DR. A.P.J. ABDUL KALAM TECHNICAL UNIVERSITY,

LUCKNOW

EVALUATION SCHEME & SYLLABUS FOR B. PHARM. 4th YEAR

On PCI Guidelines

(EFFECTIVE FROM THE SESSION: 2020-21)

Scheme of Evaluation

Bachelor of Pharmacy (B. Pharm.)

Semester VII

Effective from the Session 2020-2021

Course Code	Name of the Course	No. of Hours/wk	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP701T	Instrumental Methods of Analysis – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP702T	Industrial Pharmacy II – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP703T	Pharmacy Practice – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP704T	Novel Drug Delivery System (NDDS) – Theory	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP705P	Instrumental Methods of Analysis/NDDS – Practical	4	5	10	4 Hrs	15	35	4 Hrs	50	2
BP706PS	Practice School	12	50	100	5 Hrs	150	---	---	150	6
BP707P	Report on Hospital/Industrial Training	-	-	-	-	-	100	-	100	2
	Total	**28**	**95**	**170**	**13 Hrs**	**265**	**435**	**16 Hrs**	**700**	**26**

Scheme of Evaluation

Bachelor of Pharmacy (B. Pharm.)

Semester VIII **Effective from the Session 2020-2021**

Course Code	Name of the Course	No. of Hours/ wk	Internal Assessment				End Semester Exams		Total Marks	Credit Points
			Continuous Mode	Sessional Exams		Total	Marks	Duration		
				Marks	Duration					
BP801T	Biostatistics and Research Methodology	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP802T	Social and Preventive Pharmacy	3	10	15	1 Hr	25	75	3 Hrs	100	4
BP803ET	Pharma Marketing Management*	3 + 3 = 6	10 + 10 = 20	15 + 15 = 30	1 + 1 = 2 Hrs	25 + 25 = 50	75 + 75 = 150	3 + 3 = 6 Hrs	100 +100 =200	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science*									
BP805ET	Pharmacovigilance*									
BP806ET	Quality Control and Standardization of Herbal*									
BP807ET	Computer Aided Drug Design*									
BP808ET	Cell and Molecular Biology*									
BP809ET	Cosmetic Science*									
BP810ET	Experimental Pharmacology*									
BP811ET	Advanced Instrumentation Techniques*									
BP812ET	Dietary Supplements and Nutraceuticals*									
BP813ET	Pharmaceutical Product Development*									
BP814PW	Project Work (On Elective)	12	-	-	-	-	150	4 Hrs	150	6
BP815P	Report on Industrial Tour**	-	-	-	-	-	100	-	100	2
Total		**24**	**40**	**60**	**4 Hrs**	**100**	**550**	**16 Hrs**	**650**	**24**

*(ET: Elective subject) Every candidate has to opt for two of the elective subjects, and has to carry out project on any one of them.

**The Industrial Tour may be performed at the end of the 7th semester.

Semester VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
- Understand the chromatographic separation and analysis of drugs.
- Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

Unit -I **10 Hours**

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 Hours**

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.
Nephelo-turbidimetry- Principle, instrumentation and applications.

Unit-III **10 Hours**

Introduction to chromatography:
Adsorption and partition column chromatography- Methodology, advantages, disadvantages and applications.
Thin layer chromatography- Introduction, Principle, Methodology, Rf 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 Hours**

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

Unit-V **07 Hours**

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.

BP705P. INSTRUMENTAL METHODS OF ANALYSIS / NDDS (Practical)

4 Hours/Week

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds.
2. Estimation of sulphanilamide by colorimetry.
3. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy.
4. Estimation of quinine sulphate by fluorimetry.
5. Study of quenching of fluorescence.
6. Determination of sodium by flame photometry.
7. Determination of potassium by flame photometry.
8. Determination of chlorides and sulphates by nephelo-turbidimetry.
9. Separation of sugars by thin layer chromatography.
10. Separation of plant pigments by column chromatography.
11. Demonstration experiment on HPLC.
12. Demonstration experiment on Gas Chromatography.
13. To perform in-vitro dissolution profile of CR/SR marketed formulation.
14. To prepare sustained release matrix tablets and evaluate by UV spectroscopy.
15. Formulation of nanoparticles and evaluate by HPLC.
16. Formulation and evaluation of liposomes.
17. To prepare buccal dosage form and evaluate by UV spectroscopy.
18. To prepare paracetamol transdermal patch and evaluate by UV spectroscopy.

Recommended Books (Latest Editions)

- Instrumental Methods of Chemical Analysis by B.K Sharma.
- Organic spectroscopy by Y.R Sharma.
- Text book of Pharmaceutical Analysis by Kenneth A. Connors.
- Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel.
- Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake.
- Organic Chemistry by I. L. Finar.
- Organic spectroscopy by William Kemp.
- Quantitative Analysis of Drugs by D. C. Garrett.
- Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi.
- Spectrophotometric identification of Organic Compounds by Silverstein.
- N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

BP702T. INDUSTRIAL PHARMACY II (Theory)

45 Hours

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

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

- Know the process of pilot plant and scale up of pharmaceutical dosage forms.
- Understand the process of technology transfer from lab scale to commercial batch.
- Know different Laws and Acts that regulate pharmaceutical industry.
- Understand the approval process and regulatory requirements for drug products.

Course Content:

Unit-I **10 Hours**

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 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from RD to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipment, 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 Hours**

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 Hours**

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 Hours**

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.

Recommended Books: (Latest Editions)

- Regulatory Affairs from Wikipedia, the free encyclopaedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
- International Regulatory Affairs Updates, 2005, available at http://www.iraup.com/about.php.
- Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs. A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
- Regulatory Affairs brought by learning plus, Inc., available at http.//www.cgmp.com/ra.htm.
- Intellectual Property Rights in Pharmaceutical Industry Theory and practice by Bayya Subba Rao and Appaji.

BP703T. PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning 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.

Objectives: 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 counselling in community pharmacy.
- Appreciate the concept of rational drug therapy.

Unit-I **10 Hours**

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.

Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

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.

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 Hours**

Drug distribution system in a hospital

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

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.

Therapeutic drug monitoring

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

Medication adherence

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

Patient medication history interview

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

Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit-III **10 Hours**

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.

Drug information services

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

Patient counselling

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

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.

Prescribed medication order and communication skills

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

Unit-IV **8 Hours**

Budget preparation and implementation: Budget preparation and implementation.
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.
Over the counter (OTC) sales: Introduction and sale of over the counter and rational use of common over the counter medications.

Unit-V **7 Hours**

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.
Investigational use of drugs
Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.
Interpretation of Clinical Laboratory Tests Blood chemistry, haematology, and urine analysis.

Recommended Books (Latest Edition):

- Merchant S.H. and Dr. J.S. Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakashan; 2001.
- 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.
- William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
- Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
- Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
- Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

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

BP704T. NOVEL DRUG DELIVERY SYSTEMS (NDDS) (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able:

- To understand various approaches for development of novel drug delivery systems.
- To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation.

Course content:

Unit-I **10 Hours**

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 Hours**

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 Hours**

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

Gastro-retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS– Floating, high density systems, inflatable and gastro-adhesive systems and their applications.

Naso-pulmonary 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 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.

Unit-V **07 Hours**

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.

Recommended Books: (Latest Editions)

- Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
- Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
- Encyclopaedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim.
- N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
- S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

- Indian Journal of Pharmaceutical Sciences (IPA)
- Indian Drugs (IDMA)
- Journal of Controlled Release (Elsevier Sciences)
- Drug Development and Industrial Pharmacy (Marcel & Decker)
- International Journal of Pharmaceutics (Elsevier Sciences)

BP706PS. PRACTICE SCHOOL

150 Hours

Scope: Introduction to pharmacy practice will help in understanding of practical aspects of the field. This will also help to accomplish future endeavours as well as employability.

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

- Understand the advanced instruments used and their applications in drug analysis.
- Understand the concepts and applications of alternative medicine.
- Learn to execute and utilize softwares of pharmaceutical importance.
- Understand the calibration of various analytical instruments.
- Know analysis of drugs using various analytical instruments.

Course content:

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains. Every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages).

Domains (anyone to be opted):

- ❖ Phytomedicine
- ❖ Formulation development
- ❖ Quality control and quality assurance
- ❖ Drug design and process chemistry
- ❖ Pharmaceutical software
- ❖ Artificial intelligence
- ❖ 3D printing
- ❖ Nutraceuticals
- ❖ Cosmeceuticals
- ❖ Alternative medicine

Recommended Books (Latest Editions)

- Pharmacognosy by Trease and Evans.
- Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- Current Concepts in Drug Design by T. Durai and Ananda Kumar.
- Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
- Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
- Prescott and Dunn., Industrial Microbiology, 4^{th} edition, CBS Publishers & Distributors, Delhi.
- B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
- Harry's Cosmetology, Wilkinson, Moore, Seventh Edition, George Godwin.

- Poucher's Perfumes, Cosmetic & Soaps by Poucher W.A., Butler, H., Springer India Pvt. Ltd, New Delhi.

BP707P. REPORT ON HOSPITAL/INDUSTRIAL TRAINING

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. The student shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non-Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analysing the statistical data using Excel**.**

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

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment).
- Know the various statistical techniques to solve statistical problems.
- Appreciate statistical techniques in solving the problems**.**

Course content:

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, Pharmaceutical problems.
Correlation: Definition, Karl Pearson's coefficient of correlation, multiple correlation-Pharmaceuticals 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– 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 Hours**

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 **8 Hours**

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 experiment, R- Online Statistical Software's to Industrial and Clinical trial approach.

Unit-V **7 Hours**

Design and Analysis of experiments:

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

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

Recommended Books (Latest edition):

- Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
- Fundamental of Statistics – Himalaya Publishing House- S.C. Guptha.
- Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam.
- Design and Analysis of Experiments– Wiley Students Edition, Douglas and C. Montgomery.

BP802T. SOCIAL AND PREVENTIVE PHARMACY (Theory)

45 Hours

Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives: After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Course content:

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 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 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 program.

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.

Recommended Books (Latest edition):

- Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications.
- Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications.
- Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications.
- Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications.
- Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, Banarasidas Bhanot Publishers.
- Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad.
- Sociology for Pharmacist by Kevin Taylor, Sarah Nettleton and Geoffery Harding.

Recommended Journals:

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

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope: The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Course content:

Unit-I **10 Hours**

Marketing:
Definition, general concepts and scope of marketing, distinction between marketing & selling. Marketing environment. Industry and competitive analysis. Analysing consumer buying behaviour and industrial buying behaviour.

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; patient's choice of physician and retail pharmacist. Analysing the Market; Role of market research.

Unit-II **10 Hours**

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 Hours**

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 **08 Hours**

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 **07 Hours**

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: (Latest Editions)

- Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi.
- Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
- Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill.
- Arun Kumar and N Meenakshi: Marketing Management, Vikas Publishing, India.
- Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition).
- Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
- Shanker, Ravi: Service Marketing, Excel Books, New Delhi.
- Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.
- Pharmaceutical marketing in India by Subba Rao Chaganti.

BP804ET. PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to:

- Know about the process of drug discovery and development.
- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- Know the regulatory approval process and their registration in Indian and international markets.

Course content:

Unit-I **10 Hours**

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 Hours**

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 Hours**

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 **08 Hours**

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 **07 Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

Recommended books (Latest edition):

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

BP805ET. PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives: At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance.
- National and international scenario of pharmacovigilance.
- Dictionaries, coding and terminologies used in pharmacovigilance.
- Detection of new adverse drug reactions and their assessment.
- International standards for classification of diseases and drugs.
- Adverse drug reaction reporting systems and communication in pharmacovigilance.
- Methods to generate safety data during pre-clinical, clinical and post approval phases of drugs' life cycle.
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation.
- Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India.
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning.
- CIOMS requirements for ADR reporting.
- Writing case narratives of adverse events and their quality.

Course Content

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 defined 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.

Recommended Books (Latest edition):

- Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
- Quintessence of Pharmacovigilance: Tapan Kumar Chatterjee, PharmaMed Press.
- Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
- Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
- An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
- Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
- Textbook of Pharmaco-epidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
- A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata.
- National Formulary of India.
- Text Book of Medicine by Yashpal Munjal.
- Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna.
- http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=7297
- http://www.ich.org/
- http://www.cioms.ch/
- http://cdsco.nic.in/
- http://www.who.int/vaccine_safety/en/
- http://www.ipc.gov.in/PvPI/pv_home.html

BP806ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

45 Hours

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to:

- Know WHO guidelines for quality control of herbal drugs.
- Know Quality assurance in herbal drug industry.
- Know the regulatory approval process and their registration in Indian and international markets.
- Appreciate EU and ICH guidelines for quality control of herbal drugs.

Course Content

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 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 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.

Recommended Books: (Latest Editions)

- Pharmacognosy by Trease and Evans.
- Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- Pharmacognosy by Kokate, Purohit and Gokhale.
- Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
- Aggarwal, S.S., Herbal Drug Technology. Universities Press, 2002.
- EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
- 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.
- WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. 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.
- WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd Ed. World Health Organization, Geneva, 1981.
- WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
- 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.
- WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP807ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

- 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 Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development: Stages of drug discovery and development.

Lead discovery and Analogue 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.

Analogue 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 Taft's 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)

- Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
- Martin YC. "Quantitative Drug Design" Dekker, New York.
- Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
- Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
- Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
- Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
- Current Concepts in Drug Design by T. Durai and Ananda Kumar.
- Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
- Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
- Silverman R.B. "The Organic Chemistry of Drug Design and Drug Action" Academic Press, New York.

BP808ET. CELL AND MOLECULAR BIOLOGY (Theory)

45 Hours

Scope:
Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. This is done both on a microscopic and molecular level. Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall 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.

Course content:

Unit-I **10 Hours**

Cell and Molecular Biology: Definitions theory and basics and Applications.
Cell and Molecular Biology: History and Summation.
Properties of cells and cell membrane.
Prokaryotic versus Eukaryotic.
Cellular Reproduction.
Chemical Foundations – an Introduction and Reactions (Types).

Unit-II **10 Hours**

DNA and the Flow of Molecular Information.
DNA Functioning.
DNA and RNA.
Types of RNA.
Transcription and Translation.

Unit-III **10 Hours**

Proteins: Defined and Amino Acids.
Protein Structure.
Regularities in Protein Pathways.
Cellular Processes.
Positive Control and significance of Protein Synthesis.

Unit-IV **08 Hours**

Science of Genetics.
Transgenics and genomic analysis.
Cell cycle analysis.
Mitosis and meiosis.
Cellular Activities and checkpoints.

Unit-V **07 Hours**

Cell Signals: Introduction.
Receptors for Cell Signals.
Signaling Pathways: Overview.
Misregulation of Signaling Pathways.
Protein-Kinases: Functioning.

Recommended Books (latest edition):

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

BP809ET. COSMETIC SCIENCE (Theory)

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 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, 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. Measurement of TEWL, Skin Colour, Hair tensile strength, Hair combing properties.
Soaps and syndet bars. Evolution and skin benefits.

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 odour.

Antiperspirants and Deodorants- Actives and mechanism of action.

Recommended Books (latest edition):

- Harry's Cosmetology, Wilkinson, Moore, Seventh Edition, George Godwin.
- Poucher's Perfumes, Cosmetic & Soaps by Poucher W.A., Butler, H., Springer India Pvt. Ltd, New Delhi.
- Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- Text book of cosmetology by Sanju Nanda & Roop K. Khar, Tata Publishers.
- Cosmeceuticals by Madhusudan Rao.
- Cosmetics: Science and technology by Balsam M.S., Sagarin, E., Wiley Interscience, New York.
- Handbook of Cosmetic science and Technology by Pave M., Basel, A.O., Maibach H.I., Informa Healthcare, New York.
- Cosemeceuticals by Rao Y.N., Shayeda, PharmaMed Press, Hyderabad.

BP810ET. PHARMACOLOGICAL SCREENING METHODS (Theory)

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives: Upon completion of the course the student shall 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.

Course content:

Unit-I **10 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, anti-asthmatics,

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

Unit-III **10 Hours**

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

Unit-IV **08 Hours**

Preclinical screening models: for CVS activity – anti-hypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, anti-diabetic, anticancer and anti-asthmatics.

Unit-V **07 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.

Recommended Books (latest edition):

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

BP811ET. ADVANCED INSTRUMENTATION TECHNIQUES (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

- Understand the advanced instruments used and its applications in drug analysis.
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments.
- Know analysis of drugs using various analytical instruments.

Course Content:

Unit-I **10 Hours**

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, Analysers -Time of flight and Quadrupole, instrumentation, applications.

Unit-II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (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 **08 Hours**

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 Hours**

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

Recommended Books (Latest Editions)

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

BP812ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory)

45 Hours

Scope: This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective: This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:

- Understand the need of supplements by the different group of people to maintain healthy life.
- Understand the outcome of deficiencies in dietary supplements.
- Appreciate the components in dietary supplements and the application.
- Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

Course Content:

Unit-I **10 Hours**

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, Soybean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds.

Unit-II **10 Hours**

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 **10 Hours**

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 **08 Hours**

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.
Antioxidants: Endogenous antioxidants– enzymatic and non-enzymatic 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 **07 Hours**

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.
Pharmacopeial Specifications for dietary supplements and nutraceuticals.

Recommended Books (Latest editions)

- Dietetics by Sri Lakshmi.
- Role of dietary fibres and nutraceuticals in preventing diseases by K.T. Agusti and P. Faizal: BS Publication.
- Advanced Nutritional Therapies by Cooper. K.A., (1996).
- The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
- Prescription for Nutritional Healing by James F. Balch and Phyllis A. Balch 2nd Ed., Avery Publishing Group, NY (1997).
- G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
- Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
- 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.

- Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition).
- Shils, M.E., Olson, J.A., Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger.

BP813ET. PHARMACEUTICAL PRODUCT DEVELOPMENT (Theory)

45 Hours

Unit-I — 10 Hours

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

Unit-II — 10 Hours

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

Solvents and solubilizers.
Cyclodextrins and their applications.
Non - ionic surfactants and their applications.
Polyethylene glycols and sorbitols.
Suspending and emulsifying agents.
Semi solid excipients.

Unit-III — 10 Hours

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

Tablet and capsule excipients.
Directly compressible vehicles.
Coat materials.
Excipients in parenteral and aerosols products.
Excipients for formulation of NDDS.

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

Unit-IV — 08 Hours

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 **07 Hours**

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

Recommended Books (Latest editions)

- Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc.
- Encyclopaedia of Pharmaceutical Technology, edited by James Swarbrick, Third Edition, Informa Healthcare publishers.
- Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
- The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd. 2013.
- Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
- Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
- Pharmaceutical Dosage Forms and Drug Delivery Systems, Lloyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed. 40
- Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
- Remington – The Science and Practice of Pharmacy, 20th Ed.
- Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liebermann, Leon Lachman and Joseph B. Schwartz.
- Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
- Role of Dietary Fibres and Nutraceuticals in Preventive Diseases by KT Augusti *et. Al.*
- Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Liebermann.
- Advanced Review Articles related to the topics.

BP814PW PROJECT WORK (On Elective)

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subjects opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

BP815P. REPORT ON INDUSTRIAL TOUR

Visit of students to an industrial establishment or an approved research laboratory. The industrial/ research laboratory visit shall include: in case of industry- visit to different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory- visit to different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 7th semester.