GURU NANAK INSTITUTE OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

(An autonomous institute under MAKAUT)

M.PHARM SYLLABUS

Regulation 2020

2020-21

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Table : Course of Study for M. Pharm. (Pharmaceutical Biotechnology)

SEMESTER I

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
THEORY					
R20_MPB101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
R20_MPB102T	Microbial And Cellular Biology	4	4	4	100
R20_MPB103T	Bioprocess Engineering and Technology	4	4	4	100
R20_MPB104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
PRACTICAL					
R20_MPB105P	Pharmaceutical Biotechnology Practical I	12	6	12	200
R20_MPB106	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**700**

SEMESTER II

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
THEORY					
R20_MPB201T	Proteins and Protein Formulation-Theory	4	4	4	100
R20_MPB202T	Immunotechnology-Theory	4	4	4	100
R20_MPB203T	Computer Aided Drug Design	4	4	4	100
R20_MPB204T	Pharmaceutical Process Chemistry	4	4	4	100
PRACTICAL					
R20_MPB205P	Pharmaceutical Chemistry Practical II	12	6	12	200
R20_MPB206	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**700**

SEMESTER III

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
THEORY					
R20_MPT384T	Research Methods and Biostatistics	4	4	4	100
R20_MPT381	Journal Club	1	1	1	100
R20_MPT391	Discussion/Presentation	2	2	2	100
R20_MPT392	Research Work	28	14		100
Total		**35**	**21**	**7**	**400**

SEMESTER IV

Course Code	Name of the course	Credit hours	Credit points	Hrs./wk	Full Marks
R20_MPT481	Journal Club	1	1	1	100
R20_MPT491	Discussion/Final Presentation	3	3	3	100
R20_MPT492	Research Work	31	16		100
R20_MPT482	Co-curricular Activities	3	3	3	100
Total		**38**	**23**	**7**	**400**

Table - Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	23
Total Credit Points	96

REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm.) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B. Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B. Pharm.)

3. Duration of the program

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Phamacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

7.1. Credit assignment

7.1.1. Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

7.2. Minimum credit requirements

The minimum credit points required for the award of M. Pharm. degree is 95. However based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

8. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

SYLLABUS

Semester I

PHARMACEUTICAL BIOTECHNOLOGY

1ST SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(R20_MPB101T)

SCOPE

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoritical and practical skills of the instruments

THEORY 60 Hrs

1. (a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. 10 Hrs

(b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

(c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

(d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double 10 Hrs

resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 10 Hrs

4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: 10 Hrs

(a) Thin Layer chromatography
(b) High Performance Thin Layer Chromatography
(c) Ion exchange chromatography
(d) Column chromatography
(e) Gas chromatography
(f) High Performance Liquid chromatography
(g) Ultra High Performance Liquid chromatography
(h) Affinity chromatography
(i) Gel Chromatography

5. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 10 Hrs

(a) Paper electrophoresis (b) Gel electrophoresis (c) Capillary electrophoresis
(d) Zone electrophoresis (e) Moving boundary electrophoresis (f) Iso electric focusing X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

6. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. 10 Hrs

(a) Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

(b) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

(c) TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series

8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.

9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

MICROBIAL AND CELLULAR BIOLOGY

(R20_MPB102T)

SCOPE

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objectives

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

THEORY 60 Hrs

1. Microbiology - Introduction – Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms-examples and applications 12 Hrs

2. (i) Molecular Biology : Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. 12 Hrs

(ii) Central dogma of molecular biology: Replication, Transcription and translation.

(iii) Gene regulation : Gene copy number, transcriptional control and translational control.

(iv) RNA processing : Modification and Maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of

plasmids-types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny.

3. (i) Cell structure and function : Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications 12 Hrs

Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology–the life and death of cells in tissues.

(ii) Cell Cycle and Cytoskeleton : Cell Division and its Regulation, G-Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments**.**

(iii) Apoptosis and Oncogenes : Programmed Cell Death, Tumor cells, carcinogens & repair.

(iv) Differentiation and Developmental Biology : Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells and its Application.

4. (i) Principles of microbial nutrition : Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. 12 Hrs

(ii) Growth of animal cells in culture : General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses since in culture propagation and enumeration. In-vitro screening techniques- cytotoxicity, anti-tumor, anti-viral assays.

5. Microbial pathology : 12 Hrs

Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

REFERENCES

1. W.B. Hugo and A.D. Russel : Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.

2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.

3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.

4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.

5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.

6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.

7. Cell biology vol - I, II, III by Julio E. Cells

8. Bergeys manual of systematic bacteriology, Williams and Wilkins – A Waverly company.

BIOPROCESS ENGINEERING AND TECHNOLOGY

(R20_MPB103T)

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Objectives

At the completion of this subject it is expected that students will be able to,

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics

THEORY 60 Hrs

1. (i) Introduction to fermentation technology : Basic principles of fermentation 12 Hrs

(ii) Study of the design and operation of bioreactor : Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

(ii) Types of bioreactor: CSTR, tower, airlift ,bubble column, packed glass bead, hollow fiber, configuration and application

(ii) Computer control of fermentation process : System configuration and application

2. (i) Mass transfer : Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply 12 Hrs

of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

(ii) Rheology: Rheological properties of fermentation system and their importance in bioprocessing.

3. (i) Scale up of fermentation process : Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization. 12 Hrs

(ii) Cultivation and immobilized culture system : Cultivation system–batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

(iii) Introduction to immobilization : Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

4. (i) Scale down of fermentation process : Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery. 12 Hrs

(ii) Isolation and screening : Primary and secondary, maintenance of stock culture, strain improvement for increased yield.

5. Bioprocessing of the industrially important microbial metabolites 12 Hrs

(a) Organic solvents–Alcohol and Glycerol

(b) Organic acids–Citric acids, Lactic acids,

(c) Amino acids – Glutamic acids, Lysine, Cyclic AMP and GMP

(d) Antibiotics – Penicillin, Streptomycin, Griseofulvin,

(e) Vitamins – B12, Riboflavin and VitaminC

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids. Regulation governing the manufacturing of biological products.

REFERENCES

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.

2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.

3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.

4. Biotol Board, Bioreactor design and product yield, Butter worth and Helhemann Publishers.

5. H. Patel, Industrial microbiology, Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

(R20_MPB104T)

SCOPE

This paper has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Objectives

At the completion of this subject it is expected that students will be able to

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics.
- Learn the regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations.

THEORY 60 Hrs

1. Enzyme Technology : Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin. 12 Hrs

2. Genetic Engineering : Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E. coli and yeast. 12 Hrs

Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences. Gene library and c DNA

Applications of the above technique in the production of,
Regulatory proteins - Interferon, Interleukins
Blood products – Erythropoietin
Vaccines - Hepatitis-B
Hormones – Insulin

3. (i) Therapeutic peptides : Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. 12 Hrs
(ii) Transgenic animals : Production of useful proteins in transgenic animals and gene therapy.
(iii) Human Genome : The human genome project – a brief study, Human chromosome–Structure and classification, chromosomal abnormalities – Syndromes

4. (i) Signal transduction : Introduction, cell signalling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development,cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signalling defects and diseases. 12 Hrs
(ii) Oncogenes : Introduction, definition, various oncogenes and their proteins.

5. (i) Microbial Biotransformation : Biotransformation for the synthesis of chiral drugs and steroids. 12 Hrs
(ii) Microbial Biodegradation :
Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring.
(iii) Biosensors : Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

REFERENCES

1. Biotechnology-The biological principles : MD Trevan, S Boffey, K H Goulding and P.F. Stanbury.

2. Immobilization of cells and enzymes : Hosevear Kennadycabral & Bickerstaff

3. Principles of Gene Manipulating : RW Old and S.B. Primrose.

4. Molecular Cell Biology : Harvey Lodish, David Baltimore, Arnold Berk, S Lawence Zipursky, Paul Matsudaira, James Darnell.

5. Modern Biotechnology: S.B Primrose

6. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray

7. Current protocols in Molecular Biology, Vo1.I & II : F.M. Asubel, John wiley Publishers

8. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.

9. Principles of human genetics ; by Curt Stern, published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I
(R20_MPB105P)

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from thesoil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV-survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS–polyacrylamide gel electrophoresis for proteins

26. Polymerase chain reaction technique.

SYLLABUS

Semester II

PHARMACEUTICAL BIOTECHNOLOGY

2ND SEMESTER

PROTEINS AND PROTEIN FORMULATIONS

(R20_MPB201T)

SCOPE

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Objectives

At the completion of this course it is expected that students will be able to understand,

- Various methods of purification of proteins
- Peptides in drug development
- Protein identification and characterization
- Protein based formulations Sequencing proteins

THEORY 60 Hrs

1. Protein engineering : Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution. 12 Hrs

2. Peptidomimetics : Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics. 12 Hrs

3. (i) Proteomics : Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N- and C-terminal tags 12 Hrs

(ii) 2-Dimensionalgelelectrophoresis: Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

4. Protein formulation : Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre formulation, Liposomes, Neon-spears, Neon-particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein. 12 Hrs

5. Methods of protein sequencing : Various methods of protein sequencing, characterisation, Edman degradation, Trypticand/or Chymotryptic Peptide Mapping. 12 Hrs

REFERENCES

1. H. Lodhishet. Al. Molecular Cell Biology, W.H. Freeman and Company
2. Protein Purification –HandBook, Amersham pharmacia biotech
3. Engelbert Buxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J.Park, Jennifer R. Cochran, Protein Engineering and Design, C R C press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins – Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA, Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization ,and Stability of Protein Drugs, Kluwer Academic Publishers.

IMMUNOTECHNOLOGY

(R20_MPB202T)

SCOPE

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology - based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R & D .

Objectives

After this course, the students will be able to:-

- Understand the techniques like immunodiagnostic tests,
- Characterization of lymphocytes, purification of antigens and antibody, etc.
- Access health problems with immunological background;
- Develop approaches for the immune intervention of diseases

THEORY 60 Hrs

1. (i) Fundamental aspects of immunology : 12 Hrs

Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure. Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity.

(ii) Humoral Immunity : B–Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies.

(iii) Cell mediated Immunity : Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis.

2. Immune Regulation and Tolerance : Complement activation and types and their biological functions, cytokines and their role in immune response. 12 Hrs

(ii) Hypersensitivity : Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment

(iii) Autoimmune diseases

.**3. (i) Vaccine technology :** Vaccine and their types, conventional vaccines, novel methods for vaccine production, anti idiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics. 12 Hrs

(ii) Stem cell technology : Stem cell technology and applications to immunology

4. Hybridoma Technology :

Hybridoma techniques – fusion methods for myeloma cells and B Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry. 12 Hrs

5. (i) Immunological Disorder : 12 Hrs

Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

(ii) Immuno diagnosis : Antigen antibody interaction – Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.

REFERENCES

1. J. Kubey, Immunology – an Introduction.

2. S.C. Rastogi, Immunodiagonstics, New Age International.

3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.

4. E. Benjamini, Molecular Immunology.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY
(R20_MPB203T)

SCOPE

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objectives

Upon completion of this course it is expected that the students will be able to understand,

- Use of computers in developing a new drugs
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

THEORY 60 Hrs

1. (i) Introduction to Bioinformatics : 12 Hrs

Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics,

(ii) Biological Database : Protein and nucleic acid databases. Structural databases. Collecting and storing the sequence and Applications of Bioinformatics.

2. Sequence analysis : Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis. 12 Hrs

3. (i) Protein informatics : Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing. 12 Hrs

(ii) Protein structure prediction : Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

(iii) Docking : Docking problems, methods for protein - ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.

4. (i) Diversity of Genomes : Prokaryotic and Eukaryotic Gene Families. Genome Analysis : Introduction, Gene prediction methods, Gene mapping and applications – Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression. 12 Hrs

(ii) Completed Genomes : Bacterium, Nematode, Plant and Human

(iii) Evolution of Genomes : Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome – General Account

(iv) Phylogenetic analysis : Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide

Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.

5. Target searching and Drug Designing : Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis,and prediction of drug quality. 12 Hrs

REFERENCES

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S.C. Rastogiet. al. Bioinformatics-Concepts Skill and Applications, CBS Publishers and Distributors
3. T.E. Creighton, Protein Structure and Molecular Properties,W.H.Freeman and Company
4. Andreas D. Baxevanis, B. F.Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
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6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY

(R20_MPB204T)

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objectives

- At the completion of this subject it is expected that students will be able to,
- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs in vitro and in vivo

THEORY 60 Hrs

12 Hrs

1. (i) Biological Standardization : General principles, Scope and limitation of bio-assay, bioassay of some official drugs.

(ii) Preclinical drug evaluation : Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED 50 and LD 50 determination, special toxicity test like teratogenecity and mutagenecity.

(iii) Guidelines for toxicity studies : Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

12 Hrs

2. (i) Pyrogens : Pyrogens : Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests.

(ii) Microbiological assay : Assay of antibiotics and vitamins.

(iii) 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).

3. (a) Biologic Medicines in Development for various diseases - By Therapeutic Category : 12 Hrs

(i) Genetic Disorders

(ii) Eye related Disorders

(iii) Digestive Disorders

(iv) Diabetes/Related Conditions

(v) Cardiovascular Disease

(vi) Cancer/Related Conditions

(vii) Blood Disorders

(viii) Autoimmune Disorders

(ix) Infectious Diseases

(x) Neurologic Disorders

(xi) Skin Diseases

(xii) Organ Transplantation

(b) Biologic Medicines in Development for various diseases –by Product Category :

(i) Antisense

(ii) Vaccines

(iii) Recombinant Hormones/Proteins

(iv) Monoclonal Antibodies (mAb)

(v) Interferons

(vi) Growth Factors

(vii) Gene Therapy

(viii) RNA Interference

4. (i) Regulatory aspects : drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. 12 Hrs

(ii) Regulatory consideration : Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals

5. (i) Bioavailability : Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability. Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio- availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals. 12 Hrs

(ii) Pharmacokinetics : Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.

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1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay : Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A.Turner.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II

(R20_MPB205P)

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations
7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random/specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

SYLLABUS

Semester III

PHARMACEUTICAL BIOTECHNOLOGY

3RD SEMESTER

RESEARCH METHODOLOGY & BIOSTATISTICS

(R20_MPT384T)

UNIT–I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, cross over design, placebo, blinding techniques.

UNIT–II

Biostatistics : Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT–III

Medical Research : History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT–IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal

hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT–V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.