4-Year Bachelor of Pharmacy (B.Pharm) Curriculum and Syllabus

Course Structure

Eighth Semester

Course Code	Name of the course	No.of hours	Tutorial	Credit points
TIU-UBP-801T	Biostatistics and Research Methodology- Theory	3	1	4
TIU-UBP-802T	Social and Preventive Pharmacy- Theory	3	1	4
TIU-UBP-803ET	Pharma Marketing Management- Theory	3+3 =6	1+1= 2	4+4= 8
TIU-UBP-804ET	Pharmaceutical Regulatory Science- Theory			
TIU-UBP-805ET	Pharmacovigilance- Theory			
TIU-UBP-806ET	Quality Control and Standardization of Herbals- Theory			
TIU-UBP-807ET	Computer Aided Drug Design- Theory			
TIU-UBP-808ET	Cell and Molecular Biology- Theory			
TIU-UBP-809ET	Cosmetic Science- Theory			
TIU-UBP-810ET	Experimental Pharmacology- Theory			
TIU-UBP-811ET	Advanced Instrumentation Techniques- Theory			
TIU-UBP-812ET	Dietary Supplements and Nutraceuticals- Theory			
TIU-UBP-813PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

B.PHARM SYLLABUS

SEMESTER VIII

Biostatistics and research methodology –Theory (TIU-UBP-801T)

Contact hours: 45 hrs

Course Objectives

To know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment).
To administer the knowledge and techniques of statistical techniques in solving the problems and in research methodology.
To understandthe various statistical techniques to solve statistical problems.
To gain knowledge on Probability, Regression, correlation, parametric and non-parametric tests.

Course Outcomes

Upon completion of the course, the student shall be able

CO1.**Explain** the measures of central tendency and measures of dispersion

CO2.**Identify** and solve various statistical problems

CO3.**Ennumarate** statistical techniques for solving their problems, trial concept with study design

CO4.Compare parametric and non-parametric tests.

CO5.**Demonstrate** mean, median, mode, measures of dispersion

Course Content **45 Hours**

Unit-I **10 Hours**

- **Introduction**: Statistics, Biostatistics, Frequency distribution
- **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples
- **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceuticalproblems
- **Correlation**: Definition, Karl Pearson's coefficient of correlation, Multiple correlationPharmaceuticals examples

Unit-II **10 Hours**

- **Regression**: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples
- **Probability**: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties – problemsSample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standarderror of mean (SEM) - Pharmaceutical examples

- **Parametric test**: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One wayand Two way), Least Significance difference

Unit-III **10 Hours**

- **Non-Parametric tests**: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallistest, Friedman Test156
- **Introduction to Research**: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism
- **Graphs**: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph
- **Designing the methodology**: Sample size determination and Power of a study, Reportwriting and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.
- **Unit-IV 8 Hours**
- **Blocking and confounding system for Two-level factorialsRegression modeling**: Hypothesis testing in Simple and Multiple regression models
- **Introduction to Practical components of Industrial and Clinical Trials Problems:** Statistical Analysis Using Excel, SPSS, MINITAB, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-IV **8Hours**

Blocking and confounding system for Two-level factorials

- **Regression modeling:** Hypothesis testing in Simple and Multiple regression models **Introduction to Practical components of Industrial and Clinical Trials Problems:** Statistical Analysis Using Excel, SPSS, MINITAB ® , DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7Hours**

- **Design and Analysis of experiments**: Factorial Design: Definition, 22, 23design. Advantage of factorial design
- **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton,publisher Marcel

Dekker Inc. NewYork.

2. Fundamental of Statistics – Himalaya Publishing House- S.C. Guptha

3. Design and Analysis of Experiments –PHI Learning Private Limited, R.Pannerselvam,

4. Design and Analysis of Experiments – Wiley Students Edition,Douglas and C. Montgomery

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and Pos		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Explain** the measures of central tendency and measures of dispersion	PO2, PO3, PO6, PO8, PEO2, PEO3, PEO1
CO2	**Identify** and solve various statistical problems	PO2, PO3, PO6, PO8, PEO1, PEO2, PEO3
CO3	**Ennumarate** statistical techniques for solving their problems, trial concept with study design	PO2, PO3, PO4, PO6, PO8, PEO1, PEO2, PEO3
CO4	**Compare** parametric and non-parametric tests.	PO2, PO3, PO12, PO3, PO4, PO6, PO8
CO5	**Demonstrate** mean, median, mode, measures of dispersion	PO2, PO3, PO4, PO6, PO8, PO12, PEO1, PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-801T	Biostatistics and research methodology -Theory	-	3	3	2	-	3	-	3	-	-	-	2	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

SOCIAL AND PREVENTIVE PHARMACY- Theory (TIU-UBP-802T)

Contact hours: 45 hrs

Course Objectives

1. To acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide
2. To have a critical way of thinking based on current healthcare development.
3. To understand alternative ways of solving problems related to health and pharmaceutical issues

Course Outcomes

Upon completion of the course, the student shall be able

CO1.**Summarize** the concept of health and disease.

CO2. **Demonstrate** the relationship between food and health.

CO3.**Explain** socio cultural factors related to health and disease.

CO4. **Discuss** the impact of personal hygiene on health.

CO5. **Identify** the general principles of prevention and control of diseases.

Course Content **45 Hours**

UNIT-I **10 Hours**

Concept of health and disease:

Definition, concepts and evaluation of public health.

Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education:

Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health:

Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health:

personal hygiene and health care; avoidable habits

UNIT-II **10 Hours**

Preventive medicine:

General principles of prevention and control of diseases such ascholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chickenguinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer,drug addiction-drug substance abuse.

UNIT-III **10 Hours**

National health programs, its objectives, functioning and outcome of the following:

HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

UNIT IV **08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national programme.

UNIT V **07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Reference Books (Latest Editions)

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, SahaIndranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	Summarize the concept of health and disease.	PO1, PO11, PO12,
CO2	Demonstrate the relationship between food and health.	PO1, PO9, PO11, PO12
CO3	Explain Socio cultural factors related to health and disease.	PO1, PO9, PO11, PO12,
CO4	Discuss the impact of personal hygiene on health.	PO1, PO9, PEO1, PEO2
CO5	Identify the general principles of prevention and control of diseases.	PO1, PO2, PO5, PO9, PEO1, PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-802T	Social & Preventive Pharmacy-Theory	3	2	-	-	2	-	-	-	3	-	3	3	3	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

Pharma Marketing Management- Theory (TIU-UBP-803ET)
Contact hours: 45 hr

Course Objective:

1. To provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.
2. To develop skills related to selling and promotion of pharmaceutical products.
3. To have an overall ideas in different components of marketing like product, price, place and promotion.
4. To acquire ideas about the marketing strategies followed by market leader in pharmaceutical industries.

Course Outcomes

Upon completion of the course, the student shall be able

CO1. Understanding marketing concept and challenges in 21st century in Pharma industries.
CO2. Developing ideas of strategic planning and marketing Process related to pharma market.
CO3. Demonstrate the concept of market segmentation, targeting and positioning.
CO4. Recognize the importance of pricing, and pricing strategy of firms.
CO5. Understanding the role of marketing channels and distribution strategy.

CO6. Familiarity with the marketing promotion-mix, and effective communication strategy of firms

Course content-45 Hours

Unit-I Marketing: 6 Hrs
Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Unit- II Pharmaceutical market: 10 Hrs
Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation&targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market;Role of market research.

Unit-III Product decision: 7 Hrs
Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit IV- Promotion: 8 Hrs
Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit V- Pharmaceutical marketing channels: 8 Hrs
Designing channel, channel members, selecting the appropriate channel, conflict inchannels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):
Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit- VI Pricing: 10 Hrs
Meaning, importance, objectives, determinants of price; pricing methods and strategies,issues in price management in pharmaceutical industry.An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:
Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing;Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. DhruvGrewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. RajanSaxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S &Nanakamari, S: Marketing Managemnt:Global Perspective,

IndianContext,Macmilan India, New Delhi.

7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. SubbaRaoChanganti, Pharmaceutical Marketing in India (GIFT - Excel series) Excel Publications.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	Understanding marketing concept and challenges in 21st century in Pharma industries.	PO1, PO2, PO 10, PO12, PEO1
CO2	Developing ideas of strategic planning and marketing Process related to pharma market.	PO3, PO4,PO5, PEO2
CO3	Demonstrate the concept of market segmentation, targeting and positioning.	PO8, PO 10, PO12,
CO4	Recognize the importance of pricing, and pricing strategy of firms.	PO7, PO6, PO3, PO5
CO5	Understanding the role of marketing channels and distribution strategy	PO1, PO2, PO3, PO6
CO6	Familiarity with the marketing promotion-mix, and effective communication strategy of firms.	PO3, PO4, PO6, PO7, PO8

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-803ET	Pharma Marketing Management - Theory	2	2	2	3	2	2	3	2	-	3	-	3	3	3	-

1=weakly mapped

2= moderately mapped
3=strongly mapped

Pharmaceutical Regulatory Science –Theory (TIU-UBP-804ET)
Contact hours: 45 hr

Course Objectives

1. To know about the process of drug discovery and development.
2. To gain knowledge the regulatory authorities and agencies governing the manufacture and sale.
3. To have an overall idea about regulatory approval process and their registration in Indian and international markets.

Course Outcomes

Upon completion of the course, the student shall be able

CO1.**Describe** the stages of drug discovery, drug development process.

CO2.**Identify** the various regulatory authorities in different Describes and their drug approval processes.

CO3.**Explain** registration of Indian drug product in overseas market.

CO4.**Summarize** the clinical trials protocols and the concept of pharmacovigilance.

CO5.**Demonstrate** the various regulatory concepts relating to drug manufacturing and sale.

Course Content **45Hours**

Unit I **10Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II
10Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United Describes, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III
10Hours

Registration of Indian drug product in overseas market
Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical
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Document (eCTD), ASEAN Common Technical Document (ACTD) research.

Unit IV
08Hours
Clinical trials
Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance – safetymonitoring in clinical trials

Unit V
07Hours
Regulatory Concepts
Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):
1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, NiraliPrakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry andRobert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Healthcare Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard AGuarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / SandyWeinberg. By John Wiley &Sons.Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, andbiologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel andIsaderKaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory ComplianceBy Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I.Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Describe**the stages of drug discovery, drug development process.	PO1, PO12, PEO1, PEO2

CO2	**Identify** the various regulatory authorities in different Describes and their drug approval processes.	PO1, PO12, PEO2
CO3	**Explain**registration of Indian drug product in overseas market.	PO1, PO7,PO11, PO12,PEO1,PEO2
CO4	**Summarize** the clinical trials protocols and the concept of pharmacovigilance.	PO1, PO3, PO11,PO12,PEO1, PEO2, PEO3
CO5	**Demonstrate** the various regulatory concepts relating to drug manufacturing and sale.	PO1,PO11, PO12,PEO1,PEO2

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-804ET	Pharmaceutical Regulatory Science - Theory	3	-	2	-	-	-	2	-	-	-	2	3	3	3	2

1=weakly mapped
2= moderately mapped
3=strongly mapped

Pharmacovigilance- Theory (TIU-UBP-805ET)

Contact hours: 45 hrs

Course Objectives

1. To know the fundamentals about drug safety monitoring and thehistory and development of pharmacovigilance.

2. To administer the knowledge and techniques required Detection of new adverse drug reactions and their assessment
3. To understand theconcept of adverse drug reaction reporting systems and communication in pharmacovigilance.
4. To have an overall idea about the Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in Indiae.
5. To gain knowledge about ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning.

Course Outcomes

Upon completion of the course, the student shall be able

CO1. **Describe** the importance of drug safe monitoring.

CO2. **Demonstrate**dictionaries, coding and terminologies used in pharmacovigilance.

CO3. **Identify**new adverse drug reactions and their assessment.

CO4. **Summarize** the techniques of adverse drug reaction reporting systems

CO5.**Compare** the methods to generate safety data during pre-clinical, clinical and post approval phases of drugs' life cycle

CO6.**Demonstrate**case narratives of adverse events and analyse their quality**.**

Course Content 45 Hours

UNIT-I **10 Hours**

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

UNIT-II **10 Hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily Demonstrated doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance
- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme
- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

UNIT-III **10 Hours**

Vaccine safety surveillance
- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods
- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance
- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities &Media

UNIT IV **8 Hours**

Safety data generation
- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance
- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

UNIT V **7 Hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Reference Books (Latest Editions)

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones andBartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle,Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones&Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel,SeanHennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G.Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PKManna

Mapping between COs and Pos		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Describe** the importance of drug safe monitoring.	PO1, PO7, PO9, PO11, PEO3
CO2	**Demonstrate** dictionaries, coding and terminologies used in pharmacovigilance.	PO1, PO6, PO7, PO11, PEO2, PEO3
CO3	**Identify**new adverse drug reactions and their assessment.	PO1,PO2,PO3, PO6, PO9,PO11, PEO1,PEO2, PEO3
CO4	**Summarize** the techniques of adverse drug reaction reporting systems	PO1, PO2, PO3, PO4, PO8, PO11, PEO1, PEO2, PEO3
CO5	**Compare** the methods to generate safety data during pre-clinical, clinical and post approval phases of drugs' life cycle	PO1, PO3, PO4, PO5, PO8, PO11, PEO2, PEO3

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital p	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-805ET	Pharmacovigilance-Theory	3	2	3	2	2	3	2	2	2	-	3	-	2	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

Quality Control and Standardization of Herbals- Theory (TIU-UBP-806ET)
Contact hours: 45 hr

Course Objectives

1. To know the various guidelines about evaluation and quality control of herbal drugs.
2. To understand the different methods of evaluation and standardization of herbal drugs.
3. To gain knowledge about the method of quality assurance in herbal drug industry.
4. To know the regulatory approval process of herbal medicines.
5. To have an understanding of the requirements of GMP with respect to herbal drugs.

Course Outcomes

Upon completion of the course, the student shall be able

CO1. Describe the WHO guidelines governing the quality control of herbal drugs.

CO2.Classify the various aspects of quality assurance in herbal drug industry such as cGMP, GAP, GMP, GLP and WHO guidelines on cGMP and GACP for medicinal plants.

CO3. Discuss the EU and ICH guidelines related to quality control and research guidelines for assessing the safety and efficacy of herbals.

CO4. Demonstrate theGMP requirements, methods of stability testing and the documentation for new drug application and export registration of herbal products.

CO5.Recognize the regulatory requirements of herbal medicines and the use of chemical and biological markers in herbal drug standardization.

Course Content **45 Hours**

UNIT-I **10 Hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms
WHO guidelines for quality control of herbal drugs.
Evaluation of commercial crude drugs intended for use

UNIT-II **10 Hours**

Quality assurance in herbal drug industryof cGMP, GAP, GMP and GLP in traditional system of medicine.
WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

UNIT-III **10 Hours**

EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

UNIT IV **08 Hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.
Preparation of documents for new drug application and export registration
GMP requirements and Drugs & Cosmetics Act provisions.

UNIT V **07 Hours**

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems
Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products

Reference Books (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998.
9. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
10. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
11. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.

12. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
13. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	Describe the WHO guidelines governing the quality control of herbal drugs.	PO1, PO2, PO3,PO6, PO7,PO8,PO9, PO11, PO12, PEO1, PEO2
CO2	Classify the various aspects of quality assurance in herbal drug industry such as cGMP, GAP, GMP, GLP and WHO guidelines on cGMP and GACP for medicinal plants.	PO1, PO2, PO3,PO7,PO8,PO9, PO11, PO12, PEO1, PEO2
CO3	Discuss the EU and ICH guidelines related to quality control and research guidelines for assessing the safety and efficacy of herbals.	PO1,PO2, PO3, PO5,PO6, PO7,PO8,PO9, PO11, PO12, PEO1, PEO2
CO4	Demonstrate theGMP requirements, methods of stability testing and the documentation for new drug application and export registration of herbal products.	PO1, PO2, PO3,PO6, PO7,PO8,PO9, PO11, PO12, PEO1, PEO2
CO5	Recognize the regulatory requirements of herbal medicines and the use of chemical and biological markers in herbal drug standardization.	PO1, PO2,PO8, PO11, PO12, PEO1, PEO2

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-806ET	Quality Control and Standardization of Herbals-Theory	3	3	3	-	2	2	3	3	3	-	3	3	3	3	-

1=weakly mapped
2= moderately mapped
3=strongly mapped

Computer Aided Drug Design- Theory (TIU-UBP-807ET)
Contact hours: 45 hrs

Course Objectives

Upon completion of the course, the student shall be able to understand

1. Design and discovery of lead molecules
2. The role of drug design in drug discovery process
3. The concept of QSAR and docking
4. Various strategies to develop new drug like molecules.
5. The design of new drug molecules using molecular modeling software

Course Outcomes

Upon completion of the course, the student shall be able

CO1.**Summerize**different stages of drug discovery with special focus on in silico drug designing

CO2.**Compare**different techniques, advantage and disadvantages of ligand based and structure based drug design.

CO3.**Identify** and **implement** the uses of different database and tools for in silico drug design

CO4. **Compute** and **interpret** different statistical model as molecular prediction tools

Course Content **45 Hours**

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening,

Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.Analog Based Drug Design: Bioisosterism , Classification, Bioisosteric replacement. Any three case studies .

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. De novo drug design.

UNIT-IV **08 Hours**

Informatics & Methods in drug design Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.

3. Delgado JN, Remers WA eds "Wilson &Gisvolds'sTextBook of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and Pos		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Summerize**different stages of drug discovery with special focus on in silico drug designing	PO 1, PO 2, PO3, PEO1, PEO2, PEO3
CO2	**Compare** different techniques, advantage and disadvantages of ligand based and structure based drug design.	PO 1, PO 2, PO3, PEO1, PEO2, PEO3
CO3	**Identify** and **implement** the uses of different database and tools for in silico drug design	PO 1, PO 2, PO3, PEO1, PEO2, PEO3
CO4	**Compute** and **interpret** different statistical model as molecular prediction tools	PO 1, PO 2, PO3, PO4,PO5, PEO1, PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-	Computer aided	3	3	3	2	2	-	-	-	-	-	-	-	3	3	

807ET	drug design - Theory															3

1=weakly mapped;
2= moderately mapped;
3=strongly mapped

Cell and molecular biology- Theory (TIU-UBP-808ET)
Contact hours: 45 hrs

Course Objectives

1.To know history of cell and molecular biology, cellular functioning and composition.
2.To administer the knowledge of cell and molecular biology to examine protein structure and function.
3.To understand the basic molecular genetic mechanisms.
4.To gain knowledge Cell Cycle, cellular membrane structure and function.

Course Outcomes

Upon completion of the course, the student shall be able
CO1.**Classify** types of cells, types of RNA, types of proteins
CO2.**Identify** and solve various statistical problems, flow of molecular information
CO3.**Ennumarate** properties of cell organelles and cell cycle, receptors for cell signals, regularities in protein pathways
CO4.Compare different protein structures, DNA and RNA, transcription and translation,
CO5. **Demonstrate** transcription, translation, mitosis, meiosis

Course Content **45 Hours**

Unit I **10Hours**
a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
c) Properties of cells and cell membrane.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**
a) DNA and the Flow of Molecular Information
b) DNA Functioning
c) DNA and RNA
d) Types of RNA
e) Transcription and Translation

Unit III **10 Hours**
a) Proteins: Demonstrated **and** Amino Acids

b) Protein Structure
c) Regularities in Protein Pathways
d) Cellular Processes
e) Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

a) Science of Genetics
b) Transgenics and Genomic Analysis
c) Cell Cycle analysis
d) Mitosis and Meiosis
e) Cellular Activities and Checkpoints

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn.,Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
13. RA Goldshy et. al., :Kuby Immunology.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and Pos		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Measures** of central tendency and measures of dispersion	PO2, PO3, PO6, PO8, PEO2, PEO3, PEO1

CO2	**Identify** and **solve** various statistical problems	PO2, PO3, PO6, PO8, PEO1, PEO2, PEO3
CO3	**Ennumarate** statistical techniques for solving their problems	PO2, PO3, PO4, PO6, PO8, PEO1, PEO2, PEO3
CO4	**Compare** parametric and non-parametric tests.	PO2, PO3, PO12, PO3, PO4, PO6, PO8
CO5	**Demonstrate** mean, median, mode, measures of dispersion	PO12, PO2, PO3, PO4, PO6, PO8, PO12, PEO1, PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-808ET	Cell and molecular biology - Theory	-	3	3	2	-	3	-	3	-	-	-	2	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

COSMETIC SCIENCE – Theory (TIU-UBP-809ET)
Contact hours: 45hr

Course Objectives

1. To know the fundamentals about cosmetics and cosmeceutical agents.
2. To administer the knowledge and techniques required for the formulation of cosmetics for hair, skin and dental products.
3. To have an overall idea about the use of herbs in cosmetics.
4. To gain knowledge about the various cosmetic evaluation procedures.

Course Outcomes

Upon completion of the course, the student shall be able

CO1. **Explain** the concept of cosmetics, anatomy of the skin, hair and oral cavity, as well as general excipients used in cosmetics.
CO2. **Summarize** the formulation of cosmetics for skin and hair along with their manufacturing and evaluation.
CO3. **Recognise** the role of herbs in cosmetics.
CO4. **Describe** the principles of cosmetic evaluation.
CO5. **Identify** the various cosmetic problems relating to skin, hair and oral cavity.

Course Content **45 Hours**

UNIT I **10 Hours**

Classification of cosmetic and cosmeceutical products
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs
Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application
Skin: Basic structure and function of skin.
Hair: Basic structure of hair. Hair growth cycle.
Oral Cavity: Common problem associated with teeth and gums**.**

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:
Face wash,
Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmecuticals.
Antiperspants& deodorants- Actives & mechanism of action.
Principles of formulation and building blocks of Hair care products:
Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.Hair oils.
Chemistry and formulation of Para-phylenediamine based hair dye.
Principles of formulation and building blocks of oral care products:
Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.
Role of herbs in cosmetics:
Skin Care: Aloe and turmeric
Hair care: Henna and amla.
Oral care: Neem and clove
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin cream and toothpaste**.**

UNIT IV **08 Hours**.

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurementof TEWL, Skin Color, Hair tensile strength, Hair combing propertiesSoaps,and syndet bars. Evolution and skin benfits.

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.
Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes
Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.
Antiperspirants and Deodorants- Actives and mechanism of action

Reference books

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) Text book of cosmelicology by Sanju Nanda &Roop K. Khar, Tata Publishers.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and Pos		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Explain** the concept of cosmetics, anatomy of the skin, hair and oral cavity, as well as general excipients used in cosmetics.	PO1, PO4, PO12, PEO1, PEO2,PEO3
CO2	**Summarize** the formulation of cosmetics for skin and hair along with their manufacturing and evaluation.	PO1, PO4, PO12, PEO1,PEO3
CO3	**Recognise** the role of herbs in cosmetics.	PO1, PO4, PO11, PO12, PEO1, PEO2,
CO4	**Describe** the principles of cosmetic evaluation.	PO1,PO12,PEO1, PEO2,PEO3
CO5	**Identify** the various cosmetic problems relating to skin, hair and oral cavity.	PO1,PO2,PO6,PO11, PO12,PEO2,PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-809ET	Cosmetic Science - Theory	3	2	-	2	-	2	-	-	-	-	2	3	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

Experimental Pharmacology- Theory (TIU-UBP-810ET)
Contact hours: 45 hrs

Course Objectives

1. To gain knowledge about the applications of various commonly used laboratory animals.
2. To appreciate and demonstrate the various screening methods used in preclinical research
3. To appreciate and demonstrate the importance of biostatistics and research methodology
4. To design and execute a research hypothesis independently

Course Outcomes

Upon completion of the course, the student shall be able

CO1. **Describe** the laboratory animals and the regulatory guidelines for proper animal care and handling.
CO2. **Summarize** the preparation before preclinical research and explain the preclinical screening methods for pharmacological activities.
CO3.**Explain** the application of research methodology and biostatistics in preclinical studies

Course Content **45 Hours**

UNIT-I **8 Hours**
Laboratory Animals:

Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals.Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

UNIT-II **10 Hours**

Preclinical screening models

Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups.Rationale for selection of animal species and sex for the study.

Study of screening animal models for

Diuretics, nootropics, anti-Parkinson's,antiasthmatics,

Preclinical screening models: for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

UNIT-III **11 Hours**

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics

UNIT IV **11 Hours**

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants

Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

UNIT V **05 Hours**

Research methodology and Bio-statistics

Selection of research topic, review of literature, research hypothesis and study design

Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data

Reference Books (Latest Editions)

1. Fundamentals of experimental Pharmacology- byM.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Describe** the laboratory animals and the regulatory guidelines for proper animal care and handling.	PO1, PO4, PO11, PO12, PEO1, PEO2, PEO3
CO2	**Summarize** the preparation before preclinical research and explain the preclinical screening methods for pharmacological activities.	PO1, PO2, PO3, PO4, PO5, PO11, PO12, PEO1, PEO2, PEO3
CO3	**Explain** the application of research methodology and biostatistics in preclinical studies	PO1, PO2, PO3,PO4, PO5, PO6, PO11, PO12, PEO1,PEO2, PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-810ET	Experimental Pharmacology-Theory	3	3	3	3	2	2	-	-	-	-	3	3	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

ADVANCED INSTRUMENTATION TECHNIQUES- Theory (TIU-UBP-811ET)
Contact hours: 45 hr

Course Objectives

1. To understand the advanced instruments used and its applications in drug analysis
2. To understand the chromatographic separation and analysis of drugs.

3. To understand the calibration of various analytical instruments.
4. To know and Describe analysis of drugs using various analytical instruments.

Course Outcomes

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

CO1. **Understand** the advanced instruments used and its applications in drug analysis
CO2. **Understand** the chromatographic separation and analysis of drugs.
CO3. **Understand** the calibration of various analytical instruments
CO4. **Understand** and Describe analysis of drugs using various analytical instruments.

Course Content

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy
Principles of ^{1}H-NMR and ^{13}C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications
Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**
Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)
X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X- ray Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.

UNIT-III **10 Hours**
Calibration and validation-as per ICH and USFDA guidelines
Calibration of following Instruments
Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **8 Hours**
Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radioimmuno assay
Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V **7 Hours**
Hyphenated techniques: LC-MS/MS, GC-MS/MS, HPTLC-MS

Reference Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical ChemistrybyA.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and Pos		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Understand** the advanced instruments used and its applications in drug analysis	PO1, PO2, PO5, PO6, PO7, PO10, PO11, PEO1,PEO2,PEO3
CO2	**Understand** the chromatographic separation and analysis of drugs	PO1, PO2, PO5, PO6, PO10, PO11, PEO1,PEO2,PEO3
CO3	**Understand**thecalibration of various analytical instruments	PO1, PO2, PO3, PO4, PO5, PO6, PO7, PO8, PO10, PO11, PEO1,PEO2,PEO3
CO4	**Understand** and Describe analysis of drugs using various analytical instruments	PO1, PO2, PO3, PO4, PO5, PO6, PO7, PO8, PO10, PO11, PEO1,PEO2,PEO3

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**

TIU-UBP-811ET	Advanced Instrumentation Techniques - Theory	3	3	3	3	3	3	2	2	-	2	2	3	3	3	3

1=weakly mapped
2= moderately mapped
3=strongly mapped

Dietary Supplements and Nutraceuticals- Theory (TIU-UBP-812ET)
Contact hour: 45 hrs

Course Objectives

1. To understand the significance and need of functional foods, nutraceuticals and dietary supplements among various groups of people.
2. To know the different components of dietary supplements and their uses.
3. To have an overall idea of the regulatory and commercial aspects of dietary supplements and nutraceuticals.
4. To gain perception about free radicals and antioxidants.
5. To understand the effects of processing, storage and environmental factors on the potential of nutraceuticals.

Course Outcomes

Upon completion of the course, the student shall be able

CO1. **Classify** the various nutraceuticals and their use in the treatment of various diseases.

CO2.**Describe** the significance of phytochemicals as nutraceuticals.

CO3. **Recognize** the basic concept of free radicals and their damaging effects on the human body.

CO4. **Describe** the role of free radicals in various diseases and the different endogenous and synthetic antioxidants.

CO5. **Recall** the regulatory aspects and pharmacopoeial specifications of dietary supplements and nutraceuticals.

Course Content **45 Hours**

UNIT-I **7 Hours**

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT-II **15 Hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin
b) Sulfides: Diallyl sulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols
h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT-III **07 Hours**

a) 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.
b) Dietary fibres and complex carbohydrates as functional food ingredients

UNIT IV 10 Hours

a) 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. Free radicals theory of ageing.
b) 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.
c) Functional foods for chronic disease prevention

UNIT V **06 Hours**

a) Effect of processing, storage and interactions of various environmental factors on the potential of
nutraceuticals.
b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety.
Adulteration of foods.
c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

Reference Books (Latest Editions)

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.TAgusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger.

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Mapping between COs and POs		
	Course Outcomes (COs)	**Mapped Program Outcomes**
CO1	**Classify**the various nutraceuticals and their use in the treatment of various diseases.	PO1, PO5, PO9, PO11, PO12, PEO1, PEO2
CO2	**Describe**the significance of phytochemicals as nutraceuticals.	PO1, PO5, PO9, PO11, PO12, PEO1, PEO2
CO3	**Recognize** the basic concept of free radicals and their damaging effects on the human body.	PO1,PO9, PO11, PO12, PEO2
CO4	**Describe** the role of free radicals in various diseases and the different endogenous and synthetic antioxidants.	PO1, PO5, PO9, PO11, PO12, PEO1, PEO2
CO5	**Recall** the regulatory aspects and pharmacopoeial specifications of dietary supplements and nutraceuticals.	PO1,PO2, PO3, PO7, PO8, PO9, PO11, PO12, PEO1, PEO2

		Pharmaceutical Knowledge	Problem solving	Conduct, analyze and interpret data	Ability to design and formulating a process	Ability to understand mechanism	Demonstrate skills in problem solving	Professional and ethical responsibilities	Communication to present a technical report	Impact on society and responsibilities	Leadership qualities	Self educating and Life-long Learning	Preparation for competitive examinations	Building a theoretical knowledge base along with necessary practical skills	To build a strong foundation as per the requirements of pharmaceutical Industries, Community and Hospital Pharmacy.	Training students to achieve expertise
Course Code	**Course Title**	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PEO1**	**PEO2**	**PEO3**
TIU-UBP-812ET	Dietary Supplements and Nutraceuticals-Theory	3	2	2	-	2	-	2	2	3	-	3	3	3	3	-

1=weakly mapped
2= moderately mapped
3=strongly mapped