Semester V

Course Code	Name of the course	No. of hours per week (L/P)	Credit points
BP501T	Biomedicinal Chemistry (Theory)	3	3
BP502T	Industrial Pharmacognosy (Theory)	3	3
BP503T	Innovation and Startup Ecosystem (Theory)	2	2
BP504T	Pharmaceutical Dosage Form II (Theory)	2	2
BP505T	Pharmaceutical Quality Assurance (Theory)	3	3
BP506T	Systemic Pharmacology II (Theory)	3	3
BP507P	Biomedicinal Chemistry (Practical)	4	2
BP508P	Industrial Pharmacognosy (Practical)	3	1
BP509P	Pharmaceutical Dosage Form II (Practical)	3	1
BP510P	Systemic Pharmacology II(Practical)	4	2
Total		**30**	**22**

Course Code	Course Title		Course Type	
BP501T	**Biomedicinal Chemistry (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide comprehensive knowledge of drugs acting on the central nervous system, including anesthetics, sedatives, antipsychotics, and anticonvulsants, with emphasis on their chemical classification and structure–activity relationships (SAR).
2. Familiarize students with anti-infective chemotherapeutic agents used against tuberculosis, malaria, protozoal, viral, fungal, helminthic, and urinary tract infections, including their chemical structures and SAR.
3. Impart understanding of antibiotics and sulfa drugs, focusing on their chemical classes, mechanisms, therapeutic relevance, and structure–activity relationships.
4. Introduce antineoplastic agents and endocrine drugs, highlighting their chemical nature, classification, therapeutic applications, and structure–activity correlations.
5. Develop knowledge of antidiabetic agents and narcotic analgesics, including opioid antagonists, with emphasis on medicinal chemistry principles and SAR of key drug classes.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Classify and explain the chemistry, therapeutic use, and structure–activity relationships of drugs acting on the central nervous system, including anesthetics, sedatives, antipsychotics, and anticonvulsants.
2	Describe the chemical classification, mechanism of action, and SAR of major anti-infective agents such as antituberculars, antimalarials, antivirals, antifungals, anthelmintics, and urinary tract anti-infectives.
3	Analyze the chemistry and SAR of antibiotics and sulfonamides and correlate structural features with antimicrobial activity and spectrum of action.
4	Explain the chemical basis, therapeutic significance, and SAR of antineoplastic agents and endocrine drugs used in cancer and hormonal disorders.
5	Interpret the chemistry, pharmacological relevance, and SAR of antidiabetic agents and narcotic analgesics, including opioid agonists and antagonists, for rational drug use and development.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
	*Study of the development of the following classes of drugs includes chemical classification, structure, uses, SAR of selective drug classes, and synthesis of selected drugs as superscripted**	
I	**Drugs Acting on the Central Nervous System** **General Anesthetics** Halothane, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane, Methohexital, Thiamylal, Thiopental, Ketamine*, Ramelteon, Remimazolam, Fospropofol, Dexmedetomidine **Sedatives and Hypnotics** Barbital, Phenobarbital*, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem, Glutethimide, Meprobamate, Ethchlorvynol, Triclofos, Paraldehyde SAR of Barbiturates and Benzodiazepines **Antipsychotics** Promazine, Chlorpromazine*, Triflupromazine, Thioridazine, Piperacetazine, Prochlorperazine, Trifluoperazine, Chlorprothixene, Thiothixene, Loxapine, Clozapine, Haloperidol, Droperidol, Risperidone, Molindone, Sulpiride, Brexpiprazole, Lumateperone, Pimavanserin, Samidorphan SAR of Phenothiazines **Anticonvulsants** Phenobarbitone, Methabarbital, Phenytoin*, Mephenytoin, Ethotoin, Oxazolidinediones: Trimethadione, Paramethadione Succinimides: Phensuximide, Methsuximide, Ethosuximide Phenacemide, Carbamazepine*, Clonazepam, Primidone, Valproic acid, Gabapentin, Felbamate, Perampanel, Lacosamide, Retigabine SAR of Anticonvulsants	10 Hours
II	**Anti-Infective Chemotherapeutic Agents** **Antitubercular Agents** Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para-amino salicylic acid*, Rifampicin, Rifabutin, Cycloserine, Streptomycin, Capreomycin, Pretomanid, Clofazimine, Levofloxacin, Bedaquiline, Linezolid, Delamanid **Antimalarials** Quinine, Chloroquine*, Amodiaquine, Primaquine, Pamaquine, Quinacrine, Mefloquine, Cycloguanil pamoate, Proguanil, Pyrimethamine, Artesunate, Artemether, Atovaquone SAR of Quinoline derivatives	12 Hours

	Antiprotozoals Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine isethionate, Atovaquone,Eflornithine, Paromomycin, Nitazoxanide **Antivirals** Amantadine, Rimantadine, Idoxuridine, Acyclovir*, Ganciclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine,Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir, Valganciclovir, Peramivir, Lenacapavir **Antifungals** Amphotericin-B, Nystatin, Natamycin, Griseofulvin, Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole, Ketoconazole*, Terconazole, Itraconazole, Fluconazole, Naftifine, Tolnaftate, Posaconazole, Isavuconazole **Anthelmintics** Diethylcarbamazine, Thiabendazole, Mebendazole, Albendazole*, Niclosamide, Oxamniquine, Praziquantel, Ivermectin **Urinary Tract Anti-infective Agents** Nalidixic acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Furazolidone, Nitrofurantoin, Methenamine, Moxifloxacin SAR of Quinolones	
III	**Antibiotics and Sulfa Drugs** **Antibiotics** Penicillins, Cephalosporins, β-Lactamase inhibitors, Monobactams Aminoglycosides: Streptomycin, Neomycin, Kanamycin, Tetracyclines: Tetracycline, Oxytetracycline, Minocycline, Doxycycline, Macrolides: Erythromycin, Clarithromycin, Azithromycin Chloramphenicol*, Clindamycin, Clavulanic acid SAR of Penicillins, Tetracyclines, and Cephalosporins **Sulfa Drugs** Sulphamethizole, Sulfisoxazole, Sulphapyridine, Sulphathiazole, Sulfacetamide, Sulphamethoxazole,Sulphadiazine, Mefenide, Sulfasalazine, Trimethoprim, Cotrimoxazole, Dapsone* SAR of Sulfonamides	8 Hours
IV	**Antineoplastic Agents** Mechlorethamine, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa, Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine, Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin, Etoposide, Vinblastine, Vincristine, Paclitaxel, Camptothecin, Cisplatin, Mitotane, Carboplatin	6 Hours
V	**Endocrine Drugs, Antidiabetic Agents and Narcotic Analgesics** **Endocrine Drugs** Sex hormones: Testosterone, Nandrolone, Progesterone, Oestriol,	9 Hours

	Oestradiol, Oestrone, Diethylstilbestrol Drugs for erectile dysfunction: Sildenafil, Tadalafil Oral contraceptives: Mifepristone, Norgestrel, Levonorgestrel Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole **Antidiabetic Agents** Insulin and preparations, Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride Biguanides: Metformin Thiazolidinediones: Pioglitazone, Rosiglitazone Repaglinide, Nateglinide, Acarbose, Voglibose **Narcotic Analgesics** Morphine, Codeine, Meperidine, Anilerdine, Diphenoxylate, Loperamide, Fentanyl*, Methadone, Propoxyphene, Pentazocine, Levorphanol Nalorphine, Levallorphan, Naloxone SAR of Morphine analogues	

Recommended References (Preferably latest editions):

1. Abraham, D. J. and Griffin, J. L. *Burger's Medicinal Chemistry and Drug Discovery.* Wiley.
2. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
3. Kar, Ashuthosh. *Medicinal Chemistry.* New Age International.
4. Lednicer, D. *The Organic Chemistry of Drug Synthesis.* Wiley.
5. Li, J. J. *Modern Drug Synthesis.* Wiley.
6. Patrick, G. L. *An Introduction to Medicinal Chemistry.* Oxford University Press.
7. Vogel, A. I. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education.
8. Williams, D. A., Lemke, T. L. and Roche, V. F. *Foye's Principles of Medicinal Chemistry.* Lippincott Williams & Wilkins.
9. Wilson, C. O., Beale, J. M. and Block, J. H. *Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry.* Lippincott Williams & Wilkins.

Course Code	Course Title		Course Type	
BP502T	**Industrial Pharmacognosy (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce students to the industrial, commercial, and economic aspects of herbal drugs in national and global markets.
2. Knowledge of commercial production, quality assurance, and standardization of herbal extracts, volatile oils, and traditional AYUSH formulations
3. Train students in modern analytical techniques for the identification, characterization, and quality evaluation of plant-based drugs and herbal products
4. Develop skills in isolation, characterization, commercial production, and analysis of bioactive phytoconstituents.
5. Familiarize students with national and international regulatory frameworks, pharmacopoeial standards, and safety, efficacy, and pharmacovigilance requirements governing herbal medicinal products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe the economic significance, trade potential, emerging therapeutic categories, and institutional support for medicinal and aromatic plant–based industries at national and international levels.
2	Explain the principles of commercial production, standardization, and quality control of herbal extracts, volatile oils, cosmeceuticals, and traditional formulations in compliance with AYUSH, WHO-GMP, and global regulatory norms.
3	Demonstrate analytical competence in evaluating herbal drugs and botanicals using modern spectroscopic and chromatographic techniques such as UV, IR, NMR, MS, HPTLC, HPLC, UPLC, and GC.
4	Describe the process to isolate, characterize, identify, and analyze important phytoconstituents used in pharmaceutical, nutraceutical industries.
5	Interpret and apply international regulatory guidelines, pharmacopoeial monographs, and safety, efficacy, and pharmacovigilance requirements for herbal and traditional medicinal products

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**General Introduction to Herbal Industries, institutions and trade status of herbals** (a) Role of medicinal and aromatic plants trade in national economy of a country and introduction of Current trade status and potential of some commercially important medicinal plants/natural products like Ashwagandha, Turmeric, Ginseng, Amla and essential oils. (b) A brief account of bioeconomy, biodiversity hot spots and plant-based industries and institutions involved in research work on medicinal and aromatic plants in India. (c) Emerging therapeutic categories of Herbal Medicinal Products available in market, their composition with rationale for Aphrodisiac, Antistress, anti-diabetics, antihyperlipidemic, immunomodulator, hepatoprotective and kidney disorders (d) Emerging Herbal cosmeceuticals: Anti-Aging, Depigmenting, anti-acne, sunscreen, detoxifying, anti-irritant, nutricosmetics.	8 Hours
II	**Commercial Production and Standardization of botanicals** Significance of AYUSH/ WHO-GMP, GLP and USFDA compliant facility in production of quality herbal products. Commercial production of standardized herbal extracts with clinical relevance: Coleus, Amla, Turmeric, Ashwagandha and Senna. Commercial production and standardization of volatile oils: Eucalyptus oils, Lavender oil and Peppermint oil, Rosemary oil Preparation and standardization of Ayush formulations viz Aristas and Asawas, Ghutika/Habb, Churna/ Shafoof Arq, Sharbat, Tincture and Bhasma.	10 Hours
III	**Modern methods of analysis of Plants and Plant-based products** Basic principles and applications in analysis of botanicals: Spectroscopic methods: UV-Visible spectroscopy, IR Spectroscopy, NMR spectroscopy and Mass spectroscopy, Atomic Absorption Scpectroscopy Chromatographic methods: HPTLC, HPLC, UPLC, GC,	12 Hours
IV	**Isolation, Characterization, Commercial Production and analysis of bioactive phytoconstituents** Isolation, characterization with commercial production, identification and analysis of bioactive phytoconstituents: Artemisinin, Sennosides, Withanolids, Boswellic acid, Atropine, and Lycopene.	08 Hours
V	**International Regulatory Perspectives** (a) Overview of global regulations for herbal products (e.g., World	07 Hours

	Health Organization, United States Food and Drug Administration – Dietary Supplement Health and Education Act, European Medicines Agency, TGA-ARG Therapeutic Goods Administration – Australian Regulatory Guidelines for Complementary Medicines, Natural Health Products (Canada) (b) Harmonization challenges and mutual recognition of traditional medicine (c) Importance of safety, efficacy and pharmacovigilance in herbal product regulation (d) Study of Monographs on herbal drugs and botanicals related to Indian Pharmacopoeia, United States Pharmacopoeia Herbal Medicine and Dietary Supplement, Ayurvedic Pharmacopoeia of India and Unani Pharmacopoeia of India.	

Recommended References (Preferably latest editions)

1. Ayurvedic Pharmacopoeia Committee. *Ayurvedic Pharmacopoeia of India.* Government of India, Ministry of AYUSH.
2. European Medicines Agency. *Herbal Monographs and Regulatory Guidelines.*
3. Indian Drug Manufacturers' Association. *Indian Herbal Pharmacopoeia.*
4. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia.* Government of India.
5. International Council for Harmonisation. *ICH Guidelines on Quality, Safety, Efficacy and Multidisciplinary Topics.*
6. Natural Health Products Directorate. *Regulatory Framework for Natural Health Products.*
7. Unani Pharmacopoeia Committee. *Unani Pharmacopoeia of India.* Government of India, Ministry of AYUSH.
8. United States Pharmacopeial Convention. *United States Pharmacopeia.*
9. World Health Organization. *Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.*
10. *Drugs and Cosmetics Act and Rules (India).* Government of India.

Course Code	Course Title		Course Type	
BP503T	**Innovation and Startup Ecosystem (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE	ESE		
50	20	30		

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce students to the fundamental concepts, principles, and significance of innovation and entrepreneurship in contemporary economic and social contexts.
2. Familiarize students with the structure, components, and key stakeholders of the startup and innovation ecosystem.
3. Provide students with an understanding of the startup lifecycle, including ideation, opportunity analysis, product development, validation, and scaling.
4. Equip students with practical tools and techniques for problem identification, opportunity recognition, business model development, and idea validation.
5. Foster an entrepreneurial mindset by encouraging active participation in innovation-related events, stakeholder interactions, and experiential learning activities.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental concepts of innovation, entrepreneurship, and the structure and role of the startup ecosystem in economic and social development.
2	Identify and analyze problems, market gaps, and opportunities using ideation tools, market research techniques, and feasibility analysis.
3	Design and validate an innovative solution by developing a minimum viable product (MVP) using lean startup principles and customer feedback.
4	Develop an appropriate business model using the Business Model Canvas, and evaluate legal, intellectual property, team, and funding considerations for startups.
5	Demonstrate effective ecosystem engagement skills by participating in innovation events and presenting a concise startup pitch, incorporating future trends and scaling strategies.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Unit I: Introduction to Innovation and Entrepreneurship** **Defining Innovation and Entrepreneurship** • What is Innovation? • Types of Innovation: Product, Process, Business Model, Social • What is Entrepreneurship? • Characteristics of an Entrepreneur **Invention vs Innovation** • Distinction between Invention and Innovation • Importance of Innovation in the 21st Century Economic growth and job creation Solving societal problems • Disruptive technologies and their impact **Case Studies** • Innovative companies (e.g., Apple, Google, Tesla) **Introduction to the Startup Ecosystem** • Key components: Entrepreneurs Incubators/Accelerators Mentors Investors Government Academia Support Services • Role of each component in fostering innovation **Practical Aspect:** Participation in **National Innovation Day** and **National Startup Day**	06 Hours
II	**Unit II: Ideation and Opportunity Identification** **Identifying Problems and Market Gaps** • Problem-solving approach to entrepreneurship • Techniques for problem identification: Observation Empathy mapping User interviews • Market research basics: Understanding customer needs and pain points **Generating Innovative Ideas** • Brainstorming techniques: SCAMPER Mind Mapping	06 Hours

	Design Thinking principles ~~for ideation~~ • Lateral thinking and divergent thinking • From problem to solution: developing initial concepts **Opportunity Analysis and Feasibility** • Market sizing and potential • Competitive analysis • SWOT analysis for new ventures **Practical Aspect:** Participation in **Ideation Challenges or Hackathons** (e.g., *Smart India Hackathon* or IIC internal ideation competitions)	
III	**Unit III: Building a Minimum Viable Product (MVP) and Validation** **Lean Startup Methodology** • Introduction to Lean Startup principles • Build–Measure–Learn feedback loop • Concept of MVP: Importance Scope and objectives **Designing and Developing an MVP** • Different types of MVPs • Tools and resources for rapid prototyping • User experience basics for MVPs **Validation** • Customer interviews and feedback collection • A/B testing and split testing • Pivoting vs Persevering **Practical Aspect:** Participation in sessions/workshops on **Prototype, MVP, and Product Development**	06 Hours
IV	**Unit IV: Business Models and Startup Operations** **Business Model Canvas (BMC)** • Introduction to the 9 building blocks of BMC • Developing a BMC for a new venture • Value Proposition Design **Legal and Financial Aspects for Startups** • Legal structures: Sole Proprietorship Partnership Private Limited Company • Intellectual Property Rights (IPR): Patents Trademarks Copyrights • Startup funding: Bootstrapping Angel investors Venture capital	06 Hours

	Team Building and Mentorship • Importance of a strong founding team • Roles and responsibilities in a startup • Value of mentors and advisors **Practical Aspect:** Participation in **IPR awareness programs** or **startup funding sessions**	
V	**Unit V: Scaling, Ecosystem Engagement, and Future Trends** **Growth Strategies and Scaling Up** • Marketing and sales for startups • User acquisition and retention • Challenges of scaling and solutions • Exit strategies: Acquisition IPO **Engaging with the Startup Ecosystem** • Networking with investors, mentors, and entrepreneurs • Participation in startup competitions and pitch events • Leveraging incubators and accelerators **Future Trends in Innovation and Entrepreneurship** • Emerging technologies: Artificial Intelligence Blockchain Internet of Things (IoT) Sustainable Technologies • Social entrepreneurship and impact investing • Global startup trends **Practical Aspect:** Participation in **National Innovation Day** and student engagement activities to prepare and deliver a concise pitch for their developed idea, simulating a startup pitch event.	06 Hours

Recommended References (Preferably latest editions)

1. Eric Ries. The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses. Crown Business.
2. Thiel, P. and Masters, B. Zero to One: Notes on Startups, or How to Build the Future. Crown Business.
3. Bansal, R. *Stay Hungry Stay Foolish.* Westland.
4. Dalal, M. *Big Billion Startup: The Untold Flipkart Story.* Pan Macmillan India.
5. Ivaturi, V. K. *The Manual for Indian Start-Ups: Tools to Start and Scale-Up Your New Venture.* Notion Press.
6. Mishra, S., Patjoshi, P. K. and Patnaik, S. K. *Innovation and Entrepreneurship.* Pearson India.
7. Sardar, R. and Waghmare, G. *Startup Ecosystem in India: Text and Cases.* Himalaya Publishing House.

Course Code	Course Title		Course Type	
BP504T	**Pharmaceutical Dosage Forms II (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the principles of formulation and development of monophasic liquid dosage forms, including solvent selection and solubility enhancement techniques.
2. Acquire knowledge of biphasic liquid dosage forms, including physicochemical principles, formulation strategies, manufacturing processes, and stability considerations.
3. Develop competence in pressurised dosage forms such as aerosols, metered-dose inhalers, and dry powder inhalers, with emphasis on formulation design, device components, manufacturing, and quality evaluation.
4. Understand the formulation, manufacturing, and evaluation of semisolid dosage forms, with emphasis on drug permeation through the skin and factors affecting topical drug delivery.
5. Gain exposure to advanced drug delivery systems such as nanosuspensions, nanoemulsions, SMEDDS/SNEDDS, xerogels, and emulgels for improved therapeutic performance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental principles, classification, formulation requirements, and quality aspects of monophasic and biphasic liquid dosage forms.
2	Formulate, manufacture, and evaluate monophasic and biphasic liquid preparations, including solutions, syrups, elixirs, suspensions, and emulsions, using appropriate excipients and processing techniques.
3	Apply physicochemical principles such as solubility enhancement, Stokes' law, DLVO theory, and emulsification theories to design stable liquid dosage forms and assess their stability and performance.
4	Design and evaluate pressurised and inhalation dosage forms, including aerosols, metered dose inhalers, and dry powder inhalers, by selecting suitable formulation components, devices, and quality control parameters.
5	Formulate, evaluate, and justify the use of semisolid and advanced drug delivery systems—including ointments, creams, gels, suppositories, nanosuspensions, nano-

	emulsions, SMEDDS/SNEDDS, xerogels, and emulgels—for enhanced drug delivery, stability, and patient compliance.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Monophasic Liquids & Pressurised Dosage Forms** **Foundations:** Need, advantages/limitations; monophasic vs biphasic; solubility-enhancement techniques. **Vehicles & solvents:** Pharmaceutical waters (types; manufacturing & Quality Control of Purified/Distilled); classes of solvents as per toxicity. **Formulation & manufacturing:** Raw-material considerations and additives; processing; Quality Control of solutions/syrups/elixirs; powders for reconstitution as **solutions**. **Measuring, filling & packaging:** Techniques; container–closure integrity; **automation** in liquid manufacturing.	06 Hours
II	**Biphasic Liquids - Suspensions** **Formulation & manufacturing:** Additives; classification of suspending agents; IPQC & Quality Control; instabilities and packaging. **Advances: Nanosuspensions**; dry powder for reconstitution as **suspensions**; **raft- forming** systems.	06 Hours
III	**Biphasic Liquids - Emulsions** **Formulation & manufacturing:** Additives; classification of emulsifying agents; IPQC & Quality Control; instabilities and packaging. **Advances: Nano-emulsions, micro-emulsions, SMEDDS/SNEDDS** (overview, applications).	06 Hours
IV	**Pressurized dosage forms (Aerosols/MDIs)** Concepts; propellant classification/selection; valves & containers; formulation, manufacturing, and Quality Control (leak, spray pattern, delivered dose, particle- size/aerodynamic performance). **Dry Powder Inhalers:** valves & containers; formulation, manufacturing, and Quality Control	06 Hours

V	**Semisolid Dosage Form** **Theory of Semisolid Dosage Forms:** Definition & Purpose, Drug Permeation Pathways through skin ,Factors affecting Permeation, Permeation enhancers: Physical and Chemical. **Types of semisolid dosage form:** • **Ointments:** Base Selection, Formulation , Manufacturing and Evaluation • **Creams:** Formulation, Manufacturing and Evaluation • **Gels/Jellies:** Formulation, Manufacturing and Evaluation.	06 Hours

	• **Pastes:** Formulation, Manufacturing and Evaluation • **Suppositories and Pessaries:** Formulation, Manufacturing and Evaluation **Advances: Xerogels, emulgels** (overview, applications).	

Recommended References (Preferably latest editions)

1. Aulton, M. E. *Aulton's Pharmaceutics: The Science of Dosage Form Design.* Elsevier.
2. Gibson, M. *Pharmaceutical Preformulation and Formulation.* CRC Press.
3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors.
4. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications.* CRC Press.
5. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy.* Pharmaceutical Press.
6. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code	Course Title		Course Type	
BP505T	**Pharmaceutical Quality Assurance (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the concepts and systems of pharmaceutical quality management
2. Provide an overview of regulatory frameworks governing pharmaceutical quality.
3. Familiarize students with organizational, infrastructural, and operational requirements of pharmaceutical manufacturing and quality control.
4. Explain quality control testing of pharmaceutical products
5. Understand the documentation, validation, calibration, and data integrity essential for regulatory compliance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the concepts of QA, QC, GMP, GLP and modern Quality Management Systems.
2	Apply TQM, QbD, and ICH guidelines to ensure consistent pharmaceutical quality.
3	Understand requirements related to personnel, premises, equipment, materials, and documentation.
4	Describe quality control testing of pharmaceutical products.
5	Explain calibration, qualification, and analytical method validation as per regulatory guidelines.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Quality Assurance and Quality Management Systems** 1. Quality Assurance and Quality Management concepts: Definition and concepts of Quality Control, Quality Assurance, and GMP 2. Total Quality Management (TQM): Definition, elements, and philosophies 3. ICH Guidelines: Purpose, process of harmonization, overview of QSEM with special emphasis on Q-series guidelines 4. Quality by Design (QbD): Definition, overview, elements of QbD program, and tools	10 hours

	5. ISO 9000 and ISO 14000: Overview, benefits, elements, and steps for registration 6. NABL Accreditation: Principles and procedures	
II	**Organization, Personnel, Premises, and Materials Management** 1. Organization and Personnel: Responsibilities, training, hygiene, and personal records 2. Premises: Design, construction, plant layout, maintenance, sanitation, environmental control, utilities, and control of contamination 3. Equipment and Raw Materials: Equipment selection, User Requirement Specifications (URS), handling and maintenance of raw materials 4. Warehousing: Good warehousing practices and materials management	10 hours
III	**Quality Control and Good Laboratory Practices** 1. Quality Control Tests for Formulations: In-process and finished product quality control tests for tablets, capsules, ointments, creams, ophthalmic and parenteral preparations 2. Quality Control of Raw Materials and Packaging Materials: Tests for raw materials, containers, rubber closures, and secondary packing materials 3. Good Laboratory Practices (GLP): General provisions, organization and personnel, facilities and equipment, ALCOA principles, reference standards, testing facility operations, records and reports, and disqualification of testing facilities	10 hours
IV	**Documentation, Complaints, and Product Recall** 1. Documentation in the Pharmaceutical Industry: Batch Formula Record, Master Formula Record, Drug Master File, SOPs, quality audits, preparation, handling, archival, and distribution of records 2. Complaints and Product Recall: Handling of complaints, evaluation of complaints, returned goods, recalls, and waste disposal	08 hours
V	**Calibration and Validation** 1. Calibration and Validation: Introduction, definitions, importance, and general principles Calibration of weights and measures, pH meter Qualification of UV-Visible spectrophotometer, electronic balance, IR spectrophotometer, and HPLC 2. Analytical Method Validation: General principles of analytical method validation as per ICH Q2 guidelines	07 hours
Recommended References ***(Preferably latest editions)*** 1. Godfrey, A. B. and Juran, J. M. Juran's Quality Handbook. McGraw-Hill Education. 2. Organisation of Pharmaceutical Producers of India. Quality Assurance Guide. OPPI. 3. Weinberg, S. Good Laboratory Practice Regulations. Marcel Dekker. 4. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of		

Guidelines and Related Materials. World Health Organization.

Course Code	Course Title		Course Type	
BP506T	**Systemic Pharmacology II (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the neurohumoral transmission in the central nervous system and the role of neurotransmitters and their modulators in CNS disorders.
2. Learn the pharmacology of drugs used in pathological conditions of CNS, GIT, and endocrine system.
3. Familiarize learners with concepts of drug abuse, addiction, dependence, tolerance, and their management.
4. Impart comprehensive knowledge of chemotherapeutic agents including anticancer drugs.
5. Introduce the principles of rational use of chemotherapeutic agents.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Identify the role of neurotransmitters in CNS diseases and explain pharmacology of drugs acting on central neurotransmission.
2	Apply principles of chemotherapy to explain mechanisms and uses of chemotherapeutic agents.
3	Recall pharmacology of hormones and drugs used in endocrine disorders.
4	Describe mechanisms and therapeutic uses of drugs acting on the gastrointestinal tract.
5	Recognize issues related to drug abuse, addiction, and dependence and their management.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Pharmacology of Drugs Acting on Central Nervous System** Neurohumoral transmission in the CNS; physiological roles of GABA, glutamate, glycine, serotonin, and dopamine. a. General anesthetics, pre-anaesthetic medications, and local anaesthetic agents b. Sedative–hypnotics c. Alcohol and disulfiram d. Opioids, opiate analgesics, and antagonists e. Drugs used in epilepsy f. Drugs used in Parkinson's and Alzheimer's diseases	10 hours
II	**Pharmacology of Drugs Used in Psychiatry** a. Antipsychotics, antidepressants, anti-anxiety drugs, mood stabilizers, CNS stimulants, and hallucinogens b. Substance abuse, drug addiction, and general principles of de-addiction	07 hours
III	**Chemotherapy** **i) Introduction** a. Definitions of chemotherapy, chemotherapeutic index, antibiotics, and antimicrobial agents b. Concept of selective targeting in chemotherapy c. Classification of antimicrobial agents based on mechanism of action d. Concept of superinfection, chemoprophylaxis, and combined use of antibiotics e. Antimicrobial resistance: causes, mechanisms, and preventive measures **ii) Antimicrobial Agents** Classification, mechanism of action, adverse drug reactions, and therapeutic uses of: • Sulphonamides and cotrimoxazole • Fluoroquinolones • Penicillins and cephalosporins • Macrolides and tetracyclines • Linezolid • Carbapenems and monobactams • Chloramphenicol and aminoglycosides **iii) Chemotherapy of Diseases** Drugs used in the treatment of: • Fungal infections • Viral infections • Helminthiasis • Urinary tract infections • Tuberculosis	14 hours

	• Leprosy • Malaria • Amoebiasis • Neoplastic diseases	
IV	**Pharmacology of Drugs Acting on Endocrine System** a. Introduction to basic concepts of endocrinology b. Thyroid and antithyroid agents c. Parathormone, calcitonin, and vitamin D d. Insulin and oral hypoglycaemic agents e. ACTH and corticosteroids f. Oral contraceptives g. Drugs acting on the uterus h. PCOD	10 hours
V	**Drugs Acting on Gastrointestinal Tract** a. Drugs used in peptic ulcer b. Drugs used for constipation and diarrhoea c. Emetics and anti-emetics d. Digestants, carminatives, appetizers, and anorectics – definitions and examples	04 hours

Recommended References *(Preferably latest editions):*

1. Brunton, L., Hilal-Dandan, R. and Knollmann, B. *Goodman and Gilman's The Pharmacological Basis of Therapeutics.* McGraw-Hill Education.
2. Craig, C. R. and Stitzel, R. E. *Modern Pharmacology with Clinical Applications.* Lippincott Williams & Wilkins.
3. DiPiro, J. T., Talbert, R. L., Yee, G. C. and Matzke, G. R. *Pharmacotherapy: A Pathophysiologic Approach.* McGraw-Hill Education.
4. Katzung, B. G. and Trevor, A. J. *Basic and Clinical Pharmacology.* McGraw-Hill Education.
5. Rang, H. P., Dale, M. M., Ritter, J. M., Flower, R. J. and Henderson, G. *Rang and Dale's Pharmacology.* Elsevier.
6. Tripathi, K. D. *Essentials of Medical Pharmacology.* Jaypee Brothers Medical Publishers.

Course Code	Course Title		Course Type	
BP507P	**Biomedicinal Chemistry (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	--	--	4	60
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Comprehend the fundamental principles of drug synthesis and apply them to the preparation of selected drug molecules and intermediates.
2. Develop practical skills in performing laboratory techniques for the synthesis of organic compounds, including the use of microwave irradiation.
3. Understand and apply the principles of drug assay to quantitatively analyze the purity and concentration of given drug samples.
4. Learn and utilize computational tools to predict physicochemical and ADME properties of drug molecules.
5. Apply molecular docking techniques to predict drug-target interactions.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Successfully synthesize specified drug molecules and intermediates in the laboratory.
2	Demonstrate competence in using microwave irradiation for efficient chemical synthesis.
3	Accurately perform drug assays to determine the concentration and purity of drug samples.
4	Analyze physicochemical and ADME properties of drug candidates using computational tools.
5	Conduct and interpret molecular docking studies to understand drug-receptor binding.

Detailed Syllabus:

List of practical
1. Preparation of Drugs / Intermediates **(Any 4)** • 7-Hydroxy-4-methyl coumarin • Thiobarbituric acid • 2,3-Diphenylquinoxaline • Sulphanilamide • Triphenyl imidazole • Perform synthesis of intermediate/drug using microwave irradiation or green chemistry techniques. **2.** Assay of Drugs **(Any 4)** • Sulpha drugs • Metronidazole • Isoniazid • Phenobarbitone • Benzyl penicillin • Chloroquine **3.** Drug Design & Computational Tools **(Any 4)** • Calculate physicochemical and ADME properties using Swiss ADME (e.g. logP, molecular weight, H-bond donors/acceptors) • Perform basic molecular docking studies using any of open-source academic tools.

Recommended References *(Preferably latest editions):*

1. Abraham, D. J. and Griffin, J. L. *Burger's Medicinal Chemistry and Drug Discovery.* Wiley.
2. Finar, I. L. *Organic Chemistry.* Pearson Education.
3. Furniss, B. S., Hannaford, A. J., Smith, P. W. G. and Tatchell, A. R. *Vogel's Textbook of Practical Organic Chemistry.* Pearson Education.
4. Lednicer, D. *The Organic Chemistry of Drug Synthesis.* Wiley.
5. Patrick, G. L. *An Introduction to Medicinal Chemistry.* Oxford University Press.
6. Remington. *The Science and Practice of Pharmacy.* Pharmaceutical Press.
7. Williams, D. A., Lemke, T. L. and Roche, V. F. *Foye's Principles of Medicinal Chemistry.* Lippincott Williams & Wilkins.
8. Wilson, C. O., Beale, J. M. and Block, J. H. *Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry.* Lippincott Williams & Wilkins.
9. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.
10. Brown, N. Artificial Intelligence in Drug Discovery. Cambridge: Royal Society of Chemistry.

Course Code	Course Title		Course Type	
BP508P	**Industrial Pharmacognosy (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Apply knowledge of chromatographic and spectroscopic techniques for the separation, isolation, and analysis of phytoconstituents.
2. Learn isolation and characterization of major secondary metabolites and volatile oil constituents using standard laboratory methods.
3. Perform chemoprofiling, purification, and quantitative estimation of herbal and Ayurvedic formulations.
4. Prepare and document herbal drug monographs and traditional formulations as per IP, API, and IHP guidelines.
5. Integrate experiential learning and community-based studies for understanding the use, quality, and awareness of traditional medicines.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Apply chromatographic techniques for isolation and analysis of phytoconstituents
2	Isolate and identify key compounds from medicinal plants phytoconstituents
3	Standardize Ayurvedic formulations and determine alcohol content.
4	Prepare herbal drug monograph and assess traditional formulations.
5	Evaluate and analyze marketed and community-used traditional formulations through case studies and experiential learning.

Detailed Syllabus:

List of practical ***(Minimum 12 experiments must be performed)***
1. To perform column chromatography for isolation of phytochemicals. 2. Preparative TLC of curcuminoids. 3. Isolation and identification of Piperine. 4. Isolation and identification of Sennoside. 5. Isolation and identification of Withanolide. 6. Isolation and identification of Lycopene. 7. Acid – base purification process for the separation of alkaloids. 8. Chemoprofiling of purified alkaloidal fraction. 9. Separation of amino acid by paper chromatography. 10. TLC/HPTLC/HPLC of herbal extracts/ botanicals. 11. Isolation and determination of total aldehyde content in volatile oil. 12. Preparation of monographs on herbal drugs wrt IP, API, IHP. 13. Determination of the alcohol content of Asava and Arista. 14. Standardization of any two Ayurvedic formulations using UV-spectroscopy. 15. Preparation and evaluation of Ayurvedic churna. 16. Experiential learning-based experiments focused on the preparation and practical applications of folkloric or region-specific traditional formulations within the community. 17. Case studies analyzing community awareness and usage patterns of various traditional formulations.
Recommended References *(Preferably latest editions):* 1. Mukherjee, P. K. *Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals.* Business Horizons. 2. Sinha, D., Mukherjee, S. and Chowdhury, S. *Methods of Extraction of Phytochemicals.* IGI Global. 3. Zhang, J., Wen, C., Zhang, H., Duan, Y. and Ma, H. *Extraction of Bioactive Compounds with Subcritical Water.* Elsevier.

Course Code	Course Title			Course Type
BP509P	**Pharmaceutical Dosage Forms II (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand various solubility enhancement techniques.
2. Provide hands-on experience in manufacturing processes and evaluation of monophasic and biphasic liquid dosage forms.
3. Provide hands-on experience in manufacturing processes and evaluation of semisolid dosage forms.
4. Learn manufacturing processes and evaluation of pressurised dosage forms.
5. Understand the effects of formulation parameters on the performance of biphasic and semisolid dosage forms.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Apply the fundamentals of solubility enhancement during dosage form development.
2	Explain manufacturing processes of monophasic and biphasic liquid dosage forms.
3	Demonstrate manufacturing processes of semisolid dosage forms.
4	Provide insights into evaluation of dosage forms.
5	Compare the effects of formulation parameters on the performance of biphasic and semisolid dosage forms.

Detailed Syllabus:

List of practicals ***(Minimum 12 experiments must be performed)***
1. To enhance the solubility of a BCS Class II drug by solid dispersion technique. 2. To enhance the solubility of a BCS Class II drug by cyclodextrin complexation. 3. Preparation and evaluation of medicated syrups using simple and artificial syrup bases. 4. Preparation and evaluation of different types of pharmaceutical emulsions. 5. Preparation and evaluation of an emulsion with a small-dose oily active (e.g., calciferol). 6. Preparation and evaluation of an oral suspension. 7. To study the effect of different suspending agents/concentrations on sedimentation volume. 8. Preparation and evaluation of a dry powder for reconstitution as a suspension. 9. Preparation and evaluation of pharmaceutical creams. 10. Preparation and evaluation of pharmaceutical gels. 11. To study the effect of different gelling agents/concentrations on viscosity of gels. 12. Preparation and evaluation of medicated suppositories. 13. Preparation and evaluation of medicated pessaries. 14. Preparation and evaluation of in-situ gels. 15. Preparation and evaluation of emulgels.
Recommended References *(Preferably latest editions):* 1. Aulton, M. E. *Aulton's Pharmaceutics: The Science of Dosage Form Design.* Elsevier. 2. Gibson, M. *Pharmaceutical Preformulation and Formulation.* CRC Press. 3. Lachman, L., Lieberman, H. A. and Kanig, J. L. *The Theory and Practice of Industrial Pharmacy.* CBS Publishers & Distributors. 4. Robinson, J. R. and Lee, V. H. L. *Controlled Drug Delivery: Fundamentals and Applications.* CRC Press. 5. Troy, D. B. and Beringer, P. *Remington: The Science and Practice of Pharmacy.* Pharmaceutical Press. 6. *Indian Pharmacopoeia.* Indian Pharmacopoeia Commission.

Course Code	Course Title			Course Type
BP510P	**SYSTEMIC PHARMACOLOGY II (Practical)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	--	--	4	60
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide understanding of the theoretical and practical aspects of different pharmacological experiments using virtual simulations and video demonstrations.
2. Develop skills to assess drug effects on various systems such as cardiovascular, respiratory, skeletal muscle, and gastrointestinal using simulation models.
3. Familiarize the learners with experimental methodologies such as Langendorff's heart preparation, spasmogenic and spasmolytic effects, and PA2 value determination using Schild plot.
4. Provide knowledge of the modern techniques for drug evaluation, such as intraocular pressure measurement, nitric oxide estimation, neutrophil function tests and spirometry.
5. Explore clinical pharmacology aspects through case studies on drug interactions, management of cardiovascular and respiratory diseases, and plasma volume expanders.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the pharmacological principles and mechanisms of drug action involved in analgesic, antiepileptic, antidepressant, antipsychotic, antianxiety, and antiulcer drugs using interactive computer-based experimental models.
2	Apply experimental and simulation-based methods to evaluate drug activity using models such as Eddie's hot plate, MES-induced seizures, tail suspension test, elevated plus maze, actophotometer, Morris water maze, and ulcer models.
3	Analyse and interpret experimental pharmacological data, including bioassay results, dose-response relationships, and estimation of agonist/antagonist concentrations using 3-point/4-point bioassay, matching/bracketing methods, and hypothetical simulation datasets.
4	Demonstrate advanced biomedical and laboratory techniques, including cell culture methods, PCR for mRNA estimation, electrophoresis of DNA/proteins, and antibacterial sensitivity testing, relevant to pharmaceutical and biomedical research.
5	Utilize bioinformatics tools, open-source pharmacological databases, and network pharmacology software to predict drug targets, analyse ADME/toxicity profiles, and construct pharmacological networks.

Detailed Syllabus:

List of practical
(Minimum 12 experiments must be performed)
1. Evaluation of analgesic activity of centrally and peripherally acting analgesics using Eddie's hot plate, tail-flick, tail immersion, and acetic acid-induced writhing methods through interactive computer simulation.
2. Evaluation of antiepileptic activity using maximal electroconvulsive shock (MES)-induced seizures through interactive computer simulation.
3. Demonstration of the antiepileptic activity using pentylenetetrazol-induced seizures through interactive computer simulation.
4. Evaluation of antidepressant activity of drugs using the tail suspension test through interactive computer simulation.
5. Demonstration and study of locomotor activity using actophotometer through interactive computer simulation.
6. Evaluation of antianxiety activity using the elevated plus maze or zero maze model through interactive computer simulation.
7. Evaluation of antipsychotic activity of drugs using inhibition of conditioned response on Cook's pole climbing apparatus through interactive computer simulation.
8. Study of the effect of drugs on learning and memory using the Morris water maze test through interactive computer simulation.
9. Study of antiulcer activity using indomethacin-induced or pylorus ligation-induced ulcer models.
10. Estimation of the concentration of oxytocin on isolated rat uterus preparation using a suitable method through interactive computer-based simulation.
11. Estimation of drug concentration by 3-point or 4-point bioassay through interactive computer simulation.
12. Bioassay of histamine using matching, bracketing, or interpolation methods on suitable isolated tissue preparation with the help of interactive computer simulation.
13. Study of cell culture techniques, including types of cell culture, laboratory instruments/equipment, culture media, and growth of cell cultures in laboratory facilities.
14. Study of antibacterial sensitivity testing of urine culture using techniques such as the disc diffusion method (theoretical details/case studies).

15. Demonstration using databases and software packages for predicting drug activity, ADME properties, and toxicity.

16. Study of electrophoresis of protein and DNA samples and gel visualization techniques.

17. Construction of pharmacological networks using predicted drug targets and disease genes with activity prediction databases, disease gene databases, and suitable software.

**PCI recommended software's shall be used for performing experiments.*

Recommended References *(Preferably latest editions):*

1. Ghosh, M. N. *Fundamentals of Experimental Pharmacology.* Hilton & Company.
2. Vogel, H. G. Drug Discovery and Evaluation: Pharmacological Assays. Springer.
3. Hofmann, F. B. Handbook of Experimental Pharmacology (HEP Series). Springer Nature.

Semester VI

Course Code	Name of the course		No. of hours per week (L/P)	Credit points
BP601T	Advanced Pharmacognosy (Theory)		3	3
BP602T	Biopharmaceutics and Pharmacokinetics (Theory)		3	3
BP603T	Intellectual Property Rights (Theory)		2	2
BP604T	AI applications in Pharmaceutical Sciences (Theory)		2	2
BP605T	Pharmaceutical Analysis (Theory)		3	3
BP606T	Pharmaceutical Jurisprudence (Theory)		3	3
BP607T AEC*	BP607T AEC1	Green Chemistry	1	1
	BP607T AEC2	Materiovigilance and Hemovigilance		
	BP607T AEC3	Scientific Writing		
	BP607T AEC4	Drug Store and Business Management		
	BP607T AEC5	Career Building in Cultivation of Medicinal Plants		
	BP607T AEC6	Active Pharmaceutical Ingredients and Excipient Sciences		
BP608P	Biopharmaceutics and Pharmacokinetics (Practical)		3	1
BP609P	Pharmaceutical Analysis (Practical)		4	2
BP610P SEC*	BP610P SEC1	Computer-Aided Drug Design	2	1
	BP610P SEC2	Analytical Method Development and Validation		
	BP610P SEC3	Principles of Preclinical Studies		
BP611P VAC*	BP611P VAC1	Professional Skills	2	1
	BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science		
BP612I	Internship (Mandatory)		8	4
Total			**28**	**26**

* Only 1 course shall be selected from each elective

Course Code	Course Title		Course Type	
BP601T	**Advanced Pharmacognosy (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand reverse pharmacology and integrative approaches in natural drug discovery.
2. Apply metabolomics and systems biology tools for quality control and bioactivity evaluation of herbal medicines.
3. Explore modern AI-driven, in-silico, and high-throughput techniques for identification and optimization of natural product leads.
4. Study validation, safety, and development pathways of herbal leads including preclinical and clinical evaluation.
5. Understand legal, ethical, and patenting frameworks related to bioprospecting, traditional knowledge protection, and natural product innovation.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain reverse pharmacology, traditional knowledge databases, and bioprospecting strategies.
2	To analyze herbal drugs using metabolomics, spectral libraries, and chemoinformatics tools.
3	Employ modern in-silico and AI techniques in lead identification and optimization from natural products.
4	Evaluate preclinical safety, pharmacokinetics, and efficacy of bioactive leads.
5	Interpret global IP frameworks and develop strategies for patenting herbal products and protecting traditional knowledge.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Reverse Pharmacology and Integrative Approaches** Reverse pharmacology and integrative approaches from the AYUSH perspective. Ethnopharmacological approach to bioprospecting. Traditional medicine databases: AYUSH Research Portal, ICMR Standards on Indian Medicinal Plants, TKDL, NAPRALERT, Super Natural, etc. Molecular docking and ADMET screening of bioactives. Concept of adjuvant therapy with herbals in metabolic and non-communicable diseases.	6 hours
II	**Metabolomics and Systems Biology** Introduction to metabolomics and its tools: applications of NMR and HRMS in metabolomics, Metabolomics profiling and dereplication studies, Role of metabolomics in quality control, scientific, validation of traditional claims and pharmacological evaluation, Network pharmacology and systems biology approaches to herbal medicine, Significance of spectral libraries and chemoinformatics databases in drug discovery	11 hours
III	**Modern Techniques in Natural Product Discovery** Role of artificial intelligence (AI), Machine learning and big data in Drug discovery from natural Products. Molecular docking, Virtual Screening and Pharmacophore modelling, Use of Genomic and transcriptomic tools in medicinal plant research, High-throughput screening (HTS) and bioautography. .	10 hours
IV	**Validation and Development of Herbal Leads** Bioactivity Guided Fractionation, characterization /Structure Elucidation, Optimization of lead compounds for better efficacy, safety, and stability through SAR and QSAR modelling for semi-synthetic compounds of Salicin, Artemisinin, Piperine, Papaverine and Andrographolides. Preclinical, Clinical Evaluation and New Drug approvals: Testing for toxicity as per OECD guidelines, pharmacokinetics, and bioavailability of herbal products, extracts and lead compounds, assessment of safety and efficacy, clinical trials with or without placebo for clinical endpoints based on assessment of quality of life reporting adverse events if any, filing IND application, NDA submission, Regulatory review and post marketing surveillance.	12 hours

V	**Patenting of Natural Products** Key Terminologies and Concepts: Definitions and distinctions: Patent, Intellectual Property Rights (IPR) Farmers' Rights and Breeders' Rights, Bioprospecting and Biopiracy Patenting Aspects of Natural Products and Traditional Knowledge: Legal frameworks and challenges in patenting natural substances, Traditional Knowledge Digital Library (TKDL) and its role in protecting indigenous knowledge. Role of National Biodiversity Authority in patenting natural products and NAGOYA protocol. Case Studies: Turmeric– U.S. patent on wound healing and its revocation, Neem– Biopiracy issue and patent cancellation.	6 hours

Recommended References (Preferably latest editions)

1. Bhat, S. V., Nagasampagi, B. A. and Sivakumar, M. *Chemistry of Natural Products.* Springer.
2. Gräbley, S. and Thiericke, R. *Drug Discovery from Nature.* Springer.
3. Hanessian, S. *Natural Products in Medicinal Chemistry.* Wiley-VCH.
4. Ikan, R. *Natural Products: A Laboratory Guide.* Academic Press.
5. Kemp, W. *Spectroscopic Methods in Organic Chemistry.* Macmillan.
6. Narayanan, P. *Intellectual Property Law.* Eastern Law House.
7. Sarker, S. D., Latif, Z. and Gray, A. I. *Natural Products: Isolation, Structure Elucidation and History.* Elsevier.

Course Code	Course Title		Course Type	
BP602T	**Biopharmaceutics and Pharmacokinetics (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Describe fundamental biopharmaceutics and pharmacokinetic principles governing drug absorption, distribution, metabolism, and excretion.
2. Analyze the physicochemical and biological factors that determine drug bioavailability, protein binding, and elimination pathways.
3. Illustrate compartmental pharmacokinetic models, and their evaluations through application of mathematical equations to calculate key parameters.
4. Design, conduct, and interpret bioavailability, bioequivalence, and in vitro–in vivo correlation studies.
5. Apply pharmacokinetic principles to optimize dosing regimens—including loading and maintenance doses and steady-state kinetics—and utilize software tools to analyze both linear and non-linear drug kinetics.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Interpret fundamental pharmacokinetic and pharmacodynamic principles and apply them to patient-centered clinical scenarios.
2	Evaluate the impact of physicochemical and biological variables on drug absorption, distribution, and protein binding in clinical practice.
3	Differentiate among bioavailability classifications and develop bioequivalence study protocols that comply with international regulatory standards.
4	Solve pharmacokinetic problems using compartment models by employing numerical techniques
5	Design optimal dosing regimens, interpret non-linear pharmacokinetic behaviors, and utilize simulation software for PK/PD analysis.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Introduction to Biopharmaceutics and pharmacokinetics:** Introduction to various Pharmacokinetic parameters (using Plasma drug Concentration vs Time curve) and Pharmacodynamic parameters and drug delivery index. **Absorption**; Mechanisms of drug absorption through GIT, Physicochemical, Biological and Dosage form related factors influencing drug absorption though GIT, methods of Assessment of GIT absorption, **Distribution** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.	10 hours
II	**Elimination (Metabolism and Elimination):** Drug metabolism and basic understanding of metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, non renal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, Introduction to BCS and biopharmaceutical drug disposition classification system, methods of measurement of bioavailability (Plasma data, Urinary excretion data), Protocol for assessment of bioavailability and bioequivalence studies. *in-vitro* drug dissolution methods (test apparatus I-VII), biorelevant dissolution mediums, *in-vitro in-vivo* correlations: Concept and Applications, Biowaivers, Methods of enhancement of bioavailability.	10 hours
III	**Pharmacokinetic Models: Compartment Models:** Definition, Basis of classification, Properties of compartment, Advantages and disadvantages of compartment modelling. Kinetic considerations of One compartment open model. (a). Intravenous Injection (Bolus/rapid) (b). Intravenous infusion and (c) Extra-vascular administration. (with emphasis on Curve Fitting, Wagner –Nelson, Loo Riegelman) **Introduction to non - compartment model: Principles, estimation of PK parameters (AUC, AUMC, MRT, MAT statistical moment theory).**	10 hours
IV	**Multicompartment models:** Multiple dosage regimen: dosing interval, drug accumulation, loading dose, maintenance dose, PK Parameters Kinetic consideration of two compartment open model (a) Intravenous Injection (Bolus/rapid) and (b) Extra vascular administrations (oral administration). Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their clinical significance. Multiple dosage regimen. Introduction to pharmacokinetic consideration of Modified release drug products.	9 hours
V	**Nonlinear Pharmacokinetics:** Introduction, Reasons for Non-linearity, Michaelis-menton method of estimating parameters, Explanation with example of drugs. **Application of PK software:** Introduction of various in -silico methods for calculating various PK parameters.	6 hours
Recommended References (Preferably latest editions) 1. Shargel, L. and Yu, A. B. C. *Applied Biopharmaceutics and Pharmacokinetics.* McGraw-Hill Education.		

2. Gibaldi, M. *Biopharmaceutics and Clinical Pharmacokinetics.* Lea & Febiger.
3. Rowland, M. and Tozer, T. N. *Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications.* Wolters Kluwer.
4. Bonate, P. L. *Pharmacokinetic-Pharmacodynamic Modeling and Simulation.* Springer.
5. Brahmankar, D. M. and Jaiswal, S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise.* Vallabh Prakashan.
6. Eddy, D. M. *Modeling and Simulation in the Medical and Health Sciences.* Springer.

Course Code	Course Title		Course Type	
BP603T	**Intellectual Property Rights (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the fundamental concepts and types of intellectual property (IP) and highlight their importance in the pharmaceutical and healthcare sectors.
2. Understand the procedures and legal frameworks related to patent filing, granting, and protection of intellectual property.
3. Develop awareness of international and national IP laws and treaties, including the TRIPS agreement and Indian Patent Act, and their implications for the pharmaceutical industry.
4. Provide insights into the management and commercialization of IP, including licensing, technology transfer, and joint ventures.
5. Familiarize with common IP infringement issues and remedies, using real-world case studies from the pharmaceutical industry to illustrate key principles.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Understand the basic concepts and significance of intellectual property rights with respect to pharmaceutical industries.
2	Learn the types of intellectual property rights such as patents, copyrights, trademarks, trade secrets.
3	Understand the procedure for patent filing in India and abroad.
4	Understand the key provisions of the Indian Patent Act.
5	Evaluate and understand the strategies for IP management and product commercialization.

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Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	Introduction to Intellectual Property Definition and scope of Intellectual Property (IP), Importance and types of IP: Patents, Trademarks, Copyrights and Trade Secrets, Overview of the origin and progression of intellectual property rights in India and internationally, Role of IP in the pharmaceutical industry	6 hours
II	**Patents – Fundamentals and Process** Definition and objectives of patents, Criteria for patentability such as Novelty/innovations, Non-obviousness, Utility, Types of patents and non-patentable inventions in India, Procedure for filing a patent in India, Rights of a patent holder and term of patent protection	6 hours
III	**Patent Laws and Acts** Overview of Indian Patent Act, 1970 (latest amendments and key provisions under the act), TRIPS Agreement and its implications on the Indian pharmaceutical sector, Compulsory licensing, patent opposition, and revocation, Indian pharmaceutical patents: Case studies.	6 hours
IV	**Other Forms of Intellectual Property** Trademarks, Copyrights, Industrial designs: Definition, importance, registration process**,** Basics and protection in scientific work**,** Importance and legal framework**,** Trade secrets and geographical indications in pharma industry	6 hours
V	**IPR Management and Commercialization** Valuation and strategies for commercialization of intellectual property; processes of technology transfer, licensing agreements, and collaborative ventures; issues related to IP infringement and available legal remedies; management practices of IPR in the pharmaceutical industry supported by relevant case studies.	6 hours

Recommended References (Preferably latest editions):

1. World Intellectual Property Organization. *Introduction to Intellectual Property.* WIPO.
2. Indian IPR. https://ipindia.gov.in/
3. Ahuja, V. K. *Law Relating to Intellectual Property Rights.* LexisNexis.
4. Bouchoux, D. *Intellectual Property.* Cengage Learning.
5. Ganguli, P. *Intellectual Property Rights: Unleashing the Knowledge Economy.* Tata McGraw-Hill.
6. Narayanan, P. *Intellectual Property Law.* Eastern Law House.
7. Ramakrishna, T. *Basic Principles and Acquisition of Intellectual Property Rights.* CIPRA.
8. Sreenivasulu, N. S. *Law Relating to Intellectual Property.* Partridge Publishing.
9. Vaidhyanathan, S. *Intellectual Property: A Very Short Introduction.* Oxford University Press.
10. Wadehra, B. L. *Law Relating to Intellectual Property.* Universal Law Publishing.

Course Code	Course Title		Course Type	
BP604T	AI applications in Pharmaceutical Sciences (Theory)		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	2	--	--	30
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce applications of artificial intelligence and machine learning across major pharmaceutical disciplines.
2. Understand the structured data in natural products, medicinal chemistry, formulation science, and manufacturing
3. Interpret regression and classification models in drug discovery, product performance, and quality monitoring.
4. Build awareness of predictive modeling for pharmaceutical decision-making.
5. Understand multivariate analysis in pharmaceutical analytical techniques.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain how pharmaceutical data from various domains can be structured for machine learning applications.
2	Interpret regression and classification models used in natural products and medicinal chemistry.
3	Analyze predictive modeling approaches in formulation, release, and stability studies.
4	Evaluate AI applications in manufacturing process monitoring and quality prediction.
5	Assess analytical modeling and chemometric applications in pharmaceutical quality control.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**AI in Natural Products & Pharmacognostic Data Modeling** Overview of ML applications in natural products: • Representation of crude drug data (morphological, microscopic, phytochemical, chromatographic features) • Structuring herbal datasets for predictive modeling	6 Hours

	• Classification models for authentication of crude drugs (authentic vs adulterated) • Regression models for prediction of secondary metabolite yield • Application of AI in phytochemical screening and prioritization • Herb-drug interaction prediction using database-driven approaches • Limitations of predictive modeling in natural products.	
II	**AI in Medicinal & Pharmaceutical Chemistry** Overview of the role of AI applications in pharmaceutical chemistry with focus on drug discovery concepts: • Conversion of molecular structures into numerical descriptors (MW, logP, HBD/HBA, TPSA) • Structured chemical datasets and QSAR modeling • Regression and classification models for predicting biological activity (IC_{50}, solubility, ADMET properties), toxicities. • Virtual screening and lead optimization concepts • Limitations of ML models and importance of chemical reasoning	6 Hours
III	**AI in Drug Product Design & Performance Prediction** Overview of AI models across formulation development stages, with emphasis on the applications and limitations: • Overview of dosage form development and formulation variables • Machine learning in formulation optimization and excipient selection • Regression modeling for solubility and bioavailability enhancement • Time-concentration modeling for drug release interpretation • Stability study design and modeling degradation trends • Shelf-life estimation using regression-based approaches • Practical limitations of extrapolation in formulation science	6 Hours
IV	**AI in Process Monitoring & Production Systems** Overview of introduces multivariate analysis in pharmaceutical analytical techniques with focus on the different models and their applications: • Digital data acquisition in pharmaceutical production • Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)	6 hours

	• Correlation analysis for identifying process variability • Logistic regression models for batch pass/fail prediction • Feature importance in process monitoring, predictive maintenance concepts. Ethical and regulatory considerations in automated decision-making, and limitations of predictive models in manufacturing environments.	
V	**AI in Pharmaceutical Analysis & Chemometrics** Overview of multivariate analysis in pharmaceutical analytical techniques with focus on the different models and their applications: • Introduction to chemometrics and multivariate analytical data • Spectroscopic data modeling (UV/IR interpretation) • Regression analysis in quantitative pharmaceutical analysis • Chromatographic peak modeling and interpretation • Classification models for genuine vs counterfeit detection • Handling noise and variability in analytical datasets • Limitations of AI models in analytical decision-making •	6 Hours

Recommended References *(Preferably latest editions)*:

1. Bakeev, K. A. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. Wiley.
2. Brown, N. Artificial Intelligence in Drug Discovery. Royal Society of Chemistry.
3. Chavda, V., et al. Bioinformatics Tools for Pharmaceutical Drug Product Development.
4. Gibson, M. Pharmaceutical Preformulation and Formulation. CRC Press.
5. Hanessian, S. Natural Products in Medicinal Chemistry. Wiley.
6. Pais, A., et al. Artificial Intelligence for Drug Product Lifecycle Applications.
7. Schlindwein, W. S. and Gibson, M. Pharmaceutical Quality by Design: A Practical Approach. Wiley.
8. World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. WHO Press

Course Code	Course Title			Course Type
BP605T	**Pharmaceutical Analysis (Theory)**			Core
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE			ESE
75	30			45

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the interaction of matter with electromagnetic radiation and its application in spectroscopic methods for pharmaceutical drug analysis.
2. Study the principles, instrumentation, and pharmaceutical applications of electroanalytical techniques such as potentiometry, conductometry, polarography, and amperometry.
3. Understand and apply various chromatographic and electrophoretic separation techniques used for qualitative and quantitative analysis of drugs.
4. Impart knowledge of instrumental methods used for accurate qualitative and quantitative analysis of pharmaceutical substances.
5. Develop the ability to select, optimize, and validate suitable analytical techniques, interpret analytical data.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the theoretical basis of electrochemical methods (potentiometry, conductometry, polarography, amperometry) and spectroscopic techniques (UV-Visible, IR, fluorometry, atomic absorption).
2	Explain the instruments involved in electroanalytical and spectroscopic methods.
3	Describe the principles, instrumentation, and applications of various chromatographic and electrophoretic techniques.
4	Select suitable analytical techniques for specific pharmaceutical analysis requirements.
5	Analyze, interpret, and report analytical data accurately and draw meaningful conclusions.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Electrochemical Methods of analysis** **1. Potentiometry:** Electrode potential, electrochemical cell, construction and working of reference and indicator electrodes including membrane electrodes, measurement of potential and	10 hours

	pH, potentiometric titrations, methods of detecting end point and Karl Fischer titration. 2. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications. 3. **Polarography:** Introduction, residual current, migration current, diffusion current and limiting current, DME, polarographic wave, Ilkovic's equation (Statement Only), and applications.	
II	**Spectroscopy** 1. **Fundamentals of Spectroscopy:** Properties of electromagnetic radiation, electromagnetic spectrum. 2. **UV Visible spectroscopy:** Beer and Lambert's law, Derivation and deviations. Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors (Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode). Applications - single and multi component analysis of pharmaceuticals. 3. **IR spectroscopy:** Introduction, fundamental modes of vibrations in poly atomic molecules, factors affecting vibrations, Instrumentation of dispersive Infrared spectrophotometer (including sample handling Techniques) and FTIR. Pharmaceutical applications.	10 hours
III	**Fluorometric Analysis** 1. Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation and pharmaceutical applications. 2. **Flame Photometry and Atomic Absorption Spectrometry:** Theory, nebulisation, flame and flame temperature, interferences, instrumentation and pharmaceutical applications. 3. **Nepheloturbidometry**: Principle, instrumentation and applications.	7 hours
IV	**Introduction to Chromatographic Techniques** 1. Principle, various stationary and mobile phases, diverse development and detection techniques and applications of column, paper and thin layer chromatography. 2. **Ion-exchange chromatography**: Introduction, principles, types of ions exchange resins, factors affecting ion exchange, methodology and applications. 3. **Gel filtration and affinity chromatography**: Principles and applications. 4. **Electrophoresis**: Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.	8 hours
V	1. **Gas chromatography:** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications 2. **High performance liquid chromatography:** Introduction, theory, instrumentation, advantages and applications.	10 hours

	3. **HPTLC:** Principle, instrumentation and applications.	

Recommended References *(Preferably latest editions)*:

1. Braun, R. D. *Analytical Chemistry: A Modern Approach to Analytical Science.* McGraw-Hill.
2. Dyer, J. R. *Applications of Absorption Spectroscopy of Organic Molecules.* Prentice Hall.
3. Harvey, D. *Modern Analytical Chemistry.* McGraw-Hill.
4. Sharma, Y. R. *Organic Spectroscopy.* S. Chand.
5. Skoog, D. A., Holler, F. J. and Crouch, S. R. *Principles of Instrumental Analysis.* Cengage Learning.
6. Watson, D. G. *Pharmaceutical Analysis.* Elsevier.

Course Code	Course Title		Course Type	
BP606T	**Pharmaceutical Jurisprudence (Theory)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
3	3	--	--	45
Maximum Marks	SE		ESE	
75	30		45	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamental principles and scope of pharmaceutical legislations governing drug development, manufacture, distribution, and marketing.
2. Gain comprehensive knowledge of Indian pharmaceutical Acts and Rules, including Drugs and Cosmetics Act, Pharmacy Act, NDPS Act, and related regulations.
3. Learn the roles, responsibilities, and functions of regulatory authorities involved in regulation and control of pharmaceuticals in India.
4. Learn the code of pharmaceutical ethics and legal responsibilities in professional pharmacy practice.
5. Develop the ability to analyse regulatory frameworks, pricing controls, and emerging regulations, and assess their impact on public health, industry compliance, and patient safety.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Demonstrate understanding of major pharmaceutical legislations and explain their relevance in pharmaceutical product development and marketing.
2	Interpret and apply the provisions of various Indian pharmaceutical Acts and laws in real-world scenarios.
3	Identify regulatory bodies such as CDSCO, IPC, and state regulatory authorities, and explain their roles in drug approval, manufacturing, and distribution.
4	Exhibit ethical awareness by applying the code of ethics in professional pharmaceutical practices.
5	Critically analyze regulatory frameworks and assess their impact on public health, industry operations, and compliance requirements.

Detailed Syllabus:

Unit No.	Topics	No. of Lectures
I	**Drugs and Cosmetics Act, 1940 and its rules 1945:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules, CDSCO guidelines for Import & export of Pharmaceuticals 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.	10 hours
II	**Drugs and Cosmetics Act, 1940 and its rules 1945.** • Detailed study of Schedule G, H, H1, M, N, P, T, U, V, X, Y, Sch F, Part XII B. • 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	10 hours
III	• **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations including ER20, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties • **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic 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	8 hours
IV	• **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, *CCSEA* guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for	8 hours

	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).	
V	• **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, • Medical Termination of Pregnancy Act • Brief Introduction to Right to Information Act • Introduction New Drugs and Clinical Trials Rules, 2019 and amendments. • Cosmetic rules 2020 • Regulatory guidelines on similar biologics. • Overview of Medical Device Regulations, Guidelines on Probiotics, Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016	9 hours

Recommended References (Preferably latest editions)

1. Government of India. Drugs and Cosmetics Act and Rules. Government of India.
2. Government of India. Drugs and Magic Remedies (Objectionable Advertisements) Act. Government of India.
3. Government of India. Medicinal and Toilet Preparations (Excise Duties) Act. Government of India.
4. Government of India. Narcotic Drugs and Psychotropic Substances Act. Government of India.
5. Government of India. New Drugs and Clinical Trials Rules, 2019. Government of India.
6. Central Drugs Standard Control Organization and Department of Biotechnology. *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India*. Government of India.

Course Code*	Course Title*			Course Type	
BP607T AEC1	Green Chemistry			**Elective**	
BP607T AEC2	Materiovigilance and Hemovigilance				
BP607T AEC3	Scientific Writing				
BP607T AEC4	Drug Store and Business Management				
BP607T AEC5	Career Building in Cultivation of Medicinal Plants				
BP607T AEC6	Active Pharmaceutical Ingredients and Excipient Sciences				
Credit	Hours Per Week (L-T-P)				Max. Hours.
	L	T	P		
1	1	--	--		15
Maximum Marks	SE		ESE		
50	20		30		

* One course shall be selected from the list
The syllabi for elective subjects are given in the *appendix*

Course Code	Course Title		Course Type	
BP608P	**Biopharmaceutics and Pharmacokinetics (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	3	45
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the dissolution profiles of pharmaceutical formulations using various media and conditions.
2. Apply *in vitro* and *ex vivo* techniques to assess drug absorption, dissolution, and bioavailability.
3. Interpret pharmacokinetic parameters using plasma and urinary excretion data.
4. Establish *in vitro–in vivo correlation* (IVIVC) for drug products based on experimental datasets.
5. Utilize software tools to simulate and analyze pharmacokinetic and pharmacodynamic data.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Explain the fundamental concepts, types, and applications of NDDS in modern therapeutics and precision medicine.
2	Design and prepare advanced drug delivery systems such as orodispersible tablets, bilayer tablets, osmotic systems, microspheres, microcapsules, buccal/sublingual dosage forms, transdermal patches, gastroretentive systems, and lipid-based carriers.
3	Select appropriate excipients and techniques for the development of NDDS considering drug properties, patient needs, and target site requirements.
4	Perform evaluation and quality control tests for novel formulations to ensure efficacy, stability, and patient compliance.
5	Integrate NDDS strategies into precision medicine frameworks to optimize dosing, therapeutic targeting, and individualized treatment plans.

Detailed Syllabus:

List of Practical
1. To calculate MRT from the given data. 2. To assess the effect of protein binding of a drug 3. To report relative bioavailability of given drug product using urinary excretion data 4. To report relative bioavailability of given drug product using plasma data 5. Establish IVIVC from the given *in vitro* and *in vivo* data. 6. To calculate pharmacokinetic parameters of a drug using given plasma level data. 7. To report bioequivalence of drug products using given urinary excretion data administered 8. To calculate absorption rate constant, elimination rate constant and elimination half-life of given excretion data by sigma minus method. 9. To calculate absorption rate constant, elimination rate constant and elimination half-life of the given drug data administered by IV bolus injection represented by one compartment model. 10. To calculate the absorption rate constant by using curve fitting method. 11. To calculate various pharmacokinetic parameters using *in silico* methods. **PCI recommended software's shall be used for performing experiments.*
Recommended References (Preferably latest editions): 1. Bonate, P. L. *Pharmacokinetic-Pharmacodynamic Modeling and Simulation.* Springer. 2. Brahmankar, D. M. and Jaiswal, S. B. *Biopharmaceutics and Pharmacokinetics: A Treatise.* Vallabh Prakashan. 3. Eddy, D. M. *Modeling and Simulation in the Medical and Health Sciences.* Springer. 4. Gibaldi, M. *Biopharmaceutics and Clinical Pharmacokinetics.* Lea & Febiger. 5. Rowland, M. and Tozer, T. N. *Clinical Pharmacokinetics and Pharmacodynamics.* Wolters Kluwer. 6. Shargel, L. and Yu, A. B. C. *Applied Biopharmaceutics and Pharmacokinetics.* McGraw-Hill Education.

Course Code	Course Title		Course Type	
BP609P	**Pharmaceutical Analysis (Practical)**		Core	
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
2	--	--	4	60
Maximum Marks	SE		ESE	
50	20		30	

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamental principles behind various analytical techniques including titrations, spectrophotometry, fluorimetry, flame photometry, and chromatography.
2. Develop proficiency in performing quantitative and qualitative analyses of pharmaceutical compounds using classical and instrumental methods.
3. Learn to operate and maintain laboratory instruments such as potentiometers, conductometers, spectrophotometers, fluorimeters, flame photometers, and chromatographic systems.
4. Apply appropriate analytical techniques for specific analytical challenges and interpretation, including single and multi-component assays, identification of functional groups, and separation of mixtures.
5. Learn good laboratory practices and safety protocols in handling chemicals and operating instruments.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to:
1	Perform accurate titrations (potentiometric and conductometric) to determine the endpoint of acid-base reactions.
2	Determine absorption maxima, perform assays, and analyze multi-component formulations using spectrophotometric and colorimetric techniques.
3	Identify functional groups in compounds using FTIR spectroscopy and conduct quantitative analysis using fluorimetry and flame photometry.
4	Separate and analyze mixtures of compounds using paper chromatography, thin-layer chromatography (TLC), gas-liquid chromatography (GLC), high-performance liquid chromatography (HPLC), and high-performance thin-layer chromatography (HPTLC).
5	Interpret spectral and chromatographic data to identify compounds and quantify analytes.

Detailed Syllabus:

List of Practical **(Minimum 12 experiments must be performed)**
1. Determination of the endpoint of a acid base titration by potentiometric method. 2. Determination of end point of acid base titrations by conductometry. 3. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds 4. Assay of APIs by colorimetry. 5. Assay of single component by UV- Spectrophotometer. 6. Simultaneous estimation of multicomponent formulations by UV spectrophotometer. 7. Identification of various functional groups in official compounds by FTIR as per IP. 8. Assay of quinine sulphate by fluorimetry 9. Determination of quenching effect by fluorimetry 10. Assay of sodium chloride by flame photometry 11. Assay of potassium chloride by flame photometry 12. Determination of chlorides and sulphates by nephelo turbidometry 13. Separation of amino acids by paper chromatography 14. Separation of mixture of components by thin layer chromatography 15. Demonstration experiment on GC 16. Determination of official compounds by HPLC (anyone) 17. Demonstration experiment on HPTLC.
Recommended References (Preferably latest editions): 1. Vogel, A.I., Textbook of Quantitative Chemical Analysis. Longman Scientific & Technical. 2. Beckett, A.H., and Stenlake, J.B., Practical Pharmaceutical Chemistry: Part II. Athlone Press. 3. Skoog, D.A., Holler, F.J., and Crouch, S.R., Principles of Instrumental Analysis. Cengage Learning.

Course Code*	Course Title*		Course Type	
BP610P SEC1	Computer-Aided Drug Design		**Elective**	
BP610P SEC2	Analytical Method Development and Validation			
BP610P SEC3	Principles of Preclinical Studies			
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	2	30
Maximum Marks	SE		ESE	
50	20		30	

* One course shall be selected in each elective

Course Code*	Course Title*		Course Type	
BP611P VAC1	Professional Skills		**Elective**	
BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science			
Credit	Hours Per Week (L-T-P)			Max. Hours.
	L	T	P	
1	--	--	2	30
Maximum Marks	SE		ESE	
50	20		30	

* One course shall be selected from the list
The syllabi for elective subjects are given in the *appendix*

Course Code	Course Title		Course Type
BP612I	**Internship**		**CORE**
Credit	Hours Per Week (L-T-P)*		
	L	T	P
4	--	--	--
Maximum Marks	SE		ESE
100	00		100

* Refer section 22 of Regulation

Appendix I

List of Recommended Electives (AEC/SEC/VAC courses to be prescribed by HEI)

Semester	Elective	Course Code	Course Title	Type	Category
II	Elective 1	BP212P SEC1	Communication Skills	Practical	SEC
		BP212P SEC2	Mental Well-Being, Stress & Conflict Management	Practical	SEC
		BP212P SEC3	Fundamentals of Computer Operations	Practical	SEC
III	Elective 2	BP312P AEC1	Nutraceuticals and Functional Foods	Practical	AEC
		BP312P AEC2	Food Analysis	Practical	AEC
		BP312P AEC3	Yoga and Life Sciences	Practical	AEC
VI	Elective 3	BP607T AEC1	Green Chemistry	Theory	AEC
		BP607T AEC2	Materiovigilance and Hemovigilance	Theory	AEC
		BP607T AEC3	Scientific Writing	Theory	AEC
		BP607T AEC4	Drug Store and Business Management	Theory	AEC
		BP607T AEC5	Career Building in Cultivation of Medicinal Plants	Theory	AEC
		BP607T AEC6	Active Pharmaceutical Ingredients and Excipient Sciences	Theory	AEC
	Elective 4	BP610P SEC1	Computer Aided Drug Design	Practical	SEC
		BP610P SEC2	Analytical Method Development and Validation	Practical	SEC
		BP610P	Principles of Preclinical Studies	Practical	SEC

		SEC3			
	Elective 5	BP611P VAC1	Professional Skills	Practical	VAC
		BP611P VAC2	Process Analytical Technology (PAT) and QbD in Formulation Science	Practical	VAC
VII	Elective 6	BP708T AEC1	Current Good Manufacturing Practices (cGMP)	Theory	AEC
		BP708T AEC2	Pharmaceutical Automation	Theory	AEC
		BP708T AEC3	Modern Techniques in Cellular Biology	Theory	AEC
		BP708T AEC4	Medical Devices	Theory	AEC
		BP708T AEC5	Transformation of Food Waste into Medicinal Products	Theory	AEC
		BP708T AEC6	Biosimilars, Vaccines & Macromolecules	Theory	AEC
		BP708T AEC7	Precision Medicine	Theory	AEC
VIII	Elective 7	BP806T AEC1	Pharmaceutical Packaging	Theory	AEC
		BP806T AEC2	Supply Chain Management	Theory	AEC
		BP806T AEC3	Industrial Safety and Waste Management	Theory	AEC
		BP806T AEC4	Traditional Healing Practices of India	Theory	AEC
		BP806T AEC5	Futuristic Pharma through AR/VR: Pharma 4.0	Theory	AEC
		BP806T AEC6	Herbal Cosmetics for Industry Perspective	Theory	AEC
	Elective 8	BP809P VAC1	Cleaning Validation	Practical	VAC

SEMESTER VI

Course Code	Course Title			Course Type
BP607T AEC1	**Green Chemistry (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Comprehend the foundational principles and overarching scope of green chemistry within pharmaceutical sciences.
2. Analyze and evaluate the environmental impact of traditional pharmaceutical manufacturing processes and the significance of green chemistry metrics.
3. Acquire knowledge of diverse green chemical techniques, including alternative solvents and various catalytic approaches, for sustainable drug synthesis.
4. Recognize the industrial application of green chemistry principles in pharmaceutical manufacturing processes, focusing on waste minimization and pollution control.
5. To articulate the principles of green chemistry.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Articulate the principles of green chemistry and provide relevant pharmaceutical examples for each.
2	Identify and propose suitable green solvents and catalysts,
3	Understand the advanced synthetic methods using Green synthesis using microwave, Ultrasonic for the production of active pharmaceutical ingredients (APIs).
4	Develop strategies for waste minimization and continuous flow reactor in pharmaceutical manufacturing in industries.
5	Articulate the principles of green chemistry and provide relevant pharmaceutical examples for each.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Green Chemistry in Pharmacy** 1. Definition and scope of green chemistry in pharmaceutical sciences 2. Principles of Green Chemistry with pharmaceutical examples	3 hours
II	**Environmental Aspects and Metrics in Green Pharmacy** • Comparison of traditional vs. green chemical approaches in drug synthesis • Environmental impact of pharmaceutical manufacturing • Overview of pharmaceutical pollutants and their life cycle • Metrics: Atom economy, E-factor, Process Mass Intensity (PMI)	3 hours
III	**Green Techniques in Pharmaceutical Synthesis – I** 1. Green Solvents and use of green solvents (e.g. water, supercritical fluids, ionic liquids) in drug synthesis 2. Solvent-free reactions in pharmaceutical synthesis 3. Green Catalysis and Reaction Enhancement in pharmaceutical green chemistry – Overview of catalysis in pharmaceutical green chemistry, Photochemical Transformations, Phase Transfer Catalysis	3 hours
IV	**Green Techniques in Pharmaceutical Synthesis – II** 1. Microwave assisted reactions: Merit and demerits of its use 2. Mechanism, superheating effects of microwave 3. Effects of solvents in microwave assisted synthesis 4. Microwave technology in process optimization 5. Applications in various organic reactions and heterocycles synthesis	3 hours
V	**Green Chemistry in Industrial and Regulatory Aspects** 1. Green chemistry in pharmaceutical manufacturing processes 2. Ultrasound assisted reactions: Types of sonochemical reactions, synthetic applications 3. Continuous flow reactors: Working principle, advantages and synthetic applications 4. Waste minimization and pollution control in formulation industries 5. Role of green chemistry in Good Manufacturing Practices (GMP)	3 hours

Recommended References *(Preferably latest edition)*:

1. Anastas, P.T. and Warner, J.C., 2000. Green chemistry: theory and practice. Oxford university press.
2. Lancaster, M. (2016). Green Chemistry: An Introductory Text (3rd ed.). Royal Society of Chemistry.
3. Green Chemistry in the Pharmaceutical Industry, Edited by Peter J. Dunn, Andrew Wells, and Michael T. Williams, 2010.
4. Green Chemistry and Sustainable Technology: Biological, Pharmaceutical, and Macromolecular Systems, Edited by Satish A. Dake, Ravindra S. Shinde, Suresh C. Ameta,
A. K. Haghi, 2022.
5. Scalable Green Chemistry: Case Studies from the Pharmaceutical Industry, Edited by Stefan Koenig, 2013.

Course Code	Course Title			Course Type
BP607T AEC2	**Materiovigilance and Hemovigilance (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the concepts, scope, and importance of materiovigilance and hemovigilance systems in ensuring patient safety in healthcare.
2. Familiarize students with national and international regulatory frameworks, reporting systems, and global initiatives related to vigilance programs.
3. Identify and evaluate adverse events associated with medical devices and blood transfusion practices.
4. Develop competencies in detection, reporting, investigation, and documentation of vigilance-related incidents.
5. Promote awareness of safety culture, quality assurance, and ethical responsibilities in clinical and healthcare practices.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the principles, scope, and significance of materiovigilance and hemovigilance in ensuring patient and public health safety.
2	Describe the structure and functioning of the Materiovigilance Programme of India (MvPI) and the procedures for reporting medical device-related adverse events.
3	Outline the framework of the Hemovigilance Programme of India (HvPI) and classify different types of transfusion-related adverse reactions.
4	Compare national and international vigilance systems and apply basic methods of risk assessment, signal detection, and root cause analysis.
5	Demonstrate appropriate documentation and reporting practices and recognize the role of healthcare professionals in promoting vigilance and patient safety.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Vigilance Systems** • Overview of Materiovigilance, Hemovigilance and other vigilance system in Healthcare • Importance of post-marketing surveillance in patient safety • Scope and objectives of materiovigilance and hemovigilance programs • Basic concepts of adverse event reporting and safety monitoring • Historical evolution and global relevance of Materiovigilance, Hemovigilance practices	3 hours
II	**Materiovigilance – Principles and Practices** • Introduction to Materiovigilance Programme of India (MvPI) • Roles of NCC-MvPI and technical collaborators (e.g., Sree Chitra Tirunal Institute) • Classification of medical devices (Class A to D) based on risk • Identification and documentation of Medical Device Adverse Events (MDAEs) • Medical device reporting forms, process flow, and responsibilities • Causality assessment of Medical Device Adverse Events	3 hours
III	**Hemovigilance – Principles and Practices** • Overview of Hemovigilance Programme of India (HvPI) • Organizational structure: NIB, NBTC, hospital-based hemovigilance • Adverse Transfusion Reactions (ATRs): Types and clinical manifestations • Use of TRRF (Transfusion Reaction Reporting Form) and Haemo-Vigil software • Responsibilities of blood banks, transfusion officers, and healthcare providers • Case examples along with Causality assessment of Hemolytic reactions, TRALI, TACO, allergic responses.	3 hours
IV	**Global Regulations, Risk Assessment & Root Cause Analysis** • International frameworks: US FDA (MAUDE), EU MDR, SHOT (UK), French Hemovigilance • Comparison of Indian and global materiovigilance/hemovigilance practices • Signal detection and evaluation of adverse events • Root cause analysis (RCA) and implementation of corrective & preventive actions (CAPA) • Risk communication and role of healthcare teams in mitigation	3 hours

V	**Reporting Systems, Quality Assurance, and Professional Role** Demonstration: Reporting of MDAEs and ATRs using mock forms • Practical exercises in form-filling and event documentation • Integration of vigilance into hospital quality systems (e.g., NABH, ISO) • Strategies to enhance adverse event reporting culture • Ethical considerations and communication with patients/families • Role of pharmacists, nurses, clinicians, biomedical engineers in vigilance programs	3 hours

Recommended References *(Preferably latest edition)*:

1. Bertil Jacobson - Medical Device Safety: The Regulation of Medical Devices for Public Health and Safety, CRC Press
2. Jack Wong - Handbook of Medical Device Regulatory Affairs in Asia, Pan Stanford Publishing
3. Denise M. Harmening - Modern Blood Banking and Transfusion Practices, F.A. Davis Company
4. World Health Organization (WHO)- Blood Safety: Basic Elements

Course Code	Course Title			Course Type
BP607T AEC3	**Scientific Writing (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Develop the ability to write clearly, concisely, and effectively for scientific audiences.
2. Understand the structure and components of scientific documents such as research papers, proposals, and literature reviews.
3. Learn the principles of scientific style, tone, and formatting in academic writing.
4. Apply correct citation practices and reference management techniques.
5. Recognize and address ethical issues in scientific communication, including plagiarism and data integrity.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Understand the principles of scientific writing
2	Develop clear and concise scientific writing skills
3	Use effective scientific citation techniques
4	Understand and apply the ethical principles of scientific writing
5	Develop the ability to critically evaluate scientific literature

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Scientific Writing** • Overview of the course • Principles of scientific writing • Overview of scientific research • Introduction to Microsoft tools and its application	2 hours
II	**Writing Literature Reviews and Scientific Papers** • Structure and format of literature reviews • Conducting a literature review • Analyzing literature and developing themes	5 hours

	• Writing a compelling introduction • Developing a clear methodology • Results and analysis	
III	**Communicating Results and Data** • Understanding data presentation • Developing tables and figures • Using effective graphic design	3 hours
IV	**Scientific Citation and Referencing** • Understanding citation styles • Citation and plagiarism • Referencing in scientific writing	3 hours
V	**Ethical Issues in Scientific Writing and Peer Review and Revision** • Ethical principles in scientific writing • Misconduct and fraud in scientific writing • Peer review and publication ethics • Providing Constructive feedback • Responding to feedback	2 hours

Recommended References *(Preferably latest edition)*:

1. Day, R. A., Gastel, B. How to Write and Publish a Scientific Paper. Bloomsbury Publishing, USA.
2. Hofmann, A. H. Scientific Writing and Communication: Papers, Proposals, and Presentations. Oxford University Press, USA.
3. Schimel, J. Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded. Oxford University Press, USA.
4. Alley, M. The Craft of Scientific Writing. Springer, New York, USA.
5. Machi, L. A., McEvoy, B. T. The Literature Review: Six Steps to Success. SAGE Publications, Thousand Oaks, USA.
6. Jesson, J., Matheson, L., Lacey, F. M. Doing a Literature Review in Health and Social Care. SAGE Publications, London, UK.
7. Tufte, E. R. The Visual Display of Quantitative Information. Graphics Press, Cheshire, USA.
8. American Medical Association. AMA Manual of Style. Oxford University Press, New York, USA.
9. American Psychological Association. Publication Manual of the American Psychological Association. American Psychological Association, Washington, DC, USA.
10. National Academies of Sciences, Engineering, and Medicine. On Being a Scientist: A Guide to Responsible Conduct in Research. National Academies Press, Washington, DC, USA.

Course Code	Course Title			Course Type
BP607T AEC4	**Drug Store and Business Management (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the principles of trade, commerce, and different types of business organizations.
2. Gain knowledge on effective drug store layout, procurement, and inventory control.
3. Apply basic accounting and financial principles for pharmacy business operations.
4. Explore marketing and sales strategies applicable to pharmaceutical products.
5. Develop entrepreneurial skills and understand legal aspects of drug store management.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe different business models and their relevance to pharmaceutical trade.
2	Manage drug store operations, including procurement, storage, and customer service.
3	Maintain basic accounting records and interpret financial statements.
4	Implement inventory control techniques and pricing policies.
5	Apply marketing principles and legal guidelines for establishing a retail pharmacy.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to Trade and Industry** • Objectives and scope of business • Classification of business activities – industry, commerce, trade • Forms of business organization: sole proprietorship, partnership, cooperatives, corporations • Features and merits/demerits of each form Pharmacy business and its legal considerations	3 hours
II	**Drug Store Management** • Selection of site, space, and layout of a drug store • Types of drug stores – hospital pharmacy, community pharmacy, chain pharmacy	3 hours

	• Procurement of drugs and inventory control • Storage conditions and stock maintenance (cold storage, poisonous drugs, etc.) • Records and registers to be maintained	
III	**Inventory Control and Sales Promotion** • Introduction to inventory control: need and methods • Economic Order Quantity (EOQ), Reorder Level (ROL), Lead time • FIFO and LIFO methods • Sales promotion techniques: advertising, displays, discounts • Customer relationship management (CRM) in pharmacy	3 hours
IV	**Financial Management and Bookkeeping** • Basics of accounting: journal, ledger, trial balance • Introduction to financial statements: profit and loss account, balance sheet • Pricing policies: markup, markdown, break-even analysis • Bank transactions: types of accounts, cheques, drafts • Taxation basics: GST, income tax (as applicable to pharmacies)	3 hours
V	**Pharmaceutical Marketing and Entrepreneurships** • Definition and scope of pharmaceutical marketing • Elements of marketing mix (4Ps) for pharmacy • Drug distribution channels: wholesale and retail • Entrepreneurship development in pharmacy • Regulatory aspects of retail drug licensing (Drug and Cosmetics Act overview)	3 hours

Recommended References *(Preferably latest edition)*:

1. Elements of Business Management by T.R. Jain & Mukesh Trehan, VK Publications
2. Principles and Practice of Management by L.M. Prasad, Sultan Chand & Sons
3. Business Organization and Management by C.B. Gupta, Sultan Chand & Sons
4. Drug Store and Business Management by R.M. Mehta, Pharma Med Press
5. Pharmaceutical Marketing in India by Subba Rao Chaganti, Excel Books

Course Code	Course Title			Course Type
BP607T AEC5	**Career Building in Cultivation of Medicinal Plants (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the significance, historical background, and therapeutic importance of medicinal plants.
2. Examine the structure, scope, and economic potential of the medicinal plant industry.
3. Identify and describe important medicinal plants of India and their applications.
4. Develop knowledge of sustainable, organic, and scientific cultivation practices for medicinal plants.
5. Explore entrepreneurship opportunities and value chain development in the medicinal plant sector.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the importance and historical development of medicinal plants in traditional and modern healthcare systems.
2	Describe the structure and functioning of the medicinal plant industry and its economic significance.
3	Identify major medicinal plants of India and explain their uses and sources.
4	Apply principles of sustainable and organic cultivation practices for medicinal plants.
5	Analyze entrepreneurship opportunities and value chain development in the medicinal plant sector.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction and Industry Overview** • Definition, importance, and cultural background (Ayurveda & ethnobotany) • Global and Indian demand, healthcare and pharma role • Key stakeholders: farmers, traders, processors, exporters • Value chain, supply-demand, government/private initiatives (NMPB, AYUSH, NABARD)	3 hours

II	**Key Medicinal Plants and Cultivation Basics** • Botanical characteristics and uses of major plants: Ashwagandha, Tulsi, Aloe vera, Shatavari, Brahmi, etc. • Regional suitability and agro-climatic zones • Factors affecting Cultivation: Soil, propagation, irrigation, pest control, organic inputs • Harvesting, post-harvest management and storage	3 hours
III	**Organic Farming and Market Linkages** • Organic certification and sustainable farming practices • Biodiversity conservation and agroforestry integration • Processing, drying, packaging, branding • Market linkages: pharma, cooperatives, online platforms, export guidelines	3 hours
IV	**Policy, Entrepreneurship and Digital Tools** • Government schemes and legal frameworks (NMPB, AYUSH, forest laws, GACP) • Entrepreneurship: starting herbal farms, franchises, consulting, contract farming • Digital tools: farm management software, GIS, mobile apps, e-commerce marketing	3 hours
V	**Practical Exposure and Project Presentation** • Virtual/shortened farm/nursery visit or guest lecture (can be online) • Group/individual project: business plan or herbal enterprise pitch presentation	3 hours

Recommended References *(Preferably latest edition)*:

1. Kumar, N., Misra, J. B. M., et al. Cultivation of Medicinal and Aromatic Crops. ICAR Publications, New Delhi, India.
2. Shah, B., Seth, A. Textbook of Pharmacognosy and Phytochemistry. Elsevier / Reed Elsevier India, New Delhi, India.
3. Planning Commission / National Medicinal Plants Board. Medicinal Plants Sector in India: Challenges and Opportunities. Government of India, New Delhi, India.
4. Planning Commission (NITI Aayog). Herbal Industry in India. Government of India, New Delhi, India.
5. National Medicinal Plants Board (NMPB). Annual Reports. Ministry of AYUSH, Government of India, New Delhi, India.
6. World Health Organization. Good Agricultural and Collection Practices (GACP) for Medicinal Plants. WHO Press, Geneva, Switzerland.

Course Code	Course Title			Course Type
BP607T AEC6	**Active Pharmaceutical Ingredients and Excipient Sciences (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Understand the fundamental concepts of Active Pharmaceutical Ingredients (APIs) and excipients in dosage form development.
2. Analyse the physicochemical properties influencing API–excipient compatibility and formulation performance.
3. Develop knowledge of industrial methodologies for characterization and quality control.
4. Understand GMP protocols and regulatory frameworks governing API and excipient manufacturing.
5. Explore emerging industrial trends including green chemistry and bio-based excipients.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	To explain the classification, properties and functional roles of APIs and excipients.
2	To apply analytical and preformulation methodologies for compatibility and stability evaluation.
3	To understand manufacturing, scale-up and quality control procedures used in industry.
4	To evaluate regulatory documentation and compliance requirements for API and excipient approval.
5	To develop awareness of current industrial practices and innovation trends.

Detailed Syllabus

Unit No.	Topics	No. of Lectures
I	**Introduction to APIs and Excipients** • Definitions, classifications, and sources (synthetic, natural, biotech APIs; functional excipients). • Physicochemical properties: Solubility, polymorphism, hygroscopicity, particle characteristics. • Roles in formulations: Bioavailability enhancement, stability, manufacturability.	3 hours

	• Industry overview: Global market trends, common examples (e.g., paracetamol API, HPMC excipient).	
II	**Methodologies for Selection and Pre-formulation** • Excipient selection criteria: Functionality-related characteristics (FRC). • Compatibility studies: Binary mixtures via DSC, FTIR, XRD. • Analytical methodologies: HPLC/GC for purity, Karl Fischer titration, laser diffraction for PSD. • QbD approach: Risk assessment for API-excipient interactions.	3 hours
III	**Manufacturing Protocols** • API processes: Synthesis routes, crystallization, drying, milling; lab-to-pilot scale-up. • Excipient handling: Sieving, blending, lubrication protocols. • GMP essentials: Equipment qualification, process validation. • Unit operations: Wet/dry granulation, direct compression.	3 hours
IV	**Quality Control and Stability Protocols** • QC tests: Assay, dissolution, content uniformity (IP/USP methods). • Stability studies: ICH Q1A zones, accelerated/forced degradation. • Impurity profiling: Genotoxic impurities (ICH M7), residual solvents. • In-process controls: Blend uniformity, weight variation.	3 hours
V	**Regulatory Compliance and Industry Practices** • ICH Q7 guidelines for APIs • USP-NF excipient monographs and Schedule M requirements • Drug Master File (DMF) for APIs • Certificate of Suitability (COS) for excipients • Process and cleaning validation protocols • Regulatory inspections (USFDA 483, EMA expectations) • Emerging trends: green chemistry and bio-based excipients	3 hours

Recommended References *(Preferably latest edition)*:

1. Gibson, M. Pharmaceutical Preformulation and Formulation. Informa Healthcare, London.
2. Rowe, R. C., Sheskey, P. J., Quinn, M. E. Handbook of Pharmaceutical Excipients. Pharmaceutical Press, London.
3. Aulton, M. E. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Elsevier, London.
4. ICH Guidelines (Q7, Q8, Q1A). International Council for Harmonisation, Geneva.
5. Indian Pharmacopoeia (Latest Edition). Indian Pharmacopoeia Commission, Ghaziabad, India.
6. United States Pharmacopeia–National Formulary (USP-NF). USP Convention, USA.
7. Banker, G. S., Rhodes, C. T. Modern Pharmaceutics. CRC Press, USA.
8. Allen, L. V., Popovich, N. G., Ansel, H. C. Pharmaceutical Dosage Forms and Drug Delivery Systems. Lippincott Williams & Wilkins, USA.

SEMESTER VI

Course Code	Course Title			Course Type
BP610P SEC1	**Computer Aided Drug Design (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Familiarize students with target identification and protein preparation using biological databases and molecular visualization tools.
2. Develop skills in ligand design, optimization, and 3D conformer generation using computational chemistry software.
3. Provide practical understanding of molecular docking and interaction analysis for structure-based drug design.
4. Introduce pharmacophore modelling and QSAR techniques for virtual screening and predictive modelling.
5. Train students in ADMET prediction and molecular dynamics simulations for evaluating drug-likeness and stability of drug–target complexes.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1.	Retrieve and prepare biological targets from protein databases and analyze active sites using molecular modelling tools.
2.	Design and optimize ligand structures and generate energetically stable conformers for computational drug design studies.
3.	Perform molecular docking and analyze drug–target interactions to evaluate ligand binding affinity and stability.
4.	Apply pharmacophore modelling and QSAR methods for virtual screening and prediction of biological activity.
5.	Evaluate drug candidates using ADMET prediction tools and molecular dynamics simulations to assess drug-likeness and complex stability.

Detailed Syllabus

List of Practical
General Instruction on Computational Tools Open-source computational tools are preferred for teaching and learning purposes. However, institutions may select appropriate software platforms or online resources based on availability, institutional policy, and technical feasibility. The choice of software should enable students to perform the required computational tasks effectively. The specific software used may vary, but the learning outcomes and computational procedures described below must be achieved using suitable tools. **1. Target Identification and Preparation** • Retrieve protein sequence or structural information from publicly available biological databases. • Prepare the target protein by removing unwanted molecules, correcting structural issues, and adding necessary atoms or charges using appropriate molecular visualization or preparation tools. • Identify potential binding or active sites using computational methods that analyze structural pockets and cavities. **2. Ligand Design and Optimization** • Design or sketch candidate molecules using suitable molecular drawing tools. • Convert structures into three-dimensional form and optimize their geometry using computational chemistry methods. • Generate multiple conformations of the molecule and perform energy minimization to obtain stable structures. **3. Molecular Docking** • Perform docking simulations using computational docking platforms to predict the interaction between ligands and the target protein. • Examine binding orientations and molecular interactions using visualization tools. • Rank compounds based on predicted binding affinity and interaction quality. **4. Pharmacophore Modeling** • Identify essential molecular features responsible for biological activity such as hydrogen bond donors/acceptors, hydrophobic regions, and aromatic centers. • Construct pharmacophore models representing these key features. • Use these models to screen compound libraries for molecules that match the required feature pattern. **5. QSAR Modeling** • Calculate molecular descriptors that represent structural and physicochemical properties of compounds. • Develop predictive statistical or machine learning models that relate these descriptors to biological activity. • Validate models using appropriate validation techniques such as cross-validation and external datasets.

6. ADMET Prediction

- Evaluate pharmacokinetic and toxicity properties computationally, including:
  - Absorption
  - Distribution
  - Metabolism
  - Excretion
  - Toxicity
- Use predictive computational models and online resources to assess drug-likeness and safety profiles.

7. Molecular Dynamics Simulations

- Conduct simulations to study the dynamic behavior of the protein–ligand complex over time.
- Analyze parameters such as structural stability, atomic fluctuations, hydrogen bonding, and interaction persistence.
- Visualize simulation trajectories to understand conformational changes and binding stability.

Recommended References *(Preferably latest edition)*:

1. Leach, A.R., *Molecular Modelling: Principles and Applications*. Harlow: Prentice Hall.
2. Todeschini, R. and Consonni, V., *Molecular Descriptors for Chemoinformatics*. Weinheim: Wiley-VCH.
3. Gupta, S.P., *QSAR and Molecular Modeling*. Berlin: Springer.
4. Jorgensen, W.L., *Efficient Drug Discovery and Development*. Hoboken, NJ: Wiley.
5. Bultinck, P., De Winter, H., Langenaeker, W. and Tollenaere, J.P., *Computational Medicinal Chemistry for Drug Discovery*. New York: Marcel Dekker.
6. Andrew, L.H. and Brown, F.K., *Rational Drug Design: Novel Methodology and Practical Applications*. Washington, DC: American Chemical Society.
7. Ward, S.E. and Davis, A., *The Handbook of Medicinal Chemistry: Principles and Practice*.

Course Code	Course Title			Course Type
BP610P SEC2	**Analytical Method Development and Validation (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Provide practical exposure to analytical method development using spectrophotometric, chromatographic, and titrimetric techniques for pharmaceutical analysis.
2. Introduce principles of optimization of analytical parameters such as wavelength, mobile phase composition, column selection, flow rate, temperature, and pH for reliable analysis.
3. Familiarize students with validation requirements of analytical methods as per regulatory guidelines, including assessment of sensitivity, linearity, and specificity.
4. Expose students to advanced chromatographic applications such as dissolution testing, impurity profiling, forced degradation studies, and residual solvent analysis.
5. Bridge analytical theory with industrial and regulatory practices relevant to quality control and quality assurance of pharmaceutical products.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Develop and optimize analytical methods using UV–Visible spectrophotometry, HPLC, GC, and titrimetric techniques for pharmaceutical substances.
2	Construct calibration curves and perform quantitative estimation of APIs and formulations with appropriate analytical validation.
3	Select and optimize chromatographic conditions including column type, mobile phase composition, flow rate, temperature, and detection wavelength.
4	Apply analytical method validation parameters such as LOD, LOQ, and robustness to ensure reliability and regulatory compliance.
5	Conduct stability-indicating and impurity-related studies, including forced degradation, dissolution testing, and residual solvent analysis.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Development of a UV-Visible spectrophotometric method for the assay of paracetamol API. Construction of calibration curve for a model API using UV-Visible spectrophotometry. 2. Determination of solid dosage form by using dissolution method. 3. Analytical method development and validation of Atenolol/metformin by using HPLC. 4. Investigation of different columns for HPLC separation of a Multi-component Drug Mixture. 5. Optimization of mobile Phase composition for HPLC analysis of a selected drug. 6. Optimization of Flow rate and temperature in HPLC for paracetamol/ caffeine. 7. Selection of wavelength for spectrophotometric analysis by HPLC of Marketed drugs. 8. Determination of λmax and calibration curve for qualitative analysis of paracetamol. 9. Determination of effect of pH on Retention time in RP-HPLC. 10. Validation of HPLC method : Determination of LOD and LOQ for paracetamol by HPLC 11. Preliminary Investigation of forced Degradation studies on Ibuprofen by HPLC. 12. Method development for related substances of a drug substance using HPLC. 13. Determination of residual solvent analysis for ethanol/acetone in API by using Gas Chromatography. 14. Development of titrimetric method for the assay of marketed drugs(Ascorbic acid/sodium bicarbonate).
Recommended References *(Preferably latest edition)*: 1. Ahuja S, Dong MW, editors. Handbook of pharmaceutical analysis by HPLC. Amsterdam: Elsevier; 2005. 2. Moldoveanu SC. Method development in analytical HPLC. Amsterdam: Elsevier; 2014. 3. Swartz ME, Krull I. Analytical method development and validation. Boca Raton (FL): CRC Press; 2018. 4. Gorog S. Ultraviolet–visible spectrophotometry in pharmaceutical analysis. Boca Raton (FL): CRC Press; 2018. 5. Rehman K, Akash MSH. Essentials of pharmaceutical analysis. Singapore: Springer; 2020. 6. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q2(R2): Validation of analytical procedures. Geneva: ICH; 2023.

Course Code	Course Title			Course Type
BP610P SEC3	**Principles of Preclinical Studies (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce the role and importance of preclinical studies in the drug discovery and development process.
2. Familiarize students with laboratory animal handling, ethical considerations, and experimental protocols used in preclinical research.
3. Explain the principles of pharmacokinetics and toxicology as applied to animal models.
4. Describe the regulatory guidelines and standards governing preclinical research and animal experimentation.
5. Develop skills in analyzing and interpreting preclinical data to support decision-making for clinical trials.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Explain the role and significance of preclinical studies in drug discovery and development.
2	Demonstrate appropriate laboratory animal handling practices in accordance with ethical and regulatory guidelines.
3	Analyze pharmacokinetic parameters obtained from preclinical animal studies.
4	Design and interpret basic toxicological studies to evaluate drug safety.
5	Apply preclinical data in assessing drug candidates for progression to clinical trials.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Handling, restraining, and sex differentiation of laboratory animals (demo/video) 2. Calculation of dose for animals based on body surface area 3. Routes of administration: oral, intraperitoneal, subcutaneous (simulation) 4. Observation of behavioral effects using actophotometer/rotarod (if available) 5. Determination of acute toxicity (LD50 concept) – case-based calculation 6. Planning a 28-day sub-acute toxicity study protocol 7. Pharmacokinetic study: Cmax, Tmax, AUC calculation (sample dataset) 8. Observation of histopathological slides from toxicity studies 9. Demonstration of sampling methods – blood, urine (case or video) 10. Writing an animal study protocol using CPCSEA format 11. Identification of organs for toxicity evaluation – liver, kidney, brain 12. Visit to CPCSEA-approved animal house/laboratory 13. Observation of animal behavior – grooming, nesting (case-based) 14. Simulated ethics committee approval process (IAEC) 15. Group activity: Design of a preclinical study for a hypothetical drug **PCI recommended software's shall be used for performing experiments.*
Recommended References *(Preferably latest edition)*: 1. Preclinical and Clinical Research – A Handbook – S. K. Gupta, Jaypee Brothers Medical Publishers 2. Drug Discovery and Clinical Research – B. T. James & M. M. Gupta, CBS Publishers & Distributors 3. Hofmann, F. B. Handbook of Experimental Pharmacology (HEP Series). Springer Nature. 4. Fundamentals of Experimental Pharmacology – M. N. Ghosh, Hilton & Company 5. Textbook of Pharmacology – S. D. Seth, Elsevier India

SEMESTER VI

Course Code	Course Title			Course Type
BP611P VAC1	**Professional Skills (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Develop effective verbal and interpersonal communication skills required for professional environments.
2. Train students in workplace etiquette, interview preparation, and team collaboration.
3. Enhance problem-solving, time management, and critical thinking abilities relevant to professional settings.
4. Promote personal grooming, digital professionalism, and responsible social media etiquette.
5. Prepare students to face professional challenges through experiential learning, role play, and interactive activities.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Demonstrate professional communication skills in interviews, emails, presentations, and workplace meetings.
2	Prepare and present an industry-standard résumé and professional online profile.
3	Exhibit confidence and clarity during group discussions, presentations, and interviews.
4	Apply time management, decision-making, and conflict resolution strategies in professional situations.
5	Maintain workplace ethics, etiquette, and a professional demeanor in both physical and digital environments.

Detailed Syllabus

List of Practical
(Perform any 12 Experiments) 1. Self-introduction exercise – verbal and written presentation 2. Resume/CV writing – using current industry formats 3. Mock job interview – panel-based or peer-reviewed 4. Group discussion (GD) – on current healthcare or industry topics 5. Public speaking practice – impromptu and prepared speeches 6. Email etiquette and writing professional emails 7. Time management matrix creation (Eisenhower box) 8. Body language analysis – observe and present feedback 9. Conflict resolution role play – team-based activity 10. Creating a LinkedIn profile and optimizing it professionally 11. Debate session – critical thinking and communication 12. Listening skills test – audio-based task with Q&A 13. Workplace scenario simulation – ethics, teamwork, communication 14. Presentation skills – create and deliver PowerPoint presentations 15. Goal-setting and career mapping – using SMART goals
Recommended References *(Preferably latest edition)*: 1. Soft Skills: Enhancing Employability by Meenakshi Raman & Sangeeta Sharma, Oxford University Press 2. The 7 Habits of Highly Effective People by Stephen R. Covey, Simon & Schuster 3. Personality Development and Soft Skills by Barun K. Mitra, Oxford University Press 4. Effective Technical Communication by M. Ashraf Rizvi, Tata McGraw-Hill Education 5. The Art of Public Speaking by Stephen E. Lucas, McGraw-Hill Education

Course Code	Course Title			Course Type
BP611P VAC2	**Process Analytical Technology (PAT) and QbD in Formulation Science (Practical)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	--	--	2	30
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Introduce PAT concepts so students grasp how in-line sensors monitor critical quality attributes (CQAs).
2. Explain QbD thinking for defining design space, critical process parameters (CPPs), and risk-based control strategies.
3. Teach basic PAT tools—near-infrared (NIR) probes, focused-beam reflectance (FBRM), and multivariate models.
4. Demonstrate mini-DoE methods that link process variables to CQAs and support real-time release testing (RTRT).
5. Instil risk-analysis skills using Ishikawa diagrams and FMEA to prioritise and mitigate formulation hazards.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Describe the role of PAT and QbD in ensuring consistent product quality throughout a formulation process.
2	Identify and justify key CQAs, CPPs, and potential failure modes for a solid-dosage product.
3	Collect and interpret real-time data from an NIR or FBRM sensor and decide when a blend or granulation meets targets.
4	Design and analyse a small factorial experiment that optimises at least one CQA within a defined design space.
5	Prepare a brief risk-control plan showing ranked RPN values and proposed PAT-based monitoring to enable RTRT.

Detailed Syllabus

List of Practical
1. Identify Critical Quality Attributes (CQAs) – Brainstorm and list five tablet CQAs (hardness, dissolution, etc.) and link each to patient safety or efficacy. 2. Ishikawa (Fish-Bone) Diagram – Draw a cause-and-effect diagram for poor tablet dissolution, categorising factors into Materials, Methods, Machines and Manpower. 3. Blend-Uniformity by NIR Probe – Collect in-line near-infrared spectra during 10 min of blender operation and plot real-time API concentration trends. 4. Moisture Tracking with NIR – Use a portable NIR gun to measure LOD in wet granules every 2 min, stopping when the plot hits the 3 % target. 5. Mini DoE for Granulation – Run a 2^2 design varying impeller speed and granulation time; measure granule mean size and create main-effects plots. 6. Real-Time Release Test (RTRT) – Set up an at-line NIR hardness prediction model, test 20 tablets, and compare predicted vs. actual hardness. 7. Control Chart of Particle Size (FBRM) – Stream Focused Beam Reflectance data during milling; plot $\bar{X}$ and R for d_{50} and decide if the process is in control. 8. Multivariate Calibration Model – Build a partial-least-squares (PLS) model correlating NIR spectra to drug content; report R^2 and RMSEP. 9. FMEA Risk-Priority Number – Score severity, occurrence and detectability for three high-risk process variables; rank them by RPN and suggest mitigation. 10. PAT Model Verification Batch – Run the optimised process, capture PAT data, and confirm that all CQAs meet specification without end-product testing.
Recommended References *(Preferably latest edition)*: 1. Bakeev KA, editor. Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries. 2nd ed. Chichester: Wiley; 2010. 2. Rathore AS, Winkle H. Quality by Design for Biopharmaceuticals. 2nd ed. Hoboken: Wiley; 2019. 3. Kourti T, Bakeev K. Process Analytical Technology: Theory and Applications. 1st ed. Oxford: Butterworth-Heinemann; 2022. 4. Patil AS, Rane VP. Practical Implementation of Quality by Design (QbD) for Pharmaceutical Product Development. 1st ed. Amsterdam: Elsevier; 2019.

SEMESTER VII

Course Code	Course Title			Course Type
BP708T AEC1	**cGMP (Theory)**			Elective
Credit	Hours Per Week (L-T-P)			Max. Hours
	L	T	P	
1	1	--	--	15
Maximum Marks	SE			ESE
50	20			30

COURSE OBJECTIVES:

The objectives of this course are to:

1. Explain the structure, purpose, and implementation of Standard Operating Procedures (SOPs) in pharmaceutical operations.
2. Develop understanding of training and development systems, including training needs assessment and evaluation methods used in the pharmaceutical industry.
3. Describe the principles of current Good Manufacturing Practices (cGMP) and key regulatory guidelines relevant to pharmaceutical quality assurance.
4. Examine core pharmaceutical quality systems such as Quality Management Systems (QMS), CAPA, deviation management, and non-conformance handling.
5. Understand procedures for managing customer complaints, investigating quality issues, and ensuring product safety and regulatory compliance.

COURSE OUTCOMES (CO):

CO No.	Upon successful completion of this course, the students will be able to
1	Understand the structure of SOPs, its writing and approval system, Importance of training, development, training needs identification and evaluation.
2	Understand the major FDA guidelines (regulated and semi regulated markets) and its understanding.
3	Impart knowledge on manufacturing assurance, analytical assurance, engineering assurance etc, and handling systems for non-conformances.
4	Procedures used to investigate market complaints and its closure.
5	Impart knowledge on preparing for the regulatory audits, reports handling and drafting of compliance report, with certain understanding of Do's and Don'ts during the audits.

Appendix II-Laboratory Specifications

1. Requirements of Laboratory Specifications

Sl No.	Particular	Details
1.	Lab Size	Total area: 75 Sq. mts including preparation room Capacity: 20–30 students + 1or 2 faculty
2.	Zoning (recommended)	1. Working benches (students) 2. Instructor/demo area 3. Instrument and balance zone 4. Fuming chamber (Chemistry Lab) and exhaust zone 5. Wash and drainage zone 6. Circulation
3. Floor Design and Specifications (Material): Acid- and alkali-resistant vitrified tiles/stone (heavy duty) or Epoxy resin flooring (chemical resistant, seamless)		
	Floor Specifications	1. Thickness: ≥10 mm (tiles) / 2–3 mm epoxy 2. Finish: Matt / anti-skid 3. Chemical resistance: Acids, alkalis, solvents, salts 4. Skirting:100–150 mm epoxy or tile skirting (covered)
	Sink and Drainage Layout	One sink per six students Sink material: Chemical Resistant with acid-resistant valves
	Drainage System	Separate lab drainage line (Discharge should be suitably treated for minimizing the Environmental impact)
4. Modular Furniture Layout		
	Student Working Benches	Type: Island benches Surfaces should be sufficiently chemical resistant
	Side Wall Benches	For instruments, reagent prep, drying
	Storage	Separate flammable storage cabinet (recommended)
5. Fuming Chamber (Fume Hood) Mandatory for Synthetic Chemistry Lab		
	Quantity	Minimum one
6. Exhaust and Ventilation System		
	General Ventilation	Wall-mounted exhaust fans Labs should be well ventilated.
	Exhaust Fans	Should be placed in every lab. Acid-resistant coating Placed near fuming chamber zone
7. Lighting and Electrical (Brief)		
	Lighting	300–500 lux at bench level Emergency lighting near exits Arrangement of sufficient lighting at the work benches in HAP and Pharmacognosy Lab.
	Electrical	Sufficient number of combination sockets on side benches:

		On benches sufficient number of electrical sockets (Earthing mandatory)
8. Preparation Room (Between Two Labs)		
	Location and Purpose	Preparation room with minimum 10 sq.mt area Each laboratory should have a preparation room. However, one preparation room may be shared by two laboratories if it is located between them and both belong to the same department used for Solution preparation, Reagent storage, Sample weighing
	Design Features	Central working bench Storage cabinets (lockable) Balance table (anti-vibration) Exhaust fan Chemical-resistant floor and walls (same specs as lab)
	Access	Door from both labs (controlled access) if shared.
9. Safety Provisions (Must-Have)		
		First aid box Material Safety Data Sheet (MSDS) display Proper signage Emergency eye wash and safety shower (near wet and fume hood zones) (Desirable) Fire Extinguisher (Dry Powder Type) Provision of Double Door Access (Every Laboratory)
10.	**Balance Room**	A closed balance room is desirable for housing high-sensitivity balances to prevent disturbances caused by airflow.
11.	**Gas Connection**	A gas connection is essential in the Pharmaceutical Chemistry, Pharmacognosy, and Pharmaceutics laboratories. One Bunsen burner may be shared by two students during practical sessions.

2. Department wise List of Minimum laboratory required for the B. Pharm as per NEP2020.

Sl No	Department	Laboratory Name	Area Requirement
1	Pharmaceutics	1. Fundamental Pharmaceutics Lab 2. Advanced Formulation Development Lab 3. Pharmaceutical Biotechnology and Microbiology lab (Including Aseptic Room)	75 Sq. mts including preparation room with minimum 10 sq.mt area Each laboratory should have a preparation room. However, one preparation room may be shared by two laboratories if it is located between them and both belong to the same department.
2	Pharmaceutical Chemistry	1. Inorganic and Analytical Chemistry 2. Synthetic Chemistry 3. Biochemistry and Biomedical Chemistry	
3	Pharmacology	1. Human Anatomy and Physiology 2. Pharmacology	
4	Pharmacognosy	1. Pharmacognosy Lab	

5	Research Lab	75 Sq. mts
6	Central Instrumentation Lab	80 Sq.mts with A/C Air purifier (desirable)
7	Machine Room	75-100 Sq.mts
8	Computer Lab	75 Sq mts
9	Store-I	100 Sq.mts
10	Store-II (For Inflammable chemicals)	20 Sq.mts

3. Department wise List of Minimum laboratory required for the B. Pharm as per NEP2020 and D. Pharm

Sl No	Department	Laboratory Name	Area Requirement
1	Pharmaceutics	1. Fundamental Pharmaceutics Lab 2. Advanced Formulation Development Lab 3. Pharmaceutical Biotechnology and Microbiology lab (Including Aseptic Room)	75 Sq. mts including preparation room with minimum 10 sq.mt area Each laboratory should have a preparation room. However, one preparation room may be shared by two laboratories if it is located between them and both belong to the same department.
2	Pharmaceutical Chemistry	1. Inorganic and Analytical Chemistry 2. Synthetic Chemistry 3. Biochemistry and Biomedical Chemistry	
3	Pharmacology	1. Human Anatomy and Physiology 2. Pharmacology 3. Social Pharmacy Lab	
4	Pharmacognosy	1. Pharmacognosy Lab	
5	Research Lab		75 Sq. mts
6	Central Instrumentation Laboratory		80 Sq.mts with A/C Air purifier (desirable)
7	Machine Room		75-100 Sq.mts
8	Computer Laboratory		75 Sq mts
9	Running Model Community Pharmacy		80 Sq. mts (Including 10 Sq. mt for Drug Information Centre & 10 Sq. mt. for Patient Counseling)
10	Store-I		100 Sq.mts
11	Store-II (For Inflammable chemicals)		20 Sq.mts

4. Laboratory Equipment and Apparatus

4.1. Pharmaceutics:

Sl. No	Instrument Name	Quantity
1.	Antibiotic Zone reader	1
2.	Autoclave	1

3.	Binocular Microscope (With Phase Contrast)	1
4.	BOD Incubator	1
5.	Buchner Funnels (Small, medium, large)	5 each
6.	Bulk Density & Tapped density Apparatus	2
7.	Burette & Burette stand	10 each
8.	Capsule counter	1
9.	Centrifuge (minimum 4000 rpm)	1
10.	Compound Microscope with movable stage	15
11.	Culture Tubes	30
12.	Deep freezer (Desirable)	1
13.	Desiccator (Glass/PVC)	5
14.	Digital Balance (min. 10mg)	4
15.	Digital Colony Counter	1
16.	Digital Melting point Apparatus	2
17.	Digital pH meter	3
18.	Digital Vernier calliper (Desirable)	4
19.	Distillation Unit	2
20.	Electronic Water Bath 12 Holes	3
21.	ELISA Reader and Kits (Desirable)	1
22.	Eye Piece Micrometer	10
23.	Franz Diffusion Cell (Desirable)	5
24.	Hardness Test apparatus (Monsanto & Pfizer)	2 each
25.	Heating Mantle (500ml)	10
26.	High Speed Homogenizer with RPM Controller and Display	5
27.	Hot Air Oven	3
28.	Hot Plate	4
29.	Glass Petri Plates/Casting Plates	10
30.	Incinerator	1
31.	Incubator (Desirable)	1
32.	Lab Fermenter (Desirable)	1
33.	Laminar Air Flow	1
34.	Magnetic Stirrer (500 ml) with Temperature Control	12
35.	Mechanical stirrer with propeller type agitator	2
36.	Mechanical Stirrer with Speed Regulator	8
37.	Membrane Filtration Unit	2
38.	Micro-centrifuge	1
39.	Micropipettes (1-10 µL, 10-100 µL, 100–1000 µL)	1 set
40.	Microscope with digital camera eyepiece (Desirable)	1
41.	Mortar & Pestle (Glass)	10
42.	Mortar Pestle (Porcelain)	20
43.	Ointment slab	10
44.	Ointment spatula	10
45.	Orbital Shaker Incubator	1

46.	Orbital Shaker/Flask Shaker (6 flask holding capacity) (Desirable)	2
47.	Ostwald viscometer	15
48.	Personnel Protection Equipment (Complete Set) (Desirable)	Adequate
49.	Petri Plates	30
50.	Platinum Inoculating Loop	30
51.	Pycnometer (Specific gravity Bottle)	30
52.	Refrigerated centrifuge	1
53.	Refrigerator	1
54.	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80 (as per BIS standards)	1 Set
55.	Separating Funnel	10
56.	Spirit Lamps (Desirable)	10
57.	Stage micrometer	10
58.	Stalagmometer	15
59.	Sterility Testing Unit	1
60.	Stopwatch	5
61.	Suppository Mold	20
62.	Tablet counter	1
63.	Thermometer (Upto 300'C)	20
64.	Sonicator	1
65.	Vaccum Filtration Unit (Filtration Unit and Vaccum Pump)	2
66.	Vortex Shaker	2
67.	Water Bath (Copper)	10

4.2. Pharmaceutics Chemistry

Sl. No	Instrument Name	Quantity
1.	Boiling point apparatus (Desirable)	2
2.	Bomb Calorimeter (Desirable)	1
3.	Burette	60
4.	Centrifuge (12–16 tube capacity)	1
5.	Clinical Thermometer	10
6.	Digital Colorimeter	2
7.	Compound Microscope	5
8.	Digital potentiometer	1
9.	Desiccator	4
10.	Digital balance (10mg sensitivity)	3
11.	Digital Conductivity meter	1
12.	Digital Flame Photometer	1
13.	Digital Fluorimeter	1
14.	Digital pH meter	3
15.	Double door Refrigerator	2
16.	Fluoride ion meter (Desirable)	1
17.	Distillation Assembly (Glass)	1
18.	Double Distillation Assembly (Glass)	1

19.	Distillation Assembly (Steel- Wall Mounted))	1
20.	Fume hood	1
21.	Glass filtration assembly with 5 micron membrane filter	1
22.	Arsenic Test Apparatus (Gutzeit) apparatus	20
23.	Heating mantle (1000ml)	10
24.	Heating mantle (500 ml)	10
25.	Homogenizer	1
26.	Hot air oven	3
27.	Hot Plate	5
28.	Incubator (37°C) (Desirable)	1
29.	Ion exchanger	1
30.	Laboratory Microwave Oven (Desirable)	1
31.	Digital Melting Point apparatus	2
32.	Melting point apparatus (analog)	5
33.	Laboratory Thermometer	10
34.	Micropipettes (1-10 µL, 10-100 µL, 100–1000 µL)	1 set
35.	Magnetic stirrer with thermostat (1000ml)	5
36.	Magnetic stirrer with thermostat (500ml)	5
37.	Morter and pestle (500ml)	5
38.	Morter and pestle (Glass-250ml)	10
39.	Nessler cylinder	20 pairs
40.	Reflux flask and condenser double / triple necked	20
41.	Reflux flask and condenser single necked	20
42.	Sahli's Hemoglobinometer	15
43.	Soxhlet Apparatus (500mL)	2
44.	Stopwatch	10
45.	Vaccum pump	3
46.	TLC chamber	5
47.	UV cabinet	1
48.	Vortex Mixer (Desirable)	1
49.	Water bath with thermostat (6 holes)	3

4.3. Pharmacology:

Sl. No	Instrument Name	Quantity
1.	Adult CPR Manikin	2
2.	AED Trainer (Automated External Defibrillator) non-shocking version	1
3.	AED Trainer (Training Pads)	10
4.	Ambu Bag (Bag-Valve-Mask Resuscitator)	2
5.	Digital balance (10 mg sensitivity)	1
6.	Aneroid sphygmomanometer	5
7.	Arm Mannequin (Training Arm Model)	2
8.	Autoclave	1
9.	Barrier Devices	1
10.	Bio safety Cabinet (Class II) (Desirable)	1

11.	Biohazard Sharps Container	5
12.	Biohazard Waste Bag	1
13.	BMI Chart	Adequate
14.	Bones (set of spare bones)	1 set
15.	Centrifuge	1
16.	Charts for different organs, systems, tissues	Adequate
17.	Charts for family planning devices, contraception (birth control) methods, etc.	One for each
18.	Clinical thermometer (Digital)	10
19.	Clinical thermometer (Mercury)	10
20.	CO2 Incubator (Desirable)	1
21.	Colorimeter	1
22.	Compound Microscope	20
23.	Contraceptive devices including contraceptive pills (different types), male condom, female condom, diaphragm, copper-T, vaginal ring,	1 set
24.	Different Wound Dressing Materials	Adequate
25.	Digital blood pressure monitor	5
26.	Digital Glucometer with Test Strips	5
27.	Digital Hemoglobinometer with Test Strips	5
28.	Electrocardiograph (ECG Machine) (Desirable)	1
29.	Eye Occluder	10
30.	First Aid Kit	5
31.	Gauze Pads	20
32.	Hemocytometer (Neubauer's Chamber) with RBC/WBC Dilution Pipette	15
33.	Health promotion material (Charts, Pamphlets)	Adequate
34.	Hematology Analyzer (Desirable)	1
35.	Histopathological slides from toxicity studies	Adequate
36.	Homogenizer	2
37.	Hot plate	2
38.	Immunization chart	Adequate
39.	Incubator	1
40.	Infant/Child CPR Mannequin (Desirable)	1
41.	Infrared Thermometer	2
42.	Kneeling Pads	1
43.	Leaflet on lifestyle modifications for disease prevention.	Adequate
44.	Magnetic stirrer with hot plate	2
45.	Magnifying glass	10
46.	Masked patient reports (if available)/ theoretical case studies (at least one for each disease - anaemia, thalassemia, haemophilia, leprosy, gout, hypertension and ischemic heart disease, IBD, peptic ulcer, jaundice, hepatitis, typhoid, asthma, tuberculosis, diabetes, and thyroid disorders)	3 per diseases
47.	Measuring Tape	5
48.	Mechanical mixer	2

49.	Mercury sphygmomanometer	10
50.	Micropipettes (various ranges)	1 set
51.	Model for each organ system	1 Model for each organ system
52.	Mortar and pestle	5
53.	Peak Flow meter	10
54.	Pen torch	10
55.	Permanent Slides for various tissues (Epithelial tissue, Connective tissue, Muscle tissue, and Nervous tissue)	At least 30
56.	Personal Protective Equipment (PPE)	2
57.	pH meter	1
58.	Pocket Mask (CPR Mask)	2
59.	Pregnancy detection kit.	1 unit
60.	Pulse Oximeter	10
61.	Reflex hammer	10
62.	Refrigerator	1
63.	Sahli's Haemoglobinometer	20
64.	Skeleton	1
65.	Snellen Chart	2
66.	Specimen for various organs	15
67.	Spirometer	5
68.	Spirometer (digital)	1
69.	Stadiometer	2
70.	Stethoscope	15
71.	Stopwatch	10
72.	Student Organ Bath Complete Set up [Organ Bath assembly Single/Double unit, Sherrington Rotating Drum, Aretor, Different types of lever (Simple lever, Frontal writing lever, Starling's heart lever, Universal lever), Fulcrum, Stylus, Different types of Cannula (Arterial cannula, Venus cannula, Tracheal cannula), Clamp] **(For demonstration)**	2 set
73.	Suturing Practice Kit inclusing suturing pad (i.e. Surgical scissors, Tissue forceps, Suture needles, Suture thread, suturing pads)	10 sets
74.	Tuning fork (128 Hz)	10
75.	Two-point discriminator	5
76.	Vaccine Carrier (Desirable)	2
77.	Vortex mixer	1
78.	Water bath (at least 6 holes)	2
79.	Weighing Scale (Weighing balance upto 150 kg)	2
80.	Westergren Stand and Tube	15
81.	Wintrobe Tube and Stand	15
82.	Digital urine analyzer (Desirable)	1

4.4. Pharmacognosy

Sl. No	Instrument Name	Quantity
1.	Angle of Repose Apparatus (Desirable)	1
2.	Autoclave	1
3.	BOD incubator	1
4.	Buchner Funnel with Vacuum Pump	1
5.	Burette	30
6.	Camera lucida	10
7.	Centrifuge	1
8.	Clevenger apparatus (500ml;1L)	2sets each
9.	Column for chromatography	5 different size
10.	Compound Microscope	20
11.	Culture Bottles	10
12.	Culture flask	10
13.	Culture tubes	30
14.	Cutter Mill	1
15.	Desiccator	1
16.	Digital balance	1
17.	Digital microscope (Desirable)	1
18.	Double distillation unit (Desirable)	1
19.	Eyepiece/Ocular micrometer	20
20.	Germination Chamber (Desirable)	1
21.	Heating mantle	10
22.	Homogenizer	1
23.	Hot air oven	1
24.	Hydrometer Cylinder (Desirable)	5
25.	Liebig Condenser	15
26.	Magnetic Stirrer with hot plate	5
27.	Magnifying lens	30
28.	Micropipettes (1-10 µL, 10-100 µL, 100–1000 µL)	1 set
29.	Microtome (Desirable)	1
30.	Moisture balance	1
31.	Mortar and Pestle	15
32.	Muffle furnace	1
33.	pH meter	1
34.	Power Blender (Desirable)	1
35.	Projection microscope	2
36.	Pycnometer	5
37.	Reflux apparatus (Full setup)	15
38.	Refrigerator	1
39.	Rotary vaccum evaporator (Desirable)	1
40.	Separating funnel (250ml;500ml)	5 sets each
41.	Separating funnel (250ml;500ml)	5 sets each
42.	Sieve sets (40-60 mesh)	2 sets

43.	Silica crucible	10
44.	Simple distillation unit	1
45.	Soxhlet apparatus (Full set) (500ml; 1L)	2 sets each
46.	Spirit Lamp	30
47.	Stage micrometer	15
48.	Stereo microscope	2
49.	Sterility testing unit	1
50.	Stop watch / timer	2
51.	Test tube rack (10 slot)	5
52.	Thermometer (300 Centigrade)	15
53.	TLC chamber	10
54.	TLC glass slides	30
55.	TLC spreader	5
56.	TLC Spray bottle	5
57.	Tongs	15
58.	Sonicator	1
59.	UV Chamber (254 & 366 nm) (Desirable)	1
60.	Vernier Caliper (Desirable)	5
61.	Water bath (6holes)	2
62.	Weighing bottles with lid (Desirable)	15

4.5. Central Instrumentation Laboratory

Sl. No	Instrument Name	Quantity
1.	Autoanalyzer/Semi-autoanalyzer (Desirable)	1
2.	Conductivity Meter	1
3.	Cooling Sonicator (Desirable)	1
4.	Digital balance (1 mg sensitivity)	1
5.	Digital pH meter	1
6.	Disintegration Test Apparatus	1
7.	Dissolution test Apparatus	1
8.	Fluorimeter	1
9.	Friability Test Apparatus	1
10.	FTIR (Desirable)	1
11.	Gel Electrophoresis Unit (Desirable)	1
12.	High Performance Rotational Viscometer	1
13.	HPLC	1
14.	HPTLC (Desirable)	1
15.	Lyophilizer (Desirable)	1
16.	Refractometer	1
17.	Solid Phase Extraction apparatus (Desirable)	1
18.	Texture analyzer (Desirable)	1
19.	UV spectrophotometer	1
20.	UV Transilluminator (For Gel Electrophoresis) (Desirable)	1
21.	RT- PCR (Essential before the commencement of fifth semester)	1

4.6. Machine Room

Sl. No	Instrument Name	Quantity
1.	All-purpose equipment with all accessories (*)	1
2.	Ampoule filling and sealing machine (Jet Burner) (Desirable)	1
3.	Ampoule washing machine (Desirable)	1
4.	Ball mill (*)	1
5.	Bottle Sealing Machine	1
6.	Bottle washing Machine	1
7.	Coating pan machine (*)	1
8.	Collapsible tube - Filling and Sealing	1
9.	Double cone blender (*)	1
10.	Granulator machine	1
11.	Liquid Filling Machine	1
12.	Ointment filling machine (Desirable)	1
13.	Rotary Tablet Punching Machine (min 8 Station)	1
14.	Sieve shaker	1
15.	Stability Chamber	1
16.	Tray Dryer	1
17.	Fluidize Bed Dryer (Desirable)	1
18.	Spray Dryer (Desirable)	1
19.	Rotary Flash Evaporator (Desirable)	1
20.	Twin Screw Extruder (Desirable)	1
21.	**Note (*):** Either the marked instruments or the All-purpose equipment with all accessories must be procured.	

- Desirable instruments listed may be procured by the institute or accessed through collaboration/MoU with research centers or interdisciplinary institutions.

- The requirements specified herein apply to institutions offering the B. Pharm programme under the NEP 2020 syllabus. Institutions conducting more than one programme may share the common facilities, infrastructure, laboratories, equipment's, and other resources between the programmes, provided that such sharing complies with the norms and standards prescribed by the Pharmacy Council of India (PCI) and is adequate for all programmes.



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