ANNA UNIVERSITY, CHENNAI
NON-AUTONOMOUS COLLEGES AFFILIATED TO ANNA UNIVERSITY
M.TECH BIOPHARMACEUTICAL TECHNOLOGY
REGULATIONS - 2021
CHOICE BASED CREDIT SYSTEM
I TO IV SEMESTERS CURRICULA AND I SEMESTER SYLLABUS

SEMESTER I

S. NO.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.	BO4101	Drug Regulatory, Quality and Safety Management	PCC	3	0	0	3	3
2.	BO4102	Formulation of Pharmaceuticals	PCC	3	0	0	3	3
3.	BO4103	Molecular Pharmacology	PCC	3	0	0	3	3
4.	RM4151	Research Methodology and IPR	RMS	2	0	0	2	2
5.		Professional Elective I	PEC	3	0	0	3	3
6.		Professional Elective II	PEC	3	0	0	3	3
7.		Professional Elective III	PEC	3	0	0	3	3
8.		Audit Course I*	AC	2	0	0	2	0
PRACTICALS								
9.	BO4111	Formulation and Quality Control Methods for Pharmaceuticals Laboratory	PCC	0	0	4	4	2
			TOTAL	**22**	**0**	**4**	**26**	**22**

***Audit Course is Optional**

SEMESTER II

S. NO.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
THEORY								
1.	BO4201	Pharmacokinetics and Pharmacodynamics	PCC	3	0	0	3	3
2.	BO4202	Immunopharmacology	PCC	3	0	0	3	3
3.	BO4203	Conventional and Rational Drug Discovery Strategies	PCC	3	0	0	3	3
4.		Professional Elective IV	PEC	3	0	0	3	3
5.		Professional Elective V	PEC	3	0	0	3	3
6.		Audit course II*	AC	2	0	0	2	0
7.		Open Elective	OEC	3	0	0	3	3
PRACTICALS								
8.	BO4211	Immunopharmacology Laboratory	PCC	0	0	6	6	3
9.	BO4212	Mini project with seminar	EEC	0	1	2	3	2
			TOTAL	**20**	**1**	**8**	**29**	**23**

***Audit Course is Optional**

SEMESTER III

S. NO.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
PRACTICALS								
1.	BO4311	Modern Methods of Pharmaceutical Analysis Laboratory	PCC	0	0	6	6	3
2.	BO4312	Computational methods in Pharmaceuticals Laboratory	PCC	0	0	6	6	3
3.	BO4313	Drug Discovery Laboratory	PCC	1	0	4	5	3
4.	BO4314	Project Work I	EEC	0	0	12	12	6
		TOTAL		**1**	**0**	**28**	**29**	**15**

SEMESTER IV

S. NO.	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1.	BO4411	Project Work II	EEC	0	0	24	24	12
		TOTAL		**0**	**0**	**24**	**24**	**12**

TOTAL NO. OF CREDITS: 72

SEMESTER I, ELECTIVES I

S. NO	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1.	BO4001	Clinical Trials and Bioethics	PEC	3	0	0	3	3
2.	BO4002	Bioconjugate Technology and Applications	PEC	3	0	0	3	3
3.	BO4003	Biogenerics and Biopharmaceuticals	PEC	3	0	0	3	3
4.	BO4004	Techniques in Molecular Biology and Genetic Engineering	PEC	3	0	0	3	3

SEMESTER I, ELECTIVES II

S. NO	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1.	BO4005	Advances in Omics Sciences and Technology	PEC	3	0	0	3	3
2.	BY4251	Metabolic Process and Engineering	PEC	3	0	0	3	3
3.	BO4006	Chemistry of Natural Products	PEC	3	0	0	3	3
4.	BO4007	Modern Methods of Pharmaceutical Analysis	PEC	3	0	0	3	3

SEMESTER I, ELECTIVES III

S. NO	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1	BO4008	Protein Engineering and Industrial Applications	PEC	3	0	0	3	3
2	BO4009	Microbial Technology	PEC	3	0	0	3	3
3	BO4010	Molecular Medicine and Mechanism	PEC	3	0	0	3	3
4	BO4011	Applied Statistics for Biologists	PEC	2	1	0	3	3

SEMESTER II, ELECTIVES III

S. NO	COURSE CODE	COURSE TITLE	CATE-GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1.	BY4071	Biomaterials and Tissue Engineering	PEC	3	0	0	3	3
2.	BO4012	Computational Systems Biology	PEC	3	0	0	3	3
3.	BO4013	Novel Drug Delivery Systems	PEC	3	0	0	3	3
4.	BO4014	Nanobiotechnology	PEC	2	1	0	3	3

SEMESTER II, ELECTIVES iV

S. NO	COURSE CODE	COURSE TITLE	CATE GORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1.	BO4015	Advances in Pharmacogenomics	PEC	3	0	0	3	3
2.	BO4016	Gene Manipulation Technology	PEC	3	0	0	3	3
3.	BO4017	Human physiology and Drug Metabolism	PEC	3	0	0	3	3
4.	BO4018	Fermentation Technology	PEC	3	0	0	3	3

AUDIT COURSES (AC)

Registration for any of these courses is optional to students

SL. NO	COURSE CODE	COURSE TITLE	PERIODS PER WEEK			CREDITS
			L	T	P	
1.	AX4091	English for Research Paper Writing	2	0	0	0
2.	AX4092	Disaster Management	2	0	0	0
3.	AX4093	Constitution of India	2	0	0	0
4.	AX4094	நற்றமிழ் இலக்கியம்	2	0	0	0

BO4101 DRUG REGULATORY,QUALITY AND SAFETY MANAGEMENT L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Enable the students to learn about the various agencies in drug regulatory affairs in India and at International level.
- Acquire knowledge about intellectual property rights, drug development approval processes and safety management.

UNIT I INTRODUCTION TO DRUG REGULATORY LAWS 9

Drugs and Cosmetics Act 1940 with its amendments, The Drugs (Price Control) Order 2013 with its amendments, The Environmental Protection Act-1986 with its amendments, Consumer Protection Act-2019, TheFactories (amendment) Act-1987 and Pollution control Act-1989, The Indian Patents and Designs, Act 1911, The Grugs and Magic Remedies (Objectionable advertisements) Act 1954, Prevention of Food Adulteration Act 1954, Guidelines for evaluation of nanopharmaceuticals in India

UNIT II PHARMACOPOEIA 8

Descriptions & Monographs; Standards and Specifications; Testing of Drugs; Various Countries Pharmacopoeias; Indian, British, U.S, European, Japanese and International pharmacopoeia.

UNIT III cGMPs& REGULATORY RECORDS 10

cGMP concepts – Development, Manufacturing Record, Analytical &process Validation,Equipment & utility Qualification and Calibration, Personnel procedures; Regulatory bodies &requirements - Indian FDA, WHO GMP ; U.S. FDA, U.K. MCA, Australian TGA, Japanese PMDA.Drug dossier contents - CTD (CMC section) & data.

UNIT IV DRUG DEVELOPMENT APPROVAL PROCESS/CLINICAL TRIALS 8

Drug development stages, FDA guidelines on IND, NDA, ANDA approvals. European regulatory agency: types of filing process (Centralized, decentralized, RMS countries), Regulation of preclinical studies, Schedule-Y, pre-clinical study; Introduction to animal ethics; Animal rights and use of animals in the advancement of medical technology; Introduction to laws and regulations regarding the use of animals in research.

UNIT V PRODUCT MANAGEMENT AND QUALITY ASSURANCE 10

GLP, ISO 9000, TQM, Quality Review and Quality Documentation, Regulatory control, regulatory drug analysis, interpretation of analytical data, Basic requirements - design of product, facility,equipment selection and personnel. Industrial hazards due to fire, accident, mechanical, electricalequipment, monitoring and preventive system (Safety measures including insurance).Effluent testing, treatment and waste management. Safety and Environmental Control; ISO 14000.

TOTAL:45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Enable the students to learn the principles of drug regulation.

CO2 Insight about current regulatory process in the pharmaceutical industry.

CO3 Assure the learning of quality standards in pharmaceutical industry.

REFERENCES:

1. N Udupa and Krishnamurthy Bhat. A Concise Textbook of Drug Regulatory Affairs , Manipal University Press, Edition: 1, 2015
2. Manohar A. Potdar and Ramkumar Dubey. cGMP Current Good Manufacturing Practices for Pharmaceuticals, Pharmamed Press / Bsp Books, Second Edition, 2018.
3. Abraham, John and Smith, H.W. "Regulation of the Pharmaceutical Industry", Palgrave,Macmillan, 2003.
4. Weinberg, Sandy "Good Laboratory Practice Regulations" 4th Edition, Marcel Dekker,2007.
5. Gad, Shayne C. "Drug Safety Evaluation", Wiley-Interscience, 3rd Edition, 2016.
6. Malik, Vijay "Laws Relating to Drugs and Cosmetics Act & Rules". EBC Publishing Co, 2018.
7. "Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials", Vol. I & II, World Health Organization and Pharma Syndicate, 2002.
8. Berry, Ira R. and Harpaz, Daniel "Validation of Active Pharmaceutical Ingredients", 2ndEdition, CRC Press, 2001.
9. British Pharmacopoeia, Andesite Press, 2021.
10. United States Pharmacopoeia, 2020
11. https://cdsco.gov.in/opencms/opencms/en/Home/
12. https://pharmaceuticals.gov.in/

BO4102 FORMULATION OF PHARMACEUTICALS L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Enable the students to acquire theoretical knowledge in pharmaceutical dosage forms
- Understand the theoretical principles with application oriented problems.

UNIT I INTRODUCTION TO DOSAGE FORMS 5

History & Evolution; Definitions and Classification of Dosage forms and routes of administration (Oral, Parenteral, Topical, Rectal and Nasal), Pharmacokinetics/Pharmacodynamics parameters for Dosage form development

UNIT II PREFORMULATION AND STABILITY STUDIES 9

Physical properties of drugs - physical form, polymorphism, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic property and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs – hydrolysis, oxidation, reduction, polymorphisms racemization, polymerization and their influence on formulation and stability of products. Stabilization and stability testing protocol for various pharmaceutical products.

UNIT III SOLID DOSAGE FORMS 9

Capsules: Materials for production of hard/Soft gelatin capsules, size of capsules and method of capsule filling. Soft gelatin Capsule Manufacturing and evaluation - Micro-encapsulation-Classification, Methods of preparation and Evaluation of microcapsules. Tablets: Classification, tablet formulation excipients, Tablet Manufacturing methods: Wet granulation, dry granulation, direct compression methods. Tabletting machinery, processing problems and evaluation. Coating- Types, materials for coating, formulation, equipment, film defects and evaluation of coated tablets.

UNIT IV LIQUID, SEMI-SOLID AND AEROSOL DOSAGE FORMS 12

Liquid Dosage forms: Additives in formulations, vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubilizer, colors, flavors, manufacturing, packaging and evaluation of clear liquids, suspensions and emulsions official in pharmacopoeia. Semisolid Dosage Forms: Mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semisolids, clear gels, formulations of semisolids Cream, Gel, Paste; Suppositories, manufacturing procedure, evaluation and packaging. Aerosols: Types of propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation.

UNIT V PARENTERALS AND DRUG DELIVERY OF LARGE MOLECULES 10

Parenteral; Liquids, (Solutions, Suspensions and Emulsions); Nasal; Ophthalmic and Optic Preparations; Packaging dosage design & delivery. Delivery systems for Peptides and Proteins – Delivery of Nucleic acids Antibodies and siRNA.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Have learnt Pharmacokinetics/Pharmacodynamics parameters for dosage form development.

CO2 Learn formulation of various dosage forms of drugs.

CO3 Learn evaluation of various dosage forms of drugs.

CO4 Have knowledge of technological advancements to improve formulations at the completion course.

REFERENCES:

1. Ansel, H.C. “Pharmaceutical Dosage Forms and Drug Delivery Systems”, 11th Edition, LippincottWilliams &Wilkins, 2018.
2. Misra, Ambikanandan, Shahiwala, Aliasgar “Novel Drug Delivery Technologies”, 1st Edition, Springer, 2019
3. Lieberman, H.A. “Pharmaceutical Dosage Forms: Tablets”. Vol.1-3, 2nd Edition, Marcel Dekker, 2005.
4. Lieberman, H.A. “Pharmaceutical Dosage Forms: Parenteral Medications”, Vol.1-3, 2nd Edition, Marcel Dekker, 2005.
5. Lieberman, H.A. “Pharmaceutical Dosage Forms: Disperse Systems”, Vol.1-3, 2nd Edition,Marcel Dekker, 2005.
6. Vyas S.P, Khar K.R. “ Targeted & Controlled Drug Delivery -Novel Carrier Systems”, 1st Edition, CBS Publishers, 2012.
7. Surendra Nimesh, Ramesh Chandra, Nidhi Gupta.”Nanotechnology for the Delivery of Therapeutic Nucleic Acids”. 1ST Edition, Woodhead Publishing, 2017.
8. Manfred Ogris, David Oupicky. “Nanotechnology for Nucleic Acid Delivery”.1st Edition Humana Press, 2013.

BO4103 MOLECULAR PHARMACOLOGY L T P C

3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Study the mechanism of action of drugs at molecular level and different molecular targets.
- Provide advanced knowledge about pharmacology of drugs and toxicology.

UNIT I MOLECULAR MECHANISM OF DRUG ACTION 10

Basic concepts in molecular pharmacology: agonists, antagonists and inverse agonists; potency, intrinsic activity and efficacy; Transducer mechanisms of receptors; Receptor occupancy theory and cellular signalling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidylinositol. Ion channels and their modulators: measurement of binding and response, Voltage-gated ion channels. G protein-coupled receptors, G proteins and effectors, Mechanism of G protein-mediated signalling: - Wnt, hedgehog and notch; Signal transduction through tyrosine kinases; Receptors regulating gene expression.

UNIT II RECEPTORS AND THEIR MODE OF ACTION 8

Angiotensin receptors Excitatory amino acid receptors Kinin receptor, Adrenoceptors, Low molecular weight heparins, hirudins and GP IIB/IIIa receptor antagonists, Cholinergic receptors, Dopamine receptors, Serotonin receptors, Hormone receptors, GABA and Benzodiazepine receptors, Opioid receptors, Purinergic receptors, Glutamate receptors.

UNIT III BIOACTIVE MOLECULES 8

Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX- 2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators.

UNIT IV OVERVIEW OF DRUGS ACTING ON VARIOUS SYSTEMS 10

Central nervous system, Autonomic nervous system, Autacoids, Analgesic, Antipyretic, and Anti-inflammatory Agents, Renal and cardiovascular system, Anti Infective agents, Hormones, Hematopoietic agents.

UNIT V TOXICOLOGY 9

Principles of toxicology, Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinetics, mutagenesis and carcinogenesis, Acute, sub-acute and chronic toxicity studies according to guidelines. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC, WHO.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to

CO1 Develop research skills based on the knowledge gained about molecular basis of drug action.

CO2 Provide an insight about bioactive molecules, receptors and different classes of drugs in pharmacology.

CO3 Acquire knowledge on performing toxicity studies with appropriate guidelines.

REFERENCES:

1. Laurence Brunton, Bjorn Knollmann, RandaHilal-Dandan, “Goodman and Gilman’s: The Pharmacological basis of therapeutics”, McGraw-Hill Education / Medical, 13th edition, 2017.
2. Tripathi, K.D. “Essentials of Medical Pharmacology”, Jaypee Brothers Medical Publishers, 8 th edition, 2018.
3. RS Satoskar Nirmala Rege SD Bhandarkar, “Pharmacology and PharmacoTherapeutics”, Elsevier India, 26 th edition, 2020.
4. Francesco Clementi (Editor), Guido Fumagalli (Editor), “General and Molecular Pharmacology: Principles of Drug Action”, Wiley, 1st edition, 2015.
5. Karen Whalen, “Lippincott Illustrated Reviews: Pharmacology”, Lippincott Williams and Wilkins, 7th Edition, 2019.

6. James Ritter, Rod Flower, Graeme Henderson, Yoon Kong, Loke David, Mac Ewan Humphrey Rang "Rang and Dales Pharmacology", Elsevier, 9 th edition, 2018.
7. Katzung, B.G., "Basic and Clinical Pharmacology", 14th Edition, McGraw Hill 2017.

RM4151 RESEARCH METHODOLOGY AND IPR L T P C
2 0 0 2

UNIT I RESEARCH DESIGN 6

Overview of research process and design, Use of Secondary and exploratory data to answer the research question, Qualitative research, Observation studies, Experiments and Surveys.

UNIT II DATA COLLECTION AND SOURCES 6

Measurements, Measurement Scales, Questionnaires and Instruments, Sampling and methods. Data - Preparing, Exploring, examining and displaying.

UNIT III DATA ANALYSIS AND REPORTING 6

Overview of Multivariate analysis, Hypotheses testing and Measures of Association. Presenting Insights and findings using written reports and oral presentation.

UNIT IV INTELLECTUAL PROPERTY RIGHTS 6

Intellectual Property – The concept of IPR, Evolution and development of concept of IPR, IPR development process, Trade secrets, utility Models, IPR & Bio diversity, PCT, Role of WIPO and WTO in IPR establishments, Right of Property, Common rules of IPR practices, Types and Features of IPR Agreement, Trademark, Functions of UNESCO in IPR maintenance.

UNIT V PATENTS 6

Patents – objectives and benefits of patent, Concept, features of patent, Inventive step, Specification, Types of patent application, process E-filling, Examination of patent, Grant of patent, Revocation, Equitable Assignments, Licences, Licensing of related patents, patent agents, Registration of patent agents.

TOTAL: 30 PERIODS

REFERENCES:

1. Cooper Donald R, Schindler Pamela S and Sharma JK, Business Research Methods, Tata McGraw Hill Education, 11e (2012)
2. Intellectual property: patents, trademarks, copyrights, trade secrets. By Catherine J. Holland. Entrepreneur Press, 2007
3. Patent searching: tools & techniques. By David Hunt, et al. Wiley, 2007.
4. Professional Programme Intellectual Property Rights, Law and practice, The Institute of Company Secretaries of India, Statutory body under an Act of parliament, September 2013

BO4111	FORMULATION AND QUALITY CONTROL METHODS FOR PHARMACEUTICALS LABORATORY	L T P C 0 0 4 2

COURSE OBJECTIVES:

The course aims to

- Provide hands on experience on different forms of drug formulation
- Learn the quality control methods available for evaluation of pharmaceuticals.

PART I: FORMULATION EXPERIMENTS

1. Preparation of Nano Emulsions.
2. Preparation of Lyophilised powder
3. Preparation of solid dosage forms (Eg. Granules, Tablets, Capsules)
4. Preparation of liquid dosage forms (Eg. True Solutions, mixtures, Elixirs)
5. Preparation of biphasic dosage forms (Eg. Emulsion, Suspension)
6. Preparation of semisolid dosage forms (Eg. Ointments, Creams, Gels, lotions
7. Preparation of Parenteral and ophthalmic formulations
8. Preparation of specialized dosage forms (Eg. Suppositories, Patches)

PART II: QUALITY CONTROL METHODS FOR PHARMACEUTICALS

1. Disintegration test, weight variation.
2. Particulate matter, Transmittance of light, Viscosity, Extractables and leachable, Freeze-Thaw test.
3. pH, Dissolution, Sedimentation volume, Rheological method, Zeta potential measurement,
4. Particle size distribution, In-vitro release testing,
5. Leakage test, Pyrogen test, Sterility, Particulate matter, Preservative efficacy test.
6. Sprays & Inhalations – Valve discharge rate, Spray pattern & Plume geometry, Dosage with metered valves, Foam stability.
7. Net content and Weight loss, pH, Osmolality.
8. Stability testing for all dosage forms.

EQUIPMENTS REQUIRED

1. Mortar and Pestle
2. Sieves of all sizes
3. Granulator
4. Punching machine
5. Capsule filler
6. Disintegration, dissolution and friability testing apparatus
7. Formulation reagents (surface acting agents, glidants, diluents etc,)
8. pH meter, physical balances

TOTAL: 60 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Develop of different dosage forms of drugs.
CO2 Learn the evaluation of various dosage forms of drugs.
CO3 Get knowledge of developing new formulation.
CO4 Find out the stability of the dosage forms
CO5 Have hands on experience in dosage form formulation and pursue a career in industry.

REFERENCES:

1. Ansel, H.C. "Pharmaceutical Dosage Forms and Drug Delivery Systems", 11th Edition, Lippincott Williams & Wilkins, 2018.
2. Lieberman, H.A. "Pharmaceutical Dosage Forms: Tablets". Vol.1-3, 2nd Edition, Marcel Dekker, 2005.
3. Lieberman, H.A. "Pharmaceutical Dosage Forms: Parenteral Medications", Vol.1-3, 2nd Edition, Marcel Dekker, 2005.
4. Lieberman, H.A. "Pharmaceutical Dosage Forms: Disperse Systems", Vol.1-3, 2nd Edition,Marcel Dekker, 2005.
5. Lachman, Leon "The Theory And Practice of Industrial Pharmacy", 4th Edition, Varghese Publishing House, 2013.
6. USP NF, guidelines: http://www.usp.org, https://www.uspnf.com, & http://www.fda.gov.

BO4001 CLINICAL TRIALS AND BIOETHICS L T P C
3 0 0 3

OBJECTIVES

- To introduce the fundamentals of clinical trial design and conduction
- Provide the learning of regulations and ethical practice in clinical research.

UNIT I INTRODUCTION TO CLINICAL TRIALS 8

Fundamentals of Clinical Trials – Introduction to terminology – Clinical Trial Phases – Need of trials – Problems in the Timing of a Trial – Study Protocol – Basic statistics for clinical trials – Clinical trials in practice – Reporting and reviewing clinical trials.

UNIT II REGULATIONS OF CLINICAL TRIALS 9

Good clinical practice – Principles of ICH-GCP – Responsibilities – Functions – Operations of IRB/IEC – Investigator – Sponsor – Trial protocol and amendment(s) – Investigator Brochure; Legislation and good clinical practice – Overview of the European directives and legislation governing clinical trials in the 21st century – International perspectives of clinical trials.

UNIT III STUDY DESIGN AND POPULATION 12

Design - Randomized Control Trials – Nonrandomized Concurrent Control Studies – Historical Controls and Databases –Cross-Over Designs – Withdrawal Studies – Factorial Design – Group Allocation Designs – Hybrid Designs – Large, Simple and Pragmatic Clinical Trials - Studies of Equivalency and Noninferiority – Adaptive Designs; **Randomization –** Fixed Allocation Randomization – Adaptive Randomization Procedures – Mechanics of Randomization; **Blinding –** Types of Blinding – Protecting the Double-Blind Design – Debriefing of Participants; **Recruitment –** Considerations Before Participant Enrollment – Conduct – Monitoring; **Population** – Potential for Benefit – Likelihood of Benefit – Avoiding Adverse Effects – Competing Risk – Avoiding Poor Adherers – Pharmacogenetics – Recruitment of Study Participants.

UNIT IV ETHICAL ISSUES 8

Planning and Design – Ethics Training – Randomization Control Group – Protection from Conflicts of Interest – Informed Consent – Conduct – Trials in Low and Middle Income Countries – Recruitment – Safety and Efficacy Monitoring – Early Termination for other than Scientific and Safety Reasons – Privacy and Confidentiality – Data Falsification.

UNIT V QUALITY CONTROL AND ASSURANCE & DATA ANALYSIS 8

Quality control and assurance procedures – Performance monitoring – Training procedures – Assurances and certifications – Site visiting procedures – Audit procedures; Analysis datasets – Frequentist vs Bayesian analysis – Final analysis – Subgroup analysis; Pharma covigilance; Research governance; Trial closure and pitfalls-trial closure; Reporting and legal requirements; Common pitfalls in clinical trial management.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

- Acquire the fundamentals of clinical trials and the way of preparation of study protocol.
- Know the implementation of guidelines and responsibilities of various stakeholders of clinical trials.
- Learn the way of design of study and recruitment procedures of study participants.
- Know the ethical practices of acquirement of informed consent and trial conduction.
- Learn to assess the quality of clinical trials through monitoring and auditing procedure.

REFERENCES:

1. Lawrence M.Friedman et. al, “Fundamentals of Clinical Trials”, Mosby,1996
2. Curtis L Meinert et. al, “Clinical Trials - Design Conduct and Analysis”, Oxford University, 2012.
3. ICH - Harmonised Tripartite Guideline – Guideline for Good Clinical Practice E6 (R1) - Current Step 4 version - dated 10 June 1996.
4. Lee, Chi-Jen et. al, “Clinical Trials or Drugs and Biopharmaceuticals.” CRC/Taylor & Francis, 2011.
5. Matoren, Gary M. “The Clinical Research Process In The Pharmaceutical Industry. “Marcel Dekker, 1984.

BO4002 BIOCONJUGATE TECHNOLOGY AND APPLICATIONS L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Provide advanced theoretical knowledge on Bioconjugate technologies.
- Learn about the biological and clinical applications of bioconjugate technology.

UNIT I MODIFICATION OF FUNCTIONAL TARGETS 9

Modification of amino acids, peptides and proteins – modification of sugars, polysaccharides and glycoconjugates – modification of nucleic acids and oligonucleotides.

UNIT II CHEMISTRY OF ACTIVE GROUPS 9

Amine reactive chemical reactions – Thiol reactive chemical reactions – carboxyl reactive chemical reactions – hydroxyl reactive chemical reactions – aldehyde and ketone reactive chemical reactions - Photoreactive chemical reactions.

UNIT III BIOCONJUGATE REAGENTS 9

Zero length cross linkers – Homo bifunctional crosslinkers – Hetero bifunctional cross linkers – Trifunctional cross linkers – Cleavable reagent systems – tags and probes.

UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION 9

Properties of common enzymes – Activated enzymes for conjugation – biotinylated enzymes– chemical modification of nucleic acids – biotin labeling of DNA- enzyme conjugation toDNA – Fluorescent of DNA.

UNIT V BIOCONJUGATE APPLICATIONS 9

Preparation of Hapten-carrier Immunogen conjugates - antibody modification and conjugation – immunotoxin conjugation techniques – liposome conjugated and derivatives-Colloidal – gold labeled proteins – modification with synthetic polymers.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Understand target bio-molecules target and their active groups for conjugation.

CO2 Get knowledge about different types of bio-conjugate reagents.

CO3 Have exposured to conjugation of enzymes, antibody and nucleic acid and the application of the conjugated products.

REFERENCES:

1. Chemistry of bioconjugates : synthesis, characterization, and biomedical applications / edited by Dr. Ravin Narain, Department of Chemical and Materials Engineering, University of Alberta, Edmonton, Alberta, Canada.
2. Hermanson, G.T. “Bioconjugate Techniques”. Academic Press 3rd edition, 2013.
3. Sam Massa and Nick Devoogdt (eds.), Bioconjugation: Methods and Protocols, Methods in Molecular Biology, vol. 2033, Springer Science+Business Media, LLC, part of Springer Nature 2019.
4. Sonny S. Mark (ed.), Bioconjugation Protocols: Strategies and Methods, Methods in Molecular Biology vol. 751, DOI 10.1007/978-1-61779-151-2_1, © Springer Science+Business Media, LLC 2011.
5. Chrostof M.Niemeyer (Eds) Methods in Molecular Biology. 283. Bioconjugation Protocols Strategies and Methods. Humana Press.

BO4003 BIOGENERICS AND BIOPHARMACEUTICALS L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Introduce the students about biogenerics and biosimilars and their characterization using analytical methods.
- Correlate the conceptual learning of biopharmaceuticals with their therapeutic equivalence using case studies.

UNIT I BIOGENERICS INTRODUCTION 9

Definition: Generics and its advantages; Biogenerics and Biosimilars; why biosimilars are not (bio) generics; The advent of Biosimilars; The role of patents in the drug industry; Protein-based biopharmaceuticals; Manufacturing processes; Global market; International Non-proprietary Names (INN) nomenclature system biosimilars regulation (EU position, US pathways, Government initiatives)

UNIT II BIOSIMILARS AND ITS SCENARIO 9

Approved follow-on proteins/Biosimilars; Characteristics of high selling peptides and proteins,; Products with expired patents; Challenging originator's patents; Target products for FOB (follow-on biologics) /Biosimilars development peptides; Recombinant Non Glycosylated proteins; Recombinant glycosylated proteins; Industries dealing with biogenerics and its market value; World scenario; Indian scenario.

UNIT III CHARACTERIZATION OF BIOSIMILARS 9

Approaches to the characterization of biosimilars; Problems in characterizing biologics(Types of biologic, Peptides, Non-glycosylated proteins, Glycosylated proteins, Monoclonal antibodies); Equivalence issues; Post-translational modifications; Effect of microheterogeneity; Pharmacokinetics; Pharmacodynamics; and Clinical efficacy; Analytical Methods for the characterization of biosimilars (Chromatography, Protein sequencing, Mass Spectrometry, UV absorption, Circular dichroism, X-ray techniques, Nuclear magnetic resonance, Electrophoresis, Western blotting, Bioassays, ELISA, Immunoprecipitation and other procedures)

UNIT IV IMMUNOGENICITY OF BIOPHARMACEUTICALS 9

Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing to immunogenicity, (product-related factors and host-related factors), consequence of immunogenicity to biopharmaceuticals; Measurement of immunogenicity.

UNIT V CASE STUDIES 9

Case studies: Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon Granulocyte-macrophage-CSF, DNase, Factor VIIa, Factor IX, Factor VIII, Activated protein C, Tissue plasminogen activator, Monoclonal antibodies etc., Immunogenicity of biopharmaceuticals: Immunogenicity; Factors contributing.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,
CO1 acquire knowledge about biopharmaceutical production.
CO2 update with the regulatory aspects of biosimilars.
CO3 learn about production and characterization of biopharmaceuticals.

REFERENCES:

1. Niazi, Sarfaraz K. "Handbook of Biogeneric Therapeutic Proteins: Regulatory,Manufacturing, Testing, and Patent Issues". CRC Press, 2006.
2. Ho, Reedney J. Y., MiloGibaldi. "Biotechnology & Biopharmaceuticals TransformingProteins and Genes into Drugs", 2nd edition, 2013

BO4004 TECHNIQUES IN MOLECULAR BIOLOGY AND GENETIC ENGINEERING L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to
- Enlighten key molecular biology and genetic engineering techniques
- Apply the latest techniques in current biological research as well as in biotechnology industries.

UNIT I VECTOR SYSTEMS 9

Overview of tools in recombinant DNA technology. Artificial chromosomes – YACs and BACs. Principles for maximizing gene expression – expression vectors, pMal, GST, pET-based vectors. Protein purification – His-tag, GST-tag and MBP-tag. Intein-based vectors; Inclusion bodies; methodologies to reduce formation of inclusion bodies; mammalian expression and replicating vectors; Baculovirus and Pichia vectors system, plant based vectors, Ti and Ri plasmids as vectors, yeast vectors and shuttle vectors.

UNIT II ASSAY TECHNIQUES IN MOLECULAR BIOLOGY 8

Nuclease protection assays, Nuclease S1 mapping, Reporter assays – Mono and dual reporter assays, Electrophoretic mobility shift assay (EMSA) / Gel shift assay, Run-off transcription assay, Phage display, Ribosome display, Gene silencing – siRNAs and Morpholinos.

UNIT III HIGH-THROUGHPUT DNA SEQUENCING 9

Preparation of Next Generation Sequencing (NGS) libraries: Fragmentation versus tagmentation, end repair, clonal amplification – Bridge PCR and emulsion PCR. Basics and steps involved in NGS platforms: Illumina/Solexa, Roche 454, Ion-torrent and Pacific biosciences. Current status of Oxford nanopore sequencing. Principles of Mate pair sequencing, ChIP-seq, RIP/CLIP-Seq, Methyl seq – Restriction enzyme, enrichment and bisulfite treatment strategies.

UNIT IV GENE EXPRESSION ANALYSIS 10

Overview of gene expression and its significance. Hybridization methods: Southern and Northern. PCR methods: Reverse transcriptase PCR, End point Vs Real time PCR, Relative quantitation, Absolute quantification – Standard curve method and digital PCR. Endogenous/loading controls. High throughput analysis: Multiplex PCR, Microarray, Serial analysis of gene expression (SAGE) and Small Amplified RNA-SAGE (SAR-SAGE), Total analysis of gene expression (TOGA), Gene calling, RNA-seq and Ribosome profiling.

UNIT V GENOME EDITING TECHNOLOGIES 9

Basics and applications of genome editing methods - Zinc-finger nuclease (ZFN), Transcription activator-like effector nucleases (TALEN), Mega nucleases, CRISPR-Cas systems – Types and applications, Homing endonucleases, Transposons and Cre/lox P systems. Gene delivery systems – Physicochemical methods and viral vectors.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course the students will be able to

CO1 Acquire knowledge on the strength and limitations of tools and techniques used in molecular biology and genetic engineering.

CO2 Apply knowledge of basic principles and steps involved in DNA/RNA sequencing methods and current protocols of specific vs global gene expression analysis.

CO3 Analyse the current techniques involved in gene editing to generate appropriate genetically modified organisms.

REFERENCES:

1. Steven R. Head, Phillip Ordoukhanian, Daniel R. Salomon. “Next Generation Sequencing: Methods and protocols” 1st Edition, Humana Press, 2018.
2. Krishnarao Appasani. “Genome Editing and Engineering” Cambridge University press 2018.
3. Raghavachari Nalini, Garcia-Reyero Natàlia. “Gene expression analysis: Methods and protocols” 1st Edition, Humana Press, 2018.
4. Primrose SB and Twyman RB. “Principles of Gene manipulation and Genomics”. 7th Edition, Wiley-Blackwell, 2006.
5. Green MR and Sambrook J. “Molecular Cloning: A Laboratory Manual”. 4th Edition, CSHL press, 2012.

BO4005 ADVANCES IN OMICS SCIENCES AND TECHNOLOGY L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Provide advanced theoretical knowledge on the organization and function of genome
- Understand the principles of functional genomic analyses
- Have knowledge on the advanced methods and approaches in proteomics.

UNIT I MICROARRAYS IN GENOMICS 9

Microarrays, types, Designing and production of microarrays; cDNA microarray technology; Oligonucleotide arrays; Sample preparation, labeling, hybridization, generation of microarray data. Transcriptomics using cDNA and oligonucleotide arrays.

UNIT II NEXT GENERATION SEQUENCING TECHNOLOGIES 9

Overview of Next Generation Sequencing (NGS) technologies; Principles of NGS by Roche/454, Illumina, Life Technologies, Pacific Biosciences, Ion Torrent technologies; Applications of NGS to disease diagnosis and personalized medicine.

UNIT III PROTEIN MICROARRAYS AND YEAST TWO-HYBRID SYSTEM 9

Types of protein arrays; Protein microarray fabrication; Experimental analysis of proteins arrays. Data acquisition and processing; Applications of protein microarray types. Principles and methods in yeast two-hybrid system, Advances in yeast two hybrid system and its applications.

UNIT IV TWO-DIMENSIONAL GEL ELECTROPHORESIS OF PROTEINS 9

Sample preparation, First-dimension IEF with IPG; Second dimensional separation of proteins; Image analysis of 2-DE gels; DIGE, Protein expression profiling and comparative proteomics of complex proteomes using 2-DE.

UNIT V MASS-SPECTROMETRY 9

Basics of Mass-spectrometry (MS) and bimolecular analysis; Common ionization methods for peptide/protein analysis; Principles of Time of Flight (TOF), Ion Trap (IT), and Orbitrap mass analyzers; Mass spectrometry based proteomics: MALDI-TOF, Nano-LC-MS; Gas- chromatography coupled to Mass spectrometry; Mass-spectrometry analysis of Post-Translational Modifications of proteins.

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Understand the designing and application of microarray.

CO2 Have knowledge in next generation sequencing technologies and their use in diagnosis and personalised therapy.

CO3 Have exposure to protein analysis using high end technology such as MALDI-TOF, and 2Dgel Electrophoresis.

REFERENCES:

1. Schena M. (2000) DNA Microarrays - A Practical Approach. Oxford University Press.
2. Rinaldis E. D. and Lahm A (2007) DNA Microarrays. Horizon bioscience.Causton,H.C.
3. Muller H. J. and Roder T. (2006) Microarrays. Elsevier Academic Press.
4. Causton H. C., Quackenbush J., and Brazma A. (2004) A Beginner's Guide.
5. Schena M. (2005) Protein Microarrays. Jones and Bartlett Publishers.
6. O'Connor C. D. and Hames B. D. (2008) Proteomics. Scion Publishing Ltd.
7. Hoffman E. D. and Stroobant V. (2007) Mass Spectrometry – Principles and Applications, John Wiley & Sons Ltd.

BY4251 METABOLIC PROCESS AND ENGINEERING L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Familiarize the student with quantitative approaches for analyzing cellular metabolism and the use of theoretical and experimental tools that can give insights into the structure and regulation of metabolic networks.
- Identify the optimal strategy for introducing directed genetic changes in the microorganisms with the aim of obtaining better production strains.

UNIT I METABOLIC FLUX ANALYSIS 9

Introduction to metabolic engineering, comprehensive models of cellular reactions with stoichiometry and reaction rates; metabolic flux analysis of exactly/over/under determined systems. Shadow price, sensitivity analysis.

UNIT II EXPERIMENTALTOOLS FOR DETERMINING FLUX THROUGH PATHWAY 9

Monitoring and measuring the metabolome, Experimental determination of metabolic fluxes by isotope labeling metabolic fluxes using various separation –analytical techniques. GC-MS for metabolic flux analysis, genome wide technologies: DNA /phenotype microarrays and proteomics.

UNIT III CONSTRAINT BASED GENOMIC SCALE METABOLIC MODEL 9

Development of Genomic scale metabolic model, in-silico Cells: studying genotype-phenotype relationships using constraint-based models, case studies in E. coli, Scerevisiae metabolic network reconstruction methods, optimization of metabolic network, Identification of targets for metabolic engineering; related software and databases for genome scale modeling.

UNIT IV METABOLIC CONTROL ANALYSIS AND KINETIC MODELING 9

Fundamental of Metabolic Control Analysis, control coefficients and the summation theorems, Determination of flux control coefficients. Multi-substrate enzyme kinetics, engineering multifunctional enzyme systems for optimal conversion, and a multi scale approach for the predictive modeling of metabolic regulation.

UNIT V CASE STUDIES IN METABOLIC ENGINEERING 9

Metabolic engineering examples for bio-fuel, bio-plastic and green chemical synthesis. Study of genome scale model in various systems for the production of green chemicals using software tools. Reconstruction and Validation of the model with experimental parameters.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 understand the fundamentals of metabolic engineering.
CO2 learn experimental tools for determination of metabolic fluxes.
CO3 develop *in-silico* genome-scale metabolic model.
CO4 have experience in metabolic engineering with exposure to various case studies.

REFERENCES:

1. Stephanopoulos, G.N. “Metabolic Engineering: Principles and Methodologies”. Academic Press / Elsevier, 2012.
2. Lee, S .Y. and Papoutsakis, E.T. “Metabolic Engineering”. Marcel Dekker, 1999.
3. Nielsen, J. and Villadsen, J. “Bioreaction Engineering Principles”. Springer, 2007.

4. Smolke, Christiana D., “The Metabolic Pathway Engineering Handbook Fundamentals”, CRC Press Taylor & Francis, 2010.
5. Voit, E.O. “Computational Analysis of Biochemical Systems: A Practical Guide for Biochemists and Molecular Biologists”. Cambridge University Press, 2000.
6. Scheper, T. “Metabolic Engineering” Vol 73 (Advances in Biochemical Engineering Biotechnology) Springer, 2001.
7. Cortassa, S. et al, “ An Introduction to Metabolic and Cellular Engineering”, World Scientific Publishing, 2002.
8. Kholodenko, Boris N and H. V. Westerhoff “Metabolic Engineering in the Post GenomicEra”, Horizon Bioscience, 2004.

BO4006 CHEMISTRY OF NATURAL PRODUCTS L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Enhance theoretical knowledge of students in the chemistry of natural products
- Explore this knowledge for practical applications.

UNIT I CARBOHYDRATES AND RELATED COMPOUNDS 7

Sugars and sugar containing drugs, polysaccharides and polysaccharide containing drugs, cellulose gums and mucilages, pectin.

UNIT II GLYCOSIDES AND TANNINS 9

Biosynthesis of glycosides, Phenol and alcohol glycosides, anthraquinone glycosides, cyanophore glycosides, saponin glycosides, cardiac glycosides, isothiocyanate flavonol lactone glycosides, tannins, volatile oils, resins and resin combinations.

UNIT III ALKALOIDS AND PURINES 10

Pyridine and piperidine alkaloids, Tropane alkaloids, Quinoline Alkaloids, isoquinoline alkaloids, Indole alkaloids, Imidazole alkaloids, Steroidal alkaloids, Alkaloidal amines and purine bases. Chemistry and structural elucidation of uric acid, interrelation between caffeine, theophylline and theobromine.

UNIT IV VITAMINS, TERPENOIDS AND FLAVONOIDS 10

Chemistry, medicinal and pharmaceutical uses of vitamin A, D, E, K, B_1, B_2, B_6, B_{12} and Folic Acid. Chemistry and structural elucidation of Terpenes, camphor, menthol, carotenes. Classification and application of flavonoids (hespiridine, rutin, quercetin).

UNIT V MOLECULES FROM NATURAL SOURCES 9

Classification of Drug molecules of Plant/marine/microbial and animal sources - cytotoxic / antineoplastic agents, cardiovascular drugs - antimicrobial substances – anti-inflammatory and anti-spasmodic agents.

TOTAL :45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1: Comprehend the medicinally important carbohydrates and related compounds from natural origin

CO2: Explain the biosynthetic pathways and chemistry of important secondary metabolites including glycosides and alkaloids.

CO3: Obtain knowledge on vitamins, terpenoids and flavonoids and some harmaceutically important molecules from natural sources.

REFERENCES:

1. Evans, W.C., 'Trease and Evans Pharmacognosy', 16th Edition, Saunders, 2009.
2. Wallis, T.E. "Textbook of Pharmacognosy", 5th Edition, CBS Publishers, 2005.
3. Kokate, C.K. "Pharmacognosy", 29th Edition, Nirali Prakashan, 2004.
4. O.P. Agarwal, Chemistry of Natural Products (Vol.-1 & 2), 41st edition, Goel publishing House, 2014.
5. Varro E. Tyler, Lynn R. Brady, James E. Robbers, Pharmacognosy, 9th edition, Published by Lea & Febiger, 2011.
6. Gurdeep Chatwal, Organic Chemistry of Natural Products (Vol. 1 & 2), Himalaya Publishing House, 2015.
7. I.L.Finar, "Organic chemistry" Volume 2, 5th edition, Published by Pearson India, 2012.

BO4007 MODERN METHODS OF PHARMACEUTICAL ANALYSIS L T P C

3 0 0 3

COURSE OBJECTIVE:

- To enable students to acquire knowledge in various advanced analytical techniques used in the screening of pharmaceutical agents.

UNIT I UV-VISIBLE SPECTROSCOPY 9

Brief introduction of spectroscopy, EMR and principle of absorptions by molecule. The absorption law – Beer's and Lambert's law, limitations and Chromophores and their interaction with EMR, Theory of electronic transition theory, choice of solvent and solvent effects, modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (various qualitative and quantitative methods), Woodward – Fischer rules for calculating absorption maximum.

UNIT II IR SPECTROSCOPY AND THERMAL METHODS OF ANALYSIS 9

Infrared radiation, theory of IR absorption by a molecule, vibrational frequency and factors influencing vibrational frequency, rotational degrees of freedoms, transmission/absorption modes, types of bands, instrumentation and sampling techniques, interpretation of spectra, applications in pharmaceuticals. FT-IR-theory and applications, Attenuated Total Reflectance (ATR).Instrumentation and applications of thermal methods - Thermo Gravimetric Analysis (TGA),Differential Scanning Calorimetry (DSC), Differential Thermal Analysis (DTA) and Thermo Mechanical Analysis (TMA).

UNIT III NUCLEAR MAGNETIC RESONANCE PECTROSCOPY 9

Basic theory of NMR/PMR, excitation/emission process and instrumentation. solvents, reference compound, scale of measurement, shielding/deshielding; chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling and shift reagents, proton exchange reactions, FT- NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in pharmaceuticals, spectral interpretations, ^{13}C NMR, Natural abundance and applications.

UNIT IV MASS SPECTROMETRY 9

Basic principles, instrumentation and ionization methods; precursor ion/product ion production and fragmentation pattern; atmospheric pressure ionization (API), Chemical ionization (CI), Field Ionization (FI), Fast Atom Bombardment (FAB), Matrix assisted laser desorption ionization(MALDI), Time of Flight (TOF), hybridization with other techniques, and interpretation of mass spectrum and applications in pharmaceuticals.

UNIT IV CHROMATOGRAPHIC METHODS 9

Classification of chromatographic methods on mechanism of separation: High Performance Liquid Chromatography : Principle, instrumentation, solvents, packing materials and applications in pharmaceuticals; Gas Chromatography: principle, theory, column operations, instrumentation, derivatisation methods and applications in pharmaceuticals; HPTLC and Super Critical Fluid Chromatography (SFC): Theory, instrumentation, elution techniques and pharmaceutical applications; Principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Iso-electric focusing (IEF) and applications.

TOTAL: 45 PERIODS

COURSE OUTCOME:

- The student would have learnt various advanced analytical techniques for identification, separation, purification and quantification of pharmaceutical agents from various biological sources.

REFERENCES

1. "Chromatographic Analysis of Pharmaceuticals", John A. damovics,2nd edition, 1996.
2. "HPTLC – Quantitative Analysis of Pharmaceutical Formulations"– P. D. Sethi,1990.
3. "Identification of Drugs and Pharmaceutical Formulations by Thin LayerChromatography"– P. D. Sethi, Dilip Charegaonkar, 2nd Edition, 2014.
4. "Instrumental Methods of Analysis"– Hobert H. Willard, 7th Edition, 1992.
5. "Instrumental Methods of Chemical Analysis"– B. K. Sharma - 9th Edition,2000.
6. "Liquid Chromatography – Mass Spectrometry", W.M.A.Niessen, J. Van Der Greef, Vol.58,2006.
7. "Organic Chemistry" by I.L.Finar Vol. II – 5thedition, 1956
8. "Organic Spectroscopy"– William Kemp, 3rd Edition, 1991.
9. "Pharmaceutical Analysis – Modern Methods"– Part A, Part B, James W.Munson–2001.
10. "Practical Pharmaceutical Chemistry", Part II, A. H. Beckett &J. B. Stenlake, 4th Edition,2015.
11. "Principles of Instrumental Analysis" by Donglas A. Skoog, James, J. Leary, 4th Edition,1992.
12. "Spectrometric Identification of Organic Compounds", Robert. M. Silverstein Et Al, 8th edition, 2014.
13. "Spectroscopy of Organic Compounds" by P. S. Kalsi, 2007.
14. "Techniques and Practice of Chromatography"– Raymond P. W. Scott, Vol. 70,2003.
15. "Vogel's Text Book of Quantitative Chemical Analysis", 6th Edition, 2004.

BO4008 PROTEIN ENGINEERING AND INDUSTRIAL APPLICATIONS L T P C
3 0 0 3

COURSE OBJECTIVE:

- To provide advanced knowledge of proteins and their structure function relationship, essential for future pharmaceutical technology.

UNIT I INTRODUCTION 6

Amino acids, primary structure of proteins, amino acid composition, industrial significance, primary structure determination by chemical methods including automated sequencing and by gene sequencing, significance of primary structure determination, peptide synthesis, secondary structure and super secondary structures

UNIT II PROTEIN ARCHITECTURE 6

Tertiary structure of proteins, types of proteins, domains, quaternary structure, protein complexes, protein-protein interactions

UNIT III STRUCTURE-FUNCTION RELATIONSHIP 15

DNA-binding proteins: prokaryotic transcription factors, Helix-turn-Helix motif in DNA binding, Trp repressor, Eucaryotic transcription factors, Zn fingers, helix-turn helix motifs in homeodomain, Leucine zippers Membrane proteins: General characteristics, Transmembrane segments, prediction, bacteriorhodopsin and Photosynthetic reaction center Immunoglobulins: IgG Light chain and heavy chain architecture, Abzymes and Enzymes: Serine proteases, understanding catalytic design by engineering trypsin, chymotrypsin and elastase, substrate assisted catalysis other commercial applications.

UNIT IV PROTEIN ENGINEERING METHODS 9

Protein engineering methods, amino acid side chain reactions, chemical modification of proteins, site-directed mutagenesis, posttranslational modifications and engineering.

UNIT V INDUSTRIAL APPLICATIONS OF PROTEIN ENGINEERING 9

Examples of industrial protein engineering applications Engineering of serine proteases, engineering of antibodies, engineering of proteins for thermal stability, engineering of proteins for preventing aggregation, His-tagged proteins in purification, engineering proteins for secretion, de novo protein synthesis.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

On completion of the course, students will learn the functional characteristics of various types of proteins and engineering of proteins for production of new protein pharmaceutics.

REFERENCES:

1. Alberghina, L. “Protein Engineering in Industrial Biotechnology”. Harwood Academic Publications, 2000.
2. Branden C. and Tooze J., “Introduction to Protein Structure”, 2nd Edition, Garland Publishing,1999.
3. Creighton, T.E. “Proteins: Structure and Molecular Properties”, 2nd Edition, W.H.Freeman, 1993
4. Holland, I Barry et al., “ABC Proteins: From Bacteria to Man”. Academic Press Elsevier, 2003.
5. Moody P.C.E. and Wilkinson A.J. “Protein Engineering”. IRL Press, Oxford, 1990.
6. Rees, A.R., Sternberg, M.J.E. and Wetzel, R. “Protein Engineering: A Practical Approach”. IRL Press, 1992
7. Voet, D. and Voet, G., “Biochemistry”. 4th Edition, John Wiley and Sons, 2001.
8. Whitford, David “Proteins: Structure and Function”. John Wiley & Sons, 2005.

BO4009 **MICROBIAL TECHNOLOGY** **L T P C**
3 0 0 3

COURSE OBJECTIVE:

- To provide fundamental knowledge of pharmaceutical microbiology and microorganisms associated with the manufacture of pharmaceuticals

UNIT I BIOLOGY OF MICROORGANISMS 9

Introduction – Microscopy - Structure and form of the bacterial cell – size, shape and structure of the cell wall and cytoplasmic membrane - Appendages to the bacterial cell - Capsules and slime - Bacterial spore - process of spore formation – Germination of spores – Toxins produced by bacteria – Yeasts and moulds - Introduction – Structure- Cell wall - Properties of selected fungi - Saccharomyces cerevisiae, Neurospora crassa, Penicillium, Aspergillus, Epidermophyton, Microsporum and Trichophyton

UNIT II INFECTIOUS DISEASES 9

Introduction - Spread of infection - Common source infections – Principles of microbial pathogenicity and epidemiology - Properties of selected pathogens – Staphylococcus, Streptococcus, Neisseria, Clostridium, Listeria, Pseudomonas, Vibrio, Yersinia, Haemophilus, Escherichia, Salmonella, Shigella, Proteus, Helicobacter- Chlamydia, Rickettsia, Mycobacterium – Spirochetes – Borrelia, Treponema and Leptospira, Candida and Cryptococcus

UNIT III ANTIBIOTICS AND OTHER ANTIMICROBIAL AGENTS 9

Antibiotics – definition, sources and types of antibiotics – penicillins, cephalosporins – Lincomycins, Tetracyclines, Rifamycins and Macrolides – Structure- activity relationships – Pharmacokinetic properties – Antifungals - synthetic antimicrobial agents – Mechanism of action – Bacterial resistance to antibiotics – Antivirals – Methisazone, nucleoside analogues – interferons – Clinical uses of antimicrobial agents

UNIT IV MICROBIAL ASPECTS OF PHARMACEUTICAL PROCESSING 9

Ecology of microorganisms as it affects the pharmaceutical industry - Microbial spoilage and preservation of pharmaceutical products - Contamination of non-sterile pharmaceuticals in hospitals and community Environments - Principles and practice of sterilization - Sterilization control and sterility assurance - Sterile pharmaceutical products - Factory and hospital hygiene and good manufacturing practice

UNIT V BIOCATALYST TECHNOLOGY 9

Advantages and disadvantages of biocatalysis over chemical catalysis; Different types of biocatalysis: Microbial, enzymatic and immobilized system of biocatalysis; Current industrial biocatalysis; Biocatalysis with different enzymes: Lipase, amidase/ aminopeptidase, Acylase, Hydantoinase, lyases, Oxidoreductase, Nitrilase, Epoxide hydrolase, Hydroxylase, Aldolases, Decarboxylase;

TOTAL : 45 PERIODS

COURSE OUTCOME:

- The students would have learnt various aspects of pharmaceutical microbiology include the research and development of anti-infective agents, the use of microorganisms to detect mutagenic and carcinogenic activity in prospective drugs, and the use of microorganisms in the manufacture of pharmaceutical products.

REFERENCES:

1. Ching T. Hou. Handbook of Industrial Biocatalysis. CRC Press, 2019.
2. Frank Austen, K., Burakoff, S.J., Fred Rosen, Terry B. Strom, Therapeutic Immunology, Blackwell Science, Boston, 3rd Edition, 2006.

3. Hugo, W.B. and Russell, A.D. Pharmaceutical Microbiology – 8th Edition – Wiley-Blackwell, 2011
4. Mims C.A. The Pathogenesis of Infectious Disease, 6th Edition - London: Academic Press, 2015.
5. Thomas J. Kindt, Barbara A. Osborne, Richard A. Goldsby, Kuby Immunology, W.H., Freeman & Co, San Francisco, 6th Rev. Edition, 2006.

BO4010 MOLECULAR MEDICINE AND MECHANISM L T P C
3 0 0 3

COURSE OBJECTIVES:

The course aims to,

- Understand the molecular mechanism of the disease and advanced understanding of drug interactions.
- Learn the molecular organisation of different organ systems and its functions.

UNIT I INTRODUCTION TO MOLECULAR MEDICINE 9

Organization of the Human Genome, Chromosomes and Genes – Recombinant DNA and Genetic Techniques – Transcriptional Control of Gene Expression – transmission of Human Genetic Disease –Human Genome Project – Cell Cycle Oncogenes and Tumor suppressor Genes – Molecular Diagnostic Testing – Genetic Counseling – Transgenic Mice as Models of Disease, Introduction to gene therapy.

UNIT II CARDIOLOGY 9

Molecular Cardiology Congenital Heart Disease – Inherited Cardiomyopathies – Coronary Atherosclerosis – Endothelium – Derived Nitric Oxide and Control of Vascular Tone – Hypertension – Cardiac Arrhythmias – Cardiovascular Gene Therapy.

UNIT III PULMONOLOGY 9

Asthma – Cystic Fibrosis – Pulmonary Emphysema – Surfactant Deficiency – Lung Cancer: The Role of Tumor Suppressor Genes – Strategies for controlling the diseases.

UNIT IV ENDOCRINOLOGY 9

Mechanisms of Hormone Action – Diabetes Mellitus – Pituitary Function and Neoplasia Hormone Deficiency- Disorders –Thyroid Disorders – Disorders of the parathyroid Gland – Congenital Adrenal Hyperplasia– Adrenal Disease – Multiple Endocrine Neoplasia Type, Mechanisms of Hypoglycemia Associated with increased Insulin Production.

UNIT V NEPHROLOGY 9

Renal Development – Mechanisms of Leukocyte Extravasation – Ischemic Acute Renal Failure – Potassium Secretory Channels in the Kidney – Alport Syndrome – Nephrogenic Diabetes Insipidus – Polycystic Kidney Disease – Renal Neoplasms: Wilms' Tumor and Renal-Cell Carcinoma.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Learn about the human genome, molecular diagnostic testing and gene therapy.

CO2 Learn about various physiological systems in the human body and genetic disease associated to them.

CO3 Understand the molecular mechanism of the treatments for these genetic disease.

REFERENCES:

1. Jameson, J. L., Francis, S.C., "Principles of Molecular Medicine", Human Press, 1998.
2. Ross, D.W. "Introduction to Molecular Medicine", 3 rd Edition, Springer, 2002.
3. Ross, D.W. "Introduction to Oncogenes and Molecular Medicine", Springer, 1998.
4. Pasternak, J.J. "An Introduction to Human Molecular Genetics", 2 ndEdition, Wiley Liss, 2005.
5. Strachan, Tom and Andrew P. Read. "Human Molecular Genetics, Bios, 1996.

BO4011 APPLIED STATISTICS FOR BIOLOGISTS L T P C
2 1 0 3

COURSE OBJECTIVES:

The course aims to,

- Study the fundamentals of statistics.
- Apply the fundamentals of statistics in relation to biological and biotechnological problems.

UNIT I PROBABILITY 9

Random variable-sample spaces-Events-Axiomatic approach to probability-conditional probability-additional theorem, Multiplication theorem -Bayes theorem problems-continuous and discrete random variables, Distribution function-Expectation with properties-Moments, mean, Variance problems-for continuous and discrete distributions.

UNIT II DISTRIBUTION 9

Bivariate distribution-conditional and marginal distribution-Discrete distribution-Binomial, Poisson, geometric distribution-Continuous distribution, Normal, exponential and negative exponential, gamma distributions-simple problems-properties.

UNIT III METHODS OF CORRELATION 9

Correlation coefficient, properties-problems-Rank correlation-Regression equations problems- curve fitting by the method of least squares-fitting curves of the form ax^2+bx+c, ab^x and ax^b -Bivariate correlation application to biological problems.

UNIT IV SAMPLING 9

Concept of sampling-Methods of sampling-sampling distributions and Standard Error-Small samples and large samples-Test of hypothesis-Type I, Type II Errors-Critical region-Large sample tests for proportion, mean-Exact test based on normal, t, f and chi-square distribution-problems- Test of goodness of fit.

UNIT V DESIGN OF EXPERIMENT 9

Basic principles of experimentation - Analysis of variance-one-way, Two-way Classifications - Randomized block design, Latin square design - problems.

TOTAL : 45 PERIODS

COURSE OUTCOMES:

At the end of the course the student will be able to,

CO1 Understand basic probability and distribution in statistics.

CO2 Learn correlation and regression with sampling in biological experiments.

CO3 Design experiments and justify the statistical significance of the results of the experiment in testing hypothesis.

CO4 Understand and apply statistical methods of analysis in biological research.

REFERENCES:

1. Kapoor, V. K. “Elements of Mathematical statistics”3rd edition,2002. .
2. Vittal, P.R. and V.Malini.”Statistical and Numerical Methods”. Margham Publications. 2012.
3. Veerarajan,T. “Probability, Statistics and Random Processes”.3rd Edition., Tata McGraw- Hill, 2008.
4. Johnson, R. A.”Miller& Freund’s Probability and Statistics for Engineers”. 6 ed. PHI, 2003.
5. Arora, P. N. SmeetArora, and Arora, S. “Comprehensive Statistical Methods”. S. Chand & Co,1997.
6. Spiegel, Murray R., J.Schiller and R. AluSrinivasan. ”Schaum’sOutlines Probability and Statistics”, 2nd Edition. Tata McGraw-Hill 2000.
7. Kandasamy, P. K. Thilagavathi& K. Gunavathi.”Probability Statistics and Queuing Theory”. S. Chand & Co., 2004. 61 61 Course Articulation Matrix Course Outcome Statements rogramme Outcome (PO) 1 2 3 4 5

AUDIT COURSES

AX4091 ENGLISH FOR RESEARCH PAPER WRITING L T P C
2 0 0 0

COURSE OBJECTIVES

- Teach how to improve writing skills and level of readability
- Tell about what to write in each section
- Summarize the skills needed when writing a Title
- Infer the skills needed when writing the Conclusion
- Ensure the quality of paper at very first-time submission

UNIT I INTRODUCTION TO RESEARCH PAPER WRITING 6

Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT II PRESENTATION SKILLS 6

Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts, Introduction

UNIT III TITLE WRITING SKILLS 6

Key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check

UNIT IV RESULT WRITING SKILLS 6

Skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions

UNIT V VERIFICATION SKILLS 6

Useful phrases, checking Plagiarism, how to ensure paper is as good as it could possibly be the first-time submission

TOTAL: 30 PERIODS

COURSE OUTCOMES:

At the end of the course, students will be able to
CO1 –Understand that how to improve your writing skills and level of readability
CO2 – Learn about what to write in each section
CO3 – Understand the skills needed when writing a Title
CO4 – Understand the skills needed when writing the Conclusion
CO5 – Ensure the good quality of paper at very first-time submission

REFERENCES:

1. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011
2. Day R How to Write and Publish a Scientific Paper, Cambridge University Press 2006
3. Goldbort R Writing for Science, Yale University Press (available on Google Books) 2006
4. Highman N, Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book 1998.

AX4092 **DISASTER MANAGEMENT** **L T P C**
2 0 0 0

COURSE OBJECTIVES:

- Summarize basics of disaster
- Explain a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Illustrate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- Describe an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- Develop the strengths and weaknesses of disaster management approaches

UNIT I INTRODUCTION **6**

Disaster: Definition, Factors and Significance; Difference between Hazard And Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

UNIT II REPERCUSSIONS OF DISASTERS AND HAZARDS **6**

Economic Damage, Loss of Human and Animal Life, Destruction Of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts And Famines, Landslides And Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks And Spills, Outbreaks Of Disease And Epidemics, War And Conflicts.

UNIT III DISASTER PRONE AREAS IN INDIA **6**

Study of Seismic Zones; Areas Prone To Floods and Droughts, Landslides And Avalanches; Areas Prone To Cyclonic and Coastal Hazards with Special Reference To Tsunami; Post-Disaster Diseases and Epidemics

UNIT IV DISASTER PREPAREDNESS AND MANAGEMENT **6**

Preparedness: Monitoring Of Phenomena Triggering a Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological And Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT V RISK ASSESSMENT **6**

Disaster Risk: Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival

TOTAL: 30 PERIODS

COURSE OUTCOMES:

At the end of the course, students will be able to

CO1 Ability to summarize basics of disaster

CO2 Ability to explain a critical understanding of key concepts in disaster risk reduction and humanitarian response.

CO3 Ability to illustrate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.

CO4 Ability to describe an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.

CO5 Ability to develop the strengths and weaknesses of disaster management approaches

REFERENCES:

1. Goel S. L., Disaster Administration And Management Text And Case Studies",Deep & Deep Publication Pvt. Ltd., New Delhi,2009.
2. NishithaRai, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "'NewRoyal book Company,2007.
3. Sahni, PardeepEt.Al. ," Disaster Mitigation Experiences And Reflections", Prentice Hall OfIndia, New Delhi,2001.

AX4093 CONSTITUTION OF INDIA L T P C
2 0 0 0

COURSE OBJECTIVES:

Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional
- Role and entitlement to civil and economic rights as well as the emergence nation hood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolutionin1917and its impact on the initial drafting of the Indian Constitution.

UNIT I HISTORY OF MAKING OF THE INDIAN CONSTITUTION

History, Drafting Committee, (Composition & Working)

UNIT II PHILOSOPHY OF THE INDIAN CONSTITUTION

Preamble, Salient Features

UNIT III CONTOURS OF CONSTITUTIONAL RIGHTS AND DUTIES

Fundamental Rights, Right to Equality, Right to Freedom, Right against Exploitation, Right to Freedom of Religion, Cultural and Educational Rights, Right to Constitutional Remedies, Directive Principles of State Policy, Fundamental Duties.

UNIT IV ORGANS OF GOVERNANCE

Parliament, Composition, Qualifications and Disqualifications, Powers and Functions, Executive, President, Governor, Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualifications, Powers and Functions.

UNIT V LOCAL ADMINISTRATION

District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO, Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy(Different departments), Village level:Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT VI ELECTION COMMISSION

Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners - Institute and Bodies for the welfare of SC/ST/OBC and women.

TOTAL: 30 PERIODS

COURSE OUTCOMES:

Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization
- of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party[CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

SUGGESTED READING

1. The Constitution of India,1950(Bare Act),Government Publication.
2. Dr.S.N.Busi, Dr.B. R.Ambedkar framing of Indian Constitution,1st Edition, 2015.
3. M.P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis,2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

AX4094 நற்றமிழ்இலக்கியம் L T P C
2 0 0 0

UNIT I சங்க இலக்கியம் 6

1. தமிழின்துவக்கநூல்தொல்காப்பியம்
– எழுத்து, சொல், பொருள்
2. அகநானூறு(82)
- இயற்கைஇன்னிசைஅரங்கம்
3. குறிஞ்சிப்பாட்டின்மலர்க்காட்சி
4. புறநானூறு(95,195)
- போரைநிறுத்தியஔவையார்

UNIT II அறநெறித்தமிழ் 6

1. அறநெறிவகுத்ததிருவள்ளுவர்
- அறம்வலியுறுத்தல், அன்புடைமை, ஒப்புறவுஅறிதல், ஈகை, புகழ்
2. பிறஅறநூல்கள்- இலக்கியமருந்து
– ஏலாதி, சிறுபஞ்சமூலம், திரிகடுகம், ஆசாரக்கோவை
(தூய்மையைவலியுறுத்தும்நூல்)

UNIT III இரட்டைக்காப்பியங்கள் 6

1.கண்ணகியின்புரட்சி
- சிலப்பதிகாரவழக்குரைகாதை
2. சமூகசேவைஇலக்கியம்மணிமேகலை
- சிறைக்கோட்டம்அறக்கோட்டமாகியகாதை

UNIT IV **அருள்நெறித்தமிழ்** **6**

1. சிறுபாணாற்றுப்படை
- பாரிமுல்லைக்குத்தேர்கொடுத்தது, பேகன் மயிலுக்குப் போர்வை கொடுத்தது, அதியமான்ஔவைக்குநெல்லிக்கனிகொடுத்தது, அரசர் பண்புகள்
2. நற்றிணை
- அன்னைக்குரியபுன்னைசிறப்பு
3. திருமந்திரம் (617, 618)
- இயமம்நியமம்விதிகள்
4. தர்மச்சாலையை நிறுவிய வள்ளலார்
5. புறநானூறு
- சிறுவனேவள்ளலானான்
6. அகநானூறு (4) - வண்டு
நற்றிணை (11) - நண்டு
கலித்தொகை (11) - யானை, புறா
ஐந்தினை 50 (27) - மான்
ஆகியவைபற்றியசெய்திகள்

UNIT V **நவீனதமிழ்இலக்கியம்** **6**

1. உரைநடைத்தமிழ்,
- தமிழின்முதல்புதினம்,
- தமிழின்முதல்சிறுகதை,
- கட்டுரைஇலக்கியம்,
- பயணஇலக்கியம்,
- நாடகம்,
2. நாட்டுவிடுதலைபோராட்டமும்தமிழ்இலக்கியமும்,
3. சமுதாயவிடுதலையும்தமிழ்இலக்கியமும்,
4. பெண் விடுதலையும் விளிம்பு நிலையினரின் மேம்பாட்டில் தமிழ் இலக்கியமும்,
5. அறிவியல்தமிழ்,
6. இணையத்தில்தமிழ்,
7. சுற்றுச்சூழல் மேம்பாட்டில் தமிழ் இலக்கியம்.

TOTAL: 30 PERIODS

<u>தமிழ்இலக்கியவெளியீடுகள் / புத்தகங்கள்</u>

1. தமிழ்இணையகல்விக்கழகம் (Tamil Virtual University) - www.tamilvu.org
2. தமிழ்விக்கிப்பீடியா (Tamil Wikipedia) -https://ta.wikipedia.org
3. தர்மபுரஆதினவெளியீடு
4. வாழ்வியல்களஞ்சியம் - தமிழ்ப்பல்கலைக்கழகம், தஞ்சாவூர்
5. தமிழ்கலைக்களஞ்சியம் - தமிழ்வளர்ச்சித்துறை (thamilvalarchithurai.com)
6. அறிவியல்களஞ்சியம் - தமிழ்ப்பல்கலைக்கழகம், தஞ்சாவூர்