JAYPEEE INSTITUTE OF INFORMATION AND TECHNOLOGY

M.Tech Biotechnology

Semester I

PHYTOTHERAPEUTICS AND PHARMACOLOGY

Subject Code	17M12BT119	Semester: ODD	Semester: I Session: 2022-2023 Month from: July - Dec
Subject Name	PHYTOTHERAP	EUTICS AND PHAR	MACOLOGY
Credits	3	Contact Hours	3+1

Faculty	Coordinator(s)	1.	Professor. Vibha Rani
(Names)	Teacher(s)	1.	Professor. Vibha Rani
	(Alphabetically)		

COURSE O	COGNITIVE LEVELS	
CO130.1	Analyze the existing biotechnological techniques to develop plant-based therapeutics	Analyzing (C4)
CO130.2	Evaluate the classes, synthesis and structure functional relationship of Phyto molecules	Evaluating (C5)
CO130.3	Explain the therapeutic applications of phytochemicals	Understanding (C2)
CO130.4	Identify the current aspects of phytomedicines on toxicity and clinical trials	Applying (C3)
CO130.5	Case studies to analyze Ayurpharmaco-epidemiology	Analyzing (C4)
CO130.6	Use of bioinformatics tools and approaches to predict the molecular function of novel bioactive molecules	Creating (C6)

Module	Subtitle of the Module	Topics in the module	No. of
No.		-	Lectures for
			the module
1	Introduction	Concepts of Phototherapeutics, Trend	3
		and market analysis, Global herbal	
		medicine market, Herbal Sector in India	
2	Medicinal Plants	Introduction to metabolites, Secondary	3
	Metabolites	metabolites, properties and beneficial	
		aspects.	
3	Isolation technique	Pharmacology Approaches in	4
	extraction procedure	Phototherapeutics, Bioactive guided	
	_	discovery process	
		Isolation from medicinal plants.	
		Isolation from aromatic plants.	
		Recants advancements in extraction	
4	Characterization	Qualitative and quantitative Analysis	4
	technique	Gas Chromatography	
		High Performance Liquid	
		Chromatography: (HPLC)	
		High Performance Thin Layer	
		Chromatography: (HPTLC)	

5	Structure functional	Bioinformatics approach in predicting	4	
	relationship	relationship structure functional relationship		
		Mechanism of Action		
		Unidentified Therapeutic Intakes		
		Factors that Affect Metabolism		
6	Therapeutic Application	Free radicals and antioxidants	8	
		Plants used in Metabolic disorder		
		Plants used in respiratory system		
		Plants used in COVID Pandemic		
		Plants used with antimicrobial activity.		
		Plants used with neurodegenerative		
		alsorders		
		Plants used in cardiovascular system.		
7	Toxicity Issue and	Current aspects of phytomedicine on	6	
ľ	Clinical Trials	toxicity and clinical trials	0	
8	Case studies	Success stories, research-based case	8	
		studies related to phototherapeutics	-	
9	Potential risks associated	Discussion	2	
	and future aspects	Discussion		
		Total number of Lectures	42	
Eva	luation Criteria			
Cor	nponents Maxim	mum Marks		
T1	20			
T2	20			
End	Semester Examination 35			
TA	25 (0	Class Test-1, Assignment-1&2, PBL, Case stu	udies 1, 2& 3)	
Tot	al 100			
Proj	ect based learning: Each student wil	l opt a human health issues and diseases. To	make subject	
app	ication based, the students will anal	yze uncharacterized Indian medicinal herbs a	nd will explore	
thei	r therapeutic potential and also perfo	orm market research. Various phototherapeut	ics concepts	
will	be discussed by students. Students	would explain the critical disease targets and	mechanism of	
acti	ons of selected herbs by in silico me	thods. Understanding the concepts would enl	nances the	
stud	ent's knowledge and motivation for	herbal drug discovery and its continuously g	rowing market	
whi	ch will help their employability into	various biotechnology and health sector.		
Rec	ommended Reading material: Aut	hor(s), Title, Edition, Publisher, Year of Pub	lication etc.	
(Tez	tt books, Reference Books, Journals	, Papers, Reports, Websites etc. in the IEEE	format)	
1.	1. Plant Bioactive and Drug Discovery: Principles, Practice, and Perspectives, Valdir Cechinel-			
	Filho (Ed.). 2012 John Wiley & Sons. Inc.			
1	Filho (Ed.). 2012 John Wiley & Sc	ms, mc.		
2	Phototherapeutics (Recent Progress	s in Medicinal Plants), S. K. Sharma, J. N. G	ovil. V. K.	
2.	Phototherapeutics (Recent Progress Sing. 2005. Studium Press.	s in Medicinal Plants). S. K. Sharma, J. N. G	ovil, V. K.	
2.	Phototherapeutics (Recent Progress Sing. 2005. Studium Press.	s in Medicinal Plants). S. K. Sharma, J. N. G	ovil, V. K.	
2. 3.	Phototherapeutics (Recent Progress Sing. 2005. Studium Press. Phytotherapies: Efficacy, Safety, an Inc.	s in Medicinal Plants). S. K. Sharma, J. N. G nd Regulation. Iqbal Ramzan (Ed.) 2015 John	ovil, V. K. 1 Wiley & Sons,	
2. 3.	Phototherapeutics (Recent Progress Sing. 2005. Studium Press. Phytotherapies: Efficacy, Safety, an Inc.	nis, inc. s in Medicinal Plants). S. K. Sharma, J. N. G nd Regulation. Iqbal Ramzan (Ed.) 2015 John	ovil, V. K. n Wiley & Sons,	

BIOSENSORS

Subjec t Code	17M12BT111	Semester: Odd (specify Odd/Even)	Semester: I Session: 2022-23 July to Dec.
Subjec t Name	Biosensors		
Credits	3	Contact Hours	3

Faculty	Coordinator(s)	1. Dr. Sudha Srivastava
(Names)	Teacher(s) (Alphabetically)	1. Dr. Sudha Srivastava

COs	Cos description	Level
CO111.1	Understand biosensor, its performance characteristics and types of biosensors and advancement thereof	Understand Level 2
CO111.2	Analyze different immobilization methods and their effect on biosensor performance	Analyze level 3
CO111.3	Evaluate performance of a given biosensor, for disease diagnosis, drug screening, pathogen and pollutant detection	Evaluate level 5
CO111.4	Design methods to improve sensitivity of the biosensor	Create Level 6

Modul e No.	Subtitle of the Module	Topics in the module	No. of Lecture s
1.	Introduction:	Sensors and biosensors, definitions, types of sensors, markets, target analytes, glucose and other medical sensors	2
2.	Biosensor Advancements and nanotechnolog y	First-, second-, third generation biosensors, Nanotechnology and present day biosensors	3
3.	Basic Design Consideration s	Calibration, dynamic Range, signal to noise, sensitivity, selectivity, interference.	3
4.	The biological component	Whole cell sensors, enzymes – sensing substrates or inhibitors, antibodies (Mab, Fab). And other binding proteins, oligonucleotides and aptamers.	3

5.	Types of biosensor s	Optical biosensors, Electrochemical biosensors, Piezoelectric biosensor, Calorimetric biosensors	8
6.	Immobilizatio n method	Non-covalent immobilization - entrapment and multipoint electrostatic attachment. Covalent attachment via thiol, amino and hydroxyl groups. Affinity interactions - avidin/biotin, complementary oligonucleotides.	
7.	Techniques for sensing: Physical and chemical	Absorbance, fluorescence, chemi/bioluminescence and phosphorescence, Surface Plasmon Resonance (SPR), quartz crystal microbalance, cyclic voltammetry	8
8.	Sensor stabilizatio n	Storage and operational stability. Polyols, polymers and low Mw compounds as stabilizing agents for drying and long term storage. Stabilization mechanisms.	3
9.	Applications	Pharmaceutical, agricultural, food safety, biomedical applications, food processing: state of the field, market potential, unique design criteria and needs, current sensors in use.	8
Total nu	Total number of Lectures42		
PBL: Students form group or as individual and present a report on biosensor designing and performance for various applications like agriculture, environment and healthcare			

Recommended Reading material: Author(s), Title, Edition, Publisher, Year of Publication etc. (Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)			
1.	Ligler, F.S. and Rowe Taitt, C.A. 2002. Optical Biosensors: Present & Future. Elsevier, The Netherlands. ISBN: 0-444-50974-7.		
2.	Yang, V.C. and T.T. Ngo. 2000. Biosensors and Their Applications. Kluwer Academic/Plenum Publishers, New York, NY. ISBN: 0-306- 46087-4.		
3.	Recent research articles		

BIOMOLECULES AND CELL COMMUNICATION

Course Code	17M11BT111	Semester Odd	Semeste Session	r MTech I 2021-2022
			Month f	rom July-December
Course name	Biomolecules and (Cell Communi	cation	
Credits	3		Contact hours	3

Faculty (Names)	Coordinator(s)	Dr. Reema Gabrani
	Teacher(s)	Dr. Reema Gabrani
	(Alphabetically)	

COURSE	OUTCOMES	COGNITIVE LEVELS
C110.1	Explain the signal molecules and major cell signaling pathways	Understand Level (C2)
C110.2	Analyze cell signaling pathways in normal and diseased conditions	Analyze Level (C4)
C110.3	Interpret the mechanisms and regulation of cell cycle and cell death	Understand Level(C2)
C110.4	Analyze the therapeutic drug targets for cancer	Analyze Level (C4)

Module No.	Title of the Module	Topics in the Module	No. of lectures for the module
1.	Signal molecules	Cytokines and Hormones, Growth factors, neurotransmitters, extracellular matrix components as signaling molecules; autocrine, paracrine, juxtracrine and endocrine signaling	3
2.	G-protein linked signaling pathways	G Protein-Coupled Receptors, Heterotrimeric G Proteins, second messengers, Effector enzymes, Mechanism of transduction, Switching Off and Desensitization of receptors, Visual transduction pathway	8
3.	Signaling mediated by enzyme-linked cell surface receptor	Photoreceptor development in Drosophila, Ras to MAP kinase, Phosphoinositide-3-kinase and signaling through insulin in receptor, JAK-STAT pathway, Signal	8

		Transduction via Integrins	
4.	Nuclear receptor-based signaling	Classification and Structure of Nuclear Receptors, Signaling by steroid hormones, Retinoids, Vitamin D3, and the T3-Hormone, Mechanisms of Transcriptional Regulation by Nuclear Receptors	4
5.	Bacterial Chemotaxis	Two-component signaling pathway, histidine kinase associated receptor, Adaptation, Chemotaxis pathogenicity, symbiotic associations and biofilm	3
6.	Cell cycle Regulation and cell death	Cyclin-CDK variation, Checkpoint signaling, Ubiquitin Proteasome proteolytic system, Intrinsic and Extrinsic Apoptotic pathways	8
7.	Malfunction of Signaling Pathways and Tumorigenesis	Hallmarks of cancer, Developmental pathways, and cancer : Notchsignalingg from Drosophila to humans, Wnt signaling, Hedgehog pathway; Epigenetic changes in cancer, Signalling pathways as therapeutic targets, Analysis of ssignalingevents via case studies	8
Total number	of Lectures		42
Evaluation Cri	iteria		
Components	Maximum M	larks	
T2	20		
End Semester E	Examination 35		
ТА	25(Presentat	ion, Assignments, PBL)	
Total 100			
PBL: Students project will link therapeutic mol	will be given project in groups the signaling molecule and its ecule.	on "Bench to bedside case study in cell sign s cascade to the associated disease and the d	naling". The evelopment a of

Re (Te	Recommended Reading material: Author(s), Title, Edition, Publisher, Year of Publication etc. (Textbooks Reference Books, Journals, Reports, Websites in the IEEE format)					
1.	B. Gomperts, I. Kramer, P. Tatham "Signal transduction",2 nd Ed. Academic Press					
2.	V W Rodwell, D Bender, K M Botham, P J Kennelly, P A Weil, "Harper's Illustrated Biochemistry", 31 st Ed. McGraw-Hill Lange 2018					
3.	Alberts, Johnson, Lewis, Morgan, Raff, Roberts and Walter, "Molecular Biology of the Cell" Sixth Edition, Garland Science Publication,2014					
4.	Refereed papers from scientific journals for case studies					

Course Code 17M11BT112 Semester Odd (specify Odd/Even)		1	Semester I Session 2022-2023 Month from June to Dec					
Course Na	me	Molecular Modeling	g and Drug desi	ign				
Credits		3		Contact Hours LTP		LTP	300	
Faculty (Names)		Coordinator(s)	Dr Chakresh Jain					
		Teacher(s) (Alphabetically)	Dr Chakresh Jain					
COURSE OUTCOMES					COGNITIVE LEVELS			
C112.1	Explai and vi	n macromolecular strue sualization	ctures, their Mat	thematical r	epresenta	tion	Understanding (C2)	
C112.2	Explain structural modeling, simulation and dynamics Understanding (C2)							
C112.3	Apply computational drug designing and simulationApplying(C3)approaches for drug discovery							
C112.4	Compa	Compare <i>in-silico</i> ligand-target interaction methods Analyzing (C4)						

MOLECULAR MODELING AND DRUG DESIGN

Module No.	Title of the Module	Topics in the Module	No. of Lectures for the module
1.	Introduction to Molecular Modeling	Introduction to structure of DNA, protein and RNA. Structure representation and visualization, Coordinate Systems, Potential Energy Surfaces, Software and Hardware for molecular modeling, Tools such as Swiss pdb viewer, Pymol, VMD etc.	5
2.	Quantum Mechanics and Force Fields	Electron methods and molecular orbital calculations, General Features of Molecular mechanics force field, Bond Stretching. Angle Bending. Introduction to Non- bonded Interactions. Electrostatic Interactions. Van der Waals Mechanics. Force Field Models for the Simulation of Liquid Water.	5
3.	Energy Minimizatio n and computer simulations	Minimization and Related Methods for exploring the Energy Surface. Non-Derivative method, Minimization methods. Computer Simulation Methods. Simple Thermodynamic Properties and Phase Space. Boundaries. Analyzing the Results of a Simulation and Estimating Errors.	5

4.	Molecular Dynamics and simulation	Molecular Dynamics Simulation Methods. Molecular Dynamics Using Simple Models. Metropolis Method. Monte Carlo methods, Web Based Resources, Databases and tools such as GROMACS, AMBER, & CHARMM.				
5.	Structure Prediction	Principles of structure prediction, comparative modeling and protein folding, Comparative and <i>ab-intio</i> modeling, CASP, validations, Projects such as ROSETTA, protein folding at home.	6			
6.	Drug designing Introduction to drug discovery and drug development, Rational approach to drug design, Approaches to lead optimization such as conformation restriction, pharmacophore etc. Designing drugs against enzymes and receptors, Computer Aided Drug Design methods. ADMET, QSAR Tools and databases such as					
		Total number of Lectures	43			
Evaluation	Criteria					
Component	ts	Maximum Marks				
T1		20				
T2		20				
End Semester Examination		35				
TA		25 (Assignment-1, MCQ, Project, Presentation, PBL)				
		100				
PBL: Studen	nts will choose any pi	to the manage the diagonal and its appropriated accurations	used as a			
merapeutic 1	molecule of as a targe	et to manage the disease and its associated complications				

Reco book	Recommended Reading material: Author(s), Title, Edition, Publisher, Year of Publication etc. (Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)				
1.	Andrew R leach, V.J Gillet, "An introduction to Chemoinformatic" Springer model of publication, 2007				
2.	Gasteiger Johann, "Chemoinformatic A text book" John Wiley, 2008				
3.	Andrew R. Leach, "Molecular Modeling principles and applications" Pearson Education, Second edition, 2001				

Course Code		18M11GE111	Sei	mester Odd	Semester I Session 2022-23				
					Montl	n from Aug - l	Dec 2022		
Course Name		Research Metho	dolo	ogy and Intellectua	ll Prope	rty Rights			
Credits		2		Contact Hours			2	-0-0	
Faculty		Coordinator(s))	Dr. Shikha Pande	У				
(Names)		Teacher(s) (Alphabetically	7)	Dr. Shikha Pande	у				
COURS	ΕΟ	JTCOMES:					COGNIT	TVE LEVELS	
After pur	suing	g the above-menti	oned	d course, the stude	nts will	be able to:			
C101.1	Exp	plain the basic con	ncep	ts and types of res	earch		Unde	erstanding Level (C2)	
C101.2	Def ana	ine a research pro lyze research rela	bleı ted i	m, its formulation, information	method	lologies and	Ar	nalyzing Level (C4)	
C101.3	Exp rela	blain research ethi ted to their innov	ics, ı ative	understand IPR, pa e works.	itents ar	nd their filing	Unde	erstanding Level (C2)	
C101.4	Exp test	blain and analyze of hypothesis in t	the s	statistical data and r research problem	apply t	he relevant	Ar	nalyzing Level (C4)	
Modul e No.	Title of the Module			Topics in the Module				No. of Lectures for the module	
1.	Res	earch	N r	What is research? Types of research. What is not research? How to read a Journal paper?			'hat is not	3	
2.	Rep	oort writing	H V i	How to write report? Use of Mendeley in report writing. How to write a research paper? Problem identification and solving.			4		
3.	Ethics, IPR and Research methodologies			Research ethics, patents, intellectual property rights, plagiarism regulation 2018. Steps in research process and common methodologies to attempt solution to research paper.			8		
4.	Basics of statistics and probability distributionsBasic statistical concepts. Handling of raw data, Some common probability distributions.			7					
5.	Test of hypothesis and regression analysisHypothesis testing. Parametric and non- parametric data, Introduction to regression analysis.			on	8				
,		1.1.	1	1	To:	tal number of	Lectures	30	
(Evoluoti	Cour	se delivery metho	od: o	open ended discuss	10n, gui	ded self-study	, lectures)		
	on C ente	111011a		Maximum Ma	arks				
Mid Terr	n Exa	amination		30	41 INJ				
End Sem	ester	Examination		40					
Assignme	ents			30 (Quiz	z, Assig	nments)			
Total	Total 100								

Project-based learning: Students divided in small groups will be assigned topics related to patents, intellectual property rights, plagiarism, and statistics. Students can write a report/review paper and find its similarity through plagiarism software available online. Students may collect data and testthe relevant hypothesis. They may study some data set and do its regression analysis. The main purpose is to expose students to a wider arena of applicable knowledge of the subject.

Recommended Reading material: Author(s), Title, Edition, Publisher, Year of Publicationetc. (Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)

Stuart Melville and Wayne Goddard, Research Methodology: An Introduction for Science& Engineering Students, Kenwyn, South Africa: Juta & Co. Ltd., 1996.

Kothari, C.R., Research Methodology: Methods and Techniques, New Age International, New Delhi, 2009.

Kumar, Ranjit, Research Methodology: A Step-by-Step Guide for Beginners, 2nd Edition, Sage Publications Ltd., 2005.

Ramappa, T., Intellectual Property Rights Under WTO, S. Chand, New Delhi, 2008.

Wayne Goddard and Stuart Melville, Research Methodology: An Introduction, Kenwyn, South Africa: Juta & Co, 2001.

BIOTECHNIQUES LAB-I

Course Code		17M15BT111	Semester Odd Semester I		r I			
			(Specify Odd/Even)		Session 2022-2023			
					Month f	rom J	uly- December	
Course Na	ime	Biotechniques Lab)-I					
Credits		3		Contact H	Iours		6	
Faculty (N	ames)	Coordinator(s)	Dr. Reema Gab	orani				
Teacher(s) (Alphabetically)			Dr. Chakresh K Pammi Gauba, Mohanty, Dr. V	K. Jain, Dr. Dr. Priyada /ibha Rani	Indira P. S arshini, Di	Sareth r. Ree	y, Dr. Neeraj Wadhwa ma Gabrani, Dr. Sujat	ı, Dr. a
COURSE	OUTCO	OMES					COGNITIVE LEV	ELS
C111.1	Apply	basic analytical tech	niques in biotechno	ology			Apply Level (C3)	
C111.2	Develo	pp skills in molecular	biology technique	es			Apply Level (C3)	
C111.3	Exami	ne and analyse gene	expression				Analyze (Level C4)	
C111.4	Make	use of purification tec	chniques for natura	al products			Apply Level (C3)	
Module No.	Title of the Module		List of Experiments			CO		
1.	Analyt	ical techniques	To explore drug-protein interactions					2
2.	Molecular biology techniques		Cloning strategy: Screening of recombinants: isolate recombinant plasmid DNA from bacterial cells; Restriction enzyme digestion, separate and visualize DNA bands by agarose gel electrophoresis			4		
3.	Gene e techniq	xpression jues	Designing primers for amplification of gene of interest by PCR, PCR amplification, analyze PCR products; Analysis of a recombinant protein by polyacrylamide gel electrophoresis				3	
4.	Purific	ation techniques	To obtain antimicrobial compound from bacterial culture; to purify the antimicrobial compound by column chromatography; use of bioactivity-guided fractionation to analyze and quantify the compounds				3	
			Total					12
Evaluation	n Criteri	ia						<u> </u>
Components Maximum Marks Mid-Term Viva 20 Day-to-Day (Lab record, attendance, performance) 60 Final Viva 20 Total 100 Project Based Learning: The students learn column chromatography, molecular biology, and analytical techniques and analyze gene expression which is required for the Biotech industry								

Reco Refei	mmended Reading material: Author(s), Title, Edition, Publisher, Year of Publication, etc. Textbooks, rence Books, Journals, Reports, Websites, etc. in the IEEE format)
1.	Introduction to Biotechnology, Laboratory Manual: http://www.austincc.edu/awheeler/Files/BIOL%201414%20Fall%202011/BIOL1414_Lab%20Manual_Fall%202011.pdf
2.	Frederick M. Ausubo, Roger Brent, Robert E. Kingston, David D. Moore, J.G. Seidman, John A. Smith, Kevin Struhl (eds.) Current Protocols in Molecular Biology. John Wiley & Sons Inc; ringbou edition (December 4, 2003)
3.	Molecular Biology web book- http://www.web-books.com/MoBio/
4.	S. V. S. Rana, Biotechniques Theory and Practice. Rastogi Publications 2008.
5.	Methods standardized in lab

REGULATORY AFFAIRS

Course Code		17M12BT1	16	Semester Odd		Semester I			
				Session 202		2022	2-2023		
						Month	from	July19-De	ec19
Course N	lame	Regulatory .	Affairs						
Credits		3		Contact Hours			3		
Faculty (Names)		Coordinator(s)		Dr Shweta Dang					
		Teacher(s) (Alphabetic	cally)	Dr Shweta Dang					
COURSI	E OUT	COMES COGNII LEVELS						FIVE S	
C120.1	Explain regulatory trials		markets and agencies; preclinical and clinical				Understanding (Level 2)		
C120.2	Analy	yze the guidelines for approvals of new drugs/biologics Analyzin						g (Level 4)	
C120.3	Comp Patent	are innovator and generic pharmaceutical industry with and Non patent exclusivity							
C120.4	Interpret ICH guidelines applicab			oplicable to drug	cable to drugs and biotechnology			Understanding (Level 2)	
C120.5	Assess	sess regulatory approvals via related case studies Evaluating (Level 5)						g (Level 5)	
Module No.	Title Mod	of the ule	Topics in the Module				No. of Lectures for the module		
1.	Introe Regu agenc	ntroduction To egulatory gencies CDSCO, India USFDA, USA EMEA, European Union TGA, Australia					2		
2.	Introd Pharr and N	Inclian Pharmacopoeia (IP)nacopoeiasAonographsInternational Pharmacopoeia (USP)International Pharmacopoeia (Int. Ph.)European Pharmacopoeia (Eur. Ph.)					2		
3.	Safet effica drugs precli studio phase	y and acy of s/biologics, inical es					4		
4.	Appr pathv Drug	oval FDA, CDER, CBER, IND, NDA, BLA, recalls, Phase rays for IV, filing procedures					7		

	biopharmaceutic als in USFDA						
5.	Approval pathways for Drugs/ biologic/ biopharmaceutic als in Europe	EMEA, market authorization application. Centralized, Decentralized, National, Mutual recognition procedure. CTD, eCTD, Nees Submissions, ICH M4	4				
6.	Approval pathways for Drugs/ biologic/ biopharmaceutic als in India and Japan	Central Drug Standard Control Organization, INDIA, Pharmaceutical and Medical Devices Agency of Japan	3				
7.	Generics and Biosimilars	Hatch Wax man Act (Para I, II, III and IV filings), BPCI act USA, CDSCO guidelines, EMEA guidelines, Status of guidelines	6				
8.	Non-Patent Exclusivities	Orphan Drug law, Market exclusivity, Pediatrics exclusivity, first to file exclusivity	5				
9.	ICH Guidelines for Biologics and Good Clinical Practices	Overview of ICH guidelines, ICH QSEM, ICH Q5, Q6, ICH E6, ICH Q8,9,10	5				
11.	Case Studies	Relevant Case studies	4				
		Total number of Lectures	42				
Evaluatio	n Criteria						
Compone	ents	Maximum Marks					
$\begin{array}{cccc} 11 & 20 \\ T2 & 20 \end{array}$							
End Semester Examination 35							
TA		25 (Class Test, Assignment I and II) PBL (5 Marks)					
Total 100							
PBL: Students will be given a project to search orange book database of USFDA and prepare a patent and non-patent exclusivity status of drugs							
and non puton exercisivity suites of drugs							

Recommended Reading material: Author(s), Title, Edition, Publisher, Year of Publication etc. (Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)								
1.	Sandy Weinberg, GUIDEBOOK FOR DRUG REGULATORY SUBMISSIONS, 2009 (first							
	edition), John Wiley & Sons, Inc.							
2.	The Common Technical Document (CTD), Internet:							
	http://www.ich.org/							
3.	Guideline for submitting supporting documentation in drug applications for the manufacture of							
	drug substances,	February	1987,	Internet:				
	http://www.fda.gov/cder/guidance/drugsub.pdf							
	ICH Guideline: The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality - M4Q; Quality Overall Summary of Module 2, Module 3: Quality, Internet:							
4.								
http://www.ich.org/MediaServer.jser?@_ID=556&@_MODE=GLB								