B. PHARM. IV YEAR
SEMESTER - VII

IV B. PHARM SCHEME

SEMESTER 'VII'

S. No.	Sub. Code	Subject	L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Cr.	Maximum Marks				
										TH	CW	SW	Pr.	Total
1.	PY4Y021	Instrumental Methods of Analysis	3	1	4	3	1	2	6	75	25	15	35	150
2.	PY4Y022	Industrial Pharmacy- II	3	1	-	3	1	-	4	75	25	-	-	100
3.	PY4Y023	Pharmacy Practice	3	1	-	3	1	-	4	75	25	-	-	100
4.	PY4Y024	Novel Drug Delivery System	3	1	-	3	1	-	4	75	25	-	-	100
5.	PY4Y483	Practice School*	-	-	12	-	-	6	6	-	-	25	125	150
Total			**12**	**04**	**16**	**12**	**04**	**08**	**24**	**300**	**100**	**40**	**160**	**600**

PY4Y021: Instrumental Methods of Analysis

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	4	3	1	2	75	25	15	35	150

Course objectives:

On completion of this subject, students would be able to:

- To understand basic principle of instrumental methods of analysis.
- To provide knowledge of configuration and working of analytical instruments.
- To provide basic knowledge of sample preparation for analysis.
- To provide basic understanding & practice spectral data interpretation for qualitative and quantitative analysis of drugs.

Course outcomes:

On completion of this subject, students would be able to:

CO-1: Understand the principles & applications of advanced analytical techniques i.e UV, IR, HPLC, GC and other analytical techniques.

CO-2: Perform basic analytical experiments for the identification and determination of drug substances.

CO-3: Analyze, interpret and communicate the results of different analytical tests performed for characterization of drug substance and formulation.

CO-4: Develop various analytical skills for qualitative and quantitative determination of various chemicals.

CO-5: Develop and implement plans to organize work for different analytical tests to be performed in laboratory and industry

THEORY **DURATION (LECTURES)**

UNIT I **10**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT II **10**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors,

detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications
Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications
Nepheloturbidometry- Principle, instrumentation and applications.

UNIT III **10**

Introduction to chromatography
Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.
Thin layer chromatography- Introduction, Principle, Methodology, R_f values, advantages, disadvantages and applications.
Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications
Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT IV **08**

Gas chromatography: Introduction, theory, instrumentation, deriveatization temperature programming, advantages, disadvantages and applications.
High performance liquid chromatography (HPLC): Introduction, theory, instrumentation, advantages and applications

UNIT V **07**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications
Gel chromatography- Introduction, theory, instrumentation and applications
Affinity chromatography- Introduction, theory, instrumentation and applications

PRACTICALS
Minimum 15 practicals covering following areas:

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography

13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

BOOKS & REFERENCES RECOMMENDED

Text books

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 Chemistry by A.H. Beckett and J.B. Stenlake.

Reference books

1. Organic Chemistry by I. L. Finar
2. Organic spectroscopy by William Kemp
3. Quantitative Analysis of Drugs by D. C. Garrett
4. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
5. Spectrophotometric identification of Organic Compounds by Silverstein

PY4Y022: Industrial Pharmacy-II

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

Course outcomes:

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

CO-1: Know the process of pilot plant and scale up of pharmaceutical dosage forms.
CO-2: Understand the process of technology transfer from lab scale to commercial batch.
CO-3: Summarize different Laws and Acts that regulate pharmaceutical industry.
CO-4: Understand the approval process and regulatory requirements for drug products.
CO-5: Analyze quality management systems of pharmaceutical industry in connection to Indian regulatory requirements.

THEORY **DURATION (LECTURES)**

UNIT I **10**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT II **10**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation-confidentiality agreement, licensing, MoUs, legal issues.

UNIT III **10**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals.

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug

Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT IV **08**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP.

UNIT V **07**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

BOOKS AND REFERENCES RECOMMENDED

Text books:

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.
5. N.K. Jain, Industrial Pharmacy-II, Vallabh Prakashan, Delhi

PY4Y023: Pharmacy Practice

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objective:

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

- Various drug distribution methods in a hospital appreciate the pharmacy stores management and inventory control monitor drug therapy of patient through medication chart review and clinical review
- Obtain medication history interview and counsel the patients.
- Identify drug related problems
- Detect and assess adverse drug reactions
- Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
- Know pharmaceutical care services
- Do patient counseling in community pharmacy;
- Appreciate the concept of rational drug therapy.

Course outcomes:

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

CO-1: Understand changing scenario of pharmacy practice in India.

CO-2: Apply various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care.

CO-3: Develop various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

CO-4: Assess and design budgetary requirement for managing drug store and inventory control of pharmacy.

CO-5: Interpret the significance of various clinical laboratory tests.

THEORY **DURATION (LECTURES)**

UNIT I **10**

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

UNIT II **10**

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic DrugMonitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

UNIT III **10**

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills
Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

UNIT IV **8**

a) Budget preparation and implementation: Budget preparation and implementation
b) Clinical Pharmacy: Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.
c) Over the counter (OTC) sales: Introduction and sale of over the counter, and Rational use of common over the counter medications.

UNIT V **7**

a) Drug store management and inventory control
Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure
b) Investigational use of drugs
Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.
c) Interpretation of Clinical Laboratory Tests
Blood chemistry, hematology, and urinalysis

RECOMMENDED BOOKS:

1. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice- essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. Health Education and Community Pharmacy, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

PY4Y024: Novel Drug Delivery System

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To provide basic knowledge about development of novel drug delivery systems.
- To provide knowledge about the criteria for selection of drugs and polymers for the development of novel drug delivery systems.
- To provide knowledge about the formulation and evaluation of novel drug delivery systems.

Course outcomes:

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

CO-1: State the fundamentals of novel drug delivery systems.
CO-2: Describe the mechanism of latest technology driven formulations.
CO-3: Apply his knowledge in making strategies of formulating novel drug delivery systems.
CO-4: Assess the various evaluation parameters involved in analyzing the novel drug delivery systems.
CO-5: Develop the concept to increase the efficacy of drug at site of action.

THEORY **DURATION (LECTURES)**

UNIT I **10**

Controlled drug delivery systems: Introduction, terminology/ definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

UNIT II **10**

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

UNIT III **10**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

UNIT IV **08**

Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

UNIT V **07**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

BOOKS & REFERENCES RECOMMENDED:

Text Book:

1. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Fundamentals and Applications, Second Edition, CRC Press, Taylor & Francis group, 1987.
2. N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors Pvt Ltd., New Delhi, First edition 1997 (reprint in 2014).
3. S. P. Vyas and R. K. Khar, Controlled Drug Delivery - Concepts and Advances, Vallabh Prakashan, New Delhi, Second edition 2012.
4. Y. W. Chien, Novel Drug Delivery Systems, Second Edition, CRC Press, Taylor & Francis group, 1991
5. Gupta R. B., Nanoparticle technology for drug delivery, Taylor & Francis, New York, London, 2006, 1st Ed.
6. N.K. Jain, Introduction to Novel Drug Delivery Systems, 2020, 3rd Ed., Vallabh Prakashan, Delhi

Reference Book:

1. Mathiowitz, Encyclopedia of Controlled Delivery, Wiley Interscience Publication, John Wiley and Sons, Inc, New York, 1999.
2. G. S. Banker, C. T. Rodes, Modern Pharmaceutics, Fourth Edition, Marcel Dekker Inc. New York, 2002.
3. Wise D. L., Handbook of controlled release technology, Marcel Dekker Inc, 2000, 1st Ed.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA) 3. Journal of Controlled Release (Elsevier Sciences)
3. Drug Development and Industrial Pharmacy (Marcel & Decker)
4. International Journal of Pharmaceutics (Elsevier Sciences)

PY4Y483: Practice School

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
-	-	12	-	-	6	-	-	25	125	150

Course objectives:

- To meet the rapidly changing needs and challenges of a professional workplace.
- To acquire learning by applying the knowledge and skills, in unfamiliar, open-ended real life situations.
- To bear an economic relevance to society.
- To create the required setting for experiential and cooperative learning and education for students, under the guidance of professional experts and supervision of faculty.
- To serves as a platform that facilitates and promotes partnership and intellectual exchange between academia and industry.

Course outcomes:

Course Outcomes: Upon completion of the course, student shall be able to:

CO-1: Enables students to have a smooth transition from academics to professional world.

CO-2: Enhances interpersonal skills, communication skills, leadership qualities etc.

CO-3: Provides an opportunity to apply some of the ideas/skill sets that students learn during the academic program.

CO-4: Enables students to have awareness of personal strengths and limitations as a professional.

CO-5: Increases marketability of students after graduation. Provides link with potential future employers.

B. PHARM. IV YEAR
SEMESTER - VIII

IV B.PHARM SCHEME

SEMESTER 'VIII'

S. No.	Sub. Code	Subject	No. of Hours	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Total Cr.	Maximum Marks				
										TH	CW	SW	Pr.	Total
1.	PY4Y521	Biostatistics and Research Methodology	3	1	-	3	1	-	4	75	25	-	-	100
2.	PY4Y522	Social and Preventive Pharmacy	3	1	-	3	1	-	4	75	25	-	-	100
3.	MB4Y612 MB4Y717	Pharma Marketing Management	3+3 = **6**	1+1 = **2**	-	3+3 = **6**	1+1 **= 2**	-	4 + 4 **= 8**	75+7 5 = **150**	25+2 5 = **50**	--	--	100 + 100 = **200**
4.	PY4Y606 PY4Y708	Pharmaceutical Regulatory Science												
5.	PY4Y607 PY4Y713	Pharmacovigilance												
6.		Quality Control and Standardization of Herbals												
7.		Computer Aided Drug Design												
8.		Cell and Molecular Biology												
9.	PY4Y613 PY4Y715	Cosmetic Science												
10.		Experimental Pharmacology												
11.		Advanced Instrumentation Techniques												
12.		Dietary Supplements and Nutraceuticals												
13.	PY4Y615 PY4Y716	Pharmaceutical Product Development												
14.	PY4Y883	Project Work	-	-	12	-	-	6	6	-	-	-	**150**	**150**
Total			**12**	**4**	**12**	**12**	**4**	**6**	**22**	**300**	**100**	**-**	**150**	**550**

PY4Y521: Biostatistics and Research Methodology

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To understand the applications of Biostatics in Pharmacy.
- To know about various statistical tests, design and analysis of experiments.
- To learn about software used in statistical analysis.
- To learn about data analysis in clinical trials.

Course outcomes:

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

CO-1: Develop understanding of various statistical methodologies and data analysis tools with respect to pharmaceutical sciences.

CO-2: Understand the basic utility and operations of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment) softwares.

CO-3: Apply reasoning for design of research projects and prepare work plan for assigned research problem.

CO-4: Create effective project reports, presentations and documentation related to pharmaceutical sciences.

CO-5: Generate and/or analyze different data/trends/results obtained from various sources such as research data and demographic analysis etc..

THEORY **DURATION (LECTURES)**

UNIT I **10**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples.

UNIT II **10**

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 – problems, Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

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

UNIT III **10**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.

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, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

UNIT IV **10**

Blocking and confounding system for Two-level factorials

Regression modelling: 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 **10**

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

RECOMMENDED BOOKS:

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc., NewYork.
2. Fundamental of Statistics by S.C.Guptha, Himalaya Publishing House.
3. Design and Analysis of Experiments, R. Panner selvam, PHI Learning Private Limited.
4. Design and Analysis of Experiments by Douglas and C. Montgomery, Wiley Students Edition.
5. Fundamentals of research methodology and statistics, Y. K. Singh, New age international publishers, 2006

PY4Y522: Social and Preventive Pharmacy

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course Objectives:

- To introduce students with number of public health issues and their challenges.
- To know about the national health programmes.
- To learn the roles of the pharmacist in these contexts are also discussed.
- To learn about disease preventive medicines and practises in society.

Course outcomes:

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

CO-1: Understand the national network and programs for disease prevention and treatment.

CO-2: Develop understanding of current issues related to health and pharmaceuticals within the country and worldwide.

CO-3: Have a critical way of thinking based on current healthcare development and existing diseases in community.

CO-4: Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

CO-5: Develop new insights related to community services in rural, urban and school health.

THEORY **DURATION (LECTURES)**

UNIT I **10**

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**

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

UNIT III **10**

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 **10**

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 program

UNIT V **10**

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.

RECOMMENDED BOOKS:

1. Short Textbook of Preventive and Social Medicine, G N Prabhakara, 2nd Edition, 2010, Jaypee Publications.
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by R N Roy, I Saha, 4th Edition, 2013, Jaypee Publications.
3. Review of Preventive and Social Medicine (Including Biostatistics), V Jain, 6th Edition, 2014, Jaypee Publications.
4. Essentials of Community Medicine—A Practical Approach, L D Hiremath, D A Hiremath, 2nd Edition, 2012, Jaypee Publications.
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, Banarsidas Bhanot Publishers.
6. Community Pharmacy Practice, A Ramesh, BSP publishers, Hyderabad.
7. Nagdev S., Budhrani, A., A textbook of social and preventive pharmacy, Nirali Prakashan.

RECOMMENDED JOURNALS:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland.

Online Resources:

1. https://z-lib.org

MB4Y612/MB4Y717: Pharma Marketing Management (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.
- To build skilled and effective professionals for the Pharmaceutical sector.
- To gain knowledge about challenges in sales and product management.
- To develops skills in planning & operating management techniques.

Course outcomes:

CO-1: Learn specialized knowledge in marketing of pharmaceutical products.
CO-2: Develop the standards of the pharmaceutical industry in the current global scenario.
CO-3: Analyze and synthesize specific issues within pharmaceutical marketing by using the concepts, theories, methods and models.
CO-4: Assess and communicate problem-solving on a reflective, scientific basis.
CO-5: Understand the roles and responsibilities of pricing authorities in India.

THEORY **DURATION (LECTURES)**

UNIT I **10**

Marketing:

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

Pharmaceutical market:

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 II **10**

Product decision:

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 III **10**

Promotion:

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 IV **10**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, 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 V **10**

Pricing:

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; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

RECOMMENDED BOOKS:

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. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: 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. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.
9. Pawan Choudhary, The Rx Factor: Strategic Creativity in Pharmaceutical Marketing, 2009, The Wisdome Village Publications

PY4Y606/ PY4Y708: Pharmaceutical Regulatory Science (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To provide basic knowledge about the process of drug discovery and development.
- To impart knowledge of regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- To provide thorough acquaintance of the regulatory approval process and registration of drug products in Indian and international markets.
- To understand the regulatory components of clinical trials and various regulatory concepts.

Course outcomes:

On completion of this subject, students are expected to be able to:

CO-1: Learn the various stages of the new drug discovery and development process.
CO-2: Explain the process and requirements for regulatory approval of new drugs and drug products in regulated markets of India & other countries.
CO-3: Understand the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.
CO-4: Get acquainted with the various aspects of clinical trials.
CO-5: Learn the basic concepts, terminology and guidelines of regulatory agencies.

THEORY **DURATION (LECTURES)**

UNIT I **10**

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 **10**

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 States, European Union, Australia, Japan, Canada (organization structure and types of applications).

UNIT III **10**

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 Document (eCTD), ASEAN Common Technical Document (ACTD) research.

UNIT IV **8**

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 - safety monitoring in clinical trials.

UNIT V **7**

Regulatory Concepts: Basic terminology, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulations, Purple book.

RECOMMENDED BOOKS:

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

PY4Y607/ PY4Y713: Pharmacovigilance (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To learn about basics of Pharmacovigilance and its global scenario.
- To train students in basic methodologies to establish pharmacovigilance programme, generate and report safety data.
- To develop the skills of classifying drugs, diseases, clinical studies of drugs, adverse drug reactions and regulatory guidelines.

Course outcomes:

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

CO-1: Define and explain basics of pharmacovigilance including importance, terminology and current national and international scenario, ICH Guidelines, CDSCO and CIOMS.

CO-2: Analyze adverse drug reactions and classify them as per the guidelines.

CO-3: Apply the skills of classifying drugs, diseases, clinical studies of drugs, adverse drug reactions and regulatory guidelines.

CO-4: Utilize basic procedures of pharmacovigilance like detection and reporting of new adverse drug reactions, methods to generate safety data during preclinical, clinical and post approval phases of drugs' life cycle.

CO-5: Interpret and communicate data related to drug safety evaluation in specific population.

THEORY **DURATION (LECTURE)**

UNIT I **10**

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

b) 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

c) Basic terminologies used in pharmacovigilance
- Terminologies of adverse medication related events
- Regulatory terminologies

UNIT II **10**

a) Drug and disease classification
- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

b) Drug dictionaries and coding in pharmacovigilance
- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

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

d) 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**

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

b) 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

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

UNIT IV **10**

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

b) 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 **10**

a) Pharmacogenomics of adverse drug reactions
- Genetics related ADR with example focusing PK parameters.

b) Drug safety evaluation in special population
- Paediatrics
- Pregnancy and lactation
- Geriatrics

c) CIOMS
- CIOMS Working Groups
- CIOMS Form

d) CDSCO (India) and Pharmacovigilance
- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

RECOMMENDED BOOKS:

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z by B Cobert, P Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: E B Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: J Talbot, P Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: B Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by B L. Strom, S E Kimmel, S Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, K NyfortHansen, M C Nahata
9. National Formulary of India
10. Text Book of Medicine by Y Munjal.
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. ICH guidelines for pharmacovigilance: Clinical safety and Efficacy guidelines S and E guidelines by ICH

Online Resources:

1. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
2. http://www.ich.org/
3. http://www.cioms.ch/
4. http://cdsco.nic.in/
5. http://www.who.int/vaccine_safety/en/
6. https://z-lib.org
7. http://www.ipc.gov.in/PvPI/pv_home.html

Quality Control and Standardization of Herbals (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To educate about WHO guidelines for quality control of herbal drugs.
- To impart knowledge of Quality assurance in herbal drug industry.
- To develop understanding about regulatory approval process and their registration in Indian and international markets.
- To provide knowledge of EU and ICH guidelines for quality control of herbal drugs.

Course outcomes:

After completion of course, student should be able to:

- Develop skill of performing different evaluation techniques for quality control of herbal drugs
- Understand different chromatographic techniques for quality assurance in herbal drug industry.
- Develop Planning abilities for regulatory approval process and their registration in Indian and international markets.
- Appreciate EU and ICH guidelines for quality control of herbal drugs.

THEORY **DURATION (LECTURE)**

UNIT I **10**

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**

Quality assurance in herbal drug industry of 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**

EU and ICH guidelines for quality control of herbal drugs. Research guidelines For evaluating the safety and efficacy of herbal medicines.

UNIT IV **08**

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 IV **07**

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.

BOOKS & REFERENCES RECOMMENDED

Text books

1. Kokate C.K., Purohit A.P., Gokhale S.B., Pharmacognosy, 44th edition, 2009, Published by Nirali Prakashan, New Delhi.
2. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol.I, Carrier Pub., 2006.
3. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
4. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products, European Medicines Agency, 2011.
5. 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.

Reference books

1. Evans, W. C. "Trease and Evans Pharmacognosy", 16th edition, 2009, WB Saunders& Co, London.
2. Mukherjee P. K., Quality Control of Herbal drugs. An Approach to Evaluation of Botanicals, 2002, Business Horizons.
3. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 2002.
4. WHO, Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.
5. 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.
6. 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.
7. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
8. WHO, Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.

Computer Aided Drug Design (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

On completion of this subject, students would be able to:

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

Course outcomes:

On completion of this subject, students would be able to:

- Understand drug design concepts: QSAR , computer aided drug designing, drug target selection, molecular modeling, computational techniques.
- Perform homology modeling , docking, pharmacophore methods and techniques of modern drug design..
- Understand the relationship between chemical structure and biological activity of drug.
- Design and develop new leads on a rational basis..

THEORY **DURATION (LECTURE)**

UNIT I **10**

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**

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**

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**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT V **07**

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

BOOKS & REFERENCES RECOMMENDED

Text books

1. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger
2. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.

Reference books

1. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
2. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.
3. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.

Cell and Molecular Biology (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To develop basic knowledge and skills in cell and molecular biology and make aware of the complexity and harmony of the cell.
- To understand basic properties of cells, Prokaryotic and eukaryotic cells, Viruses, the structure and function of the nucleus, genes and chromosomes, DNA replication, transcription, translation, cytoskeleton, cell motility, cellular reproduction, and cell signaling etc.

Course outcomes:

After completion of course, student should be able to:

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle.

THEORY **DURATION (LECTURE)**

UNIT I **10**

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**

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**

a) Proteins: Defined 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**

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**

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

BOOKS AND REFERENCES RECOMMENDED:

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, 8th edition, Blackwell Scientific publications, Oxford London, 2011.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi, 2004.
3. M. J. Pelczar and Chan Kreig, Microbiology, 5th edition, McGraw Hill education publisher, 2011.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. M Frobisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed., Thomson Learning, 1974.
7. Cooper and Gunn's: Tutorial Pharmacy, 12th edition, CBS Publisher and Distribution, 2008.
8. Peppler H. J.: Microbial Technology: Fermentation Technology, 2nd edition, Academic pr, 1979.
9. Edward: Fundamentals of Microbiology, 6th edition, Jones & Bartlett Pub, 2001.
10. N. K. Jain: Pharmaceutical Microbiology, 2nd edition, Vallabh Prakashan, Delhi, 2005.
11. Bergeys manual of systematic bacteriology, 2nd edition, Springer-Verlag New York, 2001.
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C. 2002.
13. RA Goldshy et. al.,: Kuby Immunology, 4th edition, W H Freeman & Co, 2000.

PY4Y613/PY4Y715: Cosmetic Science (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To provide basic knowledge of the cosmetic and cosmeceutical products with excipients used to prepare them.
- To impart basic understanding of structure and function of skin, hair and oral cavity.
- To understand the formulation principles of various cosmetics including skin care, hair care and oral care products with their evaluation.
- To get knowledge of various cosmetic problems associated with hair, scalp and skin.

Course outcomes:

After completion of course, student should be able to:

- Understand the cosmetic and cosmeceutical products and the excipients used in their formulation.
- Know the basic structure and function of skin, hair and oral cavity.
- Understand the principles involved in formulation and evaluation of skin care, hair care and oral care cosmetic products.
- Get acquainted with the common cosmetic problems which affect hair, scalp and skin.

THEORY **DURATION (LECTURE)**

UNIT I **10**

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 applications.

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**

Principles of formulation and building blocks of skin care products: Face wash, moisturizing cream, cold cream, vanishing cream. Their advantages and disadvantages. Application of these products in formulation of cosmeceuticals. **Antiperspirants & 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-phenylenediamine based hair dye. **Principles of formulation and building blocks of oral care products:** Toothpaste for bleeding gums and sensitive teeth. Teeth whitening. Mouthwash.

UNIT III **10**

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 **8**

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, skin color, hair tensile strength, hair combing properties. Soaps and syndet bars. Evalution and skin benefits.

UNIT V **7**

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 andbody odor. Antiperspirants and deodorants- Actives and mechanism of action.

RECOMMENDED BOOKS:

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4thEdition, Vandana Publications Pvt. Ltd., Delhi.
3. Textbook of Cosmeticology by Sanju Nanda &Roop K. Khar, Tata Publishers.
4. Cosmetics Science and Technology by Marvin Balsam andEdward Sagarin. Second edition. Wiley India Pvt Ltd.

EXPERIMENTAL PHARMACOLOGY
(PHARMACOLOGICAL SCREENING METHODS) (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Course outcomes:

After completion of course, student should be able to:

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research.
- Appreciate and demonstrate the importance of biostatistics and research methodology.
- Design and execute a research hypothesis independently

THEORY **DURATION (LECTURE)**

UNIT –I **08**

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 **12**

Preclinical screening models

a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups.
b. 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 **08**

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

UNIT –IV **08**

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 **08**

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.

BOOKS AND REFERENCES RECOMMENDED:

1. Ghosh M N. "Fundamentals of Experimental Pharmacology" 6th Ed. Hilton and Company; 2008.
2. Kulkarni S. K. "Handbook of Experimental Pharmacology" 2nd ed. (reprint): Vallabh Prakashan, New Delhi; 2013.
3. CPCSEA guidelines for laboratory animal facility.
4. Vogel H.G., "Drug Discovery and Evaluation: Pharmacological Assays", 4th ed., Springer Nature publication, 2016.
5. S. K. Gupta, "Drug Screening Methods", 3rd edition, Jaypee Brothers Medical Publishers, 2016.
6. PSS Sundar Rao, J Richard, "Introduction to biostatistics and research methods", 5th edition, Prentice Hall India Learning Private Limited, 2012.
7. Prakash A, Medhi B, Practical Manual of Experimental and Clinical Pharmacology, 1/e edition, Jaypee Brothers Medical Publishers (P) Ltd. 2010

Online resources:

1. **https://z-lib.org**

Advanced Instrumentation Techniques (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

On completion of this subject, students would be able to:

- To understand basic principle of instrumental methods of analysis.
- To provide knowledge of configuration and working of analytical instruments.
- To provide basic knowledge of sample preparation for analysis.
- To understand the effect of chemical environment, physical environment, solvent and instrumental parameters in spectral outcome and chromatograms.

Course outcomes:

On completion of this subject, students would be able to:

- Understand the characterization of drug substance and formulation using NMR and Mass spectrometry. etc.
- Understand the principles & applications of hyphenated techniques i.e,GC-MS/MS ,LC-MS/MS & chromatographic techniques.
- Define the role of parameters related to sample types, sample preparation ,instrument and instrumental parameters in analysis.
- Develop methods for analysis of drug substances and drug products.

THEORY **DURATION (LECTURE)**

UNIT I **10**

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and 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**

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

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.

UNITIII **10**

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 **08**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT V **07**

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

BOOKS & REFERENCES RECOMMENDED

Text books

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 Chemistry by A.H. Beckett and J.B. Stenlake.

Reference books

1. Organic Chemistry by I. L. Finar
2. Organic spectroscopy by William Kemp
3. Quantitative Analysis of Drugs by D. C. Garrett
4. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
5. Spectrophotometric identification of Organic Compounds by Silverstein

Dietary Supplements and Nutraceuticals (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To introduce fundamentals of dietary supplements and nutraceuticals like definition, classification, scope and health benefits of functional foods.
- To provide knowledge of chemical nature and medicinal benefits of phytochemicals as nutraceuticals.
- To educate about regulatory aspects and pharmacopoeial specifications for dietary supplements.
- To develop understanding about antioxidants with their pharmaceutical applications.

Course outcomes:

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

CO-1: Describe the value of dietarysupplements and nutraceuticals in health problems and various diseases and discuss the source, marker compounds of nutraceuticals/ functional foods.

CO-2: Discuss the characteristic features of phytochemicals as nutraceuticals.

CO-3: Explain the role of reactive oxygen species and free radicals on different structural components of the cell.

CO-4: Explain the mechanism of free radicals generation in various diseases and significance of endogenous antioxidants and functional food in prevention of diseases.

CO-5: Discuss the regulatory and commercial aspects of dietary supplements and nutraceuticals including health claims..

THEORY **DURATION (LECTURE)**

UNIT I **07**

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. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

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**

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

Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin

Sulfides: Diallyl sulfides, Allyl trisulfide.

Polyphenolics: Reservetrol

Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones

Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum

Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans

Tocopherols, 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**

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. Dietary fibres and complex carbohydrates as functional food ingredients.

UNIT IV **10**

Free radicals: 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.

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. **Functional foods**: for chronic disease prevention.

UNIT V **06**

Nutraceuticals.: Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Pharmacopoeial Specifications: dietary supplements and nutraceuticals.

BOOKS & REFERENCES RECOMMENDED

Text books

1. Dietetics by Sri Lakshmi, New AgePunblication, 2007, 372.
2. K.T Agusti, P.Faizal: Role of dietary fibres and neutraceuticals in preventing diseases, BSPunblication, 2013.
3. Cooper. K.A, Advanced Nutritional Therapies.,2008

Reference books

1. Jean Carper, Simon & Schuster, The Food Pharmacy,UK Ltd.,2010.
2. James F.Balch and Phyllis A.Balch ,Prescription for Nutritional Healing, 2nd Edn., Avery Publishing Group, NY, 2009.
3. G. Gibson and C.williams Editors, Functional foods Woodhead Publ.Co.London. 2000.
4. Goldberg, I. Functional Foods. Chapman and Hall, New York, 2010.
5. Labuza, T.P., 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, 2010.
6. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition), 2016.
7. Shils, ME, Olson, JA, Shike, M.,Modern Nutrition in Health and Disease. Eighth edition. Lea and Febiger. 2010
8. C. Egbuna, G. Dable Tupas, Functional food and nutraceuticals, Springer International publishing house.

PY4Y615/ PY4Y716: Pharmaceutical Product Development (Elective)

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
3	1	-	3	1	-	75	25	-	-	100

Course objectives:

- To provide basic knowledge of preformulation and various aspects of formulation development of various dosage forms.
- To impart thorough knowledge of excipients used in pharmaceutical product development of different conventional dosage forms and novel drug delivery systems.
- To provide acquaintance of various optimization techniques used in pharmaceutical product development for quality by design.
- To provide an insight about selection of packaging materials in pharmaceutical product development from regulatory point of view.

Course outcomes:

On completion of this subject, students would be able to:

CO-1: Understand the importance of preformulation studies.

CO-2: Able to describe formulation development including stability and quality control of different dosage forms.

CO-3: Describe different excipients used in pharmaceutical product development along with their selection and applications.

CO-4: Learn the application of optimization techniques for quality by design in pharmaceutical product development.

CO-5: Articulate the regulatory aspects of packaging materials in pharmaceutical product development with their selection and quality control.

THEORY **DURATION (LECTURE)**

UNIT I **10**

Introduction to pharmaceutical product development. Objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms.

UNIT II **10**

An advanced study of pharmaceutical excipients in pharmaceutical product development with special reference to the following categories:

i. Solvents and solubilizers.
ii. Cyclodextrins and their applications.
iii. Non - ionic surfactants and their applications.
iv. Polyethylene glycols and sorbitols.
v. Suspending and emulsifying agents.
vi. Semi solid excipients.

UNIT III **10**

An advanced study of pharmaceutical excipients in pharmaceutical product development with special reference to the following categories:

i. Tablet and capsule excipients. ii. Directly compressible vehicles.

iii. Coat materials. iv. Excipients in parenteral and aerosols products.

v. Excipients for formulation of NDDS.

Selection and application of excipients in pharmaceutical formulations with specific industrial applications.

UNIT IV **8**

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples.

Optimization by factorial designs and their applications.A study of QbD and its application in pharmaceutical product development.

UNIT V **7**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

RECOMMENDED BOOKS

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by RoopK Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas andRoop K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr.,Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40.
8. Aulton's Pharmaceutics- Design and Manufacture of Medicines, Michael E.Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachmanand Joseph B. Schwartz.
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.
13. Advanced review articles related to the topics.
14. N.K. Jain, Pharmaceutical Product Development, 2018, 3rd Ed., CBS Publishers & Distributers, New Delhi

PY4Y883: Project Work

L	T	P	Th. Cr.	Tu. Cr.	Pr. Cr.	Maximum marks				
						TH	CW	SW	Pr	Total
-	-	12	-	-	6	-	-	-	150	150

Course objectives:

- To identify the key aspects having scope of research/innovation/development/new applications/value addition in any area of core branches of pharmacy or from any field beyond the syllabus.
- To develop understanding of prototype research and innovation in the field of pharmaceutical sciences.
- To provide basic understanding of sources of scientific literature, web-browsing techniques, market survey or data collection.
- To provide exposure to new experimental methodology & practical tools related to project work.
- To develop abilities and skills of problem solving, team work & resource management for timely completion of project work.

Course outcomes:

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

CO-1: Successfully complete the planned work, compile the findings, analyze the results and draw conclusions.

CO-2: Develop problem solving ability, analytical skills and decision making aptitude.

CO-3: Understand the importance of team work and individual responsibilities.

CO-4: Develop the working proficiency in MS Word, MS Excel, and MS Power Point.

CO-5: Draft project completion report and develop writing & presentation skills.