SEMESTER VII

S. No	Category	Course Code	Course Title	L	T	P	C
Theory							
1	PC	PT20701	Pharmacology and Chemotherapy	3	0	0	3
2	PC	PT20702	Biopharmaceutics and Pharmacokinetics	3	0	0	3
3	PE	PT2035*	Professional Elective III	3	0	0	3
4	PE	PT2045*	Professional Elective IV	3	0	0	3
5	OE	PT2090*	Open Elective II	3	0	0	3
Practical							
6	PC	PT20703	Pharmacokinetics and Pharmacognosy Laboratory	0	0	4	2
7	PC	PT20704	Computational Biology Laboratory	0	0	2	1
8	EE	PT20705	Project Work (Phase I)	0	0	6	3
			Total	**18**	**0**	**12**	**21**

SEMESTER VIII

S. No	Category	Course Code	Course Title	L	T	P	C
Theory							
1	PC	PT20801	Downstream Processing	3	0	0	3
2	PE	PT2055*	Professional Elective V	3	0	0	3
3	PE	PT2065*	Professional Elective VI	3	0	0	3
Practical							
4	EE	PT20802	Project Work (Phase II)	0	0	12	6
			Total	**9**	**0**	**12**	**15**

PROFESSIONAL ELECTIVE III

S. No	Category	Course Code	Course Title	L	T	P	C
1	PE	PT20351	Computer Aided Drug Design	3	0	0	3
2	PE	PT20352	Nutraceuticals	3	0	0	3
3	PE	PT20353	Bioconjugate Technology	3	0	0	3
4	PE	PT20354	Pharmacotherapeutics	3	0	0	3

PROFESSIONAL ELECTIVE IV

S. No	Category	Course Code	Course Title	L	T	P	C
1	PE	PT20451	Vaccine Technology	3	0	0	3
2	PE	PT20452	Regulatory Toxicology	3	0	0	3
3	PE	PT20453	Advances in Drug Delivery Systems	3	0	0	3
4	PE	PT20454	Precision Medicine	3	0	0	3

PROFESSIONAL ELECTIVE V

S. No	Category	Course Code	Course Title	L	T	P	C
1	PE	PT20551	Technology of Sterile Products	3	0	0	3
2	PE	PT20552	Clinical Research and Pharmacovigilance	3	0	0	3
3	PE	PT20553	Biosafety	3	0	0	3
4	PE	PT20554	Regulatory Requirements in Pharmaceutical Industry	3	0	0	3

PROFESSIONAL ELECTIVE VI

S. No	Category	Course Code	Course Title	L	T	P	C
1	PE	PT20651	Pharmacognosy	3	0	0	3
2	PE	PT20652	Stem Cell and Tissue Engineering	3	0	0	3
3	PE	PT20653	Product Development and Technology Transfer	3	0	0	3
4	PE	PT20654	Lifestyle Diseases	3	0	0	3

OPEN ELECTIVE II

S. No	Category	Course Code	Course Title	L	T	P	C
1	OE	PT20903	Fundamentals of Nanoscience	3	0	0	3
2	OE	PT20904	Introduction to Pharmaceutical Technology	3	0	0	3

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PT20701 PHARMACOLOGY AND CHEMOTHERAPY 3 0 0 3

COURSE OBJECTIVES

To enable students to

- provide the general pharmacological principles.
- make understand the pharmacology of different types of drugs acting on various physiological systems.
- develop the ability to suggest suitable techniques to synthesis different drug molecules.
- study the different adverse reactions of drugs.
- study the chemotherapy for various human systems.

UNIT I GENERAL PHARMACOLOGY 9

Routes of administration, Pharmacokinetics, Pharmacodynamics, Factors modifying drug action, adverse drug reaction, drug interactions, Bioassay of drugs, drug discovery and development.

UNIT II PERIPHERAL AND CENTRAL NERVOUS SYSTEM 9

Mechanism of action, Pharmacology of para sympathomimetics, para sympatholytics, sympathomimetics, sympatholytics, neuromuscular blocking agents, general anaesthetics, antipsychotics, antidepressants, antiepileptic, analgesics, antipyretic, anti-inflammatory (NSAIDS) and CNS stimulants

UNIT III CARDIOVASCULAR PHARMACOLOGY 9

Classification, Mechanism of action, Pharmacology of cardiac glycosides, antianginal, antihypertensive agents, vasodilators including calcium channel blockers, antiarrhythmic and antihyperlipidemic agents.

UNIT IV CHEMOTHERAPY 9

Introduction and basic principles of chemotherapy of infection, infestation and neoplastic diseases and concepts of resistance to chemotherapeutic agents. Drugs used in protozoal infections. Chemotherapy of cancer. Immunopharmocology – Cellular and biochemical mediators of inflammation and immune response, Allergic or hypersensivity reactions.

UNIT V CHEMOTHERAPY AGENTS 9

Sulphonamides, Cotrimoxazole and Quinolones. Beta lactam antibiotics – Tetracycline, chloroamphenicol. Aminoglycoside antibiotics – Macrolides. Antitubercular drugs, antileprosy drugs, anti-fungal and anti-viral drugs. malignancy and immunosuppressive agents.

TOTAL PERIODS 45

COURSE OUTCOMES

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

- gain knowledge about the various principles of general pharmacology.
- Know the pharmacology of various categories of drugs acting on nervous
- cardiovascular and gastrointestinal systems.
- familiarize the principles of chemotherapy and pharmacology of antimicrobial agents.
- they would have understood the application of basic pharmacological knowledge in the prevention and treatment of various treatments of diseases.

TEXT BOOKS

1. Tripathi, K.D., "Essentials of Medical Pharmacology", 7th Edition, Jaypee Brothers Medical Publishers (P) Ltd, 2015.
2. Satoskar, R.S., Bhandarkar, S.D. and Rege, N., "Pharmacology and Pharmacotherapeutics", 24th edition, Popular Prakashan (P) Ltd., 2015.
3. H. L. Sharma, K. K. Sharma, Principles of Pharmacology, Paras Medical Publishers, 3rd Edition, 2017.

REFERENCES

1. Laurence L. Brunton, Bjorn C. Knollmann, RandaHilal-Dandan, " Goodman and Gilman S "The Pharmalogical Basis of Therapeutics", 13thedition, McGraw-Hill Education / Medical, 2017.
2. Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, Graeme Henderson, "Rang & Dale's Pharmacology", 8th edition, Churchill Livingstone, 2015.
3. Katzung, B.G., Trevor AJ. Basic and Clinical Pharmacology, McGraw-Hill Education, 13th Edition,2015.

CO/PO MAPPING:

Mapping of Course Outcome (CO's) with Programme Outcomes (PO's) and Programme SpecificOutcomes (PSO's)

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

CO's	PO's												PSO's	
	1	2	3	4	5	6	7	8	9	10	11	12	1	2
CO1	3	2	3	1	-	2	-	-	-	3	-	2	3	3
CO2	1	2	-	2	-	-	1	-	-	-	-	1	3	3
CO3	2	2	2	1	1	2	-	-	-	-	-	-	3	2
CO4	3	1	2	1	2	2	-	-	-	-	-	2	2	2
CO5	3	2	2	1	2	2	-	-	-	-	-	2	2	2

PT20702 BIOPHARMACEUTICS AND PHARMACOKINETICS 3 0 0 3

COURSE OBJECTIVES

To enable students to

- learn important parameters involved in drug disposition and its principles in living systems
- acquire knowledge how the drug disposition takes place in the in vitro and in vivo conditions.
- To know the concepts of bioavailability and bioequivalence of drug products and their significance
- study the basics of Pharmacokinetics
- acquire knowledge on multiple dosage regimens

UNIT I DRUG ABSORPTION AND DISTRIBUTION 9

Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting Biopharmaceutics; Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis); Mechanism of drug absorption through GIT, factors influencing absorption – physiochemical, physiological, and pharmaceutical; Distribution of drugs, Tissue permeability of drugs, binding of drugs.

UNIT II DRUG ACTION, METABOLISM AND ELIMINATION 9

Mechanism of drug action; physico-chemical principles of drug metabolism; factors affecting metabolism; renal excretion of drugs; factors affecting renal excretion of drugs; Mechanism of renal clearance; non-renal routes of drug excretion of drugs; Study of drug-membrane interactions.

UNIT III BIOAVAILABILITY AND BIOEQUIVALENCE 9

Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models; in-vitro-in-vivo correlations; Design of single dose bioequivalence study and relevant statistics, methods enhance the dissolution rates and bioavailability of poorly soluble drugs

UNIT IV PHARMACOKINETICS 9

Foundation of pharmacokinetics, Significance of plasma drug concentration measurement; Pharmacokinetic models; One Compartment open model – Intravenous Bolus injection, Intravenous infusion, extra vascular administrations; Pharmacokinetics of drug absorption – Zero order and first order absorption rate constant using Wagner Nelson and Loo-riegelman method; Elimination rate constant and its half-life; AUC, C_{max} and t_{max}; Apparent volume of distribution, Renal Clearance (Q).

UNIT V MULTIPLE DOSAGE REGIMENS AND NONLINEAR PHARMACOKINETICS 9

Concept, Accumulation, Persistent and elimination factors. Calculation of dosage regimen following repetitive IV and oral administration; Nonlinear Pharmacokinetics – Introduction, factors causing Non-linearity, Michaelis-menton method of estimating pharmacokinetic parameters; Detection of non-linearity (Saturation mechanism).

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- adapt drug dispositions and its principles in living systems
- work on drug action and its metabolism
- inculcate the foundations of Pharmacokinetics
- calculate dosage regimes
- applications based on kinetics

TEXT BOOKS

1. Rosenbaum, S. E. Basic, "Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations", 2nd Edition, John Wiley and Sons, 2016.
2. Brahmankar, D.M. and Jaiswal, S.B. "Biopharmaceutics and Pharmacokinetics: a Treatise" ,3rd Edition, Vallabh Prakashan, 2015.

REFERENCES

1. Jambhekar, S.S. and Philip, J. B. "Basic Pharmacokinetics" 2nd Edition, Pharmaceutical Press,2012.
2. Gibaldi, M. "Biopharmaceutics and Clinical Pharmacokinetics", 4th Edition, Pharma Book Syndicate, 2016.
3. Shargel,L and Andrew, B.C. Yu. "Applied Biopharmaceutics and Pharmacokinetics",7th Edition, The McGraw-Hill Companies, Inc, 2016.
4. Chatwal, G.R. "Biopharmaceutics and Pharmacokinetics", 2nd Edition, Himalaya Publishing House, 2014.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	2	2	3	2	3	3	2	3	2	-	2	-	3	3
CO2	2	2	3	1	-	-	2	3	-	-	-	-	3	3
CO3	3	3	3	3	3	2	-	-	-	-	1	2	3	3
CO4	2	3	3	3	2	3	-	-	-	-	-	2	3	2
CO5	2	2	3	3	3	3	-	1	-	-	-	3	2	3

PT20703	PHARMACOKINETICS AND PHARMACOGNOSY LABORATORY	0 0 4 2

COURSE OBJECTIVES

To enable students to

- impart the knowledge of the rate and extent of drug absorption and distribution
- understand different Pharmacokinetic parameters
- study natural herbs and prepare herbarium photos
- study characteristics of crude drugs

LIST OF EXPERIMENTS

1. In-vitro dissolution study of the given sustained release dosage form using various dissolution media.
2. Study the effect of formulation on drug release (Tablet, Solution, suspension etc.).
3. Determination of effect of pH on the partition co-efficient of drug(s)
4. Determination of protein binding of the given drug(s) and the effect of protein binding on drug bioavailability.
5. In-vitro drug absorption study using everted small intestine sac technique.
6. To calculate the various Pharmacokinetic parameters from the given blood data of I.Vbolus injection (one compartment model).
7. Calculation of Ka (absorption rate constant) absorption curve- Wagner nelson method, Loo-Riegel method
8. Collection of natural herbs and preparation of herbariam/laminated photos for five drugs
9. Study of Microscopy, Macroscopy and powder characters of any three to four crude drugs
10. Identification test for two enzymes papain and casein.
11. Chemical tests for Asafoetida, Benzoin, Tannic acid, Pale catechu and Quinine.
12. Determination of proximate values -Moisture content, Ash value, Extractive values

TOTAL PERIODS: 60

COURSE OUTCOMES

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

- study the effect of different drug formulations
- determine pH and protein binding parameters
- calculate various Pharmacokinetic parameters and absorption rate
- work on Microscopy, Macroscopy and powder characters of drugs

TEXT BOOKS

1. Andrzej Cybulski, Jacob A..Moulijn, M.M. Sharma, Roger A. Sheldon "Fine Chemicals Manufacture: Technology and Engineering" Elseiver Science B.V, 2001.
2. Gopal Rao, M. and Sittig, M., "Dryden's Outlines of Chemical Technology", 3rd Edition, Affiliated East West Press Pvt. Ltd., 2001.

REFERENCES

1. Brahmankar, D.M. and Jaiswal, S.B. "Biopharmaceutics and Pharmacokinetics: a Treatise" 3rd Edition, Vallabh Prakashan, 2015.

2. Vijaya Raghavan, C and Judith Justin. "Experimental Biopharmaceutics and Pharmacokinetics", New century book house (P) Ltd., 2006
3. C.K. Kokate et.al, "Practical Pharmacognosy".
4. Iyengar, "Practical Pharmacognosy".
5. Khandelwal, "Practical Pharmacognosy".

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	3	3	2	3	2	-	-	-	-	-	-	-	2	3
CO2	1	-	-	2	-	-	-	-	-	-	-	-	2	3
CO3	2	2	2	-	1	-	-	-	-	-	-	-	3	3
CO4	2	2	2	2	-	-	-	-	-	-	-	-	3	2

PT20704 COMPUTATIONAL BIOLOGY LABORATORY 0 0 2 1

COURSE OBJECTIVES

To enable students to

- summarize the significance of biological databases
- perform sequence alignment using various sequence alignment tools.
- distinguish the structure and functions of protein molecule using 3D structure of the protein
- construct phylogenetic tree to analysis the evolution

LIST OF EXPERIMENTS

1. Biological Database (DNA) - NCBI-Genbank, EMBL
2. Biological Database (Protein) – Uniprot, Protein Data Bank
3. Sequence Alignment Programs – BLAST, FASTA, Clustal W
4. Protein 3D Structure Prediction Programs – Swissmodel, Rasmol
5. Phylogenetic Analysis Program – Phylip
6. Docking Studies – PatchDock

TOTAL PERIODS: 30

COURSE OUTCOMES

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

- discuss in detail about impotence of biological databases.
- demonstrate sequence alignment by different opensource software programs
- compare the structure of protein molecule to predict its functions.
- evaluate the phylogenetic tree Construction.

TEXT BOOKS

1. Dan Gusfield, "Algorithms on Strings, Trees and Sequences" Cambridge University Press.
2. R.Durbin, S.Eddy, A.Krogh, G.Mitchison, "Biological Sequence Analysis Probabilistic Models of proteins and nucleic acids"

REFERENCES

1. David W. Mount, "Bioinformatics Sequence and Genome Analysis" Cold Spring Harbor Laboratory Press.
2. Arthur K. Lesk, "Introduction to Bioinformatics" Oxford University Press.

CO/PO MAPPING :

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	Programmes Outcomes (POs)													
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	3	2	-	3	1	-	-	-	-	-	-	-	1	-
CO2	2	1	2	2	1	-	-	-	-	-	-	-	1	-
CO3	1	1	1	1	3	-	-	-	-	-	-	-	2	-
CO4	3	2	1	1	2	-	-	-	-	-	-	-	3	-

PT20705 **PROJECT WORK (PHASE I)** **0 0 6 3**

COURSE OBJECTIVES

To enable the students to,

- develop student knowledge for solving technical problems through structured project research study in order to produce competent and sound technologist
- improve the skills to formulate a technical project
- explain the various tasks of the project and standard procedures
- analyse the various procedures for validation of the product and analyse the cost effectiveness

GUIDENCE FOR REVIEW AND EVALUATION

The students may be grouped upto maximum of 4 members and work under a project supervisor. The prototype/simulation may be decided in consultation with the supervisor. A Project Work Phase I report to be submitted by the group and the prototype model which will be reviewed and evaluated for internal assessment by a Committee Constituted by the Head of the Department. At the endo of the semester examination the project work is evaluated based on oral presentation and the Project Work Phase I report is examined jointly by external and internal examiners constituted by the Controller of Examination. It is highly desirable to publish their Project idea in State/National level conference or Symposiums.

TOTAL PERIODS: **90**

COURSE OUTCOMES

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

- Identify the technical ideas, strategies and methodologies.
- Formulate the real-world problem, identify the requirement and develop the design solution.
- Use the new tools, techniques that contribute to obtain the solution to the project.
- Analyze and validate through conformance of the developed prototype and analysis the cost effectiveness.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

COs	Programmes Outcomes (POs)													
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	3	2	3	2			-		2		-		2	2
CO2		3	2	2		-	-	-	2		-	2	3	2
CO3	2	3	2		-	3	-	3	3		-		3	3
CO4	-	-	-	-	3	-	-	2	2	1	3	2	2	2
CO5	-	-			-	2	-	2	2	2	2	-	-	-

COURSE OBJECTIVES

To enable students to

- learn about fundamentals of downstream processes.
- analyse the different methods of product separation.
- know the concept of product recovery and concentration.
- identify the different chromatographic method for product purification.
- acquire depth knowledge on final product development and formulation.

UNIT I INTRODUCTION TO DOWNSTREAM PROCESSING 9

An overview and need to downstream processing - Principles - Characteristics of biomolecules - Cell disruption – Physical, Mechanical, Enzymatic and Chemical methods.

UNIT II PRIMARY SEPARATION AND ISOLATION 9

Pre-treatment of fermented broth, Filtration: Theory of batch filtration, equipments - plate and frame filter, press leaf filter, continuous filtration -rotary drum filter; Centrifugation: principle, design and types of industrial centrifuges (tubular bowl, multichamber bowl, disc stack and decanter centrifuge).

UNIT III PRODUCT RECOVERY AND CONCENTRATION 9

Liquid-liquid extraction, Aqueous two-phase extraction, Super critical fluid extraction, Precipitation of proteins by different methods - Salting in and salting out method; Membrane based separation - Ultrafiltration and Microfiltration, Reverse osmosis, Dialysis.

UNIT IV PRODUCT PURIFICATION 9

Chromatography – Principles, Instruments and Practice; High performance liquid chromatography; Ion exchange chromatography; Size exclusion chromatography; Hydrophobic interaction chromatography and Bioaffinity and Pseudo affinity chromatography.

UNIT V PRODUCT POLISHING 9

Crystallization: theory, equipments for crystallization; drying - theoretical considerations, drying equipments and freeze drying or lyophilisation.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- explain the physicochemical properties and different methods of cell disruption to separate the biological products.
- acquire knowledge about equipment selection and design of mechanical separation process for primary separation and isolation of biotechnological products.
- acquire knowledge on various product recovery techniques.
- concept of advanced chromatographic separation technique and their principles.
- explain the various techniques employed for final product development and formulation.

TEXT BOOKS

1. Belter PA, Cussler E and Hu WS, "Bioseparation – Downstream Processing for Biotechnology", Wiley Interscience (1988).
2. Sivasankar, B. "Bioseparations : Principles and Techniques". PHI, 2005.
3. Asenjo, Juan A. "Separation Processes in Biotechnology". Taylor & Francis / CRC,2000

REFERENCES

1. R.O. Jenkins, (Ed.), "Product Recovery In Bioprocess Technology – Biotechnology" By Open Learning Series, Butterworth-Heinemann.
2. J.C. JansonAnd L. Ryden, (Ed.), "Protein Purification – Principles, High Resolution Methods and Applications", VCH Pub. 2011.
3. R.K. Scopes, "Protein Purification – Principles and Practice", Narosa Pub. 1994.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	3	1	-	-	-	-	1	-	-	-	-	1	1	1
CO2	3	1	-	-	-	-	-	-	-	-	-	1	2	1
CO3	3	1	-	-	-	2	-	-	-	-	-	1	2	-
CO4	3	1	1	-	-	2	1	-	-	-	-	-	1	-
CO5	3	1	2	2	2	2	2	1	-	-	-	-	2	3

PT20802 **PROJECT WORK (PHASE II)** **0 0 12 6**

COURSE OBJECTIVES

To enable the students to,

- develop student knowledge for solving technical problems through structured project research study in order to produce competent and sound technologist
- improve the skills to formulate a technical project
- explain the various tasks of the project and standard procedures
- analyse the various procedures for validation of the product and analyse the cost effectiveness

GUIDENCE FOR REVIEW AND EVALUATION

The students may be grouped upto maximum of 4 members and work under a project supervisor. The prototype/simulation may be decided in consultation with the supervisor. A Project Work Phase II report to be submitted by the group and the prototype model which will be reviewed and evaluated for internal assessment by a Committee Constituted by the Head of the Department. At the endo of the semester examination the project work is evaluated based on oral presentation and the Project Work Phase II report is examined jointly by external and internal examiners constituted by the Controller of Examination. It is highly desirable to publish their Project idea in State/National level conference or Symposiums.

TOTAL PERIODS: 180

COURSE OUTCOMES

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

- Identify the technical ideas, strategies and methodologies.
- Formulate the real-world problem, identify the requirement and develop the design solution.
- Use the new tools, techniques that contribute to obtain the solution to the project.
- Analyze and validate through conformance of the developed prototype and analysis the cost effectiveness.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes
(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

COs	Programmes Outcomes (POs)													
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	3	2	3	2			-		2		-		2	2
CO2		3	2	2		-	-	-	2		-	2	3	2
CO3	2	3	2		-	3	-	3	3		-		3	3
CO4	-	-	-	-	3	-	-	2	-	1	3	2	2	2
CO5	-	-				2	-	-	2	2	2	-	-	-

COURSE OBJECTIVES

To enable students to

- know the principles of analyzing biological data, building models and testing hypotheses using computer science algorithms
- learn the stages of drug discovery and development
- know the QSAR techniques for the prediction of properties
- analyze the binding efficiency of the ligand using docking tools
- present the appropriate tools for modelling and molecular dynamics

UNIT I FUNDAMENTALS OF BIOINFORMATICS 9

Introduction to bioinformatics; Concept of biological databases; Heuristic approaches for database searching: Pairwise sequence comparisons by DOT-MATRIX and dynamic programming - Global (Needleman and Wunsch algorithm) and local (Smith and Waterman algorithm) alignments; Measures of sequence similarity (Alignment score, percentage similarity and identity); BLAST and FASTA; Multiple sequence alignment.

UNIT II DRUG DISCOVERY AND DEVELOPMENT 9

Stages of drug discovery and development; Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation

UNIT III QUANTITATIVE STRUCTURE ACTIVITY REALATIONSHIP 9

SAR versus QSAR, Types of physicochemical parameters, theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis

UNIT IV VIRTUAL SCREENING AND DOCKING 9

Drug likeness screening; Concept of pharmacophore mapping and pharmacophore-based Screening; Docking ligands to macromolecules – Structure based and ligand-based approaches, scoring functions, Docking algorithms – Introduction to AUTODOCK

UNIT V MODELING AND SIMULATION 9

Principles and practices of Homology Modelling; Introduction to ab-initio, semi-empirical & molecular mechanical methods, Introduction to Molecular Dynamic Simulations – Force Field, Energy Minimization, Introduction to GROMACS – run MD Simulation of a Protein and Analyze the results

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- learn to align sequences using dot matrices, dynamic programming, and heuristic approach
- analyze biological problems and data using the latest computational techniques
- use computational methods to help execute a biological research plan

- To develop practical skills in computational approaches to analyze, predict, and engineer biomolecules and biomolecular systems
- To interpret and practice the fundamental concepts of Molecular Modeling and Computer aided Drug Design

TEXTBOOKS

1. Mount D., "Bioinformatics: Sequence and Genome Analysis", Cold Spring Harbor Laboratory Press, New York. 2004
2. Andrew R. Leach, Molecular Modelling Principle and Application, 2nd Edition, Prentice Hall, England,2001

REFERENCES

1. Teresa K. Attwood, David J. Parry-Smith , "Introduction to Bioinformatics" Pearson Education. 1999
2. Jin Xiong, "Essential Bioinformatics", Cambridge University Press; 1st edition 2006.
3. S. C. Rastogi, "Bioinformatics: methods and applications", PHI learning; 4th edition, 2013.
4. David. C. Young, Computational Drug Design – A Guide for Computational and Medicinal Chemists, John Wiley and Sons Ltd, Hoboken, United States, 2009.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

COs	Programmes Outcomes (POs)													
	PO1	PO 2	PO3	PO4	PO 5	PO 6	PO 7	PO8	PO9	PO1 0	PO1 1	PO1 2	PSO1	PSO2
CO1	1	2	-	2	-	-	-	1	-	-	-	1	3	-
CO2	-	1	3	-	2	-	-	-	-	-	-	-	-	1
CO3	2	1	1	-	1	2	-	-	-	-	-	-	-	-
CO4	-	1	-	-	-	1	-	2	-	-	-	2	-	-
CO5	-	2	1	2	-	1	1	2	-	2	2	-	-	-

PT20352 NUTRACEUTICALS 3 0 0 3

COURSE OBJECTIVES

To enable students to

- acquire the basic concepts of Nutraceuticals and functional food, their chemical nature and methods of extraction.
- Study the structure and properties of Nutraceuticals
- study free radicals
- Inculcate anti-nutritional factors in food
- Understand different FDA regulations

UNIT I INTRODUCTION 9

Introduction to Nutraceuticals and its role in health benefits Dietary supplements, importance, definition, classification, list and specifications of dietary supplements in Indian pharmacopoeia (IP) and USP. Current status and challenges in the optimization of herbal drugs as nutraceuticals in India.

UNIT II PROPERTIES, STRUCTURE AND FUNCTIONS OF NUTRACEUTICALS 9

Occurrence and characteristic features of Melatonin, Lycopene, Reservetrol, catechins, Flavones, Lactobacillum, Phytoestrogens, Isoflavones, daidzein, eebustin, lignans and Tocopherols. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals.

UNIT III FREE RADICALS IN HEALTH AND DISEASE 9

Introduction to free radicals - Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis. Free radicals in brain metabolism and pathology, kidney damage, muscle damage.

UNIT IV ANTI-NUTRITIONAL FACTORS PRESENT IN FOODS 9

Types of inhibitors present in various foods and how they can be inactivated. General idea about role of Probiotics and Prebiotics as nutraceuticals. Recent advances in techniques & feeding of substrates. Assessment of nutritional status and Recommended Daily allowances.

UNIT V REGULATIONS IN NUTRACEUTICALS 9

Nutraceuticals and functional food regulations in India. FSSAI regulations in the production of nutraceuticals. FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. AYUSH – Regulation of claims pertaining nutraceuticals. Nutraceuticals in Herbal pharmacopoeia. USDA and FDA regulations in USA.

TOTAL PERIODS: 45

COURSE OUTCOMES

Upon completion of the course, the students will be able to

- Gain knowledge on dietary supplements
- Acquire the knowledge on properties and structure of nutraceuticals
- Work on free radicals
- Inculcate advancements in food substrates
- Know the FSSAI regulations

TEXTBOOKS

1. Kramer, Hoppe and Packer,"Nutraceuticals in Health and Disease Prevention", Marcel Dekker, Inc., NY 2001
2. Bao and Fenwick, "Phytochemicals in Helath and Disease", Marcel Decker, Inc. NY 2004.
3. Tipnis, H.P. Bioavailability and Bioequivalence: An Update New Age International

REFERENCES

1. Yashwant Pathak, "Handbook of Nutraceuticals and Functional Foods. Vol. 1. (Ingredients, formulations, and applications)" CRC Press 2005.
2. Robert Wildman, "Handbook of Nutraceuticals and Functional Foods". 2nd edition. CRC Press 2001
3. Watson, Robald Ross Functional Foods and Nutraceuticals in Cancer Prevention. Blackwell Publishing, 2007.

CO/PO MAPPING:

Mapping of Course Outcomes (CO's) with Programme Outcomes (PO's) and Programme Specific Outcomes (PSO's)

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

Cos	Programme Outcomes (POs)													
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CO1	2	2	2	3	3	1	-	-	-	-	-	-	3	2
CO2	2	3	3	3	2	-	2	-	-	-	-	-	3	2
CO3	3	3	3	3	2	-	2	-	-	-	-	-	3	3
CO4	2	2	2	-	2	1	-	-	-	-	1	-	2	2
CO5	2	3	3	2	1	3	3	2	-	1	1	-	3	3

PAVAI ENGINEERING COLLEGE, NAMAKKAL
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Pharmaceutical Technology
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PT20353 BIOCONJUGATE TECHNOLOGY 3 0 0 3

COURSE OBJECTIVES

To enable students to

- recognize the functional targets and chemistry of active groups.
- summarize the knowledge about the linkers and cleavable reagent systems.
- illustrate about the bioconjugate Reagents.
- outline about enzyme, nucleic acid modification and its application in bioconjugation.
- design and develop the synthetic polymers.

UNIT I FUNCTIONAL TARGETS 9

Amino acids - structure and nature. Derivatization of amino acids – Asp, Glu, Lys, Tyr and C and N terminal amino acids – Important functional groups of polypeptide – Protection of the native conformation and activity of proteins – Oxidative modifications of Pro, Arg, Lys, Tyr, Phe, Cys, & Met – Detection of protein oxidation.

UNIT II CHEMISTRY OF ACIVE GROUPS 9

Sugar functional groups – Derivatization of sugars, polysaccharides, and glycoconjugates - Amine, Thiol, and Photoreactive chemical reactions.

UNIT III BIOCONJUGATE REAGENTS 9

Zero length cross-linkers – Definition, examples, and reactions of carbodiimides – Homo and Hetero bifunctional cross-linkers – Classification, structure, properties, and uses - Trifunctional cross-linkers – Definition, examples – Cleavable reagent systems

UNIT IV ENZYME AND NUCLEIC ACID MODIFICATION AND CONJUGATION 9

Characteristics of common enzymes used for conjugation – Preparation of activated enzymes for conjugation – Chemical modification of nucleic acids – Biotin labeling of DNA – Enzyme conjugation to DNA.

UNIT V BIOCONJUGATE APLICATIONS 9

Preparation of hapten-carrier immunogen conjugates – Antibody modification and conjugation – Immunotoxin conjugation techniques – Conjugation of protein to liposome – Preparation of different sizes of colloidal gold – Preparation of colloidal gold-labeled proteins and their applications.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- acknowledge the modification of existing biomolecule and their reactions.
- develop the knowledge of chemical compounds and its active groups.
- classify various linkers as a Bio conjugate reagent in Genetic engineering
- learn technique to modify enzyme action and their application with the help of bio labelling and biomarkers.
- apply the Bio conjugate technology into the industrial application and medicinal purposes.

TEXT BOOKS

1. G.T. Hermanson, Bioconjugate Techniques, Academic Press, 2013.
2. Bioconjugation Protocols: Strategies and Methods (methods In Molecular Biology) illustrated edition, 2004.

REFERENCES

1. Junhua (Alex) Tao and Romas Kazlauskas, Biocatalyst for green chemistry and chemical process development, John Wiley & Sons, 2011.
2. Principles of Biochemistry, Lehninger, 7th edition,Elsevier, 2017.
3. Chemistry of Bioconjugates: synthesis, characterization and biomedical applications, 1 st edition Ravin Narain, 2013.
4. Antibody drug conjugates: fundamentals of drug development and clinical outcomes to target cancer, 1st edition, 2016.

CO/PO MAPPING:

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CO1	2	1	2	3	2	1	-	-	-	1	1	2	3	-
CO2	-	-	3	3	2	2	2	1	-	-	-	-	-	-
CO3	-	-	2	2	3	-	2	-	-	2	-	1	-	2
CO4	-	-	1	3	3	2	1	2	1	-	-	-	-	-
CO5	1	2	3	1	1	1	-	2	-	-	-	-	1	2

PT20354 PHARMACOTHERAPEUTICS 3 0 0 3

COURSE OBJECTIVES

To enable students to

- analyse the basic therapeutics
- study pathogenesis of cardiovascular and respiratory diseases
- know the basics of oncology
- gain knnowledge different infectious diseases
- Study psychiatry disorders

UNIT I BASIC CONCEPTS OF PHARMACOTHERAPY 9

Introduction; Drug use in the health care system: self-medication, compliance issuses, drug use by the eldery; Impacting the problems of drug use: medication error; Health care reform; Drug related problems; Effects of pharmacokinetic and pharmacodynamics differences on drug therapy.

UNIT II CARDIOVASCULAR DISORDERS 9

Assessment of the cardiovascular system; Hypertension; Dyslipidemia; Stable ischemic heart diseases; Chronic heart failure; Acute decompensated heart failure; Stroke; The arrhythmias; Cardiac arrest.

UNIT III RESPIRATORY DISORDERS 9

Evaluation of respiratory function; Asthma; Chronic obstructive pulmonary diseases; Pulmonary arterial hypertension; Cystic fibrosis; Drug – induced pulmonary diseases.

UNIT IV GASTROINTESTINAL DISORDERS 9

Evaluation of gastrointestinal tract; Gastroesophageal reflux diseases; Peptic ulcer diseases; Inflammatory bowel diseases; Nausea and vomiting; Diarrhea; Constipation; Irritable Bowel syndrome; Portal hypertension and Cirrhosis; Drug induced liver disease; Celiac disease.

UNIT V PSYCHIATRIC AND IMMUNOLOGICAL DISORDERS 9

Evaluation of psychiatric disorders; Hyperactivity disorder; Major depressive disorder; Sleep-wake disorder; Function and evaluation of the immune system; Systemic lupus erythematous; Drug allergy; Solid-organ transplantation.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- summarize the therapeutic approach to management of these diseases including reference to the latest available evidence
- discuss the controversies in drug therapy
- identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy
- develop the knowledge of the pathophysiology of selected disease states and the rationale for drug therapy
- learn the importance of preparation of individualized therapeutic plans based on diagnosis

TEXT BOOKS

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.
3. Pharmacotherapy: Principles and Practice, "Marie A. Chisholm – Burns, Terry L.Schwinghammer, Barbara G.Wells, Patrick M. Malone, Jill M. Kolesar, Joseph T.DiPrio", Forth edition, Mc Graw Hill Education.

REFERENCES

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
3. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
4. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

CO/PO MAPPING:

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CO1	2	3	3	2	3	3	2	3	2	-	2	-	3	3
CO2	2	2	2	1	-	-	2	3	-	-	-	-	3	3
CO3	3	3	2	2	2	2	-	-	-	-	-	-	3	3
CO4	3	3	3	3	2	3	-	-	-	-	-	-	3	2
CO5	3	2	2	3	3	3	-	1	1	-	-	1	2	3

COURSE OBJECTIVES

To enable students to

- impart basic knowledge in vaccinology.
- study the various classifications of vaccines and its preparations.
- study the various design and research conducted on vaccine.
- study the various computational tools for vaccine design.
- know the modern approaches to vaccine in animal testing, commercialization, and quality control.

UNIT I IMMUNOLOGICAL CONCEPTS IN VACCINOLOGY 9

Short history of vaccination; Requirements for induction of immunity; Epitopes - Linear and Conformational epitopes; Characterization and location of APC, MHC and immunogenicity; Rationale vaccine design based on clinical requirements - Hypersensitivity, Immunity to Infection, Autoimmunity, Transplantation, Tumor immunology, Immunodeficiency; Mechanism of adjuvant action; Scope of future vaccine strategies

UNIT II CLASSIFICATION OF VACCINES AND ITS PREPARATIONS 9

Active and passive immunization; Viral/bacterial/parasite vaccine differences; Methods of vaccine preparation - Live, killed, attenuated, sub unit vaccines; Vaccine technology- Role and properties of adjuvants, Recombinant DNA and Protein based vaccines, Plant-based vaccines, Edible vaccines, Reverse vaccinology, Combination vaccines, Therapeutic vaccines, Peptide vaccines, Conjugate vaccines; Antibody genes and Antibody engineering- Chimeric and Hybrid monoclonal antibodies.

UNIT III VACCINE RESEARCH AND DESIGN 9

Fundamental research to rational vaccine design; Antigen identification and delivery; T-Cell expression cloning for identification of vaccine targets for intracellular pathogens; Fundamentals of Immune recognition, Implications for manipulating the T-Cell repertoire, Targeting Dendritic cells; A rational approach for Vaccine development - Cellular basis of T Cell memory , Rational design of new vectors , CpG adjuvant activity, Transcutaneous immunization; Vaccination studies and recent advances in Malaria, Tuberculosis , HIV.

UNIT IV VACCINE PRODUCTION AND REGULATION 9

Vaccine manufacturing, Evolution of adjuvants across the centuries, Vaccine additives and manufacturing residuals, Regulation and testing of vaccines, Regulation of vaccines in developing countries, Vaccine safety and Legal issues.

UNIT V ANIMAL TESTING, COMMERCIALISATION, QUALITY CONTROL 9

Quality control and regulations in vaccine research - In-vitro experimental validations for predictions of vaccines by software, Animal testing, Rational design to clinical trials, Large scale production, Commercialization, Ethics.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- discuss about the overview of microbial pathogenesis.
- identify about various aspects of host pathogen interactions.
- summarise the advanced pathogen control techniques and its applications.
- familiarize about Host-Pathogen Interactions.
- study about the modern approaches for controlling pathogens.

TEXT BOOKS

1. Male, David et al., "Immunology", 7th Edition, Mosby Publication, 2007.
2. Kindt, T.J. etal., "Immunology", 6th Edition, W.H. Freeman, 2007.
3. Janeway, C.A. etal., "Immunology: The Immune Systems in Health and Diseases", 6th Edition, Garland Science, 2005.

REFERENCES

1. Coico, R. etal., "Immunology: A Short Course", 5th Edition, Wiley – Liss, 2003.
2. Parham, Peter "The Immune System", 2nd Edition, Garland Science, 2005.
3. Abbas, A.K. etal., "The Cellular and Molecular Immunology", 6th Edition, Sanders / Elsevier, 2007.
4. Lydyard, P.M. "Instant Notes in Immunology", Viva Books Pvt. Ltd., 2000

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	PO1	**PO 2**	**PO3**	**PO4**	**PO 5**	**PO 6**	**PO 7**	**PO8**	**PO9**	**PO1 0**	**PO1 1**	**PO1 2**	**PSO1**	**PSO2**
CO1	3	3	2	3	2	1	-	2	2	1	-	2	1	2
CO2	2	3	3	3	3	2	2	2	3	1	-	3	-	2
CO3	1	3	3	2	2	3	2	3	3	3	-	2	-	3
CO4	2	-	3	1	1	3	3	3	3	1	1	-	-	3
CO5	2	2	3	-	1	-	3	1	2	1	3	2	-	3

COURSE OBJECTIVES

To enable students to

- recognize the international, and national regulatory processes concerning chemical risk assessment in humans, biomaterials, and medical devices.
- discuss about how to develop awareness of how toxicology is applied in real world regulatory situations.
- explain the complexities and competing interests that are part of the regulatory decision making.
- classify the methods used to evaluate risk and produce safety guidelines, including laboratory testing, epidemiological studies
- outline the product regulations and produce alternative strategies for challenges in the future.

UNIT I INTRODUCTION 9

History and classification of Toxicology, Animal and plant toxins, Absorption and distribution of toxicants, Human health risk assessment, medical device and biomaterials, safety evaluation

UNIT II REGULATIONS GOVERNING TOXICOLOGY 9

Aim and mission, Regulatory aspects and strategy in drug products, regulatory process in toxicology, quality assurance in regulatory toxicology, toxicological risk assessment, Regulations affecting cosmetic and over-the- counter drug products

UNIT III TOXICOLOGY AND DRUG PRODUCT REGULATIONS 9

Drug discovery and development: Drug Laws, FDA, OECD, ICH, Aspects of the IND / NDA process, toxicology and other issues, pediatric drug products, drug combinations, excipients and reformulations, conclusions

UNIT IV TOXICOGENEOMICS, GENETIC TOXICOLOGY AND REGULATORY POLICY 9

History, Health impact of genetic alterations, Cancer and genetic risk assessments, Mechanisms of induction of genetic alterations - DNA damage, DNA repair, Formation of gene mutations, Formation of chromosomal alterations, Microarrays in toxicology, genomics, proteomics and metabolomics, case examples, toxicogenomics in regulatory environment. Genetic toxicology technologies and concepts. Influence of genetic toxicology research on regulatory policy, future role in safety testing strategies.

UNIT V ALTERNATIVES IN TOXICOLOGY 9

Introduction, Societal need for information about toxic chemicals, evolution of alternatives in toxicology, human science, and animal welfare, assessing alternatives, challenges and future.

TOTAL PERIODS 45

COURSE OUTCOMES

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

- define the general principles in toxicological risk assessment, both ecotoxicology and human toxicology.
- explain the safety testing strategies, legal regulations, and alternative options in toxicology.

- know the basic principles of current, cutting-edge knowledge in environmental and human health toxicology.
- demonstrate an understanding of legal, regulatory, and ethical considerations relating to toxicology within the broader societal context.
- categorise different testing strategies and alternatives for societal needs.

TEXT BOOKS

1. Shayne C. Gad, "Regulatory Toxicology", Second Edition, CRC Press, 2001.
2. Ian Dewhurst, "Regulatory Toxicology" in the European Union, Royal Society of Chemistry, 2017

REFERENCES

1. Sidney Green, "Toxicology and Regulatory Process". CRC Press, 2006.
2. Eds. Franz XaverReichl and Michael Schwenk , "Regulatory Toxicology" Springer, 2014.
3. Renuka Sengupta, "Regulatory Toxicology: Essentially Practical Aspects", Narosa Publishing House 2015

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CO's	PO's												PSO's	
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CO1	3	2	3	1	-	2	-	-	-	3	-	2	3	3
CO2	1	2	-	2	-	-	1	-	-	-	-	1	3	3
CO3	2	2	2	1	1	2	-	-	-	-	-	-	3	2
CO4	3	1	2	1	2	2	-	-	-	-	-	2	2	2
CO5	3	2	2	1	2	2	-	-	-	-	-	2	2	2

PT20453 ADVANCES IN DRUG DELIVERY SYSTEMS 3 0 0 3

COURSE OBJECTIVES

To enable students to

- Train the students on science and technology of advanced drug delivery systems
- Train the students to design drug delivery systems for passive and active targeting
- study various approaches for development of novel drug delivery systems
- imparrt the properties of polymer and its significance in drug delivery systems
- Interpret physicochemical properties of the drug with the drug delivery system modules

UNIT I INTRODUCTION 9

Introduction to Targeted Drug Delivery Concept of drug targeting. Basis for drug targeting, need for targeting, the physicochemical and physiological basis of targeting, basis for drug targeting both active and passive. Monoclonal antibodies another marker, design of targeted DDS.

UNIT II POLYMERS 9

Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems. Microencapsulation: Definition, advantages and disadvantages, microspheres/microcapsules, microparticles, methods of microencapsulation, applications

UNIT III PEPTIDE AND PROTEIN-BASED DDS 9

Chemistry and special features of peptide and protein molecules, stability, analysis, Formulation and evaluation Barriers to peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene-based DDS.

UNIT IV BRAIN DRUG DELIVERY SYSTEM 9

Receptor mediated drug targeting, Colon targeting approaches, DDS Targeting to the brain and targeting in cancer and infectious diseases.

UNIT V EVALUATION OF DRUG DELIVERY SYSTEM 9

Pharmacodynamic models for evaluation of DDS containing drugs, Toxicity testing in DDS. Design of toxicological studies, Quality assurance in toxicology studies, Toxicity by routes – Parental, oral, percutaneous and inhalation, Target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity.

TOTAL PERIODS: 45

COURSE OUTCOMES

Upon completion of the course, the students will be able to

- apply design and development of peptide-based drug delivery system
- design and development of brain drug delivery system
- kmow the design and development of polymer-based drug delivery system
- Evaluate toxicity of drug delivery system
- familiarise design and development of colon drug delivery system

TEXT BOOKS

1. Binghe wang, Teruna Siahaan and Richard A Soltero "Drug delivery principles and applications" John wiley and Sons Inc, 2005
2. Roseman, T.J.: Controlled Release Drug Delivery Ssytems, Marcel Dekker New York

3. Controlled Drug Delivery – Foudamentals& applications by J. R. Robinson-2nd edition – Marcel Dekker, 1987

REFERENCES

1. Drug targeting: organ specific strategies: By GrietjeMolema, D. K. F. Meijer 2001
2. Pulsed and Self-Regulated Drug Delivery, J. Kost, Florida, CRC Press, 1987
3. Polymeric Drugs and drug Delivery Systems Raphael M. Ottenbrite and Sung Wan Kim, eds. Technomic, 2001

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CO4	3	2	2	-	-	3	-	-	-	-	2	-	2	2
CO5	2	3	3	2	1	3	3	-	-	1	2	-	3	2

COURSE OBJECTIVES

To enable students to

- know the basis of pharmacogenomics.
- acquire knowledge on different genetic variations.
- study pharmacogenomic drugs.
- Gain knowledge on metabolism and structural genomics.
- know applications related to pharmacogenomics

UNIT I PHARMACOGENOMICS AND PERSONALIZED MEDICINE 9

Pharmacogenetics Challenges, Opportunities, and Evolving Landscapes in Pharmacogenomics and Personalized Medicine, Genetic drug response profiles, the effect of drugs on Gene expression, pharmacogenomics in drug discovery and drug development. Concept of individualized drug therapy, Drivers and the promise of personalized medicine, Strategies for application of pharmacogenomics to customize therapy, Barriers.

UNIT II HUMAN GENOME 9

Expressed sequence Tags (EST) and computational biology, Microbial genomics, computational analysis of whole genomes, computational genome analysis, Genomic differences that affect the outcome of host pathogen interactions, Protein coding genes, repeat elements, genome duplication, analysis of proteome, DNA variation, Biological complexity. Single nucleotide polymorphisms (SNP's) in Pharmacogenomics - approaches, number and types of SNPs, Study design for analysis, Analytical issues, Development of markers.

UNIT III ASSOCIATION STUDIES IN PHARMACOGENOMICS 9

Viability and Adverse drug reaction in drug response, Multiple inherited genetic factors influence the outcome of drug treatments, Association studies in pharmacogenomics, Strategies for pharmacogenomics Association studies, Benefits of Pharmacogenomics in Drug R & D.

UNIT IV GENOMICS APPLICATIONS FOR DRUG ACTION, TOXICITY AND DESIGN 9

Platform technologies and pharmaceutical process, its applications to the pharmaceutical industry, Understanding biology and diseases, Target identification and validation, Drug candidate identification and optimization, safety and toxicology studies. The need of protein structure information, protein structure and variation in drug targets-the scale of problem, Mutation of drug targets leading to change in the ligand binding pocket.

UNIT V PHARMACOGENOMICS – CASE STUDIES 9

Study of pharmacogenomics of human P-Glycoprotein, drug transporters, lipid lowering drugs, chemotherapeutic agents for cancer treatment.

TOTAL PERIODS 45

COURSE OUTCOMES

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

- know the basic pharmacogenomic drugs.
- analyse different pharmacogenomic drugs

- work on different metabolic and structural aspects of drugs.
- optimize the lead molecule in drug development

TEXT BOOKS

1. Laurence L. Brunton, Bruce A. Chabner, Björn C. Knollmann., 2011 Goodman & Gilman's, "The pharmacological basis of therapeutics", (12th ed.) by McGraw Hill education.
2. Guilherme Suarez-Kurtz., 2007, "Pharmacogenomics in Admixed Populations", by Landes Biosciences
3. Sweet, Kevin M., Michaelis, Ron C., "The busy physician's guide to Genetics, Genomics and Personalized Medicine" by Springer Publications, 2011.

REFERENCES

1. Daniel A. Brazeau, PhD, and Gayle A. Brazeau. 2006 "A Required Course in Human Genomics, Pharmacogenomics and Bioinformatics", American Journal Pharmaceutical Education, 2006..
2. Rapley, R. & Harbron, S, "Molecular analysis and Genome discovery", John Willey & Sons, Ltd., 2004.
3. Alan H.B. Wu. Kiang-Teck J. Yeo., "Pharmacogenomic Testing in Current Clinical Practices" by Humana Press, 2010.

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CO4	3	1	2	1	2	2	-	-	-	-	-	2	2	2
CO5	3	2	2	1	2	2	-	-	-	-	-	2	2	2

COURSE OBJECTIVES

To enable students to

- describe the principles of parenteral dosage form formulation.
- execute the concepts involved in the manufacture of sterile products.
- solve the difficulties associated with drug delivery to ear, ophthalmic and nasal region.
- differentiate the use of various additives in sterile formulations.
- prepare parenteral based on the guidelines of regulatory bodies.

UNIT I INTRODUCTION TO PARENTERAL PRODUCTS 9

Pre-formulation factors; Routes of administration; Water for injection; Pyrogenicity; Non-aqueous vehicles, Isotonicity and Methods of its adjustment; Formulation details - Containers and Closures and their selection, Prefilling treatment - Washing the container and closers, Preparation of solution and suspension, Filling, Closing of ampoules, vials, infusion fluids, Lyophilization, Preparation of sterile powders; Equipment for large scale manufacture and Evaluation of parenteral products.

UNIT II ASEPTIC TECHNIQUES IN PARENTERALS 9

Aseptic techniques - Source of contamination, Methods of prevention, Sterilization methods – Steam - Dry heat – Filtration – Gas - Ionizing radiation with their advantages and disadvantages. Design of aseptic area - laminar flow bench, Air handling units, Services, and Maintenance; Stability evolution of sterile pharmaceutical dosage forms

UNIT III EAR, NASAL AND OPHTHALMIC DRUG DELIVERY 9

Nasal and ocular drug delivery overview; Membrane transport processes in the eye, Nasal and Ocular drug transfer following systemic drug administration; Ocular pharmacokinetics and pharmacodynamics ocular penetration enhancers; Corneal collagen shields for ocular drug delivery; The noncorneal route in ocular drug delivery, Ocular iontophoresis; Mucoadhesive polymers in ophthalmic drug delivery; Formulation of various ophthalmic products with their characterization.

UNIT IV FORMULATION ADDITIVES 9

Study of different types of additives. antioxidants and preservatives, coloring and flavouring agents, emulsifying and suspending agents, basic materials for ointment bases, diluents and pharmaceutical solvents, regulatory perspectives: GRAS, IIG; new developments in excipient science, functional and co-processed excipients, international patented excipients. Implications of quantitative selection of each excipient in product development

UNIT V PARENTERAL REGULATIONS AND VALIDATIONS 9

cGMP regulations of parenteral drugs; Risk assessment and mitigation in aseptic processing; Development challenges and validation of fill and finish processes for bio-therapeutics; Excipients for parenteral dosage forms - Regulatory considerations and controls, Parenteral product specifications and stability, The management of extractables and leachable in pharmaceutical products, Process analytical technology and rapid microbiological methods, Quality assurance. Validation of sterility. Particulate contamination

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- describe the principle of manufacturing parenteral products.
- illustrate the various strategies involved in manufacturing of sterile products.
- demonstrate drug delivery to ear, nose and ophthalmic organs.
- examine the role of additives in formulation of sterile products.
- appraise the guidelines formulation, manufacturing, packaging, and marketing of sterile products.

TEXT BOOKS

1. Sandeep Nema, John D. Ludwig, "Pharmaceutical Dosage Forms Parenteral Medications", Third Edition Volume 3, Informa Healthcare is a trading division of Informa UK Ltd
2. Aulton, Michael E. "Pharmaceutics: The Science of Dosage Form Design" IInd Ed., Churchill Livingstone, 2002.

REFERENCES

1. Ashim K. Mitra, Marcel Dekker "Ophthalmic Drug Delivery Systems" Second Edition, Revised and Expanded, 2003
2. Allen, Loyd V. et al. "Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems"
3. Lachman "Theory and Practice of Industrial Pharmacy".

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

COs	Programmes Outcomes (POs)													
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	-	1	1	-	-	-	-	-	-	-	-	-	-
CO2	2	2	1	2	-	1	1	1	-	-	-	1	-	1
CO3	1	3	3	3	1	1	-	1	-	-	-	-	-	1
CO4	-	-	-	-	1	-	1	-	-	-	-	-	1	-
CO5	-	-	-	-	1	3	1	3	-	-	-	-	-	1

PT20552 CLINICAL RESEARCH AND PHARMACOVIGILANCE 3 0 0 3

COURSE OBJECTIVES

- compare the development and global scenario of pharmacovigilance and their establishment in an organization.
- develop the skills of classifying drugs, diseases, and adverse drug reactions.
- compare the methods of pharmacovigilance.
- distinguish the statistical methods for the evaluation of drug molecule
- teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance

UNIT I INTRODUCTION TO CLINICAL RESEARCH 9

Introduction of Clinical Research, Clinical Trial Phases, Pharmacological Principal of Clinical Research, Drug Development and Launch, ICH GCP, Schedule Y, ICMR, Indian GCP

UNIT II PROCESS IN CLINICAL RESEARCH 9

Clinical Trial study Design, Project Managements, key Stakeholders in Clinical Research, Study Setup Process, Clinical Monitoring, Investigators Broacher, Informed Consent form process, IRB/ IEC review process, Protocol

UNIT III QUALITY AND DOCUMENTATION 9

21 CRF Part 11, Site Auditing, Sponsor Compliance And Auditing, SOP For Clinical Research, Quality System In PV, Expedited Reporting Criteria, Essential documents, Trial master file, Archival of study documents

UNIT IV PHARMACOVIGILANCE 9

Introduction of Pharmacovigilance Overview of Pharmacovigilance, Standard Terms and Terminology in Pharmacovigilance, Medical Evaluation of Adverse Events in Pharmacovigilance, PV law and Guideline

UNIT V PHARMACOVIGILANCE PROCESS 9

Case Processing in Pharmacovigilance, Pharmacovigilance Reporting Database, Signal Detection, Managements And Risk Assessments & Evaluation, Medical Dictionary For Regulatory Activities medDRA

TOTAL PERIODS 45

COURSE OUTCOMES

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

- explain adverse drug reaction in proper format.
- illustrate the data generated during pharmacovigilance study.
- correlate the regulatory requirements of different countries.
- predict the phases of clinical trials and pharmacovigilance.
- evaluate the pharmacokinetics and pharmacodynamics of the drug.

TEXT BOOKS

1. Sumit Verma, S and Gulati, Y, "Fundamentals of Pharmacovigilance", Paras Medical Publishers, 2017
2. Gupta, S. K, "Textbook of Pharmacovigilance", Jaypee Brothers Medical Publishers,2011
3. Elizabeth B. Andrews, Nicholas Moore, "Mann's pharmacovigilance" third edition

REFERENCES

1. Waller, P and Harrison Woolrych, M, "An Introduction to Pharmacovigilance", Wiley- Blackwel, 2nd Edition, 2017.
2. Orleans-Lindsay, J, "Pharmacovigilance Medical Writing: A Good Practice Guide", Wiley Blackwell, 2012
3. Mohanta, G.P and Manna, P.K, "A Textbook of Pharmacovigilance: Concept and Practice", Pharma Med Press, 2015.
4. Andrews, E.B and Moore, N. Mann's "Pharmacovigilance", Wiley-Blackwel, 3rd Edition, 2014

CO/PO MAPPING:

Mapping of Course Outcome (CO's) with Programme Outcomes (PO's) and Programme SpecificOutcomes (PSO's)

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

CO's	PO's												PSO's	
	1	2	3	4	5	6	7	8	9	10	11	12	1	2
CO1	3	2	3	1	-	2	-	-	-	3	-	2	3	3
CO2	1	2	-	2	-	-	1	-	-	-	-	1	3	3
CO3	2	2	2	1	1	2	-	-	-	-	-	-	3	2
CO4	3	1	2	1	2	2	-	-	-	-	-	2	2	2
CO5	3	2	2	1	2	2	-	-	-	-	-	2	2	2

PAVAI ENGINEERING COLLEGE, NAMAKKAL
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Pharmaceutical Technology
12/8/22
AUTONOMOUS

PT20553 **BIOSAFETY** 3 0 0 3

COURSE OBJECTIVES

To enable students to

- recognize the basic knowledge on biosafety levels.
- discuss various hazards caused by the GMOs.
- classify the role of regulatory committees in controlling the risk
- outline the risk involved in using GMOs and LMOs.
- design the biosafety procedure in lab and research institutions on handling pathogenic microorganisms.

UNIT I PRINCIPLES OF BIOSAFETY 9

Introduction, Historical Background, Introduction to Biological Safety Cabinets, Primary Containment for Biohazards, Biosafety Levels, Biosafety Levels of Specific Microorganisms, Biosafety guidelines - Overview of National Regulations and relevant International Agreements including Cartegana Protocol..

UNIT II BIOSAFETY IN INDUSTRIES 9

Hazard assessment, Use of genetically modified organisms & their release in environment; special procedures for rDNA-based product production (Vaccine and Insulin); Biosafety in laboratory, Laboratory associated infections and other hazards; Prudent biosafety practices in laboratory

UNIT III BIOSAFETY – REGULATORY FRAMEWORKS 9

Bio-safety concerns at the level of individuals, institutions, society, region, country and world. Regulatory framework in India governing GMOs-Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBC), Review Committee on Genetic Manipulation, Genetic Engineering Approval Committee (GEAC), State Biosafety Coordination Committee (SBCC), District Level Committee (DLC). Rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells.

UNIT IV RISK ASSESMENT 9

Definition of GMOs & LMOs, GMO applications in transgenic microorganisms, Risk Analysis, Risk Assessment, Risk management and communication Risk assessment in various industries-pharmaceuticals, food and beverages etc., steps towards minimizing the risk operations in industries.

UNIT V SAFETY AND BIOSAFETY - CASE STUDIES 9

Recommended Biosafety Levels for Infectious Agents and Infected Animals, Rules and regulation for handling of microbes in laboratory purposes, lab construction procedure, decontamination and discarding procedure of laboratory used microorganisms. Case studies -swine flu spreading, Bhopal tragedy etc.,

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- recall the various biosafety levels.

- explain the various biosafety guidelines
- identify the role of regulatory committees in controlling the risk
- analyze the risk involved in using GMOs and LMOs products
- differentiate the various safety procedures followed in various industries

TEXT BOOKS

1. R.C. Dubey., 2014. A Text Book of Biotechnology Fifth Revised Edition, S. Chand Publications
2. Anupam Singh, Ashwani Singh, 2012. Intellectual property rights and Bio-Technology (Biosafety and Bioethics), Published by Bio-Green Books, New Delhi.

REFERENCES

1. Mueller, M.J., "Patent Law", 3rd Edition, Wolters Kluwer Law & Business, 2009.
2. V Sreekrishna, 2017. Bioethics and Biosafety in Biotechnology by New age International publishers.
3. Sateesh, M.K., 2008. Bioethics and Biosafety, IK International Publishers.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	1	1	1	1	-	-	-	-	-	1	-	1	1	1
CO2	2	2	-	2	-	-	-	-	-	-	1	1	-	1
CO3	3	-	2	1	2	-	-	1	-	-	-	-	-	-
CO4	1	1	1	1	1	1	-	-	-	-	-	-	2	-
CO5	1	1	1	-	1	-	-	-	-	-	-	-	-	1

PT20554 **REGULATORY REQUIREMENTS IN PHARMACEUTICAL INDUSTRY** 3 0 0 3

COURSE OBJECTIVES

To enable students to

- enable students to acquire knowledge in drug regulatory affairs in India and at international level
- know the implications of regulatory issues concerning pharma industries
- to acquire knowledge on intellectual property rights
- outline the regulation and guidelines follows in pharma industry.
- Study the ethical issues in health and disease.

UNIT I INDIAN DRUG REGULATORY ASPECTS 9

Pharmacopoeias; Indian, British, U.S, European, Japanese Regulatory bodies & amp; requirements - Indian FDA, WHO GMP; U.S. FDA, U.K. MCA, Australian TGA, Japanese PMDA. Monographs; Standards, Specifications of different dosage forms, CDSCO, MHFW, IPC, ICMR, NPPA, The Drugs (Prices Controls) Order, 1955. Magic Remedies and Objectionable advertisements Act, Prevention of Food Adulteration Act 1954], Intellectual property rights,Patent act- Patent, TradeMark Regn, TRIPS.

UNIT II REGULATORY ASPECTS 9

Pharmaceuticals: Drug manufacture; Personnel, Buildings and Facilities, Process Equipment, Documentation and Records, Materials Management, Production and In-Process Controls, Packaging and Identification Labelling of Finished products, API's and Intermediates, Storage and distribution, – Biotechnology derived products; Principles, Personnel, Premises and equipment, production, labelling, Lot processing records and distribution records, quality assurance and quality control

UNIT III INTELLECTUAL PROPERTY RIGHTS 9

Patent system – Different types of patents – Filing process of application for patent-Rights of patentee – Infringement of patents – The patent rules 2003 as amended by the patents (amendment) rules 2016, TRIPS and other Treaties (WIPO,WTO, GATTS)

UNIT IV REGULATIONS AND GUIDELINES 9

Introduction to ICH, ICH Committee, GCP- ICH E6, 21 CFR Part 312, GMP- ICH Q7, 21 CFR part 211, ICH Q8, 21 CFR part 58, 21 CFR part 11, NDA/ IND / ANDA Approval, Regulation of preclinical studies, Regulations in EU

UNIT V REGULATORY AND ETHICAL ISSUES IN HEALTH AND DISEASE 9

Animal experimentation: concerns of welfare, Justification of use of animals in research; use of alternatives; Human experimentation-Nuremberg code and Helsinki declaration; Assisted Reproductive Technologies, Pre-implantation genetic diagnosis, Surrogacy, Use of Embryos; Therapeutic and Reproductive Cloning-Ethical, Legal and Social Issues; genetic testing and Genetic Screening, Types of Testing, Clinical Utility and Validity of Tests, Testing processes, Social stigma, discrimination, misuse of data; HGP & ELSI, case study; Somatic and Germline gene therapy; Organ transplantation and Xenotransplantation; Biosafety and biodiversity: Classification of microorganisms based on safety, Biosafety levels, Risk groups, Risk Assessment and Management, Spill Protocols, Biosafety

Containment guidelines; Biodiversity – Need and Methods for Protection; Convention for preservation of biodiversity and farmer's rights; patenting of biodiversity: ethical issues

TOTAL PERIODS 45

COURSE OUTCOMES

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

- be familiarize with the pharmaceutical industry manufacturing practices and regulatory aspects of pharmacy products.
- know the process of patenting activities
- the quality guidelines followed for pharmaceutical products and few of the aspects involved in document preparation for pharmaceutical product registration.
- acquire knowledge about the regulatory guidelines of pharmaceutical industry practices
- update the bioethical guidelines related to various health practices.

TEXT BOOKS

1. Deborah E Bouchoux, 2012 fourth edition Intellectual Property: The Law of Trademarks, Copyrights, Patents, and Trade Secrets
2. C.V.Subbrahmanyam and J.Thimmasetty, "Pharmaceutical regulatory affairs", 1stEdn., vallabh Prakashan, New Delhi, 2012.
3. Willig, H., Tuckeman, M.M. and Hitchings, W.S., "Good Manufacturing Practices for Pharmaceuticals", 5th Edition, Marcel Dekker Drugs and the Pharmaceutical Sciences, by CRC Press, New York, 2000.

REFERENCES

1. Ira R. Berry, The Pharmaceutical Regulatory Process, marcel dekker Series: Drugs and the Pharmaceutical Sciences, by CRC Press, Newyork, 2004.
2. Mindy J. Allport-Settle, Current Good Manufacturing Practices: Pharmaceutical, Biologics, and Medical Device Regulations and Guidance Documents Concise Reference, Pharmalogika Inc., USA, 2009.
3. Sharma, P.P., "How to Practice GMPs", 3rd Edition, Vandana Publications, 2006.
4. Abraham, John and Smith, Helen Lawton, "Regulation of the Pharmaceutical Industry", Palgrave / Macmillan, 2003.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

COs	Programmes Outcomes (POs)													
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	1	1	-	-	-	-	-	1	-	1	1	1
CO2	2	2	-	2	-	-	-	-	-	-	1	1	-	1
CO3	3	-	2	1	2	-	-	-	-	-	-	-	-	-
CO4	1	1	1	1	1	-	-	-	-	-	-	-	2	-
CO5	1	1	1	-	1	-	-	-	-	-	-	-	-	1

COURSE OBJECTIVES

To enable students to

- study the basic concept of pharmacognosy.
- know about biosynthesis of secondary metabolites.
- learn to isolate the phytopharmaceuticals from different source.
- to analyze the extracted crude drug.
- study the preservation techniques used to store crude drugs.

UNIT I INTRODUCTION TO PHARMACOGNOSY 9

Definition, history, scope and development of pharmacognosy. Sources and Classification of drugs: Biological, marine, geographical and plant tissue cultures as sources of drugs. Alphabetical, morphological, taxonomical, pharmacological and chemical Classification. Cultivation, collection, processing and storage of crude drugs. Different systems of medicine existing in India their basic principles and their relation to pharmacognosy.

UNIT II BIOSYNTHESIS OF SECONDARY METABOLITES 9

Biosynthesis approach - Building blocks and metabolic pathways for the formation of secondary metabolites such as alkaloids, isoprenoids, coumarins, flavones and glycosides; Study of photosynthesis with special reference to its role in biosynthesis of natural products. Molecular Mechanisms and Gene Regulation for Biosynthesis of Medicinal Plant Active Ingredients.

UNIT III ISOLATION OF PHYTOPHARMACEUTICALS 9

Introduction to tissue culture with reference to phytopharmaceuticals; Extraction and isolation of plant drugs - conventional and modern techniques used in extraction and separation of phytoconstituents; Steroids from natural sources; Microbial Transformation of steroids.

UNIT IV ANALYSIS OF CRUDE DRUGS 9

Types and significance of standards of crude drugs included in I.P. and B.P, application of spectroscopy and chromatography techniques for isolation, identification, and analysis of phytoconstituents; Principles and methods of Quantitative microscopical analysis - Stomatal index, Stomatal number, Palisade ratio, Vein islet number and vein termination number; Lycopodium Spore method for the evaluation of starches.

UNIT V PRESERVATION OF DRUGS 9

Commercial aspects of drug production, preservation and storage of crude drugs; Changes occurring in drying and comminution; Enzyme action in vegetable drugs; Adulteration and evaluation of crude drugs; Deterioration of drugs due to insects and pests.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- know the basics of pharmacognosy
- illustrate the metabolic pathways and biosynthesis of metabolites
- adapt the knowledge on phytopharmaceuticals

- analyze and understand crude drugs
- correlate commercial aspects of pharmacognosy

TEXT BOOKS

1. W.C.Evans, Trease and Evans "Pharmacognosy", 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., "Pharmacognosy", 9th Edn., Lea and Febiger, Philadelphia, 2011.

REFERENCES

1. Dr. SH. Ansari, "Essentials of Pharmacognosy", IInd edition, Birla publications, New Delhi, 2007
2. R.D. Choudhary, "Herbal drug industry", Ist Edn, Eastern Publisher, New Delhi
3. M.A. Iyengar, "Anatomy of Crude Drugs"
4. T.E. Wallis, "Textbook of Pharmacognosy"

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	2	2	2	3	2	1	-	-	-	-	2	-	3	3
CO2	-	3	3	-	2	-	2	2	-	-	-	-	2	2
CO3	3	3	2	2	-	-	1	-	-	-	-	-	3	3
CO4	3	2	2	-	-	1	-	-	-	-	2	-	2	3
CO5	2	3	2	2	1	3	3	2	-	1	2	-	2	3

PT20652 STEM CELL AND TISSUE ENGINEERING 3 0 0 3

COURSE OBJECTIVES

To enable students to

- Gain the basic knowledge about stem cells with their properties and classification .
- acquire knowledge about various clinical applications of stem cells.
- learn about the fundamentals of tissue engineering.
- known about the tissue architecture and its dynamics.
- recogonise the concepts for producing tissue engineered therapies.

UNIT I INTRODUCTION TO STEM CELLS 9

Introduction to stem cells: Definition, Types of stem cells and their Sources; Properties of Stem cell with respect to potency, self-renewal and clonality; Embryonic stem cells; Adult stem cells; Pluripotency of embryonic stem cells, Origin and characterization of human embryonic stem cells; Derivation of human embryonic stem cells: immunosurgical isolation, mechanical isolation, using a whole intact embryo; Differentiation of human embryonic stem cells – *in vitro* and *invivo*; Embryonic versus adult stem cells.

UNIT II CLINICAL APPLICATION OF STEM CELLS 9

Stem cell Therapy for leukemia, immune deficiencies, Diabetes, Liver disease, Cardiovascular disease, Neurological disorders such as Parkinson's diseases, Huntington's diseases and Alzheimer's diseases, Organ factories; Haematopoietic Stem cells in therapy; Stem cell in cancer: Colorectal cancer, Pancreatic cancer, Prostate cancer; Ethics of Stem cell research.

UNIT III INTRODUCTION TO TISSUE ENGINEERING 9

Introduction to tissue engineering- Basic definition; Current scope of development; Use in therapeutics; Cell numbers and Growth rates; Measurement of cell characteristics - Morphology, Number viability, Motility and Functions; Measurement of tissue characteristics - Appearance, Cellular component.

UNIT IV TISSUE ARCHITECTUREAND DYNAMICS 9

Tissue types and Tissue components; Tissue repair and engineering wound healing and sequence of events - Cell-Matrix- Cell-Cell Interactions - telomeres and Self renewal- Cell migration in tissue engineering; Dynamic states of Tissues; Homeostasis in highly prolific tissues: Bone marrow, Villi in small intestine and Skin; Tissue dynamics as interacting cellular fate processes.

UNIT V PRODUCING TISSUE ENGINEERED THERAPIES 9

Product characterization - components, safety, efficacy; Preservation -freezing and drying; Patent protection; Regulation of tissue-engineered products; Ethical issues.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- explain the basic properties of stem cells and their classification.
- apply the stem cell based therapies in different clinical applications
- learn the concept of tissue engineering.
- correlate the tissue architecture, tissue repair mechanism and its dynamics.

- produce many tissue engineered therapies.

TEXT BOOKS

1. AriffBongso, EngHinLee ,"Stem cells: from bench to bedside". World scientific, 2005.
2. Robert Lanza, John Gearhart, Brigid Hagan, Douglas Melton, Roger Pedersen, E. Dannall Thomas, James thomsan and sir lan wilmut" Essentials of stem cell biology" 2nd edition, Elesvier academic press, 2009.
3. Bernhard O.Palsson, SangeetaN.Bhatia, "Tissue Engineering" Pearson Publishers 2016.

REFERENCES

1. Joseph Panno, "Stem Cell Research: Medical Applications and Ethical Controversy", 2006.
2. Tarik Regad, Thomas J. Sayers, Robert C. Rees, "Principles of stem cell biology and cancer: Future Applications and Therapeutics", Wiley - Blackwell, 2015.
3. Michael F. Ashby, Hugh Shercliff, David Cebon, "Materials: engineering, science, processing and design", 2013, 3rd Edition, Elsevier Ltd, Cambridge.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	3	2	2	1	2	1	-	1	2	-	-	3	2	3
CO2	2	1	3	-	2	1	-	1	2	-	-	3	3	2
CO3	2	2	2	1	2	1	-	1	2	-	-	3	3	3
CO4	2	2	2	1	2	1	-	1	2	-	-	3	2	3
CO5	3	3	3	2	-	-	-	-	-	-	-	3	3	2

PT20653 PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER 3 0 0 3

COURSE OBJECTIVES

To enable students to

- Study the basic principles of drug discovery and development
- Acquire knowledge pre-formulations of drugs
- develop scale-up of a pilot plant
- learn to packing of pharmaceutical products
- know the R&D and technology transfer

UNIT I PRINCIPLES OF DRUG DISCOVERY AND DEVELOPMENT 9

Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA

UNIT II PRE-FORMULATION STUDIES 9

Pre-formulations, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, cosolvency. Pre-formulation protocol, Stability testing during product development

UNIT III PILOT PLANT SCALE UP 9

Scale up, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms.

UNIT IV PHARMACEUTICAL PACKAGING 9

Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control tests.

UNIT V TECHNOLOGY TRANSFER 9

Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

TOTAL PERIODS: 45

COURSE OUTCOMES

Upon completion of the course, the students will be able to

- Know the basic principles of drug discovery and development
- Work on pre-formulations of drugs
- Develop model of a pilot plant scale-up
- Know different packing types used for pharmaceutical products
- Know about R&D and technology transfer

TEXT BOOKS

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.

2. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
3. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.

REFERENCES

1. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York
2. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
3. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis

CO/PO MAPPING:

Mapping of Course Outcomes (CO's) with Programme Outcomes (PO's) and Programme Specific Outcomes (PSO's)

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

COs	Programme Outcomes (POs)													
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CO3	3	3	3	2	-	-	2	-	-	-	-	-	2	3
CO4	3	2	2	-	-	3	-	-	-	-	2	-	2	2
CO5	2	3	3	2	1	3	3	-	-	1	2	-	3	2

COURSE OBJECTIVES

To enable students to

- provide the general pharmacological principles.
- make understand the pharmacology of different types of drugs acting on various physiological systems.
- develop the ability to suggest suitable techniques to synthesis different drug molecules.
- study the different adverse reactions of drugs.
- study the chemotherapy for various human systems.

UNIT I INTRODUCTION 9

Lifestyle diseases – Definition; Risk factors – Eating, smoking, drinking, stress, physical activity, illicit drug use; Obesity, diabetes, cardiovascular diseases, respiratory diseases, cancer; Prevention – Diet and exercise

UNIT II CANCER 9

Types - Lung cancer, Mouth cancer, Skin cancer, Cervical cancer, Carcinoma oesophagus; Causes Tobacco usage, Diagnosis – Biomarkers, Treatment

UNIT III CARDIOVASCULAR DISEASES 9

Coronary atherosclerosis – coronary artery disease; Causes -Fat and lipids, Alcohol abuse — Diagnosis - Electrocardiograph, echocardiograph, Treatment, Exercise and Cardiac rehabilitation

UNIT IV DIABETES AND OBESITY 9

Types of Diabetes mellitus; Blood glucose regulation; Complications of diabetes – Pediatric and adolescent obesity – Weight control and BMI

UNIT V RESPIRATORY DISEASES 9

Chronic lung disease, Asthma, COPD; Causes - Breathing pattern (Nasal vs mouth), Smoking – Diagnosis - Pulmonary function testing

TOTAL PERIODS 45

COURSE OUTCOMES

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

- apply the various principles of general pharmacology.
- explain the pharmacology of various categories of drugs acting on nervous
- cardiovascular and gastrointestinal systems.
- define the principles of chemotherapy and pharmacology of antimicrobial agents.
- they would have understood the application of basic pharmacological knowledge in the prevention and treatment of various treatments of diseases.

TEXT BOOKS

1. James M.R, Lifestyle Medicine, 2nd Edition, CRC Press, 2013
2. Akira miyazaki et al, New frontiers in lifestyle-related disease, springer, 2008
3. Biochemistry – U. Satyanarayana, U. Chakrapani , third edion, ISBN 81-87134-80-1

REFERENCES

1. Akira Miyazaki et al, New Frontiers in Lifestyle-Related Disease, Springer, 2008
2. Textbook of Medical Physiology, by Arthur C Guyton, John E Hall Prism Saunders 9th Edion ISBN: 81-7286-034-X.
3. Cell and Molecular Biology by Gerald Karp, John Wiley & Son, Inc. New York ISBN 978 0470-16961-2, 5th Edion.

CO/PO MAPPING:

Mapping of Course Outcome (CO's) with Programme Outcomes (PO's) and Programme SpecificOutcomes (PSO's) **(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak**														
CO's	**PO's**												**PSO's**	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**
CO1	3	2	3	1	-	2	-	-	-	3	-	2	3	3
CO2	1	2	-	2	-	-	1	-	-	-	-	1	3	3
CO3	2	2	2	1	1	2	-	-	-	-	-	-	3	2
CO4	3	1	2	1	2	2	-	-	-	-	-	2	2	2
CO5	3	2	2	1	2	2	-	-	-	-	-	2	2	2

PT20901 FUNDAMENTALS OF NANOSCIENCE 3 0 0 3

COURSEOBJECTIVES:

To enable students to

- about basis of nanoscience and importance nanotechnology.
- learn about the general preparation method of nano materials.
- learn about the different methods for synthesis of nanomaterials.
- compare different techniques to characterize nanomaterials.
- about the application of nano materials

UNIT I INTRODUCTION 9

Nanoscale Science and Technology- History and Importance of Nanotechnology; Classifications of nanostructured materials: nano particles, nanoclusters, nanotubes, quantum dots, nanowires, nanotubes, semiconductor nanoclusters, carbon nanotubes; Influence of Nano structuring on Mechanical, optical, electronic, magnetic and chemical properties.

UNIT II GENERAL METHODS OF PREPARATION 9

Bottom - up and Top - down Approach: Mechanical Alloying, severe plastic deformation, Lithography, Physical vapour deposition (PVD), Molecular beam epitaxy, Chemical vapour deposition, Colloidal or wet chemical route, Reverse micelle method; Sol-gel method; Combustion method; Atomic Layer deposition.

UNIT III NANOMATERIALS 9

Nanoforms of Carbon - Buckminster fullerene- graphene and carbon nanotube, Single wall carbon Nanotubes (SWCNT) and Multi wall carbon nanotubes (MWCNT), structure-property Relationships applications- Nanometal oxides-ZnO, TiO2, MgO, ZrO2, NiO, nanoalumina, CaO, AgTiO2, Ferrites, Nanoclays-functionalization and applications.

UNIT IV CHARACTERIZATION TECHNIQUES 9

X-ray diffraction technique, Scanning Electron Microscopy - environmental techniques, Transmission Electron Microscopy including high-resolution imaging, Surface Analysis techniques: AFM, SPM, STM, DPN.

UNIT V APPLICATIONS 9

NanoInfoTech: Information storage- nanocomputer, molecular switch, super chip, nanocrystal, Nanobiotechlogy: nanoprobes in medical diagnostics and biotechnology, Nano medicines, Targetted drug delivery, Bioimaging - Micro Electro Mechanical Systems (MEMS), Nano Electro Mechanical Systems (NEMS)- Nanosensors, nano crystalline silver for bacterial inhibition, Nanoparticles for sunbarrier products - In Photostat, printing, solar cell, battery.

TOTAL PERIODS: 45

COURSEOUTCOMES:

Upon completing this course, the students

- familiarize about the science of nanomaterials
- demonstrate the preparation of nanomaterials
- develop knowledge in screening technique of nanomaterial
- familiarize about the properties of different nano materials
- familiarize about the application of nano materials

TEXT BOOKS

1. S.M.Lindsay, "Introduction to Nanoscience", Oxford University Press, 2010.
2. Rajendra Kumar Goyal, "Nanomaterials and Nanocomposites: Synthesis, Properties, Characterization, Techniques and Application", Taylor and Francis, CRC press, 2018.
3. Chris Binns, "Introduction to Nanoscience and Nanotechnology", Wiley, 2010.

REFERENCES

1. G Timp (Editor), "Nanotechnology", AIP press/Springer, 1999.
2. Akhlesh Lakhtakia (Editor), "The Hand Book of Nano Technology,Nanometer Structure, Theory, Modeling and Simulations". Prentice-Hall of India (P) Ltd, New Delhi, 2007

CO/PO MAPPING:

Mapping of Course Outcome (CO's) with Programme Outcomes (PO's) and ProgrammeSpecific

Outcomes PSO's

(1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak

	PO's												PSO's	
CO's	1	2	3	4	5	6	7	8	9	10	11	12	1	2
CO1	3	2	2	-	-	2	-	-	-	-	-	3	3	2
CO2	3	3	3	2	-	-	2	-		-	-	3	2	3
CO3	3	3	2	2	-	2	1	-	-	1	-	3	3	2
CO4	3	2	2	-	-	2	3	1	-	-		3	2	2
CO5	3	3	2	2	-	-	-	-	-	-	-	3	3	3

PT20902 INTRODUCTION TO PHARMACEUTICAL TECHNOLOGY 3 0 0 3

COURSE OBJECTIVES

To enable students to

- know the definition of drug and production of various drug substance from biological sources
- learn about different manufacturing techniques for development of pharmaceutical substance.
- know about different types of solid dosage forms
- learn about various semi – solid and liquid dosage forms.
- explain about the concept of biopharmaceuticals

UNIT I INTRODUCTION 9

Drug- definition, Classification, physiochemical properties, Pharmaceutical substances of plant origin, Pharmaceuticals of animal origin, Pharmaceutical substances of microbial origin, Routes of administration of drug. Patenting in Biotechnology.

UNIT II THE DRUG MANUFATURING PROCESS 9

The manufacturing facility, Cleaning, decontamination and sanitation (CDS), Documentation, Specifications, Records; Compression and granulation of tablets, Coating of pharmaceutical dosage forms- film coating, modified release film coating-coating procedure and equipment. Quality control and practice.

UNIT III PHARMACEUTICAL SOLID DOSAGE FORMS 9

Definition of Dosage forms, Classification of dosage forms; Development and Evaluation of: Solid dosage forms – Tablets, Capsules, Powders, Granules, Pellets, pills, troches.

UNIT IV PHARMACEUTICAL SEMI - SOLID AND LIQUID DOSAGE FORMS 9

Liquid dosage forms: Monophasic and Biphasic lotions, solutions, suspension, emulsions, elixirs; Semi-solid dosage forms: ointments, pastes, creams, gels; Inhalations and inhalants; Extracts: Tinctures and fluid extracts.

UNIT V BIOPHARMACEUTICALS 9

Various categories of therapeutics like vitamins, laxatives, analgesics, contraceptives, antibiotics, hormones and biological.

TOTAL PERIODS: 45

COURSE OUTCOMES

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

- gain knowledge on the basic properties of pharmaceutical substances from various origin.
- produce different pharmaceutical substances using drug manufacturing processes.
- design a solid dosage forms
- design a semi –solid and liquid dosage forms
- apply the knowledge of biopharmaceuticals.

TEXT BOOKS

1. Gary Walsh, "Biopharmaceuticals", John Wiley & Sons Ltd, UK, Second Edition, 2003

2. Remington, "The Science and Practice of Pharmacy". Lippincott Williams and Wilkins, 20th edition, 2001.

REFERENCES

1. Goodman & Gilman's "The Pharmacological Basis of Therapeutics",11th edition, Mc Graw-Hill Medical Publishing Division New York, 2006.
2. Gunter Jagschies, Eva Lindskog, Karol Lacki, Parrish Galliher, "Biopharmaceutical Process: Development, Design and Implementation of Manufacturing Processes", Elsevier Publications, 2018.
3. Gary Walsh, "Biopharmaceuticals: Biochemistry and Biotechnology", Second edition, Wiley, 2013.
4. Kenneth E. Acis, Vincent L. Wu, "Biotechnology and Biopharmaceutical Manufacturing, Processing and Preservation", Drug Manufacturing Technology series-Vol.2, CRC Press, 2020.

CO/PO MAPPING:

Mapping of Course Outcomes with Programme Outcomes (1/2/3 indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak														
COs	**Programmes Outcomes (POs)**													
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**
CO1	3	2	2	1	2	1	-	1	2	-	-	3	2	3
CO2	2	1	3	-	2	1	-	1	2	-	-	3	3	2
CO3	2	2	2	1	2	1	-	1	2	-	-	3	3	3
CO4	2	2	2	1	2	1	-	1	2	-	-	3	2	3
CO5	3	3	3	2	-	-	-	-	-	-	-	3	3	2