ANNA UNIVERSITY, CHENNAI

UNDERGRADUATE CURRICULUM (UNIVERSITY DEPARTMENTS)

Campus: Alagappa College of Technology

Department: Biotechnology

Programme: B. Tech Pharmaceutical Technology

Regulations: 2023 (Revised 2024), with effect from the AY 2024 – 25 to all the students of UG Programme.

OVERVIEW OF CREDITS

Sem	PCC	PEC	ESC	HSMC	ETC	OEC	SDC	UC	SLC	Total
I	3	0	0	11	0	0	7	1	0	**22**
II	0	0	9	12	0	0	0	1	0	**22**
III	10	0	5	4	0	0	0	1	0	**20**
IV	18	0	5	0	0	0	2	2	0	**27**
V	14	0	0	0	3	0	3	3	1	**24**
VI	0	9	0	0	3	3	3	3	0	**21**
VII	8	9	0	3	0	3	1	0	0	**24**
VIII	0	0	0	0	0	0	8	0	0	**8**
Total	53	18	19	30	6	6	24	11	1	**168**
% of Category	**31.54**	**10.71**	**11.31**	**17.86**	**3.57**	**14.29**	**14.29**	**6.55**	**0.6**	**100**

CATEGORY OF COURSES

PCC – Professional Core Course
PEC – Professional Elective Course
ETC – Emerging Technology Course
OEC – Open Elective Course
SLC – Self Learning Course
ESC – Engineering Science Course
HSMC – Humanities Science and Management Course
SDC – Skill Development Course
UC – University Course

For Honours & Minor Degree, please refer the Regulations 2023 (Revised 2024).

SEMESTER – I							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	EN23C01	Foundation English	LIT	2-0-2	4	3	HSMC
2.	MA23C01	Matrices and Calculus	T	3-1-0	4	4	HSMC
3.	PH23C01	Engineering Physics	LIT	3-0-2	5	4	HSMC
4.	ME23C01	Engineering Drawing and 3DModelling	LIT	2-0-4	6	4	SDC
5.	ME23C04	Makerspace	LIT	1-0-4	5	3	SDC
6.	IB23C02	Bioorganic Chemistry	T	3-0-0	3	3	PCC
7.	UC23H01	தமிழர்மரபு/Heritage of Tamils	T	1-0-0	1	1	UC
8.	-	NCC/NSS/NSO/YRC	-	0-0-2	2	-	UC
9.	-	Audit Course – I	-	-	-	-	UC
TOTAL CREDITS						**22**	

SEMESTER – II							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	EN23C02	Professional Communication	LIT	2-0-2	4	3	HSMC
2.	MA23C02	Ordinary Differential Equations and Transform Techniques	T	3-1-0	4	4	HSMC
3.	CY23C01	Engineering Chemistry	LIT	3-0-2	5	4	HSMC
4.	PT23201	Thermodynamics	T	2-1-0	3	3	ESC
5.	CS23C02	Computer Programming in Python	LIT	3-0-2	5	4	ESC
6.	EE23C03	Basics of Electrical and Electronics Engineering	LIT	2-0-2	4	3	ESC
7.	UC23H02	தமிழரும்தொழில்நுட்பமும் / Tamils and Technology	T	2-0-0	1	1	UC
TOTAL CREDITS						**22**	

SEMESTER – III							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	MA23C05	Probability and Statistics	T	3-1-0	4	4	HSMC
2.	PT23301	Stoichiometry and Fluid Mechanics	LIT	3-0-4	7	5	ESC
3.	PT23302	Microbiology	LIT	3-0-4	7	5	PCC
4.	IB23C03	Biochemistry	LIT	3-0-4	7	5	PCC
5.	PT23303	Pharmaceutical Chemistry	T	3-0-0	3	3	PCC
6.	-	Audit Course – II	-	-	-	-	UC
					TOTAL	**24**	

SEMESTER – IV							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23401	Human Physiology	T	3-0-0	3	3	PCC
2.	PT 23402	Medicinal Chemistry	T	4-0-0	4	4	PCC
3.	PT 23403	Heat and Mass Transfer Operations	LIT	3-0-4	7	5	ESC
4.	PT 23404	Pharmaceutical Analysis	LIT	3-0-4	7	5	PCC
5.	PT23405	Physical Pharmaceutics	LIT	3-0-4	7	5	PCC
6.	-	Skill Development Course I	-	-	-	2	SDC
7.	PT23U01	Standards – Pharmaceutical Technology	T	1-0-0	1	1	UC
8.	UC23U01	Universal Human Values	T	1-0-2	3	2	UC
					TOTAL CREDITS	**27**	

SEMESTER – V (PREFERENCE FOR FOREIGN EXCHANGE)							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23501	Pharmaceutical Unit Operations	LIT	3-0-4	7	5	PCC
2.	PT23502	Pharmacology & Chemotherapy	T	4-0-0	4	4	PCC
3.	PT23503	Pharmaceutical Dosage Forms	LIT	3-0-4	7	5	PCC
4.	-	Emerging Technology Course I	T	3-0-0	3	3	ETC
5.	-	Industry Oriented Course I	-	-	-	1	SDC
6.	-	Skill Development Course II	-	-	-	2	SDC
7.	PT23U02	Perspectives of Sustainable Development –Pharmaceuticals Technology	T	3-0-0	3	3	UC
8.	PT23L01	Self-Learning Course	T	-	2	1	SLC
				TOTAL CREDITS		**24**	
COURSES FOR HONOURS DEGREE							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23D01	Capstone Design Project – Level I	CDP	0-0-12	12	6	SDC
(OR)							
1.	-	Honours Elective – I	T	3-0-0	3	3	PEC.
2.	-	Honours Elective – II	T	3-0-0	3	3	PEC.
COURSES FOR MINOR DEGREE							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	-	Minor Elective – I	T	3-0-0	3	3	PEC.
2.	-	Minor Elective – II	T	3-0-0	3	3	PEC.

SEMESTER – VI (PREFERENCE FOR FOREIGN EXCHANGE)							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	-	Professional Elective I	T	3-0-0	3	3	PEC
2.	-	Open Elective – I	T	3-0-0	3	3	OEC
3.	-	Professional Elective II	T	3-0-0	3	3	PEC
4.	-	Professional Elective III	T	3-0-0	3	3	PEC
5.	-	Emerging Technology Course II	T	3-0-0	3	3	ETC
6.	-	Industry Oriented Course II	-	-	-	1	SDC
7.	-	Skill Development Course III	-	-	-	2	SDC
8.	UC23E01	Engineering Entrepreneurship Development	LIT	2-0-2	4	3	UC
			TOTAL CREDITS			**21**	
COURSES FOR HONOURS DEGREE							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23D02	Capstone Design Project – Level II	CDP	0-0-12	12	6	SDC
(OR)							
1.	-	Honours Elective – III	T	3-0-0	3	3	PEC.
2.	-	Honours Elective – IV	T	3-0-0	3	3	PEC.
COURSES FOR MINOR DEGREE							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	-	Minor Elective – III	T	3-0-0	3	3	PEC.
2.	-	Minor Elective – IV	T	3-0-0	3	3	PEC.

SEMESTER – VII							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23701	Total Quality Management	T	3-0-0	3	3	HSMC
2.	PT23702	Biopharmaceutics and Pharmacokinetics	LIT	3-0-4	7	5	PCC
3.	PT23703	Drug Regulatory Affairs	T	3-0-0	3	3	PCC
4.	-	Professional Elective IV	T	3-0-0	3	3	PEC
5.	-	Professional Elective V	T	3-0-0	3	3	PEC
6.	-	Professional Elective VI	T	3-0-0	3	3	PEC
7.	-	Open Elective – II	T	3-0-0	3	3	OEC
8.	-	Industry Oriented Course III	-	-	-	1	SDC
TOTAL CREDITS						**24**	
COURSES FOR HONOURS DEGREE							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23D03	Capstone Design Project – Level III	CDP	0-0-12	12	6	SDC
(OR)							
1.	-	Honours Elective – V	T	3-0-0	3	3	PEC.
2.	-	Honours Elective – VI	T	3-0-0	3	3	PEC.
COURSES FOR MINOR DEGREE							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	-	Minor Elective – V	T	3-0-0	3	3	PEC.
2.	-	Minor Elective – VI	T	3-0-0	3	3	PEC.

SEMESTER – VIII							
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**	**CATEGORY**
				L-T-P	**TCP***		
1.	PT23801	Project Work / Internship cum Project Work	PW/IPW	0-0-16	16	8	SDC
TOTAL CREDITS						**8**	

PROFESSIONAL ELECTIVE COURSE VERTICALS – Regulation 2023

VERTICAL 1 DRUG DESIGN	VERTICAL 2 QUALITY CONTROL AND QUALITY ASSURANCE	VERTICAL 3 FORMULATION DEVELOPMENT	VERTICAL 4 BIOPHARMACEUTICALS
Bioinformatics and Cheminformatics	Biological Spectroscopic techniques	Technology of solid dosage forms	Process Analytical Technology in Biologicals Manufacturing
Protein Structure Prediction	Process Analytical Technology in Pharmaceutical Manufacturing	Drug Delivery Systems	Animal biotechnology
Computer Aided Drug Design	Quality assurance in Pharmaceutical Industry	Pharmaceutical Nanotechnology	Molecular biology and Genetic Engineering
Drug screening strategies	Quality Management Systems	GMP, GLP and accreditation	Enzyme technology and Applications
Pharmacogenomics	Hazards and Safety Management	Product development and Technology Transfer	Immunology
Design of Experiments	Validation of Pharmaceutical processes and products	Pharmaceutical Packaging Technology	Vaccine Technology
	Audits and regulatory compliance	Sustainable Development of Pharmaceuticals	Fundamentals of Bioprocess Engineering
		Nutraceuticals	Biophamaceuticals Downstream Processing
			Chemical Reaction Engineering

VERTICAL I: DRUG DESIGN						
S. NO.	COURSE CODE	COURSE NAME	COURSE TYPE#	PERIODS / WEEK		CREDITS
				L-T-P	TCP*	
1	PT23001	Bioinformatics and Cheminformatics	T	3-0-0	3	3
2	PT23002	Protein Structure Prediction	T	3-0-0	3	3
3	PT23003	Computer Aided Drug Design	T	3-0-0	3	3
4	PT23004	Drug screening strategies	T	3-0-0	3	3
5	PT23005	Pharmacogenomics	T	3-0-0	3	3
6	PT23006	Design of Experiments	T	3-0-0	3	3

VERTICAL II: QUALITY CONTROL AND QUALITY ASSURANCE						
S. NO.	COURSE CODE	COURSE NAME	COURSE TYPE#	PERIODS / WEEK		CREDITS
				L-T-P	TCP*	
1	PT23007	Biological Spectroscopic techniques	T	3-0-0	3	3
2	PT23008	Process Analytical Technology in Pharmaceutical Manufacturing	T	3-0-0	3	3
3	PT23009	Quality assurance in Pharmaceutical Industry	T	3-0-0	3	3
4	PT23010	Quality Management Systems	T	3-0-0	3	3
5	PT23011	Hazards and Safety Management	T	3-0-0	3	3
6	PT23012	Validation of Pharmaceutical processes and products	T	3-0-0	3	3
7	PT23013	Audits and regulatory compliance	T	3-0-0	3	3

VERTICAL III: FORMULATION DEVELOPMENT						
S. NO.	COURSE CODE	COURSE NAME	COURSE TYPE#	PERIODS / WEEK		CREDITS
				L-T-P	TCP*	
1	PT23014	Technology of solid dosage forms	T	3-0-0	3	3
2	PT23015	Drug Delivery Systems	T	3-0-0	3	3
3	PT23016	Pharmaceutical Nanotechnology	T	3-0-0	3	3
4	PT23017	GMP, GLP and accreditation	T	3-0-0	3	3
5	PT23018	Product development and Technology Transfer	T	3-0-0	3	3
6	PT23019	Pharmaceutical Packaging Technology	T	3-0-0	3	3
7	PT23020	Sustainable Development of Pharmaceuticals	T	3-0-0	3	3
8	PT23021	Nutraceuticals	T	3-0-0	3	3

VERTICAL IV: BIOPHARMACEUTICALS						
S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**
				L-T-P	**TCP***	
1	PT23022	Process Analytical Technology in Biologicals Manufacturing	T	3-0-0	3	3
2	IB23C01	Animal biotechnology	T	3-0-0	3	3
3	PT23023	Molecular biology and Genetic Engineering	T	3-0-0	3	3
4	PT23024	Enzyme technology and Applications	T	3-0-0	3	3
5	PT23025	Immunology	T	3-0-0	3	3
6	PT23026	Vaccine Technology	T	3-0-0	3	3
7	PT23027	Fundamentals of Bioprocess Engineering	T	3-0-0	3	3
8	PT23028	Biopharmaceuticals Downstream Processing	T	3-0-0	3	3
9	PT23029	Chemical Reaction Engineering	T	3-0-0	3	3

SKILL DEVELOPMENT COURSES

S. NO.	**COURSE CODE**	**COURSE NAME**	**COURSE TYPE#**	**PERIODS / WEEK**		**CREDITS**
				L-T-P	**TCP***	
1.	PT23S01	Automation in Pharmaceutical Industries	T	3-0--0	3	3
2.	PT23S02	Mind to Market Strategies	T	3-0--0	3	3
3.	PT23S03	Molecular Imaging	T	3-0--0	3	3
4.	PT23S04	Solid State Characterization	T	3-0--0	3	3

LIST OF EMERGING TECHNOLOGY COURSES

SL. NO.	**COURSE CODE**	**COURSE TITLE**	**CATE GORY**	**PERIODS PER WEEK**			**TOTAL CONTACT PERIODS**	**CREDITS**
				L	**T**	**P**		
1	PT23E01	Artificial Intelligence and Machine Learning Fundamentals	ETC	2	0	2	4	3
2	PT23E02	IoT Concepts and Applications	ETC	2	0	2	4	3
3	PT23E03	Data Science Fundamentals	ETC	2	0	2	4	3
4	PT23E04	Augmented Reality /Virtual Reality	ETC	2	0	2	4	3
5	PT23E05	Biogenerics and Biosimilars	ETC	3	0	0	3	3
6	PT23E06	Regulatory Aspects of Medical Devices	ETC	3	0	0	3	3

OPEN ELECTIVE COURSES

S. NO.	COURSE CODE	COURSE TITLE	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
			L	T	P		
1.	PT23901	Introduction to Drug science	3	0	0	3	3
2.	PT23902	Pharmaceutical Industrial Management	3	0	0	3	3
3.	PT23903	Drug Delivery Systems	3	0	0	3	3
4.	PT23904	Pharmaceutical Dosage Forms	3	0	0	3	3

COURSES TO BE STUDIED BY DIPLOMA LATERAL ENTRY STUDENTS

S. NO.	COURSE CODE	COURSE TITLE	CATEGORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1	IB23C02	Bioorganic Chemistry	PCC	3	0	0	3	3
2	PT23201	Thermodynamics	PCC	2	1	0	3	3

COURSES TO BE STUDIED BY B. SC. LATERAL ENTRY STUDENTS

S. NO.	COURSE CODE	COURSE TITLE	CATEGORY	PERIODS PER WEEK			TOTAL CONTACT PERIODS	CREDITS
				L	T	P		
1	IB23C02	Bioorganic Chemistry	PCC	3	0	0	3	3
2	PT23201	Thermodynamics	PCC	2	1	0	3	3

EN23C01 **FOUNDATION ENGLISH** **L T P C**

2 0 2 3

COURSE OBJECTIVES:

- To develop students' foundational skills in reading, writing, grammar and vocabulary to enable them to understand and produce various forms of communication.
- To enhance students' proficiency in reading comprehension, narrative and comparative writing.
- To comprehend and analyse descriptive texts and visual images
- To articulate similarities and differences in oral and written forms.
- To improve students' proficiency in reading and writing formal letters and emails.

UNIT I BASICS OF COMMUNICATION 6

Reading - Telephone message, bio-note; Writing – Personal profile; Grammar – Simple present tense, Present continuous tense, wh-questions, indirect questions; Vocabulary – Word formation (Prefix and Suffix).

LAB ACTIVITY: 6

Listening – Telephone conversation; Speaking Self-introduction; Telephone conversation – Video conferencing etiquette

UNIT II NARRATION 6

Reading – Comprehension strategies - Newspaper Report, An excerpt from an autobiography; Writing – Narrative Paragraph writing (Event, personal experience etc.); Grammar – Subject-verb agreement, Simple past, Past continuous Tenses; Vocabulary – One-word substitution

LAB ACTIVITY: 6

Listening – Travel podcast; Speaking – Narrating and sharing personal experiences through a podcast

UNIT III DESCRIPTION 6

Reading – A tourist brochure, Travel blogs, descriptive article/excerpt from literature, visual images; Writing –Descriptive Paragraph writing, Grammar – Future tense, Perfect tenses, Preposition; Vocabulary – Descriptive vocabulary

LAB ACTIVITY: 6

Listening – Railway / Airport Announcements, Travel Vlogs; Speaking – Describing a place or picture description

UNIT IV COMPARE AND CONTRAST 6

Reading – Reading and comparing different product specifications - Writing – Compare and Contrast Essay, Coherence and cohesion; Grammar – Degrees of Comparison; Vocabulary – Transition words (relevant to compare and contrast)

LAB ACTIVITY: 6

Listening – Product reviews, Speaking – Product comparison based on product reviews - similarities and differences

UNIT V EXPRESSION OF VIEWS **6**

Reading – Formal letters, Letters to Editor ; Writing – Letter writing/ Email writing (Enquiry / Permission, Letter to Editor); Grammar – Compound nouns, Vocabulary – Synonyms, Antonyms

LAB ACTIVITY: **6**

Listening – Short speeches; Speaking – Making short presentations (JAM)

TOTAL: 60 PERIODS

TEACHING METHODOLOGY

Interactive lectures, role plays, group discussions, listening and speaking labs, technology enabled language teaching, flipped classroom.

EVALUATION PATTERN

Internal Assessment
- Written assessments
- Assignment

Lab assessment
- Listening
- Speaking

External Assessment
- End Semester Examination

LEARNING OUTCOMES

By the end of the courses, students will be able to

- Use appropriate grammar and vocabulary to read different types of text and converse appropriately.
- Write coherent and engaging descriptive and comparative essay writing.
- Comprehend and interpret different kinds of texts and audio visual materials
- Critically evaluate reviews and articulate similarities and differences
- Write formal letters and emails using appropriate language structure and format

TEXT BOOKS:

1. “English for Engineers and Technologists” Volume I by Orient Blackswan, 2022
2. “English for Science & Technology - I” by Cambridge University Press, 2023

REFERENCES

1. “Interchange” by Jack C.Richards, Fifth Edition, Cambridge University Press, 2017.
2. “English for Academic Correspondence and Socializing” by Adrian Wallwork, Springer, 2011.
3. “The Study Skills Handbook” by Stella Cortrell, Red Globe Press, 2019
4. www.uefap.com

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO1 1	PO1 2
CO1										√		√
CO2										√		
CO3										√		√
CO4										√		
CO5										√		√

MA23C01	MATRICES AND CALCULUS	L	T	P	C
		3	1	0	4

OBJECTIVES:

- To develop the use of matrix algebra techniques in solving practical problems.
- To familiarize the student with functions of several variables.
- To solve integrals by using Beta and Gamma functions.
- To acquaint the student with mathematical tools needed in evaluating multiple integrals.
- To acquaint the students with the concepts of vector calculus which naturally arise in many engineering problems.

UNIT I MATRICES 9+3

Eigenvalues and Eigenvectors of a real matrix – Properties of Eigenvalues and Eigenvectors- Cayley-Hamilton theorem (excluding proof) – Diagonalization of matrices - Reduction of Quadratic form to canonical form by using orthogonal transformation - Nature of a Quadratic form.

UNIT II FUNCTIONS OF SEVERAL VARIABLES 9+3

Limit, continuity, partial derivatives – Homogeneous functions and Euler's theorem - Total derivative – Differentiation of implicit functions – Jacobians -Taylor's formula for two variables - Errors and approximations – Maxima and Minima of functions of two variables – Lagrange's method of undermined multipliers.

UNIT III INTEGRAL CALCULUS 9+3

Improper integrals of the first and second kind and their convergence – Differentiation under integrals - Evaluation of integrals involving a parameter by Leibnitz rule – Beta and Gamma functions-Properties – Evaluation of single integrals by using Beta and Gamma functions..

UNIT IV MULTIPLE INTEGRALS 9+3

Double integrals – Change of order of integration – Double integrals in polar coordinates – Area enclosed by plane curves – Triple integrals – Volume of Solids – Change of variables in double and triple integrals-
Evaluation of double and triple integrals by using Beta and Gamma functions.

UNIT V VECTOR CALCULUS 9+3

Gradient of a scalar field, directional derivative – Divergence and Curl – Solenoidal and Irrotational vector fields - Line integrals over a plane curve - Surface integrals – Area of a curved surface – Volume Integral - Green's theorem, Stoke's and Gauss divergence theorems (without proofs)– Verification and applications in evaluating line, surface and volume integrals.

TOTAL: 60 PERIODS

Laboratory based exercises / assignments / assessments will be given to students wherever applicable from the content of the course.

General engineering applications / branch specific applications from the content of each units wherever possible will be introduced to students.

Suggested Laboratory based exercises / assignments / assessments :

Matrices

1. Finding eigenvalues and eigenvectors
2. Verification of Cayley-Hamilton theorem
3. Eigenvalues and Eigenvectors of similar matrices
4. Eigenvalues and Eigenvectors of a symmetric matrix
5. Finding the powers of a matrix
6. Quadratic forms

Functions of Several Variables

1. Plotting of curves and surfaces
2. Symbolic computation of partial and total derivatives of functions

Integral Calculus

1. Evaluation of beta and gamma functions
2. Computation of error function and its complement

Multiple Integrals

1. Plotting of 3D surfaces in Cartesian and Polar forms

Vector Calculus

1. Computation of Directional derivatives
2. Computation of normal and tangent to the given surface

OUTCOMES:

CO 1 :Use the matrix algebra methods for solving practical problems.
CO 2 :Use differential calculus ideas on several variable functions.
CO 3 :Apply different methods of integration in solving practical problems by using Beta and Gamma functions.
CO 4 :Apply multiple integral ideas in solving areas and volumes problems.
CO 5 :Apply the concept of vectors in solving practical problems.

TEXT BOOKS:

1. Joel Hass, Christopher Heil, Maurice D.Weir "'Thomas' Calculus", Pearson Education., New Delhi, 2018.
2. Grewal B.S., "Higher Engineering Mathematics", Khanna Publishers, 45th Edition, New Delhi, 2020.
3. James Stewart, Daniel K Clegg & Saleem Watson "Calculus with Early Transcendental Functions", Cengage Learning, 6th Edition, New Delhi,2023.

REFERENCES:

1. Erwin Kreyszig, "Advanced Engineering Mathematics", 10th Edition, Wiley India Pvt Ltd., New Delhi, 2018.
2. Greenberg M.D., "Advanced Engineering Mathematics", Pearson Education2nd Edition, 5th Reprint, Delhi, 2009.
3. Jain R.K. and Iyengar S.R.K., "Advanced Engineering Mathematics",Narosa Publications, 5th Edition, New Delhi, 2017.
4. Narayanan S. and Manicavachagom Pillai T. K., "Calculus" Volume I and II, S. Viswanathan Publishers Pvt. Ltd., Chennai, 2009.
5. Peter V.O'Neil, "Advanced Engineering Mathematics", Cengage Learning India Pvt., Ltd, 7 th Edition, New Delhi , 2012.

6. Ramana B.V., “Higher Engineering Mathematics”, Tata McGraw Hill Co. Ltd., 11th Reprint, New Delhi, 2010.

CO – PO Mapping:

Course Outcomes	PROGRAMME OUTCOMES											
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**	**P11**	**P12**
CO1 :	3	3	2	3	1	2	1	1	1	1	1	3
CO2 :	3	3	2	3	1	2	1	1	1	1	1	3
CO3 :	3	3	2	3	1	2	1	1	1	1	1	3
CO4 :	3	3	2	3	1	2	1	1	1	1	1	3
CO5 :	3	3	2	3	1	2	1	1	1	1	1	3

PH23C01 **ENGINEERING PHYSICS** **L T P C**

(Common to all branches of B.E/B.Tech Programmes) **3 0 2 4**

COURSE OBJECTIVES

- To familiarize with crystal structure, bonding and crystal growth.
- To impart knowledge on Mechanics of Materials.
- To impart knowledge of oscillations, sound and Thermal Physics
- To facilitate understanding of optics and its applications, different types of Lasers and fiber optics.
- To introduce the basics of Quantum Mechanics and its importance.

UNIT I CRYSTAL PHYSICS **9+6**

Crystal Bonding – Ionic – covalent – metallic and van der Walls's/ molecular bonding. Crystal systems - unit cell, Bravais lattices, Miller indices - Crystal structures - atomic packing density of BCC, FCC and HCP structures. NaCl, Diamond, Graphite, Graphene, Zincblende and Wurtzite structures - crystal imperfections- point defects - edge and screw dislocations – grain boundaries. Crystal Growth – Czocharalski method – vapor phase epitaxy – Molecular beam epitaxy- Introduction to X-Ray Diffractometer.

1. Determination of Lattice parameters for crystal systems.
2. Crystal Growth – Slow Evaporation method
3. Crystal Growth Sol – Gel Method

UNIT II MECHANICS OF MATERIALS **9+6**

Rigid Body – Centre of mass – Rotational Energy - Moment of inertia (M.I)- Moment of Inertia for uniform objects with various geometrical shapes. Elasticity –Hooke's law - Poisson's ratio - stress-strain diagram for ductile and brittle materials – uses- Bending of beams – Cantilever - Simply supported beams - uniform and non-uniform bending - Young's modulus determination - I shaped girders –Twisting couple – Shafts. Viscosity – Viscous drag – Surface Tension.

4. Non-uniform bending -Determination of Young's modulus of the material of the beam.
5. Uniform bending -Determination of Young's modulus of the material of the beam
6. Viscosity – Determination of Viscosity of liquids.

UNIT III OSCILLATIONS, SOUND AND THERMAL PHYSICS **9+6**

Simple harmonic motion - Torsional pendulum –- Damped oscillations –Shock Absorber -Forced oscillations and Resonance –Applications of resonance.- Waves and Energy Transport –Sound waves – Intensity level – Standing Waves - Doppler effect and its applications - Speed of blood flow. Ultrasound – applications - Echolocation and Medical Imaging. Thermal Expansion – Expansion joints – Bimetallic strip – Seebeck effect – thermocouple -Heat Transfer Rate – Conduction – Convection and Radiation.

7. Torsional pendulum-Determination of rigidity modulus of wire and moment of inertia of the disc
8. Melde's string experiment - Standing waves.
9. Ultrasonic interferometer – determination of sound velocity and liquids compressibility

UNIT IV OPTICS AND LASERS **9+6**

Interference - Thin film interference - Air wedge- Applications -Interferometers–Michelson

Interferometer -– Diffraction - CD as diffraction grating – Diffraction by crystals -Polarization - polarizers -– Laser – characteristics – Spontaneous and Stimulated emission- population – inversion - Metastable states - optical feedback - Nd-YAG laser, CO_2 laser, Semiconductor laser - Industrial and medical applications - Optical Fibers – Total internal reflection – Numerical aperture and acceptance angle – Fiber optic communication – Fiber sensors – Fiber lasers.

10. Laser - Determination of the width of the groove of the compact disc using laser.
    Laser Parameters
    Determination of the wavelength of the laser using grating
11. Air wedge -Determination of the thickness of a thin sheet/wire
12. Optical fibre - Determination of Numerical Aperture and acceptance angle
    -Determination of bending loss of fibre.
13. Michelson Interferometer (Demonstration)

UNIT V QUANTUM MECHANICS 9+6

Black body radiation (Qualitative) – Planck's hypothesis – Einstein's theory of Radiation - Matter waves–de Broglie hypothesis - Electron microscope – Uncertainty Principle – The Schrodinger Wave equation (time-independent and time-dependent) – Meaning and Physical significance of wave function - Normalization - Particle in an infinite potential well-particle in a three-dimensional box - Degenerate energy states - Barrier penetration and quantum tunneling - Tunneling microscope.

14. Photoelectric effect – Determination of Planck's constant.
15. Black Body Radiation (Demonstration)
16. Electron Microscope (Demonstration)

TOTAL: 75 PERIODS

COURSE OUTCOMES:

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

CO1: Understand the significance of crystal structure and bonding. Learn to grow crystals.
CO2: Obtain knowledge on important mechanical and thermal properties of materials and determine them through experiments.
CO3: Conceptualize and visualize the oscillations and sound.
CO4: Grasp optical phenomenon and their applications in real life.
CO5: Appreciate and evaluate the quantum phenomenon.
CO6 Develop skill set to solve engineering problems and design experiments.

TEXT BOOKS:

1. Raymond A. Serway, John W. Jewett, Physics for Scientists and Engineers, Thomson Brooks/Cole, 2013.
2. D. Halliday, R. Resnick and J. Walker, Principles of Physics. John Wiley & Sons, 10th Edition, 2015.
3. N. Garcia, A. Damask and S. Schwarz, Physics for Computer Science Students, Springer-Verlag, 2012.
4. Alan Giambattista, Betty McCarthy Richardson and Robert C. Richardson, College Physics, McGraw-Hill Higher Education, 2012.

REFERENCES:

1. R. Wolfson, Essential University Physics. Volume 1 & 2. Pearson, 2016.
2. D. Kleppner and R. Kolenkow. An Introduction to Mechanics, McGraw Hill Education, 2017.

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	1		1							
CO2	3	2	1	1								
CO3	3	2	1	1								
CO4	3	2	1	1	1							
CO5	3	2	1	1	1							
CO6	3	2	1	2								

ME23C01	ENGINEERING DRAWING AND 3D MODELLING	L	T	P	C
		2	0	4	4

INTRODUCTION

Manual drawing tools (Mini Drafter, Set Squares, Protractor, Compass, and different grades of pencil). **'**BIS' specifications and rules of Engineering Drawing – Arrows (2H thin line body, HB Filled head and L:W = 3:1 ratio), lettering (Digital fonts, font sizes pertaining to usage and representation), types of line and their syntax (Drawing based – Continuous thin & thick, dashed, dashed dotted and Application based – extension, dimensioning, construction, projection, reference, axis, section, hatching, and break lines), scaling (up, down and equal), and dimensioning. Placing and positioning the 'A3' size drawing sheet over the drawing table. Principal planes and projection, Division of line and circle in to equal parts, and construction of polygons

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UNIT 1: ENGINEERING CURVES, PROJECTION OF POINTS AND LINES

Construction of conic curves with their tangent and normal – ellipse, parabola, and hyperbola by eccentricity method

Construction of special curves with their tangent and normal – cycloid, epicycloid, and involute

Projection of points and I angle projection of lines inclined to both principal planes by rotating line method and trapezoidal rule – marking their traces.

Lab exercises: Study exercise – Introduction to Sketching (or) Drawing, and modification tools in CAD software (AutoCAD, CREO, CATIA, Solid Works, Inventor, Fusion 360)

(6+12 = 18 Hours)

Activities based learning: Identification of the curves used in the application given in the flash card, demonstration of the instantaneous centre of rotation of governors with respect to angle of inclination of the arms of the governors

UNIT 2: PROJECTION OF SURFACES & SOLIDS, AND 2D MODELING

Projection of surfaces inclined to both the principal planes – polygonal, trapezoidal, rhomboidal and circular

Projection of solids – prisms, pyramids, and axisymmetric solids when the axis inclined to both the principal planes – freely hanging – contour resting condition on either of the planes by rotating object method

Lab exercises: Construction of basic sketches – lines, circle, polygon, spline curves, coils, along with dimensioning. Familiarizing with geometric constraints and their types

(6+12 = 18 Hours)

Activities based learning: Making the solids using cardboards, shadow mapping and contour drawing at different orientation of the solids using torches

UNIT 3: 3D PROJECTION OF SOLIDS AND 3D MODELING OF SIMPLE PARTS

Free hand sketching – I & III angle projections of engineering parts and components

Isometric projection of combination of solids – prisms, pyramids, axisymmetric solids, frustum

Perspective projection of prisms, pyramids and axisymmetric solids by visual ray method

Lab exercises: 3D Modeling and 2D drafting of machine parts

(6+12 = 18 Hours)

Activities based learning: Flipped classroom for Free hand sketching, Jig saw activity for Isometric projection, arts and crafts for perspective view

UNIT 4: SECTION OF SOLIDS AND SECTIONED DRAFTING OF ASSEMBLED COMPONENTS

Section of simple and hollow solids – prisms, pyramids and axisymmetric solids, solids with holes/ slots when the section plane perpendicular to one principal plane and inclined to other principal plane ('On the axis' and 'from the axis' conditions)

Application based – section of beams (I, T, L, and C), section of pipe bracket, wood joints, composite walls, shells, flange of a coupling and other similar applications

Lab exercises: Assembly of parts with respect to engineering constraints, and sectioned drafting of assembled components

(6+12 = 18 Hours)

Activities based learning: Making of mitered joint in wood, sectioning the beams in different angles of orientation and identifying the true shape

UNIT 5: LATERAL SURFACE DEVELOPMENT AND SHEET METAL DESIGN

Lateral surface development of sectioned solids when the section plane perpendicular to VP and inclined to HP.

Application based – construction of funnel, chimney, dish antenna, door latch, trays, AC vents, lamp shade, commercial packaging boxes with respect to sectioning conditions and other similar applications

Lab exercises: Sheet metal design and drafting, drafting of coils, springs and screw threads

(6+12 = 18 Hours)

Activities based learning: Fabrication of funnels, chimney, lamp shade, boxes using card boards, ply woods, acrylics

Total: 90 Hours

Note: Activities based learning should not be covered in the regular class hours. It should be given as assignments to the group of maximum 3 members

COURSE OBJECTIVES

After successful completion of this course, the students will be able to:

1. Understand and use the engineering curves in engineering applications and projection techniques to construct conic curves, points and lines.
2. Develop skills in projecting surfaces and solids and create 2D models using CAD software.
3. Develop skills in 3D projection and 3D modeling of simple parts manually as well as using CAD software.
4. Understand and apply sectioning techniques to solids and assemble components.
5. Develop skills in lateral surface development and sheet metal design.

COURSE OUTCOMES

After successful completion of the course, the students will be able to:

CO1: Construct and identify different types of conic curves and special curves, and project the points and lines pertaining to engineering applications

CO2: Project and visualize surfaces and solids in different orientations and utilize the CAD tools for designing.

CO3: Create and draft accurate 3D models and 2D drawings of machine parts manually as well as using CAD software

CO4: Determine the true shape of a sectioned solid and draft the assembled parts accordingly

CO5: Develop lateral surfaces of sectioned solids and design sheet metal components

TEXT BOOK

1. "Engineering Drawing" by N S Parthasarathy and Vela Murali, Oxford University Press; UK ed. Edition, 2015.
2. "Engineering Drawing + Auto CAD" by Venugopal K, V. Prabhu Raja, New Age International Publishers, Sixth edition (1 January 2022).

REFERENCES

1. "Basic Engineering Drawing: Mechanical Semester Pattern" by Mehta and Gupta, Charotar Publishing House, 2nd edition, 2018.
2. "Engineering Drawing" by Basant Agrawal and C M Agrawal, Vikas Publishing House, 3rd edition, 2020.
3. "Engineering Drawing With Auto CAD" by B V R Gupta, McGraw Hill Education, 4th edition, 2019.
4. "Engineering Drawing" by P S Gill, Tata McGraw Hill Education, 5th edition, 2018.
5. "Engineering Drawing with an Introduction to AutoCAD" by Dhananjay Jolhe, Cengage Learning, 2nd edition, 2020.
6. "Engineering Drawing" by M B Shah, Charotar Publishing House, 3rd edition, 2019
7. "Fundamentals of Engineering Drawing" by Imtiaz Hashmi, Pearson Education, 2nd edition, 2018.
8. "Computer Aided Engineering Drawing" by S Trymbaka Murthy, Scitech Publications, 3rd edition, 2020.
9. "CAED: Computer Aided Engineering Drawing for I/II Semester BE/Btech Courses" by Reddy K B, CBS Publishers & Distributors, 2nd, 2019.
10. "Computer-Aided Engineering Drawing" by Subrata Pal, Oxford University Press, 2nd, 2020.

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	3	2		1				3	1		3	3	3	2
2	3	3	2		2				3	2		3	3	3	2
3	3	3	3	1	2				3	3		3	3	3	2
4	3	3	3	1	3				3	3		3	3	3	2
5	3	3	3	1	3				3	3		3	3	3	2

ME23C04	MAKERSPACE	L	T	P	C
		1	0	4	3

COURSE OBJECTIVES:

1. To practice the usage of various tools towards assembly and dis-assembly of different items / equipment.
2. To make simple part / component using welding processes.
3. To train on the basic wiring practices of boards, machines, etc.
4. To provide a hands-on experience on the use of electronic components, equipment, sensors and actuators.
5. To expose to modern computer tools and advanced manufacturing / fabrication processes.

LIST OF ACTIVITIES **1L,4P**

(A). Dis-assembly & Assembly Practices

i. Tools and its handling techniques.

ii. Dis-assembly and assembly of home appliances – Grinder Mixer Grinder, Ceiling Fan, Table Fan & Washing Machine.

iii. Dis-assembly and assembly of Air-Conditioners & Refrigerators.

iv. Dis-assembly and assembly of a Bicycle.

(B). Welding Practices

i. Welding Procedure, Selection & Safety Measures.

ii. Power source of Arc Welding – Gas Metal Arc Welding & Gas Tungsten Arc Welding processes.

iii. Hands-on session of preparing base material & Joint groove for welding.

iv. Hands-on session of MAW, GMAW, GTAW, on Carbon Steel & Stainless Stell plates / pipes, for fabrication of a simple part.

(C). Electrical Wiring Practices

i. Electrical Installation tools, equipment & safety measures.

ii. Hands-on session of basic electrical connections for Fuses, Miniature Circuit Breakers and Distribution Box,

iii. Hands-on session of electrical connections for Lightings, Fans, Calling Bells.

iv. Hands-on session of electrical connections for Motors & Uninterruptible Power Supply.

(D). Electronics Components / Equipment Practices

i. Electronic components, equipment & safety measures.

ii. Dis-assembly and assembly of Computers.

iii. Hands-on session of Soldering Practices in a Printed Circuit Breaker.

iv. Hands-on session of Bridge Rectifier, Op-Amp and Transimpedance amplifier.

v. Hands-on session of integration of sensors and actuators with a Microcontroller.

vi. Demonstration of Programmable Logic Control Circuit.

(E). Contemporary Systems

i. Demonstration of Solid Modelling of components.

ii. Demonstration of Assembly Modelling of components.

iii. Fabrication of simple components / parts using 3D Printers.

iv. Demonstration of cutting of wood / metal in different complex shapes using Laser Cutting Machine.

TOTAL: 75 Periods (15 Lecture + 60 Practical)

COURSE OUTCOMES:

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

CO1: Assemble and dis-assemble various items / equipment.
CO2: Make simple parts using suitable welding processes.
CO3: Setup wiring of distribution boards, machines, etc.
CO4: Utilise the electronic components to fabricate a simple equipment, aided with sensors and actuators.
CO5: Take advantage of modern manufacturing practices.

REFERENCES:

1. Stephen Christena, Learn to Weld: Beginning MIG Welding and Metal Fabrication Basics, Crestline Books, 2014.
2. H. Lipson, Fabricated - The New World of 3D Printing, Wiley, 1st edition, 2013.
3. Code of Practice for Electrical Wiring Installations (IS 732:2019)

4. A.S. Sedra and K.C. Smith, Microelectronic Circuits, Oxford University Press, 7th ed. (Indian edition), 2017.
5. Mazidi, Naimi, Naimi, AVR Microcontroller and Embedded Systems: Using Assembly and C, Pearson India, 1st edition 2013.
6. Visualization, Modeling, and Graphics for Engineering Design, D.K. Lieu, S.A. Sorby, Cengage Learning; 2nd edition.

IB23C02	BIOORGANIC CHEMISTRY	L T P C
		3 0 0 3

OBJECTIVES

The course aims to,

- enable the students to understand the basics concepts of chemical reactions
- make students understand the kinetics and its reaction mechanism
- make the students understand the mechanism of synthesis of different chemical moieties
- familiarise the students with the isolation of biomolecules from natural sources

UNIT – 1: BONDING AND STEREOCHEMISTRY 9

Overview of atoms, electrons, orbitals and octet rule. Covalent and non-covalent bonds in biological systems, Electronegativity, polar and non-polar bonds. Water and its properties. Acid and base equilibria, pH and buffers – Henderson–Hasselbalch equation. Reactions of the most common functional groups in biological systems –OH, $–NH_2$, –COOH, –C=O, –CH=O, $–CH_3$, –SH, and $–PO_4$. Tetrahedral carbon and stereocenters – conformations and configurations of simple sugars and amino acids. Glycosidic and peptide linkages. Optical rotation.

UNIT – II: MECHANISMS OF SUBSTITUTION AND ADDITION REACTIONS 9

SN1and SN2 reactions on tetrahedral carbon- nucleophiles- mechanism steric eff ects– nucleophilic addition on Acetals and ketals -Aldehyde and ketone groups – reactions of carbonyl group with amines- acid catalyzed ester hydrolysis – Saponification of an ester-hydrolysis of amides. Ester enolates - Claisen. condensation – Michael condensation

UNIT – III: KINETICS AND MECHANISM 9

Kinetic method – Rate law and mechanism – Transition states- Intermediates – Trapping of intermediates – Microscopic reversibility – Kinetic and thermodynamic reversibility – Isotopes for detecting intermediates. Primary and secondary isotopes – the Arrhenius equation Eyring equation ΔG, ΔS, ΔH, Thermodynamics of coupled reactions.

UNIT – IV: CATALYSIS 9

Reactivity – Coenzymes – Proton transfer – metal ions – Intra molecular reactions – Covalent catalysis – Catalysis by organized aggregates and phases. Inclusion complexation

UNIT – V: BIOORGANIC REACTIONS 9

Timing of Bond formation and fission – Acyl group transfer – C-C bond formation and fission – Catalysis of proton transfer reactions – Transfer of hydride ion – Alkyl group. Transfer – Terpene biosynthesis – Merrifield state peptide synthesis – Sanger method for peptide and DNA sequencing

TOTAL: 45 PERIODS

OUTCOMES:

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

CO1: define and appraise Bonding and stereochemistry

CO2: classify and solve Mechanisms of substitution and addition reactions

CO3: discuss and formulate the Thermodynamics, kinetics and mechanism

CO4: describe and demonstrate Catalysis

CO5: classify and analyze Bioorganic reactions & mechanisms

TEXT BOOKS:

1. Carey, Francis A." Organic Chemistry". VIIth Edition, Tata MCGraw Hill, 2009.
2. Page, M.I. and Andrew Williams "Organic and Bio-organic Mechanisms". Pearson, 2010

REFERENCES:

1. Dugas, Hermann "Bioorganic Chemistry: A Chemical Approach to Enzyme Action" 3rd Edition, Springer, 2003**.**

PROGRAMME OUTCOMES															
CO's	**PO's**												**PSO's**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	2	2	2	1	1	1	1	-	-	-	2	2	3	1
2	3	2	2	2	3	2	2	1	1	1	-	2	3	2	2
3	3	2	2	2	2	2	-	-	-	1	-	2	2	2	2
4	1	2	2	2	1	2	1	-	1	1	-	1	2	1	1
5	2	2	2	2	2	1	2	2	2	2	-	2	3	2	3
Overall CO	2.2	2	2	2	1.8	1.6	1.5	1.3	1.3	1.3	-	1.8	2.4	2	1.8

Course 1-low, 2-medium, 3-high, '-"- no correlation **Note:** The average value of this course to be used for program articulation matrix

UC23H01	தமிழர் மரபு	L	T	P	C
		1	0	0	1

அலகு I மொழி மற்றும் இலக்கியம் 3

இந்திய மொழிக் குடும்பங்கள் – திராவிட மொழிகள் – தமிழ் ஒரு செம்மொழி – தமிழ் செவ்விலக்கியங்கள் - சங்க இலக்கியத்தின் சமயச் சார்பற்ற தன்மை – சங்க இலக்கியத்தில் பகிர்தல் அறம் – திருக்குறளில் மேலாண்மைக் கருத்துக்கள் – தமிழ்க் காப்பியங்கள், தமிழகத்தில் சமண பௌத்த சமயங்களின் தாக்கம் - பக்தி இலக்கியம், ஆழ்வார்கள் மற்றும் நாயன்மார்கள் – சிற்றிலக்கியங்கள் – தமிழில் நவீன இலக்கியத்தின் வளர்ச்சி – தமிழ் இலக்கிய வளர்ச்சியில் பாரதியார் மற்றும் பாரதிதாசன் ஆகியோரின் பங்களிப்பு.

அலகு II மரபு – பாறை ஓவியங்கள் முதல் நவீன ஓவியங்கள் வரை – சிற்பக் கலை 3

நடுகல் முதல் நவீன சிற்பங்கள் வரை – ஐம்பொன் சிலைகள்– பழங்குடியினர் மற்றும் அவர்கள் தயாரிக்கும் கைவினைப் பொருட்கள், பொம்மைகள் – தேர் செய்யும் கலை – சுடுமண் சிற்பங்கள் – நாட்டுப்புறத் தெய்வங்கள் – குமரிமுனையில் திருவள்ளுவர் சிலை – இசைக் கருவிகள் – மிருதங்கம், பறை, வீணை, யாழ், நாதஸ்வரம் – தமிழர்களின் சமூக பொருளாதார வாழ்வில் கோவில்களின் பங்கு.

அலகு III நாட்டுப்புறக் கலைகள் மற்றும் வீர விளையாட்டுகள்: 3

தெருக்கூத்து, கரகாட்டம், வில்லுப்பாட்டு, கணியான் கூத்து, ஒயிலாட்டம், தோல்பாவைக் கூத்து, சிலம்பாட்டம், வளரி, புலியாட்டம், தமிழர்களின் விளையாட்டுகள்.

அலகு IV தமிழர்களின் திணைக் கோட்பாடுகள்: 3

தமிழகத்தின் தாவரங்களும், விலங்குகளும் – தொல்காப்பியம் மற்றும் சங்க இலக்கியத்தில் அகம் மற்றும் புறக் கோட்பாடுகள் – தமிழர்கள் போற்றிய அறக்கோட்பாடு – சங்ககாலத்தில் தமிழகத்தில் எழுத்தறிவும், கல்வியும் – சங்ககால நகரங்களும் துறை முகங்களும் – சங்ககாலத்தில் ஏற்றுமதி மற்றும் இறக்குமதி – கடல்கடந்த நாடுகளில் சோழர்களின் வெற்றி.

அலகு V இந்திய தேசிய இயக்கம் மற்றும் இந்திய பண்பாட்டிற்குத் தமிழர்களின் பங்களிப்பு: 3

இந்திய விடுதலைப்போரில் தமிழர்களின் பங்கு – இந்தியாவின் பிறப்பகுதிகளில் தமிழ்ப் பண்பாட்டின் தாக்கம் – சுயமரியாதை இயக்கம் – இந்திய மருத்துவத்தில், சித்த மருத்துவத்தின் பங்கு – கல்வெட்டுகள், கையெழுத்துப்படிகள் - தமிழ்ப் புத்தகங்களின் அச்சு வரலாறு.

TOTAL : 15 PERIODS

TEXT-CUM-REFERENCEBOOKS

1. தமிழக வரலாறு – மக்களும் பண்பாடும் – கே.கே. பிள்ளை (வெளியீடு: தமிழ்நாடு பாடநூல் மற்றும் கல்வியியல் பணிகள் கழகம்).
2. கணினித் தமிழ் – முனைவர் இல. சுந்தரம். (விகடன் பிரசுரம்).
3. கீழடி – வைகை நதிக்கரையில் சங்ககால நகர நாகரிகம் (தொல்லியல் துறை வெளியீடு)
4. பொருநை – ஆற்றங்கரை நாகரிகம். (தொல்லியல் துறை வெளியீடு)
5. Social Life of Tamils (Dr.K.K.Pillay) A joint publication of TNTB & ESC and RMRL – (in print)
6. Social Life of the Tamils - The Classical Period (Dr.S.Singaravelu) (Published by: International Institute of Tamil Studies.
7. Historical Heritage of the Tamils (Dr.S.V.Subatamanian, Dr.K.D. Thirunavukkarasu) (Published by: International Institute of Tamil Studies).
8. The Contributions of the Tamils to Indian Culture (Dr.M.Valarmathi) (Published by: International Institute of Tamil Studies.)
9. Keeladi - 'Sangam City C ivilization on the banks of river Vaigai' (Jointly Published by: Department ofArchaeology & Tamil Nadu Text Book and Educational Services Corporation, Tamil Nadu)
10. Studies in the History of India with Special Reference to Tamil Nadu (Dr.K.K.Pillay) (Published by: The Author)
11. Porunai Civilization (Jointly Published by: Department of Archaeology & Tamil Nadu Text Book and Educational Services Corporation, Tamil Nadu)
12. Journey of Civilization Indus to Vaigai (R.Balakrishnan) (Published by: RMRL) – Reference Book.

UC23H01 **HERITAGE OF TAMILS** **L T P C**
1 0 0 1

UNIT I LANGUAGE AND LITERATURE 3

Language Families in India-Dravidian Languages–Tamil as a Classical Language - Classical Literature in Tamil – Secular Nature of Sangam Literature – Distributive Justice in Sangam Literature - Management Principles in Thirukural - TamilEpicsandImpactofBuddhism&JainisminTamilLand-BakthiLiteratureAzhwarsandNayanmars - Forms of minor Poetry - Development of Modern literature in Tamil - Contribution of Bharathiyarand Bharathidhasan.

UNIT II HERITAGE - ROCK ART PAINTINGS TO MODERN ART – SCULPTURE 3

Hero stone to modern sculpture - Bronze icons - Tribes and their handicrafts-Art of temple car making - Massive Terracotta sculptures, Villagedeities, Thiruvalluvar Statue at Kanyakumari, Making of musical instruments-Mridhangam,Parai, Veenai, Yazh and Nadhaswaram - Role of Temples in Social and Economic Life of Tamils.

UNIT III FOLK AND MARTIAL ARTS 3

Therukoothu, Karagattam, VilluPattu, KaniyanKoothu, Oyillattam, Leatherpuppetry, Silambattam, Valari, Tiger dance - Sports and Games of Tamils.

UNIT IV THINAICONCEPTOFTAMILS 3

Flora and Fauna of Tamils&AhamandPuramConceptfromTholkappiyam and Sangam Literature - Aram Concept of Tamils - Education and Literacy during Sangam Age - Ancient Cities and Ports of Sangam Age - Export and Import duringSangamAge -Overseas Conquestof Cholas.

UNIT V CONTRIBUTION OF TAMILS TO INDIAN NATIONAL MOVEMENT AND INDIAN CULTURE 3

Contribution of Tamils toIndian Freedom Struggle - The Cultural Influence of Tamils over the other parts of India – Self-Respect Movement - RoleofSiddhaMedicine in Indigenous Systems of Medicine – Inscriptions & Manuscripts – Print History of Tamil Books.

TOTAL : 15 PERIODS

TEXT-CUM-REFERENCEBOOKS

1. தமிழக வரலாறு – மக்களும் பண்பாடும் – கே.கே. பிள்ளை (வெளியீடு: தமிழ்நாடு பாடநூல் மற்றும் கல்வியியல் பணிகள் கழகம்).
2. கணினித் தமிழ் – முனைவர் இல. சுந்தரம். (விகடன் பிரசுரம்).
3. கீழடி – வைகை நதிக்கரையில் சங்ககால நகர நாகரிகம் (தொல்லியல் துறை வெளியீடு)
4. பொருநை – ஆற்றங்கரை நாகரிகம். (தொல்லியல் துறை வெளியீடு)
5. Social Life of Tamils (Dr.K.K.Pillay) A joint publication of TNTB & ESC and RMRL – (in print)
6. Social Life of the Tamils - The Classical Period (Dr.S.Singaravelu) (Published by: International Institute of Tamil Studies.
7. Historical Heritage of the Tamils (Dr.S.V.Subatamanian, Dr.K.D. Thirunavukkarasu) (Published by: International Institute of Tamil Studies).
8. The Contributions of the Tamils to Indian Culture (Dr.M.Valarmathi) (Published by: International Institute of Tamil Studies.)
9. Keeladi - 'Sangam City C ivilization on the banks of river Vaigai' (Jointly Published by:

Department ofArchaeology & Tamil Nadu Text Book and Educational Services Corporation, Tamil Nadu)
10. Studies in the History of India with Special Reference to Tamil Nadu (Dr.K.K.Pillay) (Published by: The Author)
11. Porunai Civilization (Jointly Published by: Department of Archaeology & Tamil Nadu Text Book and Educational Services Corporation, Tamil Nadu)
12. Journey of Civilization Indus to Vaigai (R.Balakrishnan) (Published by: RMRL) – Reference Book.

NCC Credit Course Level 1*

UC23P01	**(ARMY WING) NCC Credit Course Level - I**	**L**	**T**	**P**	**C**
		2	**0**	**0**	**2**

NCC GENERAL		**6**
NCC 1	Aims, Objectives & Organization of NCC	1
NCC 2	Incentives	2
NCC 3	Duties of NCC Cadet	1
NCC 4	NCC Camps: Types & Conduct	2
NATIONAL INTEGRATION AND AWARENESS		**4**
NI 1	National Integration: Importance & Necessity	1
NI 2	Factors Affecting National Integration	1
NI 3	Unity in Diversity & Role of NCC in Nation Building	1
NI 4	Threats to National Security	1
PERSONALITY DEVELOPMENT		**7**
PD 1	Self-Awareness, Empathy, Critical & Creative Thinking, Decision Making and Problem Solving	2
PD 2	Communication Skills	3
PD 3	Group Discussion: Stress & Emotions	2
LEADERSHIP		**5**
L 1	Leadership Capsule: Traits, Indicators, Motivation, Moral Values, Honour ‘Code	3
L 2	Case Studies: Shivaji, Jhasi Ki Rani	2
SOCIAL SERVICE AND COMMUNITY DEVELOPMENT		**8**
SS 1	Basics, Rural Development Programmes, NGOs, Contribution of Youth	3
SS 4	Protection of Children and Women Safety	1
SS 5	Road / Rail Travel Safety	1
SS 6	New Initiatives	2
SS 7	Cyber and Mobile Security Awareness	1

TOTAL : 30 PERIODS

NCC Credit Course Level 1*

UC23P02	**(NAVAL WING) NCC Credit Course Level – I**	**L T P C**
		2 0 0 2

NCC GENERAL		**6**
NCC 1	Aims, Objectives & Organization of NCC	1
NCC 2	Incentives	2
NCC 3	Duties of NCC Cadet	1
NCC 4	NCC Camps: Types & Conduct	2
NATIONAL INTEGRATION AND AWARENESS		**4**
NI 1	National Integration: Importance & Necessity	1
NI 2	Factors Affecting National Integration	1
NI 3	Unity in Diversity & Role of NCC in Nation Building	1
NI 4	Threats to National Security	1
PERSONALITY DEVELOPMENT		**7**
PD 1	Self-Awareness, Empathy, Critical & Creative Thinking, Decision Making and Problem Solving	2
PD 2	Communication Skills	3
PD 3	Group Discussion: Stress & Emotions	2
LEADERSHIP		**5**
L 1	Leadership Capsule: Traits, Indicators, Motivation, Moral Values, Honour Code	3
L 2	Case Studies: Shivaji, Jhasi Ki Rani	2
SOCIAL SERVICE AND COMMUNITY DEVELOPMENT		**8**
SS 1	Basics, Rural Development Programmes, NGOs, Contribution of Youth	3
SS 4	Protection of Children and Women Safety	1
SS 5	Road / Rail Travel Safety	1
SS 6	New Initiatives	2
SS 7	Cyber and Mobile Security Awareness	1

TOTAL : 30 PERIODS

NCC Credit Course Level 1*

UC23P03	**(AIR FORCE WING) NCC Credit Course Level – I**	**L**	**T**	**P**	**C**
		2	**0**	**0**	**2**

NCC GENERAL		**6**
NCC 1	Aims, Objectives & Organization of NCC	1
NCC 2	Incentives	2
NCC 3	Duties of NCC Cadet	1
NCC 4	NCC Camps: Types & Conduct	2
NATIONAL INTEGRATION AND AWARENESS		**4**
NI 1	National Integration: Importance & Necessity	1
NI 2	Factors Affecting National Integration	1
NI 3	Unity in Diversity & Role of NCC in Nation Building	1
NI 4	Threats to National Security	1
PERSONALITY DEVELOPMENT		**7**
PD 1	Self-Awareness, Empathy, Critical & Creative Thinking, Decision Making and Problem Solving	2
PD 2	Communication Skills	3
PD 3	Group Discussion: Stress & Emotions	2
LEADERSHIP		**5**
L 1	Leadership Capsule: Traits, Indicators, Motivation, Moral Values, Honour Code	3
L 2	Case Studies: Shivaji, Jhasi Ki Rani	2
SOCIAL SERVICE AND COMMUNITY DEVELOPMENT		**8**
SS 1	Basics, Rural Development Programmes, NGOs, Contribution of Youth	3
SS 4	Protection of Children and Women Safety	1
SS 5	Road / Rail Travel Safety	1
SS 6	New Initiatives	2
SS 7	Cyber and Mobile Security Awareness	1

TOTAL : 30 PERIODS

EN23C02	PROFESSIONAL COMMUNICATION	L T P C 2 0 2 3

COURSE OBJECTIVES:

- To read and comprehend different forms of official texts.
- To develop students' writing skills in professional context.
- To actively listen, read and understand written and oral communication in a professional context.
- To comprehend and analyse the visual content in authentic context.
- To write professional documents with clarity and precision

UNIT I CAUSE AND EFFECT 6

Reading – Newspaper articles on Social and Environmental issues; Writing – Instructions, Cause and effect essay; Grammar - Modal verbs; Vocabulary – Cause and effect, Idioms

LAB ACTIVITY: 6

Listening and Speaking – Listen to news reports and summarise in oral form.

UNIT II CLASSIFICATION 6

Reading – An article, social media posts and classifying based on the content; Writing – Definition, Note making, Note taking (Cornell notes etc.) and Summarising; Grammar – Connectives; Vocabulary – Phrasal verbs

LAB ACTIVITY: 6

Listening and speaking: Social interaction (Conversation including small talk)

UNIT III PROBLEM AND SOLUTION 6

Reading – Visual content (Tables/charts/graphs) for comprehension; Writing - Problem and Solution Essay; Grammar – If conditionals; Vocabulary – Sequential words.

LAB ACTIVITY: 6

Listening – Group discussion; Speaking – Participating in a group discussion

UNIT IV REPORT 6

Reading – Formal report on accidents (industrial/engineering); Writing – Industrial Accident report; Grammar – Active and passive voice, Direct and Indirect speech; Vocabulary – Numerical adjectives.

LAB ACTIVITY: 6

Listening / watching – Television documentary and discussing its content, purpose etc.

UNIT V JOB APPLICATION AND INTERVIEW 6

Reading - Job advertisement and company profile; Writing – Job application (cover letter and CV) Grammar – Mixed Tenses; Vocabulary – Collocations related to work environment

LAB ACTIVITY: 6

Listening – Job interview; Speaking – Mock interviews

TOTAL: 60 PERIODS

TEACHING METHODOLOGY

Interactive lectures, role plays, group discussions, listening and speaking labs, technology enabled language teaching, flipped classroom.

EVALUATION PATTERN

Internal Assessment
- Written assessments
- Assignment

Lab Assessment
- Group discussion (Peer assessment)
- Listening

External Assessment
End Semester Examination

LEARNING OUTCOMES

By the end of the courses, students will be able to

- To apply appropriate language structure and vocabulary to enhance both spoken and written communication in formal contexts.
- Comprehend different forms of official documents
- Write professional documents coherently and cohesively.
- Interpret verbal and graphic content in authentic context
- Analyse and evaluate verbal and audio visual materials.

TEXT BOOKS:

1. “English for Engineers and Technologists” Volume 2 by Orient Blackswan, 2022
2. “English for Science & Technology - II” by Cambridge University Press, 2023.

REFERENCES:

1. “Communicative English for Engineers and Professionals” by Bhatnagar Nitin, Pearson India, 2010.
2. ”Take Off – Technical English for Engineering” by David Morgan, Garnet Education, 2008.
3. “Advanced Communication Skills” by Mathew Richardson, Charlie Creative Lab, 2020.
4. www.uefap.com

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1										√		√
CO2										√		√
CO3										√		√
CO4										√		√
CO5										√		√

MA23C02	ORDINARY DIFFERENTIAL EQUATIONS AND TRANSFORM TECHNIQUES	L	T	P	C
		3	1	0	4

OBJECTIVES:

- To acquaint the students with Differential Equations which are significantly used in engineering problems.
- To make the students to understand the Laplace transforms techniques.
- To develop the analytic solutions for partial differential equations used in engineering by Fourier series.
- To acquaint the student with Fourier transform techniques used in wide variety of situations in which the functions used are not periodic.
- To develop Z- transform techniques in solving difference equations.

UNIT I ORDINARY DIFFERENTIAL EQUATIONS 9+3

Homogeneous linear ordinary differential equations of second order -superposition principle - general solution- Particular integral - Operator method - Solution by variation of parameters - Method of undetermined coefficients - Homogeneous equations of Euler–Cauchy and Legendre's type – System of simultaneous linear differential equations with constant coefficients.

UNIT II LAPLACE TRANSFORMS 9+3

Existence theorem - Transform of standard functions – Transform of Unit step function and Dirac delta function – Basic properties - Shifting theorems - Transforms of derivatives and integrals – Transform of periodic functions - Initial and Final value theorem - Inverse Laplace transforms- Convolution theorem (without proof) – Solving Initial value problems by using Laplace Transform techniques.

UNIT III FOURIER SERIES 9+3

Dirichlet's conditions – General Fourier series – Odd and even functions – Half-range Sine and Cosine series – Complex form of Fourier series – Parseval's identity – Computation of harmonics.

UNIT IV FOURIER TRANSFORMS 9+3

Fourier integral theorem – Fourier transform pair - Fourier sine and cosine transforms – Properties – Transform of elementary functions – Inverse Fourier Transforms - Convolution theorem (without proof) – Parsevals's identity.

UNIT V Z – TRANSFORM AND DIFFERENCE EQUATIONS 9+3

Z-transform – Properties of Z-transform – Inverse Z-transform – Convolution theorem – Evaluation of Inverse Z transform using partial fraction method and convolution theorem - Initial and final value theorems – Formation of difference equations – Solution of difference equations using Z - transform.

TOTAL: 60 PERIODS

Laboratory based exercises / assignments / assessments will be given to students from the content of the course wherever applicable.

Branch specific / General Engineering applications based on the content of each units will be introduced to students wherever possible.Suggested Laboratory based exercises / assignments / assessments :

Ordinary differential equations

1. Symbolic computation of linear ordinary differential equations
2. Solving System of simultaneous linear differential equations using ODE SOLVER

Laplace transforms

1. Symbolic computation of Laplace transform and Inverse Laplace transform
2. Plotting Laplace transforms

Fourier Series

1. Symbolic computation of Fourier Coefficients
2. Computation of harmonics
3. Plotting truncated Fourier Series

Fourier Transform

1. Symbolic computation of Fourier Transforms
2. Plotting truncated Fourier Transforms

Z – transform

1. Symbolic computation of Z-Transforms

OUTCOMES:

CO1 :Solve higher order ordinary differential equations which arise in engineering applications.
CO2 :Apply Laplace transform techniques in solving linear differential equations.
CO3 :Apply Fourier series techniques in engineering applications.
CO4 :Understand the Fourier transforms techniques in solving engineering problems.
CO5 :Understand the Z-transforms techniques in solving difference equations.

TEXT BOOKS:

1. Grewal B.S., “Higher Engineering Mathematics”, Khanna Publishers, 45th Edition, New Delhi, 2020.
2. Erwin Kreyszig, "Advanced Engineering Mathematics", 10^{th} Edition, Wiley India Pvt Ltd., New Delhi, 2018.

REFERENCES:

1. N.P. Bali and Manish Goyal, A text book of Engineering Mathematics, Laxmi Publications, Reprint, 2008
2. Greenberg M.D., “Advanced Engineering Mathematics”, Pearson Education2nd Edition, 5th Reprint, Delhi, 2009.
3. Jain R.K. and Iyengar S.R.K., “Advanced Engineering Mathematics”,Narosa Publications, 5 th Edition, New Delhi, 2017.
4. Peter V.O’Neil, “Advanced Engineering Mathematics”, Cengage Learning India Pvt., Ltd, 7 th Edition, New Delhi , 2012.
5. Ramana B.V., “Higher Engineering Mathematics”, Tata McGraw Hill Co. Ltd., 11th Reprint, New Delhi, 2010.

CO – PO Mapping:

Course Outcomes	PROGRAMME OUTCOMES											
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**P10**	**P11**	**P12**
CO 1 :	3	3	2	3	1	2	1	1	1	1	1	3
CO 2 :	3	3	2	3	1	2	1	1	1	1	1	3
CO 3 :	3	3	2	3	1	2	1	1	1	1	1	3
CO 4 :	3	3	2	3	1	2	1	1	1	1	1	3
CO 5 :	3	3	2	3	1	2	1	1	1	1	1	3

CY23C01 ENGINEERING CHEMISTRY L T P C
3 0 2 4

UNIT I WATER TECHNOLOGY

Water – sources and impurities – water quality parameters: colour, odour, pH, hardness, alkalinity, TDS, COD, BOD, and heavy metals. Boiler feed water – requirement – troubles (scale & sludge, caustic embrittlement, boiler corrosion and priming & foaming. Internal conditioning – phosphate, Calgon, and carbonate treatment. External conditioning – demineralization. Municipal water treatment (screening, sedimentation, coagulation, filtration, disinfection-ozonolysis, UV treatment, chlorination), Reverse Osmosis – desalination.

PRACTICAL:

- Estimation of HCl using Na_2CO_3 as the primary standard
- Determination of alkalinity in the water sample.
- Determination of hardness of water by EDTA method.
- Determination of DO content of water sample by Winkler's method.

UNIT II NANOCHEMISTRY

Basics-distinction between molecules, nanomaterials and bulk materials; size-dependent properties (optical, electrical, mechanical, magnetic and catalytic). Types –nanoparticle, nanocluster, nanorod, nanowire and nanotube. Preparation of nanomaterials: sol-gel, solvothermal, laser ablation, chemical vapour deposition, electrochemical deposition and electro-spinning. Characterization - Scanning Electron Microscope and Transmission Electron Microscope - Principle and instrumentation (block diagram). Applications of nanomaterials – medicine including AYUSH, automobiles, electronics, and cosmetics.

PRACTICAL:

- Preparation of nanoparticles by Sol-Gel method/sonication method.
- Preparation of nanowire by Electrospinning.
- Study of morphology of nanomaterials by scanning electron microscopy

UNIT III CORROSION SCIENCE

Introduction to corrosion – chemical and electrochemical corrosions – mechanism of electrochemical and galvanic corrosions – concentration cell corrosion-soil, pitting, inter-granular, water line, stress and microbiological corrosions-galvanic series-factors influencing corrosion- measurement of corrosion rate. Electrochemical protection – sacrificial anodic protection and impressed current cathodic protection. Protective coatings-metallic coatings (galvanizing, tinning), organic coatings (paints). Paints: Constituents and functions.

PRACTICAL:

- Corrosion experiment-weight loss method.
- Salt spray test for corrosion study.
- Corrosion prevention by electroplating.
- Estimation of corroded Iron by Potentiometry/UV-visible spectrophotometer

UNIT IV ENERGY SOURCES

Electrochemical cell, redox reaction, electrode potential – oxidation and reduction potential. Batteries – Characteristics; types of batteries; primary battery (dry cell), secondary battery (lead acid, lithium-ion battery) and their applications. Emerging energy sources – metal

hydride battery, hydrogen energy, Fuel cells – H_2-O_2 fuel cell. Supercapacitors –Types and Applications, Renewable Energy: solar heating and solar cells. Recycling and disposal of batteries.

PRACTICAL:

- Study of components of Lead acid battery.
- Measurement of voltage in a photovoltaic cell.
- Working of $H_2 – O_2$ fuel cell

UNIT V POLYMER CHEMISTRY

Introduction: Functionality-degree of polymerization. Classification of polymers (Source, Structure, Synthesis and Intermolecular forces). Mechanism of free radical addition polymerization. Properties of polymers: Tg, tacticity, molecular weight-number average, weight average, viscosity average and polydispersity index (Problems). Techniques of polymerization: Bulk, emulsion, solution and suspension. Compounding and Fabrication Techniques: Injection, Extrusion, Blow and Calendaring. Polyamides, Polycarbonates and Polyurethanes – structure and applications. Recycling of polymers.

PRACTICAL:

- Determination of molecular weight of a polymer using Ostwald viscometer.
- Preparation of a polymer.
- Determination of molecular weight by Gel Permeation Chromatography.

TOTAL: 75 PERIODS

COURSE OUTCOMES:

CO1: To demonstrate knowledge of water quality in various industries and develop skills in analyzing water quality parameters for both domestic and industrial purposes.

CO2: To identify and apply fundamental concepts of nanoscience and nanotechnology for engineering and technology applications, and to develop skills in synthesizing nanomaterials and studying their morphology.

CO3: To apply fundamental knowledge of corrosion protection techniques and develop skills to conduct experiments for measuring and preventing corrosion.

CO4: To study the fundamentals of energy storage devices and develop skills in constructing and experimenting with batteries.

CO5: To recognize and apply basic knowledge of different types of polymeric materials and develop skills in preparing and determining their applications for futuristic material fabrication needs.

TEXT BOOKS:

1. Jain P. C. & Monica Jain., “Engineering Chemistry”, 17th Edition, Dhanpat Rai Publishing Company (P) Ltd, New Delhi, 2015.
2. Sivasankar B., “Engineering Chemistry”, Tata McGraw-Hill Publishing Company Ltd, New Delhi, 2012.
3. Dara S.S., “A Textbook of Engineering Chemistry”, Chand Publications, 2004.
4. Laboratory Manual - Department of Chemistry, CEGC, Anna University (2023).

REFERENCES:

1. Schdeva M.V., “Basics of Nano Chemistry”, Anmol Publications Pvt Ltd, 2011.
2. Friedrich Emich, “Engineering Chemistry”, Medtech, 2014.
3. Gowariker V.R., Viswanathan N.V. and Jayadev Sreedhar, “Polymer Science” New AGE International Publishers, 2009.
4. Vogel’s Textbook of Quantitative Chemical Analysis (8th edition, 2014).

CO - PO Mapping

	PO 1	**PO 2**	**PO 3**	**PO 4**	**PO 5**	**PO 6**	**PO 7**	**PO 8**	**PO 9**	**PO10**	**PO11**	**PO12**
CO1	3	3	-	-	-	-	3	-	-	-	-	-
CO2	3	-	2	-	2	-	3	-	-	-	-	-
CO3	3	3	2	-	2	-	3	-	-	-	-	-
CO4	3	3	-	-	-	-	3	-	-	-	-	-
CO5	3	-	-	-	-	-	3	-	-	-	-	-
Avg	3	3	-	-	-	-	3	-	-	-	-	-

1’ = Low; ‘2’ = Medium; ‘3’ = High

PT23201 THERMODYNAMICS L T P C
2 1 0 3

OBJECTIVES

The course aims to,

- provide a good platform to pharmaceutical engineering students to understand, model and appreciate the concept of dynamics involved in pharmaceutical systems.
- prepare them to carry out experimental investigation and analysis at later stages of graduation

UNIT I ENERGY AND THE FIRST LAW OF THERMODYNAMICS 9

Concept of heat work and energy-forms of energy- forms of work- first law of thermodynamics-energy balance equation – batch system energy balance – internal energy and enthalpy changes-application problems – enthalpy changes in chemical and biochemical reactions - application problems- effect of temperature on chemical reactions (Kirchoff's law) Open systems-Simple applied problems

UNIT II THERMODYNAMIC PROPERTIES OF FLUIDS 8

PVT behavior of pure fluids, Equation of state of ideal gases, Equation of state for Real gases, Second law of thermodynamics, Entropy and entropy changes – Applied problems- Concept of Heat Engine – refrigeration- heat pump -fundamental equations relating first law and second law.

UNIT III FREE ENERGY 8

Helmholtz free energy, Gibbs free energy, Reversible process, Maxwell Relations for fundamental properties, Eqns for ΔG, ΔS, ΔH and Cp-Cv relationship for actual gases. Phase equilibria for single component, VLE and clausius clapeyron eqn, Latent heat of phase transformation.

UNIT IV THERMODYNAMICS OF PHYSICAL PROCESSES 10

Introduction to Physical Processes, Phase Transformations - Pure Substances, Multicomponent Systems, Solutions of Nonelectrolytes - Ideal Solutions, Non Ideal Solutions, Partitioning between Liquid Phases, Solutions of Electrolytes – Coulombic Interaction and Ionic Dissociation, Mean Ionic Activity and Activity Coefficient, The Debye–Huckel Theory, Colligative Properties and Isotonicity Calculations, Solubility - Solubility as an Equilibrium Constant, The Ideal Solubility, Temperature Dependence of the Solubility, Solubility of Slightly Soluble Salts, Solubilities of Nonelectrolytes, Surfaces and Interfaces - Thermodynamic Properties, Adsorption.

UNIT V THERMODYNAMICS OF CHEMICAL PROCESSES 10

Acid–Base Equilibria, Equilibrium criteria for homogeneous chemical reactions; evaluation of equilibrium constant; effect of temperature and pressure on equilibrium constant; calculation of equilibrium conversion and yields for single and multiple reactions, Electrical Work – Oxidation–Reduction Reactions, Electrochemical Cells, pH Measurement, Noncovalent Binding Equilibria. Thermodynamics of microbial growth stoichiometry thermodynamics of maintenance, thermodynamics and stoichiometry of Product Formation.

TOTAL: 45 PERIODS

OUTCOMES:

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

CO1: understand the laws of thermodynamics and its pharmaceutical applications

CO2: appreciate the concepts and fundamentals of thermodynamics of fluids and chemical process

CO3: learn the concepts of free energy and physical process in thermodynamics and apply the ideas in pharmaceutics and formulation development process

TEXT BOOKS:

1. Kenneth A. Connors “Thermodynamics of pharmaceutical systems: An Introduction for Students of Pharmacy”, JohnWiley & Sons, Inc., Hoboken, New Jersey, 2002.
2. Smith J.M., Van Ness H.C., And Abbot M.M. “Introduction To Chemical Engineering Thermodynamics”, VII edition. Tata Mcgraw-Hill, 2009.
3. Narayanan K.V. “A TextBook Of Chemical Engineering Thermodynamics”, II edition, PHI, 2013.
4. Christiana D. Smolke, “The Metabolic Pathway Engineering Handbook Fundamentals”, Crc Press Taylor & Francis Group, 2010.
5. Urs Von Stockar. “Biothermodynamics, The Role Of thermodynamics In Biochemical Engineering“ Crc Press Taylor & Francis Group, 2013.

REFERENCES:

1. Sandler S.I. “Chemical and Biochemical Thermodynamics”, JohnWiley,1989.
2. Peter Atkins, Julio de Paula “Physical Chemistry” VII Edition, oxford university press 2002.
3. Donald T.Haynie, “Biological Thermodynamics” II Edition. Cambridge University Press 2013.
4. Sandler S.I. “Chemical, Biochemical, and Engineering Thermodynamics”, V Edition, Wiley, 2017
5. Peter Atkins, Julio de Paula and James Keeler “Atkins' Physical Chemistry: Thermodynamics and kinetics” XI Edition oxford university press 2018.

CS23C02 COMPUTER PROGRAMMING IN PYTHON

L	T	P	C
3	0	2	4

COURSE OBJECTIVES:

- To understand fundamental structural programming concepts and problem-solving process.
- To solve problems using modular programming and decomposition techniques.
- To solve problems using data structures and abstraction techniques.
- To create programming solutions using libraries and packages.
- To design solutions to domain problems using programming problem-solving techniques.

UNIT I – STRUCTURED PROGRAMMING 9+6

Problem-Solving Strategies. Basic Problem-Solving Tools: Flowcharts, Pseudocode. Introduction to Programming Languages and Development Environments. Programming. Basic Concepts and Syntax: Variables, Identifiers, Data Types: Primitive Types and Strings, Statements, Operators, Expressions and its evaluation, Operator Precedence, Basic Arithmetic Operations. Principles of Structured Programming – Control Structures: Sequence, Selection, Iteration and Branching.

PRACTICALS:

- Design algorithms for simple computational problems
- Create Pseudo-code and Flow charts for simple computational problems
- Create Python programs using simple and nested selective control statements
- Create Python programs using simple and nested sequence & iterative control statements
- Create Python programs to generate series/patterns using control statements

UNIT II – MODULARITY AND DECOMPOSITION 9+6

Principles of Modular and Decomposition. Functions: Defining functions –Argument types – Function Name-spaces – Scoping: Global and Non-local. Principles of Recursion: Base case and Recursive cases – Develop and Analyze Recursive functions: Factorial, Fibonacci. Principles of First-Class and Higher-Order functions: Lambda functions – Functions as arguments.

PRACTICALS:

- Create Python programs using functions
- Create python program using recursion
- Create Python programs using lambda functions
- Create Python programs using first-class functions
- Create Python programs using higher-order functions

UNIT Ill – DATA STRUCTURES AND ABSTRACTIONS 9+6

Principles of Data Structures and Abstractions. String Methods and Manipulations,.Lists: List Operations and Methods, List comprehensions, Nested List comprehensions, Matrix operations using Lists. Tuples and sequences. Sets and Operations. Dictionaries:

Dictionary operations, Dictionary comprehensions, Nested Dictionary comprehensions. Comparing Data Structures. Search and Sort Data Structures. Principle of Functional Programming and Tools : map, filter, and reduce.

PRACTICALS:

- Create Python programs for strings manipulations.
- Design Python programs using Lists, Nested Lists and Lists comprehensions
- Create Python programs using Tuples, Nested Tuples, and Tuple comprehensions
- Create Python programs creating Sets and performing set operations
- Create Python programs using Dictionary, Nested Dictionary and comprehensions
- Create Python programs by applying functional programming concepts

UNIT IV – LIBRARIES AND MODULES **9+6**

Exceptions: Syntax errors, Exceptions, Exception types, Handling exceptions, Raising exceptions. Files: File Path, Type of files, opening modes, Reading and Writing text files, Handling other format Data files. Modules: Creating Modules, import and from statements, Executing modules as scripts, Standard modules. Packages and Importing from packages

PRACTICALS:

- Design Python programs to handle errors and exceptions
- Create, import, and use pre-defined modules and packages
- Create, import, and use user-defined modules and packages
- Create Python programs to perform various operations on text files
- Create Python programs to perform various operations on other data file formats.

UNIT V – SIMPLE PROBLEM SOLVING TECHNIQUES IN PROGRAMMING **9+6**

Data Structures for Problem Solving: Stack, Queue. Principles of Divide and Conquer: Binary Search. Principles of Greedy Algorithms: Minimum Coin Change Problem. Case studies on programming application of problem-solving techniques in different fields of engineering.

PRACTICALS:

- Create python programs to implement stack and queue.
- Create python programs to implement binary search.
- Create python programs to solve minimum coin change problem.
- Case study on developing python solution to a domain specific problems.

TOTAL = 45 + 30 = 75 PERIODS

COURSE OUTCOMES

1. Understand fundamental structural programming concepts and problem-solving process.
2. Solve problems using modular programming and decomposition techniques.
3. Solve problems using data structures and abstraction techniques.
4. Create programming solutions using libraries and packages.
5. Design solutions to domain problems using programming problem-solving techniques.

TEXT BOOKS

1. Reema Thareja, Python Programming using Problem Solving Approach, Oxford University Press, First Edition, 2017.
2. S. Sridhar, J. Indumathi, V. M. Hariharan, Python Programming, Pearson Education, First Edition, 2023

REFERENCE BOOKS

1. Paul Deitel, Harvey Deitel, Python for Programmers, Pearson Education, 2020.
2. John V Guttag. Introduction to Computation and Programming Using Python, With Application to Computational Modeling and Understanding Data. Third Edition, The MIT Press, 2021
3. Mark Lutz, Learning Python, 5th Edition, O'Reilly Media, Inc.
4. Python official documentation and tutorial, https://docs.python.org/3/
5. Numerical Python official documentation and tutorial, https://numpy.org/

CO's-PO's & PSO's MAPPING

CO	PO1	PO2	PO3	PO4	POS	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2	PSO3
1	2		2		1								1	1	
2	2		2		1								1	1	
3	2	1	2		1								1	1	
4	2	1	2	1	1								1	1	
5	2	1	2	1	1								1	1	
Avg	2	1	2	1	1								1	1	

1 - low, 2 - medium, 3 - **high,** '-' - **no correlation**

EE23C03	BASICS OF ELECTRICAL AND ELECTRONICS ENGINEERING	L	T	P	C
		2	0	2	3

UNIT-I BASIC ELECTRICAL CIRCUITS **6**

Basic Elements: R,L,C- DC Circuits: Ohm's Law - Kirchhoff's Laws –Mesh and Nodal Analysis(Only Independent Sources). AC Circuits: Average Value, RMS Value, Impedance Instantaneous Power, Real Power, Reactive Power and Apparent Power, Power Factor-Steady state Analysis of RL,RC and RLC circuits.

UNIT II AC AND DC MACHINES **6**

Magnetic Circuit Fundamentals -DC Machines - Construction and Working Principle, Types and Application of DC generator and Motor, EMF and Torque Equation.

AC Machines: Principle, Construction, Working and Applications of Transformer -Three phase Alternator - Three Phase Induction Motor.

UNIT III ANALOG AND DIGITAL ELECTRONICS **6**

Operation and Characteristics of electronic devices: PN Junction Diodes, Zener Diode and BJT Applications: Diode Bridge Rectifier and Shunt Regulator.

Introduction to Digital Electronics: Basics Logic Gates-Flip Flops.

UNIT IV SENSORS AND TRANSDUCERS **6**

Solenoids, electro-pneumatic systems, proximity sensors, limit switches, Strain gauge, LVDT, Piezo electric transducer, optical and digital transducers, Smart sensors, Thermal Imagers.

UNIT V MEASUREMENTS AND INSTRUMENTATION **6**

Functional Elements of an Instrument, Operating Principle of Moving Coil and Moving Iron Instruments,Power Measurement, Energy Meter, Instrument Transformers - CT and PT, Multimeter-DSO - Block Diagram Approach.

TOTAL 30

LAB COMPONENET:

1. Verification of ohms and Kirchhoff's Laws.
2. Load test on DC Shunt Motor.
3. Load test on Single Phase Transformer.
4. Load test on 3 Phase Induction Motor.
5. Uncontrolled diode bridge Rectifiers.
6. Application of Zener diode as shunt regulator.
7. Verification of truth table of logic gates and flip flops.
8. Characteristics of LVDT.
9. Three phase power measurement using two wattmeter method.
10. Study of DSO.

COURSE OUTCOMES:

- **CO1** Compute the electric circuit parameters for simple circuits.
- **CO2** Understand the working principles and characteristics of electrical machines.
- **CO3** Understand the basic electronic devices.
- **CO4** Understand the basic operating principles of sensors and transducer.
- **CO5** Understand the operating principles measuring devices

TEXT BOOKS:

1. Kotharai DP and Nagarath IJ, “Basic Electrical and Electronics Enigneering”, McGraw Hill Education, Second Edition, 2020.
2. Bhattacharya SK, “Basic Electrical and Electronics Engineering”, Pearson Education, Second Edition, 2017.

REFERENCES:

1. Mehta V.K. & Mehta Rohit, “Principles of Electrical Engineering and Electronics”, McGraw Hill Education, Second Edition, 2020.
2. Mehta V.K. & Mehta Rohit, “Principles of Electrical Machines”, S. Chand Publishing, second edition 2006.
3. Albert Malvino & David Bates, “Electronic principles”, McGraw Hill Education, Seventh Edition, 2017.

Mapping COs and POs:

	Pos												PSOs			
COs	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO1	2	1														
CO2	2	1														
CO3	2	1														
CO4	2	1														
CO5	2	1														
Avg	2	1														

UC23H02 **தமிழரும் தொழில்நுட்பமும்** **L T P C**
1 0 0 1

அலகு I **நெசவு மற்றும் பானைத் தொழில்நுட்பம்**: **3**

சங்க காலத்தில் நெசவுத் தொழில் – பானைத் தொழில்நுட்பம் – கருப்பு சிவப்பு பாண்டங்கள் – பாண்டங்களில் கீறல் குறியீடுகள்.

அலகு II **வடிவமைப்பு மற்றும் கட்டிடத் தொழில்நுட்பம்**: **3**

சங்க காலத்தில் வடிவமைப்பு மற்றும் கட்டுமானங்கள் & சங்க காலத்தில் வீட்டுப் பொருட்களில் வடிவமைப்பு- சங்க காலத்தில் கட்டுமான பொருட்களும் நடுகல்லும் – சிலப்பதிகாரத்தில் மேடை அமைப்பு பற்றிய விவரங்கள் – மாமல்லபுரச் சிற்பங்களும், கோவில்களும் – சோழர் காலத்துப் பெருங்கோயில்கள் மற்றும் பிற வழிபாட்டுத் தலங்கள் – நாயக்கர் காலக் கோயில்கள் - மாதிரி கட்டமைப்புகள் பற்றி அறிதல், மதுரை மீனாட்சி அம்மன் ஆலயம் மற்றும் திருமலை நாயக்கர் மஹால் – செட்டிநாட்டு வீடுகள் – பிரிட்டிஷ் காலத்தில் சென்னையில் இந்தோ-சாரோசெனிக் கட்டிடக் கலை.

அலகு III **உற்பத்தித் தொழில் நுட்பம்**: **3**

கப்பல் கட்டும் கலை – உலோகவியல் – இரும்புத் தொழிற்சாலை – இரும்பை உருக்குதல், எஃகு – வரலாற்றுச் சான்றுகளாக செம்பு மற்றும் தங்க நாணயங்கள் – நாணயங்கள் அச்சடித்தல் – மணி உருவாக்கும் தொழிற்சாலைகள் – கல்மணிகள், கண்ணாடி மணிகள் – சுடுமண் மணிகள் – சங்கு மணிகள் – எலும்புத்துண்டுகள் – தொல்லியல் சான்றுகள் – சிலப்பதிகாரத்தில் மணிகளின் வகைகள்.

அலகு IV **வேளாண்மை மற்றும் நீர்ப்பாசனத் தொழில் நுட்பம்**: **3**

அணை, ஏரி, குளங்கள், மதகு – சோழர்காலக் குமுழித் தூம்பின் முக்கியத்துவம் – கால்நடை பராமரிப்பு – கால்நடைகளுக்காக வடிவமைக்கப்பட்ட கிணறுகள் – வேளாண்மை மற்றும் வேளாண்மைச் சார்ந்த செயல்பாடுகள் – கடல்சார் அறிவு – மீன்வளம் – முத்து மற்றும் முத்துக்குளித்தல் – பெருங்கடல் குறித்த பண்டைய அறிவு – அறிவுசார் சமூகம்.

அலகு V **அறிவியல் தமிழ் மற்றும் கணித்தமிழ்**: **3**

அறிவியல் தமிழின் வளர்ச்சி –கணித்தமிழ் வளர்ச்சி – தமிழ் நூல்களை மின்பதிப்பு செய்தல் – தமிழ் மென்பொருட்கள் உருவாக்கம் – தமிழ் இணையக் கல்விக்கழகம் – தமிழ் மின் நூலகம் – இணையத்தில் தமிழ் அகராதிகள் – சொற்குவைத் திட்டம்.

TOTAL : 15 PERIODS

TEXT-CUM-REFERENCE BOOKS

1. தமிழக வரலாறு – மக்களும் பண்பாடும் – கே.கே. பிள்ளை (வெளியீடு: தமிழ்நாடு பாடநூல் மற்றும்
கல்வியியல் பணிகள் கழகம்).

2. கணினித் தமிழ் – முனைவர் இல. சுந்தரம். (விகடன் பிரசுரம்).
3. கீழடி – வைகை நதிக்கரையில் சங்ககால நகர நாகரிகம் (தொல்லியல் துறை வெளியீடு)
4. பொருநை – ஆற்றங்கரை நாகரிகம். (தொல்லியல் துறை வெளியீடு)
5. Social Life of Tamils (Dr.K.K.Pillay) A joint publication of TNTB & ESC and RMRL – (in print)
6. Social Life of the Tamils – The Classical Period (Dr.S.Singaravelu) (Published by: International Institute of Tamil Studies.
7. Historical Heritage of the Tamils (Dr.S.V.Subatamanian, Dr.K.D. Thirunavukkarasu) (Published by: International Institute of Tamil Studies).
8. The Contributions of the Tamils to Indian Culture (Dr.M.Valarmathi) (Published by: International Institute of Tamil Studies.)
9. Keeladi – 'Sangam City Civilization on the banks of river Vaigai' (Jointly Published by: Department of Archaeology & Tamil Nadu Text Book and Educational Services Corporation, Tamil Nadu)
10. Studies in the History of India with Special Reference to Tamil Nadu (Dr.K.K.Pillay) (Publishedby: The Author)
11. Porunai Civilization (Jointly Published by: Department of Archaeology & Tamil Nadu Text Bookand Educational Services Corporation, Tamil Nadu)
12. Journey of Civilization Indus to Vaigai (R.Balakrishnan) (Published by: RMRL) – Reference Book.

UC23H02 TAMILS AND TECHNOLOGY L T P C
1 0 0 1

UNIT I WEAVING AND CERAMIC TECHNOLOGY 3

Weaving Industry during Sangam Age – Ceramic technology – Black and Red Ware Potteries (BRW) – Graffiti on Potteries.

UNIT II DESIGN AND CONSTRUCTION TECHNOLOGY 3

Designing and Structural construction House & Designs in household materials during Sangam Age -Building materials and Hero stones of Sangam age – Details of Stage Constructions in Silappathikaram - Sculptures and Temples of Mamallapuram - Great Temples of Cholas and other worship places - Temples of Nayaka Period -Type study (Madurai Meenakshi Temple)- Thirumalai NayakarMahal -ChettiNadu Houses, Indo-Saracenic architecture at Madras during British Period.

UNIT III MANUFACTURING TECHNOLOGY 3

Art of Ship Building - Metallurgical studies -Iron industry - Iron smelting, steel -Copper and gold- Coins as source of history - Minting of Coins – Beads making-industries Stonebeads - Glass beads - Terracotta beads -Shell beads/ bone beats - Archeological evidences - Gem stone types described in Silappathikaram.

UNIT IV AGRICULTURE ANDIRRIGATION TECHNOLOGY 3

Dam, Tank, ponds, Sluice, Significance of KumizhiThoompuof Chola Period,Animal Husbandry - Wells designed for cattle use - Agriculture and Agro Processing -Knowledge of

Sea -Fisheries – Pearl - Conche diving - Ancient Knowledge of Ocean -Knowledge Specific Society.

UNIT V SCIENTIFIC TAMIL & TAMIL COMPUTING 3

Development of Scientific Tamil - Tamil computing – Digitalization of Tamil Books – Development of Tamil Software – Tamil Virtual Academy – Tamil Digital Library – Online Tamil Dictionaries – Sorkuvai Project.

TOTAL : 15 PERIODS

TEXT-CUM-REFERENCEBOOKS

1. தமிழக வரலாறு – மக்களும் பண்பாடும் – கே.கே. பிள்ளை (வெளியீடு: தமிழ்நாடு பாடநூல் மற்றும்
   கல்வியியல் பணிகள் கழகம்).
2. கணினித் தமிழ் – முனைவர் இல. சுந்தரம். (விகடன் பிரசுரம்).
3. கீழடி – வைகை நதிக்கரையில் சங்ககால நகர நாகரிகம் (தொல்லியல் துறை வெளியீடு)
4. பொருநை – ஆற்றங்கரை நாகரிகம். (தொல்லியல் துறை வெளியீடு)
5. Social Life of Tamils (Dr.K.K.Pillay) A joint publication of TNTB & ESC and RMRL – (in print)
6. Social Life of the Tamils – The Classical Period (Dr.S.Singaravelu) (Published by: International Institute of Tamil Studies.
7. Historical Heritage of the Tamils (Dr.S.V.Subatamanian, Dr.K.D. Thirunavukkarasu) (Published by: International Institute of Tamil Studies).
8. The Contributions of the Tamils to Indian Culture (Dr.M.Valarmathi) (Published by: International Institute of Tamil Studies.)
9. Keeladi – 'Sangam City Civilization on the banks of river Vaigai' (Jointly Published by: Department of Archaeology & Tamil Nadu Text Book and Educational Services Corporation, Tamil Nadu)
10. Studies in the History of India with Special Reference to Tamil Nadu (Dr.K.K.Pillay) (Publishedby: The Author)
11. Porunai Civilization (Jointly Published by: Department of Archaeology & Tamil Nadu Text Bookand Educational Services Corporation, Tamil Nadu)
12. Journey of Civilization Indus to Vaigai (R.Balakrishnan) (Published by: RMRL) – Reference Book.

MA23C05 PROBABILITY AND STATISTICS L T P C
3 1 0 4

COURSE OBJECTIVES:

- To understand the basics of random variables with emphasis on the standard discrete and continuous distributions.
- To understand the basic probability concepts with respect to two dimensional random variables along with the relationship between the random variables and the significance of the Central Limit theorem.
- To understand the basic concepts of sampling distributions and statistical properties of point and interval estimators.
- To apply the small/ large sample tests through Tests of hypothesis.
- To understand the concept of analysis of variance and use it to investigate factorial dependence.

UNIT I ONE-DIMENSIONALRANDOM VARIABLES 9 + 3

Discrete and continuous random variables – Moments – Moment generating functions – Binomial, Poisson, Geometric, Uniform, Exponential, Gamma and Normal distributions – Functions of a random variable.

UNIT II TWO-DIMENSIONAL RANDOM VARIABLES 9 + 3

Joint distributions – Marginal and conditional distributions – Covariance – Correlation and Linear regression – Transformation of random variables – Central limit theorem (for independent and identically distributed random variables)

UNIT III ESTIMATION THEORY 9 + 3

Sampling distributions – Characteristics of good estimators – Method of Moments – Maximum Likelihood Estimation – Interval estimates for mean, variance and proportions.

UNIT IV TESTS OF SIGNIFICANCE 9 + 3

Type I and Type II errors – Tests for single mean, proportion, Difference of means (large and small samples) – Tests for single variance and equality of variances –χ^2 test for goodness of fit – Independence of attributes.

UNIT V DESIGN OF EXPERIMENTS 9+3

Completely Randomized Design – Randomized Block Design – Latin Square Design – 2^2 factorial design.

TOTAL: 60 PERIODS

OUTCOMES:

On completion of the course, the students will be able to:

CO1: To analyze the performance in terms of probabilities and distributions achieved by the determined solutions.

CO2: To be familiar with some of the commonly encountered two dimensional random variables and be equipped for a possible extension to multivariate analysis.

CO3: To apply the basic principles of the estimation theory to practical situations.

CO4: To demonstrate the knowledge of large / small sample theory in statistical inference.

CO5: To obtain a better understanding of the importance of the methods in modern industrial processes.

TEXT BOOKS

1. Irwin Miller and Marylees Miller"John E. Freund's Mathematical Statistics with applications", Pearson India Education, Asia, 8th Edition, 2014.
2. Devore, J.L. "Probability and Statistics for Engineering and the Sciences", Cengage Learning, 8th Edition, 2011.

REFERENCES

1. Milton, J.S. and Arnold, J.C. "Introduction to Probability and Statistics", Tata McGraw Hill, New Delhi, 4th Edition, 3rd Reprint, 2008.
2. Ross, S.M. "Introduction to Probability and Statistics for Engineers and Scientists", Elsevier, New Delhi, 5th Edition, 2014.
3. Spiegel, M.R., Schiller, J., Srinivasan, R.A. and Goswami, D. "Schaum's Outline of Theory and Problems for Probability and Statistics", McGraw Hill Education, 3rd Edition, Reprint, 2017.
4. Walpole, R.E., Myers R.H., Myres S.L., and Ye, K. "Probability and Statistics for Engineers and Scientists", Pearson Education, Asia, 9th Edition, 2011.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	1	-	3	1	2	2	2	1	2	1	1	2	3	1
2	3	2	1	1	2	-	1	2	1	1	2	1	2	3	1
3	3	-	-	2	-	1	1	-	2	2	1	2	2	3	1
4	2	1	-	2	2	-	2	-	2	1	2	1	2	3	1
5	2	1	-	-	1	-	2	-	2	1	-	1	2	3	1
Avg	2.40	1.25	1.00	2.00	1.50	1.50	1.60	2.00	1.60	1.40	1.50	1.20	2.00	3.00	1.00
1-low, 2-medium, 3-high, '-"- no correlation between CO and PO * upto 2 decimals															

PT23301 STOICHIOMETRY AND FLUID MECHANICS

L	T	P	C
3	0	4	5

OBJECTIVES

- To learn about various units and dimensions of different physical quantities and to learn about material balance with and without chemical reactions.
- To impart knowledge on the fluid statics and dynamics, to incorporate different expressions involved in fluid flow and fluid flowing over immersed solids.
- To enhance the understanding of measurement techniques of fluid flows and to impart practical knowledge on various unit operations.

UNIT I INTRODUCTION **9**

Basic chemical calculations – Dimensions – Conversion from one system to the other – composition of mixtures and solutions – mass fraction, mass %, mole fraction, mole %, mass ratios, molarity, molality, and normality; Ideal and actual gas equations, Application to pure gas & gas mixtures – partial pressure.

UNIT II PSYCHROMETRY **9**

Humidity, Molar Humidity, Relative Humidity, % Saturation, humid Volume – Humidity chart – wet, Dry bulb, Dew point temperatures, Chemical Reaction-Limiting and excess reactant, Fractional conversion, Percent conversion, Fractional yield in multiple reactions. Simple problems, Combustion Reactions.

UNIT III STOICHIOMETRY AND MATERIAL BALANCE **9**

Basic Principles of Stoichiometry - Importance of material balance and energy balance - Dimensions, Units, conversion factors and their use –Data sources and applications. Material Balance Stoichiometric principles, Application of material balance in Unit Operations like distillation, evaporation, crystallization, drying, extraction, Leaching.

UNIT IV FLUID PROPERTIES **9+20**

Fluid properties, Barometric equations - application for incompressible and compressible fluids; Pressure changes in atmospheric air – Gauge and absolute pressure – pressure measurement with Bourdon gauge & manometers. Newtonian and non-Newtonian fluids – Classification of fluid motion.

PRACTICALS:

- Flow through straight pipe
- Flow through annular pipe
- Calibration of Orifice meter
- Calibration of Venturimeter
- Characteristic curves of centrifugal pump

UNIT V FLUID DYNAMICS **9+18**

Fluid Dynamics – equation of continuity – Bernoulli's equation. Fluid transport -Industrial application **-** fluid flow through packing- characteristics of packed bed -Laminar flow through the packed bed and turbulent flow-pressure drop experienced by the fluid-equations and application - problems. Fluidization phenomena-Industrial application and minimum fluidization velocity.

PRACTICALS:

- Pressure drop studies in packed column
- Batch filtration studies using a Leaf filter
- Hydrodynamics of fluidized bed

TOTAL: 105 (45+60) HOURS

TEXT BOOKS:

1. Bhatt B.I & SB Thakore, Stoichiometry - V edition Tata McGraw Hill 2017
2. Richard M. Felder, Ronald W. Rousseau “Elementary Principles of Chemical Process” III Ed. John Wiley & Sons Publisher 2008.
3. David M. Himmelblau and James B. Riggs “Basic Principles and Calculations in Chemical Engineering”, VIII Edition PHI 2015.
4. Mc Cabe, W.L., Smith, J.C. and Harriot, P., ‘Unit Operations in Chemical Engineering’, VII edition., McGraw-Hill, 2017.
5. Noel de Nevers, “Fluid Mechanics for Chemical Engineers “, Second Edition, McGraw-Hill, (1991).
6. Munson, B. R., Young, D.F., Okiishi, T.H. “Fundamentals of Fluid Mechanics”, 5 thEdition“, John Wiley, 2006

REFERENCES:

1. Robert W. Fox, Alan T. McDonald & Philip J. Pritchard “Introduction to Fluid Mechanics” VII Ed. John Wiley & Sons 2015.
2. James O Wilkes and Stacy G Bike, “Fluid Mechanics for Chemical Engineers’ Prentice Hall PTR (International series in Chemical Engineering) (1999)
3. White, F.M., “Fluid Mechanics “, IV Edition, McGraw-Hill Inc., 1999
4. Geankoplis. C.J” Transport Process & separation Process Principles” IV edition Prentice Hall of India 2015.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	-	-	3	-	1	2	1	2	1	1	1	3	3	2
2	3	-	-	2	1	1	-	-	2	2	1	1	3	1	1
3	3	-	1	2	-	2	1	-	2	1	2	1	3	1	3
4	2	1	1	2	2	-	-	-	1	1	2	2	3	1	3
5	3	1	2	-	1	-	1	-	2	1	-	1	3	1	3
Avg.	2.8	1	1.33	2.25	1.33	1.33	1.33	1	1.8	1.2	1.5	1.2	3	1.4	2.4

PT23302 MICROBIOLOGY L T P C
3 0 4 5

OBJECTIVES

- To help the students comprehend how an infection is spread and detected.
- To help the students comprehend the evolution of antibiotics and the emergence of their resistance.

UNIT I INTRODUCTION TO MICROBIOLOGY 9+12

History (scientists and discoveries), classification and nomenclature of microorganisms, microscopic examination of microorganisms: light, fluorescent, dark field, phase contrast, and electron microscopy. Stains and staining techniques – Definition of auxochrome, chromophores, dyes, Classification of stains, Theories of staining, Mechanism of gram staining, acid fast staining, negative staining, capsule staining, flagella staining, endospores staining.

Experiments: 1. To introduce to sterile techniques and instruments of microbiology lab
2. To prepare and sterilize nutrient broth and agar for microbial culture
3. To perform Staining methods – (a) Simple and (b) Gram's staining

UNIT II MICROBIAL NUTRITION, GROWTH AND METABOLISM 9 + 12

Nutritional classification of microorganisms based on carbon, energy and electron sources Definition of growth, balanced and unbalanced growth, growth curve and different methods to quantify bacterial growth:(counting chamber, viable count method, counting without equipment, different media used for bacterial culture (defined, complex, selective, differential, enriched), Biochemical test for identification (citrate utilization, catalase, coagulase, IMViC), Mathematics of growth-generation time, specific growth rate.

EXPERIMENTS:

4. To introduce culture techniques – Isolation and Preservation of Cultures:

   Broth, Flask, Test tubes; Solid: Pour plates, streak plates, slants, stabs

5. To identify *E.coli*, *Bacillus* using biochemical tests

6. Growth Curve in Bacteria (Demo)

UNIT III CONTROL OF MICROORGANISMS 9

Sterilization, Physical control of microorganisms dry and moist heat, pasteurization, tyndallization; radiation, ultrasonication, filtration and chemical control of microorganisms (phenolics, alcohols, halogens, heavy metals, quaternary ammonium compounds, aldehydes, sterilizing gases) Disinfection, antiseptics and fumigation. Determination of phenol coefficient of disinfectant. Host- microbe interactions (types of interaction, gnotobiotic, host defense and pathogen defense); anti-bacterial (class I, II, III), mode of action and resistance to antibiotics. development of MDR organisms

Experiments:

7. To determine the effect of pH, temperature, UV radiation on bacterial growth
8. To determine the effect of disinfectants- Phenol Coefficient

UNIT IV FUNGI AND VIRUSES 9

Structure of the Fungal Cell, Medical Significance of Fungi, Medically Important Fungal Pathogens of Humans: Candida albicans, Aspergillus fumigatus, Histoplasma capsulatum, Dermatophytes, Emerging Fungal Pathogens: Saccharomyces cerevisiae, Non-albicans Candida Species, Penicillium marneffei, Antibiotic Production by Fungi- General Structure of Viruses**,:** Virus–Host Cell Interactions,: Multiplication of Human Viruses, Coronaviruses, Human Immunodeficiency Virus (HIV), Oncogenic Viruses, Attachment to the Host Cell, Penetration of the Viral Particle, Uncoating of the Viral Particle, Replication of Viral Nucleic Acids and Translation of the Genome, Maturation or Assembly of Virions, Release of Virions into the Surrounding Environment, Viricidal Effects of Chemical and Physical Agents on Viruses, Bacterial Viruses, Overview, Bacteriophages and Their Products as Antibacterial Agents, Other Applications of Bacteriophages, Subviral Infectious Agents and Prions

Experiments: 9. To quantify microbes: Sampling and Serial Dilution; Bacterial count in Soil – TVC

UNIT V PARASITIC DISEASES AND DETECTION 9

Protozoa , Physiology of protozoa Blood and Tissue Parasites: Malaria, Disease, Life Cycle, Trypanosomatids, Intestinal Parasites: Giardia lamblia (syn. intestinalis, duodenalis), Entamoeba histolytica Trichomonas and Free-living Amoebae, Trichomonas Vaginalis Free-living Opportunist Amoebae, Host Response to Infection, Immune Response, Immune Pathology, Immune Evasion, Detection of Parasites, Methods of Detection: Antibody-based Technologies, DNA-based Technologies, Alternative Methods, Chemotherapy:Mechanisms of Action and Selective Toxicity, Drug Targets and Life Cycle Stages, Drug Resistance, Drug Repurposing.

Experiments: 10. To assay antibiotic sensitivity

TOTAL : 105 HOURS

OUTCOMES

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

CO 1 recognize microorganisms,

CO 2 design a medium for microbial growth

CO 3 describe about various physical and chemical agents influence microbial growth and also gain knowledge about the interaction of drugs with the microbial metabolism

CO4 explain about antifungal and antiviral therapy

CO 5 identify parasites and uses techniques to identify them

TEXTBOOKS

1. Prescott. Harley, Klein. “Microbiology “: Authored by Wiley, Sherwood, Woolverton, Prescott 10th edition (2017) McGraw-Hill Higher Education
2. Hugo and Russel’s Pharmaceutical Microbiology edited by Gilmore & Denyer 9th edition(2023) Wiley Blackwell

REFERENCE BOOKS

1. Ananthanarayanan, R.and Jayaram Paniker C.K., “Textbook of Microbiology”,10th Edition, 2017 Orient Longman
2. Jeremy. W. Dale Understanding Microbes: An Introduction to a Small World”. February 2013 Wiley-Blackwell
3. Geoffrey Hanlon and Norman Hodges Essential microbiology for pharmacy and Pharmaceutical Sciences 2013, Wiley Blackwell
4. James H. Jorgensen; Michael A. P faller., A Clinician's Dictionary of Pathogenic Microorganisms 2004.

CO-PO & PSO MAPPING

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	1	2	3	-	-	-	-	-	-	3	2	1	-	-
2	3	2	3	1	-	-	-	-	2	-	3	2	-	1	-
3	2	3	1	1	1	-	2	-	-	-	3	-	1	-	3
4	1	3	3		-	1	-	-	2	-	-	-	2	-	3
5	3		3		-	-	2	1	-	-	-	-	-	2	-
AVg.	12/5=2.4	9/4=2.25	12/5=2.4	5/3=1.6	1/1=1	1/1=1	4/2=2	1	4/2=2	-	9/3=3	4/2=2	4/3=1.3	3/2=1.5	6/2=3

IB23C03	BIOCHEMISTRY	L	T	P	C
		3	0	4	5

OBJECTIVES

- To understand the chemistry of biomolecules and their metabolism with reference to cellular physiology and clinical relevance.
- To understand and perform numerous methods to detect and quantify the levels of biomolecules

UNIT – I: BIOMOLECULES – I **21**

Carbohydrates: Classification. Structure and properties of simple sugars. Reactions of sugar in biological systems – Redox reactions, Acetal formation and its hydrolysis, Enzymatic (*O*- and *N*-linked glycosylation) and non-enzymatic glycosylation (HbA1c). Modified monosaccharides in biological systems. Carbohydrate derivatives and their significance – Proteoglycans, Glycosaminoglycans and glycoproteins. Glycan binding proteins and their significance. Lipids: Classification. Structure and properties of Triglycerides, Fatty acids, Sterols, Phospholipids, Sphingolipids and Glycolipids. Role of lipids in biology – Energy production, membrane biogenesis and cell signalling. Alcohol and ester groups in lipids. Reactions of lipids – Hydrolysis, Saponification, Halogenation, Hydrogenation, and Rancidity.

Practical:

1. Qualitative tests for carbohydrates: (i) Aldose Vs. Ketose, (ii) Reducing Vs. Non-reducing and (iii) Hexose Vs. Pentose
2. Extraction of lipids and its analysis using Thin Layer Chromatography (TLC).

UNIT – II: BIOMOLECULES – II **35**

Nucleic acids: Composition, structure and properties of nucleic acids. Significance of differences between DNA and RNA. Structure of DNA – Phosphodiester bond, Chargaff's rule, X–ray diffraction analysis and Watson & Crick model of double helix, Forces stabilizing the DNA structure. Conformational variants of double helical DNA (*A-, B*- and *Z*- DNA). Hoogsteen base pairing – Triple and Quadruple helix. DNA supercoiling and its significance. Reversible denaturation and hyperchromic effect. Different types of RNA and their biological functions. Amino acids and protein: Single and three letter amino acid codes, Classification of amino acids, Optical and Stereochemical properties of amino acids, pI and Zwitterionic characteristics of amino acids and their physiological relevance. Hierarchical structure of protein and stabilizing forces, Ramachandran Plot and its significance. Protein denaturation and renaturation. Protein solubility – Salting in and salting out.

Practical:

3. Determination of DNA quality and quantity using UV-spectroscopy and assessment of its denaturation.
4. Titration curve for an amino acid.
5. Quantification of amino acids and differentiation of amino acids from imino acids using ninhydrin.
6. Estimation of protein levels using Bradford's, Lowry's and Bicinchoninic acid ssay method.

UNIT – III: INTERMEDIARY METABOLISM 11

Basic concepts of intermediary metabolism and its design: Exergonic Vs. Endergonic reactions, Favourable Vs. Unfavourable reactions, Overview of Enzymes and their Coenzymes/Cofactors, Rate-limiting enzymes, General regulation of metabolism – Enzyme/Co-enzyme concentrations, Allosteric regulations, Enzyme modifications, Substrate concentrations, Compartmentalization, etc. *Metabolism and its regulation:* Glycolysis and gluconeogenesis, HMP pathway, Glycogenesis, β-oxidation of fatty acids and the role of carnitine, Biosynthesis of fatty acids and cholesterol. Pharmacological regulation of carbohydrate and lipid metabolism.

UNIT – IV: BIOENERGETICS 15

Overview of mitochondria. High energy compounds, Substrate level phosphorylation, TCA cycle and its amphibolic nature, Shuttle systems (Malate-Aspartate and Glycerol phosphate shuttle), Mitochondrial Electron transport chain (ETC) and redox potential, Chemiosmotic theory and Oxidative phosphorylation (OXPHOS), Adenine nucleotide translocase, Coupled Vs. Uncoupled respiration (Thermogenesis), Inhibitors of respiratory chain, Bioenergetics of glucose and fatty acid oxidation.

Practical:

7. Determination of glycolytic and OXPHOS capacity of a cell – Study design and data analysis.

UNIT – V: CLINICAL BIOCHEMISTRY 23

Organ function tests – Marker enzymes and Metabolites (Creatinine, Bilirubin, etc.). Disorders of carbohydrate metabolism: Diabetes mellitus, Glycosylated haemoglobin, Keto-acidosis, Glycogen storage disorder. Disorders of lipid metabolism: Niemaan Pick disease, Gaucher disease and Tay-Sachs disease, Lipoproteins (HDL, LDL, IDL, VLDL and Chylomicrons) in health and disease – Dyslipidemia and atherosclerosis.

Practical:

8. Determination of blood glucose levels using GOD-POD assay.
9. Determination of triglycerides levels in blood using coupled enzymatic assay.
10. Determination of plasma cholesterol levels.

TOTAL: 105 PERIODS

OUTCOMES:

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

CO1 Gain knowledge about the chemistry of carbohydrates and lipids
CO2 Gain knowledge about the chemistry of nucleic acids and proteins
CO3 Understand the relationship between various metabolic pathways
CO4 Understand the molecular mechanism of cellular energy production
CO5 Understand the basis of major diseases/disorders associated metabolic dysfunction

TEXT BOOKS:

1. Lehninger Principles of Biochemistry 7th Edition by David L. Nelson, Michael M. Cox W.H. Freeman and Company 2017
2. Schaum's Outline of Biochemistry, 3rd Edition (Schaum's Outline Series) Philip Kuchel,3rd Edition 2009
3. Lippincott Illustrated Reviews: Biochemistry 7th edition Denise R. Ferrier 2017
4. Rastogi, S.C. "Biochemistry" 2nd Edition, Tata McGraw-Hill, 2003.
5. Outlines of biochemistry, 5th Edition: By E E Cohn, P K Stumpf, G Bruening and R Y Doi. pp 693. John Wiley and Sons, New York. 1987.
6. Biochemistry 9th edition by Lubert Stryer. Jeremy Berg, John Tymoczko, Gregory Gatto,2015. WH Freeman Publisher 2019
7. Zubay's Principles of Biochemistry Rastogi, Aneja. Meditech publisher, 5th edition 1995
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan. 5th edition, 2013.
9. Introduction of Practical Biochemistry by David T. Phummer. (2nd Edition), 1978.

REFERENCES:

1. Berg, Jeremy M. et al. "Biochemistry", 6th Edition, W.H. Freeman & Co., 2006.
2. Voet, D. and Voet, J.G., "Biochemistry", 3rd Edition, John Wiley & Sons Inc.,2004.
3. Murray, R.K., et al., "Harper's Illustrated Biochemistry", 27th Edition, McGraw-Hill, 2006.
4. Harpers Biochemistry Ed. R.K. Murray, D.K. Granner, P.A. Mayes and V.W. Rodwell, Appleton and Lange, Stanford, Connecticut, 24th edition,1996.
5. Textbook of Biochemistry with clinical correlations. Ed. Thomas M. Devlin. Wiley Liss Publishers, 6th edition, 2006.

Course Articulation Matrix

CO's	PO's												PSO's		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	1	1	-	-	-	-	-	-	-	2	2	2	1
2	3	2	2	2	2	-	-	-	-	-	-	2	2	3	1
3	2	2	2	2	2	-	-	-	-	-	-	2	2	3	2
4	3	2	2	1	2	1	-	-	-	-	-	2	2	2	1
5	3	2	2	2	-	1	-	-	-	-	-	2	3	3	1
Over all CO	2.6	2	1.8	1.6	2	1	-	-		-	-	2	2.2	2.6	1.2

Course 1-low, 2-medium, 3-high, '-"- no correlation

Note: The average value of this course to be used for program articulation matrix

PT23303 PHARMACEUTICAL CHEMISTRY L T P C
3 0 0 3

OBJECTIVES

The aim of this course is to

- provide comprehensive information on synthesis and characterization of heterocyclic compounds
- provide comprehensive information on tests for impurities and pharmaceutical aids
- provide comprehensive information on coordinate compounds and their applications in medicine

UNIT I CHEMISTRY OF HETEROCYCLIC COMPOUNDS 9

Classification of heterocyclic compounds, nature and nomenclature, preparation and important reactions of pyrrole, furan, thiophene, pyrazole, imidazole, oxazole, isoxazole, thiazole, pyridine, pyrimidine, indole, quinoline, isoquinoline, acridine, phenothiazine, azepines, diazepines, quinolones and quinazolines and structural examples of medicinal compounds and examples prototype pharmaceutical compounds

UNIT II PROTOTYPE REACTIONS 9

Friedel–Crafts and related reaction: Principle involved, alkylation and acylation, industrial applications, Fries rearrangement, Hoesch reaction, formylation reactions– Gatterman, Gatterman-Koch, Vilsmeyer, Reimer – Tiemann, Duff, chloromethylation reaction, Kolbe reaction, preparation and properties of poly aromatic compounds, naphthalene, anthracene, phenanthrene, diphenyl methane, triphenyl methane and diphenyl ethane.

UNIT III TEST FOR PURITY IN PHARMACEUTICAL SUBSTANCES 9

Identification and characterization of impurities in Pharmaceutical substances, Limit tests: Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, heavy metals, lead and modifications with suitable examples.

UNIT IV INORGANIC COMPOUNDS IN PHARMACOPOEIA 9

Method of preparation, assay, identification test, test for purity, official preparation, storage conditions and belonging to the following categories. Gastrointestinal agents and related compounds – Acidifiers, Antacids, Adsorbents and Protectives, Saline cathartics; Topical Agents – Protectives, Astringents, Antimicrobial topical agents.

UNIT V PHARMACEUTICAL AIDS AND COORDINATION COMPOUNDS 9

Definition, principles and properties of various agents such as – Sodium bisulphate, Sodium metabisulphite, Sulphur dioxide, Bentonite, Magnesium stearate, Zinc stearate, Aluminium sulphate, Sodium carboxymethyl cellulose, Sodium methyl paraben. Theory of coordination compounds with special reference to application in Pharmacy such as – EDTA, Dimercaprol, Penicillamine, 1, 10-Phenanthroline.

TOTAL: **45 HOURS**

OUTCOME

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

CO1 describe about uses of heterocyclic compounds

CO2 explain about compound synthesis using name reactions

CO3 acquire knowledge on tests for impurities

CO4 carry out assay of inorganic compounds

CO5 understand the importance of chelating agents

TEXT BOOKS

1. Atherden L.M, "Bentley and Driver's Textbook of Pharmaceutical Chemistry", 8th Edition, Oxford University Press, 2006.
2. AB.S. Bahl and ArunBahl. A, Textbook of Organic Chemistry, S. Chand and company Pvt.Ltd, New Delhi. 2016.

REFERENCES

1. Reactions and reagents by OP Agarwal, Krishna Prakashan Media Ltd (P), 2016.
2. Chatwal, G.R. "Pharmaceutical Chemistry" Organic & Inorganic. Himalaya Publications, 2013.
3. Morrison R.T., Boyd R.N., "Organic Chemistry", Prentice- Hall of India, VI edition, 1992.
4. A.I. Vogel, B.S. Furniss, A.J. Hannaford, P.W.G. Smith, and A.R. Tatchell, Vogels "Textbook of Practical Organic Chemistry", V Edition., ELBS longman, 1994.

Course Articulation Matrix
MAPPING OF COs WITH POs AND PSO

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	1	-	3	1	2	2	2	1	2	1	1	2	3	1
2	3	2	1	1	2	-	1	2	1	1	2	1	2	3	1
3	3	-	-	2	-	1	1	-	2	2	1	2	2	3	1
4	2	1	-	2	2	-	2	-	2	1	2	1	2	3	1
5	2	1	-	-	1	-	2	-	2	1	-	1	2	3	1
Avg	2.40	1.25	1.00	2.00	1.50	1.50	1.60	2.00	1.60	1.40	1.50	1.20	2.00	3.00	1.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals

PT23U01 STANDARDS - PHARMACEUTICAL TECHNOLOGY L T P C
1 0 0 1

OBJECTIVES

The course aims to.

- To introduce the principles of Standards and Quality in order to impart knowledge about various standards and measures

UNIT I: OVERVIEW OF STANDARDS 6

Basic concepts of standardization; Purpose of Standardization, marking and certification of articles and processes; Importance of standards to industry, policy makers, trade, sustainability and innovation. Objectives, roles and functions of BIS, Bureau of Indian Standards Act, ISO/IEC Directives; WTO Good Practices for Standardization. Important Indian and International Standards.

UNIT II: 9

D&C Act, Second Schedules, cGMP, NABL guidelines, RCGM guidelines for recombinant DNA research, GMP guidelines in Biotech industries, Guidelines for Stem Cell Research and Clinical Translation, ICMR ethical
guidelines.

TOTAL: 15 PERIODS

OUTCOMES:

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

- Understand the various levels of standards and guidelines to be adopted in harmaceutical technology.

UC23U01 **UNIVERSAL HUMAN VALUES** **L T P C**
1 0 2 2

COURSE OBJECTIVE:

The objective of the course is four-fold:

1. Development of a holistic perspective based on self-exploration about themselves (human being), family, society and nature/existence.
2. Understanding (or developing clarity) of the harmony in the human being, family, society and nature/existence
3. Strengthening of self-reflection.
4. Development of commitment and courage to act.

Module I: Introduction **(3L,6P)**

Purpose and motivation for the course, recapitulation from Universal Human Values-I, Self-Exploration– Its content and process; 'Natural acceptance' and Experiential Validation- as the process for self-exploration Continuous Happiness and Prosperity- A look at basic Human Aspirations Right understanding, Relationship and Physical Facility- the basic requirements for fulfilment of aspirations of every human being with their correct priority Understanding Happiness and Prosperity correctly- A critical appraisal of the current scenario, Method to fulfil the above human aspirations: understanding and living in harmony at various levels.

Practical Session: *Include sessions to discuss natural acceptance in human being as the innate acceptance for living with responsibility (living in relationship, harmony and co-existence) rather than as arbitrariness in choice based on liking-disliking*

Module II: Harmony in the Human Being **(3L,6P)**

Understanding human being as a co-existence of the sentient 'I' and the material 'Body', Understanding the needs of Self ('I') and 'Body' - happiness and physical facility, Understanding the Body as an instrument of 'I' (I being the doer, seer and enjoyer), Understanding the characteristics and activities of 'I' and harmony in 'I', Understanding the harmony of I with the Body: Sanyam and Health; correct appraisal of Physical needs, meaning of Prosperity in detail, Programs to ensure Sanyam and Health.

Practical Session: *Include sessions to discuss the role others have played in making material goods available to me. Identifying from one's own life. Differentiate between prosperity and accumulation. Discuss program for ensuring health vs dealing with disease.*

Module III: Harmony in the Family and Society **(3L,6P)**

Understanding values in human-human relationship; meaning of Justice (nine universal values in relationships) and program for its fulfilment to ensure mutual happiness; Trust and Respect as the foundational values of relationship, Understanding the meaning of Trust; Difference between intention and competence, Understanding the meaning of Respect, Difference between respect and differentiation; the other salient values in relationship, Understanding the harmony in the society (society being an extension of family): Resolution, Prosperity, fearlessness (trust) and co-existence as comprehensive Human Goals, Visualizing a universal harmonious order in society- Undivided Society,

Universal Order- from family to world family.

Practical Session*: Include sessions to reflect on relationships in family, hostel and institute as extended family, real life examples, teacher-student relationship, goal of education etc. Gratitude as a universal value in relationships. Discuss with scenarios. Elicit examples from students' lives*

Module IV: Harmony in the Nature and Existence (3L,6P)

Understanding the harmony in the Nature, Interconnectedness and mutual fulfilment among the four orders of nature- recyclability and self regulation in nature, Understanding Existence as Co-existence of mutually interacting units in all- pervasive space, Holistic perception of harmony at all levels of existence.

Practical Session: *Include sessions to discuss human being as cause of imbalance in nature (film "Home" can be used), pollution, depletion of resources and role of technology etc.*

Module V: Implications of Harmony on Professional Ethics (3L,6P)

Natural acceptance of human values, Definitiveness of Ethical Human Conduct, Basis for Humanistic Education, Humanistic Constitution and Humanistic Universal Order, Competence in professional ethics: a. Ability to utilize the professional competence for augmenting universal human order b. Ability to identify the scope and characteristics of people friendly and eco-friendly production systems, c. Ability to identify and develop appropriate technologies and management patterns for above production systems. Case studies of typical holistic technologies, management models and production systems, Strategy for transition from the present state to Universal Human Order: a. At the level of individual: as socially and ecologically responsible engineers, technologists and managers b. At the level of society: as mutually enriching institutions and organizations, Sum up.

Practical Session: *Include Exercises and Case Studies will be taken up in Sessions E.g. To discuss the conduct as an engineer or scientist etc.*

TOTAL: 45 (15 Lectures + 30 Practicals) PERIODS

COURSE OUTCOME:

By the end of the course, the students will be able to:

1. Become more aware of themselves, and their surroundings (family, society, nature);
2. Have more responsible in life, and in handling problems with sustainable solutions, while keeping human relationships and human nature in mind.
3. Have better critical ability.
4. Become sensitive to their commitment towards what they have understood (human values, human relationship and human society).
5. Apply what they have learnt to their own self in different day-to-day settings in real life, at least a beginning would be made in this direction.

REFERENCES:

1. Human Values and Professional Ethics by R R Gaur, R Sangal, G P Bagaria, Excel Books, New Delhi, 3rd revised edition, 2023.

2. Jeevan Vidya: Ek Parichaya, A Nagaraj, Jeevan Vidya Prakashan, Amarkantak, 1999.
3. Human Values, A.N. Tripathi, New Age Intl. Publishers, New Delhi, 2004.
4. The Story of Stuff (Book).
5. The Story of My Experiments with Truth - by Mohandas Karamchand Gandhi
6. Small is Beautiful - E. F Schumacher.
7. Slow is Beautiful - Cecile Andrews.
8. Economy of Permanence - J C Kumarappa
9. Bharat Mein Angreji Raj - PanditSunderlal
10. Rediscovering India - by Dharampal
11. Hind Swaraj or Indian Home Rule - by Mohandas K. Gandhi
12. India Wins Freedom - Maulana Abdul Kalam Azad
13. Vivekananda - Romain Rolland (English)
14. Gandhi - Romain Rolland (English)

Web URLs:

1. Class preparations: https://fdp-si.aicte-india.org/UHV-II%20Class%20Note.php
2. Lecture presentations: https://fdp-si.aicte-india.org/UHV-II_Lectures_PPTs.php
3. Practice and Tutorial Sessions: https://fdp-si.aicte-india.org/UHV-II%20Practice%20Sessions.php

Articulation Matrix:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1						1	1	1	3			3
CO2						1	1	1	3			3
CO3						3	3	2	3		1	3
CO4						3	3	2	3		1	3
CO5						3	3	3	3		2	3

PT23401 **HUMAN PHYSIOLOGY** **L T P C**
3 0 0 3

OBJECTIVES

The course aims to enable the students
to acquire the comprehensive understanding of homeostasis and to
develop an understanding about various organ systems of human and its coordinated working patterns.

UNIT I CELLULAR TRANSPORT AND ELECTROPHYSIOLOGY 9

Homeostasis - Protein channels, ion channels, receptors - Types of Transport - uniport, symport, antiport, Intracellular movement, Intercellular movement, Movement of molecules across the plasma membrane- active, passive, vesicular transport mechanism, protein sorting, protein isolation, purification and separation methods. intercellular communication – signal molecules, chemical messengers, role of signal sequence. Resting Membrane potential – Action Potential – Graded Potentials – Refractory period

UNIT II NEUROPHYSIOLOGY AND PHYSIOLOGY OF MUSCLE CONTRACTION 9

Excitable Tissue: Nerve -Excitable Tissue: Muscle - Synaptic & Junctional Transmission - Neurotransmitters & Neuromodulators - Somatosensory Neurotransmission: physiology of muscle tissue – skeletal, smooth, cardiac, contraction – Central Nervous System - Spinal and Cranial nerves, autonomic nervous system, Electrical Activity of the Brain, Sleep–Wake States, & Circadian Rhythms - Learning, Memory, Language, & Speech

UNIT IV CARDIOVASCULAR AND RESPIRATORY PHYSIOLOGY 9

Origin of the Heartbeat & the Electrical Activity of the Heart -The Heart as a Pump - Blood as a Circulatory Fluid & the Dynamics of Blood & Lymph Flow - Cardiovascular Regulatory Mechanisms - Circulation Through Special Regions - Introduction to Pulmonary Structure & MechanicsGas Transport & pH -Regulation of Respiration

UNIT IV GASTROINTESTINAL PHYSIOLOGY AND RENAL PHYSIOLOGY 9

Overview of Gastrointestinal Function & Regulation Digestion & Absorption of Nutrients Gastrointestinal Motility -Transport & Metabolic Functions of the Liver – Role of kidneys in Homeostasis - Renal Function & Micturition - Regulation of Extracellular Fluid Composition & Volume -Acidification of the Urine & Bicarbonate Excretion

UNIT V ENDOCRINE AND REPRODUCTIVE PHYSIOLOGY 9

Basic Concepts of Endocrine Regulation-Hypothalamic Regulation of Hormonal Functions - The Pituitary Gland -The Adrenal Medulla & Adrenal Cortex -The Thyroid Gland -Hormonal Control of Calcium & Phosphate Metabolism & the Physiology of Bone -Reproductive Development & Function of the Female Reproductive System -Function of the Male Reproductive System -Endocrine Functions of the Pancreas & Regulation of Carbohydrate Metabolism

TOTAL: **45 HOURS**

OUTCOMES:

At the end of the course the students will be able

CO1 to understand the morphology of cells and techniques to study the cellular transport mechanisms

CO2 to understand the physiology of cells and transport mechanism of molecules in cells.

CO3 to explain the physiological process of nervous and musculoskeleton system

CO4 to explain the physiological process of gastrointestinal and renal system

CO5 to describe the coordinated functioning patterns of cardiovascular, respiratory and endocrine system.

TEXTBOOKS

1. Ganong, W.F., "Review of Medical Physiology", 26thEdition (A Lange Medical book series) McGraw – Hill (International Ed.) 2019.
2. Guyton, A.C. and Hall, J.E., "Textbook of Medical Physiology", 14th Edition, Saunders, 2020

REFERENCES

1. Vander, A.J., Sherman J.H. and Luciano D.S., "Human Physiology: The Mechanisms ofBody Function", 14thEdition, McGraw – Hill, 2016.

MAPPING OF COs WITH POs AND PSOs

CO	**PO**												**PSO**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	1	2	2	1	1	2	-	-	-	-	3	3	3	2
2	2	1	2	2	1	1	2	-	-	-	-	2	3	3	2
3	3	1	3	3	1	1	3	-	-	-	-	2	3	3	2
4	2	1	2	3	1	1	3	-	-	-	-	3	3	3	2
5	2	1	2	2	1	1	2	-	-	-	-	1	3	3	2
Avg.	2.2	1	2.2	2.4	1	1	2.4	-	-	-	-	2.2	3	3	2

PT23402 MEDICINAL CHEMISTRY L T P C
4 0 0 4

OBJECTIVE

The course aims to

Enable the students to acquire the comprehensive understanding of homeostasis and to develop an understanding about various organ systems of human and its coordinated working patterns.

UNIT I GENERAL ASPECTS 12

Introduction to Modern Drug Discovery- Rational design, Molecular modeling, Genetics and DNA technology - Classification of Drugs - Physicochemical Properties and Drug Metabolism: Passage of molecule through biological barriers: membrane transport (paracellular, transcellular), drug ionization, pKa, acids and bases used for salt formation, physicochemical properties, log P and log D - Drug absorption: drug dosage form, gastric emptying, gastric permeability to drug, first pass effect -Drug distribution: drug-plasma binding, blood brain barrier, drug accumulation in tissues - Drug Elimination - Biotransformation reactions: functionalization, conjugation reactions, reactions leading to toxic metabolite – Prodrugs - Drug Toxicity - Strategies for enhancing oral bioavailability and brain penetration: Physicochemical properties, metabolic stability, structural rigidity - Molecular targets

UNIT II DRUG RECEPTOR INTERACTIONS 12

General Aspects: drug targets, concepts of drug binding, affinity, selectivity a) Types of bonds in ligand receptor interactions, role of functional groups - Types drug-target interaction: competitive, uncompetitive, allosteric interactions - Concept of druggable targets - Enzymes as Drug Targets: - Receptors as Drug Targets - Types and properties of receptors- Cellular responses to ligand-receptor interactions - Small molecules as drugs - Strategies for hit identification - systematic and random screening, - Drug Design: Introduction to molecular mechanics, Ligand based (pharmacophore modeling) and receptor based drug design(protein crystallography, molecular docking), drug repurposing, fragment based drug discovery - Lead Optimization: - - homologs, concepts of bioisosterism, isosteric replacements, ring transformations, conformational restrictions, homo/ heterodimer ligands and chemical hybridization - QSAR: Concept of SAR, effects of substituents and functional groups, introduction to QSAR

UNIT III CHEMOTHERAPEUTIC AGENTS 12

Antibacterial Agents: Antibiotics: β-lactam antibiotics including Penicillins, Cephalosporins, Carbapenems, Monobactams Tetracyclincs and Glycylcyclins Marcolides and Ketolides Aminoglcosides Miscellaneous including Chloramphenicol, Vancomycin, Bacitracin and Newer Agents Synthetic Antibacterials: Sulfonamides and DHFR inhibitors, Quinolones, Oxazolidinediones and other miscellaneous agents - Antiparasitic Agents: Antiamoebics, Antimalarials, Anthelmintics - Antifungal Agents - Antimycobacterial Agents: - Anticancer Agents: Alkylating agents, Nitrosoureas: Procarbazines, Triazines and miscellaneous. Organoplatinum agents Antibiotics, Antimetabolites including DNA polymerase inhibitors, Pyrimidine and purine antagonists and miscellaneous agents Mitosis inhibitors and Emerging Anticancer and Cancer Stem Cell (CSC) Inhibitors - Antiviral Agents: General aspects, Nucleic acid synthesis inhibitors Amantidine and its analogs - Interferons (IFNs) and its inducers Neuraminidase inhibitors - Antiretroviral drugs including NRTI, NNRTI and protease inhibitors - Drugs against Emerging Viral Infections, e.g., Coronaviruses

UNIT V NEUROPHARMACOLOGICAL AGENTS 12

Introduction to Drugs Acting on Cholinergic Nervous System: Cholinergic receptors - Acetylcholine - Cholinergic agonists - Cholinergic Antagonists and Cholinesterase Inhibitors - Pharmacotherapy of Alzheimer's Disease - Introduction to Drugs Acting on Adrenergic Nervous System - Adrenergic receptors - Norepinephrine and Epinephrine - Adrenergic agonists - Adrenergic Antagonists - Mixed Adrenergic agonists and antagonists - Introduction to Drugs Acting on Central Nervous System: General anaesthetics - Sedatives and Hypnotics - Anticonvulsants - Antidepressants Antipsychotics - Hallucinogens - Analeptics and Psychedelics - Anxiolytics - Central stimulants Miscellaneous agents – Antiparkinsonian agents - Antiemetics, Irritable Bowel Syndrome - Introduction to Centrally-Acting Analgesics: Opioid or Narcotic analgesics: μ-Agonists, other analgesics - Mixed agonist/antagonist analgesics - μ-Antagonists Antidiarrheal agents - Cough suppressants – Antitussives.

TOTAL: 60 hours

COURSE OUTCOMES:

CO1 apply basic knowledge on physicochemical properties of drugs for understanding design principles.

CO2 theoretically predict absorption, distribution, metabolism and excretion of drugs and related concept of prodrugs

CO3 understand and appreciate the molecular design principles by studying Structure-Activity Relationship (SAR) and molecular mechanism of action.

CO4 follow the unmet medical need for newer agents for treating various infectious diseases such as COVID-19 and multidrug-resistant microbial infections.

CO5 understand the discovery and development of central nervous system drugs including those for neurodegenerative diseases.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	-	-	3	1	2	2	2	1	2	1	1	3	2	2
2	2	2	1	1	3	-	1	2	1	1	1	1	3	2	2
3	1	-	-	1	-	1	2	-	2	2	2	2	3	2	3
4	2	1	-	2	2	1	-	3	2	1	2	1	3	3	3
5	3	1	-	-	1	-	1	-	2	1	-	2	3	2	3
Avg.	2.00	1.33	1.00	1.75	1.75	1.33	1.50	2.33	1.60	1.40	1.50	1.40	3.00	2.20	2.60

PT23403 HEAT AND MASS TRANSFER OPERATIONS L T P C
3 0 4 5

OBJECTIVE

This course is designed to introduce a basic study of the phenomena of heat and mass transfer, to develop methodologies for solving a wide variety of practical engineering problems, and to provide useful information concerning the performance and design of particular systems and processes.

UNIT I CONDUCTION 9+12

General Differential equation of Heat Conduction– Cartesian and Polar Coordinates – One Dimensional Steady State Heat Conduction –– plane and Composite Systems – Conduction with Internal Heat Generation – Extended Surfaces – Unsteady Heat Conduction – Lumped Analysis – Semi Infinite and Infinite Solids –Use of Heisler's charts.

PRACTICALS

Experiment 1. Performance studies on Cooling Tower
Experiment 2. Batch drying kinetics using Tray Dryer

UNIT II CONVECTION 9+18

Free and Forced Convection – Hydrodynamic and Thermal Boundary Layer. Free and Forced Convection during external flow over Plates and Cylinders and Internal flow through tubes. Reynold's analogy, Prandtl and Coulburnanalogy. Dimensional analysis in heat transfer, heat transfer coefficient for flow through a pipe, flow past flat plate, flow through packed beds.

PRACTICALS

Experiment 3. Heat transfer in Open Pan Evaporator
Experiment 4. Boiling Heat Transfer
Experiment 5. Heat Transfer through Packed Bed

UNIT III PHASE CHANGE HEAT TRANSFER AND HEAT EXCHANGERS 9+12

Nusselt's theory of condensation – Regimes of Pool boiling and Flow boiling. Correlations in boiling and condensation. Heat Exchanger Types – Overall Heat Transfer Coefficient – Fouling Factors – Analysis – LMTD method – NTU method.

PRACTICALS

6. Heat Transfer in a Double Pipe Heat Exchanger
7. Heat Transfer in a Bare and Finned Tube Heat Exchanger

UNIT IV RADIATION 9+18

Black Body Radiation – Grey body radiation – Shape Factor – Electrical Analogy – Radiation Shields. Radiation through gases.Theory of evaporation - single effect and multiple effect evaporation – Design calculation for single and multiple effect evaporation. Radiation heat transfer – Blackbody radiation, Emissivity, Stefan - Boltzman law, Plank's law, radiation between surfaces

PRACTICALS

Experiment 8. Heat Transfer in a Condenser
Experiment 9. Heat Transfer in Helical Coils
Experiment 10. Heat Transfer in Agitated Vessels

UNIT V MASS TRANSFER 9

Basic Concepts – Diffusion Mass Transfer – Fick's Law of Diffusion – Steady state Molecular Diffusion – Convective Mass Transfer – Momentum, Heat and Mass Transfer Analogy – Convective Mass Transfer Correlations.

TOTAL: 105 HOURS

OUTCOMES

CO1 To classify and apply mass transfer equations and correlations to formulate heat exchangers design.

CO2 To understand the applications of heat transfer equipment and analyze the efficiency of evaporators and heat exchangers.

CO3 To define and discuss various concepts involved in heat conduction.

CO4 To recognize and describe the principles of heat convection

CO5 To understand and analyze the radiation heat and mass transfer.

TEXTBOOKS

1. McCabe, W.L., Smith, J.C., and Harriot, P., "Unit Operations in Chemical Engineering", 7th Edn., McGraw-Hill, 2005.
2. Yunus A. Cengel, Afshin J. Ghajar."Heat and Mass Transfer", 6th Edition, McGraw-Hill, 2020

REFERENCES

1. Ozisik, M. N., Heat Transfer: A Basic Approach, McGraw-Hill, 19841.
2. Kern, D.Q., "Process Heat Transfer ", McGraw-Hill, 1999.
3. Coulson, J.M. and Richardson, J.F., "Chemical Engineering "Vol. I, 4th Edn., Asian Books Pvt. Ltd., India, 1998.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	-	-	3	1	2	2	2	1	2	1	1	3	2	2
2	2	2	1	1	3	-	1	2	1	1	1	1	3	2	2
3	1	-	-	1	-	1	2	-	2	2	2	2	3	2	3
4	2	1	-	2	2	1	-	3	2	1	2	1	3	3	3
5	3	1	-	-	1	-	1	-	2	1	-	2	3	2	3
Avg.	2.00	1.33	1.00	1.75	1.75	1.33	1.50	2.33	1.60	1.40	1.50	1.40	3.00	2.20	2.60

PT23405 **PHYSICAL PHARMACEUTICS** **L T P C**
3 0 4 5

OBJECTIVES

The course aims to,

- provide knowledge on fundamental principles and concepts involved in pharmaceutical powders, liquid flow, dispersions, drug diffusion,
- dissolution, complexation and protein binding.
- provide the knowledge about kinetics and drug stability

UNIT I MICROMERITICS AND POWDER RHEOLOGY 9 + 24

Particle size and distribution, particle number, methods for determining particle volume, optical microscopy, sieving, sedimentation, Dynamic light scattering (DLS) technique, measurement of particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness and flow properties.

PRACTICALS

Expt1) Determination of particle size and particle size distribution using sieving method.
Expt 2) Determination of particle size and particle size distribution using Microscopic method.
Expt 3) Determination of bulk density, true density and porosity, angle of repose, surface area
Expt 4) Determination of surface area of powders.

UNIT II SURFACE AND INTERFACIAL PHENOMENON, VISCOSITY AND RHEOLOGY 91+ 12

Liquid interface, surface and interfacial tension, surface free energy, measurement of surface and interfacial tensions, free energy, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB classification, solubilization, detergency, adsorption at solid interface, solid gas and solid-liquid interface, complex films, electrical properties of the interface. Newtonian system, Law of flow, kinematic viscosity, effect of temperature on viscosity, non-Newtonian systems, plastic, pseudoplastic, dilatant, thixotropy, thixotropy in formulation, determination of viscosity: capillary, falling ball, rotational viscometers.

PRACTICALS

Expt 5) Determination of surface tension of given liquids by drop count and drop weight method.
Expt 6) Determination of critical micellar concentration (CMC) of surfactants.

UNIT III DISPERSION SYSTEMS 9

Colloidal dispersions: Definition, types, properties of colloids, protective colloids, applications of colloids in pharmacy. Suspensions and Emulsions: Interfacial properties of suspended particles, settling in suspension, theory of sedimentation, effect of Brownian movement, sedimentation of flocculated particles, sedimentation parameters, wetting of particles,

controlled flocculation, flocculation in structured vehicles, rheological considerations, emulsions; types, theories, physical stability.

PRACTICALS

Expt 7) Study of rheological properties of various types of systems using different viscometers.
Expt 8) Preparation of various types of suspensions and determination of their sedimentation parameters.

UNIT IV DIFFUSION, DISSOLUTION, COMPLEXATION & PROTEIN BINDING 9

Definitions, Steady state diffusion, Procedures and apparatus for diffusion, dissolution and drug release, factors affecting dissolution, Complexation and protein binding; Metal complexes, organic molecular complexes, inclusion compounds, methods of analysis of complexes, crystalline structures of complexes and thermodynamic basis of stability constants. Protein binding and drug action, protein binding studies.

UNIT V KINETICS AND DRUG STABILITY 9

General considerations and concepts of drug reaction kinetics; zero order, first order and pseudo first order, half-life determination, Influence of temperature, light, catalytic species, solvent and other factors, Stabilization of drugs, Accelerated stability study – shelf-life

PRACTICALS

Expt 9) Preparation and stability studies of emulsions.
Expt 10) Determination of half-life, rate constant and order of reaction.

TOTAL: 105 PERIODS

OUTCOMES:

At the end of the course the students will be able to,
CO1 understand the importance of micromeritics in dosage form design
CO2 understand the surface, interfacial phenomena and the rheology of liquids
CO3formulate and evaluate liquid dispersions
CO4 carry out dissolution and diffusion studies
CO5 determine half -life and shelf life of pharmaceutical products

TEXT BOOKS:

1. Manavalan, R. and Ramasamy. C. “Physical Pharmaceutics” 2nd Ed., Vignesh Publishers, 2015.
2. C.V.S. Subrahmanyam, “Text book of physical pharmaceutics”, 3rdEdn., Vallabhprakashan, 2015.
3. Hadkar. U. B., “Physical Pharmacy”, Nirali Prakashan, 12th edition, 2017.

REFERENCES:

1. Eugene L. Parrott, WitoldSaski, Experimental Pharmaceutics, IVth Ed, Burgess Pub. Co., 1977.

2. Liberman H.A., RiEgor M.M, & Banker GS. Pharmaceutical dosage forms – Disperse systems, Vol 1, 2 and 3, IInd Edition, Marcel Dekker Inc, New York, 1996.

REFERENCES:

1. Alfred N. Martin, Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences: Physical Chemical and Biopharmaceutical Principles in the Pharmaceutical Sciences, sixth edition, Lippincott Williams & Wilkins, 2011.
2. David B. Troy, Paul Beringer, Remington: The science and practice of pharmacy, 21st Edition, Lippincott Williams and Wilkins, 2006
3.Humphrey Moynihan and Abinacrean "Physicochemical Basis of Pharmaceuticals" Oxford University Press, 2009.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	2	2	1	2	2	1	-	-	-	-	2	2	1	2
2	3	1	2	1	2	2	1	-	-	-	-	2	2	1	2
3	3	2	2	1	2	2	1	-	-	-	-	2	1	1	1
4	3	3	2	1	2	2	1	-	-	-	-	2	3	1	3
5	3	3	2	1	2	2	1	-	-	-	-	2	2	1	3
Avg.	3.00	2.20	2.00	1.00	2.00	2.00	1.00	-	-	-	-	2.00	2.00	1.00	2.20

SEMESTER V

PT23501 PHARMACEUTICAL UNIT OPERATIONS L T P C
2 1 0 3

OBJECTIVE:

- To provide the basic fundamentals and various unit operations such as size reduction, separation, filtration, centrifugation, crystallization andevaporation.

UNITI MECHANICAL AND MEMBRANE SEPARATIONS 12 + 18

Theory of filtration, filter aids, filter media- Factors affecting filtration- industrial filters including filter press, rotary filter, edge filter, etc., - mathematical problems on filtration. Principles of centrifugation- industrial centrifugal filters - sedimentation centrifuges - Membrane separation Processes – Microfiltration - Ultrafiltration – Reverse Osmosis - Dialysis

Practical

Expt 1. Batch Filtration.
Expt 2. Centrifugation
Expt 3. Ultrafiltration and Microfiltration

UNIT II SIZE REDUCTION, SCREENING & AGGLOMERATION 9 + 12

Properties and characterization of particulate solids — Introduction to storage and conveying of solids - Analysis and technical methods for size determination of powders - Size reduction equipment – Screening equipment; thecases of above operations prevalent in pharmaceutical bulk and formulation industries.

Practical

Expt 4. Determination of particle size and particle size distribution using sieving method and microscopy
Expt 5. Preparation and evaluation of sodium bicarbonate granules by et granulation method

UNIT III MIXING OPERATIONS SOLIDS AND LIQUIDS 9

Mixing of powdered materials – Mechanism of random mixing and interactive mixing. Sampling techniques, size and mixing indices. Factors affecting the mixing process. Mixing of liquids – Mixing aerated vessels - Power requirement calculations – Types of mixing equipment for solid and liquid mixing - characteristics and operation of mixers.

UNITIV EVAPORATION AND DRYING 9 + 24

Types of evaporators – Performance of tubular evaporators, Psychrometry, Theory of Drying - Drying Curve - Drying of solids – Cross circulation drying – Freeze drying – Drying equipment – Dryers for solids and pastes – Dryers for solutions and slurries – Spray dryers – Fluidised bed dryers.

Practical

Expt: 6. To determine individual heat transfer film coefficient in forced convection.
Expt 7. To determine condensing heat transfer coefficient in vertical condenser.
Expt 8. Drying kinetics
Expt 9. To characterize the behavior of Fluidized bed.

UNITV CRYSTALLIZATION 6 + 6

Characters of crystals like purity, size, shape, geometry, habit, forms, size and its factors- Solubility curves- Super saturation theory and its limitations- nucleation

mechanism and crystal growth- crystallisers- Swenson Walker crystalliser - Caking of crystals and its prevention and numerical problems onyields; thecases of above operations prevalent in pharmaceutical bulk and formulation industries.

Practical

Expt 10: Crystallization and Mixing Experiment

TOTAL (L: 45 + P: 60): 105 PERIODS

OUTCOMES:

The student will be able to

- Recognize the various categories of materials used in pharmaceutical industry.
- Apprehend the fundamental concepts of Size reduction, separation, filtration, centrifugation in Pharmaceutical industry.

  Comprehend the fundamental concepts of crystallization and evaporation.

TEXT BOOKS:

1. McCabe WL, Smith J.C and Harriott “Unit operations of Chemical Engineering” McGraw Hill International Book Co. London 2004.
2. Lachman and Lieberman’s The theory and Practice of Industrial Pharmacy, 4th Edition Edited by Roop K Khar, SP Vyas, Farhan J Ahmad, Gaurav K Jain
3. Girish K.Jani, “Pharmaceutical Engineering I, Unit Operation I” B. S. Shah Prakashan, India, 2006.
4. Cooper and Gunn's Tutorial Pharmacy, Edited by S J Carter, CBS Publishers, New Delhi, 2005

REFERENCES:

1. Badger, W.L and Banchero, J.T “Introduction to Chemical Engineering” Tata McGrawHill, 2002
2. Coulson, J.M. and Richardson, J.F.”Chemical Engineering, 3rdEdition, Butterworth Heinemann Publication,2001.
3. K. Sambamurthy, Pharmaceutical Engineering New Age International (P) Ltd., Publishers, New Delhi,1998.

COURSE OUTCOMES:

On completion of the course students are expected to

CO1. Have a comprehensive understanding of the principles and equipment for filtration and centrifugation and membrane processes

CO2. Be able to understand principles of equipment selection and design of size reduction and size enlargement processes

CO3. Be able to understand the theory and equipment selection for solids mixing processes

CO4. Have a thorough understanding of theory and equipment selection for drying and evaporation in pharmaceutical industry

CO5. Have complete knowledge of principles of crystallization process and equipment selection

CO6. Apply principles of various unit operations used in pharmaceutical technology and enhance problem solving techniques

Course Articulation Matrix:

Course Outcomes	Statement	Program Outcome															
		PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**	**PSO4**
CO1	Have a comprehensive understanding of the principles and equipment for filtration and centrifugation and membrane processes	3	3	3	3	3	3							3			
CO2	Be able to understand principles of equipment selection and design of size reduction and size enlargement processes	3	3	3	3	3	3							3			
CO3	Be able to understand the theory and equipment selection for solids mixing processes	3	3	3	3	3	3							3			
CO4	Have complete knowledge of principles of crystallization process and equipment selection	3	3	3	3	3	3							3			
CO5		2	2	2	2	2	2							2			
Overall CO		3	3	3	3	3	3							3			

1, 2 and 3 are correlation levels with weightages as Slight (Low), Moderate (Medium) and Substantial (High) respective

PT23404 PHARMACEUTICAL ANALYSIS L T P C
3 0 4 5

OBJECTIVE

The course aims to provide information on instrumentation and applications of various equipments

UNIT I INTRODUCTION 9 + 24

Pharmacopoeia, monograph, precision, accuracy, Titrations- non aqueous, redox and complexometric titrations. Thermal methods analysis- Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Scanning Calorimetry (DSC).

Practicals:

1. Standardization of analytical weights and calibration of volumetric apparatus.

2 - 4 Experiments involving titrimetric methods (permanganimetry, iodometry, iodimetry, non aqueous).

UNIT II ULTRAVIOLET SPECTROSCOPY AND FLUORIMETRY 9 + 18

Introduction to spectroscopy, colorimeter, Ultraviolet Spectroscopy- theory of atomic and molecular spectra, Electronic transitions, Beer and Lambert's law - derivation and deviations, Chromophores, Auxochromes, Spectral shifts, Solvent effect on absorption spectra. Instrumentation and applications. Fluorimetry – theory, types of fluorescence, factors affecting fluorescence, quenching of fluorescence, instrumentation and applications.

Practicals:

5. Determination of λmax. and Validation of beer Lambert's law.
6. Quantitative and qualitative analysis of drug molecule using standard comparison method by UV/Vis spectroscopy.
7. Quantitative analysis by fluorimetry.

UNIT III IR AND NMR SPECTROSCOPY 9 + 6

Infrared spectroscopy – principle, types of vibrations, instrumentation, applications. NMR spectroscopy- principle, instrumentation, shielding and deshielding, chemical shift and applications, Principles of H-NMR and C-NMR.

Practicals:

7. Interpretation of IR, NMR spectra.

UNIT IV ATOMIC ABSORPTION AND MASS SPECTROSCOPY 9

Atomic absorption spectroscopy- Principle, instrumentation and applications. Advantages and limitations of Atomic absorption spectroscopy. Mass Spectroscopy - Principles, instrumentation, Ionization techniques - chemical ionization (CI), electron impact ionization (EI), fast atom bombardment (FAB), matrix assisted laser desorption ionization (MALDI), Types of peaks, Applications, LC-MS/MS, GC-MS/MS.

UNIT V CHROMATOGRAPHIC TECHNIQUES 9 + 12

Introduction to chromatography. Principles, classification, Paper chromatography and TLC. High Performance Liquid Chromatography (HPLC)- theory, Columns, Packing materials, Detectors, Normal and reversed phase, Solvents, HPLC terms, retention factor, symmetry factor, resolution, HETP. Column and gas chromatography – principle, technique and applications.

Practicals:

9. Analysis of drug molecule using standard comparison method by HPLC.
10. Separation of components using paper, TLC and column chromatography.

TOTAL : 105 PERIODS

OUTCOME

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

CO1 acquire knowledge on pharmacopoeia and explain the importance of thermal analysis

CO2 create basic ideas about spectrosopic analysis to determine the properties of drugs

CO3 acquire knowledge on IR and NMR applications

CO4 characterize and analyze different sources of analytes by Mass and atomic absorption spectroscopy

CO5 create basic ideas about chromatographic analysis to determine the properties of drugs.

TEXTBOOKS

1. A. H. Beckett & J. B. Stenlake, “Practical Pharmaceutical Chemistry”, Part II, 4 th Edition,Bloomsbury Academic, 2001.
2. Gurdeep R. Chatwal, Instrumental methods of chemical analysis” Himalaya publishing house, 5 th edition, 2018
3. Siddiqui, Anees A. “Pharmaceutical Analysis”. 3rd edition, Vol.I&II, CBS, 2014.
4. Dr. S. Ravi Sankar “Text of pharmaceutical analysis” 4 th edition, Rx Publications.2010.

REFERENCES

1. Gennaro, Alfonso R. “Remington: The Science and Practice of Pharmacy” Vol. I & II, XXth Edition, Lippincott Williams & Wilkins / B.I. Publication, 2000.
2. Douglas A. Skoog, F. James Holler, Stanley R. Crouch, “Principles of Instrumental Analysis”, 7 th Edition, Brooks Cole, 2017.
3. 3. Connors, Kenneth A. “A Textbook of Pharmaceutical Analysis”. IIIrd Edition,John-Wiley & Sons, 1982.
4. A.I. Vogel, Text Book of Quantitative Inorganic analysis, 3rd edition 1996.

Course Articulation Matrix

MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	2	1	2	2	1	3	2	3	3	3	3	3	3
2	3	3	1	3	3	2	2	2	3	1	3	3	3	2	3
3	3	2	2	3	3	3	2	2	3	2	3	3	2	2	2
4	3	2	2	3	3	2	2	1	2	1	2	3	2	2	3
5	3	2	2	2	3	3	2	3	3	3	2	3	3	3	3
AVg.	2.8	2.2	1.8	2.4	2.8	2.4	1.8	2.2	2.6	2	2.6	3	2.6	2.4	2.8

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO* upto 2 decimals

PT23503 PHARMACEUTICAL DOSAGE FORMS LT P C

3 0 4 5

OBJECTIVE

The aim of the course is to provide knowledge on the formulation and development of solid dosage forms

UNIT I PREFORMULATION STUDIES 9 +12

Study of physical/physiochemical properties of drugs like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic properties and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc. and their influence on formulation. Stability studies: Basic concepts and objectives of stability study.

Practicals:

1. Preparation and preformulation studies on granules
2. Preparation and evaluation of solutions

UNIT II LIQUID AND SEMI SOLID DOSAGE FORMS 9 +12

Introduction, types of additives used, vehicles, stabilizers, preservatives, emulsifying agents, solubilizers, colors, flavours, manufacturing, packaging and evaluation of solutions, suspensions and emulsions. Definitions, types, mechanisms of drug penetration through skin, factors influencing penetration, semisolid bases and their selection. General formulation/ manufacture of semisolids, clear gels, evaluation and packaging.

Practicals

4. Preparation and evaluation of creams
5. Preparation and Evaluation of ointments

UNIT III SOLID DOSAGE FORMS 9 + 18

Classification of different types of tablets, tablets equipments, granulation technology on large scale by various techniques. Advantages & disadvantages of capsule dosage form, extraction of gelatin, production of hard and soft gelatin capsules

Practicals

6. Preparation of tablets from wet and dry granules
7. Tablets prepared by direct compression
8. Formulation and filling of hard gelatin capsules

UNIT IV PARENTERAL PRODUCTS 9 +18

Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity & methods of its adjustment. Formulation details, containers and closures and their selection.

Practicals:

Preparation and evaluation of parenterals

9. Ascorbic acid injection
10. Calcium gluconate injection
11. Sodium chloride injection

UNIT V PHARMACEUTICAL AEROSOLS AND COSMETICS 9

Definition, propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation. Cosmetics Formulation and preparation of

dentifrices, hair creams, lipsticks, face powders, shaving preparations, skin creams, shampoos, hair dyes, depilatories, manicure preparations etc.

TOTAL: 105 PERIODS

OUTCOME

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

CO1 understand various pre formulation characteristics of solid/ semi-solid dosage forms.

CO2 have knowledge on basic requirements to formulate and evaluate semi-solid dosage forms.

CO3 understand formulation and evaluation techniques of tablets and capsules.

CO4 explain formulation and evaluation of parenteral products

CO5 acquire knowledge on pharmaceutical aerosols and cosmetics

TEXTBOOKS

1. Pharmaceutical dosage forms: tablets, vol 3, rational design and formulation, larry l. augsburger, stephen w. hoag, by informa healthcare USA, inc, IIIrd edition, 2008.
2. Lachman, Leon et al. “The Theory and Practice of Industrial Pharmacy” IIIrd Ed., Varghese Publishing House, 1987.
3. Aulton, Michael E. “Pharmaceutics: The Science of Dosage Form Design” IInd Ed., Churchill Livingstone, 2002.
4. Allen, Loyd V.. “Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems” IX th Ed., Wolters Kluwer/LippinCott Williams & Wilkins, 2011.
5. H. A. Liberman,, L. Lachman, and J. B. Schwartz: Pharmaceutical dosage forms: Tablets, Vol. 1,2 and 3, IInd Edition Marcel Dekker, 1989.

REFERENCES

1. Remington’s Pharmaceutical Sciences, A. R. Gennaro Mac Pub. Co. Easton, Pennsylvania 1990
2. Coated Pharmaceutical Dosage Forms, K. H. Bauer, CRC Press, Boca Raton. Med Pharm.1998
3. Pharmaceutical Coating Technology, G. C. Cole, New York,1990.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	3	1	1	2	3	-	1	1	2	1	2	3	2	3
2	3	2	1	2	3	3	3	1	-	1	2	1	3	3	1
3	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
4	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
5	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
AVg.	2.80	2.80	1.00	1.80	2.80	2.40	1.50	1.60	1.00	1.80	1.20	1.50	3.00	2.20	1.40

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO

* upto 2 decimals

PT23502 PHARMACOLOGY AND CHEMOTHERAPY L T P C
4 0 0 4

OBJECTIVES

The aim of the course is to,

- Provide the general pharmacological principles
- understand the drug action on various physiological systems.

UNIT I PHARMACOLOGICAL PRINCIPLES 9

Sources of drugs, dosage forms and routes of drug administration, mechanism of action of drugs. Combined effect of drugs, factors modifying drug action, tolerance and dependence. Absorption,Distribution, Metabolism and Excretion of drugs. Principles of basic and clinical pharmacokinetics. Adverse drug reactions. Drug interactions, Bioassay of drugs and biological standardisation.

UNIT II DRUGS ACTING ON AUTONOMIC NERVOUS SYSTEM AND CENTRAL NERVOUS SYSTEM 15

Autonomic and somatic nerve transmission, parasympathomimetics, parasympatholytics, sympathomimetics, sympatholytics, neuron blocking agents, ganglionic agonists and antagonists agents, neuromuscular blocking agents, local anaesthetic agents. Nerve conduction/transmission in the C.N.S, general anaesthetics, sedatives, hypnotics, antianxiety agents and centrally acting muscle relaxants, Psychopharmacological agents – Antipsychotics, antidepressants, neuroleptics, anti-maniacs and hallucinogens, thymoleptics, antiepileptic drugs, Anti-parkinsonism drugs, analgesics, antipyretics, anti-inflammatory (NSIADs) and anti-gout drugs, narcotic analgesics and antagonists, C.N.S. stimulants, drug addiction and drug abuse.

UNIT III DRUGS ACTING ON CARDIOVASCULAR SYSTEM AND KIDNEY 9

Cardiac glycosides, anti-hypertensive drugs, anti-anginal and vasodilator drugs including calcium channel blockers and beta adrenergic antagonists, Anti-arrhythmic drugs, antihyperlipidemic drugs, Drugs used in the therapy of shock. Fluid and electrolyte balance, Diuretics and Antidiuretics.

UNIT IV DRUGS ACTING ON RESPIRATORY SYSTEM AND GASTROINTESTINAL TRACT 12

Antacids, anti-secretory and anti-ulcer drugs, Laxatives and Anti-diarrhoeal drugs, Appetite stimulants and suppressants, Emetics and anti-emetics. Anti-asthmatic drugs including bronchodilators, leukotriene inhibitors, anti-tussives and expectorants, Respiratory stimulants. Histamine and antihistamine.

UNIT V CHEMOTHERAPY OF INFECTIONS AND MALIGNANCY 15

General principles of chemotherapy, Sulfonamides, Antibiotics – Penicillins, Cephalosporins, Chloramphenicol, macrolides, Quinolones, fluroquinolones and other antibiotics. Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy and immuno suppressive agents.

TOTAL: 60 PERIODS

OUTCOME:

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

CO1 understand the various principles of general pharmacology
CO2 understand the pharmacology of various categories of drugs acting on nervous and cardiovascular systems
CO3 understand the principles of chemotherapy and pharmacology of antimicrobial agents
CO4 understand the pharmacology of various categories of drugs acting on gastrointestinal systems
CO5 acquire knowledge on OECD guidelines and explain factors influencing toxicity studies

TEXTBOOKS:

1. Tripathi, K.D., “Essentials of Medical Pharmacology”, 7 th 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, Randa Hilal-Dandan, " Goodman and Gilman’s: The Pharmacological Basis of Therapeutics", 13th edition, 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.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	2	1	1	2	2	1	3	2	1	-	1	1	2
2	3	1	2	1	2	2	1	2	3	2	3	2	3	2	3
3	2	2	2	1	1	2	2	1	3	2	1	-	1	1	2
4	3	1	2	1	2	2	1	2	3	2	3	2	3	2	3
5	3	1	2	1	2	2	1	2	3	2	3	2	3	2	3
Avg.	2.60	1.40	2.00	1.00	1.60	2.00	1.40	1.60	3.00	2.00	2.20	2.00	2.20	1.60	2.60

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO

* upto 2 decimals

PT23U02 PERSPECTIVES OF SUSTAINABLE DEVELOPMENT – PHARMACEUTICAL TECHNOOGY

L T P C
3 0 0 3

OBJECTIVES

The course aims to,

- Deliver perspectives about the possible sustainable developments in biotechnology

Unit I – INTRODUCTION **6**

Principles & Historical perspectives, Importance and need for sustainability in engineering and technology, impact and implications. United Nations Sustainability Development Goals (SDG), UN summit – Rio & outcome, Sustainability and development indicators.

6

Unit II - ENVIRONMENTAL SUSTAINABILITY

Climate change, Biodiversity loss, Pollution and waste management, Renewable vs. non-renewable resources, Water and energy conservation, Sustainab`le agriculture and forestry. National and international policies, Environmental regulations and compliance, Ecological Footprint Analysis

Unit III – SOCIAL & ECONOMIC SUSTAINABILITY **6**

Equity and justice, Community development, Smart cities and sustainable infrastructure, Cultural heritage and sustainability, Ethical considerations in sustainable development. Triple bottom line approach, Sustainable economic growth, Corporate social responsibility (CSR), Green marketing and sustainable product design, Circular economy and waste minimization, Green accounting and sustainability reporting.

Unit IV: SUSTAINABLE DEVELOPMENT GOALS IN PHARMACEUTICAL TECHNOLOGY
6

Quality Medicines for All – Awareness on Counterfeit Medications Unscientific remedies and Good health and well-being – Personalized and precision medicine, Advanced Drug design and development methods, Development of innovative new drugs development. Clean water and sanitation. Affordable and clean energy. Climate action.

Unit V: SUSTAINABILITY PRACTICES **6**

Suggested Practices not limited to

 Energy efficiency – how to save energy (energy efficient equipment, energy saving behaviours).

 Chemical use and storage - the choice of chemicals being procured, the safe disposal of leftover chemicals, the impact of chemicals on the environment and long-term health impacts on humans.

 Green building, green building materials, green building certification and rating: green rating for integrated habitat assessment (GRIHA), leadership in energy and environmental design (LEED)

 Tools for Sustainability - Environmental Management System (EMS), ISO14000, life cycle assessment (LCA)

 Ecological footprint assessment using the Global Footprint Network spreadsheet calculator

 National/Sub national Status of Sustainable Development Goals

TOTAL: 30 PERIODS

OUTCOMES:

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

Understand the importance of sustainability and to develop potential novel strategies

TEXT BOOKS:

1. Allen, D., &Shonnard, D. R. (2011). Sustainable engineering: Concepts, design and case studies. Prentice Hall.
2. Munier, N. (2005). Introduction to sustainability (pp. 3558-6). Amsterdam, The Netherlands: Springer.
3. Blackburn, W. R. (2012). The sustainability handbook: The complete management guide to achieving social, economic and environmental responsibility. Routledge.
4. Clini, C., Musu, I., &Gullino, M. L. (2008). Sustainable development and environmental management. Published by Springer, PO Box, 17, 3300.
5. Bennett, M., James, P., &Klinkers, L. (Eds.). (2017). Sustainable measures: Evaluation and reporting of environmental and social performance. Routledge.
6. Seliger, G. (2012). Sustainable manufacturing for global value creation (pp. 3-8). Springer Berlin Heidelberg.
7. Stark, R., Seliger, G., & Bonvoisin, J. (2017). Sustainable manufacturing: Challenges, solutions and implementation perspectives. Springer Nature.
8. Davim, J. P. (Ed.). (2013). Sustainable manufacturing. John Wiley & Sons.

UC23E01 ENGINEERING ENTREPRENEURSHIP DEVELOPMENT

L	T	P	C
2	0	2	3

COURSE OBJECTIVES:

1. Learn basic concepts in entrepreneurship, develop mind-set and skills necessary to explore entrepreneurship
2. Apply process of problem - opportunity identification and validation through human centred approach to design thinking in building solutions as part of engineering projects
3. Analyse market types, conduct market estimation, identify customers, create customer persona, develop the skills to create a compelling value proposition and build a Minimum Viable Product
4. Explore business models, create business plan, conduct financial analysis and feasibility analysis to assess the financial viability of a venture ideas & solutions built with domain expertise
5. Prepare and present an investible pitch deck of their practice venture to attract stakeholders

MODULE – I: ENTREPRENEURIAL MINDSET **4L,8P**

Introduction to Entrepreneurship: Definition – Types of Entrepreneurs – Emerging Economies – Developing and Understanding an Entrepreneurial Mindset – Importance of Technology Entrepreneurship – Benefits to the Society.

Case Analysis: Study cases of successful & failed engineering entrepreneurs - Foster Creative Thinking: Engage in a series of Problem-Identification and Problem-Solving tasks

MODULE – II: OPPORTUNITIES **4L,8P**

Problems and Opportunities – Ideas and Opportunities – Identifying problems in society – Creation of opportunities – Exploring Market Types – Estimating the Market Size, - Knowing the Customer and Consumer - Customer Segmentation - Identifying niche markets – Customer discovery and validation; Market research techniques, tools for validation of ideas and opportunities

Activity Session: Identify emerging sectors / potential opportunities in existing markets - Customer Interviews: Conduct preliminary interviews with potential customers for Opportunity Validation - Analyse feedback to refine the opportunity.

MODULE – III: PROTOTYPING & ITERATION **4L,8P**

Prototyping – Importance in entrepreneurial process – Types of Prototypes - Different methods – Tools & Techniques.

Hands-on sessions on prototyping tools (3D printing, electronics, software), Develop a prototype based on identified opportunities; Receive feedback and iterate on the prototypes.

MODULE – IV: BUSINESS MODELS & PITCHING **4L,8P**

Business Model and Types - Lean Approach - 9 block Lean Canvas Model - Riskiest Assumptions in Business Model Design – Using Business Model Canvas as a Tool – Pitching Techniques: Importance of pitching - Types of pitches - crafting a compelling pitch – pitch presentation skills - using storytelling to gain investor/customer attention.

Activity Session: Develop a business model canvas for the prototype; present and receive feedback from peers and mentors - Prepare and practice pitching the business ideas- Participate in a Pitching Competition and present to a panel of judges - receive & reflect feedback

MODULE – V: ENTREPRENEURIAL ECOSYSTEM **4L,8P**

Understanding the Entrepreneurial Ecosystem – Components: Angels, Venture Capitalists, Maker Spaces, Incubators, Accelerators, Investors. Financing models – equity, debt, crowdfunding, etc, Support from the government and corporates. Navigating Ecosystem Support: Searching & Identifying the Right Ecosystem Partner – Leveraging the Ecosystem - Building the right stakeholder network

Activity Session: Arrangement of Guest Speaker Sessions by successful entrepreneurs and entrepreneurial ecosystem leaders (incubation managers; angels; etc), Visit one or two entrepreneurial ecosystem players (Travel and visit a research park or incubator or makerspace or interact with startup founders).

TOTAL: 60 PERIODS

COURSE OUTCOMES:

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

CO1: Develop an Entrepreneurial Mind-set and Understand the Entrepreneurial Ecosystem Components and Funding types

CO2: Comprehend the process of opportunity identification through design thinking, identify market potential and customers

CO3: Generate and develop creative ideas through ideation techniques

CO4: Create prototypes to materialize design concepts and conduct testing to gather feedback and refine prototypes to build a validated MVP

CO5: Analyse and refine business models to ensure sustainability and profitability Prepare and deliver an investible pitch deck of their practice venture to attract stakeholders

REFERENCES:

7. Robert D. Hisrich, Michael P. Peters, Dean A. Shepherd, Sabyasachi Sinha (2020). Entrepreneurship, McGrawHill, 11th Edition
8. Bill Aulet (2024). Disciplined Entrepreneurship: 24 Steps to a Successful Startup. John Wiley & Sons.
9. Bill Aulet (2017). Disciplined Entrepreneurship Workbook. John Wiley & Sons.
10. Ries, E. (2011). The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses. Crown Business
11. Blank, S. G., & Dorf, B. (2012). The Startup Owner's Manual: The Step-by-Step Guide for Building a Great Company. K&S Ranch
12. Osterwalder, A., & Pigneur, Y. (2010). Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers. John Wiley & Sons
13. Marc Gruber & Sharon Tal (2019). Where to Play: 3 Steps for Discovering Your Most Valuable Market Opportunities. Pearson.

SEMESTER VII

PT23701	TOTAL QUALITY MANAGEMENT	L T P C 3 0 0 3

COURSE OBJECTIVES:

- Teach the need for quality, its evolution, basic concepts, contribution of quality gurus, TQM framework, Barriers and Benefits of TQM.
- Explain the TQM Principles for application.
- Define the basics of Six Sigma and apply Traditional tools, New tools, Benchmarking and FMEA.
- Describe Taguchi's Quality Loss Function, Performance Measures and apply Techniques like QFD, TPM, COQ and BPR.
- Illustrate and apply QMS and EMS in any organization.

UNIT I INTRODUCTION 9

Introduction - Need for quality - Evolution of quality - Definition of quality - Dimensions of product and service quality –Definition of TQM-- Basic concepts of TQM –-Gurus of TQM (Brief introduction) -- TQM Framework- Barriers to TQM –Benefits of TQM.

UNIT II TQM PRINCIPLES 9

Leadership - Deming Philosophy, Quality Council, Quality statements and Strategic planning Customer Satisfaction –Customer Perception of Quality, Feedback, Customer complaints, Service Quality, Kano Model and Customer retention – Employee involvement – Motivation, Empowerment, Team and Teamwork, Recognition & Reward and Performance Appraisal-- Continuous process improvement – Juran Trilogy, PDSA cycle, 5S and Kaizen - Supplier partnership – Partnering, Supplier selection, Supplier Rating and Relationship development.

UNIT III TQM TOOLS & TECHNIQUES I 9

The seven traditional tools of quality - New management tools - Six-sigma Process Capability; Bench marking - Reasons to benchmark, Benchmarking process, what to Bench Mark, Understanding Current Performance, Planning, Studying Others, learning from the data, Using the findings, Pitfalls and Criticisms of Benchmarking - FMEA - Intent, Documentation, Stages: Design FMEA and Process FMEA.

UNIT IV TQM TOOLS & TECHNIQUES II 9

Quality circles – Quality Function Deployment (QFD) - Taguchi quality loss function – TPM – Concepts, improvement needs – Performance measures- Cost of Quality - BPR.

UNIT V QUALITY MANAGEMENT SYSTEM 9

Introduction-Benefits of ISO Registration-ISO 9000 Series of Standards-Sector-Specific Standards - AS 9100, TS16949 and TL 9000-- ISO 9001 Requirements-Implementation-Documentation Internal Audits-Registration-ENVIRONMENTAL MANAGEMENT SYSTEM: Introduction—ISO 14000 Series Standards—Concepts of ISO 14001—Requirements of ISO 14001-Benefits of EMS.

TOTAL: 45 PERIODS

COURSE OUTCOMES:

At the end of this course, the students are expected to,

CO1. Explain the TQM concepts in a selected enterprise.

CO2. Summarize the TQM principles in a selected enterprise.

CO3. Apply the six sigma, traditional tools, new tools, benchmarking and FMEA as TQM tools in leather manufacturing.

CO4. Analyze Taguchi's Quality Loss Function and Performance Measures on leather manufacturing sector and apply QFD, TPM, COQ and BPR.

CO5. Adapt QMS and EMS in leather based organization.

TEXT BOOKS AND REFERENCES:

1. Dale H. Besterfiled, Carol B. Michna,Glen H. Bester field, Mary B. Sacre, Hemant Urdhwareshe and Rashmi Urdhwareshe, “Total Quality Management”, Pearson Education Asia, Revised Third Edition, Indian Reprint, Sixth Impression,2013.
2. Joel.E. Ross, “Total Quality Management – Text and Cases”, Routledge.,2017.
3. Kiran.D.R, “Total Quality Management: Key concepts and case studies, Butterworth – Heinemann Ltd, 2016.
4. Oakland, J.S. “TQM – Text with Cases”, Butterworth – Heinemann Ltd., Oxford, Third Edition, 2003.
5. Suganthi,L and Anand Samuel, “Total Quality Management”, Prentice Hall (India) Pvt. Ltd., 2006.

COURSE ARTICULATION MATRIX:

Course Outcome	Program Outcome														
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11	PO 12	PSO1	PSO2	PSO 3
CO1	1	1	2	2	2	2	1	3	3	1	2	2	-	-	3
CO2	-	1	2	1	-	2	1	2	3	2	1	3	2	2	3
CO3	1	1	2	2	3	2	1	2	3	2	1	2	1	2	3
CO4	2	2	3	1	2	1	1	2	3	1	2	2	1	3	3
CO5	2	2	2	2	2	2	2	2	3	1	1	2	2	3	3

1, 2 and 3 are correlation levels with weightings as Slight (Low), Moderate (Medium) and Substantial (High) respectively.

PT23702 BIOPHARMACEUTICS AND PHARMACOKINETICS L T P C
3 0 4 5

OBJECTIVE

The course aims to,

- learn important parameters involved in drug disposition and its principles in living systems.
- make the students to understand how the drug disposition takes place in the in vitro and in vivo conditions.
- understand the concepts of bioavailability and bioequivalence of drug products and their significance

UNIT I DRUG ABSORPTION AND DISTRIBUTION 9 + 24

Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non-per oral extravascular routes, Distribution of drugs, Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.

Practicals:

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
3. Study the effect of formulation on drug release: Solution
4. Study the effect of formulation on drug release suspension

UNIT II ELIMINATION 9 +12

Drug metabolism, metabolic pathways, factors affecting metabolism, renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non- renal routes of drug excretion of drugs.

Practicals:

5. Determination of effect of pH on the partition coefficient of drug(s)
6. Determination of protein binding of the given drug(s) and the effect of protein binding on drug bioavailability.

UNIT III BIOAVAILABILITY AND BIOEQUIVALENCE 9 +12

Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

Practicals:

7. In-vitro drug absorption study using everted small intestine sac technique.
8. To calculate the various Pharmacokinetic parameters from the given blood data of I.V bolus injection (one compartment model).

UNIT IV PHARMACOKINETICS 9 +12

Introduction to Pharmacokinetics, Pharmacokinetic models, One compartment open model-Intravenous Bolus Injection – Intravenous infusion - Extra vascular administrations.

Determination of pharmacokinetics parameters and their significance - Absorption Rate Constant (ka), Elimination Rate Constant (K) & Elimination Half- life (t½), AUC, Cmax, and tmax. Apparent Volume of Distribution (Vd) & Renal Clearance (Q).

Practicals:

9. To calculate various Pharmacokinetic parameters from the given urinary excretion data of I.V bolus injection using both methods (Rate of elimination & sigma minus method one compartment model).
10. To determine the various Pharmacokinetic parameters from the given blood data of oral dosage form.

UNIT V NONLINEAR PHARMACOKINETICS 9

Nonlinear Pharmacokinetics - Introduction, factors causing Non-linearity, Michaelis-Menton method of estimating pharmacokinetic parameters.

TOTAL: 105 HOURS

OUTCOME:

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

CO1 explain the various factors influencing the drug absorption, drug disposition and various pharmacokinetic parameters.

CO2 identify and explain the factors affecting elimination process

CO3 design and interpret the bioavailability and bioequivalence of dosage forms.

CO4 calculate pharmacokinetic parameters using compartment models and apply the calculated value in designing of dosage regimen

CO5 explain the factors causing non linearity and estimate pharmacokinetic parameters using non-linear kinetics.

TEXT BOOKS

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

REFERENCES

1. Chatwal, G.R. “Biopharmaceutics and Pharmacokinetics”, 2nd Edition, Himalaya Publishing House, 2014.
2. Shargel,L and Andrew, B.C. Yu. “Applied Biopharmaceutics & Pharmacokinetics”,7th Edition, The McGraw-Hill Companies, Inc, 2016.
3. Gibaldi, M. “Biopharmaceutics & Clinical Pharmacokinetics”, 4th Edition, Pharma Book.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	-	-	-	-	-	-	-	-	-	2	1	-	3
2	2	2	-	-	-	-	-	-	-	-	-	2	1	-	3
3	2	2	1	2	2	-	1	-	-	-	-	2	1	1	3
4	2	2	2	2	2	-	1	-	-	-	-	2	1	1	3
5	2	2	2	2	2	-	1	-	-	-	-	2	1	1	3
Avg.	2.00	2.00	1.67	2.00	2.00	-	1.00	-	-	-	-	2.00	1.00	1.00	3.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

PT23703 DRUG REGULATORY AFFAIRS L T P C
3 0 0 3

OBJECTIVE:

The course aims to,

- enable students to acquire knowledge in drug regulatory affairs in India and at International level.
- understand the implications of regulatory issues concerning pharma industries

UNIT I INDIAN DRUG REGULATORY ASPECTS 9

Drug regulatory bodies in India, Drugs and Cosmetics Act 1940 and its rules 1945,Drug regulatory bodies in India –CDSCO, MHFW, IPC, ICMR, NPPA,The Drugs (Prices Controls) Order, 1955. The Indian Patents and Designs, Act 1970, Magic Remedies and Objectionable advertisements Act,Prevention of Food Adulteration Act 1954],Intellectual property rights ,Patent act- Patent, Trade Mark Regn, TRIPS.

UNIT II PHARMACOPOEIA AND REGULATORY BODIES, PHARMACOPOEIA AND REGULATORY BODIES 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.

UNIT III GMPS & DRUG DOSSIERS 9

Good manufacturing practices for active pharmaceutical ingredients (bulk drug substances), pharmaceutical excipients, pharmaceutical products, sterile pharmaceutical products, biological products, manufacture of herbal medicines and radiopharmaceutical products documentation, good laboratory practices (GLPs), good clinical practices (GCPs) Drug dossier contents - CTD (CMC section) & data

UNIT IV PRECLINICAL/CLINICAL TRIALS AND VARIOUS PHASES 9

Schedule-Y, pre-clinical study requirements, clinical trial phases, types of trials, bioethics & stakeholders, Bioavailability & Bioequivalence studies, Drug development stages, FDA guidelines on IND, new drug approvals (NDA), ANDA approvals. European regulatory agency, types of filing process (Centralized, de-centralized, RMS countries),Regulation of preclinical studies, Design of clinical studies CFR /ICH/EU GCP guidelines.

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, Riskgroups, 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: 45 HOURS

OUTCOME:

CO1 Explain the rationale behind regulatory requirements and ways and means of complying with them.

CO2 Handle documentation and general principles involved in regulatory writing and submission to agencies.

CO3 Prepare and implement the check lists and SOPs for various Good Regulatory Practices.

CO4 Demonstrate knowledge of regulations and guidelines for conducting clinical research

CO5 Demonstrate knowledge about various laws, legislation and guidance related to safety, efficacy ethical conduct and regulatory approval of clinical research.

TEXT BOOKS

1. C.V.Subbrahmanyam & J.Thimmasetty, "Pharmaceutical regulatory affairs", 1 stEdn., vallabh Prakashan, New Delhi, 2012.
2. Willig, H., Tuckeman, M.M. and Hitchings, W.S., "Good Manufacturing Practices for Pharmaceuticals", 5 th 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. N Udupa, Krishnamurthy Bhat, "A Concise Textbook of Drug Regulatory Affairs", Manipal University Press (MUP); First Edition, 2015.
4. Gad. Shayne C. "Drug Safety Evaluation", John Wiley Intersciences, 2002.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
2	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
3	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
4	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
5	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
Avg.	-	-	1.00	1.00	2.00	1.00	2.40	1.80	2.40	1.80	1.80	2.00	2.00	1.00	2.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

SEMESTER VIII

PT23801	**PROJECT WORK**	**L T P C**
		0 0 16 8

OBJECTIVES :

The course aims to

- Train students to analyze a problem
- Make them understand how to find solutions innovatively
- Enable them to acquire technical and experimental skills to validate the solution, analyze the results and communicate.

OUTCOME

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

CO1 formulate and analyze a problem

CO2 plan experiments to find solutions in a logical manner

CO3 analyze the results, interpret and communicate for commercialisation

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	3	2	2	2	1	-	2	2	2	1	3	2	3	3
2	2	3	2	2	2	1	-	2	2	2	1	2	2	3	3
3	2	3	2	2	2	1	-	2	2	2	1	3	2	3	3
AVg.	1.67	3.00	2.00	2.00	2.00	1.00	-	2.00	2.00	2.00	1.00	2.67	2.00	3.00	3.00

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO

* upto 2 decimals

VERTICAL-1

PT23005 PHARMACOGENOMICS L T P C
3 0 0 3

OBJECTIVE

- To study about pharmacogenomics and its application in drug development

UNIT I FUNDAMENTALS OF PHARMACOGENOMICS 9

Pharmacogenomics: Inter individual differences in therapeutic response to drugs, susceptibility to adverse effects, polymorphism of drug metabolizing enzymes, sub-therapeutic and supra-therapeutic concentration of drugs; Pharmacogenomics in PK and PD: Species difference, extrapolation to humans, selection of animal models.

UNIT II GENOMICS APPLICATIONS FOR DRUG ACTION AND TOXICITY 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.

UNIT III PHARMACOGENOMICS IN DRUG DEVELOPMENT 9

Role of Pharmacogenomics in different phases of drug development, Drug target screening and Identification, Preclinical Animal toxicology studies, Phase I-Phase IV Studies, Challenges in applying Pharmacogenomics in drug development.

UNIT IV APPLIED PHARMACOGENOMICS 9

Single Nucleotide Polymorphisms and other genetic variations, their impact on clinical medicine and clinical outcomes; Translation of genetic variations to drug selection, dosing regimen, adverse effects, regimen optimization.

UNIT V PHARMACOGENOMICS-CASE STUDIES 9

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

TOTAL: 45 PERIODS

OUTCOME:

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

CO1 Define and explain the pharmacokinetics and pharmacodynamics of the drug molecules.

CO2 Illustrate the genomic applications in drug action and its toxicology

CO3 Demonstrate the importance of pharmacogenomics in different stages of preclinical and clinical trials in drug development.

CO4 Describe the role of single nucleotide polymorphism as a biomarker for the prediction of risk, therapeutic response and prognosis of malignancies.

CO5 Evaluate various case studies to understand the importance of pharmacogenomics.

TEXTBOOK:

1. Zdanowicz MM. Concepts in pharmacogenomics. ASHP; 2010.

REFERENCES:

1. Magdum CS, Velingkar VS, Gupta MK. Pharmacogenomics: The search for the Individualized Therapy. Indian journal of pharmaceutical education and research.

2006;40(2):84.
2. Yan Q. From pharmacogenomics and systems biology to personalized care: A framework of systems and dynamical medicine. Pharmacogenomics in Drug Discovery and Development. 2014:3-17.
3. Brazeau DA, Brazeau GA. Principles of the human genome and pharmacogenomics. American Pharmacists Association; 2011.
4. Werner, K., Meyer, U.A., Tyndale, R.F. “Pharmacogenomics”, Second Edition, Taylor and Francis, 2005.
5. Yan Q, editor. Pharmacogenomics in drug discovery and development. Totowa: Humana Press; 2008.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	2	1	1	1	-	-	-	1	-	-	2	2	1	3
2	3	2	1	1	1	-	-	-	1	-	-	2	2	1	3
3	3	2	1	1	1	-	-	2	1	-	-	2	2	1	3
4	3	2	1	1	1	-	-	-	1	-	-	2	2	1	3
5	3	2	1	1	1	-	-	2	1	-	-	2	2	1	3
Avg.	3.00	2.00	1.00	1.00	1.00	0.00	0.00	2.00	1.00	0.00	0.00	2.00	2.00	1.00	3.00

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23001 BIOINFORMATICS AND CHEMINFORMATICS L T P C
3 0 0 3

OBJECTIVE:

- To introduce students to the principles and fundamental concepts of cheminformatics and drug discovery and familiarize students with the use of molecular databases and computational tools for chemical data analysis.

UNIT I INTRODUCTION TO CHEMINFORMATICS AND DRUG DISCOVERY 9

Introduction to cheminformatics and its role in drug discovery, Overview of the drug discovery process, Molecular databases and data mining techniques, Introduction to computational chemistry tools and techniques.

UNIT II CHEMICAL DATA ANALYSIS AND VISUALIZATION 9

Chemical data representation and molecular descriptors, Chemical structure drawing and molecular visualization tools, Exploratory data analysis and statistical methods, Cheminformatics in property prediction and SAR analysis, Tools and databases in ADME-Toxicity prediction, AI/ML models for effective drug toxicity and safety assessment.

UNIT III STRUCTURE-ACTIVITY RELATIONSHIP MODELLING 9

Protein-ligand interactions, docking techniques and scoring functions, Pharmacophore modeling and virtual screening, Quantitative structure-activity relationship (QSAR) analysis, Molecular mechanics and molecular dynamics simulations,Quantum chemistry methods and calculations

UNIT IV HIGH-THROUGHPUT VIRTUAL SCREENING STRATEGIES 9

Introduction to high-throughput Virtual screening (HTVS) strategies, Risks/challenges in HTVS predictions, Ligand-based and structure-based drug screening approaches, Integration of cheminformatics with experimental high-throughput screening (HTS)Automation, Hit/Lead identification and optimization strategies

UNIT V CASE STUDIES AND APPLICATIONS 9

Case studies on successful drug discovery projects, Case studies of successful applications in industry and academia, Application of cheminformatics in lead optimization and drug repurposing, Future trends and emerging technologies in cheminformatics.

TOTAL: 45 HOURS

OUTCOME:

At the end of the course the students will be able to
CO1 Illustrate and understand about cheminformatics and its role in drug
CO1 Illustrate and understand about cheminformatics and its role in drug designing.
CO2 Understand and analyze chemical data and visualize the data.
CO3 Apply, Illustrate and make use of Structure Activity Relationship Modelling
CO4 Understand, apply and formulate high throughput virtual screening strategies.

CO5 Analyse case studies and real-world examples of successful drug discovery and screening.

TEXTBOOKS :

1. Bajorath J, editor. Chemoinformatics: concepts, methods, and tools for drug discovery. Springer Science & Business Media; 2008 Feb 4.

REFERENCES:

1. Codding PW, editor. Structure-based drug design: experimental and computational approaches. Springer Science & Business Media; 2013 Apr 17.
2. Steinberg P, editor. High-throughput screening methods in toxicity testing. John Wiley & Sons; 2013 Feb 26.
3. " Maxwell RA, Eckhardt SB. Drug discovery: a casebook and analysis. Springer Science & Business Media; 2012 Dec 6.
4. Leach AR, Gillet VJ. An introduction to chemoinformatics. Springer; 2007 Sep 4.
5. Gasteiger J, Engel T, editors. Chemoinformatics: a Textbook John Wiley & Sons; 2006 Dec 13.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
2	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
3	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
4	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
5	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
AVg.	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23003 COMPUTER AIDED DRUG DESIGN L T P C
3 0 0 3

OBJECTIVE

- To introduce Modern techniques of drug design, which include quantitative structure activity relationship (QSAR) and impart knowledge in Computer aided drug design (CADD) and train for Planning and selection of In-silco approaches and tools

UNIT I STEREOCHEMISTRY AND DRUG DESIGN 9

Introduction to Drug Discovery and Development and its Stages, Target and Lead Identification, Drug properties and Data bases, Drug likeness, Drug Solubility, ADME, Structurally Rigid Groups - Conformation - Configuration.

UNIT II STRUCTURE ACTIVITY RELATIONSHIP 9

Changing size and shape - degree of unsaturation, Addition and removal of ring system - new substitutions methyl - halogen; Basic groups - changing existing substituents for a lead compound, Structure and property.

UNIT III QUANTITATIVE STRUCTURE – ACTIVITY RELATIONSHIP 9

QSAR- Pharmacophore based approach, Target based design, Partitional parameters - partition coefficients - hepo substituent constants - electronic parameters - Hammet constant steric parameters - Hansch analysis, 3D QSA

UNIT IV DOCKING 9

Structure based and ligandbased approaches, docking ligands to macromolecules - Scoring functions, docking algorithms - Introduction to Docking Software, Protein-ligand docking.

UNIT V MOLECULAR SIMULATIONS 9

Introduction to Molecular Dynamic Simulations - Force Field, Energy Minimisation, Introduction to MD Simulation Software - Setup, run MD Simulation of a protein, results analysis and inference.

TOTAL : 45 PERIODS

OUTCOME

At the end of the course the students will be able to
CO1 Illustrate and understand various stereo chemical aspects of drug binding.
CO2 Understand and apply Structure Activity Relationship.
CO3 Apply, Illustrate and make use of Quantitative Structure Activity Relationship.
CO4 Build, formulate and interpret various in-silico docking experiments in drug research.
CO5 Build, compile various MD Simulation studies to predict and give solution for biological questions.

TEXTBOOK:

1. Patrick Bultinck , Hans De Winter , Wilfried Langenaeker, Jan P. Tollenare, Computational Medicinal Chemistry for Drug Discovery 1st Edition Marcel Dekker Inc. , 2004.

REFERENCES

1. Andrew R. Leach Molecular Modeling Principles and Applications (2nd Ed.). Prentice Hall ,2009
2. Cohen, N.C. “Guide Book on Molecular Modeling on Drug Design”, Academic Press / Elsevier, 2006
3. Eliel, E.L. “Stereo Chemistry of Organic Compounds”, John Wiley, 1994.
4. Frenkel, Dean and Berend Smith “Understanding Molecular Simulation: From Algorithms to Applications”, 2nd Edition Academic Press, 2002
5. Lee, Mike S. “Integrated Strategies for Drug Discovery using Mass Spectrometry” John Wiley – Interscience, 2005.

Course Articulation Matrix
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
2	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
3	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
4	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
5	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
AVg.	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

PT23004 DRUG SCREENING STRATEGIES L T P C
3 0 0 3

OBJECTIVE:

- To understand the principles, methods, and strategies involved in drug discovery and screening and explore different screening approaches and technologies that is used to identify potential drug candidates.

UNIT I INTRODUCTION TO DRUG DISCOVERY AND TARGET SCREENING 9

Overview of the drug discovery process, Challenges and opportunities in drug discovery, Methods for target identification - genomics, proteomics, Target validation techniques- gene knockout, RNA interference, Importance of appropriate target selection and validation in drug discovery.

UNIT II LEAD GENERATION AND OPTIMIZATION 9

Introduction to lead generation and combinatorial chemistry, Screening compound libraries - natural products, chemical libraries, Rational drug design approaches - structure-based, ligand-based, Fragment-based drug design, Strategies for improving potency, selectivity and ADME properties, Medicinal chemistry approaches and optimization techniques.

UNIT III PRECLINICAL TESTING AND SAFETY ASSESSMENT 9

In vitro assays for assessing efficacy and toxicity, In vivo models and animal testing, Pharmacokinetics and pharmacodynamics studies, Regulatory considerations and safety assessment.

UNIT IV HIGH-THROUGHPUT SCREENING (HTS) 9

Introduction to HTS and its applications, Assay development and optimization for HTS, Automation and robotics in HTS, Data analysis and interpretation in HTS, Molecular docking and Virtual Screening Methods.

UNIT V CHALLENGES AND FUTURE DIRECTIONS IN DRUG DISCOVERY AND SCREENING 9

Drug resistance and emerging challenges, Targeting protein-protein interactions and undruggable targets, Advances in omics technologies and data analysis, Precision medicine and personalized drug discovery, Analysis of screening strategies in specific disease areas, Case studies of successful drug discovery and screening campaigns.

TOTAL: 45PERIODS

OUTCOME

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

CO1 Understand the fundamentals of drug discovery and drug screening strategies.

CO2 Gain insights into lead generation techniques and strategies.

CO3 Understand the process of preclinical testing and safety assessment.

CO4 Explore different screening approaches, including high-throughput screening and virtual screening.

CO5 Analyze case studies and real-world examples of successful drug discovery and screening.

TEXTBOOK:

1. "Drug Discovery and Development: Technology in Transition" by Raymond G. Hill

REFERENCES:

1. "Target Identification and Validation in Drug Discovery" by Darryl Leboeuf
2. "Lead Generation Approaches in Drug Discovery" by Wei-Qin (Tony) Tong
3. "Medicinal Chemistry: The Modern Drug Discovery Process" by Erland Stevens
4. Preclinical Drug Development" by Mark F. Knepper
5. "High-Throughput Screening Methods in Toxicity Testing" by Harry Salem

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
2	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
3	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
4	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
5	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3
AVg.	3	2	3	2	3	3	3	2	2	2	3	2	2	1	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23006 **DESIGN OF EXPERIMENTS** **L T P C**
3 0 0 3

OBJECTIVE

- To introduce students to the terminologies, methodologies and fundamental concepts of design of experiment and familiarize students with the use of full factorial DoE and response surface methodology.

UNIT I INTRODUCTION **9**

DoE terminology, methodology, Experimental design and their selection, DoE model development; DoE of various dosage forms and drug delivery systems.

UNIT II DOE BY HAND CALCULATIONS **9**

Factorial experiments (categorical and numeric factors), Two and three factorial designs; Manual calculation of main effects, Manual calculation of interactions, Exercises with Excel.

UNIT III FULL FACTORIAL DOE EXPERIMENTS **9**

Two factor full DoE experiments; Interactions between two factors; Plotting Main effects and Interactions; Interpretation of DoE Minitab output; General full factorial DoE; Exercises with Excel.

UNIT IV OPTIMISATION WITH RESPONSE SURFACE METHODOLOGY **9**

22 factorial experiments with RSM; Contour plot; Surface plot; Concept of Design Space; Exercises: optimization of drug solubility with RSM design; Effect of process parameters on dissolution assay and variability.

UNIT V STRATEGY OF DOE IN DRUG DEVELOPMENT PROCESS **9**

Screening experiments; Fractional experiments; Full factorial experiments; Optimisation experiments: Surface Response Methodology; Design Space versus Proven Operating Range (PAR), Normal Operating Range (NOR), Robustness of experiments of a process/method.

OUTCOME

At the end of the course the students will be able to
CO1 Illustrate and understand the basics of design of experiments with respect to drug delivery systems.
CO2 Understand and perform DoE manual hand calculations and by using excel.
CO3 Explain the full factorial DoE and assess exercises in excel.
CO4 Understand, apply and formulate experiments with response surface methodology.
CO5 Explain the various strategies of DoE in drug development process.

TEXTBOOKS

1. Ii V, Case P. Design of Experiments for Pharmaceutical Product Development. Beg S, editor. Singapore:: Springer; 2021.

REFERENCES

1. Montgomery DC. Design and analysis of experiments. John wiley & sons; 2017.
2. Antony J. Design of experiments for engineers and scientists. Elsevier; 2014 Feb 22.
3. Anderson VL, McLean RA. Design of experiments: a realistic approach. CRC Press; 1974 Feb 1.
4. Mathews PG. Design of Experiments with MINITAB. Quality Press; 2004 Jul 7.
5. Rekab K, Shaikh M. Statistical design of experiments with engineering applications. CRC press; 2005 Apr 8.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
2	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
3	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
4	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
5	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
AVg.	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

VERTICAL-2

PT23007 BIOLOGICAL SPECTROSCOPIC TECHNIQUES L T P C
3 0 0 3

OBJECTIVE

- To instruct the students on various spectroscopic and microscopic techniques that are used in research and practice in biotechnology and understand the role of spectroscopy in biological systems.

UNIT I CIRCULAR DICHROISM (CD) AND OPTICAL ROTATORY DISPERSION (ORD) 9

Polarized light - optical rotation - circular dichroism - circular dichroism of nucleic acids and proteins .

UNIT II FLUORESCENCE AND RAMAN SPECTROSCOPY 9

Molecular energy level diagrams - principles of fluorescence and Raman - parameters for measurement - excited state processes - fluorescence polarization - Forster Resonance Energy Transfer - fluorescence quenching - single molecule spectroscopy - application to proteins and nucleic acids.

UNIT III NUCLEAR MAGNETIC RESONANCE AND MASS SPECTROMETRY 9

Chemical shifts - spin - spin coupling - relaxation mechanisms - nuclear overhauser effect - multidimensional NMR spectroscopy - determination of macromolecular structure by NMR - magnetic resonance imaging; Ion sources sample introduction - mass analyzers and ion detectors - biomolecule mass spectrometry - peptide and protein analysis - carbohydrates and small molecules - specific applications.

UNIT IV X-RAY DIFFRACTION 9

Scattering by X- rays - diffraction by a crystal - measuring diffraction pattern - Bragg reflection - unit cell - phase problem - anomalous diffraction - determination of crystal structure - electron and neutron diffraction.

UNIT V SPECIAL TOPICS 9

Electron microscopy - transmission and scanning electron microscopy; CryoElectron Microscopy - scanning tunneling and atomic force microscopy (AFM); Fluorescence Correlation Spectroscopy (FCS); FRAP; Two-photon Microscopy; STED and STORM microscopies.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 Understand the principle of spectroscopic techniques widely used in many quantitative experiments

CO2 Understand the central techniques associated with the elucidation of structure and composition molecules in natural and life sciences

CO3 Understand the applications of nuclear magnetic resonance and mass spectroscopy

CO4 Comprehend the high-resolution imaging techniques to assess surface and intracellular complexity.
CO5 Explain and understand various imaging microscopic techniques and its various applications

TEXTBOOKS

1. Banwell, Colin N. and E.M. McCash. “Fundamentals of Molecular Spectroscopy” IVthEdition, Tata McGraw-Hill, 2017.
2. Aruldas, G. “Molecular Structure and Spectroscopy”. IIndEdition, Prentice Hall of India, 2007.

REFERENCES

1. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to spectroscopy. Cengage learning; 2014.
2. Fleming I, Williams DH. Spectroscopic methods in organic chemistry. New York: McGraw-hill; 1966.
3. Siuzdak G. Mass spectrometry for biotechnology. Elsevier; 1996 Feb 12.
4. Hammes GG. Spectroscopy for the biological sciences. John Wiley & Sons; 2005.
5. Campbell I.D and Dwek R.A., “Biological Spectroscopy “, Benjamin Cummins and Company, 1986. 4. Atkins P.W., “Physical Chemistry “, Oxford IV Edition, 1990.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	1	2	1	-	-	-	-	-	-	2	1	2	2
2	1	2	1	3	2	1	-	-	-	-	1	1	2	2	1
3	1	2	2	1	2	2	-	-	-	-	2	2	1	2	1
4	1	2	1	3	2	1	-	-	-	-	1	1	2	2	1
5	1	2	2	1	2	2	-	-	-	-	2	2	1	2	1
AVg.	1.20	2.00	1.40	2.00	1.80	1.50	-	-	-	-	1.50	1.60	1.40	2.00	1.20

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23008 PROCESS ANALYTICAL TECHNOLOGY IN PHARMACEUTICAL MANUFACTURING **L T P C 3 0 0 3**

OBJECTIVE

- The Course aims to provide information on various analytical and chemometric techniques.

UNIT I PROCESS ANALYTICAL TECHNOLOGIES FOR IMPURITIES AND POLYMORPHISM 9

Importance of PAT – Quality of medicines - Qualitative and quantitative analysis of Active Pharmaceutical Ingredients, Formulation Excipients, proteins, nucleic acids, polysaccharides and small molecules such as antibiotics, vitamins, natural products etc.

UNIT II DEVELOPMENT AND APPLICATION OF MODERN ANALYTICALINSTRUMENTATION: 9

FT-IR - TGA - UV-VIS-Spectrophotometry – Zeta potential measurement - Electrophoretic techniques; Capillary electrophoresis, Gel electrophoresis, PAGE; native, SDS, 2D PAGE, TGGE, DGGE, PULSE, Isoelectric focusing

UNIT III QUALITY BY DESIGN CONCEPT 9

QbD for Drug Discovery and Formulation Development – ICH Guidelines - Key steps for implementing QbD - quality target product profile (QTPP) - Identifying QTPP – Critical Quality Attributes (CQA) – Quality risk and quality risk management (QRM) – Definition of Process Design Spaces – Defining Process Control Strategy - FDA's QbD pilot program for biopharmaceuticals

UNIT IV APPLICATIONS OF CHEMOMETRIC TECHNIQUES 9

External variables on calibration – Multiplicative influential mode – Composition related influential mode – Loading space standardization - Extended Loading Space standardization – Spectral calibration Issues – Principal Component Analysis – Smoothed PCA

UNIT V PAT AND ADVANCED PROCESS CONTROL 9

Models for critical attributes –critical parameters – Continuous data quality monitoring and verification – Univariate –Multivariate – Real time quality control using spectral data – Integrated data management – Closed loop control – Advanced PAT tools

TOTAL: 45 PERIODS

OUTCOME

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

CO1 carry out characterization studies for API and excipients
CO2 explain the applications of electrophoretic techniques
CO3 understand the role of QbD in drug discovery
CO4 understand the concept of Principal component analysis
CO5 gain knowledge on PAT tools

REFERENCES

1. ICH, Q8(R1): Pharmaceutical Development, InternationalConference on Harmonisation; 2009; Geneva, Switzerland.
2. ICH, Q10: Pharmaceutical Quality Systems, InternationalConference on Harmonisation. 2009; Geneva, Switzerland.
3. ICH, Q9: Quality Risk Management, International Conferenceon Harmonisation; 2005; Geneva, Switzerland.
4. PDA, TR42. Process Validation of Protein Manufacturing. Parenteral Drug Association, Bethesda (MD), PDA Journal59; 2005; supplement 4.
5. ICH, Q6A: Specifications, test procedures and acceptancecriteria for new drug substances and new drug products:chemical substances. In: International Conference on Harmonisation;2000; Geneva, Switzerland.
6. FDA. Guidance for industry, PAT--a framework for innovativepharmaceutical development, manufacturing, and qualityassurance. Rockville (MD); 2004.

MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
2	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
3	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
4	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
5	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
AVg.	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23009 QUALITY ASSURANCE IN PHARMACEUTICAL INDUSTRY L T P C
3 0 0 3

OBJECTIVE

- To impart knowledge on the various aspects of quality assurance aspects of pharmaceutical industries.

UNIT I INTRODUCTION 9

Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT II ROLES AND RESPONSIBILITIES 9

Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

UNIT III DOCUMENTATION IN PHARMACEUTICAL INDUSTRY 9

Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principle - How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record.

UNIT IV QUALITY AUDIT PLAN AND REPORTS 9

Specification and test procedures, Protocols and reports; Distribution records. Electronic data handling; Concepts of controlled and uncontrolled documents; Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD); Concept of regulated and non-regulated markets.

UNIT V MANUFACTURING OPERATIONS AND CONTROLS 9

Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal.

OUTCOME

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

CO1 Understand the responsibilities of QA departments.
CO2 Understand the scope of quality certifications applicable to Pharmaceutical industries.
CO3 appreciate the importance of documentation.
CO4 arrange and prepare quality audit plans and reports.
CO5 Explain the various manufacturing regulations and guidelines and controls.

TEXTBOOKS

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3 rd revised edition, Volume I & II, Mumbai, 1996.

REFERENCES

1. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2 nd edition, WHO Publications, 1999
2. World Health Organization. The international pharmacopoeia. World Health Organization; 2006.
3. Donabedian AV. The effectiveness of quality assurance. International journal for quality in health care. 1996 Jan 1;8(4):401-7.
4. QA Manual – D.H. Shah, 1 st edition, Business Horizons, 2000.
5. Donabedian A. An introduction to quality assurance in health care. Oxford University Press; 2002 Dec 26.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	1	1	2	2	-	1	-	2	2	2	2	2	1	2
2	1	1	1	2	2	-	1	-	2	2	2	2	2	1	2
3	-	1	1	2	2	-	1	-	2	2	2	2	2	1	2
4	-	1	1	2	2	-	1	1	2	2	2	2	2	1	2
5	-	1	1	2	2	-	1	-	2	2	2	2	2	1	2
AVg.	1	1	1	2	2	-	1	1	2	2	2	2	2	1	2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23010 QUALITY MANAGEMENT SYSTEMS L T P C
3 0 0 3

OBJECTIVE

- To impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

UNIT I INTRODUCTION TO QUALITY 9

Evolution of Quality, Definition of Quality, Dimensions of Quality, Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers, Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.

UNIT II PHARMACEUTICAL QUALITY MANAGEMENT 9

Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review; OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements. Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system.

UNIT III CONCEPT OF SELF INSPECTION 9

Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release; Concept of IPQC, area clearance/ Line clearance.

UNIT IV DRUG STABILITY 9

ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.

UNIT V STATISTICAL PROCESS CONTROL (SPC) 9

Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability; Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.

TOTAL: 45 PERIODS

OUTCOME

At the end of the course the students will be able to
CO1 Define and explain ISO management systems
CO2 Understand and use the tools for quality improvement
CO3 Peform Analysis of issues in quality and Quality evaluation of pharmaceuticals
CO4 Perform Stability testing of drug and drug substances
CO5 Illustrate Statistical approaches for quality

TEXTBOOKS

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000 Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
2. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001

REFERENCES

1. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
2. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
3. Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001 The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
4. uran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
5. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	1	1	2	2	-	1	-	2	2	2	2	2	1	2
2	1	1	1	2	2	-	1	-	2	2	2	2	2	1	2
3	-	1	1	2	2	-	1	-	2	2	2	2	2	1	2
4	-	1	1	2	2	-	1	1	2	2	2	2	2	1	2
5	-	1	1	2	2	-	1	-	2	2	2	2	2	1	2
AVg.	1	1	1	2	2	-	1	1	2	2	2	2	2	1	2

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix

PT23011 HAZARDS AND SAFETY MANAGEMENT L T P C
3 0 0 3

OBJECTIVE

- This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

UNIT I MULTIDISCIPLINARY NATURE OF ENVIRONMENTAL STUDIES 9

Natural Resources, Renewable and nonrenewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d)Energy resources; e) Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

UNIT II AIR BASED HAZARDS 9

Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

UNIT III CHEMICAL BASED HAZARDS 9

Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard,Management of over-Exposure to chemicals and TLV concept.

UNIT IV FIRE AND EXPLOSION 9

Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion,multiphase reactions, transport effects and global rates.Preventive and protective management from fires and explosion electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

UNIT V HAZARD AND RISK MANAGEMENT 9

Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.

TOTAL: 45 PERIODS

OUTCOME

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

- Impart basic knowledge about the environment and its allied problems.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an idea to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology to provide safe industrial atmosphere.

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers,Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blushing Pvt.Ltd., Ahmedabad, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

COURSE ARTICULATION MATRIX

MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
2	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
3	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
4	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
5	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
AVg.	2.00	2.00	1.00	2.00	2.00	-	-	1.00	2.00	2.00	2.00	3.00	1.00	2.00	2.00

1-low, 2-medium, 3-high, '-"- no co2rrelation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23012 VALIDATION OF PHARMACEUTICAL PROCESSES AND PRODUCTS **L T P C 3 0 0 3**

OBJECTIVE

- The main purpose of the subject is to understand validation and how it can be applied to industry and thus improve the quality of the products.
- The subject covers the complete information about validation, types, methodology, and application.

UNIT I INTRODUCTION TO VALIDATION 9

Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation.Calibration of weights and measures. Advantages of Validation, scope of Validation,Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification,Performance qualification, ReQualification (Maintaining status-Calibration Preventive Maintenance, Change management).

UNIT II QUALIFICATION OF MANUFACTURING EQUIPMENTS 9

Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression(Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

UNIT III QUALIFICATION OF LABORATORY EQUIPMENTS 9

Hardness tester,Friability test apparatus, tap density tester, Disintegration tester,Dissolution test apparatusValidation of Utility systems: Pharmaceutical water system &pure steam, HVAC system, Compressed air and nitrogen.

UNIT IV PROCESS VALIDATION 9

Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

UNIT V CLEANING VALIDATION 9

Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment,Cleaning of Facilities. Cleaning in place (CIP).Validation of facilities in sterile and non-sterile plant.Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP

TOTAL: 45 PERIODS

OUTCOME

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

1. Understand the concepts of calibration, qualification and validation

2. Explain the process of qualification of various equipments and instruments
3. Validate analytical method for estimation of drugs
4. Carry out Process validation of different dosage forms
5. Describe Cleaning validation process of equipments employed in the manufacture of pharmaceuticals

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs andPharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman,Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House,Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood Internationalpublishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton&Agalloco,(Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci.Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide forAchieving Compliance in the Pharmaceutical, Medical Device, and BiotechIndustries, Syed ImtiazHaider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing.Interpharm Press

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
2	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
3	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
4	-	-	1	1	2	1	3	3	3	3	3	2	2	1	2
5	-	-	1	1	2	1	3	3	3	3	3	2	2	1	2
Avg.	-	-	1.00	1.00	2.00	1.00	2.40	1.80	2.40	1.80	1.80	2.00	2.00	1.00	2.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

PT23013 AUDITS AND REGULATORY COMPLIANCE L T P C
3 0 0 3

OBJECTIVE

- This course deals with the understanding and process for auditing in pharmaceutical industries.
- This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

UNIT I INTRODUCTION 9

Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies.

UNIT II ROLE OF QUALITY SYSTEMS AND AUDITS IN PHARMACEUTICAL MANUFACTURING ENVIRONMENT 9

cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit check list for drug industries.

UNIT III AUDITING OF VENDORS AND PRODUCTION DEPARTMENT 9

Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

UNIT IV AUDITING OF MICROBIOLOGICAL LABORATORY 9

Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

UNIT V AUDITING OF QUALITY ASSURANCE AND ENGINEERING DEPARTMENT 9

Quality Assurance Maintenance, Critical systems: HVAC, Water for Injection systems, ETP.

TOTAL: 45 HOURS

OUTCOME

Upon completion of this course the student should be able to
CO1 understand the importance of auditing
CO2 understand the methodology of auditing
CO3 carry out audit process
CO4 prepare the auditing report
CO5 prepare the check list for auditing

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsburyand Gil Bismuth, Interpharm/CRC, Boca Raton, London New York,Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc.,Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, NormanA. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C.Singer, Raluca-

loana Stefan, Jacobus F. Van Staden. Taylor and Francis 2005.

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	1	2	3	1	-	-	-	2	-	1	3	3	1	3
2	3	2	2	2	2	-	-	-	1	-	1	2	3	1	3
3	2	1	2	1	3	-	-	-	1	-	2	1	3	1	3
4	3	1	2	3	3	-	-	-	3	-	2	1	3	1	3
5	3	2	2	2	3	-	-	-	2	-	2	1	3	1	3
AVg.	2.60	1.40	2.00	2.20	2.40	-	-	-	1.80	-	1.60	1.60	3.00	1.00	3.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals

VERTICAL 3

PT23021 NUTRACEUTICALS L T P C
3 0 0 3

OBJECTIVE

- To study the fundamentals of nutraceuticals and functional foods, their functions in health and disease, and the laws governing them.

UNIT I INTRODUCTION AND SIGNIFICANCE 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 PHYTOCHEMICALS AS NUTRACEUTICALS 9

Phytochemicals as nutraceuticals: classification, occurrence and characteristic features (chemical nature medicinal benefits) of following a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein b) Sulfides: Diallyl sulfides, Allyl trisulfide,c) Polyphenolics: Resveratrol d) Flavonoids- Rutin , Naringin, Quercetin, Anthocyanidins, catechins, Flavones e) Prebiotics / Probiotics,Fructo oligosaccharides, Lactobacillus f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans g) Tocopherols.

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; free radicals involvement in other disorders.

UNIT IV MECHANISM OF ANTIOXIDANT DEFENSE 9

Free radicals and oxidative stress - antioxidant mechanisms; the biochemical basis for nutraceuticals for the chemoprevention of disease; application of herbs to functional foods; free radical theory of ageing; Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin synthetic antioxidants: butylated hydroxy toluene, butylated hydroxy anisole

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; adulteration of foods. AYUSH – Regulation of claims pertaining nutraceuticals - Overview of regulations in other Asian countries - China, Japan and Europe. Nutraceuticals in Herbal pharmacopoeia.USDA and FDA regulations in USA.European food regulations (EFSA).

TOTAL: 45 HOURS

OUTCOME:

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

CO1: define and classify the concept of nutraceuticals and dietary supplements along with the classification with respect to health benefits, chemical nature and mechanism of action.

CO2: Classify and explain health benefits of numerous phytochemical groups and their key chemical characteristics

CO3: Define and analyse the basic concepts of nutraceuticals and its role in health and disease

CO4: Understand the significance of safety and stability studies of nutraceuticals.

CO5: Understand nutraceuticals regulations in India and other important nations

TEXTBOOK

1. Wildman RE, Wildman R, Wallace TC. Handbook of nutraceuticals and functional foods. CRC press; 2016.

REFERENCES

1. Shi J, Ho CT, Shahidi F, editors. Functional foods of the east. CRC Press; 2010 Oct 21.
2. Watson RR, editor. Foods and dietary supplements in the prevention and treatment of disease in older adults. Academic press; 2015 Jan 27.
3. Wansink B. Marketing nutrition: Soy, functional foods, biotechnology, and obesity. University of Illinois Press; 2005 Jun 8.
4. G R Gibson and C M Williams,Functional foods: Concept to Product; Wood head Publ., 2000
5. Hanson JR. Natural products: the secondary metabolites. Royal Society of Chemistry; 2003.

MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	3	2	3	3	3	-	-	-	3	-	-	3	3	3	3
2	3	3	3	2	3	-	-	-	3	-	-	3	3	3	3
3	3	3	3	2	3	-	-	-	3	-	-	3	3	3	3
4	3	3	3	2	3	-	-	-	3	-	-	3	3	3	3
5	3	3	3	2	3	-	-	-	3	-	-	3	3	3	3
Avg	3.00	2.80	3.00	2.20	3.00	-	-	-	3.00	-	-	3.00	3.00	3.00	3.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO * upto 2 decimals

PT23016 PHARMACEUTICAL NANOTECHNOLOGY L T P C
3 0 0 3

OBJECTIVE

- To study about development and characterization of different nanoformulations

UNIT I INTRODUCTION 9

Concepts, nanomedicine and nanotherapeutics, Biological requirements and advantages as delivery systems.

UNIT II TARGETING AND CONTROLLED DRUG RELEASE SYSTEMS 9

Biological barriers and transport mechanisms, Drug Activation and targeting, Controlled release; Administration routes, Actual available systems and future perspectives.

UNIT III NANOSYSTEMS 9

Liposomes, Lipid nanoparticles, Polymeric nanoparticles, Polymeric micelles, Nanofibers, Dendrimers, Nanogels and biosilica, Quantum dots, Nanotubes and fullerenes, Magnetic and metallic nanoparticles.

UNIT IV ANALYTICAL TOOLS 9

Physicochemical characterization, Drug delivery and Permeation of biological barriers.Exposure routes,Biological barriers Interactions between nanosystems and the biological environment.

UNIT V NANO-TOXICOLOGY 9

In vitro models, In vivo models and Pharmacokinetic models.

TOTAL: 45 HOURS

OUTCOME:

At the end of the course the students will be able to:
CO1: Illustrate the importance of nanotechnology in drug development
CO2: Define and explain the drug administration, action and controlled release
CO3: mechanism and importance of nanoparticles in pharmacology
CO4: Analyze and predict the analytical tools for pharmacodynamics studies
CO5: Predict and evaluate the models for toxicology

TEXTBOOKS:

1. Demetzos C. Pharmaceutical nanotechnology. Fundamentals and practical applications. 2016.

REFERENCES:

1. Jain K: The Handbook of Nanomedicine: Humana Press; 2012.
2. Vogel U, Savolainen K, Wu Q, van Tongeren M, Brouwer D, Berges M: Handbook of Nanosafety: Measurement, Exposure and Toxicology: Elsevier Science; 2013.
3. Baldi A, K Jain N. Editorial (Thematic Issue: Advances in Pharmaceutical Nanotechnology and Nanomedicine). Pharmaceutical Nanotechnology. 2015 Dec 1;3(4):224-7.
4. Fresta M. Pharmaceutical nanotechnology meets natural products. Planta Medica. 2014 Oct;80(16):PL4.
5. Allen LV, Ansel HC, Popovich NG. Pharmaceutical dosage forms and drug delivery systems. Evaluation. 2011;56:44.

COURSE ARTICULATION MATRIX:
MAPPING OF COs WITH POs AND PSOs
Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

PT23014 TECHNOLOGY OF SOLID DOSAGE FORMS L T P C
3 0 0 3

OBJECTIVE

- To study about formulation and evaluation of solid dosage forms

UNIT I FORMULATION AND MACHINERY 9

Classification of different types of tablets, tablets equipments, granulation technology on large scale by various techniques; Tablets tooling, different types of tablets compression machinery, processing problem of tablets and evaluation of tablets.

UNIT II EXCIPIENTS 9

Disintegrants, Lubricants, Glidants and Anti adherents, Surfactants and Colors in Tablets, Swellable and Rigid Matrices – Controlled Release Matrices with Cellulose Ethers, Carrageenans in Solid Dosage Form Design, Direct Compression and the Role of Filler-binders

UNIT III TABLET COATING 9

Types of coating, Sugar coating, film forming materials, formulation of coating solution, equipment for coating, film defects and evaluation of coated tablets.

UNIT IV FORMULATION CHALLENGES OF MODIFIED RELEASE SYSTEMS 9

Orally disintegrating tablets and related tablet formulations, specialty tablets formulation for slow oral dissolution, osmotic systems, tableting of multi particulate modified release systems

UNIT V CAPSULES 9

Advantages & disadvantages of capsule dosage form, extraction of gelatin, production of hard gelatin capsules, size of capsules and method of capsule filling. Soft gelatin capsule, Nature of capsule shell & capsule content, importance of base adsorption, minimum gm factors in soft capsules, production, quality control, stability testing and storage of capsule dosage forms.

TOTAL: 45 HOURS

OUTCOME:

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

CO1: Define and describe the theoretical basis of machineries used in tablet manufacturing
CO2: Explain and justify the order of addition of ingredients to each dosage form
CO3: List and describe tablet coating processes
CO4: Discuss the challenges encountered during development of controlled release systems.
CO5: Explain the formulation and evaluation studies of capsules

TEXTBOOKS:

1. Allen, Loyd V. et al. “Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems” IXth Ed., WoltersKluver/LippinCott Williams & Wilkins, 2011.

REFERENCES:

1. H. A. Liberman,, L. Lachman, and J. B. Schwartz: Pharmaceutical dosage forms: Tablets, Vol. 1,2 and 3, IInd Edition Marcel Dekker, 1989.
2. Aulton, Michael E. “Pharmaceutics: The Science of Dosage Form Design” IInd Ed.,

Churchill Livingstone, 2002.
3. Remington JP, Gennaro AR. Remington's pharmaceutical sciences. Mack Pub.; 1985.
4. Lachman, Leon et al. “The Theory and Practice of Industrial Pharmacy” IIIrd Ed., Varghese Publishing House, 1987.
5. Mahato RI, Narang AS. Pharmaceutical dosage forms and drug delivery. CRC Press; 2011 Oct 25.

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs
Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	3	1	1	2	3	-	1	1	2	1	2	3	2	3
2	3	2	1	2	3	3	3	1	-	1	2	1	3	3	1
3	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
4	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
5	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
Avg	2.80	2.80	1.00	1.80	2.80	2.40	1.50	1.60	1.00	1.80	1.20	1.50	3.00	2.20	1.40

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

PT23017 GMP, GLP AND ACCREDITATION L T P C
3 0 0 3

OBJECTIVE

- To acquire knowledge on GMP, GLP and accreditation

UNIT I BASIC CONCEPTS 9

Quality control,Quality assurance,Total Quality Management, NABL accreditation and ISO

UNIT II GOOD MANUFACTURING PRACTICES 9

Definition,Elements,Standard operating Procedures,Release of Bulk and filled finished product.GMP for investigational medicinal products and chemical analysis.

UNIT III GMP FOR STERILE PRODUCTS 9

Clean room standards and GMP Guideline, sterile manufacturing area,personnel and control of the sterilization process

UNIT IV GOOD LABORATORY PRACTICE 9

Scope of GLP, Quality assurance in GLP, Master schedule Index, SOPs for GLP, Issues of quality in pathology.

UNIT V APPLICATIONS OF GLP 9

GLP in Analytical chemistry, Drug metabolism ,Pharmacokinetics and ecotoxicology

TOTAL: 45 PERIODS

OUTCOME:

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

CO1: Discuss and recall the basic regulatory guidelines in drug development
CO2: Describe good manufacturing practice guidelines
CO3: Explain good manufacturing practice of sterile products
CO4: Describe good laboratory practice guidelines
CO5: List the applications of good laboratory practice guidelines

TEXTBOOKS

1. Carson PA, Dent NJ, editors. Good clinical, laboratory and manufacturing practices: techniques for the QA professional. Royal Society of Chemistry; 2007.

REFERENCES

1. Ruževičius J. Products quality religious-ethnical requirements and certification. Ekonomika ir vadyba. 2012;17:761-7.
2. Ermer J, Miller JH, editors. Method validation in pharmaceutical analysis: A guide to best practice. John Wiley & Sons; 2006 Mar 6.
3. Willig, H., Tuckeman, M.M. and Hitchings, W.S., “Good Manufacturing Practices for Pharmaceuticals”, 5 th Edition, Marcel Dekker Drugs and the Pharmaceutical Sciences, by CRC Press, New York, 2000
4. N Udupa, Krishnamurthy Bhat, “A Concise Textbook of Drug Regulatory Affairs”, Manipal University Press (MUP); First Edition, 2015.
5. C.V.Subbrahmanyam & J.Thimmasetty, “Pharmaceutical regulatory affairs”, 1 st Edn., vallabh Prakashan, New Delhi, 2012.

COURSE ARTICULATION MATRIX MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
2	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
3	-	-	1	1	2	1	2	1	2	1	1	2	2	1	2
4	-	-	1	1	2	1	3	3	3	3	3	2	2	1	2
5	-	-	1	1	2	1	3	3	3	3	3	2	2	1	2
Avg	-	-	1.00	1.00	2.00	1.00	2.40	1.80	2.40	1.80	1.80	2.00	2.00	1.00	2.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23019 PHARMACEUTICAL PACKAGING TECHNOLOGY L T P C
3 0 0 3

OBJECTIVE:

- To gain knowledge on packaging materials and its sterilization processes

UNIT I INTRODUCTION TO PHARMACEUTICAL PACKAGING 9

Packaging, Classification of Packaging, Packaging Essential Requirements, Functions of Packaging, Importance / significance of Pharma Packaging;The main packaging materials;The Ideal Package, Properties of Ideal Packaging Materials; Packaging formats in Pharma Industry;Packaging recycling symbols and Future of Packaging

UNIT II PACKAGE DESIGN 9

Pharmaceutical Container-Glass; Plastic and Metal containers; Approach to package design And New Trends in the pharmaceutical packaging

UNIT III STERILISATION OF PACKAGING MATERIALS 9

Introduction, Pharmaceutical Importance of Sterilization,Physical and Chemical Factors that affect sterilization;Classification of Sterilization Methods,Sterilization of Packaging Materials; Tests for Sterility,Incubation and examination of sterility tests,Interpretation of the test results; Evaluation of Sterilization Method;Process of Microbial Destruction,Evaluation and In Process Monitoring of Sterilization Procedures.

UNIT IV BLISTER AND STRIP PACKAGING 9

Blister Package,Blister design parameters,Materials,Formation,Types of Blisters,Advantages and disadvantages of Blister Packaging.Types of Problems/ Defects Blister Packing Machine; Other packages Strip Packs- High Barrier Laminates Strip Packaging Process,Packaging Materials,Properties of Materials,Child-resistant strip package,Strip Sealing Machine; Strip Packing Machinery,Multi-Dose Strip Packaging.

UNIT V LABELING OF PACKAGES 9

Functions of Labels, Types of Labels, Label Substrate/Materials Barcodes, Printing Processes, Legal Requirements of Labels, GMPs and Pharmaceutical Labeling, Printing.

OUTCOME:

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

CO1: Define and classify the various categories of packaging materials used in pharmaceutical industry.

CO2: Evaluate and Choose proper packaging materials for different pharmaceutical dosage forms.

CO3: Define and discuss the various sterilization methods for packaging materials.

CO4: Evaluate and list the types of blister and strip packages.

CO5: Define and describe the types and functions of labeling in packages.

TEXTBOOKS

1. Lockhart, H. and Paine, F.A., Packaging of Pharmaceuticals and Healthcare Products, Blackie Academic & Professional, London, 1996.

REFERENCES

1. Dean, D.A., Evans, E.R., and Hall, I.H.Pharmaceutical Packaging Technology, Taylor and Francis, London, 2000.
2. Brody, A.L. and Marsh, K.S. The Wiley Encyclopedia of Packaging Technology, 3rd Edition, Wiley-Interscience, New York, 2009.
3. Soroka, W., Fundamentals of Packaging Technology, 4th Edition, Institute of Packaging Professionals, Virginia, 2009.
4. Lockhart, H. and Paine, F.A., Packaging of Pharmaceuticals and Healthcare Products, Blackie Academic & Professional, London, 1996.
5. Dhakar V, Kaushik A, Chaurasia B. Textbook of Pharmaceutical Packaging Technology. Journal of Drug Delivery and Therapeutics. 2012 May 14;2(3).

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
Avg	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

PT23020 SUSTAINABLE DEVELOPMENT OF PHARMACEUTICALS LT P C 3 0 0 3

OBJECTIVE

- To knowledge about the development of sustainable pharmaceuticals

UNIT I GREEN SYNTHETIC METHODS IN DRUG DISCOVERY AND DEVELOPMENT 9

Catalysis-Homogeneous and Heterogeneous. On-traditional activation methods and energy efficiency of chemical Processes-Microwave assisted organic synthesis, Ultrasonic activation, Photochemical activation and Electrochemical activation. Advances in drug development with the applications of Artificial Intelligence.

UNIT II VIRTUAL SCREENING TECHNIQUES IN PHARMACEUTICAL RESEARCH 9

Structure based drug design, Molecular docking and ligand based drug discovery

UNIT III SUSTAINABLE SEPARATIONS IN PHARMACEUTICAL MANUFACTURING 9

Separation concepts, Green chromatographic techniques, membrane based separations and continuous purification processes.

UNIT IV DIRECTED EVOLUTION 9

Introduction,methods for gene manipulation,Methods for screening and selection of enzyme libraries and applications of directed evolution in drug development.

UNIT V ADVANCED TREATMENT METHODS FOR THE REMOVAL OF PHARMACEUTICALS IN WASTE WATER 9

Overview of conventional waste water treatment and its effectiveness in removing pharmaceuticals, Advanced treatment processes-Ozonation,membrane based technologies and advanced oxidative processes, Case studies

OUTCOME:

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

CO1: Define and discuss about the conventional and non- conventional synthetic methods in drug discovery and development.

CO2: Define and illustrate the in silico screening techniques in pharmaceutical research

CO3: Describe the separation techniques and explain purification processes

CO4: Describe the methods of gene manipulation and explain the applications of directed evolution in drug development

CO5: discuss various methods of waste water treatment

TEXTBOOKS:

1. Contemporary chemical approaches for Green and sustainable Drugs,Mariana Torok Sustainable synthesis of Pharmaceuticals,Mariette M.Pereira

REFERENCES:

1. Kokate C. Textbook of pharmaceutical biotechnology. Elsevier India; 2011.
2. Fictorie CP. Book Review of the Occurrence and Fate of Pharmaceuticals and

Personal Care Products in the Environment.
3. Farrell S, Slater S, Savelski MJ, Calvo WJ. Introductory level Textbook problems illustrating concepts in pharmaceutical engineering.
4. Griffin JP, O'Grady J, editors. The Textbook of pharmaceutical medicine. Blackwell; 2006.
5. Kulshreshtha AK, Singh ON, Wall GM, editors. Pharmaceutical suspensions: from formulation development to manufacturing. Springer Science & Business Media; 2009.

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3
Avg	2	1	1	2	2	1	2	-	1	1	1	2	1	2	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

PT23029 CHEMICAL REACTION ENGINEERING L T P C
2 1 0 3

OBJECTIVE

- The course aims to, provide the basic concepts of types of reactions, variable affecting the rate of reaction, predicting the rate equations, different reactor systems, deriving the performance equations and predicting the rate equations in chemical reaction engineering system.

UNIT I ANALYSIS OF REACTION RATE DATA AND OF BATCH REACTOR DESIGN 9

Rate equation, elementary, non-elementary reactions, theories of reaction rate and Prediction; Design equation for constant and variable volume batch reactors, analysis of experimental kinetics data, integral and differential analysis.

UNIT II DESIGN AND ANALYSIS OF IDEAL FLOW REACTORS 9

Design of continuous reactors - stirred tank and tubular flow reactor, recycle reactors,combination of reactors, size comparison of reactors.

UNIT III REACTOR DESIGN FOR MULTIPLE AND PARELLEL REACTIONS 9

Design of reactors for multiple reactions - consecutive, parallel and mixed reactions -factors affecting choice, optimum yield and conversion, selectivity, reactivity and yield.

UNIT IV NON ISOTHERMAL REACTOR DESIGN 9

Non-isothermal homogeneous reactor systems, adiabatic reactors, rates of heat exchangers for different reactors, design for constant rate input and constant heat transfer coefficient, operation of batch and continuous reactors, optimum temperature progression.

UNIT V NON-IDEAL FLOW IN REACTORS 9

The residence time distribution as a factor of performance; residence time functions and relationship between them in reactor; basic models for non-ideal flow; conversion in non-ideal reactors.

OUTCOME:

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

CO1: Apply the principles of reaction kinetics, formulate rate equations and analyse the batch reactor data.

CO2: Analyse the experimental kinetic data to select a suitable reactor for a particular application and to workout conversion and space time for different types of reactors.

CO3: Evaluate selectivity, reactivity and yield for parallel and mixed reactions.

CO4: Examine how far real reactors deviate from the ideal.

CO5: Identify the ideal performance reactor and estimate the design and affecting factors of reactors performance.

TEXTBOOKS:

1. Levenspiel O. “Chemical Reaction Engineering”, III edition, John Wiley, 2012.
2. Fogler H.S. “Elements Of Chemical Reaction Engineering”,IV edition, Pearson Education India, 2015.

REFERENCES:

1. Missen R.W., Mims C.A., and Saville B.A. “Introduction to Chemical Reaction Engineering and Kinetics”, John Wiley & sons, 1999.
2. Dawande, S.D., “Principles of Reaction Engineering”, I edition, Central Techno Publications, 2001.
3. Richardson, J.F. and Peacock, D.G., “Coulson & Richardson’s Chemical Engineering, Vol. III”, III edition, Butterworth- Heinemann- Elsevier, 2014.
4. Froment. G.F. &K.B.Bischoff, “Chemical Reactor Analysis and Design”, John Wiley and Sons, 1979

Course Articulation Matrix
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	-	-	3	1	2	2	2	1	2	1	1	3	2	2
2	2	2	1	1	3	-	1	2	1	1	1	1	3	2	2
3	1	-	-	1	-	1	2	-	2	2	2	2	3	2	3
4	2	1	-	2	2	1	-	3	2	1	2	1	3	3	3
5	3	1	-	-	1	-	1	-	2	1	-	2	3	2	3
Avg.	2.00	1.33	1.00	1.75	1.75	1.33	1.50	2.33	1.60	1.40	1.50	1.40	3.00	2.20	2.60

VERTICAL 4

PT23028 BIOPHARMACEUTICALS DOWNSTREAM PROCESSING L T P C
3 0 0 3

OBJECTIVE

The course aims to

- understand the fundamentals of biological product recovery, isolation separation purification and formulation
- acquire in depth knowledge and hands on training on design and optimization of Downstream process operations and equipment

UNIT I DOWNSTREAM PROCESSING 9

Introduction to downstream processing, principles, characteristics of bio-molecules and bioprocesses. Cell disruption for product release – mechanical, enzymatic and chemical methods. Pre-treatment and stabilisation of bio-products.

UNIT II PHYSICAL METHODS OF SEPARATION 9

Unit operations for solid-liquid separation - filtration and centrifugation.

UNIT III ISOLATION OF PRODUCTS 9

Adsorption, liquid-liquid extraction, aqueous two-phase extraction, membrane separation – ultrafiltration and reverse osmosis, dialysis, precipitation of proteins by different methods.

UNIT IV PRODUCT PURIFICATION 9

Chromatography – principles, instruments and practice, adsorption, reverse phase, ion-exchange, size exclusion, hydrophobic interaction, bio-affinity and pseudo affinity chromatographic techniques.

UNIT V FINAL PRODUCT FORMULATION AND FINISHING OPERATIONS 9

Crystallization, drying and lyophilization in final product formulation.

TOTAL : 45 PERIODS

OUTCOME:

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

CO1: have a comprehensive understanding of the physicochemical properties of biotechnological products and economics of downstream processing

CO2: be capable of equipment selection and design of mechanical separation process for recovery of biotechnological products

CO3: be able to identify and optimize the suitable bio product isolation process at laboratory and pilot scale

CO4: have a thorough understanding of chromatographic separation processes and equipment selection

CO5: have complete knowledge of stability of biotechnology products and should be capable of formulation and stabilization for enhanced shelf-life

TEXT BOOKS

1. Belter, P.A., E.L. Cussler and Wei-Houhu “Bioseparations – Downstream Processing for Biotechnology”, John Wiley, 1988
2. Ghosh, Raja “Principles of Bioseparations Engineering”. World Scientific, 2006.

3. Roger G. Harrison, Paul W. Todd, Scott R. Rudge, and Demetri P. Petrides “Bioseparations Science and Engineering “ Oxford University Press 2006.

REFERENCES

1. Michael C Flickinger “Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology” John Wiley & Sons 2010.
2. Michael R Ladisch “Bioseparations Engineering” John Wiley & Sons 2001.

Course Articulation Matrix

MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	1	1	1	-	-	-	-	-	-	3	3	2	2
2	2	3	1	-	-	1	-	-	-	1	-	2	2	2	2
3	2	2	2	3	1	1	-	-	-	-	-	3	2	3	3
4	2	2	2	2	3	2	1	1	-	1	-	2	3	3	3
5	3	3	3	3	2	2	1	1	-	-	-	2	3	3	3
AVg.	2.2	2.4	1.8	2.3	1.8	1.5	1	1	-	1	-	2.4	2.6	2.6	2.6

IB23C01 **ANIMAL BIOTECHNOLOGY** **LT P C**
3 0 0 3

OBJECTIVE:

The course aims to

- discuss the culturing methods of animal cell.
- explain about advanced technologies in therapeutics

UNIT I ANIMAL CELL CULTURE 9

Introduction to basic tissue culture techniques; chemically defined and serum free media; animal cell cultures, their maintenance and preservation; various types of cultures- suspension cultures, continuous flow cultures, immobilized cultures; somatic cell fusion; cell cultures as a source of valuable products; organ cultures.

UNIT II ANIMAL DISEASES AND THEIR DIAGNOSIS 9

Bacterial and viral diseases in animals; monoclonal antibodies and their use in diagnosis; molecular diagnostic techniques like PCR, in-situ hybridization; northern and southern blotting; RFLP.

UNIT III THERAPY OF ANIMAL DISEASES 9

Recombinant cytokines and their use in the treatment of animal infections; monoclonal antibodies in therapy; vaccines and their applications in animal infections; gene therapy for animal diseases.

UNIT IV MICROMANIPULATION OF EMBRYO'S 9

What is micromanipulation technology; equipments used in micromanipulation; enrichment of x and y bearing sperms from semen samples of animals; artificial insemination and germ cell manipulations; in vitro fertilization and embryo transfer; micromanipulation technology and breeding of farm animals.

UNIT V TRANSGENIC ANIMALS 9

Concepts of transgenic animal technology; strategies for the production of transgenic animals and their importance in biotechnology; stem cell cultures in the production of transgenic animals.

TOTAL: 45 PERIODS

OUTCOME:

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

CO1: gain the knowledge about animal cell culturing methods and its various applications.
CO2: understand the diagnosis of disease and develop different strategies of treatment
CO3: learn the concept of recombination technology in animal diseases
CO4: understand the micromanipulation techniques in animal embryos
CO5: gain knowledge in the production of transgenic animal technology

TEXTBOOKS

1. Ranga M.M. Animal Biotechnology. Agrobios India Limited, 2002
2. Ramadass P, Meera Rani S. Text Book of Animal Biotechnology. Akshara Printers,

1997

3. Culture of Animal Cells: A Manual of Basic Technique and Specialized Applications, Sixth Edition R. Ian Freshney 2010

REFERENCES:

1. Masters J.R.W. Animal Cell Culture: Practical Approach. Oxford University Press.2000
2. Animal Cell Biotechnology: Methods and Protocols. Author(s): Ralf Pörtner Series: Methods in Biotechnology, Publisher: Humana Press, Year: 2007
3. Animal cells as bioreactors. Terence Cartwright Series: Cambridge Studies in Biotechnology Publisher: Cambridge University Press, Year: 2008
4. Animal Biotechnology. Models in Discovery and Translation Author(s): Ashish Verma and Anchal Singh (Eds.) Publisher: Academic Press, Year: 2014

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	1	-	-	-	-	-	-	-	-	1	3	3	-
2	3	3	2	2	2	-	-	-	-	-	-	2	3	3	2
3	3	3	3	3	2	-	-	-	-	-	-	3	3	3	2
4	3	3	3	2	2	2	2	1	-	-	-	1	3	3	2
5	3	2	3	3	2	3	2	1	-	-	-	1	3	3	2
AVg.	2.8	2.6	2.4	2.5	2.0	2.5	2	1	-	-	-	1.6	3	3	2

PT23023 MOLECULAR BIOLOGY AND GENETIC ENGINEERING L T P C
3 0 0 3

OBJECTIVE

The course aims to

- enlighten key molecular biology and genetic engineering techniques
- apply the latest techniques in current biological research as well as in biotechnology industries.

UNIT I CHEMISTRY OF NUCLEIC ACIDS & DNA REPLICATION 9

Introduction to nucleic acids: Nucleic acids as genetic material, Structure and physico chemical properties of elements in DNA and RNA, Biological significance of differences in DNA and RNA. Primary structure of DNA: Chemical and structural qualities of 3',5'-Phosphodiester bond. Secondary Structure of DNA: Watson & Crick model, Chargaff's rule, X–ray diffraction analysis of DNA, Forces stabilizes DNA structure, Conformational variants of double helical DNA, Hogsteen base pairing, Triple helix, Quadruple helix, Reversible denaturation and hyperchromic effect. Tertiary structure of DNA: DNA supercoiling. Overview of Central dogma. Organization of prokaryotic and eukaryotic chromosomes. DNA replication: Meselson& Stahl experiment, bi– directional DNA replication, Okazaki fragments, Proteomics of DNA replication, Fidelity of DNA replication, Inhibitors of DNA replication, Overview of differences in prokaryotic and eukaryotic DNA replication, Telomere replication in eukaryotes.

UNIT II TRANSCRIPTION 9

Structure and function of mRNA, rRNA and tRNA. Characteristics of promoter and enhancer sequences. RNA synthesis: Initiation, elongation and termination of RNA synthesis, Proteomics of RNA synthesis, Fidelity of RNA synthesis, Inhibitors of transcription, Differences in prokaryotic and eukaryotic transcription. Basic concepts in RNA world: Ribozymes, RNA processing: 5'-Capping, Splicing-Alternative splicing, Poly 'A' tail addition and base modification.

UNIT III TRANSLATION 9

Introduction to Genetic code: Elucidation of genetic code, Codon degeneracy, Wobble hypothesis and its importance, Prokaryotic and eukaryotic ribosomes. Steps in translation: Initiation, Elongation and termination of protein synthesis. Inhibitors of protein synthesis. Post translational modifications and its importance.

UNIT IV BASICS OF RECOMBINANT DNA TECHNOLOGY 9

Manipulation of DNA and RNA – Restriction and Modification enzymes, Design of linkers and adaptors. Characteristics of cloning and expression vectors based on plasmid and bacteriophage, Vectors for insect, yeast and mammalian system, Prokaryotic and eukaryotic host systems, Introduction of recombinant DNA in to host cells and selection methods. Construction of genomic and cDNA libraries, Artificial chromosomes – BACs and YACs, Chromosomal walking, Screening of DNA libraries using nucleic acid probes and antisera.

UNIT V SEQUENCING AND AMPLIFICATION OF DNA 9

Maxam Gilbert's and Sanger's methods of DNA sequencing. Inverse PCR, Nested PCR, AFLPPCR, Allele specific PCR, Assembly PCR, Asymmetric PCR, Hot start PCR, inverse

PCR, Colony PCR, single cell PCR, Real-time PCR/qPCR – SYBR green assay, Taqman assay, Molecular beacons. Site directed mutagenesis.

OUTCOME

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

CO1: gain knowledge on DNA structure and explain replication

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

CO3: understand the current techniques involved in gene editing to generate appropriate genetically modified organisms

CO4: understand the concept of manipulation techniques and artificial chromosomes

CO5: gain knowledge on DNA sequencing and carry out PCR techniques

TEXTBOOKS:

1. Friefelder, David, “Molecular Biology”, IInd Edition, Narosa Publishing House,1999.
2. Lewin Benjamin, “Genes IX” Jones and Bartlett, 2008.
3. Weaver, R.F. “Molecular Biology”, IIIrd Edition, McGraw Hill, 2005.
4. Primrose, S. Twyman, R. “Principles of Gene Manipulation and Genomics” VIIth Edition, Blackwell Publishing, 2006.
5. Brown, T.A. “Gene Cloning & DNA Analysis: An Introduction”, Vth Edition, Blackwell Publishing, 2006.

REFERENCES:

1. Waston, J.D. “Molecular Biology of the Gene”, Vth Edition, Pearson Education, 2004.
2. Walker, J.M. and R. Rapley “Molecular Biology and Biotechnology” IVth Edition, Panima,2002.
3. Glick, B.R. and J.J. Pasternak “Molecular Biotechnology: Principles and Applications of Recombinant DNA”, IIIrd Edition, ASM, 2003.

MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	1	2	1	2	1	-	1	-	-	-	1	2	2	2
2	1	1	3	3	1	2	-	1	-	-	-	3	2	2	3
3	1	1	3	3	2	2	-	1	-	-	-	3	3	3	3
4	1	1	3	3	2	1	-	1	-	-	-	3	3	3	3
5	1	1	3	3	2	2	-	1	-	-	-	3	3	2	2
AVg.	1	1	2.8	2.6	1.8	1.6	-	1	-	-	-	2.6	2.6	2.4	2.6

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23024 ENZYME TECHNOLOGY AND APPLICATIONS L T P C
3 0 0 3

OBJECTIVE

The course aims to,

- Teach principles of enzyme engineering and enzyme technology.
- Learn about immobilisation techniques and kinetics in enzyme technology.

UNIT I INTRODUCTION TO ENZYMES 9

Classification of enzymes. Mechanisms of enzyme action; concept of active site and energetics of enzyme substrate complex formation; specificity of enzyme action; principles of catalysis – collision theory, transition state theory; role of entropy in catalysis.

UNIT II KINETICS OF ENZYME ACTION 9

Kinetics of single substrate reactions; estimation of Michelis – Menten parameters, multisubstrate reactions- mechanisms and kinetics; turnover number; types of inhibition & models –substrate, product. Allosteric regulation of enzymes, Monod Changeux Wyman model, pH and temperature effect on enzymes & deactivation kinetics.

UNIT III ENZYME IMMOBILIZATION AND BIOSENSORS 9

Physical and chemical techniques for enzyme immobilization – adsorption, matrix entrapment, encapsulation, cross-linking, covalent binding etc., - examples, advantages and disadvantages, design of enzyme electrodes and their application as biosensors in industry, healthcare and environment.

UNIT IV PURIFICATION AND CHARACTERIZATION OF ENZYMES FROM NATURAL SOURCES 9

Production and purification of crude enzyme extracts from plant, animal and microbial sources; methods of characterization of enzymes; development of enzymatic assays

UNIT V INDUSTRIAL AND CLINICAL USES OF ENZYMES 9

Industrial Enzymes- Thermophilic enzymes, amylases, lipases, proteolytic enzymes in meat and leather industry, enzymes used in various fermentation processes, cellulose degrading enzymes, Metal degrading enzymes. Clinical enzymes- Enzymes as thrombolytic agents, Anti-inflammatory agents, streptokinasae, asparaginase, Isoenzymes like CK and LDH, Transaminases (AST, ALT), Amylases, Cholinesterases, Phosphatases. Immobilization of enzymes, ELIZA. Biosensors. Enzyme Engineering and site directed mutagenesis, Designer enzymes

TOTAL: 45 PERIODS

OUTCOME:

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

CO1: classify enzymes and explain the mechanism of enzyme action

CO2: gain knowledge on enzyme kinetics and different types of enzyme inhibition.

CO3: acquire deep knowledge on enzyme immobilization and biosensors

CO4: carry out enzyme production, purification and characterization

CO5: learn the applications of enzymes.

TEXTBOOKS:

1. Trevor Palmer , Enzymes II ed Horwood Publishing Ltd

2. Faber K , Biotransformations in Organic Chemistry, IV edition , Springer

REFERENCES

1. Harvey W. Blanch, Douglas S. Clark, Biochemical Engineering, Marcel Dekker, Inc.

2. James M. Lee, Biochemical Engineering, PHI, USA.
3. James. E. Bailey & David F. Ollis, Biochemical Engineering Fundamentals, McGraw Hill.
4. Wiseman, Enzyme Biotechnology, Ellis Horwood Pub.

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	-	1	-	2	-	1	-	-	-	-	2	1	2	2
2	2	1	1	-	-	1	-	-	-	-	-	2	2	2	2
3	2	2	3	2	1	2	2	1	1	-		3	2	3	3
4	2	2	2	3	2	2	2	1	1	1	1	2	3	3	3
5	2	2	2	2	3	2	2	1	-	1	1	2	2	3	3
Avg.	1.8	1.7	1.8	2.3	2	1.7	1.7	1	1	1	1	2.2	2	2.6	2.6

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23025 **IMMUNOLOGY** **L T P C**
3 0 0 3

OBJECTIVE

The course aims to,

- Discuss the structure, functions and integration of the immune system.
- Explain the antigen-antibody interactions and how the immune system is protecting the body from foreign pathogens/germs.
- Explain various techniques of monoclonal and engineered antibodies (important therapeutic molecules) production, for treating most of the human diseases.

UNIT I INTRODUCTION TO IMMUNE SYSTEM 9

Organisation and classification of immune system – immune cells and organs; innate and acquired immunity; Toll receptors and responses, classification of antigens – chemical and molecular nature; haptens, adjuvants; cytokines; complement pathway, antigen presenting cells; major histocompatibility complex.

UNIT II HUMORAL AND CELLULAR IMMUNITY 9

Development, maturation, activation, regulation, differentiation and classification of T-cells andB-cells, antigen processing and presentation, theory of clonal selection, TCR; antibodies: structure and functions; antibodies: genes and generation of diversity; antigenantibody reactions: precipitation, Agglutination, complement fixation, IFT, RIA, ELISA.

UNIT III IMMUNITY AGAINST PATHOGENS AND TUMORS 9

Inflammation; protective immune responses to viruses, bacteria, fungi and parasites; tumor antigens, tumor immune response, tumor diagnosis, tumor immunotherapy.

UNIT IV IMMUNE TOLERANCE AND HYPERSENSITIVITY 9

Immune tolerance, Immunodeficiencies; Transplantation – genetics of transplantation; laws of transplantation; Allergy and hypersensitivity – Types of hypersensitivity, Autoimmunity, Autoimmune disorders and diagnosis.

UNIT V APPLIED IMMUNOLOGY 9

Monoclonal antibodies, engineering of antibodies; Classification of Vaccines, methods of vaccine development, immunodiagnostic methods (Immunodiffusion ELISA, FACS), immunomodulatory drugs.

OUTCOME:

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

CO1: understand about immune system, its structure and functions.

CO2: gain knowledge on various concepts of antibodies

CO3: learn about immune responses to various pathogens.

CO4: understand the principles behind the production of therapeutic /diagnostic molecules.

CO5: understand the various methods of vaccine development

TEXTBOOKS:

1. Roitt I, Male, Brostoff. Immunology, Mosby Publications, XII edition, 2011.
2. Kuby J, Immunology, WH Freeman & Co., VII edition, 2012.
3. Ashim K. Chakravarthy, Immunology, Tata McGraw-Hill, 2006.

REFERENCES:

1. Coico, Richard, “Immunology: A Short Course”, VI Edition, John Wiley, 2008.
2. Khan, Fahim Halim, “Elements of Immunology”, Pearson Education, 2009.
3. Abbas, Lichtman and Shiv Pillai, “Cellular and Molecular Immunology”, VI edition, Elsevier, 2017

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	1	1	1	-	1	1	1	-	-	-	2	2	2	2
2	2	2	3	2	2	1	2	1	-	-	-	2	2	2	3
3	2	2	2	2	2	1	1	-	-	-	-	3	3	2	2
4	3	2	2	2	2	-	1	2	-	-	-	3	3	2	3
5	2	2	2	2	2	1	2	2	-	2	-	2	2	2	3
Avg.	2	1.8	2	1.8	2	1	1.4	1.5	-	2	-	2.4	2.4	2	2.6

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO * upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix

PT23026 **VACCINE TECHNOLOGY** **L T P C**
3 0 0 3

OBJECTIVES

The course aims to

- Develop understanding and provide scientific basics of the life processes at the molecular level
- Understand the structure-function and inter-relationships of biomolecules and their deviation from normal and their consequences for interpreting and solving clinical problems.

UNIT I IMMUNOLOGICAL CONCEPTS IN VACCINOLOGY 9

Short history of vaccination, requirements for induction of immunity, Epitopes, linear and conformational epitopes, characterisation and location of APC, MHC and immunogenicity, Rational 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, subunit 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; Catalytic antibodies and generation of immunoglobulin gene libraries, Transfusion of immuno-competent cells; Cell based vaccines

UNIT III V ACCINE 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 TCell memory , Rational design of new vectors , CpG adjuvant activity , Transcutaneous immunisation , Vaccination studies and recent advances in Malaria, Tuberculosis , HIV

UNIT IV COMPUTATIONAL TOOLS FOR VACCINE DESIGN 9

Antigen Sequence analysis, Epitope Mapping, Predictions of Immunogenic peptides of T-Cell and B-Cells. Prediction of HLA binding peptides, Comparative Genomics as a tool for vaccine design, introduction to online epitope databases

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 , Commercialisation , ethics.

OUTCOMES:

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

CO1: Explain different types of immunity and gain knowledge on future vaccine strategies.
CO2: Gain knowledge on design and preparation of vaccines
CO3: Gain knowledge about validation, testing and quality control of vaccines
CO4: Gain knowledge on sequencing and bioinformatics databases.
CO5: Understand the importance of vaccine research and its regulations along with the product commercialization and ethics.

TEXTBOOKS

1. Male, David et al., "Immunology", 7 th Edition, Mosby Publication, 2007.
2. Kindt, T.J. etal., "Immunology", 6 th Edition, W.H. Freeman, 2007.
3. Janeway, C.A. etal., "Immunology: The Immune Systems in Health and Diseases", 6 th Edition, Garland Science, 2005.
4. Lydyard, P.M. "Instant Notes in Immunology", Viva Books Pvt. Ltd., 2000.

REFERENCES:

1. S. Hockfield, S. Carlson, C. Evans, P. Levitt, J. Pintar, L. Silberstein, Selected Methodsfor Antibody and Nucleic Acid probes, Volume1, Cold Spring Harbor Ed Harlow, David Lane, Antibodies Laboratory Manual, Cold Spring Harbor Laboratory Press, 1988 Laboratory Press,1993.
2. Coico, R, "Immunology: A Short Course", 5 th Edition, Wiley – Liss, 2003.
3. Parham, Peter "The Immune System", 2 nd Edition, Garland Science, 2005.
4. Abbas, A.K., "The Cellular and Molecular Immunology", 6 th Edition, Sanders / Elsevier, 2007.
5. Weir, D.M. and Stewart, John "Immunology", 8 th Edition, Churchill Pvt. Ltd., 2000.

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	1	1	1	-	1	1	1	-	-	-	2	2	2	2
2	2	2	3	2	2	1	2	1	-	-	-	2	2	2	3
3	2	2	2	2	2	1	1	-	-	-	-	3	3	2	2
4	3	2	2	2	2	-	1	2	-	-	-	3	3	2	3
5	2	2	2	2	2	1	2	2	-	2	-	2	2	2	3
AVg.	2	1.8	2	1.8	2	1	1.4	1.5	-	2	-	2.4	2.4	2	2.6

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO * upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23027 FUNDAMENTALS OF BIOPROCESS ENGINEERING L T P C
3 0 0 3

OBJECTIVES

- To provide knowledge on fundamentals of Enzyme kinetics, Inhibition kinetics and Immobilization.
- To provide concept of basic fermentation processes and its control systems during scale up operations.

UNIT I INTRODUCTION TO ENZYMES 9

Classification of enzymes. Mechanisms of enzyme action; Principles of catalysis – collision theory, transition state theory; role of entropy in catalysis. Enzyme Kinetics- Single substrate reactions; Estimation of Michaelis–Menten parameters, Multi substrate reactions -Enzyme Immobilization and kinetics.

UNIT II STERILIZATION KINETICS 9

Thermal death kinetics of microorganisms, batch and continuous heat sterilization of liquid media, filter sterilization of liquid media, air sterilization and design of sterilization equipment-batch and continuous.

UNIT III METABOLIC STOICHIOMETRY AND ENERGETICS 9

Stoichiometry of cell growth and product formation, elemental balances, degrees of reduction of substrate and biomass, available electron balances, yield coefficients of biomass and product formation, maintenance coefficients, energetic analysis of microbial growth and product formation, oxygen consumption and heat evolution in aerobic cultures, thermodynamic efficiency of growth.

UNIT IV KINETICS OF MICROBIAL GROWTH AND PRODUCT FORMATION UNSTRUCTURED KINETIC MODELS 9

Modes of operation - batch, fed batch and continuous cultivation. Simple unstructured kinetic models for microbial growth, Monod model, growth of filamentous organisms. Types of reactor- Air Lift Reactor, Bubble Column Reactor, Immobilized enzyme reactors- packed bed, fluidized bed, membrane reactors.

UNIT V BIOREACTOR SCALE – UP 9

Regime analysis of bioreactor processes, oxygen mass transfer in bioreactors – Mass transfer Coefficient - methods for the determination of mass transfer coefficients; mass transfer correlations. Power requirements of Bioreactors. Scale-up considerations on heat transfer oxygen transfer, power consumption and impeller tip speed.

TOTAL: 45 PERIODS

OUTCOMES:

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

CO1: Gain knowledge on enzymes and its mechanisms.
CO2: Understand about the sterilization types in media.
CO3: Gain knowledge on stoichiometry and energetics involved in cell growth and product formation.
CO4: Learn about types of reactors and kinetics.
CO5: Understand the mass transfer correlations in bioprocess.

TEXT BOOKS:

1. Shuler, M.L. and Kargi, F. “Bioprocess Engineering: Basic Concepts”, IInd Edition, PHI, 2002.
2. Bailey, J.E. and Ollis, D.F. “Biochemical Engineering Fundamentals” IInd Edition, McGraw – Hill, 1988.

REFERENCES:

1. Wiseman, Alan “Handbook of Enzyme Biotechnology”, IIIrd Edition, Ellis Harwood Publications, 1999.
2. Moser, Anton. “Bioprocess Technology: Kinetics and Reactors”, Springer –Verlag, 1988.
3. Stanbury, P.F. et al. “Principles of Fermentation Technology”, Butterworth – Heinemann/Elsevier, IInd Edition, 1995.

COURSE ARTICULATION MATRIX

MAPPING OF COs WITH POs AND PSOs

Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	1	2	1	1	-	-	-	-	-	-	3	1	1	2
2	2	2	2	2	2	-	-	-	-	-	-	2	2	1	2
3	2	2	2	1	2	1	1	1	-	1	-	2	2	2	1
4	2	2	2	2	2	2	1	1	1	-	-	2	1	2	2
5	3	2	2	1	3	2	3	3	1	2	-	3	3	3	3
AVg.	2.2	1.8	2	1.4	2	1.6	1.6	1.6	1	1.5	-	2.4	1.8	1.8	2

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

OPEN ELECTIVE

PT23901 INTRODUCTION TO DRUG SCIENCE L T P C
3 0 0 3

OBJECTIVE

The course aims to

- provide knowledge on formulation of various dosage forms and its mechanism of action

UNIT I INTRODUCTION 9

Sources of drugs, Dosage forms, needs and types of dosage forms. Stages of drug discovery and development.

UNIT II SOLID DOSAGE FORMS 9

Tablets – Definition, Types of tablets, Additives used in tablets, Manufacturing and Evaluation of Tablets. Capsules - Definition, Extraction of Gelatin, Types of capsules, Manufacturing and Evaluation of Capsules.

UNIT III LIQUID AND SEMISOLID DOSAGE FORMS 9

Solution – Solubility, Vehicles used in liquid preparations, Oral solution, Syrup, Elixir, Tinctures, Dispersed systems – Suspensions and Emulsions, Preparations and Evaluation. Semisolid – Ointments, Ointments bases, Creams, Gels, Pastes

UNIT IV PHARMACOKINETICS AND PHARMACODYNAMICS 9

Mechanism and factors affecting drug Absorption, Distribution – Factors of drug distribution, volume of distribution, Protein binding, Metabolism – Phase I and Phase II reaction and Excretion. Principle of drug action, Receptor - ligand-gated ion channels, Transmembrane G protein–coupled receptors, Enzyme-linked receptors and Intracellular receptors.

UNIT V PHARMACEUTICAL PRODUCTS 9

Classifications, mechanism of action, Pharmacology and Toxicity of the following class of drugs – Analgesic, Antihypertensive, Ant diabetics, Anticancer, Antibiotic – Beta lactam and protein synthesis inhibitor.

TOTAL : 45 HOURS

OUTCOME:

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

- Classify dosage forms and understand the various steps involved in drug discovery and development
- Formulate and evaluate tablets and capsules
- formulate liquid and semisolid dosage forms and evaluate them for their quality .
- describe metabolic pathways and explain the principles of drug action
- classify and understand the mechanism of action of various drug categories

TEXTBOOKS:

1. Lachman, Leon et al. “The Theory and Practice of Industrial Pharmacy” IIIrd Ed., Varghese Publishing House, 1987.
2. Aulton, Michael E. “Pharmaceutics: The Science of Dosage Form Design” IInd Ed., Churchill Livingstone, 2002.
3. Allen, Loyd V.. “Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems” IX th Ed., Wolters Kluwer/LippinCott Williams & Wilkins, 2011.
4. Brahmankar, D.M. and Jaiswal, S.B. “Biopharmaceutics and Pharmacokinetics: a

Treatise", 3rd Edition, Vallabh Prakashan, 2015.
5. Tripathi, K.D., "Essentials of Medical Pharmacology", 7 th Edition, Jaypee Brothers Medical Publishers (P) Ltd, 2015.

REFERENCES

1. Remington's Pharmaceutical Sciences, A. R. Gennaro Mac Pub. Co. Easton, Pennsylvania 1990
2. Shargel,L and Andrew, B.C. Yu. "Applied Biopharmaceutics & Pharmacokinetics",7th Edition, The McGraw-Hill Companies, Inc, 2016.
3. Laurence L. Brunton, Bjorn C. Knollmann, Randa Hilal-Dandan, " Goodman and Gilman's: The Pharmacological Basis of Therapeutics", 13th edition, McGraw-Hill Education / Medical, 2017.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	**PO**												**PSO**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	3	1	1	2	3	-	1	1	2	1	2	3	2	3
2	3	2	1	2	3	3	3	1	-	1	2	1	3	3	1
3	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
4	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
5	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
AVg.	2.80	2.80	1.00	1.80	2.80	2.40	1.50	1.60	1.00	1.80	1.20	1.50	3.00	2.20	1.40

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals

PT23902 PHARMACEUTICAL INDUSTRIAL MANAGEMENT L T P C
3 0 0 3

OBJECTIVE

The objectives of this course are to:

- Understand the basic framework, transformation processes and their extensions in relation to pharma operations
- understand the concept of an operations strategy planning and management
- provide the students exposure to modern marketing concepts, tools, and techniques, and help them develop abilities and skills required for the performance of marketing functions in industry.

UNIT I INTRODUCTION TO PRODUCTION AND OPERATIONS MANAGEMENT 9

Definition, concept and Evolution of Production and operations management, Nature and Scope of production/operations management, Production function and its environment, Functions of production/operations manager

UNIT II FACILITIES AND LAYOUT PLANNING 9

Product selection and design, service design, Process and technology, selection, Location of manufacturing/service facility, Centre of gravity and median models, dimensional analysis, Brown and Gibson model. Product layout, process layout, fixed position and group layout, layout design, Relationship based and load-distance cost matrix, Materials handling concepts.

UNIT III MATERIALS PLANNING AND INVENTORY 9

Need and definition, factors affecting planning- external and internal, dependent and independent demand system, techniques of planning, Material Budgeting and Purchasing Inventory Control: Importance and scope, costs, economic order quantity, Inventory control techniques.

UNIT IV QUALITY CONTROL & MANAGEMENT 9

Quality control functions, Acceptance sampling, Statistical Process control, Application of control charts, Operating characteristic curve and its applications, Total Quality improvement

UNIT V PHARMACEUTICAL MARKETING 9

Pharmaceutical Marketing and Its Structure, Promotional Activities of Pharmaceutical Marketing. Pharmaceutical market research and analysis, Distribution channels in pharmaceutical marketing, Controlling aspect in pharmaceutical marketing, General aspects of pharmaceutical marketing. Designing, printing aspect in pharmaceutical sales promotion and advertising. Pricing strategies and Promotions- Understanding Pricing, Pricing decisions, methods of pricing of pharmaceutical products, selecting the final price, price discounts.

TOTAL : 45 PERIODS

OUTCOME:

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

CO1: Understand various manufacturing operations within the framework of company organization like facility planning, capacity planning, product and process selection, resource allocation with special emphasis on pharmaceutical production

CO2: Understand the importance and processes involved in location and layout planning, resources planning and production planning and control

CO3: Gain knowledge about effective and efficient purchase, different inventory policies and models, effective and efficient inventory management and control

CO4: Understand the importance and application of quality management measures and statistical techniques effectively for the particular operations during Pharmaceutical production.

CO5: State the role and functions of marketing in Pharmaceutical industry.

TEXTBOOKS:

1. Operations Management by Bernard Taylor
2. Production and Operations Management by Adam, Ronald and Ebert
3. Phillip Kotler, Kevin Lane Keller Marketing management, 15th edition. Pearson Education India.

REFERENCES:

1. Production and Operations Management by Aswathappa and Bhat
2. Douglas J. Dalrymple, William L. Cron, Thomas E. DeCarlo. "Sales Management", John Wiley & Sons, New Jersey, USA. 2004

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
2	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
3	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
4	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
5	2	2	1	2	2	-	-	1	2	2	2	3	1	2	2
AVg.	2.00	2.00	1.00	2.00	2.00	-	-	1.00	2.00	2.00	2.00	3.00	1.00	2.00	2.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

EMERGING TECHNOLOGY COURSES

PT23E05 BIOGENERICS AND BIOSIMILARS L T P C
3 0 0 3

OBJECTIVE

The objectives of this course are to:

- Understand the basic framework, transformation processes and their extensions in relation to pharma operations
- Understand the concept of an operations strategy planning and management
- Provide the students exposure to modern marketing concepts, tools, and techniques, and help them develop abilities and skills required for the performance of marketing functions in industry.

UNIT I BIOGENERICS INTRODUCTION 9

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

UNIT II BIOSIMILARS AND ITS SCENARIO 9

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

UNIT III CHARACTERIZATION OF BIOSIMILARS 9

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

UNIT IV IMMUNOGENECITY OF BIOPHARMACEUTICALS 9

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

UNIT V CASE STUDIES 9

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

TOTAL: 45 PERIODS

TEXT BOOKS AND REFERENCES

1. Biosimilars of Monoclonal Antibodies: A Practical Guide To Manufacturing, Preclinical And Clinical Development Cheng Liu, PhD, and K. John Morrow, Jr., PhD, Wiley-Interscience, Year: 2017
2. Biosimilars: Regulatory, Clinical and Biopharmaceutical Development Hiten J. Gutka,

Harry Yang, ShefaliKakar AAPS Advances in the Pharmaceutical Sciences Series 34, Springer International Publishing, Year: 20181. Sarfaraz K. Niazi, Handbook of Biogeneric Therapeutic Proteins: Regulatory, Manufacturing, Testing, and Patent Issues, CRC Press, 2006.
3. Rodney J Y Ho, MILO Gibaldi, Biotechnology & Biopharmaceuticals Transforming proteins and genes into drugs, 1st Edition, Wiley Liss, 2003.

REFERENCES:

1. Nonclinical Development of Novel Biologics, Biosimilars, Vaccines And Specialty Biologics Lisa M. Plitnick, MS, PhD and Danuta J. Herzyk, PhD (ed) 2013 Elsevier Inc.
2. Biologics, Biosimilars And Biobetters, An Introduction To Pharmacists, Physicians And Health Practitioners (ed) Iqbal Ramzan, WILEY 2021

PROGRAMME OUTCOMES															
CO's	**PO's**												**PSO's**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	2	1	-	-	-	-	-	-	-	-	1	1	3	-
2	3	3	2	2	2	-	-	-	-	-	-	2	3	3	2
3	3	3	3	3	2	-	-	1	-	-	-	3	3	3	2
4	3	3	3	2	2	2	2	1	1	-	-	1	3	3	2
5	3	2	3	3	2	3	2	1	1	-	1	1	1	3	-
Overall CO	**2.8**	**2.6**	**2.4**	**2.5**	**2.0**	**2.5**	**2**	**1**	**1**	**-**	**1**	**1.6**	**2.4**	**3**	**2**

Course 1-low, 2-medium, 3-high, '-"- no correlation
Note: The average value of this course to be used for program articulation matrix

PT23S01 AUTOMATION IN PHARMACEUTICAL INDUSTRIES L T P C
3 0 0 3

OBJECTIVES

The objectives of this course are to:

- Understand the basic framework, transformation processes and their extensions in relation to automation of pharma operations
- understand the concepts and application of automated process analytical methods
- provide the students exposure to modern marketing concepts, tools, and techniques, and help them develop abilities and skills required for the performance of marketing functions in industry.

UNIT I INTRODUCTION TO PHARMACEUTICAL AUTOMATION AND ITS NEEDS 9

Pharmaceutical Process Automation - Automated Quality Testing Laboratories - Automated Biotechnology Laboratory System – Module 3: Automated Drug Discovery Laboratory Systems - Automation in Clinical Laboratory Systems (Virtual Clinical Trial)

UNIT II AUTOMATED ANALYTICAL AND BIOANALYTICAL TECHNIQUES 9

Instrumentation - Utilities - Designs and models

UNIT III AUTOMATION IN COMPUTER SYSTEMS AND SOFTWARE BASED SOLUTIONS 9

Automation in computer systems (CSV and CSA) - Software Based Solution- LIMS, LIS and PDES - Automation in Documentation and Data Management

UNIT IV AUTOMATION IN OPERATIONAL AND DIGITAL INFORMATION TECHNOLOGIES USED IN PHARMA 9

Artificial Intelligence, Machine Learning, Cloud technology, big data, block chain, ERP, EAM, MES, SCM, IoT, etc.

UNIT V MODULE 16: REGULATORY REQUIREMENTS FOR PHARMACEUTICAL AUTOMATION 9

Regulatory aspects with reference to Indian context – cGMP – guidelines - International Perspective – FDA –CFR – ICH guidelines

OUTCOMES

The Course will enable students to

CO1 Comprehend importance and fundamental principles of automation in Pharma Industry

CO2 Understand applications of Automated Drug Discovery Laboratory Systems

CO3 Understand the importance of Automation in Product Research and Development

CO4 Understand the importance of Automation in Marketing, Supply Chain and Inventory Management

CO5: Understand the importance of Automation in Clinical Laboratory Systems (Virtual Clinical Trial)

OUTCOMES

This program will enable the students to:

- Comprehend and automation principles in the modern pharmaceutical industry and acquire a comprehensive knowledge on the critical pharma business domains from drug discovery, product research and development, clinical trials, quality testing, marketing and distribution, pharmacovigilance and safety monitoring, and finally data management
- Apply principles in the expansion of technological startups, device new patents with the expiration of multiple significant patents, accelerate interorganizational partnerships, and a viable regulatory environment are all fueling pharmaceutical industry innovation
- Promote technology breakthroughs and innovation in pharmaceutical in order to fulfill expanding healthcare demands
- Strategize Pharmaceutical Automation as it is considered to be the future of industry due to reduced cost, error reduction and improved quality of process. It promotes the experts to face the real world issues by implementing the skills of Lab Automation
- Develop approaches for reduction in errors which saves millions of revenue for pharmaceutical and biomedicine companies. By encompassing new technologies, labs can ensure they comply with health and safety regulations and avoid potential non-compliance

PT23S03 **MOLECULAR IMAGING** **L T P C**
3 0 0 3

OBJECTIVES

Objectives of the course are to enable the students

- Understand principles of imaging physics
- Understand and design molecular probes and contrast media.
- Understand applications of molecular imaging in biological model systems
- Understand applications of molecular imaging in drug discovery
- Understand applications of molecular imaging in clinical imaging studies

UNIT I IMAGING PHYSICS AND INSTRUMENTATION 9

Production of radionuclides - Interaction of radiation with matter – Detectors - Formation of images - Imaging modalities - x-ray production – Gamma -camera performance - PET performance - Tomographic reconstruction - Image processing

UNIT II MOLECULAR PROBES AND CONTRAST AGENTS 9

Probe design - Coordination chemistry - Conjugation chemistry - Quality control - Probe evaluation – Automated Synthesis - MRI and optical probes - Combinatorial chemistry - Synthetic chemistry - GMP issues; CMC component

UNIT III BIOLOGIC MODEL SYSTEMS 9

Animal models, anatomy, physiology - Anesthesia, biologic systems - Imaging and biodistribution - Ethics and compliance - Stem cell and trafficking - 3-dimensional organ cultures - Pathophysiology models - Animal monitoring - Specialized surgery

UNIT IV APPLICATIONS IN DRUG DISCOVERY & PHARMACOLOGY 9

Target selection – Pharmacodynamics – Pharmacokinetics - Sampling and analyses – Toxicology – Pharmacologic classification – Receptor Interactions – Use of radiotracers – Analytical methods – IND preparation

UNIT V APPLICATIONS IN CLINICAL IMAGING OF DISEASE 9

Modality selection - Probe selection - Imaging methods - Biomarker metrics – Regulatory aspects - Response metrics - Targeted imaging - Anatomy and physiology – Informatics - Compliance for IND

TOTAL: 45 HOURS

TEXT BOOK

1. Fred Mettler Jr., Milton J Guiberteau, “Essentials of Nuclear Medicine and Molecular Imaging” 7th Ed, Elsevier, 2019

REFERENCE

1. David Gilmore & Kristen M. Waterstram-Rich, “Nuclear Medicine and Molecular Imaging, 9th Edition, Elsevier, 2023

OUTCOMES

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

- CO1 Illustrate and understand principles of imaging physics.
- CO2 Understand and design molecular probes and contrast media.
- CO3 Apply, Illustrate and make use of molecular imaging in biological model systems
- CO4 Apply, Illustrate and make use of molecular imaging in drug discovery
- CO5 Understand, Illustrate and make use of molecular imaging in clinical imaging studies

COURSE ARTICULATION MATRIX

MAPPING OF COs WITH POs AND PSOs

PROGRAMME OUTCOMES															
CO's	**PO's**												**PSO's**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	2	1	-	-	-	-	-	-	-	-	1	1	3	-
2	3	3	2	2	2	-	-	-	-	-	-	2	3	3	2
3	3	3	3	3	2	-	-	1	-	-	-	3	3	3	2
4	3	3	3	2	2	2	2	1	1	-	-	1	3	3	2
5	3	2	3	3	2	3	2	1	1	-	1	1	1	3	-
Overall CO	**2.8**	**2.6**	**2.4**	**2.5**	**2.0**	**2.5**	**2**	**1**	**1**	**-**	**1**	**1.6**	**2.4**	**3**	**2**

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

PT23S04 SOLID STATE CHARACTERIZATION TECHNIQUES LT P C
3 0 0 3

UNIT I INTRODUCTION TO THE SOLID STATE 9

Physical Properties and Processes - Neutral Pharmaceutical Molecules - Thermodynamics and Phase Diagrams - Neutral Pharmaceutical Molecules in the Solid State - Salt Formation and Acid-Base Equilibrium - Polymorphs, Solvates and Mixed Crystals - Phase Transitions and Kinetics - Screening for 'Polymorphs' (Ansolvates and Solvates)

UNIT II X-RAY DIFFRACTION AND SPECTROSCOPIC METHODS 9

Generation and Properties of X-Rays - Crystal, Lattices, Unit Cells and Symmetry - The Interaction of X-rays with Crystals - Collecting Intensity Data for Single Crystals - Determining Crystal Structures - Powder Diffraction - Amorphous Powders - Particle Size - Vibrational Spectroscopy - Mid- and Near-Infrared Spectroscopy - Near-Infrared Spectroscopy - Raman Spectroscopy - Chemical Imaging and Mapping Microscopy - Nuclear Magnetic Resonance Spectroscopy - Terahertz Pulsed Spectroscopy

UNIT III THERMAL METHODS 9

Differential Scanning Calorimetry (DSC) - Thermogravimetric Analysis (TGA) - Dynamic Mechanical Analysis (DMA) - Determining the Melting Behaviour of Crystalline Solids – Polymorphism - Solvates and Hydrates (Pseudopolymorphism) - Evolved Gas Analysis (EGA) and Simultaneous Measurements - Amorphous Content - Purity Determination Using DSC - Excipient Compatibility – Isothermal calorimetry – Applications – Solution Calorimetry - Applications

UNIT IV SORPTION AND MICROSCOPIC METHODS 9

Inverse Gas Chromatography - Dynamic Vapour Sorption - Light Microscopy - Crystal Shape - Particle Size - Nonambient Light Microscopy - Scanning Electron Microscopy - Elemental X-Ray Microanalysis - Atomic Force Microscopy

UNIT V MECHANICAL PROPERTIES AND PARTICLE SIZE DISTRIBUTION 9

Tableting/Comminution Process - Indentation and Nanoindentation Testing - Deformation Behaviour of Powders - Evaluation of Deformation Behaviour and Compressibility - Solubility Parameters (δ) and Cohesive Energy Density (CED) and Mechanical Properties - Influence of Crystal Structure on Mechanical Properties - Polymorphism and Mechanical Properties - Particle Size and Shape - Particle Shape Analysis - Particle Diameter - Particle Size Distribution - The Average Particle Size - Particle Size Measurement - Surface Area Measurement - Particle Size Reduction - Particle Size Assessment and Pharmaceutical Development - Case Studies

TEXT BOOKS

1. Richard A. Storey, Ingvar Ymén, "Solid State Characterization of Pharmaceuticals", Blackwell Publishing, 2011

OUTCOMES

CO1 To make the student to understand about the solid state properties
CO2 To make the student to understand the spectroscopic methods and XRD
CO3 To facilitate them in understanding the thermal methods of characterization
CO4 To facilitate them learn the microscopic methods and sorption based characterization methods
CO5 To make the student understand and analyse particle size distribution and mechanical properties characterization

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	1	1	1	1	2	2	-	-	-	-	2	1	1	2
2	2	1	1	1	1	2	2	-	-	-	-	2	1	2	3
3	2	1	1	1	1	2	2	-	-	-	-	2	1	2	3
Avg	2.00	1.00	1.00	1.00	1.00	2.00	2.00	-	-	-	-	2.00	1.00	1.67	2.67

PT23002 PROTEIN STRUCTURE PREDICTION L T P C
3 0 0 3

UNIT – I: PROTEIN ARCHITECTURE 9

Primary structure: peptide mapping, peptide sequencing - automated Edman method & mass-spec High-throughput protein sequencing setup Secondary structure: Alpha, beta and loop structures and methods to determine Super-secondary structure: Alpha-turn-alpha, beta-turn-beta (hairpin), beta-sheets, alpha-beta-alpha, topology diagrams, up and down & TIM barrel structures nucleotide binding folds, prediction of substrate binding sites.

UNIT – II: TERTIARY STRUCTURE 9

Tertiary structure: Domains, folding, denaturation and renaturation, overview of methods to determine 3D structures. Quaternary structure: Modular nature, formation of complexes. Computer exercise on the above aspects

UNIT – III CONFORMATION OF PROTEINS` 9

Conformation of the peptide bond – secondary structures – Ramachandran plots – use of potential functions – tertiary structure – folding – hydration of proteins – hydropathy index – protein dynamics – structural motifs – contact map – membrane proteins – protein structure prediction – Intrinsically Disordered Proteins (IDP) – Protein folding mechanisms – protein aggregation and neurotoxicity.

UNIT – IV: STRUCTURE-FUNCTION RELATIONSHIP 9

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

UNIT – IV: MACHINE LEARNING, MOLECULAR MODELLING AND DOCKING 9

Phylogenetics: Introduction, Distance based trees, Character-based trees, Bootstrapping. Protein Structure: Tertiary structure prediction methods, Homology modeling, Molecular docking principles and applications. Machine learning techniques: ANN for prediction of protein secondary structures and Hidden markov models for gene finding. Introduction to Systems Biology, Bioinformatics approaches for drug discovery.

TOTAL: 45 PERIODS

OUTCOMES:

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

- CO 1: classify amino acids and their properties
- CO 2: understand and analyze the existence of basic levels of protein structure
- CO 3: illustrate and analyze the tertiary structure of proteins
- CO 4: how these protein structures relate to protein functions
- CO5: have knowledge on basic tools to study protein – protein interaction

TEXT BOOKS:

1. Branden C. and Tooze J., “Introduction to Protein Structures” 2nd Edition, Garland Publishing, 1999.
2. Creighton T.E. “Proteins” 2nd Edition. W.H. Freeman, 1993.

REFERENCES:

1. Pennington, S.R and M.J. Dunn, “Proteomics: Protein Sequence to Function”. Viva Books, 2002
2. Liebler, “Introduction to Proteomics” Humana Press, 2002.

3. Voet D. and Voet G., “Biochemistry”. 3rd Edition. John Wiley and Sons, 2008.
4. Haggerty, Lauren M.“Protein Structure : Protein Science and Engineering”.Nova Science Publications, 2011.
5. Williamson, Mike “How Proteins Work”. Garland Science, 2012.

PROGRAMME OUTCOMES															
CO’s	**PO’s**												**PSO’s**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	1	-	-	2	2	-	-	-	-	-	-	-	1	2	-
2	2	2	1	3	3	-	-	-	-	-	-	1	2	2	-
3	3	3	2	3	3	-	-	-	-	-	-	1	2	2	-
4	3	3	2	2	3	2	2	-	-	-	-	3	2	2	2
5	3	3	2	3	1	2	1	-	-	-	1	3	2	2	2
Overall CO	**2.4**	**2.7**	**1.7**	**2.6**	**2.6**	**2**	**1.5**	**-**	**-**	**-**	**1**	**2.0**	**1.8**	**2**	**2**

Course 1-low, 2-medium, 3-high, ‘-“- no correlation
Note: The average value of this course to be used for program articulation matrix

PT 23904 PHARMACEUTICAL DOSAGE FORMS L T P C
3 0 0 3

OBJECTIVE

The aim of the course is to provide knowledge on the formulation and development of solid dosage forms

UNIT I PREFORMULATION STUDIES 9

Study of physical/physiochemical properties of drugs like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic properties and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc. and their influence on formulation. Stability studies: Basic concepts and objectives of stability study.

UNIT II LIQUID AND SEMI SOLID DOSAGE FORMS 9

Introduction, types of additives used, vehicles, stabilizers, preservatives, emulsifying agents, solubilizers, colors, flavours, manufacturing, packaging and evaluation of solutions, suspensions and emulsions. Definitions, types, mechanisms of drug penetration through skin, factors influencing penetration, semisolid bases and their selection. General formulation/ manufacture of semisolids, clear gels, evaluation and packaging.

UNIT III SOLID DOSAGE FORMS 9

Classification of different types of tablets, tablets equipments, granulation technology on large scale by various techniques. Advantages & disadvantages of capsule dosage form, extraction of gelatin, production of hard and soft gelatin capsules

UNIT IV PARENTERAL PRODUCTS 9

Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity & methods of its adjustment. Formulation details, containers and closures and their selection.

UNIT V PHARMACEUTICAL AEROSOLS AND COSMETICS 9

Definition, propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation. Cosmetics Formulation and preparation of dentifrices, hair creams, lipsticks, face powders, shaving preparations, skin creams, shampoos, hair dyes, depilatories, manicure preparations etc.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 understand various pre formulation characteristics of solid/ semi-solid dosage forms.
CO2 have knowledge on basic requirements to formulate and evaluate semi-solid dosage forms.
CO3 understand formulation and evaluation techniques of tablets and capsules.
CO4 explain formulation and evaluation of parenteral products
CO5 acquire knowledge on pharmaceutical aerosols and cosmetics

TEXTBOOKS

1. Pharmaceutical dosage forms: tablets, vol 3, rational design and formulation, larry l. augsburger, stephen w. hoag, by informa healthcare USA, inc, IIIrd edition, 2008.
2. Lachman, Leon et al. “The Theory and Practice of Industrial Pharmacy” IIIrd Ed., Varghese Publishing House, 1987.
3. Aulton, Michael E. “Pharmaceutics: The Science of Dosage Form Design” IInd Ed., Churchill Livingstone, 2002.

4. Allen, Loyd V.. “Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems” IX th Ed., Wolters Kluwer/LippinCott Williams & Wilkins, 2011.
5. H. A. Liberman,, L. Lachman, and J. B. Schwartz: Pharmaceutical dosage forms: Tablets, Vol. 1,2 and 3, IInd Edition Marcel Dekker, 1989.

REFERENCES

1. Remington’s Pharmaceutical Sciences, A. R. Gennaro Mac Pub. Co. Easton, Pennsylvania 1990
2. Coated Pharmaceutical Dosage Forms, K. H. Bauer, CRC Press, Boca Raton. Med Pharm.1998
3. Pharmaceutical Coating Technology, G. C. Cole, New York,1990.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	3	1	1	2	3	-	1	1	2	1	2	3	2	3
2	3	2	1	2	3	3	3	1	-	1	2	1	3	3	1
3	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
4	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
5	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
AVg.	2.80	2.80	1.00	1.80	2.80	2.40	1.50	1.60	1.00	1.80	1.20	1.50	3.00	2.20	1.40

1-low, 2-medium, 3-high, ‘-“- no correlation between CO and PO
* upto 2 decimals

PT23015 DRUG DELIVERY SYSTEMS L T P C
3 0 0 3

OBJECTIVE

The course aims to study the importance and applications of various drug delivery systems

UNIT I SUSTAINED RELEASE FORMULATIONS 9

Introduction, concept advantages and disadvantages. Physicochemical and biological properties of drugs relevant to sustained release formulations.

UNIT II TRANSDERMAL DRUG DELIVERY SYSTEMS 9

Permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers.

UNIT III PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS 9

Approaches for injectable controlled release formulations and development of Implantable drug delivery systems**.**

UNIT IV TARGETED DRUG DELIVERY SYSTEMS 9

Concept. Advantages and disadvantages, biological processes and events involved in drug targeting, nanoparticles, liposomes, resealed erythrocytes, microspheres, and monoclonal antibodies.

UNIT V FUTURE DIRECTIONS OF DRUG DELIVERY AND TARGETING 9

Plasmid based Gene therapy, Protein delivery system, Nucleic acids delivery, Integrating Drug Discovery and delivery and New Generation Technology.

TOTAL: **45 HOURS**

OUTCOME

CO1 explain the principles and technology used in the design of sustained release and controlled release drug delivery systems
CO2 explain the formulation and characterization of transdermal drug delivery systems
CO3 discuss various approaches for the development of parenteral drug delivery systems
CO4 discuss various approaches for the development of targeted drug delivery systems
CO5 understand the various approaches involved in protein and peptide drug delivery

TEXTBOOKS

1. Binghe wang, Teruna Siahaan and Richard A Soltero “Drug delivery principles and applications” John wiley and Sons Inc, 2005.
2. Junginger H.E, “Drug Targeting and Delivery- concepts in dosage form design”, Ellis Harwood series in Pharmaceutical Technology, 1992

REFERENCES

1. S.P.Vyas and R.K.Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi,First edition 2002.Remington: The science and practice of pharmacy, 20th edition Pharmaceutical Science (RPS)
2. Theory And Practice Of Industrial Pharmacy by Liberman & Lachman,2014
3. Pharmaceutics-the science of dosage form design by M.E.Aulton, Churchill livingstone, 2001
4. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea & febiger, Philadelphia, 5th edition, 2005.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	1	1	2	2	2-	1	-	-	-	-	2	1	1	3	3
2	3	1	2	2	3	-	1	-	-	-	-	2	1	1	3
3	2	1	1	-	3	-	1	-	-	-	-	2	1	-	3
4	3	1	2	2	3	-	1	-	-	-	-	2	1	1	3
5	3	1	2	2	3	-	1	-	-	-	-	2	1	1	3
Avg.	2.40	1.00	1.80	2.00	3.00	1.00	1.00	-	-	-	2.00	1.80	1.00	1.50	3.00

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals

PT23018 PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER L T P C
3 0 0 3

OBJECTIVE

To study about various processes involved from candidate drug selection to completion of 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), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

UNIT II PRE-FORMULATION STUDIES 9

Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility; Techniques for the study of Crystal properties and polymorphism; Pre-formulation protocol, Stability testing during product development.

UNIT III PILOT PLANT SCALE UP 9

Concept, 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. New era of drug products: opportunities and challenges.

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 test: Containers, closures and secondary packing materials.

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: 45 PERIODS

OUTCOME

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

CO1 Define and illustrate the regulatory requirements of drug discovery and development
CO2 Explain the concept of preformulation studies for various formulations
CO3 Explain the design of pilot plant and product scale up
CO4 Describe various pharmaceutical packaging systems and assess their quality
CO5 Explain the concept of technology transfer and their importance

TEXTBOOK

1. O'Donnell JJ, Somberg J, Idemyor V, O'Donnell JT, editors. Drug Discovery and Development. CRC Press; 2019 Nov 21.

REFERENCES

1. Hariharan D. Formulation and Evaluation of Bioequivalent Product for Viloxazine Sustained Release Tablets
2. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms--tablets/edited by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz.

3. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn. Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia. 1995
4. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

- Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1.	2	2	2	2	3	2	2	-	2	2	2	3	3	3	3
2.	2	2	2	2	3	2	2	-	2	2	2	3	3	3	3
3.	2	2	2	2	3	2	2	-	2	2	2	3	3	3	3
4.	2	2	2	2	3	2	2	-	2	2	2	3	3	3	3
5.	2	2	2	2	3	2	2	-	2	2	2	3	3	3	3
Avg	2	2	2	2	3	2	2	-	2	2	2	3	3	3	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO* upto 2 decimals
Note: The average value of this course is to be used for program articulation matrix.

PT 23022 PROCESS ANALYTICAL TECHNOLOGY IN BIOLOGICAL MANUFACTURING **L T P C 3 0 0 3**

OBJECTIVE

The Course aims to provide information on various analytical and chemometric techniques.

UNIT I PROCESS ANALYTICAL TECHNOLOGIES FOR IMPURITIES AND POLYMORPHISM 9

Importance of PAT – Quality of medicines - Qualitative and quantitative analysis of Active Pharmaceutical Ingredients, Formulation Excipients, proteins, nucleic acids, polysaccharides and small molecules such as antibiotics, vitamins, natural products etc.

UNIT II DEVELOPMENT AND APPLICATION OF MODERN ANALYTICAL INSTRUMENTATION: 9

FT-IR - TGA - UV-VIS-Spectrophotometry – Zeta potential measurement - Electrophoretic techniques; Capillary electrophoresis, Gel electrophoresis, PAGE; native, SDS, 2D PAGE, TGGE, DGGE, PULSE, Isoelectric focusing

UNIT III QUALITY BY DESIGN CONCEPT 9

QbD for Drug Discovery and Formulation Development – ICH Guidelines - Key steps for implementing QbD - quality target product profile (QTPP) - Identifying QTPP – Critical Quality Attributes (CQA) – Quality risk and quality risk management (QRM) – Definition of Process Design Spaces – Defining Process Control Strategy - FDA's QbD pilot program for biopharmaceuticals

UNIT IV APPLICATIONS OF CHEMOMETRIC TECHNIQUES 9

External variables on calibration – Multiplicative influential mode – Composition related influential mode – Loading space standardization - Extended Loading Space standardization – Spectral calibration Issues – Principal Component Analysis – Smoothed PCA

UNIT V PAT AND ADVANCED PROCESS CONTROL 9

Models for critical attributes –critical parameters – Continuous data quality monitoring and verification – Univariate –Multivariate – Real time quality control using spectral data – Integrated data management – Closed loop control – Advanced PAT tools

TOTAL: 45 PERIODS

OUTCOME

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

CO1 carry out characterization studies for API and excipients
CO2 explain the applications of electrophoretic techniques
CO3 understand the role of QbD in drug discovery
CO4 understand the concept of Principal component analysis
CO5 gain knowledge on PAT tools

REFERENCES

1. ICH, Q8(R1): Pharmaceutical Development, International Conference on Harmonisation; 2009; Geneva, Switzerland.
2. ICH, Q10: Pharmaceutical Quality Systems, International Conference on Harmonisation. 2009; Geneva, Switzerland.
3. ICH, Q9: Quality Risk Management, International Conference on Harmonisation; 2005; Geneva, Switzerland.
4. PDA, TR42. Process Validation of Protein Manufacturing. Parenteral Drug Association, Bethesda (MD), PDA Journal59; 2005; supplement 4.
5. ICH, Q6A: Specifications, test procedures and acceptance criteria for new drug substances and new drug products: chemical substances. In: International Conference on Harmonisation;2000; Geneva, Switzerland.

6. FDA. Guidance for industry, PAT--a framework for innovative pharmaceutical development, manufacturing, and quality assurance. Rockville (MD); 2004.

MAPPING OF COs WITH POs AND PSOs

- Every course outcome must be mapped with 1,2,3 scale against POs and PSOs

COURSE ARTICULATION MATRIX

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
2	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
3	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
4	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
5	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3
AVg.	2	2	2	2	2	2	1	-	-	-	-	2	3	2	3

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO

* upto 2 decimals

Note: The average value of this course is to be used for program articulation matrix.

PT23S02 MIND TO MARKETING STRATEGIES L T P C
3 0 0 3

COURSE OUTLINE

This course will discuss marketing in Pharmaceutical Industry as well as a range of real life current and classical examples & cases to help participants improve their strategic marketing thinking and activation skills.

OBJECTIVE

The objectives of this course are to:

- Understand the basic framework, transformation processes and their extensions in relation to pharma operations
- understand the concept of an innovative operations strategy planning and management of Pharmaceuticals
- provide the students exposure to modern marketing concepts, tools, and techniques, and help them develop abilities and skills required for the performance of marketing functions in industry.

UNIT I MARKET OPPORTUNITY RECOGNITION AND EVALUATION 9 HOURS

Marketing as strategy in Pharmaceutical Industry - Understanding new era - organizations and the marketing environment today, the role of market orientation, technological advances, global marketing imperative, marketing ethics & social responsibility. Internal analysis, External analysis. The marketing information system, Buyer behaviour, Segmentation & targeting. Internal analysis, External analysis, the marketing information system, Buyer behavior, Segmentation & targeting.

UNIT II BROADER CONCERNS IN THE PHARMACEUTICAL INDUSTRY 9 HOURS

Stake holder Concerns & issues Sustainable & Green marketing New paradigms for Organizations & Consumers in Pharmaceutical Industry

UNIT III PRODUCTS, SERVICES & INNOVATION 9 HOURS

Marketing's role in new product/new service development in Pharmaceutical Industry - Managing across the life cycle - Marketing channels and the marketing ecosystems

UNIT IV MARKETING PLANNING AND EXECUTION 9 HOURS

Different approaches to planning for Marketing in Pharmaceutical Industry - Forecasting & Scenario planning in Pharmaceutical Industry - Marketing mix & Resource allocation in Pharmaceutical Industry - Marketing communication – Multi channel integration in Pharmaceutical Industry - Pricing, Branding, Value driven Relationship

UNIT V NEW CHALLENGES IN PHARMACEUTICAL INDUSTRY 9 HOURS

Marketing & the creative industries - Marketing & the new media - Marketing to the bottom of the pyramid - Frugal & grass root Marketing

TOTAL: 45 HOURS

TEXT BOOK

1. Phillip Kotler, Kevin Lane Keller Marketing Management, 15th edition. Pearson Education India, 2016.

REFERENCES:

1. Production and Operations Management by Aswathappa and Bhat
2. Douglas J. Dalrymple, William L. Cron, Thomas E. De Carlo. "Sales Management", John Wiley & Sons, New Jersey, USA. 2004

COURSE ARTICULATION MATRIX
MAPPING OF COs WITH POs AND PSOs

PROGRAMME OUTCOMES															
CO's	**PO's**												**PSO's**		
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**	**3**
1	2	2	1	-	-	-	-	-	-	-	-	1	1	3	-
2	3	3	2	2	2	-	-	-	-	-	-	2	3	3	2
3	3	3	3	3	2	-	-	1	-	-	-	3	3	3	2
4	3	3	3	2	2	2	2	1	1	-	-	1	3	3	2
5	3	2	3	3	2	3	2	1	1	-	1	1	1	3	-
Overall CO	**2.8**	**2.6**	**2.4**	**2.5**	**2.0**	**2.5**	**2**	**1**	**1**	**-**	**1**	**1.6**	**2.4**	**3**	**2**

PT23E06 REGULATORY ASPECTS OF MEDICAL DEVICES L T P C
3 0 0 3

OBJECTIVES

- Identify the Medical Device Regulatory Framework for any given country based upon device type and create potential regulatory pathway strategies to gain market entry.
- Identify and incorporate basic risk management concepts into the Quality Management System and medical device design throughout the medical device product lifecycle.
- Be familiar with the use of harmonized approaches and standards leveraged in device design and Quality Management Systems.
- Understand the post-marketing requirements associated with medical devices and how to communicate with competent authorities when post-market issues arise.

UNIT I OVERVIEW OF MEDICAL DEVICES 9

Definition, Classification, Difference between drug and medical device, In-vitro diagnostics, Labelling of medical devices and in-vitro diagnostics, Overview of combination products.

UNIT II MEDICAL DEVICE REGULATION 9

Medical Device regulation in India (CDSCO), Medical Device regulation in USA (USFDA), Medical Device regulation in European Union (EMA)/European Medical Device Regulations, Medical Device Regulations-WHO.

UNIT III REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND APPROVALS: 9

Regulatory requirements of biocompatibility of medical devices (ISO10993), Clinical Investigation of medical devices, Regulation of investigational medical devices, Post marketing surveillance and materiovigilance, Dossier preparation of common technical document (CTD) and eCTD submission, How to obtain a license to manufacture a medical device, Import and export of medical device and in-vitro diagnostics.

UNIT IV STANDARDS OF MEDICAL DEVICES, QUALITY MANAGEMENT SYSTEMS 9

National and international standard system for medical devices, Performance evaluation of medical devices with reference laboratories in India, Material selection for medical devices, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Documentation Practice (GDP).

UNIT V MEDICAL DEVICE SAFETY AND RISK MANAGEMENT: 9

Quality management system for medical devices, Total product life cycle, Effective of medical device, Adulteration, Misbranding.

TOTAL: 45 HOURS

OUTCOMES

The course will enable the students to acquire

CO1: the core concepts of the global medical device regulatory framework
CO2: a foundation for the practical application of the regulatory framework
CO3: exposure to actual application of the regulations
CO4: understanding of core concepts embedded within the regulations
CO5: skills to apply the regulatory framework in real world scenarios

REFERENCES

1. Medical Devices Rules, 2017, Related Guidance documents available at CDSCO websites.
2. US-FDA Regulation of Medical Devices
3. European Union Regulation of Medical Devices
4. Medical Device regulations: global overview and guiding principles, World Health Organization.

5. Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo Medical Devices: Regulations, Standards and Practices; 1st Edition, Imprint: Woodhead Publishing; Hardcover ISBN: 9780081002896
6. Jagdish Chaturvedi, “Inventing Medical Devices: A Perspective from India”, Create space Independent Pub; (ISBN-10: 1519467184; ISBN-13: 978-1519467188).
7. John J. Tobin, Gary Walsh, “Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices” ISBN: 978-3-527-31877-3; Wiley-Blackwell publisher; 2008.

PT23904 PHARMACEUTICAL DOSAGE FORMS L T P C
3 0 0 3

OBJECTIVE

The aim of the course is to provide knowledge on the formulation and development of solid dosage forms

UNIT I PREFORMULATION STUDIES 9

Study of physical/physiochemical properties of drugs like physical form, particle size, shape, density, wetting, dielectric constant, solubility, dissolution, organoleptic properties and their effect on formulation, stability and bioavailability. Study of chemical properties of drugs like hydrolysis, oxidation, reduction, racemization, polymerization etc. and their influence on formulation. Stability studies: Basic concepts and objectives of stability study.

UNIT II LIQUID AND SEMI SOLID DOSAGE FORMS 9

Introduction, types of additives used, vehicles, stabilizers, preservatives, emulsifying agents, solubilizers, colors, flavours, manufacturing, packaging and evaluation of solutions, suspensions and emulsions. Definitions, types, mechanisms of drug penetration through skin, factors influencing penetration, semisolid bases and their selection. General formulation/ manufacture of semisolids, clear gels, evaluation and packaging.

UNIT III SOLID DOSAGE FORMS 9

Classification of different types of tablets, tablets equipments, granulation technology on large scale by various techniques. Advantages & disadvantages of capsule dosage form, extraction of gelatin, production of hard and soft gelatin capsules

UNIT IV PARENTERAL PRODUCTS 9

Preformulation factors, routes of administration, water for injection, pyrogenicity, non-aqueous vehicles, isotonicity & methods of its adjustment. Formulation details, containers and closures and their selection.

UNIT V PHARMACEUTICAL AEROSOLS AND COSMETICS 9

Definition, propellants, general formulation, manufacturing, packaging methods, pharmaceutical applications and evaluation. Cosmetics Formulation and preparation of dentifrices, hair creams, lipsticks, face powders, shaving preparations, skin creams, shampoos, hair dyes, depilatories, manicure preparations etc.

TOTAL: 45 PERIODS

OUTCOME

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

CO1 understand various pre formulation characteristics of solid/ semi-solid dosage forms.
CO2 have knowledge on basic requirements to formulate and evaluate semi-solid dosage forms.
CO3 understand formulation and evaluation techniques of tablets and capsules.
CO4 explain formulation and evaluation of parenteral products
CO5 acquire knowledge on pharmaceutical aerosols and cosmetics

TEXTBOOKS

1. Pharmaceutical dosage forms: tablets, vol 3, rational design and formulation, larry l. augsburger, stephen w. hoag, by informa healthcare USA, inc, IIIrd edition, 2008.
2. Lachman, Leon et al. “The Theory and Practice of Industrial Pharmacy” IIIrd Ed., Varghese Publishing House, 1987.
3. Aulton, Michael E. “Pharmaceutics: The Science of Dosage Form Design” IInd Ed., Churchill Livingstone, 2002.
4. Allen, Loyd V.. “Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems” IX th Ed., Wolters Kluwer/LippinCott Williams & Wilkins, 2011.

5. H. A. Liberman,, L. Lachman, and J. B. Schwartz: Pharmaceutical dosage forms: Tablets, Vol. 1,2 and 3, IInd Edition Marcel Dekker, 1989.

REFERENCES

1. Remington's Pharmaceutical Sciences, A. R. Gennaro Mac Pub. Co. Easton, Pennsylvania 1990
2. Coated Pharmaceutical Dosage Forms, K. H. Bauer, CRC Press, Boca Raton. Med Pharm.1998
3. Pharmaceutical Coating Technology, G. C. Cole, New York,1990.

Course Articulation Matrix: MAPPING OF COs WITH POs AND PSOs

CO	PO												PSO		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
1	2	3	1	1	2	3	-	1	1	2	1	2	3	2	3
2	3	2	1	2	3	3	3	1	-	1	2	1	3	3	1
3	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
4	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
5	3	3	1	2	3	2	1	2	1	2	1	-	3	2	1
AVg.	2.80	2.80	1.00	1.80	2.80	2.40	1.50	1.60	1.00	1.80	1.20	1.50	3.00	2.20	1.40

1-low, 2-medium, 3-high, '-"- no correlation between CO and PO
* upto 2 decimals