



Sanjivani Rural Education Society'

Sanjivani College of Pharmaceutical Education and Research, Kopergaon.

(An Autonomous Institute Affiliated to SPPU, Pune; NBA Accredited &
NAAC Grade-A) Best College Award SPPU, Pune (2023-24)

Final Year B. Pharmacy syllabus 7th and 8th Semester.

Academic Year 2025-26



Sanjivani Rural Education Society'
Sanjivani College of Pharmaceutical Education and Research, Kopergaon

SUBJECT: Table – VII: Course of study for semester VII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3/45	1	4
BP702T	Industrial Pharmacy-II – Theory	3/45	1	4
BP703T	Pharmacy Practice – Theory	3/45	1	4
BP704T	Novel Drug Delivery System – Theory	3/45	1	4
BP705P	Instrumental Methods of Analysis – Practical	4/60	-	2
BP706PS	Practice School*	12/180	-	6
Total		28/420	5	24

* Non University Examination (NUE)

Table – VIII: Course of study for semester VIII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3/45	1	4
BP802T	Social and Preventive Pharmacy	3/45	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6/90	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
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			
BP813PW	Project Work	12/180	-	6
Total		24/360	4	22



Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)

SUBJECT: BP701T Instrumental Methods of Analysis
(THEORY 45 HOURS)

Teaching Scheme

Lectures: 03Hr/Week

Practical: NA

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam: 25 Marks

End SEM Exam: 75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

Scope:

This subject focuses on the principles and application of modern instrumental techniques for qualitative and quantitative analysis of pharmaceuticals. It aims to build a strong foundation in spectroscopy, chromatography, and emerging instrumental methods used in the pharmaceutical industry and regulatory laboratories.

Objectives:

Upon completion of the course, the student shall be able

1. Explain the interaction of matter with electromagnetic radiation and its role in drug analysis.
2. Understand the fundamentals and instrumentation of various spectroscopic and chromatographic techniques.
3. Apply modern instrumental methods for quality control and assurance in pharmaceutical analysis.
4. Analyse and interpret data generated from analytical instruments.

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy Level	Descriptor
CO 1	Describe and interpret the interaction of matter with electromagnetic radiation.	2 – Understand	Explain ideas or concepts
CO 2	Understand and explain the working principles of absorption and emission spectroscopy.	2 – Understand	Summarize, explain, and interpret
CO 3	Demonstrate understanding of chromatographic principles and instrument setup.	3 – Apply	Use information in new situations

CO's	Course Outcomes	Bloom Taxonomy Level	Descriptor
CO 4	Explain separation techniques and evaluate their analytical applications.	4 – Analyze	Draw connections among ideas; differentiate, compare
CO 5	Apply analytical instrumentation in qualitative and quantitative drug analysis.	3 – Apply	Implement, demonstrate, and solve practical problems
CO 6	Relate analytical data to pharmaceutical quality standards and regulatory guidelines.	5 – Evaluate	Justify decisions; assess and integrate standards

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENTS

Instrumental Methods of Analysis

7th Semester

Unit	Chapter/Topic	Duration (hrs)
1	University of Cambridge <i>Principles of Instrumental Analysis</i> by Skoog et al.	10 hrs
2	IR Spectroscopy • Molecular vibrations, sample prep, radiation sources, detectors • Applications in impurity profiling Atomic Spectroscopy: Flame photometry, AAS, Nephelometry, Turbidometry Added modern IR applications, impurity profiling, and updated detector systems University of Michigan <i>Quantitative Chemical Analysis</i> by Daniel Harris	10 hrs
3	Chromatography Overview: Adsorption & partition, TLC, Paper chromatography Electrophoresis: Paper, gel, capillary electrophoresis; biomolecule analysis Introduced capillary electrophoresis, enhanced focus on biomolecule separation ETH Zurich <i>Chromatography: Concepts and Contrasts</i> by J. M. Miller	10 hrs
4	Gas Chromatography (GC): Principles, detectors (FID, TCD), derivatization, temp. programming HPLC: Mobile/stationary phases, detectors (UV, PDA, RI), gradient elution Integrated modern detectors (PDA/RI), emphasized real-time applications and stability studies Monash University <i>Modern HPLC for Practicing Scientists</i> by	08 hrs

Unit	Chapter/Topic	Duration (hrs)
	Michael W. Dong	
5	Ion Exchange Chromatography: Resin classification, mechanisms, uses Gel Chromatography: Size exclusion, setup, MW estimation Affinity Chromatography: Ligand-receptor binding, bioseparation, pharmaceutical applications Focused on biomolecule estimation, biopharma applications and advanced pharmaceutical relevance University of Toronto <i>Bioseparations Science and Engineering</i> by Harrison et al.	07 hrs

Recommended Books (Latest Editions)

1. **Instrumental Methods of Chemical Analysis** – B.K. Sharma
2. **Organic Spectroscopy** – Y.R. Sharma
3. **Textbook of Pharmaceutical Analysis** – Kenneth A. Connors
4. **Vogel's Textbook of Quantitative Chemical Analysis** – A.I. Vogel
5. **Practical Pharmaceutical Chemistry (Vol I & II)** – A.H. Beckett & J.B. Stenlake
6. **Organic Chemistry (Vol I & II)** – I.L. Finar
7. **Organic Spectroscopy** – William Kemp
8. **Quantitative Analysis of Drugs** – D.C. Garrett
9. **Quantitative Analysis of Drugs in Pharmaceutical Formulations** – P.D. Sethi
10. **Spectrometric Identification of Organic Compounds** – Robert M. Silverstein



Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)

SUBJECT: BP702T.INDUSTRIAL PHARMACY II
(THEORY 45 HOURS)

Teaching Scheme

Lectures: 03Hr/Week

Practical: NA

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam: 25 Marks

End SEM Exam: 75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

Course competency:

1. Ability to design and evaluate pilot plant operations for various dosage forms with proper documentation and regulatory compliance (e.g., SUPAC).
2. Competency in planning, executing, and documenting technology transfer from R&D to manufacturing following WHO and national standards.
3. Understanding the global and Indian regulatory environments (e.g., CDSCO, FDA), including drug approval processes, IND/NDA preparation, and clinical trial management.
4. Skill in implementing quality systems such as QbD, TQM, Six Sigma, ISO standards, and GLP in industrial practice.
5. Familiarity with Indian regulatory authorities and procedures including COPP, new drug approvals, and state licensing norms.

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:

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

SRES's Sanjeevani College of Pharmaceutical Education and Research, Kopargaon

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO1	Understand and apply pilot plant scale-up techniques, including personnel, space, and documentation considerations for solids, liquids, and semi-solids, in line with SUPAC guidelines and platform technologies.	1	Recall facts & basic concept
CO 2	Demonstrate knowledge of technology transfer (TT) processes from R&D to production, including WHO guidelines, regulatory documentation, equipment qualification, and TT agencies in India.	2	Explain ideas or concept
CO 3	Explain the structure and function of regulatory affairs, including global and Indian drug approval processes, IND/NDA submissions, and management of clinical studies.	2	Explain ideas or concept
CO 4	Apply principles of quality management systems such as Total Quality Management (TQM), Quality by Design (QbD), Six Sigma, and understand ISO, NABL, and GLP standards.	3	Apply
CO 5	Understand the Indian regulatory framework, including CDSCO, State Licensing Authorities, and procedures for new drug approvals and COPP certification.	2	Explain ideas or concept

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENTS

Unit	Details	Hours
1	UNIT-I 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. Industry 4.0 and Digitalization: Incorporate discussions on the role of digital technologies, such as IoT, AI, and machine learning, in optimizing scale-up processes.	10
2	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	10

	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. International Technology Transfer: Cultural and legal considerations, Risk assessment and mitigation, Cross-border collaboration.	
3	Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professional 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. Post-marketing Surveillance: Pharmacovigilance and risk management. Regulatory Affairs for Medical Devices: Quality System Regulations (QSR), Medical Device Directive (MDD) and Medical Device Regulation (MDR), Medical Device Regulations in India. Regulatory Affairs for Biologics: Biosimilars and interchangeability, Advanced therapy medicinal products (ATMPs), Drug Price Control Order (DPCO).	10
4	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. Pharmaceutical Quality System (PQS): Current Good Manufacturing Practices (cGMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP). Continuous Improvement: Lean Six Sigma, Kaizen, Total Productive Maintenance (TPM), Supplier Quality Management.	8
5	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. Clinical Trials in India	7

Recommended Books :(Latest Editions)

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>



Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopargaon (Autonomous)

SUBJECT: BP703T PHARMACY PRACTICE
(THEORY 45 HOURS)

Teaching Scheme	Examination Scheme:
Lectures: 03Hr/Week	In SEM Exam: 25 Marks
Practical: NA	End SEM Exam: 75 Marks
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

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

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy

Upon completion of the course a student shall be able to understand -

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	To Understand about Hospital and its organization, Hospital pharmacy and its organization, Adverse drug reaction, Community Pharmacy	1	Apply
CO 2	To Understand about Drug distribution system in a hospital, Hospital formulary, Therapeutic drug monitoring, Medication adherence, Patient Medication history, Community pharmacy management	2	Apply
CO 3	To Understand about Pharmacy and therapeutic committee, Drug information services, Patient Counseling, Education and training program in the hospital, Prescribed medication order and communication skills	3	Apply
CO 4	To Understand about preparation and implementation, Clinical Pharmacy, Over the counter (OTC) sales	3	Apply
CO 5	To Understand about Drug store management and inventory control,	3	Apply

	Investigational use of drugs		
CO 6	To Understand about Interpretation of Clinical Laboratory Tests	3	Apply

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENTS

Unit	Details	Hours
1	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. Automation and Technology in Hospital Pharmacy(Automated Dispensing Systems,Barcoding and Scanning) 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. Sustainability and Environmental Impact (Green Pharmacy Practices,Waste Management). Emerging trends in community pharmacy practice.	10+1+1+1
2	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.	10+

	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 Drug Monitoring, 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.	
3	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, Computerized 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. Emerging Technologies in Communication (Telehealth and Telepharmacy, Digital Health Tools) 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. Simulation in Hospital Pharmacy Practice e) Prescribed medication order and communication skills Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	10+1+1
4	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.	8
5	a) Drug store management and inventory control Organization of	7

	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 urine analysis	
	TOTAL	45+5=50

Reference Books (Latest Editions to be adopted):

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, 1 st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Fibiger; 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.
- 7."Information Technology in Pharmacy: An Integrated Approach" by Stephen Goundrey-Smith (Springer)
- 8."Green and Sustainable Pharmacy: Principles and Practice" by K. Kümmerer (Springer)
- 9."Digital Health: Understanding the Digital Transformation of Health Care" by J. Thomas and J. S. Thomas (University of Toronto Press)
10. Al-Worafi, Y.M. (2023). Simulation in Hospital Pharmacy Practice. In: Al-Worafi, Y.M. (eds) Comprehensive Healthcare Simulation: Pharmacy Education, Practice and Research. Comprehensive Healthcare Simulation. Springer, Cham.

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)
4. "Automation of In-Hospital Pharmacy Dispensing: A Systematic Review" by Sarah Batson et al. (European Journal of Hospital Pharmacy)



Sanjivani Rural Education Society'
Sanjivani College of Pharmaceutical Education and Research, Kopergaon

**SUBJECT: BP704T. NOVEL DRUG DELIVERY SYSTEM
(THEORY 45 HOURS)**

Teaching Scheme

Lectures: 03Hr/Week

Practical:

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam:25 Marks

End SEM Exam:75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

Scope

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

Course Objectives:

Upon completion of the course a student shall be able to understand -

- 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 Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	The students should be able to understand the fundamentals/terminology/definitions and rationale of Control release formulation	1	Recall facts and basic concept.
CO 2	The student should be understanding the basic terms and classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems	1,3	Recall facts and basic concept, Apply
CO 3	To explain basic concepts, definition, principles, merit, demerit and learn the formulation and development techniques of Microencapsulation, Mucosal Drug Delivery system, & Implantable Drug Delivery Systems	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 4	To clarify basic principles, rationale, approaches & formulation techniques of Transdermal Drug Delivery Systems, Gastroretentive drug delivery systems, and Nasopulmonary drug delivery system.	1,2,3	Recall facts and basic concept, explain ideas or concept, Apply
CO 5	To Understand Concepts and approaches advantages and disadvantages of Targeted drug Delivery	2,3	Explain ideas or concept, Apply
CO 6	To Understand Concepts and approaches advantages and disadvantages of Ocular Drug Delivery Systems and Intrauterine Drug Delivery Systems, Application of 3D Printing Technology in the Development of Novel Drug Delivery Systems	2,3	Explain ideas or concept, Apply

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENTS

Unit	Details	Hours
1	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.	10
2	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	07
3	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	07
4	Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, Niosomes, nanoparticles, monoclonal antibodies and their applications. Application of 3D Printing Technology in the Development of Novel Drug Delivery Systems: Introduction, Fabrication of various novel drug delivery systems using 3Dprinters, Challenges in 3D printing technology	14
5	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	7

	disadvantages, development of intra uterine devices (IUDs) and applications	
	TOTAL	45

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. Alain Rolland; Sean M Sullivan
Pharmaceutical gene delivery systems New York: Marcel Dekker, ©2003
5. Controlled Release Veterinary Drug Delivery, Biological and Pharmaceutical Considerations, 1st Edition - July 20, 2000, Editors: M.J. Rathbone, R. Gurny
eBook ISBN: 9780080529974

Text Books:

1. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

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



Sanjivani Rural Education Society'
Sanjivani College of Pharmaceutical Education and Research, Kopergaon

BP705P - INSTRUMENTAL METHODS OF ANALYSIS (Practical) 4 Hours / Week

(PRACTICAL 60 HOURS)

Teaching Scheme

Lectures: 03Hr/Week

Practical:

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam: 25 Marks

End SEM Exam: 75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

Scope

This course provides hands-on training in modern analytical instruments used in pharmaceutical quality control and research. It focuses on spectroscopic and chromatographic techniques, enabling students to perform pharmacopoeial assays, interpret spectral data, and ensure drug quality and regulatory compliance.

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

1. **Understand and apply** the principles behind instrumental techniques such as UV-Visible spectroscopy, fluorimetry, flame photometry, IR spectroscopy, TLC, and paper chromatography in the analysis of pharmaceutical substances.
2. **Develop technical competence** in the operation, calibration, and troubleshooting of modern instruments including UV spectrophotometers, fluorimeters, flame photometers, FTIR, and HPLC systems.
3. **Execute analytical procedures** conforming to Pharmacopoeial standards (IP/BP/USP), including assay techniques, calibration curves, and multicomponent estimations.
4. **Interpret spectral data** (UV and IR) and relate it to structural, qualitative, and quantitative drug evaluation.
5. **Demonstrate laboratory accuracy and precision** through proper sample handling, documentation, and application of good laboratory practices (GLP).
6. **Enhance analytical thinking and teamwork** through mini-projects, peer-led instrument demonstrations, and real-time case-based simulations in drug analysis.

Course Outcomes:

CO No.	Course Outcome	Bloom's Taxonomy Level	Descriptor
CO1	Apply theoretical and practical understanding of spectroscopic techniques for the qualitative and quantitative analysis of pharmaceutical substances.	Apply (Level 3)	Use acquired knowledge to perform UV/Vis, fluorimetric, and colorimetric assays practically.
CO2	Demonstrate proficiency in	Analyze	Break down formulation matrices to

CO No.	Course Outcome	Bloom's Taxonomy Level	Descriptor
	chromatographic methods for the separation and analysis of drug components and formulations.	(Level 4)	identify and quantify components using TLC, paper chromatography, and column methods.
CO3	Gain conceptual clarity and technical familiarity with modern analytical instruments, supporting industrial and research applications.	Understand (Level 2)	Explain the working principles of HPLC, FTIR, AAS, and apply knowledge in simulated/real-time experiments.
CO4	Develop skills in interpretation of spectra and application of pharmacopoeial procedures for analytical standardization.	Evaluate (Level 5)	Assess spectral data and compare with pharmacopoeial standards to validate identity and purity of pharmaceutical samples.

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENT

Sr. No.	Name of Experiment	Duration (Hours)
1	Overview of Weights and Measures; Role of Pharmacopoeia in Analytical Practices Basic foundational experiment	4
2	Determination of Absorption Maxima (λ_{max}) and Effect of Solvent Polarity on UV Absorption of Organic Compounds Enhanced focus on solvent effect studies (New update)	4
3	Assay of Paracetamol Tablets using UV-Visible Spectrophotometry as per Indian Pharmacopoeia (IP)	4
4	Calibration Curve Method: Assay of Selected API (e.g., Aspirin or Caffeine)	4
5	Colorimetric Estimation: Assay of a Drug (e.g., Iron, Sulfanilamide) using Colorimetry	4
6	Simultaneous Estimation of a Multicomponent Formulation using UV Spectroscopy (Simultaneous Equation/ Q-Analysis method) Added simultaneous multicomponent estimation using Q-analysis (New)	4
7	Estimation of Fluorescent Drugs (e.g., Quinine Sulphate) by Fluorimetry Inclusion of fluorescence quenching studies (New update)	4
8	Study of Fluorescence Quenching and Factors Influencing It	4
9	Quantification of Sodium and Potassium using Flame Photometry	4
10	Separation and Identification of Amino Acids by Paper Chromatography	4
11	Separation of Monosaccharides and Disaccharides by Thin Layer Chromatography (TLC)	4
12	Column Chromatography: Separation of Plant Pigments or Herbal Constituents	4
13	Demonstration and Working Principle of HPLC Instrumentation Practical exposure and demonstration of HPLC instrumentation (New) (1 hrs)	4
14	Demonstration and Application of FTIR Instrumentation Practical exposure and demonstration of FTIR instrumentation (New)	4
15	Interpretation of IR Spectra of Organic Compounds in line with Pharmacopoeial Standards Emphasis on IR spectra interpretation aligned with pharmacopoeial standards (New) (1 hrs)	4

Recommended Books:

1. **Vogel's Textbook of Quantitative Chemical Analysis** – A.I. Vogel
2. **Practical Pharmaceutical Chemistry** – A.H. Beckett and J.B. Stenlake
3. **Instrumental Methods of Analysis** – B.K. Sharma
4. **Quantitative Analysis in Pharmaceutical Practice** – P.D. Sethi (*recommended for current industrial methods*)

SRES's Sanjeevani College of Pharmaceutical Education and Research, Kopergaon



Sanjivani Rural Education Society'
Sanjivani College of Pharmaceutical Education and Research, Kopergaon

SUBJECT: BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY
(THEORY 45 HOURS)

Teaching Scheme

Lectures: 03Hr/Week
 Practical:
 Tutorials: 01Hr/Week
 Credits: 4

Examination Scheme:

In SEM Exam: 25 Marks
 End SEM Exam: 75 Marks
 Continuous Assessment: 10 Marks
 Total Marks: 100 Marks

Scope:

To
 understand
 the
 applications

of Biostatistics 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, analyzing the statistical data using Excel.

Objectives:

Upon completion of the course the student shall be able to

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

Sr. No	Content	Hrs
1	UNIT-I 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	10 Hours
2	UNIT-II 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, (Oneway and Two way), Least Significance difference	10 Hours

3	UNIT-III 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, Cohort studies, Observational studies, Experimental studies, Designing clinical trial, various phases.	10
4	UNIT-IV Blocking and confounding system for Two-level factorials Regression modeling: Hypothesis testing in Simple and Multiple regression models Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach	08
5	UNIT-V Design and Analysis of experiments: Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design Response Surface methodology: Central composite design, Historical design, Optimization Techniques	07

Recommended Books (Latest edition):

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



**Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopargaoon (Autonomous)**

**SUBJECT: BP802T SOCIAL AND PREVENTIVE PHARMACY (Theory)
(THEORY 45 HOURS)**

Teaching Scheme

Lectures: 03Hr/Week

Practical: NA

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam:25 Marks

End SEM Exam:75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

Scope
: The
purpo
se 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: Upon completion of the course, the student shall be able to

1. Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
2. Develop a critical way of thinking based on current health care development.
3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Upon completion of the course a student shall be able to understand -

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	To Understand about 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. 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.	1	Apply
CO 2	To Understand about 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	2	Apply
CO 3	To Understand about 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,	3	Apply
CO 4	To Understand about National health programs, its objectives, functioning and outcome of the following: National programme for prevention and control of	3	Apply

	deafness, Universal immunization programme, programme for control of blindness, Pulse polio programme.		
CO 5	To Understand about 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	3	Apply
CO 6	To Understand about 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. Machine Learning and Artificial Intelligence in Social and Preventive Pharmacy	3	Apply

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENTS

Unit	Details	Hours
1	UNIT-I 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. 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.	10 Hours
2	UNIT-II Preventive medicine General principles of prevention and control of diseases such as cholera, SARS, COVID-19, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse	10+2 Hours
3	UNIT-III 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	10 Hours

	mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.	
4	UNIT-IV 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	8 Hours
5	UNIT-V 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. Machine Learning and Artificial Intelligence in Social and Preventive Pharmacy	7+4 Hours
	TOTAL	45+6

Reference Books (Latest Editions to be adopted)

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

Recommended Journals:

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



**Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopargaoon (Autonomous)**

SUBJECT: BP803T PHARMACEUTICAL MARKETING (Theory) (45 HOURS)

Teaching Scheme	Examination Scheme:	Scope
Lectures: 03Hr/Week	In SEM Exam:25 Marks	:
Practical: NA	End SEM Exam:75 Marks	The
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks	phar
Credits: 4	Total Marks: 100 Marks	mace

utical 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.

Sr. No	Content	45 Hours
1	UNIT-I 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.	10 Hours
2	UNIT-II Product decision: Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labelling decisions, Product management in pharmaceutical industry.	10 Hours

3	UNIT-III 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.	10 Hours
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SRES's Sanjeevani College of Pharmaceutical Education and Research, Kopergaon

4	UNIT-IV 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.	08 Hours
5	UNIT-V 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.	07 Hours

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC GrawHill
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 Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi, Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.



Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)

SUBJECT: BP804ET PHARMACEUTICAL REGULATORY SCIENCE (Theory) (45 HOURS)

Teaching Scheme	Examination Scheme:	Scope:
Lectures: 03Hr/Week	In SEM Exam:25 Marks	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.
Practical: NA	End SEM Exam:75 Marks	
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks	
Credits: 4	Total Marks: 100 Marks	

ned 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;

1. Know about the process of drug discovery and development
2. 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

Sr. No	Content	Hrs
1	UNIT-I 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.	10 Hours
2	UNIT-II 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)	10 Hours
3	UNIT-III 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.	10 Hours

4	UNIT-IV 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	08 Hours
5	UNIT-V Regulatory Concepts Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	07 Hours

Recommended books (Latest edition):

- Drug Regulatory Affairs by SachinItkar, Dr. N.S. Vyawahare, NiraliPrakashan.
- The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. InformaHealth carepublishers.
- New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino,MD,5thedition, Drugsand 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, andbiologics /edited by Douglas J. Pisano, David Mantus.
- Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland IsaderKaufer, Marcel Dekker series,Vol.143
- Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance By Fay A. Rozovsky and Rodney K.Adams
- Principles and Practices of Clinical Research, Second Edition Edited by JohnI. Gallin and Frederick P.Ognibene Drugs: From Discovery to Approval, Second Edition By RickNg



**Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)**

SUBJECT: BP805T PHARMACOVIGILANCE (Theory) (45 HOURS)

Teaching Scheme	Examination Scheme:	Scope
Lectures: 03Hr/Week	In SEM Exam:25 Marks	:
Practical: NA	End SEM Exam:75 Marks	Scope:
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks	This
Credits: 4	Total Marks: 100 Marks	

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):
- Understand importance of drug safety monitoring.
- Explain History, development, National and international scenario of pharmacovigilance & comprehend dictionaries, coding and terminologies used in pharmacovigilance
- Understand detection and assessment of new adverse drug reactions, Adverse drug reaction reporting systems and communication in pharmacovigilance, 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
- Comprehend methods of safety data during pre-clinical, clinical and post approval phases of drugs' lifecycle.
- Write case narratives of adverse events and their quality.

Sr. No.	Content	Hrs.
1	UNIT-I 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	10 Hours

2	UNIT-II Drug and disease classification Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses, International Nonproprietary Names for drugs Drug dictionaries and coding in pharmacovigilance WHO adverse reaction terminologies, MedDRA and Standardized MedDRA queries, WHO drug dictionary, Eudravigilance medicinal product dictionary Information resources in pharmacovigilance Basic drug information resources, Specialized resources for ADRs Establishing pharmacovigilance programme Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (CROs), Establishing a national programme.	10 Hours
3	UNIT-III 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	10 Hours
4	UNIT-IV 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	08 Hours

5	UNIT-V Pharmacogenomics of adverse drug reaction Genetics related ADR with example focusing PK parameters. CIOMS CIOMS Working Groups, CIOMS Form CDSCO (India) and Pharmacovigilance D&C Act and Schedule Y Differences in Indian and global pharmacovigilance requirements	07 Hours
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Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. <http://www.who.unc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html



**Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopargaon (Autonomous)**

**SUBJECT: BP806T QUALITY CONTROL AND STANDARDIZATION OF HERBALS
(Theory) 45 HOURS)**

Teaching Scheme

Lectures: 03Hr/Week

Practical: NA

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam: 25 Marks

End SEM Exam: 75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

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;

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

Sr. No	Content	Hrs
1	UNIT-I 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	10 Hours
2	UNIT-II • 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.	10 Hours
3	UNIT-III • EU and ICH guidelines for quality control of herbal drugs. • Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	10 Hours

4	UNIT-IV - 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.	08 Hours
5	Unit V Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Comparison of various Herbal Pharmacopoeias.	07 Hrs

Recommended books

- Role Pharmacognosy by Trease and Evans
- Pharmacognosy by Kokate, Purohit and Gokhale
- Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I, Carrier Pub., 2006.
- Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
- EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
- Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
- 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 edn. 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.



Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)

SUBJECT: BP807T COMPUTER AIDED DRUG DESIGN (Theory) (45 HOURS)

Teaching Scheme

Lectures: 03Hr/Week

Practical: NA

Tutorials: 01Hr/Week

Credits: 4

Examination Scheme:

In SEM Exam: 25 Marks

End SEM Exam: 75 Marks

Continuous Assessment: 10 Marks

Total Marks: 100 Marks

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

1. Understand the design and discovery of lead molecules
2. Classify the role of drug design tools for drug discovery process
3. Understand and analyse concepts of QSAR and docking
4. Analyse and apply various strategies to develop new drug like molecules.
5. Use various molecular modeling software to design new drug molecule

Sr. No	Content	Hrs
1	UNIT-I Introduction to Drug Discovery and Development - Stages of drug discovery and development, Lead discovery approaches - 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. Introduction to Ligand based and Structure Based DD Analog Based Drug Design - Bioisosterism, Bioisosteric replacement Case studies - Ligand based (Design of inhibitors of tubulin polymerization eg. Colchicine), Structure based (Design of HMG-CoA reductase inhibitors. eg. Statins) and Analog based DD (Design of H2 histamine antagonist eg. Cimetidine)	14 Hours
2	UNIT- II Introduction to Computational tools Molecular Modeling - Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination. Molecular docking - Rigid docking, flexible docking, manual docking, Docking based screening.	10 Hours

3	UNIT- III Quantitative Structure Activity Relationship (QSAR) and Pharmacophore modeling Introduction - SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters 2D QSAR - Experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. Hansch's analysis, Free Wilson analysis 3D-QSAR approaches - COMFA and COMSIA. Pharmacophore modeling - Drug likeness screening, Concept of Pharmacophore mapping and Pharmacophore based screening	14 Hours
4	UNIT- IV Informatics & Methods in drug design Introduction to Bioinformatics, chemo informatics Databases - Chemical database, Natural compound database, Drug like compound database , Drug bank	07 Hours

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Korolkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.
10. D. J. Triggle, John Bodenhan Taylor, Peter Kennewell, Comprehensive Medicinal Chemistry, Volume I-VIII : Germany: Elsevier Science.



**Sanjeevani Rural Education Society's
Sanjeevani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)**

SUBJECT: BP808T CELL AND MOLECULAR BIOLOGY (Theory) 45 HOURS)

Teaching Scheme	Examination Scheme:	Scope
Lectures: 03Hr/Week	In SEM Exam: 25 Marks	:
Practical: NA	End SEM Exam: 75 Marks	Scope:
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks	Cell
Credits: 4	Total Marks: 100 Marks	1

biology is a branch of biology that studies cells—their physiological properties, their structure, the organelles they contain, interactions with their environment, their lifecycle, 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:

1. Summarize cell and molecular biology history, cellular functioning and Composition & describe the chemical foundations of cell biology.
2. Describe cellular membrane structure and function properties and functions of DNA, Cell Cycle.
3. Describe basic molecular genetics mechanisms.
4. Understand the cell signaling pathways with their regulations and role in disease process.

Sr. No.	Content	Hours
1	UNIT-I 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)	10 Hours
2	UNIT-II DNA and the Flow of Molecular Information, DNA Functioning, DNA and RNA, Types of RNA, Transcription and Translation	10 Hours
3	UNIT-III Proteins: Defined and Amino Acids, Protein Structure, Regularities in Protein Pathways, Cellular Processes, Positive Control and significance of Protein Synthesis	10 Hours
4	UNIT-IV Science of Genetics, Transgenics and Genomic Analysis, Cell Cycle analysis, Mitosis and Meiosis, Cellular Activities and Checkpoints Clinical phase, Post approval phase (PMS)	08 Hours
5	UNIT-V Cell Signals: Introduction, Receptors for Cell Signals, Signaling Pathways: Overview, Misregulation of Signaling Pathways, Protein-Kinases: Functioning	07 Hours

Recommended Books (latest edition):

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



**Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)**

**SUBJECT: BP810ET EXPERIMENTAL PHARMACOLOGY (Theory)
(THEORY 45 HOURS)**

Teaching Scheme	Examination Scheme:	Scope
Lectures: 03Hr/Week	In SEM Exam: 25 Marks	: This subject is
Practical: NA	End SEM Exam: 75 Marks	
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks	
Credits: 4	Total Marks: 100 Marks	

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

1. Understand the applications of various commonly used laboratory animals.
2. Demonstrate the various screening methods used in preclinical research.
3. Comprehend and demonstrate the importance of biostatistics and research methodology.
4. Design and execute a research hypothesis independently.

Upon completion of the course a student shall be able to understand -

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	To Understand about 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.	1	Apply
CO 2	To Understand about 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. Rationale for selection of animal species and sex for the study.	2	Apply
CO 3	To Understand about Preclinical screening models b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS	3	Apply

	activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease.		
CO 4	To Understand about Preclinical screening models: For ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	3	Apply
CO 5	To Understand about Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics	3	Apply
CO 6	To Understand about 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. Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development	3	Apply

Mapping of Course Outcomes to Program Outcomes:

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

COURSE CONTENTS

Unit	Details	Hours
1	UNIT-I 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.	10 Hours
2	UNIT-II Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug	10 Hours

	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. b. 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.	
3	UNIT-III Preclinical screening models: For ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	10 Hours
4	UNIT-IV Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics	8 Hours
5	UNIT-V 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. Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development	7 +4 Hours
	TOTAL	45+4

Reference Books (Latest Editions to be adopted):

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

Journals:

1. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8726514/>



**Sanjivani Rural Education Society's
Sanjivani College of Pharmaceutical Education and Research, Kopergaon (Autonomous)**

BP811ET: Advanced Instrumentation Techniques (Theory) (Allotted Hrs 45)

Teaching Scheme	Examination Scheme:	Scope
Lectures: 03Hr/Week	In SEM Exam:25 Marks	: The subject Advanced Instrumentation Techniques
Practical:	End SEM Exam:75 Marks	
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks	
Credits: 4	Total Marks: 100 Marks	

Advanced Instrumentation Techniques is designed to equip final-year pharmacy students with comprehensive knowledge and practical skills in sophisticated analytical and diagnostic instrumentation used in pharmaceutical research, drug development, quality control, and regulatory compliance.

Course Objectives:

Upon completion of the course student shall be able to

- 1 Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	Explain the principles and working of advanced analytical instruments used in pharmaceutical analysis.	1	Understand
CO 2	Demonstrate the ability to operate instruments such as HPLC, GC, UV-Vis, and FTIR.	4	Apply
CO 3	Apply instrumental techniques for the qualitative and quantitative analysis of pharmaceutical substances.	2	Apply
CO 4	Interpret analytical data and validate methods in accordance with regulatory guidelines	3	Analyze / Evaluate
CO 5	Perform routine maintenance and calibration of instruments following Good Laboratory Practices (GLP).	5	Apply/ Analyze
CO 6	Analyze the role of advanced instrumentation in quality control, bioanalytical studies, and research applications.	1, 6	Analyze

Descriptor: 1- Recall facts and basic concept, 2- Explain ideas or concept, 3- Apply, 4- Analyze, 5- Evaluate, 6- Create

Mapping of Course Outcomes to Program Outcomes:

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

Low-1, Medium-2, High-3

COURSE CONTENTS

Unit	Details	Hours
1	UNIT-I Nuclear Magnetic Resonance spectroscopy Principles of ¹ H-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications ¹³ C-NMR- Introduction to ¹³ C-NMR spectroscopy Mass Spectrometry Principles, , Ionization techniques –Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, Fragmentation, applications Simple structural elucidation problems	14 hrs.
2	UNIT-II Thermal Methods of Analysis Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)	7 hrs.
3	UNIT-III Electrophoresis Introduction, factors affecting electrophoretic mobility, Techniques of gel, capillary electrophoresis, applications Calibration of following Instruments Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, HPLC.	10 hrs.,
4	UNIT-IV Hyphenated techniques Introduction to hyphenated techniques and types of techniques Details of LCMS, GC-MS, HPTLC-MS, MS/MS	8hrs.
5	UNIT-V Radio immuno assay, ELISA, Bioluminescence assays Principle, different methods, Importance, various components, Limitation and Applications of Radioimmunoassay Extraction techniques General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.	06 hrs.

	TOTAL	45
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Reference Books (Latest Editions to be adopted):

Reference Books:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

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