1.3: CURRICULUM ENRICHMENT

1.3.1: Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability into the Curriculum

INDEX		
Sr. No.	**TITLE**	**Page No.**
1.	Institute integrates Crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environmental and Sustainability into the curriculum	3-6
	A. Summary of Supporting Courses into the Curriculum	3-5
	B. Summary of Co-Curricular Activities	6
2.	Supporting Courses	7-46
	A. B.Pharm.	7-32
	B. M.Pharm.	33-38
	C. Pharm.D	39-46
3.	Supporting Co-Curricular Activities	47-51

SUMMARY

Shree Chanakya Education Society's

Indira College of Pharmacy, Pune

"Redefining Pharmacy Education"

NAAC : B++

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CROSSCUTTING ISSUES RELEVANT TO PROFESSIONAL ETHICS, GENDER, HUMAN VALUES, ENVIRONMENT AND SUSTAINABILITY INTO THE CURRICULUM

Sr.No.	Course	Name of the Subject	Subject Code	Professional Ethics	Gender Equality	Human Values	Environment & Sustainability
1.	F.Y. B.Pharm (Sem-I)	Communication skills	BP105T	–	√	√	√
2	F.Y. B.Pharm (Sem-II)	Computer Applications in Pharmacy	BP205T	–	–	–	√
3	F.Y. B.Pharm (Sem-II)	Environmental Sciences	BP206T	–	–	√	√
4	F.Y.B.Pharm. (Sem-II)	Democracy, Election and Governance	–	–	√	√	–
5	T.Y.B.Pharm. (Sem-V)	Industrial Pharmacy	BP502	√	√	–	–
6	T.Y.B.Pharm. (Sem-V)	Pharmaceutical Jurisprudence	BP505	√	–	–	–
7	T.Y.B.Pharm (Sem-VI)	Pharmaceutical Quality Assurance	BP606	√	–	–	√
8	Final year B.Pharm. (Sem- VII)	Industrial Pharmacy	BP702	√	–	–	–
9	Final year B.Pharm. (Sem- VII)	Pharmacy Practice	BP703	√	–	√	√

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Sr.No.	Course	Name of the Subject	Subject Code	Professional Ethics	Gender Equality	Human Values	Environment & Sustainability
10	Final year B.Pharm. (Sem- VII)	Practice School	BP706PS	√	–	√	√
11	Final year B.Pharm. (Sem- VIII)	Pharma Marketing Management	BP803ET	√	–	√	–
13	Final year B.Pharm. (Sem- VIII)	Pharmaceutical Regulatory Science	BP804ET	√	–	–	–
14	Final year B.Pharm. (Sem- VIII)	Experimental Pharmacology	BP810ET	–	–	–	√
15	Final year B.Pharm. (Sem- VIII)	Dietary Supplements and Nutraceuticals	BP812ET	√	√	–	–
16	Final year B.Pharm. (Sem- VIII)	Project Work	BP813PW	–	–	–	√
17	F.Y. M.Pharm. (MPH)	Regulatory Affair	MPH104T	√		–	√

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2

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Sr.No.	Course	Name of the Subject	Subject Code	Professional Ethics	Gender Equality	Human Values	Environment & Sustainability
18	F.Y. M.Pharm. (MPH)	Computer Aided Drug Development	MPH203T	–	–	–	√
19	F.Y. M.Pharm. (MQA)	Hazards and Safety Management	MQA201T	√	–	–	√
20	F.Y. M.Pharm. (MQA)	Audits and Regulatory Compliance	MQA203T	√	–	–	√
21	S.Y. M.Pharm. (MPH, MQA)	Introduction to Constitution	–	–	√	√	–
22	S.Y. M.Pharm. (MPH, MQA)	Journal Club	MPH302 MQA302	√	–	–	√
23	S.Y. Pharm.D	Community Pharmacy	2.5	√	–	–	–
24	Fourth Yr. Pharm. D	Clinical Pharmacy	4.3	–	–	–	√
25	Fifth Yr. Pharm.D	Clinical Research	5.1	√	–	–	–

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CO-CURRICULAR ACTIVITIES

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Sr.No.	Supporting Activities	Professional Ethics	Gender Equality	Human Values	Environment & Sustainability
1	Pharmacists Day	√	–	–	–
2	National Pharmacy Week	√	–	–	–
3	Constitutional Day	√	–	–	–
4	Women's Day	–	√	–	–
5	Sessions on Gender Equality	–	√	–	–
6	NSS	–	√	√	–
7	Blood Donation Camp	–	–	√	–
8	Pulse Polio Vaccination	–	–	√	–
9	Yoga Day	–	–	√	–
10	Tree Plantation	–	–	√	√
11	E-Waste Drive	–	–	–	√
12	Plastic and Tobacco free Campus	–	–	√	√
13	Environmental field visit	–	–	–	√

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4

Back to Index

SUPPORTING COURSES

B.Pharm.

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I **07 Hours**

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II **07 Hours**

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

43

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UNIT – III **07 Hours**

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV **05 Hours**

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V **04 Hours**

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

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44

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BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

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

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I **06 hours**

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II **06 hours**

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III **06 hours**

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

67

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UNIT – IV **06 hours**

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V **06 hours**

Computers as data analysis in Preclinical development:
Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

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68

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BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

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

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I **10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II **10hours**

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

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70

BP 502 T. Industrial Pharmacy I (Theory)

UNIT-I

Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study o physicochemical characteristics of drug substances.

UNIT-II 14

Hours

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, preformulation and Formulation of tablets, granulation methods, compression and processing problems, Equipmen and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, method of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Preformulation, Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III **08 Hours**

Capsules:

a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. Size of capsules Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. Soft gelatin capsules: Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests.

Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV

Hours

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls, aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids.

Quality control tests of parenteral products. Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V **10 Hours**

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

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Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; preformulation, formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and restricted license. Offences and penalties Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics,

List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III **10 Hours**

Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and 122 Penalties

Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

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UNIT-IV **08 Hours**

Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **07 Hours**

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist"s oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

BP 606T PHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

COURSE CONTENT

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP, Introduction to Regulatory agencies like CDSCO, USFDA, WHO, PIC/S.

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: Brief overview of QSEM, ICH stability testing guidelines

Quality by design (QbD): Definition, Overview, Elements of QbD program

ISO 9000 & ISO14000: Overview, Benefits and Elements

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance,purchase specifications and maintenance of stores for raw materials.

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UNIT – III **10 Hours**

Quality Control of Packaging material: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices &Role of CPCSEA

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry in brief: Batch Formula Record, Master Formula Record, SOP, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, type of validation.

General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

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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:

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

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 R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoU's, 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

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Product Development, Data Presentation for FDASubmissions, Management of Clinical Studies.

UNIT-IV **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.

UNIT-V **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

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 athttp://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.

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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 counseling 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.

Course Content:

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.

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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 labelling, 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, Computerized services, and storage and retrieval of information.

Patient counseling
Definition of patient counseling; steps involved in patient counseling, 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.

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UNIT-IV **08 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 **07 Hours**

Drug store management and inventory control

Organization 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, hematology, and urinalysis

Recommended Books (Latest Edition):

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

Journals:

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

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BP706PS PRACTICE SCHOOL* **150 Hours**

In the VII semester, 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 for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

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BP803ET PHARMACEUTICAL MARKETING (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; Analyzing consumer buying behaviour; 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; patients' choice of physician and retail pharmacist. Analyzing 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 labelling 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.

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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)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, Indian Context, Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

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BP804ET PHARMACEUTICAL REGULATORY SCIENCE (Theory) **45 Hours**

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;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. 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.

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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):

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

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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

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

Course Content

UNIT-I **14 Hours**

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)

UNIT- II **10 Hours**

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.

UNIT- III **14 Hours**

Quantitative Structure Activity Relationship (QSAR) and Pharmacophore modeling

Introduction -

SAR versus QSAR, History and development of QSAR, Types of physicochemical

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parameters

2D QSAR -

Experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts 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

UNIT- IV **07 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemo informatics

Databases -

Chemical database, Natural compound database, Drug like compound database , Drug bank

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, NewYork.
3. Delgado JN, Remers WA eds "Wilson &Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, NewYork.
4. Foye WO "Principles of Medicinal chemistry 'Lea &Febiger.
5. Korolkovas A, BurckhalterJH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, NewYork.
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" WrightBoston.
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,ComprehensiveMedicinal Chemistry, Volume I-VIII : Germany: Elsevier Science.

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BP810ET EXPERIMENTAL PHARMACOLOGY (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,
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.

Course contents

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
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.
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.

UNIT-III **10 Hours**

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

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UNIT-IV **08 Hours**

Preclinical screening models:

for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants

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

UNIT-V **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):

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

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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:

1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Recognize the components in dietary supplements and the application.
4. Acquaint with the regulatory and commercial aspects of dietary supplements including health claims.

Course content:

UNIT-I **07 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, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT-II **15 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,

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Wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT-III **07 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 **10 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 nonenzymatic antioxidant defense, 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-IV **06 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.

Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

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

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BP813PW PROJECT WORK

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 subject 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).

The internal and external examiner appointed for evaluation of the project shall be approved teachers of SPPU /Industrial Experts appointed by Principal of the respective institute.

Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below

Evaluation of Dissertation Book

Objective(s) of the work done		15 Marks
Methodology adopted		20 Marks
Results and Discussions		20 Marks
Conclusions and Outcomes		20 Marks
	Total	**75 Marks**

Evaluation of Presentation:

Presentation of work		25 Marks
Communication skills		20 Marks
Question and answer skills		30 Marks
	Total	**75 Marks**

Explanation:

The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

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Back to Index

M.Pharm.

REGULATORY AFFAIRS
(MPH 104T)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY **60 Hrs**

1. a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in–vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**

   b) Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. **12 Hrs**

2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hrs**

3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). **12 Hrs**

40

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4. Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA – new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. **12 Hrs**

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. 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.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga–basics

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PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(MQA 204T) **60 Hrs**

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this course it is expected that students will be able to Understand -

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

UNIT-I

- **Pharmaceutical industry developments**: Legal requirements and Licenses for API and formulation industry, Plant location- Factors influencing.
- **Plant layout**: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. **12 Hrs**
- **Production planning**: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

UNIT-II

- **Aseptic process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).
- **Advanced sterile product manufacturing technology** : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. **12 Hrs**
- **Process Automation in Pharmaceutical Industry**: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

UNIT-III

- **Non sterile manufacturing process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). **12 Hrs**
- Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products,
- **Improved Tablet Production**: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing

129

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Tathawade, Pune - 411 033

HAZARDS AND SAFETY MANAGEMENT (MQA 201T)	60 Hrs
Scope This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations. **Objectives** At completion of this course it is expected that students will be able to • Understand about environmental problems among learners. • Impart basic knowledge about the environment and its allied problems. • Develop an attitude of concern for the industry environment. • Ensure safety standards in pharmaceutical industry • Provide comprehensive knowledge on the safety management • Empower an ideas to clear mechanism and management in different kinds of hazard management system • Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.	
UNIT-I • Multidisciplinary nature of environmental studies Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources • **Ecosystems**: Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	**12 Hrs**
UNIT-II • Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.	**12 Hrs**
UNIT-III • **Chemical based hazards**: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard. Control measures for chemical hazards. Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, MSDS, Labelling guidelines, Management of over-Exposure to chemicals and TLV concept, Disposal of hazardous material.	**12 Hrs**
UNIT-IV • **Fire and Explosion**: Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations • **Fire protection system**: Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers.	**12 Hrs**

123

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UNIT-V • **Hazard and risk management**: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools, Preliminary hazard analysis • Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.	**12 Hrs**

REFERENCES

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Quantitative Risk Assessment in Chemical Process Industries, American Institute of Chemical Industries, Centre for Chemical Process safety.
3. T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press
4. M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5. Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6. H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982.
7. C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
8. Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, An imprint of Elsevier Science.

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124

AUDITS AND REGULATORY COMPLIANCE **60 Hrs**
(MPA 203T)

SCOPE

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

Objectives

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT-I

- **INTRODUCTION**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies — **12 Hrs**

UNIT-II

- **Role of quality systems and audits in pharmaceutical manufacturing environment**: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, transitioning to quality system approach, Audit checklist for drug industries. — **12 Hrs**

UNIT-III

- Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging. — **12 Hrs**

UNIT-IV

- **Auditing of Microbiological laboratory**: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. — **12 Hrs**

UNIT-V

- **Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. — **12 Hrs**

REFERENCES

1. Karen Ginsbury and Gil Bismuth,Compliance auditing for Pharmaceutical Manufacturers. Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Shayne Cox Gad, Pharmaceutical Manufacturing Handbook, Regulations and Quality, Wiley-Interscience, A John Wiley and sons, Inc. Publications.
3. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of microbiological Quality control,CRC Press. 2000.
4. C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden, Laboratory auditing for quality and regulatory compliance. Donald Taylor and Francis (2005).

128

Indira College of Pharmacy Pune

PRINCIPAL
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Tathawade, Pune - 411 033

Back to Index

PHARM. D

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know pharmaceutical care services;
   b. know the business and professional practice management skills in community pharmacies;
   c. do patient counselling & provide health screening services to public in community pharmacy;
   d. respond to minor ailments and provide appropriate medication;
   e. show empathy and sympathy to patients; and
   f. appreciate the concept of Rational drug therapy.

   Text Books:
   a. Health Education and Community Pharmacy by N.S.Parmar.
   b. WHO consultative group report.
   c. Drug store & Business management by Mohammed Ali & Jyoti.

   Reference books:
   a. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
   b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

   Special requirements:
   1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
   2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. **Scheme of evaluation (80 Marks)**
   1. Synopsis 10
   2. Major Experiment 30
      (Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)
   3. Minor Experiment(Ability to measure B.P/ CBG / Lung function) 15
   4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) 15
   5. Viva – Voce 10

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4. **Lecture wise programme :**

Topics

1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist

2 **Community Pharmacy Management**
a) Selection of site, Space layout, and design
b) Staff, Materials- coding, stocking
c) Legal requirements
d) Maintenance of various registers
e) Use of Computers: Business and health care soft wares

3 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.

4 **Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.

6 **Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7 **Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 **Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function and Cholesterol testing

9 **OTC Medication- Definition, OTC medication list & Counselling**

10 **Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,
Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist

11 **Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

12 **Essential Drugs concept and Rational Drug Therapy**
Role of community pharmacist

13 **Code of ethics for community pharmacists**

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4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilisation evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services

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3. **Patient data analysis**
   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

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Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. **Drug development process:**
   Introduction
   Various Approaches to drug discovery
   1. Pharmacological
   2. Toxicological
   3. IND Application
   4. Drug characterization
   5. Dosage form

2. **Clinical development of drug:**
   1. Introduction to Clinical trials
   2. Various phases of clinical trial.
   3. Methods of post marketing surveillance
   4. Abbreviated New Drug Application submission.
   5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
   6. Challenges in the implementation of guidelines
   7. Ethical guidelines in Clinical Research
   8. Composition, responsibilities, procedures of IRB / IEC
   9. Overview of regulatory environment in USA, Europe and India.
   10. Role and responsibilities of clinical trial personnel as per ICH GCP
       a. Sponsor
       b. Investigators
       c. Clinical research associate
       d. Auditors
       e. Contract research coordinators
       f. Regulatory authority
   11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
   12. Informed consent Process
   13. Data management and its components
   14. Safety monitoring in clinical trials.

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Savitribai Phule Pune University, Pune
For All faculties

2 credit Compulsory course for all the First Year students in All Faculties
Democracy, Election and Governance

Objectives:

1. To introduce the students meaning of democracy and the role of the governance
2. To help them understand the various approaches to the study of democracy and governance

Module 1 Democracy- Foundation and Dimensions

a. Constitution of India
b. Evolution of Democracy- Different Models
c. Dimensions of Democracy- Social, Economic, and Political

Module 2 Decentralization

a. Indian tradition of decentralization
b. History of panchayat Raj institution in the lost independence period
c. 73rd and 74th amendments
d. Challenges of caste, gender, class, democracy and ethnicity

Module 3 Governance

a. Meaning and concepts
b. Government and governance
c. Inclusion and exclusion

References:

1. Banerjee-Dube, I. (2014). *A history of modern India*. Cambridge University Press.
2. Basu, D. D. (1982). *Introduction to the Constitution of India*. Prentice Hall of India.
3. Bhargava, R. (2008). *Political theory: An introduction*. Pearson Education India.

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INTRODUCTION TO CONSTITUTION

(TWO CREDITS)

Course Objectives: This course introduces students to the Constitution of India. The Constitution, being supreme law of the land, must be known to every citizen of India. It begins with the Preamble, which indicates the source and objects of it. We, the people of India, are the source of the Constitution and have resolved to constitute India into a sovereign, socialist, secular, democratic and republic. The Course has been designed for everyone to make acquaint themselves with their fundamental rights and of others. No right is absolute one; it is subject to others right, as well. Directive Principles of State Policy are nothing but rights, though not enforceable by any court. These Directive Principles are basically 'Fundamental Principles' in the governance of the country. Powers and freedoms come with responsibility, State's responsibility to implement Directive Principles and citizens must perform their duties towards others, society and nation.

Expected Course Outcomes:
To introduce the philosophy of Constitution of India to students.
To acquaint them with their freedoms and responsibilities.

UNIT 1: PHILOSOPHY OF THE INDIAN CONSTITUTION (5 Hours)

a) Constitutional History of India
b) Role of Dr. B.R. Ambedkar in Constituent Assembly
c) Preamble – Source and Objects
d) Sovereign and Republic
e) Socialist and Secular
f) Democratic – Social and Economic Democracy
g) Justice – Social, Economic and Political
h) Liberty – Thought, Expression, Belief, Faith and Worship
i) Equality – Status and Opportunity
j) Fraternity, Human Dignity, Unity and Integrity of the Nation

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UNIT 2: FUNDAMENTAL RIGHTS (10 Hours)

a) Right to equality
b) Right to freedoms
c) Right against exploitation
d) Right to freedom of religion
e) Cultural and educational rights
f) Right to property
g) Right to constitutional remedies

UNIT 3: DIRECTIVE PRINCIPLES OF STATE POLICY (10 Hours)

a) Equal Justice and free legal aid
b) Right to work and provisions for just and humane conditions of work
c) Provision for early childhood, Right to education and SC,ST, weaker section
d) Uniform Civil Code
e) Standard of Living, nutrition and public health
f) Protection and improvement of environment
g) Separation of Judiciary from executive
h) Promotion of International peace and security

UNIT 4: FUNDAMENTAL DUTIES (5 Hours)

a) Duty to abide by the Constitution
b) Duty to cherish and follow the noble ideals
c) Duty to defend the country and render national service
d) Duty to value and preserve the rich heritage of our composite culture
e) Duty to develop scientific temper, humanism ,the spirit of inquiry & reform
f) Duty to safeguard public property and abjure violence
g) Duty to strive towards excellence

Text/Reference Books:

a) D. D. Basu, Introduction to the Constitution of India, LexisNexis
b) Granville Austin, The Constitution of India: Cornerstone of a Nation, Oxford University Press
c) Subhash Kashyap, Our Constitution, National Book Trust
d) M.P. Jain, Indian Constitutional Law, LexisNexis

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Back to Index

SUPPORTING ACTIVITIES

Shree Chanakya Education Society's

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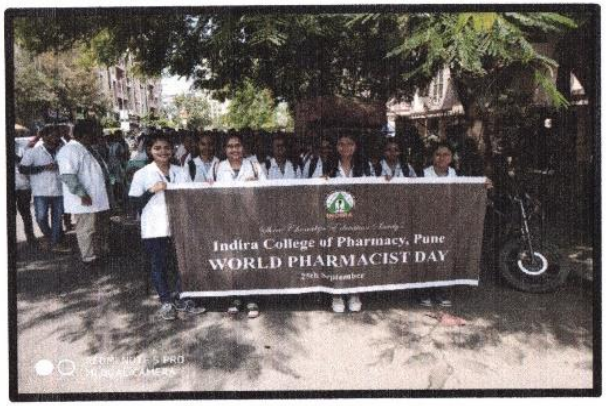
"Redefining Pharmacy Education"



World Pharmacist Day

National Pharmacy Week

Constitutional Day

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Shree Chanakya Education Society's

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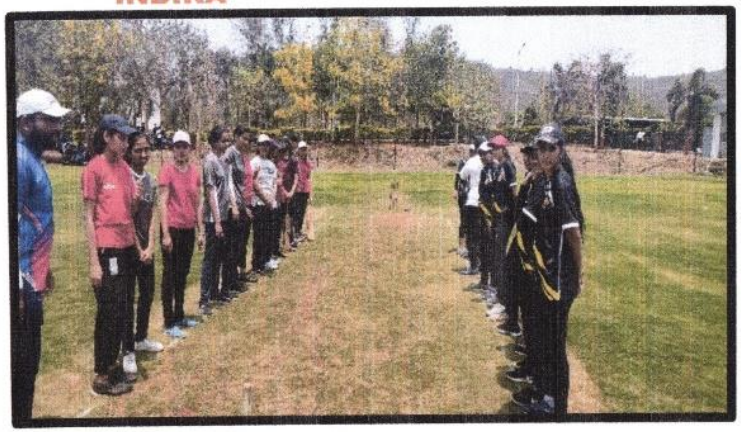
"Redefining Pharmacy Education"



Sports

Women's Day

Sessions on Gender equality

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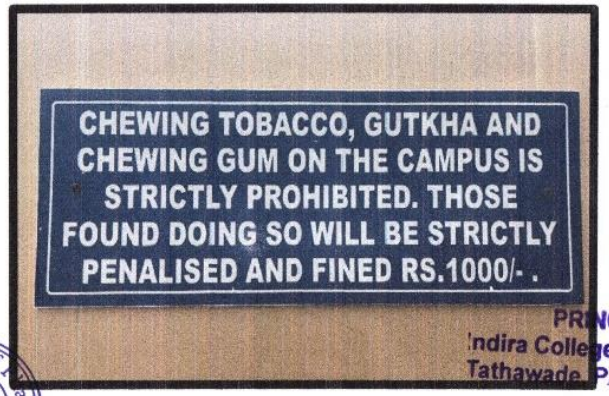
"Redefining Pharmacy Education"

Tree Plantation

E-Waste Collection Drive

Plastic free campus



Tobacco free campus

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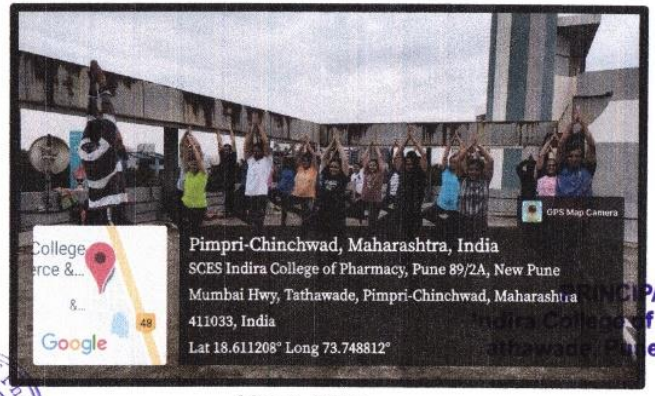
"Redefining Pharmacy Education"

Blood Donation Camp

Pulse Polio Vaccination

NSS



Yoga Day

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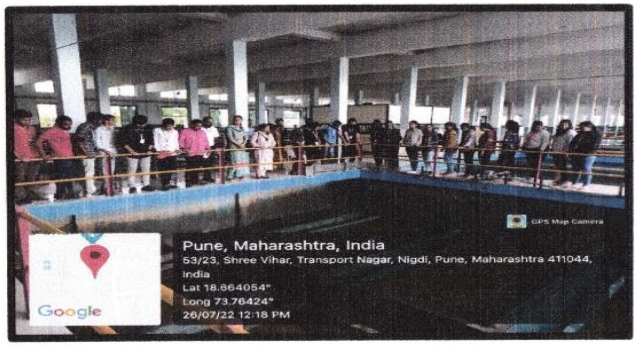
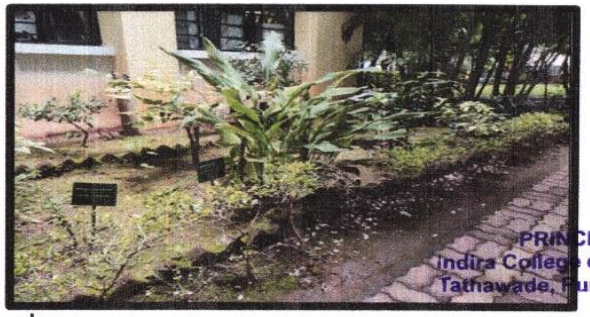
"Redefining Pharmacy Education"



Environmental field trip visit to water treatment plant



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Medicinal Garden

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Back to Index