Constitution, and
 - 2.1.2 Functions
 - 2.2 Central Drug Laboratory (CDL)-
 - 2.2.1 Composition
 - 2.2.2 Functions, and
 - 2.2.3 Identification of CDL s' for Analysis different Classes of Drug Formulations.
 - 2.3 Central Drug Consultative Committee-
 - 2.3.1 Composition, and
 - 2.3.2 Functions
3. Manufacture/Import, Sale & Distribution (excluding Homeopathic Medicines)
 - 3.1 Procedure for Grant of Manufacturing/Loan License and License & Registration for import of Drugs
 - 3.2 Approval for Manufacture of New Drug & Procedure for Import of Drugs (including statements to accompany & Documents to be submitted to Custom)
 - 3.3 Prohibition for Manufacture & Import of Certain Drugs & Cosmetics
 - 3.4 Good Manufacturing Practices A
 - 3.5 Suspension & Cancellation of Sale, Manufacturing and Import License & Registration
 - 3.6 Redress of Grievances including Defence available to Wholesalers & Retailers
 - 3.7 Various Offences & their Penalties
4. Powers of Central & State Governments to make Rules
5. Licensing & Controlling Authorities:
 - 5.1 Drug Inspectors-
 - 5.1.1 Appointment, Powers & Duties
 - 5.1.2 Procedure of Inspection, Seizer & Dispatch of Samples for Analysis to Government Analyst/CDL
 - 5.1.3 Filing of Prosecution
 - 5.2 Government Analyst-
 - 5.2.1 Appointment & Duties
 - 5.2.2 Procedure of Receiving Sample
 - 5.2.3 Report of Results of Test & Analysis
 - 5.2.4 Legal Validity of Test & Analysis Reports as Evidence
6. Drug Schedules: Important Schedules Pertaining to
 - 6.1 Prescription Drugs (Schedule G & H)
 - 6.2 Exemptions from Certain Provisions (Schedule K) _
 - 6.3 Special Provisions for Biological Products (Schedule C & Cl)
 - 6.4 Blood & Biological Products (Schedule F)
 - 6.5 Psychotropic & Narcotic Drugs (Schedule X)
 - 6.6 Clinical Trials (Schedule Y)

PS803: NANOPHARMACEUTICALS

1. Need for Nanoparticulate Drug Delivery Systems, Role of Nanoparticulate Formulations in Drug Development, and Use of Nanotechnology in Drug Discovery.
2. Preparation of Nanoparticulate Dosage Forms. (High Pressure Homogenization - Wet milling, Solvent Evaporation, etc.)
3. Development of Intravenous and Oral Nanoparticulate Formulations.
4. In vitro Characterization and Physical & Chemical stability evaluation of Nanoparticulate Dosage Forms.(Particle—Size Distribution by Laser Diffraction, PCS, XRD, DSC, Zeta Potential etc. and changes there in during ageing)
5. In vivo performance of Nano Systems and their impact on Pharmacokinetics and Pharmacodynamics.
6. Limitations of Nano Dosage Forms with respect to Safety, Formulation, Processing and Stability.
7. Regulatory aspects of Nanoparticulate Formulations for use in Humans.

PS804: PHYTOCHEMICAL METHODS

1. General methods of plant analysis and their application; Isolation, Purification, Identification and characterization using Instrumental Chromatography and other modern analytical methods.
2. Application based discussion of — UV-VISIBLE spectroscopy, FT-IR spectroscopy, NMR spectroscopy, MASS spectroscopy and Elemental Analysis with special reference to Natural Products.
3. Chemistry of therapeutically important Phytoconstituents of Taxol, Podophyllum, Ginkgo, Ginseng and Artemisia.
4. General Pharmacological methods and statistical Analysis for representation of experimental data in the screening of new drugs belonging to following categories: Analgesic — antipyretics, anti-inflammatory, antipsychotic, antianxiety agents, antidepressant drugs, antiepileptics, antiulcer agents, anticonvulsants, antihypertensive, antidiabetics, antileprosy, antifilaria, local anaesthetics, anti-histaminics, antiemetics, androgenic, anabolic activity anovulatory agents.

BOOKS RECOMMENDED:

1. Screening Methods in Pharmacology by R.A. Tumer, Vol. I & II Academic Press, New York and London.
2. Fundamental of Experimental Pharmacology, by M..N. Ghosh, Scientific Book Agency, Calcutta.
3. Handbook of Experimental Pharmacology by S.S. Kulkarni. Vallabh Prakashen, Delhi.
4. Pharmacological Experiments on Intact and Isolated preparations, Edinburgh University Pharmacology Staff Livingstone.
5. Drug Discovery and evaluation by H.G. Vogel & W.H. Vogel. Springer Verlag, Berlin Heideleberg.
6. Phytochemical Methods by Harborne.
7. Spectrometric Identification of Organic Compounds by Silverstein
8. Instrtumental Methods of Analysis by Willard

PS805/MPS5001: CHEMICAL AND BIOLOGICAL METHODS OF EVALUATION

1. Application based discussion on UV—VIS spectroscopy, FT-IR spectroscopy, NMR spectroscopy, MASS spectroscopy, GC—MS, LC—MS and Elemental Analysis with special reference to synthetic medicinal agents.
2. Radio Ligand Assay — Basic Principles and Applications, Alternatives to animal Screening procedure.
3. General Pharmacological methods and statistical Analysis for representation of experimental data in the screening of new drugs belonging to following categories: Analgesic — antipyretics, anti-inflammatory, antipsychotic, antianxiety agents, antidepressant drugs, antiepileptics, antiulcer agents, anticonvulsants, antihypertensive, antidiabetics, antileprosy, antituberculosis, local anaesthetics, antihistaminics, antiemetics, androgenic, anabolic activity and ovulatory agents.

BOOK RECOMMENDED:

1. Screening Methods in Pharmacology by R.A. Turner, Vol. I & II Academic Press, New York and London.
2. Fundamental of Experimental Pharmacology, by M.N. Ghosh, Scientific Book Agency, Calcutta.
3. Handbook of Experimental Pharmacology, by S.S. Kulkarni. Vallabh Prakashan, Delhi.
4. Pharmacological Experiments on Intact and Isolated preparations, Edinburgh University Pharmacology Staff Livingstone.
5. Drug Discovery and evaluation by H.G. Vogel & W.H. Vogel. Springer Verlag, Berlin Heidelberg.
6. Spectrometric Identification of Organic Compounds by Silverstein.
7. Instrumental Methods of Analysis by Willard.

PS806: ADVANCED PHARMACEUTICAL MICROBIOLOGY

1. Classification of microbes & their taxonomy: Structure of bacterial cell, actinomycetes, rickettsia, fungi and virus
2. Isolation & Identification of microbes: Screening of soil and water for microbes, isolation of pure cultures, staining methods—simple and differential techniques, various biochemical techniques of identification of various bacterial genera
3. Development of media: Discussion on various types of media, interactions of ingredients, incompatibility of culture, sterilization problem of media on large scale, media optimization techniques.
4. Modification of microbes: General methods of mutation, mutating agents, biochemical basis of mutation, various process of isolation of mutants
1. 5 Sources and management of microorganisms: Problem in maintaining stable cultures, problem of degeneration and loss of strains, general methods of preservation of microbes used in industrial and laboratory scale.
5. Validation of sterilization process: Various sterilization techniques and their respective validation, biological indicator, sterility testing techniques.
6. Evaluation of antibacterial, antifungal and antiviral activity of natural and synthetic products by various standard methods.
7. Application of microbiology in detection, monitoring and control of environmental pollutants, Pathological basis of air and water borne disease

BOOKS:

1. Pelczar et al: Microbiology, 5th edn, Tata Mc Graw Hill, 1993
2. Hugo & Russell: Pharmaceutical Microbiology, 1st edn , Blackwell Scientific Publication, 1977
3. Controller of Publication: Pharmacopoeia of India, 4th edn, Vols I & II, 1996 ,
4. Strainer & Ingraham, General Microbiology, Wheelis & Painter`
1. S. Berger's Manual of Determinative Bacteriology
5. Sallee: Industrial Microbiology
6. Maier: Environmental Microbiology

PS807: ONCOLOGY — FUNDAMENTALS

Epidemiology, genetics, viruses, oncogenes, chemical carcinogenesis, radiation carcinogenesis, tumor growth, metastasis, biochemistry of cancer cells, tumor markers, hormones and cancer, cancer immunobiology, radiotherapy, chemotherapy and immunotherapy.

Application of deductive logic in formulating testable hypotheses in oncology research and designing experimental protocols to test such hypotheses.

DBT102: TECHNIQUES IN MOLECULAR BIOLOGY & GENETIC ENGG.

Nucleic acids: Isolation of genomic DNA from bacteria, plants and animal tissues, Organeller DNA, Plasmid DNA; conventional and column-based procedures to purify DNA; total cellular RNA and purification of mRNA.

Gel electrophoresis: Agarose and PAGE for DNA, formaldehyde—agarose for RNA, Denaturing gels, native PAGE, SDS—PAGE, IEF, 2-D gels, Southern, Northern and Western blotting and hybridization techniques.

Polymerase Chain Reaction; Thermostable DNA polymerases, primer designing, PCR technique and its variants, applications of PCR, Real Time PCR, RT-PCR, isothermal amplifications.

Recombinant DNA; X phage, plasmid, cosmid and fosmids based cloning and expression vectors, artificial chromosomes, preparation of inserts, ligation techniques, competent cells, transformation techniques, Ti plasmids and Agrobacterium mediated transformation, transfection.

Analyses of recombinant clones: Antibiotics based, blue—white colony selection, PCR based, excision of the insert and restriction analysis of the excised insert, Sequence analysis of the insert, analyses of gene expression (reporter gene and immuno detection)

Library preparation: Genomic DNA, cDNA, EST and reduced representation libraries. DNA microarray, DNA sequencing techniques.

Protein purification: Precipitation, ultra filtration, column based chromatographic techniques, peptide sequencing, mass spectroscopy in proteomic study, lab-scale production and IMAC purification of recombinant proteins.

Books Recommended:

1. Alberts et al, Molecular Biology of the Cell
2. Lodish et al, Molecular Cell Biology.
3. Walt Ream and Katharine Field, Molecular Biology Techniques: An Intensive
1. Laboratory Course
4. Old and Primorose- Gene Manipulation
5. Watson, Recombinant DNA.
6. Huang, et al, Genetic Engineering Techniques: Recent Developments
7. Sambrook, Maniatis and Fritz, Laboratory Manual: Molecular cloning

DBT205: IMMUNOLOGY & MEDICAL BIOTECHNOLOGY

Introduction to the immune system, antibodies — structure/function, structure and properties of antigens, identification and measurement of antibodies and antigens, biological aspects of antibody-antigen interaction, the genetic basis of antibody diversity, role of lymphocytes in humoral and cell—mediated immunity, major histocompatibility complex, monoclonal antibodies.

Immunology — Introduction & History, Innate and acquired immune system, Components of immune system, Complement, Hypersensitivity, Immunological disorders, Catalytic antibodies, Development of DNA Vaccines.

Microbial diseases, _diseases transmitted by animal, insects and ticks, sexually transmitted diseases, food and water born diseases, emerging and re-emerging infectious diseases.

Host-parasite relationship, distribution of normal flora in the body, interaction between commensals and human body, virulence and pathogenicity factors, pathogenesis of virus infections.

Life cycle and molecular biology involved in human immunodeficiency virus, malaria, hepatitis, tuberculosis, leishmaniasis and filariasis. Brief description od antimicrobial and antifungal agents used in chemotherapy.

Books Recommended:

1. Roitt, Essential immunology
2. Jareway et al, Immunology, the immune system in health and disease.
3. Das, H. K., Text book of Biotechnology, Wiley dreamtech India Pvt. Ltd.