



#### HIGHER EDUCATION COMMISSION

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#### SUBJECT: REVISED CURRICULUM FOR DEGREE PROGRAMS IN PHARMACY

The Higher Education Commission (HEC) of Pakistan, as mandated by its law, provides guidance to Higher Education Institutions (HEIs) on curricula for tertiary education levels in alignment with the National Qualifications Framework (NQF). To address evolving academic trends and market demands, HEC has revised the curriculum standards for Pharmacy degree program at NQF levels 6. These updated standards are aligned with HEC's Undergraduate Education Policy V 1.1 (2023) ensuring coherence with national priorities and adherence to international benchmarks.

- 2. The revised curriculum for Doctor of Pharmacy (Pharm. D) program is hereby notified. All universities offering this program are required to align their Pharmacy curriculum with these updated standards / framework as the minimum benchmark for quality and compliance. In addition, the Pharmacy Council of Pakistan has undertaken an extensive in-house exercise to prepare detailed contents of the respective courses outlined in the HEC curriculum. These contents are attached at **Annex-A** as reference only for Higher Education Institutions (HEIs) offering the Pharm.D program to seek guidance if desired. An electronic version of the revised curriculum is also available on the HEC official website.
- 3. Through the effective implementation of these standards, HEC envisions a future where Pakistani graduates in Pharmacy not only achieve academic excellence but also demonstrate leadership in research, scientific discovery, and technological innovation in the field of Pharmacy.

HIDAYATULLAH KASI

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# **CURRICULUM**

# **FOR**

### **DOCTOR OF PHARMACY**

(PHARM. D)

(2025)



# HIGHER EDUCATION COMMISSION ISLAMABAD – PAKISTAN

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#### **PREFACE**

The curriculum, with varying definitions, is said to be a plan of the teaching-learning process that students of an academic program are required to undergo to achieve some specific objectives. It includes a scheme of studies, objectives & learning outcomes, course contents, teaching methodologies and assessment/ evaluation. Since knowledge in all disciplines and fields is expanding at a fast pace and new disciplines are also emerging; it is imperative that curricula be developed and revised accordingly.

Higher Education Commission, since its inception, has been involved in developing /revising the curricula on periodic basis through National Curriculum Revision Committees (NCRCs) comprising of eminent academics, researchers from HEC recognized universities/DAIs, professional councils, R&D organizations of repute and industry professionals. So far, HEC has developed and revised curricula of 150+ disciplines for undergraduate and graduate programs in various fields of Natural Sciences, Applied Sciences, Social Sciences, Art & Humanities, Engineering & Technology, Medical, Allied Health Sciences, Agriculture, Computing, Law, and Administration.

Over the period of time, labor markets in the world have substantially changed, hence, the demand for workforce skills has also altered. Due to these transformations, there is a need to produce well-rounded individuals who not only have the required knowledge base of specific discipline but also possess the required skills to increase their market readiness for them to contribute to the overall socio-economic development of the country. HEC has introduced the Undergraduate Education Policy 2023, which provides an overarching framework for undergraduate programs. This curriculum document is prepared in light of the UGE Policy 2023.

The revised Pharmacy curriculum has been designed to incorporate the latest global trends in the field, with a stronger emphasis on hands-on training in line with industry requirements. It also introduces optional specialization tracks, allowing HEIs and students to pursue areas that further broaden their career prospects. Moreover, the inclusion and encouragement of international certifications in relevant domains of Pharmacy will help enhance the global recognition and acceptance of Pakistani graduates.

I extend my sincere gratitude to the Pharmacy Council of Pakistan for their active and consistent involvement throughout this process. In particular, I am thankful to Mr. Sardar Shabbir Ahmed, Secretary, Pharmacy Council of Pakistan, and his dedicated team for their valuable contributions. This collaborative approach between HEC, the Pharmacy Council, and academia and industry will significantly elevate the standards of Pharmacy education in Pakistan, aligning it with international best practices and the evolving needs of healthcare systems worldwide.

**Dr. Amjad Hussain**Director General
Academics Division

#### **GUIDING PRINCIPLES**

#### **MINIMUM STANDARDS**

The curriculum standards and guidelines prescribed under this policy are mandatory at minimum level. Universities or the departments concerned may, however, set higher standards provided that the standards prescribed herein are not reduced or compromised.

#### COMPETENCY FRAMEWORK FOR A PHARMACIST



#### **COURSE LEARNING OUTCOMES**

Course learning outcomes (CLOs) are the bare minimum standards of learning that students must achieve upon completing a specific course. These outcomes serve as essential benchmarks, ensuring consistency in the quality of education across institutions. The CLOs prescribed herein represent the minimum level of competency and understanding expected from students. While these standards must not be compromised, departments are encouraged to enhance the rigor of the CLOs by incorporating additional learning outcomes, provided these do not alter the essence of the prescribed standards.

#### **COURSE SYLLABUS**

This document serves as a comprehensive guideline describing the course learning outcomes (CLOs) for each course offered in the Pharm D program as minimum standards. The offering department may modify, and tailor the syllabus/contents of each course, ensuring alignment with the stipulated learning outcomes. It is in this regard imperative that the department utilizes instructional, reference, and reading materials that it deems appropriate to effectively meet the CLOs.

#### REQUIREMENT OF FIELD EXPERIENCE / INTERNSHIP

It is a mandatory degree award requirement of three (03) credit hours for the Pharm. D Program. Internships of six (06) to eight (08) weeks (preferably undertaken during semester or summer break)

must be graded by a faculty member in collaboration with the supervisor in the field. This requirement cannot be substituted with additional course work, capstone or project work.

#### MANDATORY REQUIREMENT OF CERTIFICATIONS (Non- Credited)

Pharm. D students are required to complete three international certifications (non-credited, equivalent to 3 credit hours in total) over the period of five-year program as a mandatory condition for degree completion. Each certification will be considered equivalent to 1 credit hour if it comprises at least 16 hours. The respective department will guide students in selecting relevant certifications, ensuring alignment with current market needs and the program's objectives.

#### REQUIREMENT OF CAPSTONE PROJECT

It is a mandatory degree award requirement of three (03) credit hours for the Pharm. D Program. A capstone project is a multifaceted body of work that serves as culminating academic and intellectual experience for students. The capstone project must be supervised and graded by a faculty member as per the protocols prescribed by the department concerned. This requirement cannot be substituted with additional course work or internship.

#### DOCTOR OF PHARMACY (PHARM. D)

#### PROGRAM DESCRIPTION

The five year 'Doctor of Pharmacy' program provides students with a comprehensive foundation in pharmaceutical sciences and clinical practice. The curriculum is designed to build expertise in the core areas of Pharmaceutics, Pharmacology, Pharmaceutical Chemistry, Pharmacognosy and Pharmacy Practice. Additionally, courses in Basic Medical Sciences provide a strong understanding of human anatomy, physiology, and pathology, forming the basis for effective healthcare delivery.

The program integrates these foundational sciences with advanced training in Pharmacy Practice, ensuring students develop the clinical skills needed for patient-centered care. Through practical experiences such as hospital rotations, community pharmacy internships, and case-based learning, students gain real-world exposure to medication management, patient counseling, and healthcare collaboration. This blend of theoretical knowledge and hands-on practice equips graduates to excel in diverse pharmacy roles, from clinical and hospital pharmacy to research, regulatory affairs, and pharmaceutical industry positions. The program's multidisciplinary approach fosters innovation, ethical practice, and lifelong learning, preparing graduates to contribute meaningfully to the advancement of healthcare. The program emphasizes critical thinking, ethical practice, and effective communication, ensuring graduates are prepared to play a key role in improving patient outcomes.

Graduates of the Pharm. D. program are well-positioned to work in hospitals, community pharmacies, pharmaceutical industries, regulatory agencies, government departments, non-governmental organizations, various disease control programs, international health organizations, become entrepreneurs, and pursue further specialization. The curriculum is structured to not only meet national and international standards but also instill a commitment to lifelong learning, ensuring that graduates remain at the forefront of advancements in pharmacy and healthcare.

#### STANDARD NOMENCLATURE

For the sake of standardization, all the undergraduate degree programs (National Qualifications Framework - level 6 qualifications) in the discipline of Pharmacy shall be offered with the title of **Doctor of Pharmacy** abbreviated as **Pharm. D** and henceforth, degree programs at equivalent level with same purpose and scope having different nomenclatures shall accordingly be renamed.

#### PROGRAM LEARNING OUTCOMES

By the completion of Doctor of Pharmacy degree program, the graduates will be able to:

- Apply knowledge, attitudes, and skills to contribute effectively to pharmaceutical manufacturing, quality control and product development.
- Integrate principles of pharmaceutical sciences and product development to optimize drug therapy and human health outcomes.
- Apply the in-vogue Pharmacotherapy protocols for rational use of medication for optimum delivery of health care systems.
- Design and evaluate personalized medication plan for specialized and critically ill patients for safe and efficient practice of medicine and Pharmacy.
- Demonstrate innovation, competence, and entrepreneurial skills to advance the pharmaceutical industry, academia, and related professional practices.
- Utilize expertise to develop sustainable technopreneurial projects addressing national and global healthcare needs.
- Demonstrate commitment to lifelong learning and continuous professional growth to stay updated with evidence-based pharmacy practices.
- Exhibit effective communication, teamwork, and leadership skills in different practicing sectors of healthcare system including community and hospital, Industry and at academia levels.

#### ELIGIBILITY AND ADMISSION CRITERIA

Higher Secondary School Certificate (involving 12 years of schooling) or an IBCC equivalent qualification in **Pre-Medical Group** with at least **60% cumulative score** is the basic eligibility requirement for admission in the Doctor of Pharmacy (Pharm. D) program. The admitting university may or may not conduct entry / admission test through its own testing body or an external testing services provider of repute as per the screening, admission and merit calculation criteria approved by its statutory bodies.

#### PROGRAM STRUCTURE – DOCTOR OF PHARMACY

The Doctor of Pharmacy program is structured in accordance with the provisions of the HEC Undergraduate Education Policy V 1.1., comprises of minimum 195 credit hours and spread over ten (10) regular semesters.

AWARD OF PHARM D DECREE		195 (if specialization is not opted)	
		210 (if specialization is opted)	
		s optional and may be chosen at the discretion of the	
students and/or the	HEIs; it is not a mandatory requ	irement.	
GENERAL EI	DUCATION COURSES	34 credit hours (14 courses as prescribed by	
		HEC)	
MAJOR	Core Courses	141 credit hours (38 courses)	
(141 CREDITS)	i. Pharmacology		
	ii. Pharmacy Practice		

M	1
iii. Pharmaceutics	
iv. Pharmacognosy	
v. Pharmaceutical	
Chemistry	
INTERDISCIPLINARY / ALLIED	14 credit hours (4 courses)
COURSES	
FIELD EXPERIENCE (PHARMACY	3 credit hours (Clinical Pharmacy Clerkship)
PRACTICE EXPERIENCE)	
CAPSTONE PROJECT	3 credit hours
PROGRAM DURATION	Minimum: 5 Years
	Maximum: 7 Years
	(Further extendable to another year subject to
	approval of university's statutory body)
SEMESTER DURATION	16-18 weeks for regular semesters
	(1-2 weeks for examination)
	8-9 weeks for summer semesters
	(1 week for examination)
COURSE LOAD (PER SEMESTER)	15-21 credit hours for regular semesters
	Up-to 8 credit hours for summer semesters
	(for remedial/deficiency/failure/repetition
	courses only)
3 CREDIT HOURS (THEORY)	3 classes (1 hour each) OR 2 classes (1.5 hour
	each) OR 1 class (3 hours) per week throughout
	the semester
1 CREDIT HOUR (LAB / FIELD	1 credit hour in laboratory or practical work
WORK)	would require lab / field contact of 3 hours per
	week throughout the semester.

Standard Scheme of Study for the program of Doctor of Pharmacy program is given as under:

#### **SEMESTER I**

S. NO	COURSE	CREDIT	CATEGORY
		HOURS	
1	Physical Pharmacy - I	3+1	Major: Core
2	Organic Chemistry - I	3+1	Major: Core
3	Biochemistry - I	2+1	Major: Core
4	Physiology-I	3+1	Allied/Interdisciplinary
5	Functional English *	3	General Education
TOTAL CREDITS (18)			

#### **SEMESTER II**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Physical Pharmacy - II	3+1	Major: Core	
2	Organic Chemistry - II	3+1	Major: Core	
3	Biochemistry - II	2+1	Major: Core	
4	Anatomy & Histology	2+1	Allied/Interdisciplinary	
5	Physiology-II	3+1	Allied/Interdisciplinary	
6	Islamic Studies*	2	General Education	
	TOTAL CREDITS (20)			

#### **SEMESTER III**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Drug Delivery Systems and Formulation	3+1	Major: Core	
	Science - I			
2	Pharmacology and Therapeutics-I	3+1	Major: Core	
3	Pharmacognosy - (Basic I)	3+1	Major: Core	
4	Pathology	2+1	Allied/Interdisciplinary	
5	Basic Pharmaceutical Microbiology**	2+1	General Education	
			(Natural Sciences)	
	TOTAL CREDITS (18)			

#### **SEMESTER IV**

S. NO	COURSE	CREDIT	CATEGORY		
		HOURS			
1	Drug Delivery Systems and Formulation	3+1	Major: Core		
	Science - II				
2	Applied Pharmaceutical Microbiology and	3+1	Major: Core		
	Immunology				
3	Artificial Intelligence in Pharmacology and	3+1	Major: Core		
	Therapeutics				
	(Pharmacology and Therapeutics-II)				
4	Pharmacognosy (Basic - II)	3+1	Major: Core		
5	Pakistan Studies *	2	General Education		
6	Fehm-e-Quran I*	1	General Education		
	TOTAL CREDITS (19)				

#### **SEMESTER V**

S. NO	COURSE	CREDIT	CATEGORY		
		HOURS			
1	Pharmacognosy (Applied)	3+1	Major: Core		
2	Pharmaceutical Analysis-I	3+1	Major: Core		
3	Pharmacology and Therapeutics-III	3+1	Major: Core		
4	Hospital and Community Pharmacy	2	Major: Core		
5	Quantitative Reasoning – I *	3	General Education		
6	Ideology & Constitution of Pakistan *	2	General Education		
7	Fehm-e-Quran II*	1	General Education		
	TOTAL CREDITS (20)				

#### **SEMESTER VI**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Pharmacognosy (Advanced)	3+1	Major: Core	
2	Dispensing, Social & Administrative	2	Major: Core	
	Pharmacy			
3	Pharmaceutical Analysis-II	3+1	Major: Core	
4	Pharmacology and Therapeutics-IV	3+1	Major: Core	
5	Applications of ICT (Especial focus	2+1	General Education	
	on Pharmacy)*			
6	Quantitative Reasoning-II*	3	General Education (Contents of	
			Biostatics added)	
	TOTAL CREDITS (20)			

#### **SEMESTER VII**

S. NO	COURSE	CREDIT	CATEGORY
		HOURS	
1	Industrial Pharmacy - I	3+1	Major: Core
2	Biopharmaceutics and Pharmacokinetics - I	3+1	Major: Core
3	Clinical Pharmacy-I	3+1	Major: Core
4	Pharmaceutical Quality Management System	3	Major: Core
5	Expository Writing *	3	General Education
6	Entrepreneurship *	2	General Education
TOTAL CREDITS (20)			

#### **SEMESTER VIII**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Industrial Pharmacy - II	3+1	Major: Core	
2	Biopharmaceutics and Pharmacokinetics - II	3+1	Major: Core	
3	Clinical Pharmacy-II	3+1	Major: Core	
4	Civics & Community Engagement*	1+1	General Education	
	(Fulfill requirement of Pharmacy Practice-III)			
5	Pharmaceutical Quality Control	2+1	Major: Core	
6	Pharmaceutical Management and Marketing**	2	General Education	
			(Social Sciences)	
	TOTAL CREDITS (19)			

#### **SEMESTER IX**

S. NO	COURSE	CREDIT	CATEGORY
		HOURS	
1	Pharmaceutical Technology - I	3+1	Major: Core
2	Pharmaceutical Regulatory Science-I	3	Major: Core
3	Medicinal Chemistry-I	3+1	Major: Core
4	Advanced Clinical Pharmacy-I	3+1	Major: Core
5	Clinical Pharmacology	2+1	Major: Core
TOTAL CREDITS (18)			

#### **SEMESTER X**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Pharmaceutical Technology - II	3+1	Major: Core	
2	Pharmaceutical Regulatory Science-II	3	Major: Core	
3	Medicinal Chemistry-II	3+1	Major: Core	
4	Advanced Clinical Pharmacy-II	3+1	Major: Core	
5	Bioethics (Arts & Humanities Category) **	2	General Education	
6	Capstone Project ***	3	Capstone Project	
	TOTAL CREDITS (20)			

- \* HEC designed model courses may be used by the university.
- \*\* The courses recommended by NCRC under the categories of Natural Science, Social Science and Arts & Humanities.
- \*\*\* Capstone project can be supervised by faculty members of any core discipline of Pharmacy

#### **DEGREE AWARD REQUIREMENTS**

The following minimum requirements are prescribed for the award of Doctor of Pharmacy:

- a) All courses in the General Education category as prescribed in HEC Undergraduate Education Policy V 1.1. including the courses of "Pakistan Studies and Fehm-e-Quran" must be completed.
- b) Minimum of 195 credit hours are required for the award of Pharm-D degree, in case no specializations is opted by student.
- c) Minimum of 210 credit hours are required for the award of Pharm-D degree with specialization in particular domain as mentioned in the document.
- d) Capstone / research project of three (03) credit hours must be completed in accordance with HEC Undergraduate Education Policy V 1.1.
- e) Internship/Field experience of three (03) credit hours must be completed in accordance with HEC Undergraduate Education Policy V 1.1. This requirement cannot be substituted with additional coursework, capstone, research or project work.
- f) CGPA must not be below 2.00/4.00 at the time of completion of the degree program. The university may, however, set a higher standard in this regard.
- g) A student who is declared fail in practical shall have to re-appear in practical only, while a student who is declared fail in theory shall have to re-appear in theory only. The weightage distribution of theory and practical for the calculation of CGPA in all courses shall be as per distribution of the marks.
- h) Universities can allocate course codes to courses as per their own policies approved by the statutory bodies.
- i) External evaluation shall be mandatory for all practical courses of every exam. All Universities / Institutes imparting Pharm. D program shall allot equal weightage to external and internal evaluation. Further, the teacher concerned shall be an internal evaluator/examiner and no other internal evaluator/examiner shall be appointed from whatsoever university affiliating any institute imparting pharmacy education.
- j) Universities should use various appropriate teaching, learning, and assessment methods to effectively deliver curricula and evaluate student understanding.

# OPTIONAL SPECIALIZATION CLUSTER SCHEME FOR DOCTOR OF PHARMACY (PHARM-D) PROGRAM – 15 CREDITS (ELECTIVES TO BE CHOSEN FROM ANY CLUSTER)

HEIs are encouraged to offer students multiple specialization options in Pharm-D program aligned with market and industry needs through subject clusters. Each student will select one subject cluster (specialization track) from the available options. Within each track, a pool of elective courses will be provided. After choosing a specialization track, the student must complete minimum 5–6 courses (15 credits) from the respective cluster to fulfill the requirements of that specialization.

HEIs may introduce additional clusters or courses based on faculty expertise, available resources, and evolving market demands. The chosen specialization will be indicated on the student's transcript or degree, in parentheses, subject to approval by the university's statutory bodies.

All pharmacy degrees, regardless of specialization, are considered equivalent for employment where a Pharm-D is required. However, graduates with specific specializations may apply for roles within their niche areas as demanded by employers.

- 1. Pharmacology
- 2. Pharmacy Practice
- 3. Pharmaceutics
- 4. Pharmacognosy
- 5. Pharmaceutical Chemistry / Medicinal Chemistry
- 6. Pharmaceutical Analysis / Quality Control
- 7. Industrial Pharmacy
- 8. Hospital and Community Pharmacy
- 9. Regulatory Affairs
- 10. Clinical Research in Pharmacy
- 11. Pharmaceutical Marketing
- 12. Pharmaceutical Management

#### Note:

- 1. HEIs shall adjust the additional courses of specialization track in the scheme and get it approved from statutory bodies of the concerned university.
- 2. At least One relevant Certification Course comprising of 3 credits in each specialization cluster shall be offered. (1 credit hour equivalent to 16 contact hours in duration)
- 3. In case no specialization track is opted by students, the Pharm-D degree shall be awarded with no specialization mentioned on transcript or degree.
- 4. If a student opts for a degree with specialization (i.e., 210 credits), the non-credited certifications equivalent to 3 credit hours, as outlined in the section titled *Mandatory Requirement of Certifications (Non-Credited)*, will not be required.

#### PHARMACEUTICAL CHEMISTRY

#### **Organic Chemistry**

#### **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Understand organic chemistry concepts such as bonding, hybridization, and reactivity, with a focus on pharmaceuticals.
- 2. Synthesize and characterize organic compounds for drug development, emphasizing nomenclature and reaction mechanisms.
- 3. Analyze organic reactions like oxidation, reduction, and substitution, focusing on pharmaceutical applications.
- 4. Apply green chemistry and synthesis methods to develop pharmaceutical compounds, emphasizing sustainability.
- 5. Describe the preparation, properties, and pharmaceutical relevance of key heterocyclic compounds and fused ring systems.
- 6. Explain mechanisms involving reactive intermediates and named organic reactions with applications in drug synthesis.
- 7. Apply advanced organic synthesis methods including green chemistry and microwave-assisted synthesis in pharmaceutical compound development.
- 8. Demonstrate laboratory proficiency in synthesizing pharmaceutically important compounds using classical and green organic methods.

#### **Biochemistry**

#### **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Understand Pharmaceutical Biochemistry concepts and its role in pharmacy, including its medical and pharmaceutical applications.
- 2. Explain biochemical processes of carbohydrates, lipids, proteins, and nucleic acids, focusing on metabolism, disorders, and pharmaceutical relevance.
- 3. Analyze the role of enzymes, hormones, vitamins, and secondary messengers in metabolic regulation and their pharmaceutical applications.
- 4. Demonstrate proficiency in biochemical lab techniques, including analysis of biological samples and clinical chemistry tests with pharmaceutical focus.
- 5. Explain advanced biochemical roles of proteins, amino acids, and enzymes, including their metabolism, disorders, and pharmaceutical significance.
- 6. **Analyze** the structure, function, and therapeutic relevance of nucleic acids in gene therapy, drug delivery, and diagnostic applications.
- 7. Interpret the clinical significance of biochemical markers (e.g., bilirubin, creatinine, uric acid) in diagnosing liver and kidney disorders prevalent in Pakistan.
- 8. Demonstrate accurate use of biochemical lab methods (e.g., Biuret, Jaffe, LFT/KFT) for quantitative analysis of biomolecules in biological samples.

#### **Pharmaceutical Analysis**

#### **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Demonstrate proficiency in applying chemical and instrumental methods of analysis for pharmaceutical compounds.
- 2. Interpret experimental results from different analytical techniques.
- 3. Develop practical skills in performing pharmaceutical assays, determining compound concentrations, and evaluating purity.

- 4. Understand the significance of each analytical technique in pharmaceutical quality control and regulatory compliance.
- 5. Explain the principles and pharmaceutical applications of spectroscopic and chromatographic techniques including UV, IR, NMR, MS, AAS, HPLC, and GC.
- 6. Interpret spectra and chromatograms to assess identity, purity, and concentration of pharmaceutical substances.
- 7. Apply instrumental methods to develop, optimize, and validate analytical procedures in line with pharmacopeial and regulatory standards.
- 8. Demonstrate laboratory proficiency in operating instruments and performing assays, spectral analysis, and chromatographic separations for pharmaceutical compounds

#### **Pharmaceutical Quality Control**

#### **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Understand the concept and basis of quality of pharmaceuticals and related chemical substances.
- 2. Describe the role of regulatory agencies for the quality of pharmaceuticals and herbal products.
- 3. Understand the method development protocols and validation process as per regulatory requirements.
- 4. Describe the latest concept of quality being practiced in the pharmaceutical industry.

#### **Medicinal Chemistry**

#### **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Explain key concepts of drug discovery and design, including SAR, QSAR, and Lipinski's Rule of Five.
- 2. Apply physicochemical principles to improve drug properties like solubility, lipophilicity, and bioavailability.
- 3. Analyze the structure, SAR, and therapeutic relevance of major drug classes used in CNS, cardiovascular, endocrine, infectious, and parasitic diseases prevalent in Pakistan.
- 4. Explain the chemical structures, SAR, and therapeutic roles of cardiovascular, antidiabetic, diuretic, and antimicrobial agents relevant to diseases prevalent in Pakistan.
- 5. Analyze structure–activity relationships (SAR) of drug classes including antituberculars, antimalarials, antivirals, and immunomodulators.
- 6. Apply principles of medicinal chemistry to identify, synthesize, and characterize key pharmaceutical compounds using modern synthetic and analytical techniques.
- 7. Evaluate therapeutic potential and mechanism of action of drug molecules using medicinal chemistry concepts to support rational drug design and discovery.
- 8. Perform basic synthesis and identification of pharmaceutical compounds using medicinal chemistry lab techniques.

#### PHARMACY PRACTICE

#### **Expository Writing**

#### **Course Learning Outcomes**

By the end of the course, students will be able to:

- 1. Understand the essentials of the writing process by integrating pre-writing, drafting, editing, and proofreading to produce well-structured essays relevant to pharmacy.
- 2. Demonstrate proficiency in diverse expository writing forms to address varied academic and professional purposes across pharmacy disciplines.
- 3. Uphold ethical practices and apply critical thinking to develop original, well-substantiated written work aligned with scientific and regulatory standards.

#### **ENTREPRENEURSHIP**

#### **Course Learning Outcomes:**

At the end of the course the student shall be in a position to:

- 1. Understand entrepreneurship fundamentals in the pharmaceutical industry.
- 2. To utilize the foundational knowledge and skills in entrepreneurship, emphasizing leadership, effective communication, ethical considerations, and essential awareness within the pharmaceutical sector.
- 3. Communicate effectively in professional and business settings.
- 4. Explore entrepreneurial opportunities in Pakistan's pharmaceutical landscape.

#### Dispensing, Hospital, Community, and Social & Administrative Pharmacy

#### **Course Learning Outcomes:**

At the end of the course the student will be able to:

- 1. Analyze the structure of pharmacy services within the Pakistani healthcare system, understand the roles of pharmacists in various settings and public health, and apply the minimum standards for hospital and community pharmacy practice.
- 2. Evaluate medication management and use processes, identify potential risks, propose mitigation strategies based on the best international practices and regulatory requirements, and understand the role of technology in enhancing medication safety.
- 3. Apply regulatory requirements to pharmacy operations, develop strategies for formulary management, implement inventory control systems, understand pharmacoeconomic principles, and describe the function of a Pharmacy and Therapeutics Committee.
- 4. Describe the processes for the selection and procurement of therapeutic goods, manage the pharmaceutical supply chain effectively, implement proper medication storage practices for various drug types, and evaluate medication orders for appropriateness to ensure patient safety, utilizing evidence-based practices and clinical decision support systems.

#### **Clinical Pharmacy**

#### **Course Learning Outcomes:**

At the end of the course, students shall be able to:

- 1. Explain the fundamentals of clinical pharmacy and describe the roles of clinical pharmacists in patient care and public health.
- 2. Interpret and apply information from medication history and patient profiles to optimize medication therapy.

- 3. Identify and manage adverse drug reactions, drug interactions, medication errors, and therapeutic drug levels using standard tools and guidelines.
- 4. Demonstrate a basic understanding of clinical trials and evaluate clinical literature to promote evidence-based pharmacy practice.
- 5. Develop, implement, and monitor patient-centered drug therapy plans using standardized frameworks, care processes, effective documentation, and evidence-based decision-making.
- 6. Apply medication management and optimization strategies, including Medication Therapy Management (MTM), Drug Utilization Review (DUR), and antimicrobial stewardship, to promote rational pharmacotherapy.
- 7. Provide pharmaceutical care across diverse settings using current practices, advanced digital tools, and telepharmacy while maintaining ethical, legal, and professional standards.
- 8. Improve medication adherence and therapeutic outcomes through appropriate assessment, effective communication, and individualized patient education strategies.

#### Civics and Community Engagement

#### **Course Learning Outcomes**

By the end of this course, students will be able to:

- 1. Describe the principles of civic responsibility and their relevance to the professional practice of pharmacy.
- 2. Analyze the role of pharmacists in promoting public health, advancing community welfare, and ensuring equitable access to medications and healthcare services.
- 3. Demonstrate knowledge of the healthcare governance structure in Pakistan and how pharmacists contribute to health policy and regulation.
- 4. Evaluate pharmacist-led strategies for community engagement, health education, and social responsibility.
- 5. Apply ethical and inclusive practices in pharmacy services to support civic values such as equity, access, and social justice.
- 6. Utilize digital platforms responsibly for community health awareness, advocacy, and professional communication.
- 7. Serving the community's wellbeing: Students will dedicate 100 hours throughout the degree program to community service in pharmacy related assignments, contributing to the welfare and health of the community. Students have to submit a report regarding this assignment to the class teacher.

#### Pharmaceutical Management and Marketing

#### **Course Learning Outcomes**

At the completion of this course students will be able to:

- 1. Apply Foundational Marketing Principles within the Ethical and Regulatory Framework of the Pharmaceutical Industry in Pakistan and Develop Patient-Centric Marketing Strategies.
- 2. Evaluate Pharmaceutical Product Lifecycle Management and Develop Effective Branding and Market Access Strategies Relevant to Pakistan and Implement Strategic Marketing Plans for Pharmaceutical Products within the Pakistani Healthcare System.
- 3. Synthesize core digital marketing principles with the unique legal, ethical, and regulatory landscape of the pharmaceutical industry to develop and implement comprehensive online marketing strategies for both prescription and over-the-counter products, considering AI tools for optimization and adhering to relevant regulations in Pakistan and internationally.

- 4. Develop and manage efficient and compliant e-commerce operations for pharmaceutical products, including secure online dispensing, order fulfillment, and customer relationship management, while strategically managing the pharmaceutical supply chain to ensure product integrity, regulatory compliance, and timely delivery to online customers.
- 5. Apply relevant management theories and financial management principles to formulate strategic business development plans for pharmaceutical e-commerce ventures, encompassing effective HR management for specialized teams, sound financial planning for online operations, and strategic decision-making for sustainable growth and profitability in the digital pharmaceutical market.

#### **Pharmaceutical Regulatory Sciences**

#### **Course Learning Outcomes**

After the completion of this course students will be in a position to:

- 1. Analyze the foundational principles and the significance of pharmaceutical regulations, with a comprehensive understanding of key global and national regulatory bodies.
- 2. Explain the basis of regulatory functions and the operational processes across the product life cycle for Therapeutic goods.
- 3. Describe the basic documentation required for regulatory submission and assessment
- 4. Describe various platforms of regulatory interactions and the major contributions in shaping regulatory approaches and collaborations.
- 5. Analyze and propose solutions to regulatory challenges in pharmacovigilance, ensuring drug safety and patient well-being.
- 6. Evaluate and apply ethical principles and guidelines in various aspects of pharmaceutical regulation, including drug development, manufacturing, and marketing.
- 7. Understand the Drug Regulatory Authority of Pakistan (DRAP) and its governing legislation (DRAP Act 2012). This outcome emphasizes understanding the 'why' and 'who' of pharmaceutical regulation, focusing on DRAP's structure and legal basis.

#### **Advanced Clinical Pharmacy**

#### **Course Learning Outcomes**

At the completion of this course students will be able to

- 1. Identify individual patient needs and apply this understanding to develop and optimize pharmacotherapy plans that align with those needs. This includes considering patient-specific factors and ensuring the pharmacotherapy regimen is tailored for maximum benefit.
- 2. Integrate knowledge of disease pathophysiology and etiology with current evidence-based practices to formulate effective pharmacotherapy and comprehensive pharmaceutical care plans. This encompasses making informed clinical decisions grounded in scientific literature and best practice guidelines.
- 3. Perform thorough medication reconciliation to ensure medication safety and identify patient-specific risk factors that may impede optimal treatment outcomes. This includes the ability to analyze medication histories and recognize potential barriers to successful therapy.
- 4. Effectively educate and counsel patients on various aspects of their disease management and medications. This includes communicating complex information in an understandable manner, addressing patient concerns, and empowering patients to actively participate in their care.
- 5. Identify systemically individual patient needs and apply this understanding to develop and

optimize pharmacotherapy plans that align with those needs. This includes considering patient-specific factors and ensuring the pharmacotherapy regimen is tailored for maximum benefit.

#### **PHARMACEUTICS**

#### **Physical Pharmacy**

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Describe the historical evolution of pharmacy through ancient Greek, Arab, and Muslim contributions and the significance of official compendia and texts.
- 2. Understand basic physico-chemical principles relevant to drug delivery systems and formulations.
- 3. Apply the physico-chemical principles in drug kinetics and drug stability.

#### **Drug Delivery Systems and Formulation Science**

#### **Course Learning Outcomes:**

After completion of this course the students will be able to:

- 1. Explain the need for dosage forms with respect to routes of administration.
- 2. Develop different conventional dosage forms and drug delivery systems.
- 3. Explain the need for dosage forms with respect to routes of administration.
- 4. Develop different conventional dosage forms and drug delivery systems.

#### Pharmaceutical Microbiology

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Identify, classify, and signify the importance of microbes in ecosystems.
- 2. Describe the general characteristics and functional anatomy of microorganisms and their relevance in pharmaceutical applications.
- 3. Explore the use of microbes in industrial processes and product development.
- 4. Understand the human immune system and its theranostic application.
- 5. Explain the applications of biotechnology and antimicrobial aspects in the pharmaceutical industry.

#### **Industrial Pharmacy**

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Describe various industrial operational techniques and applications in pharmaceutical manufacturing.
- 2. Understand the large-scale production equipment and their utilization.
- 3. Develop a pharmaceutical industry layout design with all its components.
- 4. Understand the role of manufacturing equipment design and developing new technologies in pharmaceutical engineering.

#### Biopharmaceutics and Pharmacokinetics

#### **Course Learning Outcomes:**

After completion of this course the students will be able to:

- 1. Demonstrate the inter-relationship of the physico-chemical properties of the drug, the dosage forms and the route of administration.
- 2. Understand principles of bioavailability, bioequivalence and data analysis.
- 3. Analyze the pharmacokinetic behavior of drug administered different routes and pathological condition.
- 4. Understand pharmacokinetic modelling and its applications.

#### Pharmaceutical Quality Management Systems

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Identify components of quality management systems in the manufacturing of therapeutic goods.
- 2. Document the industrial compliance protocols.
- 3. Practice quality assurance and its applications in the manufacturing of therapeutic goods

#### Pharmaceutical Technology

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explore the recent advancements in pharmaceutical technologies.
- 2. Describe and demonstrate the emerging concepts and techniques in the development of novel drug delivery systems.
- 3. Explain the development of biological, biotechnological, and biosimilar products.
- 4. Describe and demonstrate the emerging concepts and techniques in the development of novel drug delivery systems.

#### **PHARMACOGNOSY**

#### Pharmacognosy-I (Basic)

#### **Course Learning Outcomes:**

After completing this course, students will be able to:

- 1. Explain pharmacognosy's historical development, scope, and modern concepts, including its role in the national economy and herbal pharmacopoeias.
- 2. Demonstrate an understanding of traditional and alternative systems of medicine, such as Unani, Ayurveda, Homeopathy, and Traditional Chinese Medicine.
- 3. Identify, classify, and describe the sources, constituents, and uses of plant, animal, mineral, and microbial origin crude drugs.
- 4. Evaluate crude drugs using organoleptic and microscopic methods, also recognize types of adulteration in crude drugs.
- 5. Describe the chemistry, extraction methods, sources, and pharmacological uses of crude drugs containing active constituents.

- 6. Understand marine natural products, highlighting their bioactive compounds and potential medicinal applications.
- 7. Reinforce theoretical knowledge through hands-on experience in extracting and identifying active constituents from crude plant materials through practical sessions.

#### Pharmacognosy-II (Applied)

#### **Course Learning Outcomes:**

After completing this course, students will be able to:

- 1. Understand and apply chromatographic techniques, including paper, thin layer, and column chromatography, for the identification and isolation of natural products, with basic knowledge of advanced hyphenated techniques.
- 2. Learn conventional and modern extraction techniques used for isolating plant-based compounds.
- 3. Apply molecular pharmacognosy techniques such as DNA barcoding, molecular markers, tissue culture, and genetic regulation of plant metabolites.
- 4. Understand the clinical relevance, efficacy, and safety of selected herbal drugs used in common ailments
- 5. Learn of chromatography and plant authentication by DNA barcoding through practical work.
- 6. Explain clinical efficacy, mechanisms of action, dosage, and safety profiles of herbal drugs used in treating various ailments, including infectious, renal, cardiac, respiratory, CNS, and reproductive disorders.
- 7. Understand industrial applications of pharmacognosy by explaining the formulation, production technologies, and regulatory frameworks involved in the development and commercialization of herbal medicinal products.
- 8. Apply standard analytical and regulatory methodologies for the evaluation, quality control, and standardization of raw materials and finished herbal formulations by official standards.
- 9. Understand the role, formulation, and health benefits of nutraceuticals and natural cosmetics, with their active constituents and excipients.
- 10. Equip with skills in physicochemical evaluation and quantitative analysis of phytoconstituents in herbal materials and formulations through practical sessions.

#### PHARMACOLOGY & BASIC MEDICAL SCIENCES

#### Physiology

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain the structure and function of cell components, how molecules move across membranes, and key processes like fluid balance, the cell cycle, and apoptosis in maintaining cellular stability.
- 2. Describe how the nervous system controls body functions, including how neurons work, how action potentials and synapse function, the role of neurotransmitters and sensory receptors, and the structure and function of the central and autonomic nervous systems.
- 3. Explain the structure and types of skeletal muscles, how they contract, and the role of the neuromuscular junction in muscle activity.

- 4. Describe the structure and function of the heart, including the cardiac cycle, blood flow, heart sounds, and electrical conduction, and interpret ECG patterns and their clinical relevance.
- 5. Outline the process of digestion and absorption, including digestive secretions, how they are regulated, and the steps from eating to defecation.
- 6. Explain the structure, formation, and functions of blood components, describe the process of blood clotting and blood typing, and relate these to common disorders like anemia and leukopenia.
- 7. Describe the structure and function of the circulatory and lymphatic systems, including blood vessels, and explain how blood pressure is regulated.
- 8. Explain how the respiratory system works, including gas exchange, breathing control, and the different lung volumes and capacities.
- 9. Describe kidney function and urine formation, and explain how the body maintains fluid, electrolyte, and acid-base balance.
- 10. Explain the physiology of the male and female reproductive systems, including gamete formation, the menstrual cycle, and stages such as puberty, pregnancy, and menopause.

#### **Pathology**

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Define and differentiate core pathological terms (e.g., ischemia, necrosis, neoplasia) and explain the mechanisms of inflammation, cellular injury, adaptation, and repair.
- 2. Describe the pathogenesis, morphological changes, and clinical implications of common diseases affecting major organ systems (cardiovascular, nervous, gastrointestinal, endocrine/metabolic).
- 3. Compare benign and malignant tumors, interpret the hallmarks of cancer, and apply the TNM classification system.
- 4. Correlate pathological changes with disease manifestations in key conditions (e.g., myocardial infarction, diabetes, peptic ulcers, neurodegenerative disorders).

#### Anatomy & Histology

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Identify and describe the anatomy of the thoracic region, including the skeletal, respiratory, and cardiovascular structures
- 2. Understand and explain the positions, structures, and functions of the major abdominal organs and related systems.
- 3. Demonstrate knowledge of the structures and functions of the urinary system, limbs, and nervous system, including the spinal cord, brain, cranial nerves, eye, and ear.
- 4. Explain histological techniques and their pharmacological relevance in the context of tissue analysis and drug interactions.

#### Pharmacology & Therapeutics-I

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze fundamental principles of General Pharmacology, including pharmacokinetic and pharmacodynamic parameters, and apply this understanding to evaluate individual drug pharmacology.
- 2. Classify molecular drug targets including receptor types, secondary messengers, and signaling pathways, and demonstrate their therapeutic implications through specific drug examples.
- 3. Evaluate pharmacological mechanisms of autonomic nervous system drugs and justify their clinical applications in professional healthcare scenarios.
- 4. Demonstrate comprehensive knowledge of gastrointestinal drug pharmacology and implement this understanding in appropriate clinical decision-making contexts.
- 5. Explore the emerging field of pharmacomicrobiomics and its potential impact on personalized therapeutics, focusing on how gut microbiota can influence drug metabolism and therapeutic outcomes.
- 6. Analyze pharmacogenomic principles and their clinical applications, evaluate ethical implications, and interpret the FDA Table of Pharmacogenetic Associations in therapeutic decision-making.
- 7. Evaluate cardiovascular drug mechanisms, co-relate international treatment guidelines (ACC/AHA/ESH), and implement evidence-based pharmacological interventions in clinical practice.
- 8. Demonstrate endocrine drug pharmacology, integrate AACE diabetes management algorithms, and design appropriate therapeutic regimens for endocrine disorders.
- 9. Explain respiratory drug actions and utilize this knowledge to optimize treatment strategies for pulmonary conditions in clinical settings.

#### Pharmacology & Therapeutics-II

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze the pharmacology of antimicrobial and anticancer agents, interpret WHO and DRAP treatment guidelines, and apply this knowledge to optimize therapeutic regimens in clinical practice.
- 2. Evaluate the mechanisms of anti-inflammatory and anti-rheumatic drugs, implement ACR guidelines for gout and rheumatoid arthritis management, and design evidence-based treatment plans.
- 3. Demonstrate knowledge of monoclonal antibodies and immunomodulators and utilize these therapies according to current clinical protocols in autoimmune and neoplastic disorders.
- 4. Analyze the pharmacology of CNS-acting drugs, interpret clinical guidelines from the European Federation of Neurological Societies, British Association of Pharmacology, and American Psychiatric Association (APA), and apply this knowledge to optimize neuropharmacological therapy in clinical practice.
- 5. Evaluate toxicological principles, select appropriate antidotes for drug poisoning and envenomation cases, and demonstrate expertise in chelation therapy pharmacology.
- 6. Implement artificial intelligence applications in pharmacological research, including machine learning for drug discovery and AI-driven pharmacological data analysis, to enhance therapeutic decision-making.

#### Clinical Pharmacology

#### **Course Learning Outcomes**

At the end of this course the student will be able to:

- 1. Explain how pregnancy alters the pharmacokinetics and pharmacodynamics of drugs, and evaluate the risks of teratogenicity when selecting drug therapies.
- 2. Describe the pharmacokinetic and pharmacodynamic differences in infants and children, and apply this knowledge to ensure rational and safe pediatric drug use.
- 3. Analyze the considerations for drug use during lactation, including the potential for drug transfer through breast milk and its effects on infants.
- 4. Discuss age-related changes in drug absorption, distribution, metabolism, and excretion, and adjust drug therapy appropriately in geriatric patients.
- 5. Evaluate how co-morbid conditions such as hepatic impairment, renal dysfunction, and diabetes affect drug response, and modify treatment regimens accordingly.
- 6. Min 10 Practical in Clinical Pharmacology are required.
  - i. **Pregnancy:** UTI, Nausea/Vomiting, Hypertension/Eclampsia, Gestational Diabetes
  - ii. Lactation: Antibiotics, Antidepressants
  - iii. Pediatrics: Febrile Seizures, Asthma, Otitis Media
  - iv. **Geriatrics:** Polypharmacy, Fall Risk
  - v. **Dose Calculation:** Renal, Liver, Pediatric, Geriatric
  - vi. **Comorbidities:** NSAIDs in CKD, Diabetic Foot Infection

#### PHARMACY PRACTICE EXPERIENCE (CLINICAL CLERKSHIP)

Students can start PPE in third year. The PPE shall be graded by faculty members in fifth year.

#### Preface:

The clinical pharmacy field experience is an integral part of the Pharm. D program which is meant to offer an opportunity for the students to have hands-on practice of what they learn in the classroom. The students under the supervision of various departments and preceptors will integrate their knowledge of physical assessment, pharmacology, pharmaceutics, communication skills, pharmacokinetics, pharmacodynamics, and management guidelines of various diseases in assessing therapeutic plans and evaluating the selected drugs for patients. PPE can be performed in Community Pharmacy, Pharmaceutical Industry, Regulatory and Sales & Marketing including Hospital & clinical settings.

#### Overall Training learning outcomes

By the end of this PPE student should be able to:

#### 1.1. Participate as an inter-professional team member:

Interact appropriately with other members of the healthcare team. The student must demonstrate the ability to deliver patient-centered care as a member of an Inter- Professional team, emphasizing evidence-based practice, quality improvement approaches, and informatics. The student must also be able to assess how well the group functions as a team.

In case of Hospital & clinical settings internship following components may be performed.

#### 1.2. Perform Patient Assessments

The student must demonstrate the ability to collect patient data (e.g., a medication history, the medical chart, and/or laboratory data) and assess a patient's health status. The goal of

performing this patient assessment is to prevent, identify, and solve medication-related problems.

#### 1.3. Conduct Drug Therapy Reviews

The student must demonstrate the ability to successfully review a medication profile or medication administration record and identify medication-related problems.

#### 1.4. Demonstrate Written/Verbal Communication

The student must demonstrate the ability to communicate a variety of pharmacotherapy topics and issues. Furthermore, the student must demonstrate the ability to perform this competency both verbally and in writing. Students are also expected to demonstrate the ability to verbally present pharmacotherapy content/topics and discuss the topic with the audience.

#### 1.5. Perform Pharmacokinetic Monitoring

The student must demonstrate the ability to apply pharmacokinetic concepts in establishing a therapeutic regimen when a patient is receiving a drug that has a narrow therapeutic range. Specifically, the student must demonstrate the ability to design a dosage regimen based on population pharmacokinetic parameters and when serum drug levels are available, assess whether the current regimen is providing the desired effect.

#### 1.6. Use Systems Management to Improve Therapeutic Outcomes

The student must demonstrate the ability to manage a medication distribution system and informatics so that therapeutic outcomes are optimized. For example, the student must demonstrate the ability to resolve potential and actual medication errors and develop strategies for preventing future occurrences.

Learning outcomes for PPE in domains of learning, assessment methods and teaching strategy

	Learning Domains	Teaching	Assessment
	and Learning Outcomes	Strategies	Methods
1.0	Knowledge		
1.1	Describe the symptomatology, physical findings, pathophysiology, diagnostic procedures, laboratory tests, concentrated electrolytes, therapeutic duplication primary and alternative pharmacotherapies, and non-pharmacological treatments for all the encountered infectious diseases	Clinical Rounds	Case presentations/OSCE Case Discussions, Journal Clubs Assignments
2.0	Cognitive Skills		
2.1	Perform and practice: Clinical skills including collecting and recording patient-specific data, measuring and documenting patient outcomes, problem-solving, medication monitoring, dosing, therapeutic recommendations,	Clinical Rounds	Case presentations/OSCE Case Discussions, Journal Clubs Assignments

2.2	medication reconciliation, patient education and discharge counseling, medication error reporting, and responding to drug information queries with effective communication skills (verbal & written).  Gather and relate to the patient's clinical and diagnostic data, pathophysiology, differential diagnosis, pharmacokinetic monitoring, pharmacologic, therapeutic,	Clinical Rounds	Case presentations, Case discussions, Journal clubs Assignments
2.0	pharmacoeconomics, and surgical interventions employed in those patients with cardiac disease.		
3.0	Interpersonal Skills & Responsibility		
3.1	Demonstrate the ability to interact with patients or patient care givers in a manner consistent with the patient's age, level of understanding, physical disabilities, or other barriers common to the critical care environment.	Clinical Rounds	Case presentations/OSCE
4.0	Communication, Information Technology, N	umerical	
4.1	Communicate to both patients and healthcare Prescribers	Clinical Rounds	Case presentations Oral exam/OSCE
	Interview patients and take medication history	Clinical Rounds	Case presentations
4.2	Effectively communicate therapeutic interventions to other members of the health-care team.	Clinical Rounds	Oral exam/OSCE
4.3	Assess patient medications and provide medication reconciliation for diabetic, asthmatic and hypertensive Patients	Clinical Rounds	Case presentations/OSCE
5.0	Psychomotor		
5.1	Medication appropriateness review.	Clinical Rounds	Oral viva exam/OSCE Case presentations
5.2	Identify and prevent all clinically significant drug Interactions	Clinical Rounds	Oral viva exam/OSCE Case presentations
5.4	Participate in ambulatory clinics. Provide drug information and pharmaceutical services to medical Clinic staff and patients.	Clinical Rounds	Oral Viva Exam/OSCE Case Presentations
5.5.	Develop Pharmaceutical care plans	Clinical Rounds	Oral Viva Exam/OSCE Case Presentations
5.6	Antimicrobial Stewardship and oncology stewardship, Narcotic stewardship	Clinical Rounds	Oral Viva Exam/OSCE Case Presentations

5.7	Drug utilization review	Clinical Rounds	Oral Viva
	_		Exam/OSCE Case
			Presentations
5.8	Assessment and management of adverse drug	Clinical Rounds	Oral Viva
	reactions (ADRs)		Exam/OSCE Case
			Presentations
5.9	Medicine Reconciliation	Clinical Rounds	Oral Viva
			Exam/OSCE Case
			Presentations

#### CAPSTONE PROJECT FOR ALL 5 DISCIPLINES

Main Discipline: Pharmaceutics, Pharmacy Practice, Pharmacology, Pharmaceutical

Chemistry, Pharmacognosy

#### **Course Learning Outcomes**

At the completion of this course students will be able to:

- 1. Integrate their foundational knowledge in pharmaceutical sciences (pharmacology, pharmaceutics, medicinal chemistry, pharmacognosy, etc.) with practical skills to identify, analyze, and propose evidence-based solutions to contemporary challenges in pharmacy practice, pharmaceutical care, or the pharmaceutical industry within the Pakistani healthcare context.
- Critically evaluate scientific literature, conduct independent research (qualitative or quantitative, as appropriate), analyze data using relevant methodologies, and synthesize findings to draw informed conclusions and formulate well-supported recommendations related to their chosen project topic.
- 3. Communicate complex pharmaceutical information clearly, concisely, and professionally through various mediums, including written reports, oral presentations, and potentially visual aids, tailored to diverse audiences such as healthcare professionals, patients (in simulated scenarios), and academic peers, demonstrating effective communication skills essential for future pharmacy practice in Pakistan.
- 4. Demonstrate professionalism, adhere to ethical principles relevant to pharmacy practice and research, and exhibit an understanding of the broader healthcare system in Pakistan, including regulatory frameworks, patient safety considerations, and the pharmacist's role in multidisciplinary healthcare teams. This includes considering the socio-economic and cultural factors influencing healthcare delivery in the local context.

#### Doctor of Pharmacy (Pharm. D) Capstone Project: Contents and Assessment Method

#### 1. Project Objectives

The **Capstone Project** serves as the culminating academic experience for Doctor of Pharmacy students, designed to synthesize and apply the knowledge and skills acquired throughout the program. The project should demonstrate clinical, research, or practice-based expertise while addressing a relevant healthcare or pharmacy-related issue. Students are expected to employ evidence-based decision-making to enhance patient care, public health initiatives, or pharmacy practice.

#### 2. Project Components

#### A. Proposal Development

The first phase of the Capstone Project involves the development of a formal proposal. Students must select a topic that is pertinent to pharmacy practice, such as clinical research, medication therapy management, public health interventions, or pharmacoeconomic analyses. A comprehensive literature review should be conducted to critically appraise existing evidence and justify the project's significance. The proposal must outline clear, measurable objectives and hypotheses, along with a detailed methodology that includes study design, data collection strategies, and analysis plans where applicable. Ethical considerations must also be addressed, including Institutional Review Board (IRB) approval if the project involves human subjects.

#### B. Project Execution

During the execution phase, students will carry out their proposed work. For research-based projects, this includes data collection and analysis. Practice-based projects may involve implementing interventions, conducting patient case studies, or developing new protocols or policies within a healthcare setting. The execution phase should reflect rigorous methodology, adherence to ethical guidelines, and the application of pharmacy knowledge to real-world scenarios.

#### C. Final Deliverables

Upon completion of the project, students must submit a **written report** structured similarly to a thesis or research manuscript. The report should include an abstract, introduction and background, methods, results (if applicable), discussion of findings, conclusions, and references. Additionally, students will deliver an **oral presentation and defense**, lasting approximately 15-20 minutes, followed by a question-and-answer session with faculty and peers. Some programs may also require a **poster presentation** to showcase the project's outcomes.

#### 3. Assessment Methods

#### A. Evaluation Criteria

The Capstone Project is assessed based on several key components, each contributing to the final grade. The **proposal quality** accounts for 20% of the evaluation, with emphasis on clarity, feasibility, relevance, and literature support. The **research or practice work** constitutes 30% of the assessment, evaluating the rigor of methodology, data accuracy (where applicable), and ethical compliance. The **written report** represents 25% of the grade, judged on organization, depth of analysis, writing quality, and adherence to formatting guidelines. Finally, the **presentation and defense** make up the remaining 25%, assessing communication skills, the ability to justify conclusions, and overall professionalism.

#### B. Grading Rubric

A detailed grading rubric is used to evaluate student performance across multiple categories. Projects demonstrating **originality and impact** with high relevance and innovative approaches receive the highest marks, while those lacking significance are graded lower. The **methodology** is assessed based on design rigor, with well-structured projects earning top scores and poorly designed ones receiving lower grades. **Analysis and discussion** sections are evaluated for critical thinking and evidence-based reasoning, with superficial analyses scoring lower. **Presentation skills** are judged on engagement, clarity, and professionalism during the oral defense.

#### C. Final Grade Determination

The final grade is determined by the overall quality of the project. A **Pass with Distinction (A)** is awarded for outstanding work that excels in all areas. A **Pass (B or C)** is granted to projects that meet

expectations but may have minor deficiencies. A failing grade (**D** or **F**) is assigned to projects with significant gaps in quality, incomplete components, or failure to meet core objectives.

#### 4. Timeline & Milestones

The Capstone Project follows a structured timeline to ensure timely completion. During the **first two months**, students submit their proposals for approval. If the project involves human subjects, IRB approval should be secured by the **third month**. Data collection or intervention implementation occurs between the **fourth and sixth months**, followed by a draft submission in the **seventh month**. The final report and presentation are due by the **eighth or ninth month**, allowing sufficient time for revisions and preparation.

#### 5. Faculty Supervision & Feedback

Throughout the project, students receive guidance from a faculty advisor, with scheduled bi-weekly or monthly meetings to monitor progress. Peer review sessions may be incorporated to provide additional constructive feedback. The final assessment is conducted by a committee of two to three faculty members, ensuring a comprehensive and unbiased evaluation.

# **COURSE CONTENTS**

# **DOCTOR OF PHARMACY**

(PHARM. D)

(2025)



Pharmacy Council of Pakistan

#### **CONTRIBUTIONS (PHARMACY COUNCIL OF PAKISTAN)**

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- 41. Mr. Omar Akhlaq Bhutta, Director & Head of Pharmacy Services, Shaukat Khanum Memorial Hospital
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# **SCHEME OF STUDIES**

# **SEMESTER I**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Physical Pharmacy - I	3+1	Major: Core	
2	Organic Chemistry - I	3+1	Major: Core	
3	Biochemistry - I	2+1	Major: Core	
4	Physiology-I	3+1	Allied/Interdisciplinary	
5	Functional English *	3	General Education	
TOTAL CREDITS (18)				

# **SEMESTER II**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Physical Pharmacy - II	3+1	Major: Core	
2	Organic Chemistry - II	3+1	Major: Core	
3	Biochemistry - II	2+1	Major: Core	
4	Anatomy & Histology	2+1	Allied/Interdisciplinary	
5	Physiology-II	3+1	Allied/Interdisciplinary	
6	Islamic Studies*	2	General Education	
TOTAL CREDITS (20)				

# **SEMESTER III**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Drug Delivery Systems and Formulation	3+1	Major: Core	
	Science - I			
2	Pharmacology and Therapeutics-I	3+1	Major: Core	
3	Pharmacognosy - (Basic I)	3+1	Major: Core	
4	Pathology	2+1	Allied/Interdisciplinary	
5	Basic Pharmaceutical Microbiology**	2+1	General Education	
			(Natural Sciences)	
TOTAL CREDITS (18)				

# **SEMESTER IV**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Drug Delivery Systems and Formulation	3+1	Major: Core	
	Science - II			
2	Applied Pharmaceutical Microbiology and	3+1	Major: Core	
	Immunology			
3	Artificial Intelligence in Pharmacology and	3+1	Major: Core	
	Therapeutics			
	(Pharmacology and Therapeutics-II)			
4	Pharmacognosy (Basic - II)	3+1	Major: Core	
5	Pakistan Studies *	2	General Education	
6	Fehm-e-Quran I*	1	General Education	
TOTAL CREDITS (19)				

# SEMESTER V

S. NO	COURSE	CREDIT	CATEGORY		
		HOURS			
1	Pharmacognosy (Applied)	3+1	Major: Core		
2	Pharmaceutical Analysis-I	3+1	Major: Core		
3	Pharmacology and Therapeutics-III	3+1	Major: Core		
4	Hospital and Community Pharmacy	2	Major: Core		
5	Quantitative Reasoning – I *	3	General Education		
6	Ideology & Constitution of Pakistan *	2	General Education		
7	Fehm-e-Quran II*	1	General Education		
	TOTAL CREDITS (20)				

# **SEMESTER VI**

S. NO	COURSE	CREDIT	CATEGORY		
		HOURS			
1	Pharmacognosy (Advanced)	3+1	Major: Core		
2	Dispensing, Social & Administrative	2	Major: Core		
	Pharmacy				
3	Pharmaceutical Analysis-II	3+1	Major: Core		
4	Pharmacology and Therapeutics-IV	3+1	Major: Core		
5	Applications of ICT (Especial focus	2+1	General Education		
	on Pharmacy)*				
6	Quantitative Reasoning-II*	3	General Education (Contents of		
	_		Biostatics added)		
	TOTAL CREDITS (20)				

# **SEMESTER VII**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Industrial Pharmacy - I	3+1	Major: Core	
2	Biopharmaceutics and Pharmacokinetics - I	3+1	Major: Core	
3	Clinical Pharmacy-I	3+1	Major: Core	
4	Pharmaceutical Quality Management System	3	Major: Core	
5	Expository Writing *	3	General Education	
6	Entrepreneurship *	2	General Education	
TOTAL CREDITS (20)				

# **SEMESTER VIII**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Industrial Pharmacy - II	3+1	Major: Core	
2	Biopharmaceutics and Pharmacokinetics - II	3+1	Major: Core	
3	Clinical Pharmacy-II	3+1	Major: Core	
4	Civics & Community Engagement*	1+1	General Education	
	(Fulfill requirement of Pharmacy Practice-III)			
5	Pharmaceutical Quality Control	2+1	Major: Core	
6	Pharmaceutical Management and Marketing**	2	General Education	
			(Social Sciences)	
TOTAL CREDITS (19)				

# **SEMESTER IX**

S. NO	COURSE	CREDIT	CATEGORY
		HOURS	
1	Pharmaceutical Technology - I	3+1	Major: Core
2	Pharmaceutical Regulatory Science-I	3	Major: Core
3	Medicinal Chemistry-I	3+1	Major: Core
4	Advanced Clinical Pharmacy-I	3+1	Major: Core
5	Clinical Pharmacology	2+1	Major: Core
TOTAL CREDITS (18)			

# **SEMESTER X**

S. NO	COURSE	CREDIT	CATEGORY	
		HOURS		
1	Pharmaceutical Technology - II	3+1	Major: Core	
2	Pharmaceutical Regulatory Science-II	3	Major: Core	
3	Medicinal Chemistry-II	3+1	Major: Core	
4	Advanced Clinical Pharmacy-II	3+1	Major: Core	
5	Bioethics (Arts & Humanities Category) **	2	General Education	
6	Capstone Project ***	3	Capstone Project	
	TOTAL CREDITS (20)			

<sup>\*</sup> HEC designed model courses may be used by the university.

<sup>\*\*</sup> The courses recommended by NCRC under the categories of Natural Science, Social Science and Arts & Humanities.

# \*\*\*

# **DEGREE AWARD REQUIREMENTS**

The following minimum requirements are prescribed for the award of Doctor of Pharmacy:

- a) All courses in the General Education category as prescribed in HEC Undergraduate Education Policy V 1.1. including the courses of "Pakistan Studies and Fehm-e-Quran" must be completed.
- b) Minimum of 195 credit hours are required for the award of Pharm-D degree, in case no specializations is opted by student.
- c) Minimum of 210 credit hours are required for the award of Pharm-D degree with specialization in particular domain as mentioned in the document.
- d) Capstone / research project of three (03) credit hours must be completed in accordance with HEC Undergraduate Education Policy V 1.1.
- e) Internship/Field experience of three (03) credit hours must be completed in accordance with HEC Undergraduate Education Policy V 1.1. This requirement cannot be substituted with additional coursework, capstone, research or project work.
- f) CGPA must not be below 2.00/4.00 at the time of completion of the degree program. The university may, however, set a higher standard in this regard.
- g) A student who is declared fail in practical shall have to re-appear in practical only, while a student who is declared fail in theory shall have to re-appear in theory only. The weightage distribution of theory and practical for the calculation of CGPA in all courses shall be as per distribution of the marks.
- h) Universities can allocate course codes to courses as per their own policies approved by the statutory bodies.
- i) External evaluation shall be mandatory for all practical courses of every exam. All Universities / Institutes imparting Pharm. D program shall allot equal weightage to external and internal evaluation. Further, the teacher concerned shall be an internal evaluator/examiner and no other internal evaluator/examiner shall be appointed from whatsoever university affiliating any institute imparting pharmacy education.
- j) Universities should use various appropriate teaching, learning, and assessment methods to effectively deliver curricula and evaluate student understanding.

#### PHARMACEUTICAL CHEMISTRY:

# Pharmaceutical Chemistry IA (Organic Chemistry I)

# **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Understand organic chemistry concepts such as bonding, hybridization, and reactivity, with a focus on pharmaceuticals.
- 2. Synthesize and characterize organic compounds for drug development, emphasizing nomenclature and reaction mechanisms.
- 3. Analyze organic reactions like oxidation, reduction, and substitution, focusing on pharmaceutical applications.
- 4. Apply green chemistry and synthesis methods to develop pharmaceutical compounds, emphasizing sustainability.

#### **Contents**

The following topics will be taught with special reference to their Pharmaceutical Applications.

- 1. **Basic concepts:** Chemical Bonding and concept of Hybridization, Conjugation, Resonance, Hyperconjugation, Aromaticity, Electronegativity, Dipole Moment, Inductive effect, Mesomeric Effect, Electrometric effect, Hydrogen bonding, Steric effect, and Tautomerism (keto-enol in tetracyclines and lactam-lactim).
- 2. Synthesis, structure, nomenclature, properties, and pharmaceutical applications of functional organic compounds in drugs synthesis: Alkane, Alkenes, Alkynes, Alcohol, phenols, ethers, amines, Ketones, Aldehydes, Carboxylic Acids, Esters, Amides, Alkyl halide, and Aromatic compounds.
- 3. Types of reactions in aliphatic and aromatic systems and their applications: Organic Reactions Mechanism: Oxidation, Reduction, Acylation, Esterification, and Nucleophilic Substitution reactions (SN1, SN2). Elimination Reactions, Addition Reactions, Rearrangement, and Polymerization Reactions.
- 4. **Stereochemistry and Conformational Analysis:** Stereoisomerism, Optical Isomerism; Molecules with more than one chiral center, Geometrical Isomerism, (cis/trans, E/Z system), Optical Isomerism including chirality and dextro/levo, R/S system. Resolution of racemic mixture, Conformational analysis (emphasizing Perspective formula and Fischer projection) and Applications in pharmacy.

#### **Recommended Readings**

- 1. Lemke, T. L., & Williams, D. A. (2013). Foye's principles of medicinal chemistry (7th ed.). Lippincott Williams & Wilkins.
- 2. Johnson, W. S. (2003). Organic chemistry in the laboratory. W. H. Freeman and Company.
- 3. Abraham, D. J. (2017). Burger's medicinal chemistry and drug discovery (8th ed.). Wiley.
- 4. Brown, W. H., & Bursten, M. L. (2014). Introduction to organic chemistry (8th ed.). Wiley.
- 5. Vollhardt, K. P. C., & Schore, N. E. (2014). Organic chemistry: Structure and function (7th ed.). W. H. Freeman and Company.

- 6. Thomas, G. (2013). Medicinal chemistry: A molecular and biochemical approach. Oxford University Press.
- 7. Carey, F. A. (2007). Advanced organic chemistry: Part A: Structure and mechanisms (5th ed.). Wiley.
- 8. Prasad, N. D. V. G. S., & Shinde, S. C. (2009). *Pharmaceutical organic chemistry*. Pharma Book Syndicate.
- 9. Silverman, R. B. (2014). The organic chemistry of drug design and drug action (2nd ed.). Academic Press.

# **Practical**

- 1. Good laboratory practice for organic chemistry lab (Protocol for Chemical Handling of flammable, non-flammable, and acids) and introduction to organic chemistry lab apparatus and instruments.
- 2. Identify the functional group present in given organic compound by systemic analysis. (carboxylic acids, phenol, aldehydes, ketones, amines, hydrazine, amide, thioamide, ester, nitro group, alcohol etc.).
- 3. To identify compounds by synthesizing of its derivatives (such as ester, amides and salts of COOH; acetate, benzoate of alcohol; benzoate, 2,4-dinitrophenyl ether of phenol etc.
- 4. Determination of melting point and boiling points of different organic compounds (Picric acid, oxalic acid, salicylic acid, citric acid, tartaric acid, succinic acid).
- 5. Purification of various organic compounds by crystallization (e.g. Benzoic acid).
- **6.** Identification of various organic compounds (E.g. Oxalic acid, Salicylic acid, Phthalic acid, Benzoic acid, Cresol, Resorcinol.

# Pharmaceutical Chemistry IB (Organic Chemistry-II)

(DNA/RNA), benzoxazole, benzothiazole.

#### **Course Learning Outcomes**

- 1. Describe the preparation, properties, and pharmaceutical relevance of key heterocyclic compounds and fused ring systems.
- 2. Explain mechanisms involving reactive intermediates and named organic reactions with applications in drug synthesis.
- **3.** Apply advanced organic synthesis methods including green chemistry and microwave-assisted synthesis in pharmaceutical compound development.
- **4.** Demonstrate laboratory proficiency in synthesizing pharmaceutically important compounds using classical and green organic methods.

- Heterocyclic Chemistry: Preparation and properties of medicinally important Heterocyclic Compounds such as pyrrole, furan, thiophene, pyridine, pyrimidine and pyrazine.
   Preparation and properties of heterocyclic compounds in which benzo-ring is fused with five and six membered rings containing one hetero atom; Indole, Quinoline and Isoquinoline. Additional Rings and Pharmaceuticals: imidazole (histamine, antifungals), purine/pyrimidine bases
- 2. **Reaction Mechanisms and Reactive Intermediates:** An Overview of Reactive Intermediates: Carbocations, Carbanions, Carbenes, Nitrenes, Benzynes and Free Radicals and Free radical scavengers and their applications. Mechanism and applications of various reactions: Arndt-Eistert

reaction, Baeyer-Villiger oxidation, Diels Alder reaction; Grignard's reaction, Metal Hydride reduction and Wolff Kishner reduction, Friedel Craft's reaction, Perkin reaction, Cannizzaro's reaction, Mannich reaction, Pinacol-Pinacolone, Wagner-Meerwein, Wolff, Hofmann and Beckmann rearrangements, Condensation reaction (Aldol condensation, Favorskii rearrangement, Wittig rearrangement). Pericyclic and Photochemical Reactions.

3. **Advanced Organic Chemistry:** Brief introduction of Organic synthesis, Total Synthesis, Semi Synthesis Biocatalyst, Green Chemistry, Microwave assisted Synthesis

#### **Practical**

- 1. Synthesize salicylic acid from phenol using the Riemer-Tiemann reaction, involving the formation of the phenoxide ion, carboxylation, and hydrolysis.
- 2. Synthesize salicylic acid from phenol using Kolbe's electrolysis, a simple and recent method in organic compound synthesis, especially for drugs.
- 3. Synthesize Nifedipine using the classical Hantzsch method, involving condensation and reduction reactions.
- 4. Synthesize paracetamol (acetaminophen) through nucleophilic and elimination reactions.
- 5. Development of Green Methodology for Surfactant-Assisted Williamson Synthesis of 4-Benzyloxy Benzoic Acid (Ether) in Aqueous Media.
- 6. Synthesis of Sulfathiazole using a safer and convenient sulfonylation method.
- 7. Synthesis of Dibenzalacetone using crossed aldol (or mixed-aldol) reaction which used extensively in organic synthesis to form C-C bonds.
- 8. Synthesis of Methyl salicylate by condensation reaction.
- 9. Synthesis of iodoform
- 10. Synthesis of Aspirin (Acetylsalicylic Acid) via SN Nucleophilic Acyl Substitution.
- 11. Synthesis of Acetanilide via nucleophilic Acyl Substitution reaction.
- 12. Synthesis of 2,4,6-Tribromophenol via electrophilic aromatic Substitution
- 13. Synthesis of Acetone from Isopropyl Alcohol via Elimination (E1) reaction.
- 14. Synthesis of Butyl Acetate (Fruit Fragrance) via Nucleophilic Acyl Substitution
- 15. Synthesis of 1-Bromo-3-Chloropropane via SN2 Nucleophilic Substitution

#### **Recommended Readings**

- 1. Lemke, T. L., & Williams, D. A. (2013). Foye's principles of medicinal chemistry (7th ed.). Lippincott Williams & Wilkins.
- 2. Johnson, W. S. (2003). Organic chemistry in the laboratory. W. H. Freeman and Company.
- 3. Abraham, D. J. (2017). Burger's medicinal chemistry and drug discovery (8th ed.). Wiley.
- 4. Brown, W. H., & Bursten, M. L. (2014). Introduction to organic chemistry (8th ed.). Wiley.
- 5. Vollhardt, K. P. C., & Schore, N. E. (2014). Organic chemistry: Structure and function (7th ed.). W. H. Freeman and Company.
- 6. Thomas, G. (2013). Medicinal chemistry: A molecular and biochemical approach. Oxford University Press.
- 7. Carey, F. A. (2007). Advanced organic chemistry: Part A: Structure and mechanisms (5th ed.). Wiley.
- 8. Prasad, N. D. V. G. S., & Shinde, S. C. (2009). *Pharmaceutical organic chemistry*. Pharma Book Syndicate.

9. Silverman, R. B. (2014). The organic chemistry of drug design and drug action (2nd ed.). Academic Press.

# Pharmaceutical Chemistry IIA (Biochemistry-I)

# **Course Learning Outcomes**

- 1. Understand Pharmaceutical Biochemistry concepts and its role in pharmacy, including its medical and pharmaceutical applications.
- 2. Explain biochemical processes of carbohydrates, lipids, proteins, and nucleic acids, focusing on metabolism, disorders, and pharmaceutical relevance.
- 3. Analyze the role of enzymes, hormones, vitamins, and secondary messengers in metabolic regulation and their pharmaceutical applications.
- 4. Demonstrate proficiency in biochemical lab techniques, including analysis of biological samples and clinical chemistry tests with pharmaceutical focus.

#### **Contents:**

- **1. General introduction to Pharmaceutical Biochemistry:** Role of Pharmaceutical Biochemistry in the Pharmacy Profession.
- 2. Biochemistry of Carbohydrates: Define carbohydrates, classification, isomerism, optical activity, structural representation of sugar molecules, chemical properties of carbohydrates, pharmaceutical importance. Carbohydrate digestion, absorption, metabolism and excretion, glycolysis dysregulations, feeder pathways of glycolysis, pentose phosphate pathway dysregulations, glucuronate pathway, glycogenolysis, glycogenesis, gluconeogenesis, citric acid cycle and dysregulation, energetics of various metabolic processes of carbohydrates. Brief overview of carbohydrate metabolic disorders.
- **3. Bioenergetics**: Principles of bioenergetics, Electron transport chain and oxidative phosphorylation and disorders, reactive oxygen species generation and scavenging.
- 4. Biochemistry of Lipids: Define lipids, classifications (based on reactivity of lipids and based on complexity of structure), essential fatty acids, omega-3 fatty acids, eicosanoids, reactions of fatty acids and lipids, pharmaceutical importance. Lipids digestion, absorption, metabolism and excretion, oxidation of saturated and unsaturated, odd and even number fatty acids and dysregulation, Biosynthesis of fatty acids and dysregulation, cholesterol synthesis and its dysregulation, biosynthesis of neutral lipids, ketone bodies, energetics of various metabolic processes of lipids. Brief overview of lipid metabolic disorders.
- **5. Biochemistry of Vitamins**: Vitamins, classification, structures, metabolic functions, physiological role, natural and synthetic sources, deficiencies and toxicities, pharmacological interactions of vitamins with drugs, pharmaceutical importance of vitamins.
- **6. Biochemistry of Hormones**: Hormones, chemical classification, pharmaceutical importance of hormones.

#### **Practical**

Qualitative and Quantitative analysis of Carbohydrates (monosaccharides, disaccharides, reducing sugars) by following methods: *Molisch's test*, Benedict's test, Fehling's test, Salivanoff's test, Barfoed

test, Iodine test, Osazone test, Bial Orcinol test, Anthrone Test) and lipids and Sterols (Cholesterol), Bile salts, Billirubin, Analysis of Cholesterol and Creatinine in Blood.

# **Recommended Readings**

- 1. Berg, J. M., Tymoczko, J. L., & Gatto, G. J. (2019). *Stryer's biochemistry* (8th ed.). W. H. Freeman and Company.
- 2. Akash, M. S. H., & Rehman, K. (2025). Biochemical aspects of metabolic disorders. Elsevier Academic Press.
- 3. Nelson, D. L., & Cox, M. M. (2017). Lehninger principles of biochemistry (7th ed.). W. H. Freeman and Company.
- 4. Devlin, T. M. (2016). Textbook of biochemistry with clinical correlations (8th ed.). Wiley-Liss.
- 5. Gout, A. M. (2019). Biochemistry for the pharmaceutical sciences (4th ed.). Wiley.
- 6. Berg, J. M., & Stryer, L. (2020). Biochemistry (9th ed.). W. H. Freeman and Company.
- 7. Hodges, R. S. (2019). Biochemistry: A short course (3rd ed.). Wiley.
- 8. Tortora, G. J., & Derrickson, B. H. (2020). Principles of anatomy and physiology (15th ed.). Wiley.
- 9. Alberts, B., Johnson, A., Lewis, J., Raff, M., Roberts, K., & Walter, P. (2015). *Molecular biology of the cell* (6th ed.). Garland Science.
- 10. Lippincott Williams & Wilkins. (2020). Lippincott's illustrated reviews: Biochemistry. Lippincott Williams & Wilkins.
- 11. Rodwell, V. W., Bender, D. A., Botham, K. M., Kennelly, P. J., & Weil, P. A. (2017). *Harper's illustrated biochemistry* (31st ed.). McGraw-Hill Education.

### Pharmaceutical Chemistry IIB (Biochemistry-II)

# Course Learning Outcomes (CLOs)

- 1. Explain advanced biochemical roles of proteins, amino acids, and enzymes, including their metabolism, disorders, and pharmaceutical significance.
- 2. Analyze the structure, function, and therapeutic relevance of nucleic acids in gene therapy, drug delivery, and diagnostic applications.
- 3. Interpret the clinical significance of biochemical markers (e.g., bilirubin, creatinine, uric acid) in diagnosing liver and kidney disorders prevalent in Pakistan.
- 4. Demonstrate accurate use of biochemical lab methods (e.g., Biuret, Jaffe, LFT/KFT) for quantitative analysis of biomolecules in biological samples.

#### **Contents**

1. Biochemistry Proteins and Amino acids: Proteins and Amino acids: Define proteins and amino acids, classifications of proteins and amino acids, essential amino acids, peptide bonds, organizational levels, amphoteric properties, pharmaceutical importance of proteins and amino acids. Proteins and amino acids digestion, absorption, metabolism and excretion, biosynthesis and degradation of amino acids and its disorders, protein metabolism disorders, urea cycle and its disorders, biosynthesis and degradation of heme. Brief overview of protein and amino acid metabolic disorders.

- 2. **Biochemistry of Nucleic Acids**: Nucleic acid, purine and pyrimidine bases, nucleic acid uses in gene therapy, drug delivery, diagnostics, vaccines, targeted therapies, antisense therapy, bioanalysis, nanotechnology pharmaceutical importance.
- 3. **Biochemistry of Enzymes**: Enzymes, classification, inhibition, activation, specificity, allosteric enzymes, factors affecting rate of enzyme-catalyzed reaction, drug-enzyme interactions, pharmaceutical importance of enzymes, Coenzymes and their role in the regulation of metabolic processes.
- 4. **Biochemistry of Secondary Messengers**: Role of cAMP, Calcium ions and phosphoinositol in the regulation of metabolic processes.
- 7. Introduction to clinical biochemistry: Introduction and importance of clinical biochemistry. laboratory tests in diagnosis of diseases including uric acid, cholesterol, bilirubin and creatinine.

#### **Practical**

Amino acids, Peptides and Proteins using Biuret and Ninhydrin method. Analysis of normal and abnormal components of Urine-Sugar, Uric acid, Billirubin, Cholesterol and Creatinine. Estimation of Blood Glucose Level, Quantitative Analysis of Total Plasma Proteins by Biuret's Method, Construction of a Standard Curve, Estimation of Blood Urea Nitrogen, Estimation of Serum Bilirubin Level, Estimation of Serum Calcium Level, Estimation of Serum Uric Acid Level. Estimation of Serum Creatinine Level by Jaffe's Method, Heller's Test, Lead Sulfide Test, Nitroprusside Test. Liver Function Test. Kidney Function Test.

#### **Recommended Readings**

- 1. Berg, J. M., Tymoczko, J. L., & Gatto, G. J. (2019). *Stryer's biochemistry* (8th ed.). W. H. Freeman and Company.
- 2. Akash, M. S. H., & Rehman, K. (2025). Biochemical aspects of metabolic disorders. Elsevier Academic Press.
- 3. Nelson, D. L., & Cox, M. M. (2017). Lehninger principles of biochemistry (7th ed.). W. H. Freeman and Company.
- 4. Devlin, T. M. (2016). Textbook of biochemistry with clinical correlations (8th ed.). Wiley-Liss.
- 5. Gout, A. M. (2019). Biochemistry for the pharmaceutical sciences (4th ed.). Wiley.
- 6. Berg, J. M., & Stryer, L. (2020). Biochemistry (9th ed.). W. H. Freeman and Company.
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- 8. Tortora, G. J., & Derrickson, B. H. (2020). Principles of anatomy and physiology (15th ed.). Wiley.
- 9. Alberts, B., Johnson, A., Lewis, J., Raff, M., Roberts, K., & Walter, P. (2015). *Molecular biology of the cell* (6th ed.). Garland Science.
- 10. Lippincott Williams & Wilkins. (2020). *Lippincott's illustrated reviews: Biochemistry*. Lippincott Williams & Wilkins.
- 11. Rodwell, V. W., Bender, D. A., Botham, K. M., Kennelly, P. J., & Weil, P. A. (2017). *Harper's illustrated biochemistry* (31st ed.). McGraw-Hill Education.

# Pharmaceutical Chemistry IIIA: Pharmaceutical Analysis I

# **Course Learning Outcomes**

After completion of this course the students will be able to:

- 1. Demonstrate proficiency in applying chemical and instrumental methods of analysis for pharmaceutical compounds.
- 2. Interpret experimental results from different analytical techniques.
- 3. Develop practical skills in performing pharmaceutical assays, determining compound concentrations, and evaluating purity.
- 4. Understand the significance of each analytical technique in pharmaceutical quality control and regulatory compliance.

#### Contents

# 1. Introduction to Pharmaceutical Analysis.

Definition, types, principle, objectives, errors and scope of pharmaceutical analysis.

# 2. Titrimetric Methods:

Theory, principle, working and applications of the following titrimetric method of analysis.

- 2.1. Acid Base Titration
- 2.2. Redox Titration
- 2.3. Non-aqueous Titration
- 2.4. Complexometric Titration

#### 3. Electrochemical Methods:

Theory, principle, working and applications of the following electro chemical methods of analysis.

- 3.1. Conductometry
- 3.2. Potentiometry
- 3.3. Polarography
- 3.4. Fluorimetry
- 3.5. Karl Fischer

#### 4. Thermal and Gravimetric Methods:

Theory, principle, working and applications of the following thermal and gravimetric method of analysis.

- 4.1. Thermo gravimetric analysis (TGA)
- 4.2. Differential Scanning Calorimetry (DSC)
- 4.3. Differentials Thermal Analysis (DTA)

#### **Practical**

To perform at least ten (10) practical's; one(1) from each method / technique

- 1. Acid-Base titration of a chemical substance used in Pharmaceuticals.
- 2. Non-Aqueous titration of different Pharmaceutical compounds.
- 3. Complexometric titration of metal ion.
- 4. Redox titration of different Pharmaceutical compounds.
- 5. Potentiometric determination of assay of H<sub>2</sub>SO<sub>4</sub>.
- 6. Potentiometric determination of pH & concentration of a solution.

- 7. Potentiometric titration of strong a acid and strong base.
- 8. Conductometric determination of different water samples for their quality assessment.
- 9. Conductometric determination of the solubility of sparingly soluble salt.
- 10. Conductometric determination of ionization constant of a weak Acid.
- 11. Conductometric titration of acids and bases.
- 12. Polarimetric determination of sugars, amino acid and other raw materials.
- 13. Polarographic determination of amount of nitrobenzene in solutions.
- 14. Determination of the concentration of API's in solutions.
- **15.** Fluorimetric determination of a standard drug in a given sample.
- **16.** Determination of water content is pharmaceutical raw material / excipient using Karl Fischer method.

- 1. Skoog, D. A., West, D. M., Holler, F. J., & Crouch, S. R. (2014). Fundamentals of Analytical Chemistry (9th ed.). Cengage Learning.
- 2. Golden W. Evings, (1985). Instrumental methods of chemical analysis (5<sup>th</sup> edition) Mc Graw Hill, London.
- 3. David G. Watson (2007). Pharmaceutical analysis, a text book for pharmacy students and pharmaceutical chemistry (2<sup>nd</sup> edition) Elsevier Churchill Livingston, UK.
- 4. Mendham J. Denney R.C, Barnes J.D, Thomas M and Sivasankar B (2011) vogels text book of quantitative chemical analysis (6<sup>th</sup> edition). Dorling Kindersley India.
- 5. Satinder Ahuja and Stephen Skypinski (2005). Hand book of modern pharmaceutical analysis academic press, California.
- 6. Akash, M. S. H., & Rehman, K. (2025). Essentials of pharmaceutical analysis. 2nd Edition. Springer Nature.
- 7. The International Pharmacopoeia (3<sup>rd</sup> edition) WHO. AITBS publisher, Kishan Nova Delhi.
- 8. United States Parmacopeia (2020). United States Parmacopeia and National Formulary (USP 43-NF 38). Rockville, MD: USP.British Parmacopeia Commission (2022). British Parmacopeia London: Stationary Office.

# Pharmaceutical Chemistry IIIB: Pharmaceutical Analysis II

#### Course Learning Outcomes (CLOs)

- 1. Explain the principles and pharmaceutical applications of spectroscopic and chromatographic techniques including UV, IR, NMR, MS, AAS, HPLC, and GC.
- 2. Interpret spectra and chromatograms to assess identity, purity, and concentration of pharmaceutical substances.
- 3. Apply instrumental methods to develop, optimize, and validate analytical procedures in line with pharmacopeial and regulatory standards.
- 4. Demonstrate laboratory proficiency in operating instruments and performing assays, spectral analysis, and chromatographic separations for pharmaceutical compounds.

#### **Contents**

#### 1. Spectroscopic Methods in Pharmaceutical Analysis:

Introduction, principle of photometry, spectrophotometry, electromagnetic spectrum, electromagnetic radiation, energy levels and transitions, types of spectra, factors affecting spectrum, determination of absorption maxima, applications of spectroscopic techniques.

- 1.1. Atomic Absorption and Emission Spectroscopy
- 1.2. Ultraviolet Spectroscopy
- 1.3. Infrared Spectroscopy
- 1.4. Nuclear Magnetic Resonance Spectroscopy
- 1.5. Mass Spectrometry

# 2. Chromatographic Methods:

Principle and theory of chromatography, working and components of the following chromatographic methods, sample preparation for chromatography, applications.

- 2.1. Thin Layer Chromatography (TLC)
- 2.2. High Performance Liquid Chromatography (HPLC)
- 2.3. Gas Chromatography (GC)
- 2.4. Ion Exchange Chromatography

#### **Practical**

# To perform at least ten (10) practical's; one(1) from each method / technique

- 1. Determination of UV-Visible absorption spectra of any API/raw material.
- 2. Determination of absorption maxima ( $\lambda$  max) of a given sample.
- 3. Determination of  $A_1^1$  of a given sample by UV-Visible spectrophotometry.
- 4. Assay of Pharmaceutical substances based on spectrophotometric methods.
- 5. Separation, identification and quantification of pharmaceutical substances by chromatographic methods such as TLC or HPLC or GC.
- **6.** Method development procedure for pharmaceutical. Substance by UV-Visible Spectrophotometry or TLC or GC or HPLC.
- 7. Experimental methodology of validation of the developed method.

## **Recommended Readings:**

- 1. Skoog, D. A., West, D. M., Holler, F. J., & Crouch, S. R. (2014). Fundamentals of Analytical Chemistry (9th ed.). Cengage Learning.
- 2. Golden W. Evings, (1985). Instrumental methods of chemical analysis (5<sup>th</sup> edition) Mc Graw Hill, London.
- 3. David G. Watson (2007). Pharmaceutical analysis, a text book for pharmacy students and pharmaceutical chemistry (2<sup>nd</sup> edition) Elsevier Churchill Livingston, UK.
- 4. Mendham J. Denney R.C, Barnes J.D, Thomas M and Sivasankar B (2011) vogels text book of quantitative chemical analysis (6<sup>th</sup> edition). Dorling Kindersley India.
- 5. Satinder Ahuja and Stephen Skypinski (2005). Hand book of modern pharmaceutical analysis academic press, California.

- 6. Akash, M. S. H., & Rehman, K. (2025). Essentials of pharmaceutical analysis. 2nd Edition. Springer Nature.
- 7. The International Pharmacopoeia (3<sup>rd</sup> edition) WHO. AITBS publisher, Kishan Noya Delhi.
- 8. United States Parmacopeia (2020). United States Parmacopeia and National Formulary (USP 43-NF 38). Rockville, MD: USP.British Parmacopeia Commission (2022). British Parmacopeia London: Stationary Office.

### Pharmaceutical Chemistry IV: Pharmaceutical Quality Control

# **Course Learning Outcomes**

- 1. Understand the concept and basis of quality of pharmaceuticals and related chemical substances.
- 2. Describe the role of regulatory agencies for the quality of pharmaceuticals and herbal products.
- 3. Understand the method development protocols and validation process as per regulatory requirements.
- 4. Describe the latest concept of quality being practiced in the pharmaceutical industry.

#### Contents

# 1. Quality Control of Chemical Substances and Regulations

- 1.1. Definition of quality, quality control and quality assurance.
- 1.2. Basis and concept of quality in pharmaceuticals.
- 1.3. Sources of impurities in raw material and chemical substances used in pharmaceutical and herbal products.
- 1.4. Limit test for impurities.
- 1.5. Role of quality control in ensuring safety of raw materials.
- 1.6. Overview of national and international agencies (DRAP/WHO/PICs) dealing with the quality of API's and raw materials.
  - 1.10. Preparation of BOP's and SOP's.
    - 1.11. Good laboratory practices (GLP)

# 2. General requirements for the quality evaluation of API's, raw materials and chemical substances

- 2.1. A brief account of analytical methods used in drug analysis (only name and principles).
- 2.2. Calibration of glassware and instruments.
- 2.3. Sampling, procedure, handling, storage and documentation of APIs.
- 2.4. Standards and standardization process.
- 2.5. Pharmacopeial tests and specifications.
- 2.6. Evaluation of Pharmaceuticals and herbal products
- 2.7. Causes of poor quality and general requirements.

#### 3. Analytical Method Development and Validation

3.1. Selection criteria of analytical method/technique based on analyte properties.

- 3.2. Parameters of analytical method for instance UV, HPLC, GC.
- 3.3. Analytical method development, validation and optimization of its parameters as per ICH guidelines.
- 4. Quality Risk Management and Product Development:
- 4.1. Introduction to ICH Q9, Risk Definition, Assessment, Control, and Review, Tools in Quality Risk Management, change control.
- 4.2. Overview of ICH Q10, Lifecycle Stage Goals, Management Responsibilities, Enablers: Knowledge Management and Quality Risk Management, Continual Improvement of Process Performance and Product Quality, Continual Improvement of the Pharmaceutical Quality System.

#### **Practical**

- 1. Calibration of glass wares.
- 2. Calibration of analytical balance
- 3. Evaluation of raw materials in pharmaceuticals.
- 4. Chemical testing of various APIs, raw materials and chemical substances as per pharmacopeial specifications.
- 5. Standardization of reagents.
- 6. Determination of impurities (limit test as per pharmacopeial specification).
- 7. Method development procedure analytical techniques such as UV-visible spectrophotometry or chromatographic methods.
- 8. Validation methodology of any developed method.
- 9. Risk management and change control.

# **Recommended Readings:**

- 1. International Conference on Harmonization. (2005). ICH harmonized tripartite guideline: Validation of analytical procedures: Text and methodology Q2(R1).
- 2. Akash, M. S. H., & Rehman, K. (2025). Essentials of pharmaceutical analysis. 2<sup>nd</sup> Edition. Springer Nature.
- 3. World Health Organization. (2007). WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues.
- 4. Swartz, M. E., & Krull, I. S. (2012). Analytical method development and validation. CRC Press.
- 5. Ermer, J., & Nethercote, P. W. (2018). Method validation in pharmaceutical analysis: A guide to best practice (2<sup>nd</sup> ed.). Wiley-VCH.
- 6. World Health Organization. (2024). Quality assurance of pharmaceuticals: A compendium of guidelines and related materials (10<sup>th</sup> ed.). WHO Press.
- 7. World Health Organization. (2011). Laboratory quality management system: Handbook. WHO Press.
- 8. Skoog, D. A., West, D. M., Holler, F. J., & Crouch, S. R. (2014). Fundamentals of Analytical Chemistry (9th ed.). Cengage Learning.
- 9. United States Pharmacopeial Convention. (2020). United States Pharmacopeia and National Formulary (USP 43–NF 38). Rockville, MD: USP.
- 10. British Pharmacopoeia Commission. (2022). British Pharmacopoeia. London: Stationery Office.

#### Pharmaceutical Chemistry VA: Medicinal Chemistry I

After completion of this course the students will be able to:

# **Course Learning Outcomes**

- 1. Explain key concepts of drug discovery and design, including SAR, QSAR, and Lipinski's Rule of Five.
- 2. Apply physicochemical principles to improve drug properties like solubility, lipophilicity, and bioavailability.
- 3. Analyze the structure, SAR, and therapeutic relevance of major drug classes used in CNS, cardiovascular, endocrine, infectious, and parasitic diseases prevalent in Pakistan.
- 4. Perform basic synthesis and identification of pharmaceutical compounds using medicinal chemistry lab techniques.

#### **Contents**

- 1. Brief Introduction, history and development of medicinal chemistry.
- 2. **Introduction to Drug Design**: *In-silico* Drug Design Approaches including Structure-Based Drug Design (SBDD) and Ligand-Based Drug Design (LBDD). Structure-Activity Relationship (SAR) & Quantitative SAR (QSAR). Lead Compounds, Lipinski's Rule of 5, Drug Repurposing, Combinatorial Chemistry and High-Throughput Screening (HTS).
- 3. Prodrugs and Biosisteres: General description and its pharmaceutical applications.

# General properties, Chemistry, SAR, Biological action and therapeutic uses of the following:

#### 1. Anesthetics

- i. **Local Anesthetics**: Ester derivatives and amide derivatives (Procaine, Benzocaine and Lidocaine)
- ii. **General Anesthetics**: Inhalational (Halothane, Methoxyflurane and Nitrous oxide) and IV (Thioamylal, Thiopental and Ketamine) anesthetics.
- 2. **Sedatives & Hypnotics:** Benzodiazepines (Diazepam and related analogues), Non-Benzodiazepines (Zolpidem) and Barbiturates (Phenobarbital and related analogues).
- 3. Analgesics and Antipyretics
  - i. **NSAIDs**: Salicylates (aspirin, soluble aspirin and phenyl salicylate, p-aminophenol derivatives (Phenacetin and Paracetamol), and Pyrazolone and Pyrazolodione derivatives (Antipyrine), N-aryl anthranilic acid (Mefanemic acid and Mechlofenamic acid) and Arylacetic Acids derivatives (Ibuprofen and Diclofenac sodium/potassium).
  - ii. Narcotic Analgesics: Morphine and related analogues.
- 4. Hormones and Related Agents
  - i. **Sex Hormones & Modulators**: Androgens e.g. Testosterone, Nandrolone, Estrogens e.g. Estradiol, Diethylstilbestrol, Progestins e.g. Progesterone, Levonorgestrel).
  - ii. Corticosteroids: Glucocorticoids (Prednisolone, Dexamethasone)
  - iii. Thyroid Drugs: L-Thyroxine, Anti-Thyroid Agents (Propylthiouracil)
- 5. **Antineoplastic agents:** Alkylating agents, Anti metabolites, Antibiotics, Hormones and natural products.

#### **Practical**

**NOTE:** Practical of the subject shall be designed from time to time on the basis of the above-mentioned theoretical topics and availability of the facilities.

**Dry Lab Practicals (***In-Silico***):** Structure drawing (2D & 3D) and reaction mechanisms using ChemDraw®; calculation of physicochemical properties such as logP, clogP, molar refractivity (MR), molecular weight, hydrogen bond donors and acceptors; drug-likeness screening using Lipinski's Rule of Five; prediction of drug properties via Swiss ADME and Molinspiration; protein structure modeling

using Phyre2 and I-TASSER; basic docking studies using CB-Dock and PatchDock.

Wet Lab Practicals: Estimation of functional groups (carboxylic, hydroxy, amino, nitro); determination of molecular weights of organic compounds; synthesis of Paracetamol, Salicylic Acid, Methyl Salicylate, Azobenzene, Benzoic Acid, 5-Hydroxy-1,3-benzoxazol-2-one, Aspirin, p-Nitrosophenol, 3-Nitrophthalic Acid, o-Chlorobenzoic Acid; assay of drugs such as Sulpha drugs, Aspirin, Paracetamol, Benzyl Penicillin, and selected inorganic preparations.

(Note: A minimum of 10 practicals will be conducted).

# **Recommended Readings:**

- 1. Silverman, R. B., & Holladay, M. W. (2020). The Organic Chemistry of Drug Design and Drug Action (3rd ed.). Academic Press.
- 2. Wermuth, C. G., & Livi, G. P. (2019). *Chemistry of Drug Design and Drug Action* (4th ed.). Academic Press.
- 3. Foye, W. O., Lemke, T. L., & Williams, D. A. (2020). Foye's Principles of Medicinal Chemistry (8th ed.). Lippincott Williams & Wilkins.
- 4. Hansch, C., & Fujita, T. (2020). *Theoretical Drug Design: Volume I Structure-Activity Relationships* (2nd ed.). Springer.
- 5. Patel, M. (2018). *Medicinal Chemistry: An Introduction* (2<sup>nd</sup> ed.). Wiley-Blackwell.
- 6. Eger, E. I. (2020). Principles of Medicinal Chemistry (2<sup>nd</sup> ed.). Springer.

# Pharmaceutical Chemistry VB: Medicinal Chemistry-II

#### **Course Learning Outcomes**

At the end of this course the student will be able to:

- 1. Explain the chemical structures, SAR, and therapeutic roles of cardiovascular, antidiabetic, diuretic, and antimicrobial agents relevant to diseases prevalent in Pakistan.
- 2. Analyze structure–activity relationships (SAR) of drug classes including antituberculars, antimalarials, antivirals, and immunomodulators.
- 3. Apply principles of medicinal chemistry to identify, synthesize, and characterize key pharmaceutical compounds using modern synthetic and analytical techniques.
- 4. Evaluate therapeutic potential and mechanism of action of drug molecules using medicinal chemistry concepts to support rational drug design and discovery.

#### **Contents**

# General properties, Chemistry, SAR, Biological action and therapeutic uses of the following:

- 1. Cardiovascular Agents
  - i. **Antihypertensives**: ACE Inhibitors (Captopril and Enalapril), β-Blockers (Propranolol and Pindolol), Ca<sup>2+</sup> Channel Blockers (Verapamil)
  - ii. Antihyperlipidemics: Statins (Atorvastatin)
- **2. Antidiabetics**: Biguanides (*Metformin and related analogues*), Sulfonylureas (Glibenclamide and *related analogues*), DPP-4 Inhibitors (Sitagliptin and *related analogues*).
- **3. Diuretics**: Carbonic anhydrase inhibitors (Acetazolamide and Dichlorphenamide) Thiazides and hydrothiazide derivatives (Hydrochlorothiazide and Benzthiazide) Loop Diuretics (Furosemide).
- 4. Antimicrobial & Antiparasitic Agents
  - i. **Antibiotics**: β-Lactams, Macrolides, Aminoglycoside, Tetracyclines and Quinolones.
  - ii. **Antitubercular Drugs**: First-Line (Isoniazid and Rifampicin), MDR/XDR Drugs Diarylquinoline (Bedaquiline) and Oxazolidinone (Linezolid).

- iii. **Sulfonamides:** N¹-Substituted (Sulfanilamide, Sulfadimidine, Sulfacetamide and Sulfafurazole) and N⁴-Substituted (Succinyl Sulfathiazole and Phthalyl Sulfathiazole)
- iv. **Antimalarials:** 4-Aminoquinolines (Chloroquine), 8-Aminoquinolines (Pamaquine), 9-Aminoacridines (Mepacrine), Biguanides (Proguanil), Endoperoxides (Artemisinin).
- v. **Antivirals**: Nucleoside Analogues (*Acyclovir* and *Ribavirin*), Protease Inhibitors (*Ritonavir*).
- **5. Immunomodulators**: Cyclic Polypeptide (Cyclosporine) and Purine Antimetabolite (Azathioprine).

#### **Practical**

**NOTE:** Practical of the subject shall be designed from time to time on the basis of the above-mentioned theoretical topics and availability of the facilities.

# **Synthetic Medicinal Chemistry Practicals:**

Synthesis of Benzimidazole, Benzotriazole, Benzocaine, 3-methyl-1-phenyl pyrazole-5-one, 4-benzylidene-2-phenyl oxazole-5-one, Barbituric acid, Phenytoin, Phenothiazine, Acetanilide, Paracetamol, Aspirin derivatives, Salicylic Acid, Methyl Salicylate, Azobenzene, Benzoic Acid, 5-Hydroxy-1,3-benzoxazol-2-one, p-Nitrosophenol, 3-Nitrophthalic Acid, o-Chlorobenzoic Acid, and Phenylalanine.

# **Identification Tests for Raw Materials:**

Paracetamol – oxidation with sodium hypochlorite (violet color); Aspirin – FeCl<sub>3</sub> test after hydrolysis (violet complex); Salicylic Acid – FeCl<sub>3</sub> test (deep violet color); Benzoic Acid – sublimation and effervescence with NaHCO<sub>3</sub> (confirms carboxylic acid group); Benzocaine – diazotization-coupling test (orange-red azo dye formation); Barbituric Acid – copper sulfate test (violet color); Acetanilide – melting point (~114°C) or nitration to form yellow p-nitroacetanilide. (Note: A minimum of 10 practicals will be conducted).

# **Recommended Readings:**

- 1. Silverman, R. B., & Holladay, M. W. (2020). The Organic Chemistry of Drug Design and Drug Action (3rd ed.). Academic Press.
- 2. Wermuth, C. G., & Livi, G. P. (2019). *Chemistry of Drug Design and Drug Action* (4th ed.). Academic Press.
- 3. Foye, W. O., Lemke, T. L., & Williams, D. A. (2020). Foye's Principles of Medicinal Chemistry (8th ed.). Lippincott Williams & Wilkins.
- 4. Hansch, C., & Fujita, T. (2020). Theoretical Drug Design: Volume I Structure-Activity Relationships (2nd ed.). Springer.
- 5. Patel, M. (2018). *Medicinal Chemistry: An Introduction* (2<sup>nd</sup> ed.). Wiley-Blackwell.
- 6. Eger, E. I. (2020). Principles of Medicinal Chemistry (2<sup>nd</sup> ed.). Springer.

#### PHARMACY PRACTICE:

#### **EXPOSITORY WRITING**

### **Course Learning Outcomes**

# By the end of the course, students will be able to:

- 1. Understand the essentials of the writing process by integrating pre-writing, drafting, editing, and proofreading to produce well-structured essays relevant to pharmacy.
- 2. Demonstrate proficiency in diverse expository writing forms to address varied academic and professional purposes across pharmacy disciplines.
- 3. Uphold ethical practices and apply critical thinking to develop original, well-substantiated written work aligned with scientific and regulatory standards.

#### **Contents:**

# 1. Introduction to Expository Writing:

- Understanding expository writing (definition, types, purpose and applications)
- Characteristics of effective expository writing (clarity, coherence and organization)
- Introduction to paragraph writing
- Application of expository writing in pharmacy-related documentation and communication

# 2. The Writing Process:

- Pre-writing techniques (brainstorming, free-writing, mind-mapping, listing, questioning and outlining etc.)
- Drafting (three stage process of drafting techniques)
- Revising and editing (ensuring correct grammar, clarity, coherence, conciseness etc.)
- Proof reading (fine-tuning of the draft)
- Peer review and feedback (providing and receiving critique)

# 3. Essay Organization and Structure:

- Introduction and hook (engaging readers and introducing the topic)
- Thesis statement (crafting a clear and focused central idea)
- Body Paragraphs (topic sentences, supporting evidence and transitional devices)
- Conclusion (types of concluding paragraphs and leaving an impact)
- Ensuring cohesion and coherence (creating seamless connections between paragraphs)

# 4. Different Types of Expository Writing:

- Description
- Illustration
- Classification
- Cause and effect (exploring causal relationships and outcomes)
- Process analysis (explaining step-by-step procedures)
- Comparative analysis (analyzing similarities and differences)

# 5. Writing for Specific Purposes and Audiences:

- Writing to inform (e.g., medication guides), analyze (e.g., literature reviews), persuade (e.g., therapeutic justifications), and educate (e.g., patient leaflets)
- Writing for academic purposes (e.g., scholarly essays, term papers, research proposals, clinical case analyses, course assignments, training reports, scientific manuscripts, and theses/dissertations)
- Writing for professional practice, regulatory and industrial applications (e.g., clinical documentation/communication, standard operating procedures (SOPs), dossiers for drug

registration and approval, quality assurance protocols, good manufacturing practice (GMP) documentation, labelling content, and product information leaflets compliant with national and international regulatory guidelines)

- Writing for public audiences (engaging, informative and persuasive language)
- Different tones and styles for specific purposes and audiences
- Adjusting tone, style, and structure for audiences such as researchers, clinicians, pharmacists, patients, and regulators

#### 6. Ethical Considerations:

- Academic and professional integrity in scientific writing
- Ensuring original writing (finding credible sources, evaluating information etc.)
- Proper citation and referencing (APA, MLA, Vancouver, or other citation styles)
- Integrating quotes and evidences (quoting, paraphrasing, and summarizing)
- Avoiding plagiarism (ethical considerations and best practices)
- Transparency in writing (clearly presenting data, avoiding misrepresentation, and disclosing limitations)
- Respect for confidentiality (avoiding unauthorized disclosure of patient information or proprietary industrial data in any written form)

#### Recommended Readings

- 1. Axelrod, R. B., & Cooper, C. R. (2021). The St. Martin's Guide to Writing (13th ed.). Bedford/St. Martin's.
- 2. Graff, G., & Birkenstein, C. (2024). They Say / I Say: The Moves That Matter in Academic Writing (6th ed.). W. W. Norton & Company.
- 3. Rosenwasser, D., & Stephen, J. (2023). Writing Analytically (9th ed.). Cengage.
- 4. Williams, J. M., & Bizup, J. (2021). Style: Lessons in Clarity and Grace (13th ed.). Pearson.
- 5. Strunk, W., & White, E. B. (2000). The Elements of Style (4th ed.). Longman.
- 6. American Medical Association. (2020). AMA Manual of Style: A Guide for Authors and Editors (11th ed.). Oxford University Press.
- 7. Lang, T. A. (2010). How to Write, Publish, and Present in the Health Sciences: A Guide for Clinicians & Laboratory Researchers. American College of Physicians.
- 8. Katz, M. J. (2009). From Research to Manuscript: A Guide to Scientific Writing (2nd ed.). Springer.
- 9. Zeiger, M. (2000). Essentials of Writing Biomedical Research Papers (2nd ed.). McGraw-Hill.
- 10. Battisti, W. P., et al. (2015). Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Annals of Internal Medicine, 163(6), 461–464.

#### **ENTREPRENEURSHIP**

#### **Course Learning Outcomes:**

#### At the end of the course the student shall be in a position to;

- 1. Understand entrepreneurship fundamentals in the pharmaceutical industry.
- 2. To utilize the foundational knowledge and skills in entrepreneurship, emphasizing leadership, effective communication, ethical considerations, and essential awareness within the pharmaceutical sector.
- 3. Communicate effectively in professional and business settings.
- 4. Explore entrepreneurial opportunities in Pakistan's pharmaceutical landscape.

#### **Contents:**

- Entrepreneurship drives innovation and growth within pharmaceutical sciences specific to Pakistani context.
- 2. An entrepreneurial mindset in pharmacy emphasizes innovation, opportunity recognition, and calculated risk.
- 3. Pakistan's pharmaceutical industry offers specific challenges and opportunities for entrepreneurs.
- 4. Various avenues exist for pharmaceutical entrepreneurship, including retail, marketing, and specialized services.
- 5. Strategic Marketing Planning and Implementation: Develop the skills to formulate comprehensive marketing plans, set strategic objectives, allocate resources effectively, implement marketing campaigns, and evaluate their performance within the specific context of the Pakistani pharmaceutical market.
- 6. Pharmaceutical Product Lifecycle and Branding: Examine the stages of a pharmaceutical product's lifecycle from discovery to maturity and decline, focusing on strategic branding, product differentiation, and intellectual property considerations relevant to the Pakistani market.
- 7. Market Research and Data Analytics in Pharmacy: Learn methodologies for conducting market research to understand patient needs, prescriber preferences, market trends, and the use of data analytics to inform marketing decisions and measure campaign effectiveness within the local context.
- 8. Understanding the Pharmaceutical Market Environment: Analyze the dynamics of the healthcare market, including patient behavior, prescriber influence, payer systems, competitive forces, and the impact of health policies and regulations on pharmaceutical marketing strategies in Pakistan.
- 9. Effective leadership and team-building skills are crucial in healthcare and pharmaceutical settings.
- 10. Strong communication and presentation skills are essential for pharmaceutical professionals and ventures.
- 11. Ethical considerations are paramount in all aspects of pharmaceutical entrepreneurship.
- 12. Basic business planning, including market analysis and financial concepts, is foundational.

#### **Recommended Readings:**

- 1. Zorich, George S. Entrepreneurs in Pharmacy: And Other Leaders. Outskirts Press, 2017.
- 2. George S. Zorich. Entrepreneurs in Pharmacy and Other Leaders: Strategies and Stories for Success, 2nd Edition, 2024.
- Management, Leadership and Entrepreneurship in Pharmacy, Zubin Austin, 2023

# Pharmacy Practice-IA: Social and Administrative Pharmacy (Hospital and Community Pharmacy)

#### Course Learning Outcomes:

At the end of the course the student shall be able to:

- 1. Analyze the structure of pharmacy services within the Pakistani healthcare system, understand the roles of pharmacists in various settings and public health, and apply the minimum standards for hospital and community pharmacy practice.
- Evaluate medication management and use processes, identify potential risks, propose mitigation strategies based on the best international practices and regulatory requirements, and understand the role of technology in enhancing medication safety.

- 3. Apply regulatory requirements to pharmacy operations, develop strategies for formulary management, implement inventory control systems, understand pharmacoeconomic principles, and describe the function of a Pharmacy and Therapeutics Committee.
- 4. Describe the processes for the selection and procurement of therapeutic goods, manage the pharmaceutical supply chain effectively, implement proper medication storage practices for various drug types, and evaluate medication orders for appropriateness to ensure patient safety, utilizing evidence-based practices and clinical decision support systems.

#### Contents:

- 1. Pharmacy Services & Healthcare in Pakistan: Overview of hospital and community pharmacy services, the Pakistani healthcare system, and the pharmacist's role in various settings and public health.
- 2. Minimum Service Standards: Understanding the mandatory standards for both hospital and community pharmacy operations in Pakistan.
- Safe Medication Use Processes (MMU): Introduction to safe medication practices, risk assessment, mitigation strategies, and alignment with international standards (JCI, ISMP, WHO).
- 4. Technology in Medication Management: Exploring the use of modern software and technology to enhance medication management and use processes.
- 5. Regulatory Compliance & Inventory Management: Understanding regulations, formulary management, inventory control (par levels, EOQ, TOR), and the Medication Management System (MMS).
- 6. Pharmacoeconomics & P&TC: Introduction to pharmacoeconomics, cost-effective initiatives, and the function of the Pharmacy and Therapeutics Committee.
- 7. Therapeutic Goods Selection & Procurement: Criteria for selecting medications and understanding the procurement processes in both public and private sectors, including regulatory requirements.
- 8. Supply Chain Management: Management of the pharmaceutical supply chain, including cold chain, narcotics control, diversion prevention, and expiry/BUD management.
- 9. Good Medication Storage Practices: Understanding and implementing proper storage conditions (temperature, humidity) and specific protocols for High Alert, LASARA, Concentrated Electrolytes, and Hazardous medications.
- 10. Medication Orders & Prescription Review: Different types of medication orders, the importance of prescription appropriateness review for patient safety, pharmacy clinical interventions, patient care plans, evidence-based practices, and clinical decision support systems (CDSS).

# Recommended Readings

- 1. Hospital Pharmacy (3rd Edition); Editors: Raliat Onatade & Martin Stephens; Publisher: Pharmaceutical Press; Publication Date: January 9, 2025
- Hospital and Community Pharmacy: Comprehensive Guide for Professional Practice Authors: Prof. S. Shobha Rani & Dr. A. Muralidhar Rao; Publisher: Notion Press Publication Date: May 20, 2024
- 3. Advanced Pharmacy Practice (3rd Edition) Author: Anita Lambert; Publisher: Cengage; Publication Date: 2024

# Pharmacy Practice-IB: Social and Administrative Pharmacy (Dispensing Social and Administrative Pharmacy)

# **Course Learning Outcomes:**

At the end of the course the student shall be able to:

- 1. To analyze the structure of pharmacy services within the Pakistani healthcare system, understand the roles of pharmacists in various settings and public health, and apply the minimum standards for hospital and community pharmacy practice.
- 2. To evaluate medication management and use processes, identify potential risks, propose mitigation strategies based on international best practices.
- 3. To Apply regulatory requirements to pharmacy operations, develop strategies for formulary management, implement inventory control systems, understand pharmacoeconomic principles, and describe the function of a Pharmacy and Therapeutics Committee.

#### **Contents:**

- 1. Reading and transcribing physicians' orders, medical profiles and medication administration records
- 2. Medication cart filling and documentation
- 3. Recording and management of narcotic drugs
- 4. Drug Preparation included Aseptic Services in Hospital Pharmacy
  - a. Fundamental learning of drug preparation and dispensing (Aseptic/ Sterile area services in hospital settings and compounding services in hospital and community settings),
  - b. Pharmaceutical Calculations: Some Fundamentals of Measurements and Calculations. The Metric System. The Common Systems. Conversions. Calculation of Doses. Percentage calculations, Reducing and Enlarging Formulas. Weights and Volumes of Liquids. HLB Values. Industrial Calculations. Calculations involving parenteral admixtures. Some calculations involving Hydrogen-ion concentration. Calculations involving isotonic, electrolyte and buffer solutions.
  - c. Role of pharmacist in radiopharmaceuticals.
  - d. Drug Administration, follow up and safety procedures in dispensing
- 5. Basic of drug administration for safe use of medications, including seven rights of drug administration.
- 6. Understand the drug devices, drug libraries, and ready to administer mediations
- 7. Self-administration and home care services.
  - a. Education for patient, public and health care professionals.
  - b. Evaluation, promote public health and provide education to the patients, public and health care providers.
    - i. Understand the patient's need, psychology, behavioral sciences and expectations
    - ii. Development of patient education leaflets, and newsletter.
    - iii. To provide patient education on safe use of antimicrobials, family planning, etc
    - iv. Effective medication counselling and drug adherence.
    - v. Patient feedback / satisfaction survey tools
    - vi. Drug information services, authentic sources like Lexicomp etc

# c. Miscellaneous

d. Drug shortages and liaison with prescribers with the best therapeutic alternatives.

- e. Managing Pharmaceutical waste and energy sustainable initiatives in pharmacy services.
- f. Drug recalls and response to safety alerts
- g. Dispensing of extemporaneous preparations
- h. Dispensing of Vaccine, and Biologics: EPI program Pakistan, Essential vaccinations for travelling, Counselling and patient education relevant to Vaccination.

- 1. Patient Safety and Healthcare Improvement at a Glance S. King, P. Greaves
- 2. Medication Safety Officer's Handbook C. E. Anderson
- 3. Clinical Informatics Board Review S. M. Gadd, R. Chapman
- 4. ISMP Medication Safety Guidelines Institute for Safe Medication Practices (ISMP)
- 5. WHO Patient Safety Curriculum Guide: Multi-professional Edition
- 6. Relevant journal articles on emerging technologies and trends in medication safety (JAMA, BMJ Safety, AJHP).

# Pharmacy Practice-IIA (Clinical Pharmacy-I)

# **Course Learning Outcomes:**

#### At the end of the course, students shall be able to:

- 1. Explain the fundamentals of clinical pharmacy and describe the roles of clinical pharmacists in patient care and public health.
- 2. Interpret and apply information from medication history and patient profiles to optimize medication therapy.
- 3. Identify and manage adverse drug reactions, drug interactions, medication errors, and therapeutic drug levels using standard tools and guidelines.
- 4. Demonstrate a basic understanding of clinical trials and evaluate clinical literature to promote evidence-based pharmacy practice.

- 1. Fundamentals of Clinical Pharmacy: (1) Definition and scope of clinical pharmacy, relationship between pharmaceutical care and clinical pharmacy (2) Impact of clinical pharmacy on healthcare systems and patient outcomes (3) Evolution of clinical pharmacy in Pakistan, including the transition from a dispensing-focused role to patient-centered care (4) Overview of the various roles and responsibilities of clinical pharmacists, including their functions in diverse healthcare settings such as hospitals, ambulatory care, community pharmacies, clinics, and nursing homes.
- 2. Comprehensive Patient Assessment and Therapy Optimization through Patient Data: (1) Patient clinical profile, including case history: basic understanding by pharmacists and their applications in pharmaceutical care (2) Taking medication history: components, techniques, applications (3) Clinical labs tests monitoring by pharmacists and their application in optimizing medication therapy.
- 3. Medication Safety and Health Informatics: Systems Approach to Safe Medication Use: (1) Importance of Medication Safety in Healthcare, (2) Medication Errors: Definition and types, (3) Near-Misses, (4) High-Risk Medicines: Look-Alike Sound-Alike (LASA) medicines, High-Alert Medication (HAM) protocols, and risk mitigation strategies, (5) Safety Standards/Guidelines: Institute for Safe Medication Practices (ISMP), World Health Organization (WHO), International Patient Safety Goals (IPSG), and hospital protocols, (6) Informatics Tools: Electronic Health Record (EHR), Computerized Physician Order Entry (CPOE), Clinical Decision Support System (CDSS),

Barcoded Medication Administration (BCMA), and smart infusion pumps, (7) Approaches for Analysis and Prevention: Swiss Cheese Model for error prevention, process vulnerabilities, Root Cause Analysis (RCA), and Failure Modes and Effects Analysis (FMEA), (8) Reporting of Medication Errors: Voluntary and mandatory systems, (9) Quality Improvement: Key Performance Indicators (KPIs), Plan-Do-Study-Act (PDSA) cycles, Lean methodology, and Six Sigma methodology, (10) Pharmacist's Role: Safety leadership, policy input, and compliance with guidelines.

- 4. Pharmacovigilance and Adverse Drug Reactions: Clinical Surveillance, Reporting, and Management: (1) Pharmacovigilance: Definition, scope, and applications; (2) Adverse Drug Reactions (ADRs): Definition and classification (Rawlins & Thompson; DoTS); assessment and grading of ADR severity; onset of ADRs; (3) Main Mechanisms of ADRs: Excessive primary pharmacological effects, secondary pharmacological effects, allergic (immunological) reactions, and idiosyncratic reactions; (4) Monitoring and Detection of ADRs; (5) Reporting: Definition of adverse drug events (ADEs); differentiation between ADEs and ADRs; reporting forms; reporting at local, national, and international levels (WHO-UMC), including the Spontaneous Reporting System; (6) Causality Assessment: WHO-UMC system and Naranjo algorithm; (7) Management of ADRs.
- 5. **Drug Interactions: Assessment, Evaluation and Management**: (1) Introduction and clinical significance of drug interactions; (2) Mechanisms and Types; (3) Factors affecting drug interactions; (4) Levels of drug interactions (severity, onset, documentation); (5) Identification, clinical evaluation and management of drug interactions.
- 6. Therapeutic Drug Monitoring (TDM): (1) The concept of narrow therapeutic index drugs and the importance of therapeutic drug monitoring (2) TDM of digoxin, theophylline, gentamicin, vancomycin, lithium, phenytoin, carbamazepine, valproate, cyclosporine, tacrolimus, and sirolimus.
- 7. Clinical Trials of Drug Substances: (1) Introduction; (2) Why clinical trials are needed; (3) Phases of clinical trials; (4) Various designs used in clinical trials; (5) Inclusion and exclusion criteria; (6) Monitoring of clinical trials.
- 8. **Utilizing Clinical Drug Literature:** (1) Introduction; (2) Drug literature selection; (3) Drug literature evaluation; (4) Drug literature communication.
- 9. Clinical Pharmacy and Public Health: Recognizing the pharmacist's role in health promotion, disease prevention and screening, lifestyle counseling, immunization, pharmacoepidemiology, public health emergencies (pandemics and disasters), with an emphasis on collaboration with healthcare teams, policy involvement, and community-based interventions to enhance public health outcomes.

#### **Practical**

#### **Course Learning Outcomes:**

#### At the end of the course, students shall be able to:

- Demonstrate the ability to collect, interpret, and apply patient-specific clinical data including medication history, lab values, renal function, and drug levels to identify drug-related problems and support safe, effective pharmacotherapy.
- 2. Effectively utilize drug information resources, medication safety principles, ADR and interaction assessment tools, and therapeutic drug monitoring to optimize pharmacotherapy and contribute to public health initiatives.

#### Note:

 Instructors may use a variety of educational strategies based on availability, such as case studies (paper-based or digital), simulated clinical scenarios, standardized patients (SPs), role-play, small-group discussions, problem-based learning (PBL), patient profile reviews, and digital tools to support practical skill development. • At least 10 practicals must be conducted during the course; however, more are encouraged to enhance practical learning.

#### Content

- 1. Identify components of a comprehensive patient clinical profile.
- 2. Demonstrate techniques for collecting medication history.
- 3. Interpret patient case histories for therapy planning.
- 4. Assess renal function and adjust doses accordingly.
- 5. Evaluate patient profiles to identify drug-related problems.
- 6. Interpret laboratory data relevant to pharmacotherapy.
- 7. Compare different drug information tools/resources.
- 8. Use drug information resources to answer clinical questions.
- 9. Apply retrieved drug information to clinical scenarios.
- 10. Develop lists of drugs frequently prescribed or used in clinical settings, along with their clinical uses.
- 11. Extract clinical data from patient documentation systems.
- 12. Classify types and causes of medication errors.
- 13. Recognize high-alert and look-alike sound-alike medications.
- 14. Analyze medication use processes using safety models.
- 15. Demonstrate the use of medication informatics systems.
- 16. Conduct error analysis using structured evaluation tools.
- 17. Develop plans for improving medication safety practices.
- 18. Create performance indicators for medication safety.
- 19. Classify adverse drug reactions (ADRs) using standard classification systems.
- 20. Assess causality of ADRs using structured tools.
- 21. Complete and submit ADR reporting documentation.
- 22. Formulate a plan for managing adverse drug reactions.
- 23. Identify and screen drug interactions using various methods and tools.
- 24. Manage drug interactions in vulnerable patient groups.
- 25. Interpret and apply serum drug concentrations in therapeutic drug monitoring, considering all relevant clinical factors.
- 26. Develop a community-based pharmacy plan to address a specific public health issue (e.g., hypertension or diabetes mellitus screening).
- 27. Search and retrieve relevant clinical drug literature using appropriate databases.

#### **Recommended Readings**

- 1. Walker, R., & Whittlesea, C. (2019). *Clinical pharmacy and therapeutics* (6th ed.). Churchill Livingstone/Elsevier.
- 2. DiPiro, J. T., Yee, G. C., Posey, L. M., Haines, S. T., Nolin, T. D., & Ellingrod, V. L. (2023). *Pharmacotherapy: A pathophysiologic approach* (12th ed.). McGraw Hill.
- 3. Schwinghammer, T. L., DiPiro, J. T., DiPiro, C. V., & Ellingrod, V. L. (2023). *DiPiro's pharmacotherapy handbook* (12th ed.). McGraw Hill.
- 4. Gupta, V., Nguyen, T., Clark, M., Williams, E., Cone, C., & Desselle, S. (2022). *Pharmacy practice skills: A guide for students and instructors* (2nd ed.). McGraw Hill.
- 5. Jones, R. M. (2015). Patient assessment in pharmacy practice (3rd ed.). Lippincott Williams & Wilkins.
- 6. Nemire, R. E., Kier, K. L., & Assa-Eley, M. T. (2015). *Pharmacy student survival guide* (3rd ed.). McGraw Hill.

- 7. Schwinghammer, T. L., Koehler, J. M., Borchert, J. S., Slain, D., & Park, S. K. (2020). *Pharmacotherapy casebook: A patient-focused approach* (11th ed.). McGraw Hill.
- 8. Shargel, L., Mutnick, A. H., Souney, P. F., & Swanson, L. N. (2012). *Comprehensive pharmacy review for NAPLEX* (9th ed.). Lippincott Williams & Wilkins.
- 9. Cipolle, R. J., Strand, L. M., & Morley, P. C. (2012). Pharmaceutical care practice: The patient-centered approach to medication management services (3rd ed.). McGraw Hill.
- 10. Remington, J. P., Troy, D. B., & Beringer, P. (2020). Remington: The science and practice of pharmacy (23rd ed.). Lippincott Williams & Wilkins.
- 11. Lacy, C. F., Armstrong, L. L., Goldman, M. P., & Lance, L. L. (2024). *Drug information handbook* (32nd ed.). Lexi-Comp.
- 12. Anderson, C. E. (2018). *Medication safety officer's handbook* (2nd ed.). American Society of Health-System Pharmacists.
- 13. Institute for Safe Medication Practices. (2024). Targeted medication safety best practices for hospitals. Institute for Safe Medication Practices. Retrieved 8 April 2025, from <a href="https://psnet.ahrq.gov/issue/targeted-medication-safety-best-practices-hospitals">https://psnet.ahrq.gov/issue/targeted-medication-safety-best-practices-hospitals</a>.
- 14. UpToDate. (Online Database). *Clinical decision support for pharmacotherapy*. Wolters Kluwer Health. Retrieved 8 April 2025, from <a href="https://www.uptodate.com">https://www.uptodate.com</a>.
- 15. PharmaGuide Publishing Company. (2025). PharmaGuide. (32nd ed.). Karachi, Pakistan.

# Pharmacy Practice-IIB (Clinical Pharmacy-II)

#### At the end of the course students shall be able to:

- 1. Develop, implement, and monitor patient-centered drug therapy plans using standardized frameworks, care processes, effective documentation, and evidence-based decision-making.
- Apply medication management and optimization strategies, including Medication Therapy Management (MTM), Drug Utilization Review (DUR), and antimicrobial stewardship, to promote rational pharmacotherapy.
- 3. Provide pharmaceutical care across diverse settings using current practices, advanced digital tools, and telepharmacy while maintaining ethical, legal, and professional standards.
- 4. Improve medication adherence and therapeutic outcomes through appropriate assessment, effective communication, and individualized patient education strategies.

- 1. Pharmacotherapy and Drug Therapy Plans: From Foundational Framework to Development and Monitoring: (1) Introduction: Overview of pharmacotherapy and drug therapy plans; essential roles in pharmaceutical care, (2) Pharmacist's Workup of Drug Therapy (PWDT): A foundational framework for pharmacists, (3) Pharmacist Patient Care Process (PPCP): Core components and clinical applications, (4) Drug Therapy Problems (DTPs) / Drug-Related Problems (DRPs): Common categories and integration into drug therapy plans, (5) Drug Therapy Plan: Development, implementation, and monitoring, (6) Clinical Documentation: Importance and principles of effective documentation; common formats: SOAP notes, FARM notes, PRIME pharmacotherapy problems, CORE pharmacotherapy plan, (7) The Role of Drug Therapy Plans in Modern Pharmacy Practice.
- 2. **Pharmacotherapy Decision-Making:** (1) Transition from advisor to practitioner, (2) Identify opportunities for decision-making, (3) Proactively engage, (4) Formulate evidence-based decision rationale, (5) Pursue the highest levels of decision-making, (6) Seek independence with accountability, (7) Implement decisions with professional responsibility.
- 3. Optimizing Medication Use and Combating Antimicrobial Resistance: Core principles of

- medication optimization. Antimicrobial resistance (AMR): causes and impact. Antimicrobial stewardship: goals and approaches. WHO AWaRe classification of antibiotics and its clinical applications.
- 4. **Medication Therapy Management (MTM) Services:** Defining the core components and importance of MTM, including medication review, developing Medication-Related Action Plans (MAPs), providing patient education, and effectively identifying and resolving drug-related problems with appropriate documentation and follow-up.
- 5. **Drug Utilization Evaluation (DUE) and Drug Utilization Review (DUR):** Definitions, types, and applications. General methodology for developing drug-use criteria (or drug-use protocols). Development of drug-use criteria for selected drugs such as vancomycin, piperacillin/tazobactam, and meropenem.
- 6. **Online Pharmaceutical Care Services:** Introduction to remote pharmacy services; Core Functions; Technology; Legal/Ethical Considerations; Trends & Challenges.
- 7. Provision of Pharmaceutical Care in Multiple Environments: Delivery of pharmaceutical care across multidisciplinary and culturally diverse settings, encompassing variations in language, health literacy, patient needs, and other contextual factors, with a focus on professionalism, ethical practice, and patient-centered outcomes.
- 8. Leveraging Advanced Clinical Pharmacy Tools and Technologies: Exploring the integration and application of Electronic Medical Records (EMRs), Clinical Decision Support Systems (CDSS), mobile health (mHealth) applications, smart devices, pharmacogenomics, wearable technologies, and the emerging role of Artificial Intelligence (AI) and machine learning in optimizing pharmacotherapy and advancing personalized medicine.
- 9. **Medication Adherence:** Definition and clinical significance; types of non-adherence; assessment tools; barriers to adherence; and strategies to improve adherence.
- 10. **Patient Education and Communication:** Definitions, core counselling and communication skills, patient-centered care, health literacy assessment, motivational interviewing, targeted communication (pediatric, geriatric, chronic disease populations, specific drugs/dosage forms etc), aids (visual/digital/print), shared decision-making.

#### **Practical**

# **Course Learning Outcomes:**

#### At the end of the course, students shall be able to:

- 1. Design, implement, monitor, and document individualized drug therapy plans using standardized approaches (e.g., PWDT, PPCP), incorporating clinical data, patient-specific factors, and evidence-based guidelines.
- 2. Demonstrate effective patient-centered care through communication, patient education, adherence strategies, pharmacotherapy optimization, digital health tools, and the application of medication safety, MTM, and antimicrobial stewardship principles across diverse populations and care settings.

#### Note

- Instructors may use a variety of educational strategies based on availability, such as case studies (paper-based or digital), simulated clinical scenarios, standardized patients (SPs), role-play, small-group discussions, problem-based learning (PBL), patient profile reviews, and digital tools to support practical skill development.
- At least 10 practicals must be conducted during the course; however, more are encouraged to enhance practical learning.

- 1. Develop a comprehensive drug therapy plan using standardized approaches such as the Pharmacist's Workup of Drug Therapy (PWDT) and the Pharmacist Patient Care Process (PPCP).
- 2. Identify and categorize drug therapy problems (DTPs) in patient profiles and propose appropriate interventions.
- 3. Develop therapeutic outcome goals and design a structured monitoring plan.
- 4. Implement a pharmacotherapy plan effectively, considering patient-specific factors, collaboration with healthcare providers, and resource availability.
- 5. Document pharmacotherapy interventions using formats such as SOAP, FARM, PRIME, or CORE notes.
- 6. Formulate and justify pharmacotherapy decisions based on evidence-based clinical guidelines and patient-specific data.
- 7. Assess a patient case and implement evidence-based modifications to therapy.
- 8. Assess medication adherence using validated tools; analyze contributing factors and classify types of non-adherence.
- 9. Design and implement individualized strategies to improve medication adherence.
- 10. Apply patient education and communication strategies suited to the needs of special populations (e.g., pediatrics, geriatrics).
- 11. Conduct a simulated counseling session using motivational interviewing and shared decision-making techniques.
- 12. Prepare and deliver a structured patient education session using digital or visual aids.
- 13. Assess drug safety in pregnancy and lactation and develop an appropriate patient counseling and education plan.
- 14. Demonstrate appropriate drug administration techniques for various dosage forms and routes, including specialized forms such as inhalers, insulin pens, transdermal patches, nasal sprays, nasal drops, and eye preparations.
- 15. Educate a patient on proper self-administration of medications using specialized devices (e.g., nebulizers, insulin pens, inhalers), emphasizing correct technique, storage, and error prevention.
- 16. Educate patients about home-based monitoring of chronic diseases (e.g., diabetes mellitus, hypertension) and advise when to consult healthcare professionals.
- 17. Evaluate pharmacotherapy in geriatric patients; identify common challenges and propose patient-centered solutions.
- 18. Review pediatric medication use, including dosing adjustments, formulation issues, and caregiver education.
- 19. Evaluate antibiotic use in clinical scenarios; propose stewardship strategies and apply the WHO AWaRe classification.
- 20. Design and document an antimicrobial stewardship intervention based on a clinical case.
- 21. Perform a complete Medication Therapy Management (MTM) review, including development of a Medication-Related Action Plan (MAP).
- 22. Identify and resolve drug-related problems in MTM cases with appropriate documentation and follow-up.
- 23. Conduct a Drug Utilization Review (DUR) or Drug Use Evaluation (DUE) for selected high-risk or high-cost medications.
- 24. Develop and apply drug-use criteria for selected medications or therapeutic classes.
- 25. Review and evaluate a telepharmacy case, addressing legal, ethical, and clinical considerations.
- 26. Develop pharmaceutical care plans for culturally diverse patient populations.
- 27. Propose a strategy to integrate advanced tools and health technologies into patient care delivery.
- 28. Demonstrate the use of digital clinical tools (e.g., EMRs, CDSS, mHealth apps) in therapeutic decision-making.

- 1. Benedict, K., & Madaras-Kelly, K. (2020). *Antimicrobial Stewardship in Pharmacy Practice*. American Society of Health-System Pharmacists (ASHP).
- 2. Hughes, R. E., & Martin, D. (2021). Developing critical thinking in pharmacy students. *American Journal of Pharmaceutical Education*, 85(5), Article#8539.
- 3. American Pharmacists Association (APhA) & National Association of Chain Drug Stores Foundation. (2020). *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model.* (12th ed.). APhA & NACDSF.
- 4. Whalen, K., & Hardin, H. C. (2021). Medication Therapy Management: A Comprehensive Approach (2nd ed.). McGraw Hill.
- 5. American Society of Health-System Pharmacists (ASHP). (2022). ASHP Statement on Telepharmacy. American Journal of Health-System Pharmacy, 79(5), 381–385.
- 6. Walker, R., & Whittlesea, C. (2019). *Clinical pharmacy and therapeutics* (6th ed.). Churchill Livingstone/Elsevier.
- 7. DiPiro, J. T., Yee, G. C., Posey, L. M., Haines, S. T., Nolin, T. D., & Ellingrod, V. L. (2023). *Pharmacotherapy: A pathophysiologic approach* (12th ed.). McGraw Hill.
- 8. Schwinghammer, T. L., DiPiro, J. T., DiPiro, C. V., & Ellingrod, V. L. (2023). *DiPiro's pharmacotherapy handbook* (12th ed.). McGraw Hill.
- 9. Gupta, V., Nguyen, T., Clark, M., Williams, E., Cone, C., & Desselle, S. (2022). *Pharmacy practice skills: A guide for students and instructors* (2nd ed.). McGraw Hill.
- 10. Jones, R. M. (2015). Patient assessment in pharmacy practice (3rd ed.). Lippincott Williams & Wilkins.
- 11. Nemire, R. E. (Ed.). (2023). Pharmacy student survival guide (4th ed.). McGraw Hill.
- 12. Schwinghammer, T. L., Koehler, J. M., Borchert, J. S., Slain, D., & Park, S. K. (2020). *Pharmacotherapy casebook: A patient-focused approach* (11th ed.). McGraw Hill.
- 13. Shargel, L., Mutnick, A. H., Souney, P. F., & Swanson, L. N. (2012). *Comprehensive pharmacy review for NAPLEX* (9th ed.). Lippincott Williams & Wilkins.
- 14. Cipolle, R. J., Strand, L. M., & Morley, P. C. (2021). Pharmaceutical care practice: The patient-centered approach to medication management services (3rd ed.). New York, NY: McGraw Hill.
- 15. Remington, J. P., Troy, D. B., & Beringer, P. (2020). Remington: The science and practice of pharmacy (23rd ed.). Lippincott Williams & Wilkins.
- 16. Lacy, C. F., Armstrong, L. L., Goldman, M. P., & Lance, L. L. (2024). *Drug information handbook* (32nd ed.). Lexi-Comp.
- 17. UpToDate. (Online Database). *Clinical decision support for pharmacotherapy*. Wolters Kluwer Health. Retrieved 8 April 2025, from <a href="https://www.uptodate.com">https://www.uptodate.com</a>.
- 18. PharmaGuide Publishing Company. (2025). PharmaGuide. (32nd ed.). Karachi, Pakistan.

#### Pharmacy Practice-III: Civics and Community Engagement

# **Course Learning Outcomes**

By the end of this course, students will be able to:

- 1. Describe the principles of civic responsibility and their relevance to the professional practice of pharmacy.
- 2. Analyze the role of pharmacists in promoting public health, advancing community welfare, and ensuring equitable access to medications and healthcare services.
- 3. Demonstrate knowledge of the healthcare governance structure in Pakistan and how pharmacists contribute to health policy and regulation.
- 4. Evaluate pharmacist-led strategies for community engagement, health education, and social

- responsibility.
- 5. Apply ethical and inclusive practices in pharmacy services to support civic values such as equity, access, and social justice.
- Utilize digital platforms responsibly for community health awareness, advocacy, and professional communication.

#### **Contents**

# Foundations of Civics and Civic Responsibility in Pharmacy

- Introduction to civics and citizenship within healthcare systems.
- Professional accountability and ethical conduct as civic duties.
- The pharmacist as a health advocate and responsible citizen.

# Health Governance and the Role of Pharmacists in Society

- Overview of healthcare governance in Pakistan.
- Regulatory and professional pharmacy bodies.
- Pharmacists' role in public health systems, policy-making, and service delivery.

# Community Health Engagement and Social Outreach

- Concepts of community development and public health promotion.
- Models of pharmacist-led interventions.
- Interprofessional collaboration, working in a multidisciplinary environment, and fostering public trust.

# Equity, Inclusion, and Social Justice in Pharmacy Practice

- Addressing health disparities: socioeconomic, gender, rural/urban divides, etc.
- Ensuring equitable and inclusive pharmacy services for all segments of the population.
- Pharmacist's role in promoting ethical and equitable healthcare.

# Advocacy and Public Health Leadership

- Public health advocacy: promoting the responsible and rational use of medicines, preventing the
  irrational use of antibiotics and other medications, and preventing drug abuse and misuse, along
  with related initiatives.
- Strategies for effective communication and civic leadership.
- Mobilizing community participation in health promotion initiatives.

# Digital Citizenship and Professional Ethics

- Responsible use of digital platforms for health promotion.
- Cyber ethics and confidentiality in digital health communication.
- Bridging the digital divide in pharmacy services and patient education.

# **Recommended Readings**

- 1. Carter, J. T., & Slack, M. K. (2010). *Pharmacy in public health: Basics and beyond.* Bethesda, MD: American Society of Health-System Pharmacists.
- 2. Mattson, K. (2017). *Digital citizenship in action: Empowering students to engage in online communities.* Washington, DC: International Society for Technology in Education.
- 3. Clarke, M., & Steckel, M. M. (2019). *Creating social change: A blueprint for a better world* (2nd ed.). Lanham, MD: Rowman & Littlefield.
- 4. Kymlicka, W., & Norman, W. (2000). Citizenship in diverse societies. Oxford, UK: Oxford University Press.
- 5. Youniss, J., & Levine, P. (2009). Engaging youth in civic life. Nashville, TN: Vanderbilt University Press.
- 6. Feldpausch, B. J., & Omilian, S. M. (2015). *Community engagement: Principles, strategies, and practices.* Ann Arbor, MI: CreateSpace Independent Publishing Platform.
- 7. Government of Pakistan. (1973). *The Constitution of the Islamic Republic of Pakistan*. Islamabad: National Assembly of Pakistan.

# Pharmacy Practice-IV: Pharmaceutical Management and Marketing

#### **Course Learning Outcomes**

At the completion of this course students will be able to;

- 1. Apply Foundational Marketing Principles within the Ethical and Regulatory Framework of the Pharmaceutical Industry in Pakistan and Develop Patient-Centric Marketing Strategies.
- Evaluate Pharmaceutical Product Lifecycle Management and Develop Effective Branding and Market Access Strategies Relevant to Pakistan and Implement Strategic Marketing Plans for Pharmaceutical Products within the Pakistani Healthcare System.
- 3. Synthesize core digital marketing principles with the unique legal, ethical, and regulatory landscape of the pharmaceutical industry to develop and implement comprehensive online marketing strategies for both prescription and over-the-counter products, considering AI tools for optimization and adhering to relevant regulations in Pakistan and internationally.
- 4. Develop and manage efficient and compliant e-commerce operations for pharmaceutical products, including secure online dispensing, order fulfillment, and customer relationship management, while strategically managing the pharmaceutical supply chain to ensure product integrity, regulatory compliance, and timely delivery to online customers.
- 5. Apply relevant management theories and financial management principles to formulate strategic business development plans for pharmaceutical e-commerce ventures, encompassing effective HR management for specialized teams, sound financial planning for online operations, and strategic decision-making for sustainable growth and profitability in the digital pharmaceutical market.

- Fundamentals of Pharmaceutical Marketing: Explore core marketing principles, the
  unique aspects of pharmaceutical marketing compared to other industries, and the evolving
  role of marketing in the pharmaceutical sector, including ethical considerations and
  regulatory landscapes.
- 2. Pharmaceutical Promotion and Communication Strategies: Investigate various promotional channels and communication strategies targeting healthcare professionals and patients, including digital marketing, detailing, medical education, and public relations, while adhering to local regulations and ethical guidelines.
- 3. Pricing, Reimbursement, and Market Access in Pakistan: Analyze different pricing strategies for pharmaceutical products, understand the complexities of reimbursement systems and health economics in Pakistan, and explore strategies for achieving optimal market access for new and existing medications.
- 4. **Pharmaceutical Distribution and Supply Chain Management:** Examine the distribution channels for pharmaceutical products in Pakistan, including wholesalers, pharmacies, and hospitals, and understand the principles of efficient supply chain management and inventory control.
- 5. **Digital Pharmaceutical Marketing Principles & Legalities:** Navigating the unique landscape of online pharmaceutical marketing, encompassing core digital marketing principles while strictly adhering to the complex legal and regulatory frameworks governing online promotion, advertising, and sales of pharmaceutical products (including DTCA regulations and local Pakistani laws).
- 6. **AI-Powered Marketing Strategies & Business Development:** Leveraging AI tools for enhanced marketing strategies, including personalized customer engagement, predictive

- analytics for market trends, and automation of marketing tasks, all within the framework of robust business development plans focused on growth and market penetration in the pharmaceutical e-commerce sector.
- 7. Management Theories & HR in Pharmaceutical Business Development: Applying fundamental management theories to structure and lead pharmaceutical e-commerce ventures, emphasizing effective HR management practices for talent acquisition, training, and retention of specialized personnel within this regulated industry.
- 8. Financial Management for Pharmaceutical E-commerce/online marketing: Implementing sound financial management principles tailored to the pharmaceutical industry, addressing aspects like pricing strategies, reimbursement complexities, investment in digital infrastructure, and managing profitability in the online space.
- Operational & Workflow Management in Online Pharmacy: Optimizing operational
  efficiency and workflow management specifically for online pharmacy services, including
  secure online dispensing, prescription verification processes, and efficient handling of online
  orders and customer service.
- 10. Pharmaceutical Supply Chain Management: Understanding and managing the intricacies of the pharmaceutical supply chain, ensuring product integrity, secure online distribution channels, and efficient delivery to online customers while complying with pharmaceutical regulations.
- 11. Foundations of Pharmaceutical Market Understanding: Establishing a strong foundation in marketing principles applied to the pharmaceutical sector, including analyzing the unique marketing environment (macro and micro factors), understanding consumer behavior in healthcare (patients and prescribers), and mastering market segmentation, targeting, and positioning strategies for pharmaceutical products online.
- 12. Pharmaceutical Product Lifecycle & Branding in the Digital Age: Managing the lifecycle of pharmaceutical products and building strong online brands, considering the regulatory constraints and ethical considerations unique to pharmaceutical branding in the digital space.

- 1. Pharmacy Management, Third Edition 3rd Edition. by Shane Desselle, David Zgarrick, Greg Alston
- 2. Essentials of Pharmacy Management Second Edition; Edited by Dennis H Tootelian, Albert I; Wertheimer, Andrey;

# Pharmacy Practice-VA: Pharmaceutical Regulatory Sciences-I

# **Course Learning Outcomes**

After the completion of this course students will be in a position to;

- 1. Understand the basis of legislation, legislative process, analyze the foundational principles and the significance of pharmaceutical regulations, with a comprehensive understanding of key global and national regulatory bodies.
- 2. Explain the basis of regulatory functions and the operational processes across the product life cycle for Therapeutic goods.
- 3. Describe the basic documentation required for regulatory submission and assessment
- 4. Describe various platforms of regulatory interactions and the major contributions in shaping regulatory approaches and collaborations.

- 1. **Introduction to Legislative Process/Type of Laws----** Covers the process of law making, types of laws including Acts, Ordinances, Rules, Regulations etc, difference between criminal and civil laws, judicial structure in Pakistan.
- 2. **History of Drug Regulation in Pakistan— A brief i**ntro to Drugs Act, 1940 and eras of drug regulation thereafter.
- 3. **An overview of regulatory framework in Pakistan** Covers structure of DRAP, Provincial Drug Controls, various Boards and their functions;
- 4. **An overview of S&F products** Classification of S&F products, their definition and related aspects including investigation functions.
- 5. **Investigation and Prosecution of Drug Offences** Covers the definition, scope, and importance of pharmaceutical regulation, focusing on global and national bodies like DRAP (Drug Regulatory Authority of Pakistan).
- 6. **Drugs Act, 1976** Covering all sections of Drugs Act, 1976, their interpretation and application in regulatory landscape of Pakistan.
- 7. A brief overview of the Rules framed under the Drugs Act, 1976 with special emphasis on respective provincial sale rules

- 1. Pharmaceutical Regulatory Affairs Sachin Itkar (adaptable to local laws)
- 2. Drug Act, 1976 Official Government of Pakistan publication
- 3. Manual of Drug Laws
- 4. WHO Guidelines for Pharmaceutical Regulations
- 5. Pakistan Drug Rules 1976 and amendments

# Pharmacy Practice-VB: Pharmaceutical Regulatory Sciences-II

After the completion of this course students will be in a position to

- 1. Understand the Drug Regulatory Authority of Pakistan (DRAP) and its governing legislation (DRAP Act 2012).
- 2. Understand the 'why' and 'who' of pharmaceutical regulation, focusing on DRAP's structure and legal basis.
- 3. Compare international regulatory pathways for biosimilar approvals, identifying key considerations for global market access.

- 1. **DRAP Act 2012** –, licensing, registration, pricing, pharmacovigilance, and the PIRMS (Pakistan Integrated Regulatory Management System).
- 2. **Global & National Regulatory Frameworks**—An overview of SRAs and Regulatory Bodies of neighboring countries, WHO Benchmarking Tools, **Introduction to PICs guidelines**
- 3. **Drug Registration & Lifecycle Management** The curriculum covers **ICH CTD/eCTD dossier requirements**, clinical/non-clinical data evaluation, and global procedures for product approvals, variations, and post-market changes.
- 4. Good Manufacturing Practices (GMP) & Inspections Key topics include GMP compliance, regulatory inspections (facility, clinical, lab), and the use of digital tools like PIRMS for audit management and corrective actions.
- 5. Pharmacovigilance & Post-Market Surveillance The program emphasizes adverse event monitoring, signal detection, and risk management plans (RMPs), highlighting the roles of manufacturers, regulators, and healthcare providers in ensuring drug safety.

- 6. **Medical Devices & Medicated Cosmetics Regulation** Students learn about **device classification (Class I-IV)**, registration pathways, re-registration requirements, and the oversight of **medicated cosmetics** under frameworks like APACMed and SARC.
- 7. Study of related laws in Pakistan Pharmacy Act 1967, PPRA Rules, 2004/respective provincial procurement related rules and an overview of CNSA, 1997.

- 1. Pharmaceutical Regulatory Affairs Sachin Itkar (adaptable to local laws)
- 2. DRAP Act 2012 Official Government of Pakistan publication
- 3. DRAP Guidelines & Notices (www.drap.gov.pk)
- 4. WHO Guidelines for Pharmaceutical Regulations
- 5. Pakistan Drug Rules 1976 and amendments
- 6. Drug Regulatory Affairs: Principles and Practices Author: Javed Ali, Roop Khar
- 7. New Drug Development: A Regulatory Overview Author: Mark Mathieu
- 8. International Conference on Harmonisation (ICH) Guidelines
- 9. Key Guidelines:
  - a. ICH E6(R2) Good Clinical Practice (GCP)
  - b. ICH M4 Common Technical Document (CTD) Structure
  - c. ICH Q8 Pharmaceutical Development (Quality by Design)

# Pharmacy Practice-VIA: Advanced Clinical Pharmacy-I

#### **Course Learning Outcomes**

At the completion of this course students will be able to

- 1. Identify individual patient needs and apply this understanding to develop and optimize pharmacotherapy plans that align with those needs. This includes considering patient-specific factors and ensuring the pharmacotherapy regimen is tailored for maximum benefit.
- 2. Integrate knowledge of disease pathophysiology and etiology with current evidence-based practices to formulate effective pharmacotherapy and comprehensive pharmaceutical care plans. This encompasses making informed clinical decisions grounded in scientific literature and best practice guidelines.
- 3. Perform thorough medication reconciliation to ensure medication safety and identify patientspecific risk factors that may impede optimal treatment outcomes. This includes the ability to analyze medication histories and recognize potential barriers to successful therapy.
- 4. Effectively educate and counsel patients on various aspects of their disease management and medications. This includes communicating complex information in an understandable manner, addressing patient concerns, and empowering patients to actively participate in their care

- 1. CNS disorders/infections [Epilepsy, Anxiety/Stress, Meningitis, Stroke, Typhoid
- 2. Common GIT disorders i.e Stomach Ulcer, GERD, Diarrhea, Constipation,
- 3. Dermatological infections [ Bacterial (Folliculitis, Boil, Erysipelas, Impetigo, Erysipelas, Cellulitis and gangrene); Viral (warts, HPV, Herpes simplex infection Type 1 and Type 2) and Fungal infections (Tinea, Ringworm (Tinea), Athlete's Foot (Tinea Pedis), Jock Itch (Tinea Cruris), Nail Fungus (Onychomycosis), Oral Thrush (Candidiasis)
- 4. Common conditions like wound care management, fever, cough, common cold/ flu, wound care, pain management, bacterial and viral conjunctivitis
- 5. Hyperlipidemia, Diabetes Mellitus, Hypertension, Hyper and Hypothyroidism.

- 1. DiPiro, J. T., Talbert, R. L., Yee, G. C., Matzke, G. R., Wells, B. G., & Posey, L. M. (11 Eds.). (2022). Pharmacotherapy: a pathophysiological approach.
- 2. Koda-Kimble, M.A. ed., 2007. Handbook of applied therapeutics. Lippincott Williams & Wilkins.
- 3. DiPiro's Pharmacotherapy Handbook, 12th Edition
- 4. Chisholm-Burns, Marie A., Terry L. Schwinghammer, Patrick M. Malone, Jill M. Kolesar, Kelly C. Lee, and P. Brandon Bookstaver. *Pharmacotherapy principles and practice*. McGraw-Hill, 2022.

#### **Practical**

- 1. Students must be able to prepare SOAP Notes or Pharmaceutical care plan for the disease discussed in this unit. Case studies can be either simulated or real cases depending on availability.
- 2. Patient counselling and Education to achieve optimum therapeutic goals specific to the diseases covered in this unit.
- 3. Dose adjustments, Selection of Alternates, Non-Pharmacological measure to improve the therapeutic outcomes and well-being
- 4. Interpretation of Lab values and identification of suitable interventions as per evidence based guidelines.

# Pharmacy Practice-VIB: Advanced Clinical Pharmacy-II

# **Course Learning Outcomes**

# At the completion of this course students will be able to

- 1. To systematically identify individual patient needs and apply this understanding to develop and optimize pharmacotherapy plans that align with those needs. This includes considering patient-specific factors and ensuring the pharmacotherapy regimen is tailored for maximum benefit.
- 2. To integrate knowledge of disease pathophysiology and etiology with current evidence-based practices to formulate effective pharmacotherapy and comprehensive pharmaceutical care plans. This encompasses making informed clinical decisions grounded in scientific literature and best practice guidelines.
- 3. To perform thorough medication reconciliation to ensure medication safety and identify patient-specific risk factors that may impede optimal treatment outcomes. This includes the ability to analyze medication histories and recognize potential barriers to successful therapy.
- 4. To effectively educate and counsel patients on various aspects of their disease management and medications. This includes communicating complex information in an understandable manner, addressing patient concerns, and empowering patients to actively participate in their care

- 1. Selection and Dosing of IV fluid therapy, Incompatibilities and monitoring parameters
- 2. Management of common infectious disease specific to Pakistani setting i.e Malaria, Dengue, Sepsis, Tuberculosis, Sinusitis, Laryngitis, Pharyngitis, Pneumonia
- 3. Oncology: Breast cancer, Prostate Cancer, Benign Prostate Hyperplasia
- 4. Renal and Hepatic Failure and its management along with the pharmacotherapy of other comorbid conditions

- 5. Urology: Nephrotic syndrome, Urinary tract infection, Prostatitis, Chlamydia, Syphilis, Gonorrhea
- 6. Common Coagulation and bleeding disorders over the counter and in hospital setting eg. Deep vein thrombosis, Thrombocytopenia and Pulmonary Embolism. With specific focus on the use of warfarin, heparin, aspirin and non-vitamin K antagonist
- 7. Management of Hematological disorders i.e. Anemia, Thalassemia
- 8. Management of Asthma and COPD
- 9. Management of Patients and pharmacotherapy optimization in emergency situations, poisoning and patient drug need relevant to the administration of the antidotes

# **Recommended Readings:**

- 1. DiPiro, J. T., Talbert, R. L., Yee, G. C., Matzke, G. R., Wells, B. G., & Posey, L. M. (11 Eds.). (2022). Pharmacotherapy: a pathophysiological approach.
- 2. Koda-Kimble, M.A. ed., 2007. Handbook of applied therapeutics. Lippincott Williams & Wilkins.
- 3. DiPiro's Pharmacotherapy Handbook, 12th Edition
- 4. Chisholm-Burns, Marie A., Terry L. Schwinghammer, Patrick M. Malone, Jill M. Kolesar, Kelly C. Lee, and P. Brandon Bookstaver. *Pharmacotherapy principles and practice*. McGraw-Hill, 2022.

### **Practical**

- 1. Students must be able to prepare SOAP Notes or Pharmaceutical care plan for the disease discussed in this unit. Case studies can be either simulated or real cases depending on availability.
- 2. Patient counselling and Education to achieve optimum therapeutic goals specific to the diseases covered in this unit.
- 3. Dose adjustments, Selection of Alternates, Non-Pharmacological measure to improve the therapeutic outcomes and well-being
- 4. Interpretation of Lab values and identification of suitable interventions as per evidence based guidelines.
- 5. Students must practice Therapeutic drug monitoring for the following drug: Vancomycin, Amakacin, Gentamicin, Phenytoin, Amiodarone, Digoxin, Cyclosporin, Must practice on cases to learn what dose to administer and what parameters to monitor for effective outcomes

### PHARMACEUTICS:

# Pharmaceutics-IA: Physical Pharmacy I

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Describe the historical evolution of pharmacy through ancient Greek, Arab, and Muslim contributions and the significance of official compendia and texts.
- 2. Explain basic physicochemical principles relevant to drug delivery systems and formulations.

### **Contents:**

# 1. Introduction to Pharmacy and History:

- i. Introduction and orientation to the Pharmacy Profession with the current scope and latest applications.
- ii. A survey of the history of pharmacy through ancient, Greek, and Arab periods with special reference to the contribution of Muslim scientists to pharmacy and allied sciences.
- iii. The Industrial Revolution and the development of Pharmaceuticals in the 20<sup>th</sup> century.
- iv. The developments in the 21<sup>st</sup> century, especially with reference to Biotechnology, nanotechnology, and artificial intelligence.
- **2. Introduction to Pharmaceutical Literature:** Introduction to the scientific literature, literature types in pharmacy, official texts and compendia, and their significance.

## 3. Introductory concepts in Physical Pharmacy

- i. Fundamentals and overview of the concepts of physicochemical properties and their application in product development.
- ii. Basic concepts of physical pharmacy in dosage forms science and its various applications.

## 4. Physico-Chemical Principles:

- i. **Solutions:** Types, concentration expressions, ideal and real solutions, colligative properties, and applications in pharmacy.
- ii. **Solubility and Solubilization:** Definition and concepts of solubility and Solubilization, mechanism, factors affecting solubility and solubilization.
- iii. **Dissolution and Permeation:** Definition and concepts, types, Factors affecting dissolution and permeation, Noves-Whitney equation
- iv. **Polymorphism:** Basic concept, lattice structure, and significance in pharmaceuticals. Amorphous and crystalline solids and their effect on thermodynamics. Role in dissolution.

### 5. Ionization and Buffers:

- i. Strong vs. Weak Electrolytes, pH, pKa, and buffer systems and capacity. Henderson-Hasselbalch Equation and application in drug formulation.
- ii. Hypo, hyper, and Isotonic solutions and pharmaceutical applications.

### 6. Micromeritics:

- i. Particle size and its distribution, Texture and morphological characteristics of pharmaceutical powders. Role and importance in pharmacy and medicines.
- ii. Methods of particle size analysis, distribution, and morphological determination (sieving, microscopy etc.).
- iii. Flow properties: Carr's Index, Hausner's ratio, angle of repose.

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain basic physicochemical principles relevant to drug delivery systems and formulations.
- 2. Apply the physico-chemical principles in drug kinetics and drug stability.

# **Experiments:**

- 1. Concepts of Physicochemical Principles and Applications.
- 2. Preparation of Solutions, Dilutions, and Construction of Standard Curve.
- 3. Understanding different expressions of concentration like Molarity (M), Normality (N), Percentage, etc.
- 4. Study of different Solubility determination techniques with emphasis on solubility enhancement.
- 5. Buffer solutions: Calibration of a pH meter. Preparation of different official buffers.
- 6. Characterization of different powders based on particle size, Carr's Index, Hausner's ratio, angle of repose, etc.

# Note: Minimum of 10 practical's shall be conducted

# **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). *Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science*: Wiley.
- 3. Allen, L. V. (2021). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems: Wolters Kluwer Health.
- 4. Anderson, S. (2005). Making Medicines: A Brief History of Pharmacy and Pharmaceuticals: Pharmaceutical Press.
- 5. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 6. Brun, P. L., Crauste-Manciet, S., Krämer, I., Smith, J., & Woerdenbag, H. (2023). *Practical Pharmaceutics: An International Guideline for the Preparation, Care and Use of Medicinal Products*: Springer International Publishing.
- 7. Denton, P., & Rostron, C. (2013). Pharmaceutics: The Science of Medicine Design: OUP Oxford.
- 8. European Pharmacopeia (11<sup>th</sup> edition). European Directorate for the Quality of Medicines & Healthcare.
- 9. Fahr, A., & Scherphof, G. L. (2018). Voigt's Pharmaceutical Technology: Wilev.
- 10. Lovett, A. W. (2014). Introduction to the Pharmacy Profession: Jones & Bartlett Learning.
- 11. Ma, J. K. H., & Hadzija, B. (2013). Basic Physical Pharmacy: Jones & Bartlett Learning
- 12. Sinko, P. J. (2023a). Martin's Physical Pharmacy and Pharmaceutical Sciences: Wolters Kluwer Health.
- 13. Swarbrick, J. (2013). Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print): Taylor & Francis.
- 14. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 15. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention
- 16. Zebroski, B. (2015). A Brief History of Pharmacy: Humanity's Search for Wellness: Taylor & Francis.

# Pharmaceutics-IB: Physical Pharmacy II

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

1. Explain basic physicochemical principles relevant to drug delivery systems and formulations.

### **Contents:**

### 1. Surface and Interfacial Phenomena:

- i. Surface and interfacial tension.
- ii. Types of surfactants, techniques to reduce surface tension, and pharmaceutical applications.
- iii. Micellization and its application in dosage forms.
- **2. Adsorption:** Mechanisms, types of adsorption, adsorption isotherms.

### 3. Disperse Systems:

- i. **Colloids:** Introduction, types, methods of preparation, optical/kinetic/electrical properties, stability and pharmaceutical applications.
- ii. **Emulsions:** Types, theories of emulsification, emulsifying agents (classification and properties), stability issues, pharmaceutical applications.
- iii. **Suspensions:** Types, methods of preparation, properties, types of suspending agents, stability concerns, pharmaceutical applications.

# 4. Rheology:

- i. Fluid flow behaviors, rheograms.
- ii. Newtonian and non-Newtonian liquids.
- iii. Thixotropy, anti-thixotropy, and rheopexy.
- iv. Factors affecting and significance in pharmaceutical formulations.

### 5. Stability Studies in Pharmacy:

- i. Introduction, factors affecting stability, types of stability studies.
- ii. Rate of reactions and order of kinetics
- iii. Drug degradation: Phase separation, hydrolysis, oxidation, photolysis and other pathways of drug degradation. Role of pH, temperature and ionic strength.

# 6. Unit Operations in Pharmacy:

i. Introduction to terminologies and concepts of Precipitation, crystallization, evaporation, distillation, efflorescence, deliquescence, lyophilization, elutriation, desiccation, ignition, fusion, sublimation, calcination, decantation, adsorption, centrifugation, trituration, levigation, and dialysis.

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain basic physicochemical principles relevant to drug delivery systems and formulations.
- 2. Apply the physico-chemical principles in drug kinetics and drug stability.

### **Experiments:**

- 1. Chemical Kinetics:
  - i. Effect of temperature on the stability of a model drug by determining reaction rate constant; determining the order of reaction (zero-order, first-order);
  - ii. Determination of expiry date using the Arrhenius equation.
- 2. Interfacial Phenomena:
  - i. Determining Critical Micelle Concentration (CMC) of different surfactants.
  - ii. Determination of flocculation volume of a given suspension and effect of surfactant concentration on flocculation volume.
- 3. Rheology:
  - i. Determination of the viscosity of different systems.

- ii. Plotting rheograms after shearing the system and determining rheological characteristics.
- iii. Studying the effect of viscosity on the stability of suspensions.

## **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 3. Allen, L. V. (2021). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems: Wolters Kluwer Health.
- 4. Anderson, S. (2005). *Making Medicines: A Brief History of Pharmacy and Pharmaceuticals*: Pharmaceutical Press.
- 5. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 6. Brun, P. L., Crauste-Manciet, S., Krämer, I., Smith, J., & Woerdenbag, H. (2023). *Practical Pharmaceutics: An International Guideline for the Preparation, Care and Use of Medicinal Products*: Springer International Publishing.
- 7. Denton, P., & Rostron, C. (2013). Pharmaceutics: The Science of Medicine Design: OUP Oxford.
- 8. European Pharmacopeia (11<sup>th</sup> edition). European Directorate for the Quality of Medicines & Healthcare.
- 9. Fahr, A., & Scherphof, G. L. (2018). Voigt's Pharmaceutical Technology: Wiley.
- 10. Lovett, A. W. (2014). Introduction to the Pharmacy Profession: Jones & Bartlett Learning.
- 11. Ma, J. K. H., & Hadzija, B. (2013). Basic Physical Pharmacy: Jones & Bartlett Learning
- 12. Sinko, P. J. (2023a). Martin's Physical Pharmacy and Pharmaceutical Sciences: Wolters Kluwer Health.
- 13. Swarbrick, J. (2013). Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print): Taylor & Francis.
- 14. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 15. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention
- 16. Zebroski, B. (2015). A Brief History of Pharmacy: Humanity's Search for Wellness: Taylor & Francis.

# Pharmaceutics-IIA: Drug Delivery Systems and Formulation Science-I

After completion of this course the students will be able to:

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain the need for dosage forms with respect to routes of administration.
- 2. Develop different conventional dosage forms and drug delivery systems.

### **Course Content:**

- 1. Introduction to Dosage Forms and Drug Delivery Systems
  - i. Purpose of dosage forms and relation to routes of administration and bioavailability.
  - ii. Concept of modern terminology of drug delivery systems and its various examples
- 2. **Selection of Dosage forms:** Concept of pre-formulation studies, drug characteristics and other relevant information for the selection of suitable dosage forms
- 3. Solid Dosage Forms
  - i. **Powders**: Definition, properties, advantages, disadvantages, types, preparation.

- ii. **Tablets**: Definition, types, essentials, formulation, Granulation techniques, advantages and disadvantages.
- iii. Capsules: Hard and soft capsules, advantages, disadvantages, types.
- iv. **Miscellaneous Solid Forms**: Suppositories, medicated pencils, cements, surgical dressings, glycerogelatins.

# 4. Basic Principles of Pharmaceutical Compounding and Extemporaneous Preparations

- i. Weights and measures.
- ii. Calculation techniques for compounding and extemporaneous formulations.
- iii. Fundamental preparations in compounding.
- iv. Containers and closures for pharmaceutical products.
- v. Concept and practice of Good Compounding Practices.

### 5. Pharmaceutical Incompatibilities

i. Types, manifestations, correction, and prevention (with examples).

### **Practical**

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Apply various formulation techniques in the development of drug delivery systems.
- 2. Analyse the role of various pharmaceutical excipients in extemporaneous compounding.

### **Course Content:**

- 1. Weighing Techniques for Solid and Liquid Formulations: Demonstrate balance calibration procedures and discuss environmental factors affecting balance performance. Demonstrate accurate weighing of APIs and excipients for solid and liquid preparations.
- 2. Compounding Practices for Different Dosage Forms: Demonstrate proper compounding methods to ensure dosage accuracy. 1) Use of volumetric glassware for measuring liquids. 2) Techniques for transferring liquids without contamination. Compounding Practices for Powders, Tablets, Capsules, and miscellaneous solid dosage forms such as suppositories, etc.
- 3. Liquid Dosage Forms for Oral and External Use: Aromatic water, Syrups, Spirits, Tinctures, Extracts, Elixirs, Linctus, Solutions, Drops, Lotions, and Liniments
- 4. Monophasic Liquid Dosage Forms for Special Use: Gargles, Mouthwashes, Paints, Ear drops, Nasal drops, Inhalations

### **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 3. Allen, L. V. (2021). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems: Wolters Kluwer Health.
- 4. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 5. Brunaugh, A. D., Moraga-Espinoza, D., Bahamondez-Canas, T. F., Smyth, H. D. C., & Williams, R. O. (2024). Essential Pharmaceutics: Springer International Publishing
- 6. Denton, P., & Rostron, C. (2013). Pharmaceutics: The Science of Medicine Design: OUP Oxford.
- 7. European Pharmacopeia (11th edition). European Directorate for the Quality of Medicines & Healthcare.

- 8. Gibson, M. (2016). Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form: CRC Press.
- 9. Mahato, R. I., Narang, A. S., & Kumar, V. (2024). *Pharmaceutical Dosage Forms and Drug Delivery:* CRC Press.
- 10. Marriott, J. F. (2010). Pharmaceutical Compounding and Dispensing: Pharmaceutical Press.
- 11. Stockton, S. J. (2021). Stoklosa and Ansel's Pharmaceutical Calculations: Wolters Kluwer Health.
- 12. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines. Elsevier.
- 13. Tovey, G. D. (2018). Pharmaceutical Formulation: The Science and Technology of Dosage Forms: RSC.
- 14. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention

# Pharmaceutics IIB: Drug Delivery Systems and Formulation Science II

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain the need for dosage forms with respect to routes of administration.
- 2. Develop different conventional dosage forms and drug delivery systems.

### **Course Content:**

- 1. Parenteral Dosage Forms
  - i. Definition, history, types, advantages, disadvantages, and uses.
  - ii. Formulation components, vehicles, containers, and closures.
  - iii. Concept of sterile/aseptic area
- 2. Semi-solid Dosage Forms
  - i. **Ointments**: Bases, methods of preparation, and application
  - ii. **Miscellaneous Semi-solids**: Creams, pastes, poultices, plasters. Liniments.
- 3. Introduction to Novel Drug Delivery Systems
  - i. Overview of novel drug delivery systems, types, and various examples.
  - ii. Introduction to Cosmeceuticals.
- 4. I.V. Admixtures
  - i. Preparation, stability, and compatibility issues.
- 5. Introductions of Radiopharmaceuticals
  - i. Formulation, safety, regulation, and compounding aspects.
- 6. Introductions and Preparation of Aerosols and Sprays
  - **i.** Fundamentals, preparation, types, and applications.

### **Practical**

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Apply various formulation techniques in the development of drug delivery systems.
- 2. Analyse the role of various pharmaceutical excipients in extemporaneous compounding.

### **Course Content:**

- 1. Biphasic Liquid Dosage Forms:
  - i. Suspensions
  - ii. Emulsions
  - iii. Magmas
  - iv. Gels
- 2. Pharmaceutical Powders: Divided powders, Bulk powders
- 3. Pharmaceutical Semi-Solid Preparations:
  - . Ointments

- ii. Creams
- iii. Pastes
- iv. Gels
- 4. **Capsule Filling:** Manual capsule filling, Semi-automatic capsule filling using bench-top machine

### **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 3. Allen, L. V. (2021). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems: Wolters Kluwer Health.
- 4. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 5. Brunaugh, A. D., Moraga-Espinoza, D., Bahamondez-Canas, T. F., Smyth, H. D. C., & Williams, R. O. (2024). Essential Pharmaceutics: Springer International Publishing
- 6. Denton, P., & Rostron, C. (2013). Pharmaceutics: The Science of Medicine Design: OUP Oxford.
- 7. European Pharmacopeia (11<sup>th</sup> edition). European Directorate for the Quality of Medicines & Healthcare.
- 8. Gibson, M. (2016). Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form: CRC Press.
- 9. Mahato, R. I., Narang, A. S., & Kumar, V. (2024). *Pharmaceutical Dosage Forms and Drug Delivery*: CRC Press.
- 10. Marriott, J. F. (2010). Pharmaceutical Compounding and Dispensing: Pharmaceutical Press.
- 11. Stockton, S. J. (2021). Stoklosa and Ansel's Pharmaceutical Calculations: Wolters Kluwer Health.
- 12. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 13. Tovey, G. D. (2018). Pharmaceutical Formulation: The Science and Technology of Dosage Forms: RSC.
- 14. *United States Pharmacopeia-National Formulary* (USP-NF 2024). United States Pharmacopeial Convention.

# Pharmaceutics-IIIA: Pharmaceutical Microbiology I

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Identify, classify, and signify the importance of microbes in ecosystems.
- 2. Describe the general characteristics and functional anatomy of microorganisms and their relevance in pharmaceutical applications.

### **Course Content:**

### 1. Introduction to Pharmaceutical Microbiology

- i. Scope and historical foundation of Pharmaceutical Microbiology.
- i. General characterization of microorganisms and nomenclature.

## 2. Functional anatomy of bacteria.

- i. Bacterial classification based on phenotype and genotype.
- ii. Nutritional requirements of bacteria: sources and functions of essential nutrients.
- iii. Bacterial growth and factors affecting growth.

### 3. Microbial Techniques

- i. Culture media and culturing techniques.
- ii. Obtaining and preserving pure cultures.
- ii. Visualizing bacteria: principles of microscopy and staining techniques.

### 4. Environmental Microbiology

- i. Microorganisms in the air, aquatic, and terrestrial environments.
- ii. Role of microorganisms in different ecosystems.

# 5. Human-Microbiome Interactions

- i. Normal microbiota and their significance.
- ii. Symbiosis, pathogenicity, and virulence.

### 6. Diseases Caused by Microorganisms

- i. Fungi, classification, cultivation techniques, disease-causing ability, identification, and characterization of few important diseases.
- ii. Protozoal and helminthic infections.
- iii. Representative bacterial infections (Gram-negative and Gram-positive bacteria).

# 7. Pharmaceutical Applications of Microbes

- i. Industrial microbiology and its role in pharmaceutical applications.
- ii. Microbial assessment of various dosage forms

### **Practical**

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Demonstrate the principles and techniques of microbial control.
- 2. Interpret and analyze microbial data with respect to regulatory compliance.

### **Course Content:**

1. **Orientation and Introduction to Laboratory Tools**: Introduction to lab equipment, apparatus, and microbiological culture media.

### 2. Fundamental Techniques in Microbiological Laboratory Analysis

- i. Microscopy techniques, including simple staining and Gram staining.
- ii. Other staining procedures (spore, capsule etc)
- iii. Microbiological culture media preparation and sterilization.
- iv. Aseptic isolation and inoculation techniques.

### 3. Biochemical Tests for Microorganism Identification e.g.

- i. Catalase test.
- ii. Coagulase test.
- iii. Pyrogen test.

### 4. Studying Microbial Growth

- i. Culture characteristics of bacteria.
- ii. Bacterial growth curve analysis.
- iii. The effect of temperature, pH, and osmotic pressure on microbial growth.

## **Recommended Readings**

- 1. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 2. Brooks, G. F. (2013). Janetz Melnick & Adelbergs Medical Microbiology: McGraw-Hill Education.
- 3. Carlton, R. A. (2011). Pharmaceutical Microscopy: Springer New York.
- 4. Crommelin, D. J. A., Sindelar, R. D., & Meibohm, B. (2024). *Pharmaceutical Biotechnology: Fundamentals and Applications*: Springer International Publishing.
- 5. European Pharmacopeia (11th edition). European Directorate for the Quality of Medicines & Healthcare.
- 6. Finch, R. (2012). Antimicrobial Chemotherapy: OUP Oxford.
- 7. Gilmore, B. F., & Denyer, S. P. (2023). Hugo and Russell's Pharmaceutical Microbiology: Wiley.
- 8. Haider, S. I., & Asif, E. S. (2012). *Quality Operations Procedures for Pharmaceutical, API, and Biotechnology*: Taylor & Francis.
- 9. Hanlon, G., & Hodges, N. A. (2012). Essential Microbiology for Pharmacy and Pharmaceutical Science: Wiley.
- 10. Lorian, V. (2005). Antibiotics in Laboratory Medicine: Lippincott Williams & Wilkins.
- 11. Pommerville, J. C. (2007). *Alcamo's Laboratory Fundamentals of Microbiology*: Jones & Bartlett Learning, LLC.
- 12. Roesti, D., & Goverde, M. (2019). Pharmaceutical Microbiological Quality Assurance and Control: Practical Guide for Non-Sterile Manufacturing: Wiley.
- 13. Schwalbe, R., Steele-Moore, L., & Goodwin, A. C. (2007). *Antimicrobial Susceptibility Testing Protocols*: CRC Press.
- 14. Shen, W. C., & Louie, S. G. (2019). Immunology for Pharmacy Students: Taylor & Francis.
- 15. Tortora, G. J., Funke, B. R., & Case, C. L. (2013). Microbiology: An Introduction: Pearson.
- 16. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention

# Pharmaceutics-IIIB: Pharmaceutical Microbiology-II: Applied Pharmaceutical Microbiology and Immunology

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Describe the use of microbes in industrial processes and product development.
- 2. Introduction to the human immune system and its theranostic application.

### Content:

# 1. Controlling Microorganisms: Disinfection, Preservation, and Sterilization

- i. The terminology of microbial control and sensitivity of microorganisms.
- ii. Survivor plots, sterility assurance level, and sterilization kinetics.
- iii. Physical methods of microbial control.
- iv. Chemical agents for microbial control.
- v. Bioburden determination and environmental monitoring.

### 2. Development of Antimicrobial Chemotherapeutic agents:

- i. Classification of antimicrobials according to spectrum of activity & mechanism.
- ii. Development of antibmicrobial products: history and advances
- iii. Bactdreial Resistance against antibiotics.

### 3. Viruses, Viroids, and Prions

- i. General characteristics of viruses, viral structure, and classification (Baltimore classification).
- ii. Growing and visualizing viruses in the lab.
- iii. Multiplication of viruses.

- iv. Diseases caused by DNA and RNA viruses.
- v. Healthcare-associated infections (HAIs) and mechanisms of transfer.
- vi. Common causative agents of HAIs and prevention methods.
- vii. Representative diseases with causative agent, morphology, diagnosis, pathogenesis, clinical implication and treatment of few important viral diseases.

### 4. Introduction to the human immune system and its theranostic applications.

- 1. Introduction and types of Immunity: Innate (non-specific) and Adaptive (specific) immunity
- 2. Cellular & humoral components of immunity
- 3. Autoimmunity, tolerance and immune disorders
- 4. Antigen Antibody reactions and their clinical and diagnostic applications.
- 5. Hypersensitivity reactions and their clinical implications.
- 6. Vaccination and Immunization

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Demonstrate the principles and techniques of microbial control
- 2. Interpret and analyze microbial data with respect to regulatory compliance.

### **Course Content:**

### 1. Control of Microorganisms Using Physical and Chemical Methods

- i. Sterilization using moist heat, dry heat, ultraviolet radiation, and filtration.
- ii. Studying the effectiveness of different antiseptics and disinfectants.

### 2. Preservative Efficacy Testing (PET)

Challenge test with common bacterial and fungal lab strains

# 3. Antibiotic Susceptibility Testing

- i. Kirby-Bauer antibiotic disc diffusion assay.
- ii. MIC determination using agar and broth dilution method.

### 4. Sterility and Endotoxin Testing

- i. Sterility test.
- ii. Pyrogen test

### 5. Environmental Sampling and Bioburden Testing

- i. Settle plate method to determine bioburden in the air.
- ii. Qualitative and quantitative analysis of water.

# **Recommended Readings**

- 1. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 2. Brooks, G. F. (2013). Jawetz Melnick & Adelbergs Medical Microbiology: McGraw-Hill Education.
- 3. Carlton, R. A. (2011). *Pharmaceutical Microscopy:* Springer New York.
- 4. Crommelin, D. J. A., Sindelar, R. D., & Meibohm, B. (2024). *Pharmaceutical Biotechnology: Fundamentals and Applications*: Springer International Publishing.
- 5. European Pharmacopeia (11<sup>th</sup> edition). European Directorate for the Quality of Medicines & Healthcare.
- 6. Finch, R. (2012). Antimicrobial Chemotherapy: OUP Oxford.
- 7. Gilmore, B. F., & Denyer, S. P. (2023). Hugo and Russell's Pharmaceutical Microbiology: Wiley.
- 8. Haider, S. I., & Asif, E. S. (2012). *Quality Operations Procedures for Pharmaceutical, API, and Biotechnology:* Taylor & Francis.
- 9. Hanlon, G., & Hodges, N. A. (2012). Essential Microbiology for Pharmacy and Pharmaceutical Science: Wiley.

- 10. Lorian, V. (2005). Antibiotics in Laboratory Medicine: Lippincott Williams & Wilkins.
- 11. Pommerville, J. C. (2007). *Alcamo's Laboratory Fundamentals of Microbiology*: Jones & Bartlett Learning, LLC.
- 12. Roesti, D., & Goverde, M. (2019). Pharmaceutical Microbiological Quality Assurance and Control: Practical Guide for Non-Sterile Manufacturing: Wiley.
- 13. Schwalbe, R., Steele-Moore, L., & Goodwin, A. C. (2007). *Antimicrobial Susceptibility Testing Protocols*: CRC Press.
- 14. Shen, W. C., & Louie, S. G. (2019). *Immunology for Pharmacy Students:* Taylor & Francis.
- 15. Tortora, G. J., Funke, B. R., & Case, C. L. (2013). Microbiology: An Introduction: Pearson.
- 16. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention

# Pharmaceutics-IVA: Industrial Pharmacy I

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Describe various industrial operational techniques and applications in pharmaceutical manufacturing.
- 2. Understand the large-scale production equipment and their utilization.

### **Course Content:**

### 1. Mixing Operations

- i. **Fundamentals and Mechanisms:** a) Objectives of mixing in pharmaceutical processes. b) Mechanisms of mixing: diffusion, convection, and shear.
- ii. **Factors Affecting Mixing:** a) Particle size, shape, and density. b) Mixer geometry and speed. c) Material properties and flow characteristics.

# iii. Mixing Equipment:

- a. Liquid/liquid, liquid/solid, and solid/solid mixing.
- b. Types of mixers: i) *Tumbling Mixers*: V-type, double cone. ii) *Agitator Mixers*: Paddle, turbine, propeller. iii) *Special Mixers*: Pneumatic, Entolator impact mixers. iv) *Mixers for Semisolids*: Beaters, kneaders, mixer-extruders.
- iv. **Mixing Indices:** Evaluation of blend uniformity and homogeneity.

### 2. Size Reduction (Comminution)

- i. **Purpose and Importance:** Reasons for size reduction: enhancing dissolution, uniformity, and processing.
- ii. **Factors Influencing Size Reduction:** Material properties, equipment design, operational parameters.
- iii. **Equipment:** Sieving, energy mills (ball mill, edgerunner, edge runner mill). Colloid mill, hammer mill, cutter mill, fluid energy mill.

# 3. Drying Operations

- i. **Theories and Mechanisms:** a) Moisture content, equilibrium moisture, and drying rate. B) Rate of drying curve: constant rate period and falling rate period.
- ii. Factors Affecting Drying: Temperature, humidity, airflow, and material properties.
- iii. **Drying Equipment:** Tray dryer, drum dryer, spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- iv. **Applications:** Drying of solids, granules, and powders.

### 4. Filtration and Clarification

- i. **Principles and Theory:** Mechanisms of filtration: size exclusion, adsorption, and depth filtration.
- ii. **Filter Media and Aids:** Types of filter media: membrane, depth, and surface filters. Use of filter aids to enhance filtration efficiency.

iii. **Filtration Equipment:** Plate and frame filter, cartridge filter, vacuum filter. Clarification techniques for liquids.

# 5. Evaporation

- i. **General Principles:** Evaporation as a concentration process. Factors affecting evaporation rate: temperature, surface area, vapor pressure.
- ii. **Evaporators:** Types: steam jacketed kettles, horizontal and vertical tube evaporators. Forced circulation evaporators, multiple effect evaporators.
- iii. Applications: Concentration of solutions in pharmaceutical manufacturing.

# 6. Compression and Compaction

- i. **Solid-Air Interface:** Angle of repose, flow rates, and mass-volume relationships.
- ii. **Density and Consolidation:** Bulk density, tapped density, and compressibility index.
- iii. **Granulation:** Wet and dry granulation methods. Importance of granule properties in compression.
- iv. **Compression Techniques:** Tablet compression and slugging. Heckle analysis, physics of tableting: force, pressure, and material behavior.
- v. **Tableting Equipment:** Tablet presses, tooling, and tooling design.
- vi. Common problems in tableting and troubleshooting.

### 7. Tablet Coating

- i. **Coating Techniques:** a) Pan coating, air suspension coating. b) Film coating: aqueous and non-aqueous systems.
- ii. **Coating Equipment:** Coating pans, fluidized bed coaters. Spray systems and coating parameters.
- iii. Common problems in coating and troubleshooting

### 8. Encapsulation

- i. **Capsule Types:** a) Hard gelatin capsules: filling techniques, sealing methods. b) Soft gelatin capsules: manufacturing processes, filling materials.
- ii. Encapsulation Equipment: a) Capsule filling machines.

### **Practical**

## **Course Learning Outcomes:**

At the end of this course the student will be able to:

1. Evaluation and application of different equipment used in pharmaceutical manufacturing and assessment of the different parameters of the manufacturing area.

### **Course Content:**

- 1. **Relative Humidity Evaluation:** Determination of relative humidity using Hygrometer at room temperature and in an air-conditioned room.
- Moisture Content Determination: Determination of moisture content and loss on drying of given materials.
- 3. **Size Reduction and Milling:** Size reduction of the given material using Cutter Mill and Ball Mill.
- 4. **Granulation Process:** Use of Fluid Bed Granulator and Dryer for preparing granules.
- 5. **Tablet Preparation Methods:** Tablets preparation by direct compression, wet granulation, and dry granulation methods.
- **6.** Compression and Compaction Analysis: a) Evaluation of tabletability, manufacturability, compressibility, compactability. b) Determining yield pressure by Heckel analysis. c) USP 1062 profiling.
- 7. **Defects in Tablet Manufacturing:** a) Identification of defects arising during tablet manufacturing and remedies for those defects. b) Find the defects for the given tablets and draw control charts for fraction defective tablets.

### **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 3. Allen, L. V. (2017). *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*: Wolters Kluwer Health.
- 4. Augsburger, L. L., & Hoag, S. W. (2016). Pharmaceutical Dosage Forms Tablets: CRC Press.
- 5. Augsburger, L. L., & Hoag, S. W. (2017). Pharmaceutical Dosage Forms: Capsules: CRC Press.
- 6. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 7. Brun, P. L., Crauste-Manciet, S., Krämer, I., Smith, J., & Woerdenbag, H. (2023). *Practical Pharmaceutics: An International Guideline for the Preparation, Care and Use of Medicinal Products:*Springer International Publishing.
- 8. Brunaugh, A. D., Moraga-Espinoza, D., Bahamondez-Canas, T. F., Smyth, H. D. C., & Williams, R. O. (2024). *Essential Pharmaceutics*: Springer International Publishing.
- 9. Denton, P., & Rostron, C. (2013). Pharmaceutics: The Science of Medicine Design: OUP Oxford.
- 10. European Pharmacopeia (11th edition). European Directorate for the Quality of Medicines & Healthcare.
- 11. Fahr, A., & Scherphof, G. L. (2018). Voigt's Pharmaceutical Technology: Wiley.
- 12. Florence, A. T., & Siepmann, J. (2016). Modern Pharmaceutics, Two Volume Set: CRC Press.
- 13. Hickey, A. J., & Giovagnoli, S. (2025). *Pharmaceutical Powder and Particles*: Springer Nature Switzerland.
- 14. Koo, O. M. Y. (2016). Pharmaceutical Excipients: Properties, Functionality, and Applications in Research and Industry: Wiley.
- 15. Nayak, A. K., Pal, K., Banerjee, I., Maji, S., & Nanda, U. (2021). Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies: Academic Press.
- 16. Nema, S., & Ludwig, J. D. (2016). Pharmaceutical Dosage Forms Parenteral Medications: Volume 3: Regulations, Validation and the Future: CRC Press.
- 17. Parikh, D. M. (2024). *Handbook of Pharmaceutical Granulation Technology*: Taylor & Francis Group.
- 18. Patravale, V. B., Disouza, J. I., & Rustomjee, M. (2016). *Pharmaceutical Product Development: Insights Into Pharmaceutical Processes, Management and Regulatory Affairs*: CRC Press.
- 19. Qiu, Y., Chen, Y., Zhang, G. G. Z., Yu, L., & Mantri, R. V. (2016). Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice: Academic Press.
- 20. Swarbrick, J. (2013). Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print): Taylor & Francis.
- 21. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 22. Tovey, G. D. (2018). Pharmaceutical Formulation: The Science and Technology of Dosage Forms: RSC.
- 23. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention.

## Pharmaceutics-IVB: Industrial Pharmacy-II

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Develop a pharmaceutical industry layout design with all its components.
- 2. Understand the role of manufacturing equipment design and developing new technologies in pharmaceutical engineering.

## **Contents**

# 1. Pharmaceutical Facility Design Principles

- i. Overview of pharmaceutical manufacturing facilities and their importance.
- ii. Key concepts in facility design, including compliance with Good Manufacturing Practices (GMP) and international regulations. With special reference to Oral Solid Dosage (OSD), Semi-Solids, Liquid, Sterile Manufacturing, Packaging and Warehousing Facilities.
- iii. Importance of process, personnel, and material flow in facility layout.

# 2. Architectural Design Considerations

- i. Hygienic zones and design details to prevent contamination.
- ii. Selection of materials for pharmaceutical manufacturing areas to ensure cleanliness and compliance.

# 3. Facility Utility Systems

- i. Heating, Ventilation, and Air Conditioning (HVAC) Systems: Design and function of HVAC systems in pharmaceutical facilities and Importance of maintaining controlled environments for product quality and compliance.
- ii. Other Utility Systems: a) Supply air handling, exhaust, and return air systems. b) Vapor and fume handling and treatment. c) Process and piping systems. d) Fire protection and electrical systems. e) Design considerations for hazardous areas.

### 5. Regulatory Compliance and Safety Standards

- i. Overview of building and zoning codes relevant to pharmaceutical facilities.
- ii. Occupational health and safety considerations, including: a) Accident prevention and control. b) Electrical safety and fire protection. c) Handling hazardous and reactive materials.
- **6. Pressure Vessels, Reactors, and Fermenters:** a) Basics of pressure vessel design. b) Fundamentals of pharmaceutical reactors. c) Heat and mass transfer aspects of reactors. d) Safety and fire hazard considerations in reactors.
- **7. Reliability, Availability, and Maintainability (RAM):** a) Introduction to RAM concepts. b) Role of reliability and maintainability in pharmaceutical manufacturing

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Assess the impact of package and packaging materials and processes on pharmaceutical products.
- 2. Pharmaceutical quality evaluation and characterization by statistical analysis.

# **Course Content:**

- Ointment and Paste Preparation: Preparation of Ointment and Paste using Three Roller Mills.
- 2. **Preparation of Effervescent Granules:** Preparation of Effervescent Sodium Phosphate Granules using the fusion method.
- 3. **Emulsion Preparation:** Preparation of Emulsion using bench top industrial homogenizers.
- 4. Lyophilization Process: Preparation of Lyophilized formulation using Freeze dryers.
- 5. **Film Coating Techniques:** Aqueous film coating and non-aqueous film coating of the given tablets.
- 6. Sugar Coating of Tablets: Sugar Coating of the given tablets.
- 7. **Enteric Coating:** Enteric Coating of tablets.
- 8. **Fluid Bed Coating:** Fluid bed coating using Wurster Coater for pellets.
- 9. **Single Point Dissolution Test:** Single Point Dissolution test to evaluate tablet performance.

10. **Statistical Evaluation of Pharmaceutical Quality:** Quality evaluation of tablets using control charts and statistical analysis to assess manufacturing consistency.

Note: Visit of at least five (05) renowned pharmaceutical industries

# **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Agalloco, J. P., DeSantis, P., Grilli, A., & Pavell, A. (2022). *Handbook of Validation in Pharmaceutical Processes*: CRC Press.
- 3. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 4. Allen, L. V. (2017). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems: Wolters Kluwer Health.
- 5. Asif, E. S. (2021). Pharmaceutical Vendors Approval Manual: A Comprehensive Quality Manual for API and Packaging Material Approval: CRC Press.
- 6. Asif, E. S., & Usmani, S. B. (2024). Basics of Pharmaceutical Manufacturing and Quality Operations: A Comprehensive Guide: CRC Press.
- 7. Augsburger, L. L., & Hoag, S. W. (2016). Pharmaceutical Dosage Forms Tablets: CRC Press.
- 8. Augsburger, L. L., & Hoag, S. W. (2017). Pharmaceutical Dosage Forms: Capsules: CRC Press.
- 9. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 10. Bunn, G. P. (2019). Good Manufacturing Practices for Pharmaceuticals, Seventh Edition: CRC Press.
- 11. European Pharmacopeia (11th edition). European Directorate for the Quality of Medicines & Healthcare.
- 12. Fahr, A., & Scherphof, G. L. (2018). Voigt's Pharmaceutical Technology: Wiley.
- 13. Haider, S. I. (2018). Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries: Taylor & Francis Group.
- 14. Haider, S. I., & Asif, E. S. (2012). Quality Operations Procedures for Pharmaceutical, API, and Biotechnology: Taylor & Francis.
- 15. Haider, S. I., & Asif, E. S. (2018). Quality Control Training Manual: Comprehensive Training Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories: CRC Press.
- 16. Hickey, A. J., & Ganderton, D. (2016). Pharmaceutical Process Engineering: CRC Press.
- 17. Hout, S. A. (2021). Sterile Manufacturing: Regulations, Processes, and Guidelines: CRC Press.
- 18. Jacobs, T., & Signore, A. A. (2022). Good Design Practices for GMP Pharmaceutical Facilities: CRC Press.
- 19. Kolhe, P., Shah, M., & Rathore, N. (2016). Sterile Product Development: Formulation, Process, Quality and Regulatory Considerations: Springer New York.
- 20. Prager, G. (2018). Practical Pharmaceutical Engineering. Wiley.
- 21. Qiu, Y., Chen, Y., Zhang, G. G. Z., Yu, L., & Mantri, R. V. (2016). Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice: Academic Press.
- 22. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 23. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention.

# Pharmaceutics-VA: Biopharmaceutics and Pharmacokinetics-I

# **Course Learning Outcomes:**

After completion of this course the students will be able to

1. Demonstrate the inter-relationship of the physico-chemical properties of the drug, the

- dosage forms and the route of administration.
- 2. Principles of bioavailability, bioequivalence and data analysis.

### **Course Content:**

- 1. Introduction and fundamentals of Biopharmaceutics and Pharmacokinetics: Biopharmaceutics, biopharmaceutics classification system (BCS), Pharmacokinetics, drug disposition, bioavailability and bioequivalence.
- 2. **Drug Absorption:** Drug absorption mechanisms, Physicochemical, physiological and formulation factors affecting drug bioavailability. Absorption of different oral dosage forms.
- 3. Biopharmaceutics of Topical, Transdermal, inhalation and injectable formulations
- 4. Biopharmaceutics assessment using in vitro, in silico, in situ and ex vivo tools
- 5. **Bioavailability and Bioequivalence:** Introduction, Bioavailability types, parameters, significance and study protocol, Methods of Assessment of Bioavailability, Bioequivalence study designs, components and application, Biowaivers.
- 4. **Drug Metabolism and Elimination:** Drug Metabolism, Drug Elimination, Drug Biotransformation reactions, (Phase-I reactions and phase-II reactions), First pass effect.
- 5. **Drug Excretion and Clearance:** Renal excretion, Tubular Secretion and Tubular Reabsorption. Pulmonary excretion, Biliary excretion, salivary excretion, Mammilary excretion, Skin excretion and Genital excretion. Drug clearance and factors affecting drug clearance.
- **6. Protein Binding:** Introduction, types, kinetics, determination and clinical significance of drug-protein binding.
- 7. Biopharmaceutical Aspects in Developing a Dosage Form: Role of biopharmaceutics in developing a new dosage form. Biopharmaceutical evaluation of dosage forms. Biopharmaceutics classification system (BCS). Introduction to invitro in vivo (IVIVC) correlation studies.

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

1. Demonstrate the inter-relationship of the physico-chemical properties of the drug, the dosage forms and the route of administration.

### **Course Content:**

- 1. **Ionization Studies:** Investigate the effect of various physiological pH on the percentage ionization of different drugs.
- Permeability Assessments: Conduct permeability studies of selected drugs, including
  acidic salt of weakly basic drugs and basic salt of weakly acidic drugs, Dialysis membranes,
  Franz diffusion cells.
- 3. **Partition Coefficient Determinations:** Determine the true partition coefficient and distribution coefficient of selected drugs.
- 4. **Effective Permeability Coefficient:** Determine the apparent/effective permeability coefficient of selected drugs.
- 5. **Noyes-Whitney Equation Application:** Study the effect of Noyes-Whitney's equation parameters on the percentage drug release.
- **6. Formulation and Process Variables:** Examine the impact of different formulation and process variables on the percentage drug release.
- 7. **In Vitro-In Vivo Correlation (IVIVC):** Develop IVIVC for two model drugs by comparing dissolution profiles with in-vivo data.

### **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 3. Banakar, U. V. (2021). Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond: Wiley.
- 4. Batchelor, H. (2021). Biopharmaceutics: From Fundamentals to Practice: Wiley.
- 5. Berner, B., Gordi, T., Benson, H. A. E., & Roberts, M. S. (2021). *Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics*: Wiley.
- 6. Boroujerdi, M. (2015). Pharmacokinetics and Toxicokinetics: Taylor & Francis.
- 7. Chow, S. C., & Liu, J. (2009). Design and Analysis of Bioavailability and Bioequivalence Studies: CRC Press.
- 8. Curry, S. H., & Whelpton, R. (2022). Drug Disposition and Pharmacokinetics: Principles and Applications for Medicine, Toxicology and Biotechnology: Wiley.
- 9. Derendorf, H., & Schmidt, S. (2019). Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications: Wolters Kluwer Health.
- 10. Dressman, J. B., & Reppas, C. (2016). Oral Drug Absorption: Prediction and Assessment, Second Edition: CRC Press.
- 11. Ducharme, M. P., Shargel, L., & Yu, A. B. C. (2022). Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th Edition: McGraw Hill LLC.
- 12. Jambhekar, S. S., & Breen, P. J. (2024). Basic Pharmacokinetics: Pharmaceutical Press.
- 13. Krishna, R., & Yu, L. (2010). Biopharmaceutics Applications in Drug Development: Springer US.
- 14. Mukherjee, B. (2022). *Pharmacokinetics: Basics to Applications*: Springer Nature Singapore.
- 15. Niazi, S. K. (2014). Handbook of Bioequivalence Testing, Second Edition: Taylor & Francis.
- 16. Rosenbaum, S. E. (2016). Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations: Wiley.
- 17. Sarmento, B., Pereira, C. L., & Das Neves, J. (2024). Concepts and Models for Drug Permeability Studies: Cell and Tissue based In Vitro Culture Models: Woodhead Publishing.
- 18. Steffansen, B., Brodin, B., & Nielsen, C. U. (2010). Molecular Biopharmaceutics: Aspects of Drug Characterisation, Drug Delivery and Dosage Form Evaluation: Pharmaceutical Press.
- 19. Sugano, K. (2012). Biopharmaceutics Modeling and Simulations: Theory, Practice, Methods, and Applications: Wiley.
- 20. Swarbrick, J. (2013). Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print): Taylor & Francis.
- 21. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 22. Washington, N., Washington, C., & Wilson, C. (2000). Physiological Pharmaceutics: Barriers to Drug Absorption: Taylor & Francis.

# Pharmaceutics-VA: Biopharmaceutics and Pharmacokinetics-II

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze the pharmacokinetic behavior of drug administered different routes and pathological condition.
- 2. Principles of bioavailability, bioequivalence and data analysis.
- 3. Understand pharmacokinetic modelling and its applications.

### **Course Content:**

- 1. **Pharmacokinetics**: Introduction, Linear and Non-linear Pharmacokinetics Application of pharmacokinetics in various situations. Pharmacokinetics and its related fields (Clinical Pharmacokinetics, population pharmacokinetics, Pharmacodynamics, Toxicokinetic, Clinical toxicology, clinical pharmacology, forensic science, therapeutic drug monitoring, pharmacogenetics).
- 2. **Biological Half Life and Volume of Distribution:** Zero order and first order half-life, factors affecting and application of half-life. Apparent volume of distribution, concepts and factors affecting volume of distribution.
- 3. **Pharmacokinetic modelling**: Introduction and types of PK modelling, Compartment models, Non-compartmental approach, Concept and PK parameters after IV bolus single dose administration. Compartment models for extravascular administration of Drugs. Application of compartment models to determine various PK parameters of extra-vascularly administered drugs. Concepts of Wagner-Nelson Method, Flip-flop Phenomenon, Loo-Riegelman Method.
- 4. **Multiple Dosage Regimen**: Introduction, concept and PK parameters in Multiple dosing Pharmacokinetics after IV administration, Drug Accumulation and Principle of superposition.
- 5. **Pharmacokinetics of Intravenous Infusions**: Introduction and assessment of various parameters in Pharmacokinetics of IV infusion.
- 6. **Pharmacokinetics Variations in Disease States**: Determination of pharmacokinetics variations in renal and hepatic diseases, general approaches for dose adjustment in renal and hepatic diseases.
- 7. Pharmacokinetic and Pharmacodynamic (PK/PD) correlation.
- 8. Introduction to in-silico mechanistic modelling for physiologically based pharmacokinetic (PBPK) and whole body PBPK.

### **Practical**

## **Course Learning Outcomes:**

At the end of this course the student will be able to:

1. Analyze the pharmacokinetic behavior of drugs administered via different routes and under various pathological conditions.

### **Course Content:**

- 1. **Pharmacokinetic Parameter Computation:** Compute pharmacokinetic parameters using simulated pharmacokinetic models.
- 2. **Bioanalytical Method Development:** Demonstration and understanding of bioanalytical methods for the quantification of drugs in biological matrices using High-Performance Liquid Chromatography (HPLC).
- 3. **Bioavailability Calculations:** Calculate the bioavailability (F) of drugs and compare Area Under the Curve (AUC<sub>0</sub>- $\infty$ ) for oral versus intravenous administration using published data.
- 4. **Determination of Biological Half Life:** Zero order and first order half-life.
- **5. Bioequivalence Studies:** Demonstration of Bioequivalence Assessment and determination of various parameters based on ICH/FDA guidelines.
- **6. Computational Pharmacokinetics:** Utilize in-silico and computational methods to calculate compartmental, non-compartmental, Physiologically Based Pharmacokinetic (PBPK), and population pharmacokinetic parameters using various software tools such as PK-Sim, Phoenix WinNonlin, Monolix, Simcyp, and NONMEM.

# **Recommended Readings**

- 1. Adejare, A. (2020). Remington: The Science and Practice of Pharmacy: Academic Press.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.

- 3. Banakar, U. V. (2021). Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond: Wiley.
- 4. Batchelor, H. (2021). Biopharmaceutics: From Fundamentals to Practice: Wiley.
- 5. Berner, B., Gordi, T., Benson, H. A. E., & Roberts, M. S. (2021). *Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics*: Wiley.
- 6. Boroujerdi, M. (2015). Pharmacokinetics and Toxicokinetics: Taylor & Francis.
- 7. Chow, S. C., & Liu, J. (2009). Design and Analysis of Bioavailability and Bioequivalence Studies: CRC Press.
- 8. Curry, S. H., & Whelpton, R. (2022). Drug Disposition and Pharmacokinetics: Principles and Applications for Medicine, Toxicology and Biotechnology: Wiley.
- 9. Derendorf, H., & Schmidt, S. (2019). Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications: Wolters Kluwer Health.
- 10. Dressman, J. B., & Reppas, C. (2016). Oral Drug Absorption: Prediction and Assessment, Second Edition: CRC Press.
- 11. Ducharme, M. P., Shargel, L., & Yu, A. B. C. (2022). Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th Edition: McGraw Hill LLC.
- 12. Jambhekar, S. S., & Breen, P. J. (2024). Basic Pharmacokinetics: Pharmaceutical Press.
- 13. Krishna, R., & Yu, L. (2010). Biopharmaceutics Applications in Drug Development: Springer US.
- 14. Mukherjee, B. (2022). Pharmacokinetics: Basics to Applications: Springer Nature Singapore.
- 15. Niazi, S. K. (2014). Handbook of Bioequivalence Testing, Second Edition: Taylor & Francis.
- 16. Rosenbaum, S. E. (2016). Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations: Wiley.
- 17. Sarmento, B., Pereira, C. L., & Das Neves, J. (2024). Concepts and Models for Drug Permeability Studies: Cell and Tissue based In Vitro Culture Models: Woodhead Publishing.
- 18. Steffansen, B., Brodin, B., & Nielsen, C. U. (2010). Molecular Biopharmaceutics: Aspects of Drug Characterisation, Drug Delivery and Dosage Form Evaluation: Pharmaceutical Press.
- 19. Sugano, K. (2012). Biopharmaceutics Modeling and Simulations: Theory, Practice, Methods, and Applications: Wiley.
- 20. Swarbrick, J. (2013). Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print): Taylor & Francis.
- 21. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 22. Washington, N., Washington, C., & Wilson, C. (2000). Physiological Pharmaceutics: Barriers to Drug Absorption: Taylor & Francis.

# Pharmaceutics-VI: Pharmaceutical Quality Management Systems

## **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Identify components of quality management systems in the manufacturing of therapeutic goods.
- 2. Document the industrial compliance protocols.
- 3. Practice quality assurance and its applications in the manufacturing of therapeutic goods

### **Course Content:**

- 1. Pharmaceutical Quality Management System (PQM):
  - Definition of Quality, Determinants of Drug Quality, International Drug Compendia and Regulatory Bodies, Conformance to Regulatory Standards and Consequences of Noncompliance.

- ii. Elements and Description of PQM, Key Objectives of QMS, Various Models of QMS; ICH Q10, ISO 9001:2015, FDA 21 CFR Part 820
- iii. Definition and Objectives of Good Manufacturing Practices (cGMP)
- iv. Good Documentation Practices, Good storage practices (GSP)
- v. Overview of International cGMP Guidelines: WHO GMP Guidelines, FDA 21 CFR Part 211, PICS, ISPE, MHRA-UK, EU, DRAP
- 2. **Core Components of QMS**: Quality Manual, Standard Operating Procedures (SOPs), Good Documentation Practices (GDPs), ALCOA Principles, Approval, Update, and Archival of Documents, Drug Master Files / Active Pharmaceutical Ingredients (APIs), cGMP Training, Production and Packaging Operations.
- 3. Validation in Pharmaceutical Industry:
  - i. Introduction to Validation, Types and Stages of Validation, Validation and Qualification, Calibration and Verification, Validation Master Plan.
  - ii. Prospective Process Validation (life-cycle approach), Retrospective Process Validation, Concurrent Validation.
  - iii. Qualification of Systems and Equipment.
  - iv. Cleaning Validation, Validation of Sterilization Methods.
  - v. Validation of Water and Air Handling Systems
  - vi. Validation of Computerized Systems

### **Recommended Readings**

- 1. Akers, M. J. (2016). Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality: CRC Press.
- 2. Asif, E. S. (2021). Pharmaceutical Vendors Approval Manual: A Comprehensive Quality Manual for API and Packaging Material Approval: CRC Press.
- 3. Botet, J. (2015). Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook: Bentham Science Publishers, Limited.
- 4. Breitkreitz, M. C., & Goicoechea, H. (2023). *Introduction to Quality by Design in Pharmaceutical Manufacturing and Analytical Development:* Springer International Publishing
- 5. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 6. Çelik, M. (2016). Pharmaceutical Powder Compaction Technology: CRC Press.
- 7. European Pharmacopeia (11<sup>th</sup> edition). European Directorate for the Quality of Medicines & Healthcare.
- 8. Gad, S. C. (2008). Pharmaceutical Manufacturing Handbook: Regulations and Quality: Wiley.
- 9. Ghante, M., Potdar, M., & Bhusari, V. (2024). Modern Aspects of Pharmaceutical Quality Assurance: Developing & Proposing Application models, SOPs, practical audit systems for Pharma Industry: Springer Nature Singapore.
- 10. Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories: CRC Press.
- 11. Haider, S. I., & Asif, E. S. (2012). *Quality Operations Procedures for Pharmaceutical, API, and Biotechnology:* Taylor & Francis.
- 12. Haider, S. I., & Asif, E. S. (2018). *Quality Control Training Manual: Comprehensive Training:* CRC Press
- 13. Jain, N. K., & Bajwa, N. (2024). Introduction to Quality by Design (QbD): From Theory to Practice: Springer Nature Singapore.
- 14. Jameel, F., Hershenson, S., Khan, M. A., & Martin-Moe, S. (2016). *Quality by Design for Biopharmaceutical Drug Product Development*: Springer New York.

- 15. Kolhe, P., Shah, M., & Rathore, N. (2016). Sterile Product Development: Formulation, Process, Quality and Regulatory Considerations: Springer New York.
- 16. Mittal, B. (2019). How to Integrate Quality by Efficient Design (QbED) in Product Development: Elsevier Science.
- 17. Patravale, V. B., Disouza, J. I., & Rustomjee, M. (2016). *Pharmaceutical Product Development: Insights Into Pharmaceutical Processes, Management and Regulatory Affairs:* CRC Press.
- 18. Schlindwein, W. S., & Gibson, M. (2018). *Pharmaceutical Quality by Design: A Practical Approach:* Wiley.
- 19. Shargel, L., & Kanfer, I. (2013). Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition: CRC Press.
- United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention
- 21. Welty, G. (2013). Quality Assurance: Problem Solving and Training Strategies for Success in the Pharmaceutical and Life Science Industries: Woodhead Publishing.
- 22. Wingate, G. (2016). Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance: CRC Press.

# Pharmaceutics-VIIA: Pharmaceutical Technology I

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explore the recent advancements in pharmaceutical technologies.
- 2. Describe and demonstrate the emerging concepts and techniques in the development of novel drug delivery systems.

### **Course Content:**

- 1. **Novel Drug Delivery Systems**: Definitions and concepts: modified release, controlled release, extended release, delayed release, and targeted drug delivery. Matrix systems, membrane systems, osmotic systems. Buccal, gastroretentive, stimuli responsive DDS, colon-specific drug delivery systems, Hydrogels and other polymeric NDDS.
- 2. **Polymers for Modified Release Drug Delivery Systems**: Types, applications and examples.
- 3. Advanced Drug Delivery Routes: Transdermal, ocular, pulmonary, and nasal drug delivery systems.
- 4. **Pharmaceutical Nanotechnology**: Overview and formulation of polymeric nanoparticles, nanotubes, nanospheres, nanocapsules, dendrimers, liposomes, niosomes, nano-hydrogels, spray-dried particles, gold nanoparticles.
- QbD-Based Formulation Development for Modified Release Systems: Concept of Quality by Design (QbD), risk management, design of experiments, software tools for formulation design.
- 6. **Artificial Intelligence (AI) and Machine Learning in Drug Delivery**: Role of AI in controlled release, Artificial Neural Networks (ANN), AI-based formulation and process design tools.
- 7. **Emerging Technologies in Pharmaceutical Sciences:** Introduction and applications of 3D/4D/5D Printing in Pharmaceuticals, hotmelt extrusion technology and Electerospinning technology.
- 8. Introduction and Fundamentals of Computational Pharmaceutics

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explore the recent advancements in pharmaceutical technologies.
- 2. Describe and demonstrate the emerging concepts and techniques in the development of novel drug delivery systems.

### **Course Content:**

- 1. **Pre-formulation evaluation of pharmaceutical excipients**: Detailed micromeritic characterization of various powders (bulk density, tapped density, Carr's Index, Hausner's Ratio) and particle size analysis using frequency distribution and plots.
- Formulation development and optimization by Quality by Design (QbD) and Artificial Intelligence (AI): Application of DoE methodologies like Central Composite Design (CCD), Factorial Design, Box-Behnken Design in development of tablet formulations.
- 3. **Development, validation, and calibration of manufacturing processes**: Blending time, drying time, compression force analysis.
- 4. **Determination and comparison of dissolution profiles**: Perform comparative dissolution profiling using model-dependent (zero-order, first-order, Higuchi, Korsmeyer-Peppas, Baker-Lonsdale) and model-independent (f1, f2 factors) methods.
- 5. **Preparation of matrix tablets**: For poorly and highly water-soluble drugs (polymer selection and manufacturing method selection and optimization).
- 6. **Preparation and characterization of matrix-based and coated pellets**: Pelletization, spheronization, geometry, and surface analysis using stereomicroscope.
- 7. **Comparison and evaluation of swelling and disintegration profiles**: Physical analysis of expired vs. valid film-coated, enteric-coated tablets and hard gelatin capsules.

### **Recommended Readings**

- 1. Azar, A. T. (2021). Modeling and Control of Drug Delivery Systems: Academic Press.
- 2. Benson, H. A. E., Roberts, M. S., Williams, A. C., & Liang, X. (2021). Fundamentals of Drug Delivery: Wiley.
- 3. Bhupathyraaj, M., Rani, K. R. V., & Essa, M. M. (2023). Artificial intelligence in Pharmaceutical Sciences: CRC Press.
- 4. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 5. Bruschi, M. L. (2015). Strategies to Modify the Drug Release from Pharmaceutical Systems: Woodhead Publishing.
- 6. Cornier, J., Owen, A., Kwade, A., & Van de Voorde, M. (2016). *Pharmaceutical Nanotechnology: Innovation and Production*: Wiley.
- 7. Donnelly, R. F., & Singh, T. R. R. (2015). *Novel Delivery Systems for Transdermal and Intradermal Drug Delivery*: Wiley.
- 8. Donnelly, R. F., Singh, T. R. R., Morrow, D. I. J., & Woolfson, A. D. (2012). *Microneedle-mediated Transdermal and Intradermal Drug Delivery*: Wiley.
- 9. European Pharmacopeia (11th edition). European Directorate for the Quality of Medicines & Healthcare.
- 10. Florence, A. T., & Siepmann, J. (2016). Modern Pharmaceutics, Two Volume Set: CRC Press.
- 11. Ghosh, T. K. (2020). Dermal Drug Delivery: From Innovation to Production: CRC Press.
- 12. Gibson, M. (2016). Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form: CRC Press.
- 13. Grumezescu, A. M. (2017). Nanoscale Fabrication, Optimization, Scale-up and Biological Aspects of Pharmaceutical Nanotechnology: Elsevier.
- 14. Hillery, A., & Park, K. (2016). Drug Delivery: Fundamentals and Applications, Second Edition: CRC Press.

- 15. Ita, K. (2020). Transdermal Drug Delivery: Concepts and Application: Academic Press.
- 16. Martins, J. P., & Santos, H. A. (2020). Nanotechnology for Oral Drug Delivery: From Concept to Applications: Elsevier Science.
- 17. Mohapatra, S., Ranjan, S., Dasgupta, N., Thomas, S., & Mishra, R. K. (2018). *Nanocarriers for Drug Delivery: Nanoscience and Nanotechnology in Drug Delivery:* Elsevier Science.
- 18. Nayak, A. K., Pal, K., Banerjee, I., Maji, S., & Nanda, U. (2021). Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies: Academic Press.
- 19. Opara, E. (2023). Controlled Drug Delivery Systems: Taylor & Francis Group.
- 20. Ouyang, D., Smith, S. C., Douroumis, D., Fahr, A., Siepmann, J., Snowden, M. J., & Torchilin, V. P. (2015). *Computational Pharmaceutics: Application of Molecular Modeling in Drug Delivery*: Wiley Press.
- 21. Rathbone, M., Hadgraft, J., Roberts, M. S., & Lane, M. E. (2008). *Modified-Release Drug Delivery Technology:* CRC Press.
- 22. Saharan, V. A. (2022). Computer Aided Pharmaceutics and Drug Delivery: An Application Guide for Students and Researchers of Pharmaceutical Sciences: Springer Nature Singapore.
- 23. Swarbrick, J. (2013). Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, Six Volume Set (Print): Taylor & Francis.
- 24. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention
- 25. Vizirianakis, I. S. (2014). Handbook of Personalized Medicine: Advances in Nanotechnology, Drug Delivery, and Therapy: Pan Stanford.
- 26. Washington, N., Washington, C., & Wilson, C. (2000). *Physiological Pharmaceutics: Barriers to Drug Absorption*: Taylor & Francis.
- Weissig, V., & Elbayoumi, T. (2020). Pharmaceutical Nanotechnology: Basic Protocols: Springer New York.
- 28. Wen, H., & Park, K. (2011). Oral Controlled Release Formulation Design and Drug Delivery: Theory to Practice: Wiley.
- 29. Wilson, C. G., & Crowley, P. J. (2011). Controlled Release in Oral Drug Delivery: Springer US.

# Pharmaceutics VIIB: Pharmaceutical Technology II

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain the development of biological, biotechnological, and biosimilar products.
- 2. Describe and demonstrate the emerging concepts and techniques in the development of novel drug delivery systems.

### **Course Content:**

- 1. Scope, Application, and New Findings in Pharmaceutical Biotechnology: Innovations, research frontiers, development, and production techniques of products like Antibiotics, amino acids, insulin, enzymes, vaccines, etc.
- 2. Role of Pharmaceutical Biotechnology in New Product Development (NPD): How biotechnology influences drug development pipelines
- Gene Drug Delivery Systems: Concepts, technologies, and applications in gene-based products (mRNA, siRNA etc., based vaccines and therapeutics. Development pipelines and future outlook).
- 4. **Biosimilars and Biobetters**: Introduction, regulatory perspectives, development challenges and business opportunities.
- 5. **Artificial Intelligence Applications in Biotechnology**: AI in biologics development, quality prediction, and bioprocess optimization.

### 6. Monoclonal & Polyclonal antibodies:

Antibody structure, Development of antibody-based therapeutics, Methods of Production and characterization, Applications of monoclonal and polyclonal antibodies

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explore the recent advancements in pharmaceutical technologies.
- 2. Describe and demonstrate the emerging concepts and techniques in the development of novel drug delivery systems.

### **Course Content:**

- 1. **Development of transdermal patches**: Formulation of patches with suitable active pharmaceutical ingredients (APIs).
- 2. Preparation of microemulsions:
- 3. **Preparation of dissolving microneedles**: Fabrication techniques for transdermal drug delivery.
- 4. **Development of fast dispersible tablets and gastroretentive floating tablets**: Evaluation of buoyancy parameters.
- 5. Preparation and characterization of pharmaceutical hydrogels.
- 6. Molecular Biology and Biotechnology Techniques
  - a. Demonstration and understanding of the following techniques.
  - b. Extraction of nucleic acids (DNA/RNA)
  - c. Polymerase chain reaction (PCR)
  - d. Gel electrophoresis (DNA/Protein)
  - e. DNA quantification
  - f. Sequencing techniques
  - g. Antigen-antibody based reactions

### **Recommended Readings**

- 1. Aebisher, D. (2020). *An Essential Guide to Biopharmaceuticals:* Nova Science Publishers, Incorporated.
- 2. Al-Achi, A., Gupta, M. R., & Stagner, W. C. (2022). Integrated Pharmaceutics: Applied Preformulation, Product Design, and Regulatory Science: Wiley.
- 3. Allen, L. V. (2021). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems: Wolters Kluwer Health.
- 4. Altman, R. B., Altman, R., Flockhart, D., & Goldstein, D. B. (2012). *Principles of Pharmacogenetics and Pharmacogenomics:* Cambridge University Press.
- 5. British Pharmacopeia Commission (2024). *British Pharmacopeia 2025*. Medicines and Healthcare Products Regulatory Agency.
- 6. Crommelin, D. J. A., Sindelar, R. D., & Meibohm, B. (2024). *Pharmaceutical Biotechnology: Fundamentals and Applications:* Springer International Publishing.
- 7. Curry, S. H., & Whelpton, R. (2022). Drug Disposition and Pharmacokinetics: Principles and Applications for Medicine, Toxicology and Biotechnology: Wiley.
- 8. Donnelly, R. F., & Singh, T. R. R. (2015). *Novel Delivery Systems for Transdermal and Intradermal Drug Delivery*: Wiley.
- 9. Donnelly, R. F., Singh, T. R. R., Morrow, D. I. J., & Woolfson, A. D. (2012). *Microneedle-mediated Transdermal and Intradermal Drug Delivery*: Wiley.

- 10. European Pharmacopeia (11th edition). European Directorate for the Quality of Medicines & Healthcare.
- 11. Fahr, A., & Scherphof, G. L. (2018). Voigt's Pharmaceutical Technology. Wiley.
- 12. Florence, A. T., & Siepmann, J. (2016). Modern Pharmaceutics, Two Volume Set: CRC Press.
- 13. Ghosh, T. K. (2020). Dermal Drug Delivery: From Innovation to Production: CRC Press.
- 14. Gutka, H. J., Yang, H., & Kakar, S. (2018). *Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development:* Springer International Publishing.
- 15. Haider, S. I., & Asif, E. S. (2012). *Quality Operations Procedures for Pharmaceutical, API, and Biotechnology:* Taylor & Francis.
- 16. Hillery, A., & Park, K. (2016). Drug Delivery: Fundamentals and Applications, Second Edition: CRC Press.
- 17. Ho, R. J. Y. (2013). Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs: Wiley.
- 18. Ita, K. (2020). Transdermal Drug Delivery: Concepts and Application: Academic Press.
- 19. Jameel, F., Hershenson, S., Khan, M. A., & Martin-Moe, S. (2016). *Quality by Design for Biopharmaceutical Drug Product Development*: Springer New York.
- 20. Liu, C., & Morrow, K. J. (2016). Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical, and Clinical Development: Wiley.
- 21. Pathak, Y. (2022). Gene Delivery Systems: Development and Applications: CRC Press.
- 22. Rathbone, M., Hadgraft, J., Roberts, M. S., & Lane, M. E. (2008). *Modified-Release Drug Delivery Technology:* CRC Press.
- 23. Rathore, A. S., Baseman, H., & Rudge, S. (2023). Process Validation in Manufacturing of Biopharmaceuticals: CRC Press.
- 24. Taylor, K., & Aulton, M. E. (2021). Aulton's Pharmaceutics: The Design and Manufacture of Medicines: Elsevier.
- 25. United States Pharmacopeia-National Formulary (USP-NF 2024). United States Pharmacopeial Convention

### PHARMACOGNOSY:

### Pharmacognosy-IA (Basic-I)

### **Course Learning Outcomes:**

After completing this course, students will be able to:

- 1. Explain pharmacognosy's historical development, scope, and modern concepts, including its role in the national economy and herbal pharmacopoeias.
- 2. Demonstrate an understanding of traditional and alternative systems of medicine, such as Unani, Ayurveda, Homeopathy, and Traditional Chinese Medicine.
- 3. Identify, classify, and describe the sources, constituents, and uses of plant, animal, mineral, and microbial origin crude drugs.
- 4. Evaluate crude drugs using organoleptic and microscopic methods, also recognize types of adulteration in crude drugs.
- 5. Perform practical skills like section cutting and powder drug microscopy in the lab.

### **Contents:**

### 1. General Introduction and Scope of Pharmacognosy

- i. Historical development, scope and importance of pharmacognosy
- ii. Role of medicinal plants in the national economy
- iii. Flora of Pakistan and indigenous medicinal plant resources
- iv. Study of herbal pharmacopoeia

- v. Modern concepts of pharmacognosy and the role of pharmacognosist
- vi. Traditional and alternative systems of medicine (Unani, Ayurveda, Homeopathy, Chinese Traditional Medicine,)

# 2. Crude Drugs

- i. Introduction and sources of crude drugs
- ii. Preparation of crude drugs for commercial market and industry: Cultivation, collection, garbling, drying, storage, preservation, and packaging
- iii. Regulatory guidelines for the cultivation and collection of herbal drugs
- iv. Classification of crude drugs with special emphasis on chemical and therapeutic system of classification
- v. Organoleptic and microscopic evaluation of crude drugs
- vi. Definition, types and detection of adulteration

# 3. Drugs from Plants: Carbohydrates, Fixed oils, Resins, Tannins, Phytoenzymes

- i. Carbohydrates: Cellulose, Tragacanth, Acacia, Agar, Xanthan, Algin, Pectin
- ii. Fixed oils: Castor oil, Olive oil, Coconut oil, Almond oil, Linseed oil, Mustard oil
- iii. Resins: Introduction, classification, active constituents and medicinal uses of Jalap, Asafoetida, Cannabis, Podophyllum
- iv. Tannins: Introduction, classification, identification tests. Study of Catechu, Nutgall, Myrobalan
  - v. Phytoenzymes: Papain, Bromelain and Malt Extract

# 4. Drugs from Animal, Mineral and Microbial Origin

- i. Animal origin drugs: Honey, Gelatin, Musk, Shellac, Cantharide, Cod liver oil, Rennin, Pepsin, Pancreatin, Pancrealipase, Chymotrypsin
- ii. Mineral origin drugs: Shilajeet, Asbestos, Kaolin
- iii. Microbial origin drugs: Penicillin, Streptomycin, Streptokinase, Serratiopeptidase, Sutilains, Asparaginase

### **Practical**

# 1. Organoleptic (Macroscopic) Evaluation of Crude Drugs

- i. Evaluation of organized crude drugs, i.e., roots, rhizomes, barks, leaves, flowers, fruits and seeds.
- ii. Evaluation of unorganised drugs, i.e., gums, latex, exudates and oils

### 2. Microscopic Evaluation of Crude Drugs

- Transverse section cutting and staining:
   Introduction and methodology of transverse section cutting and staining for root, fruit, leaf, stem and bark crude drugs.
- ii. Powder microscopy of crude drugs:
   Microscopic evaluation of powdered crude drugs and their comparison with the standard monographs.

(Note: A minimum of 10 practicals will be conducted.)

### **Recommended Readings**

- 1. Evans, W. C. (2020). Trease and Evans' Pharmacognosy (17th ed), Saunders.
- 2. Perveen, S. (2021). Pharmacognosy: Medicinal plants. IntechOpen.
- 3. Heinrich, M., Barnes, J., Prieto-Garcia, J., Gibbons, S., & Williamson, E. M. (2017). Fundamentals of Pharmacognosy and Phytotherapy, Elsevier Health Sciences.
- 4. Kayne, S. B. (2008). Textbook of Complementary and Alternative Medicine (2<sup>nd</sup> ed.). Pharmaceutical Press.

- 5. Hussain, A., & Qarshi, I. A. (2021). Dictionary of Pakistani Medicinal Plants (Vol. I). Qarshi University Lahore.
- 6. Dastur, J. F. (1970). Medicinal Plants of India and Pakistan. D B Taraporevala Sons & Co Private Ltd.
- 7. Rasool, S. (2024). Textbook of Pharmacognosy, theory and practicals. CNC Publisher.
- 8. Tyler, V. E., Brady, L. R., & Robbers, J. E. (1988). Pharmacognosy (9<sup>th</sup> ed.). Philadelphia, PA: Lea & Febiger.
- 9. Jackson, B. P., & Snowdon, D. W. (1968). Powdered Vegetable Drugs: An atlas of microscopy for use in the identification and authentication of some plant materials employed as medicinal agents. Churchill.
- 10. Wallis, T. E. (2005). Textbook of Pharmacognosy (5th ed.). CBS Publishers & Distributors.

# Pharmacognosy-IB (Basic-II)

# **Course Learning Outcomes:**

After completing this course, students will be able to:

- 1. Classify and describe the chemistry, extraction methods, sources, and pharmacological uses of crude drugs containing volatile oils.
- 2. Learn about classification, chemistry, source, active constituents and medicinal uses of crude drugs belonging to various classes of glycosides and alkaloids.
- 3. Understand marine natural products, highlighting their bioactive compounds and potential medicinal applications.
- 4. Reinforce theoretical knowledge through hands-on experience in extracting and identifying active constituents from crude plant materials through practical sessions.

### **Contents:**

# 1. Volatile Oils (Essential Oils) Containing Drugs

Introduction, significance, methods of obtaining volatile oils, chemistry, and classification of volatile oils. Study of crude drugs belonging to various classes of volatile oils, including;

- i. Hydrocarbon volatile oils: Cubeb, Turpentine
- ii. Alcoholic volatile oils: Peppermint, Coriander, Cardamom
- iii. Aldehydic volatile oils: Orange peel, Lemon peel, Lemon grass, Cinnamon
- iv. Ketonic volatile oils: Camphor, Spearmint, Caraway
- v. Phenolic volatile oils: Clove, Thyme
- vi. Phenolic ether volatile oils: Fennel, Anise, Myristica
- vii. Oxide volatile oils: Eucalyptus
- viii. Ester volatile oils: Rosemary, Lavender, Winter Green

# 2. Glycosides Containing Drugs

Introduction and classification of glycosides. Study of sources, active constituents and medicinal uses of crude drugs belonging to various classes of glycosides, including.

- i. Steroidal glycosides: Digitalis, Strophanthus
- ii. Anthraquinone glycosides: Aloe, Senna
- iii. Saponin glycosides: Glycyrrhiza, Ginseng
- iv. Cyanophore glycosides: Wild Cherry, Bitter Almond
- v. Isothiocyanate glycosides: Mustard, Moringa
- vi. Aldehyde glycosides: Vanilla
- vii. Flavonoid glycoside: Silybum
- viii. Alcoholic glycosides: Salix

# 3. Alkaloids Containing Drugs

Introduction and classification of alkaloids. Study of sources, active constituents and medicinal uses of crude drugs belonging to various classes of alkaloids, including;

- i. Pyridine-Piperidine Alkaloids: Areca, Tobacco
- ii. Tropane Alkaloids: Belladonna, Hyoscyamus, Datura
- iii. Quinoline Alkaloids: Cinchona
- iv. Isoquinoline Alkaloids: Opium, Ipecac, Berberis
- v. Indole alkaloids: Catharanthus, Rauwolfia, Ergot
- vi. Imidazole alkaloids: Pilocarpus
- vii. Steroidal alkaloids: Aconite, Ashwagandha
- viii. Alkaloidal Amines: Ephedra, Colchicum
- ix. Purine Bases: Tea, Coffee

### 4. Marine Natural Products

- i. Definition, introduction, historical perspective and present status
- ii. Classification of important bioactive agents from marine sources
- iii. Chemistry and biology of marine natural products
- iv. General methods of collection, extraction, isolation and purification
- v. Marine compounds with cardiovascular, antispasmodic, anticoagulants and antimicrobial activities

### **Practical**

The practicals of the subject shall be designed from time to time based on the above-mentioned theoretical topics and the availability of the facilities.

1. Extraction and chemical identification of phytoconstituents of crude drugs, containing carbohydrates, tannins, resins, volatile oils, glycosides and alkaloids.

# Minimum of 10 practicals will be conducted)

**NOTE:** A study tour will be an integral part of the syllabus and will be arranged before the end of the session to collect medicinal plants from the country, and a herbarium sheet will be prepared.

### **Recommended Readings:**

- 1. Heinrich, M., Barnes, J., Prieto-Garcia, J., Gibbons, S., & Williamson, E. M. (2017). Fundamentals of Pharmacognosy and Phytotherapy. Elsevier Health Sciences.
- 2. Evans, W. C. (2020). Trease and Evans' Pharmacognosy (17th ed), Saunders.
- 3. Tyler, V. E., Brady, L. R., & Robbers, J. E. (1988). Pharmacognosy (9<sup>th</sup> ed.). Philadelphia, PA: Lea & Febiger.
- 4. Wallis, T. E. (2005). Textbook of Pharmacognosy (5<sup>th</sup> ed.). CBS Publishers & Distributors.
- 5. Hussain, A., & Qarshi, I. A. (2022). Medicinal Plants of Qarshi Botanical Garden. Qarshi University Lahore.
- 6. Rasool, S. (2024). Textbook of Pharmacognosy, theory and practicals. CNC Publisher.
- 7. Shah, B. (2019). Textbook of Pharmacognosy & Phytochemistry (2<sup>nd</sup> ed.). Elsevier.
- 8. Fattorusso, E., Gerwick, W. H., & Taglialatela-Scafati, O. (2012). Handbook of Marine Natural Products. Springer.
- 9. Sha, C.L. (2024). Pharmacological Potential of Marine Natural Products. MDPI.

### Pharmacognosy-IIA (Applied)

# **Course Learning Outcomes:**

After completing this course, students will be able to:

1. Understand and apply chromatographic techniques, including paper, thin layer, and column chromatography, for the identification and isolation of natural products, with basic knowledge of advanced hyphenated techniques.

- 2. Learn conventional and modern extraction techniques used for isolating plant-based compounds.
- 3. Introduce molecular pharmacognosy techniques such as DNA barcoding, molecular markers, tissue culture, and genetic regulation of plant metabolites.
- 4. Understand the clinical relevance, efficacy, and safety of selected herbal drugs used in common ailments.
- 5. Support learning of chromatography and plant authentication by DNA barcoding through practical work.

### **Contents:**

### 1. Chromatographic Techniques for Identification and Isolation of Natural Products

- i. Introduction and types of chromatography, i.e., adsorption and partition chromatography, commonly used stationary and mobile phases in chromatography, Normal phase and reverse phase chromatography
- ii. Detailed study of chromatographic techniques, including paper chromatography, thin layer chromatography (TLC), and column chromatography
- iii. A brief introduction of hyphenated chromatographic techniques, i.e., HPLC-DAD, HPTLC-MS, GC-MS, LC-MS, GC-FTIR, LC-FTIR, LC-NMR

# 2. Extraction Techniques for Natural Products

i. Conventional extraction techniques

Definition, process, merits, and demerits of various conventional extraction techniques of natural products, including maceration, percolation, digestion, infusion, decoction, and Soxhlet extraction.

ii. Advanced extraction techniques

Definition, process, merits, and demerits of various advanced extraction techniques of natural products, including ultrasonic-assisted extraction, microwave-assisted extraction, supercritical fluid extraction, and pressurized solvent extraction.

## 3. Molecular Pharmacognosy

- i. General introduction to molecular pharmacognosy
- ii. Basic tools used in molecular pharmacognosy
- iii. Molecular authentication techniques for medicinal plants, including DNA barcoding, molecular markers like RAPD, AFLP, and SSR
- iv. Molecular methods for the detection of adulteration and substitution in drugs
- v. Metabolic pathways in plants and their genetic regulations for the production of desired constituents
- vi. Cell and tissue culture techniques
- vii. Bioprocessing technologies, including biologics
- viii. Applications of molecular pharmacognosy

### 4. Natural Medicine Practice-I

- i. General introduction
- ii. A detailed study of clinical efficacy, mechanism of action, part used, dose, dosage form, and adverse effects of herbal drugs in various ailments, including;
- iii. Skin diseases: Aloe barhadensis, Curcuma longa, Angelica archangelica, Mentha piperita, Melaleuca alternifolia, Glycyrrhiza glabra
- iv. Musculoskeletal disorders: Nigella sativa, Phycotis ajowan, Trigonella foenum-graecum, Zingiber officinale
- v. Hepatitis: Berberis vulgaris, Silybum marianum, Melaleuca alternifolia
- vi. Diabetes: Gymnema sylvestre, Momordica charantia, Cinnamomum zeylanicum, Syzygium jambulana, Withania coagulans
- vii. G.I.T. disorders: Foeniculum vulgare, Ferula foetida, Cassia angustifolia

### **Practical**

The practicals of the subject shall be designed from time to time based on the above-mentioned theoretical topics and availability of the facilities.

- 1. Chromatographic separation of various constituents from crude drugs / natural products using paper, TLC, and column chromatography.
- 2. DNA extraction and/or barcoding for plant authentication.

# Minimum of 10 practicals will be conducted)

# **Recommended Readings:**

- 1. Braithwaite, A., & Smith, F. J. (2012). Chromatographic Methods (5<sup>th</sup> ed.). Springer.
- 2. Gong, X. (2023). Separation, Extraction, and Purification of Natural Products from Plants. MDPI.
- 3. Prado, J., & Rostagno, M. (2022). Natural Product Extraction: Principles and Applications (2<sup>nd</sup> ed.). Royal Society of Chemistry.
- 4. Purkait, M. K., Haldar, D., & Duarah, P. (2022). Advances in Extraction and Applications of Bioactive Phytochemicals. Elsevier.
- 5. Huang, L.Q. (2019). Molecular Pharmacognosy (2<sup>nd</sup> ed.). Springer.
- Bhatt, M., Joshi, M., & Sharma, S. (2024). Molecular Pharmacognosy Advances in DNA-based techniques for authentication of botanicals in medicinal food and herbal drugs. In M. Kaneria & K. Rakholiya, Drug discovery update: Herbal formulations, phytochemistry and pharmacognosy (pp. 153–164). Elsevier.
- 7. Benzie, I. F. F., & Wachtel-Galor, S. (2011). Herbal Medicine: Biomolecular and Clinical Aspects (2<sup>nd</sup> ed.). CRC Press/Taylor & Francis.
- 8. Pizzorno, J. E., & Murray, M. T. (2012). Textbook of Natural Medicine (4th ed.). Elsevier.
- 9. Rasool, S. (2024). Textbook of Pharmacognosy, theory and practicals. CNC Publisher.
- 10. McTaggart, L. A. (2018). Herbal Therapeutics: A Clinical Guide. Springer.
- 11. Braun, L. (2009). Clinical Guide to Herbal Medicine. Elsevier.

### Pharmacognosy-IIB (Advanced)

# **Course Learning Outcomes:**

After completing this course, students will be able to:

- 1. Learn the clinical efficacy, mechanisms of action, dosage, and safety profiles of herbal drugs used in treating various ailments, including infectious, renal, cardiac, respiratory, CNS, and reproductive disorders.
- 2. To get insight into the industrial applications of pharmacognosy by explaining the formulation, production technologies, and regulatory frameworks involved in the development and commercialization of herbal medicinal products.
- 3. To apply standard analytical and regulatory methodologies for the evaluation, quality control, and standardization of raw materials and finished herbal formulations by official standards.
- 4. Understand the role, formulation, and health benefits of nutraceuticals and natural cosmetics, with their active constituents and excipients.
- 5. Equip with skills in physicochemical evaluation and quantitative analysis of phytoconstituents in herbal materials and formulations through practical sessions.

### **Contents:**

### 1. Natural Medicine Practice-II

- i. A detailed study of clinical efficacy, mechanism of action, part used, dose, dosage form, and adverse effects of herbal drugs in various ailments, including;
  - Infectious diseases: Allium sativum, Azadirachta indica, Curcuma longa, Melaleuca alternifolia, Glycyrrhiza glabra
  - Renal disorders: Cucumis melo, Zea mays, Berberis vulgaris, Vaccinium macrocarpon
  - Tumor/Cancer: Catharanthus roseus, Podophyllum peltatum, Begonia malabarica, Taxus brevifolia
  - Cardiac diseases: Digitalis, Allium sativum, Strophanthus kombe, Urgenia indica, Punica granatum
  - Respiratory diseases: Ephedra sinica, Monis nigra, Ficus religiosa, Glycyrrhiza glabra, Hedera helix
  - CNS disorders: Erythroxylin coca, Atropa belladonna, Cannabis sativa
  - Reproductive disorders: Withania somnifera, Vitex agnus-castus, Tribulus terrestris, Oenothera biennis
- ii. Herbal drug interactions

### 2. Industrial Pharmacognosy

- i. Introduction, scope and applications of industrial pharmacognosy
- ii. Evolution of modern natural pharmaceuticals
- iii. Infrastructure of the herbal drug industry as per regulatory requirements
- iv. Specialized technology used for the preparation of herbal products
- v. Dosage forms and drug design for various natural medicines
- vi. Conventional medicinal preparations including herbal teas, candies and distillates
- vii. Incompatibilities in herbal formulations
- viii. Export potential of Pakistani herbs and herbal products

### 3. Quality Control and Standardization of Herbal Drugs

- i. Introduction to evaluation, quality control and standardization
- ii. Pharmacopoeial/official standards for herbal products
- iii. Challenges in quality control of herbal drugs
- iv. Standardization of raw materials and extracts
- v. Quality control methods for various herbal drugs
- vi. Stability testing of primary and secondary herbal products
- vii. Role of marker and reference compounds in the evaluation of herbal drugs
- viii. Analysis of heavy metals and pesticide residues

### 4. Nutraceuticals and Natural Cosmetics

- i. Definition and classification of nutraceuticals
- ii. Plants and other sources of nutraceuticals
- iii. Role of secondary metabolites in designing nutraceuticals
- iv. Functional ingredients in nutraceuticals
- v. Dosage forms of nutraceuticals
- vi. Health benefits of nutraceuticals
- vii. Introduction and benefits of natural cosmetics
- viii. Natural ingredients used as active constituents and excipients in cosmetics
- ix. Different dosage forms of natural cosmetics
- x. Natural cosmetics for skin care, hair care and makeup

### **Practical**

The practicals of the subject shall be designed from time to time based on the above-mentioned theoretical topics and the availability of the facilities. It may include

- Evaluation of crude drugs for their physicochemical parameters, including moisture contents, ash values, extractive values, swelling index, and foaming index
- Quantitative determination (assay) of phytoconstituents in crude extracts and herbal formulations.

### Minimum of 10 practicals will be conducted)

**NOTE:** A study tour to a well-renowned herbal or nutraceutical industry from the country will be an integral part of the syllabus and will be arranged before the end of the session, and a report will be submitted.

# **Recommended Readings:**

- 1. Benzie, I. F. F., & Wachtel-Galor, S. (2011). Herbal Medicine: Biomolecular and Clinical Aspects (2<sup>nd</sup> ed.). CRC Press/Taylor & Francis.
- 2. Pizzorno, J. E., & Murray, M. T. (2012). Textbook of Natural Medicine (4th ed.). Elsevier.
- 3. McTaggart, L. A. (2018). Herbal Therapeutics: A Clinical Guide. Springer.
- 4. Braun, L. (2009). Clinical Guide to Herbal Medicine. Elsevier.
- 5. Kalia, A. N. (2023). Textbook of Industrial Pharmacognosy (14<sup>th</sup> reprint). CBS Publishers & Distributors.
- 6. Gandla, K., Sayyada, S., Momina, K., & Suresh, K. (2024). Textbook of Industrial Pharmacognosy. BFC Publications Private Limited.
- 7. Mukherjee, P. K. (2019). Quality Control and Evaluation of Herbal Drugs: Evaluating Natural Products and Traditional Medicine. Elsevier.
- 8. Rasool, S. (2024). Textbook of Pharmacognosy, theory and practicals. CNC Publisher.
- 9. Roberts, A. J., O'Brien, M. E., & Subak-Sharpe, G. J. (2001). Nutraceuticals: The Complete Encyclopedia of Supplements, Herbs, Vitamins, and Healing Foods. Berkley Publishing Group.
- 10. Balakrishnan, P., & Gopi, S. (2022). Handbook of Nutraceuticals and Natural Products: Biological, Medicinal, and Nutritional Properties and Applications. Wiley.
- 11. Kathuria, D., Sharma, A., Verma, M., & Nayik, G. A. (2024). Bioprospecting of Natural Sources for Cosmeceuticals. Royal Society of Chemistry.

## PHARMACOLOGY & BASIC MEDICAL SCIENCES:

# Physiology-I

## **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Explain the structure and function of cell components, how molecules move across membranes, and key processes like fluid balance, the cell cycle, and apoptosis in maintaining cellular stability.
- 2. Describe how the nervous system controls body functions, including how neurons work, how action potentials and synapse function, the role of neurotransmitters and sensory receptors, and the structure and function of the central and autonomic nervous systems.
- 3. Explain the structure and types of skeletal muscles, how they contract, and the role of the neuromuscular junction in muscle activity.
- 4. Describe the structure and function of the heart, including the cardiac cycle, blood flow, heart sounds, and electrical conduction, and interpret ECG patterns and their clinical relevance.
- 5. Outline the process of digestion and absorption, including digestive secretions, how they are regulated, and the steps from eating to defecation.

### **Contents**

### 1. Basic Cell Functions

- a) Overview of the physical structure of the cell.
- b) Extracellular fluid, intracellular fluid, phagocytosis, pinocytosis, cell cycle, apoptosis, movement of molecules across cell membranes: diffusion, active transport, co-transport, counter-transport,

basic principles of osmosis, osmotic pressure and osmotic equilibrium, endocytosis and exocytosis.

### 2. Neural Control Mechanisms

functional classes of neurons, voltage-gated sodium and potassium channels, resting membrane potential, initiation and propagation of action potential, refractory period, all or nothing principle, synapses, types of synapses, physiological anatomy of synapses, excitatory and inhibitory receptors in the postsynaptic membrane, excitatory and inhibitory postsynaptic potentials, classification of sensory receptors, neurotransmitters and neuromodulators.

# 3. Central Nervous System

Physiological anatomy of brain and spinal cord, blood-brain barrier, functions of cerebrospinal fluid, types of sleep.

# 4. Autonomic Nervous System

Physiological anatomy of sympathetic and parasympathetic nervous system, pre-ganglionic and post-ganglionic neurons, synthesis and secretion of acetylcholine and nor-epinephrine from nerve terminal, effects of sympathetic and parasympathetic nervous system on various organs of the body, denervation supersensitivity and its mechanism, autonomic reflexes

# 5. Muscle Physiology

Physiological anatomy of skeletal muscle, types of skeletal muscle fibers, general and molecular mechanisms of muscle contraction, physiological anatomy of neuromuscular junction.

### 6. The Heart

Physiological anatomy of heart muscle, structure of heart, course of blood flow through heart, the cardiac cycle, conduction system of heart, heart sounds, murmurs, characteristics of normal electrocardiogram, relationship of electrocardiogram to the cardiac cycle, clinical significance of abnormal electrocardiographic patterns. Definitions: (systole, diastole, stroke volume, cardiac output, preload, afterload, ejection fraction).

# 7. Digestion and Absorption of Food

Gastro-intestinal secretions (salivary secretions, gastric secretions, pancreatic secretions, biliary secretions), nervous and hormonal regulation of gastric secretions, mastication, deglutition, gastric emptying, intestinal movements (peristalsis, segmenting & mixing), biliary enterohepatic circulation, defecation, overview of enteric nervous system.

### **Practical**

By the end of this course, students will be able to:

- 1. Determine the systolic and diastolic blood pressure of human volunteer using mercury sphygmomanometer and the heart rate by palpatory method
- 2. Determine the blood pressure and heart rate of human volunteer during physical activity (exercise)
- 3. Demonstrate the technique of venous blood sampling from human volunteer or using simulators/training model.
- 4. Demonstrate the administration technique of intramuscular injection to human volunteer or using simulators/training model.
- 5. Demonstrate the administration technique of subcutaneous injection to human volunteer or using simulators/training model.
- 6. Demonstrate the administration technique of intra-venous injection to human volunteer or using simulators/training model.
- 7. Determine the body mass index (BMI) of a human volunteer
- 8. Observe the peristaltic activity (spontaneous contractions) of rabbit jejunum
- 9. Determine the visual acuity, far vision, near vision and field of vision (Perimetry).
- 10. Explain the various abnormal electrocardiogram patterns and discuss the clinical significance

11. Observe the effects of different concentrations of salt solutions on red blood cells (isotonic, hypotonic, and hypertonic).

Note: A minimum of 10 practicals should be conducted

# **Recommended Readings**

- 1. Barrett, K. E., Barman, S. M., Brooks, H. L., & Yuan, J. X. J. (2019). *Ganong's review of medical physiology* (26th ed.). McGraw-Hill Education.
- 2. Costanzo, L. S. (2024). BRS physiology (7th ed.). Wolters Kluwer
- 3. Firdaus, M. (2021). Firdaus review of physiology: Included BCQs and viva (21st ed.). Riaz Medical Publishers.
- 4. Hall, J. E. (2021). Guyton and Hall textbook of medical physiology (14th international ed.). Elsevier.
- 5. Sembulingam, K., & Sembulingam, P. (2022). Essentials of medical physiology (9th ed.). Jaypee Brothers Medical Publishers
- 6. Sherwood, L. (2016). Human physiology: From cells to systems (9th ed.). Cengage Learning.
- 7. Wecker, L., & Ingram, S. L. (2024). *Brody's human pharmacology: Mechanism-based therapeutics* (7th ed.). Elsevier.
- **8.** Widmaier, E. P., Raff, H., & Strang, K. T. (2023). Vander's human physiology: The mechanisms of body function (16th ed.). McGraw-Hill Education.

# Physiology-II

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- Explain the structure, formation, and functions of blood components, describe the process of blood clotting and blood typing, and relate these to common disorders like anemia and leukopenia.
- 2. Describe the structure and function of the circulatory and lymphatic systems, including blood vessels, and explain how blood pressure is regulated.
- **3.** Explain how the respiratory system works, including gas exchange, breathing control, and the different lung volumes and capacities.
- **4.** Describe kidney function and urine formation, and explain how the body maintains fluid, electrolyte, and acid-base balance.
- **5.** Explain the physiology of the male and female reproductive systems, including gamete formation, the menstrual cycle, and stages such as puberty, pregnancy, and menopause.

### **Contents**

### 1. The Blood Cells

Red blood cells, erythropoiesis, formation and destruction of hemoglobin, types of white blood cells, genesis of white blood cells, roles of different white blood cells, types of T-cells and their functions, B-cells and memory cells, antibodies, formation of pus, anemia and leukopenia, platelets, formation of platelet plug, mechanism of blood coagulation, extrinsic and intrinsic pathways of initiating clotting, lysis of blood clot, blood types, agglutinogens, Rh blood types, plasma, serum.

### 2. Circulation

Basic theory of circulatory function, structure and function of blood vessels (arteries, arterioles, capillaries, veins), blood pressure, total peripheral vascular resistance and total pulmonary vascular resistance, clinical methods of measuring systolic and diastolic blood pressures, arterial pressure and baroreceptor reflex, renin-angiotensin system, hematocrit, lymph channels of the body, formation of lymph.

## 3. Respiratory Physiology

Physiological anatomy of lungs, mechanism of inspiration and expiration, definitions of various lung volumes and capacities, exchange of gases in alveoli and tissues, transport of oxygen in blood, transport of carbon dioxide in Blood, transport of hydrogen ions between tissues and lungs, regulation of respiration, pulmonary edema, pleural effusion, non-respiratory functions of the Lungs.

# 4. Renal Physiology

Physiological anatomy of kidney and nephron, Functions of the kidney, Urine formation, glomerular filtration, glomerular filtration rate (GFR), mechanisms of tubular reabsorption and secretion, formation of dilute and concentrated urine, micturition, buffering of H<sup>+</sup> ion, renal sodium regulation, renal potassium regulation, renal water regulation.

# 5. Endocrine and Reproductive Physiology

Physiological roles of hormones secreted from major endocrine glands (pituitary, thyroid, adrenal, and pancreas), along with reproductive physiology including gametogenesis, menstrual cycle regulation, and life-stage transitions.

### 6. Temperature Regulation

Mechanisms of body temperature regulation and pathophysiology fever and hypothermia.

### **Practical**

### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Determine the Hemoglobin (Hb) content in human blood
- 2. Determine the erythrocyte sedimentation rate (ESR) in human blood
- 3. Determine the red blood cell count in human blood
- 4. Determine the bleeding time in human blood
- 5. Determine the coagulation time in human blood
- 6. Determine an individual's blood type using anti-sera for ABO and Rh typing.
- 7. Determine the lung tidal volume, inspiratory reserve volume, expiratory reserve volume and vital capacity.
- 8. Measure and record changes in respiratory rate and oxygen saturation under different conditions (e.g., at rest vs. after exercise).
- 9. Learn the technique of nebulization using normal saline as the nebulizing solution.
- 10. Learn cardiopulmonary resuscitation (CPR) technique using CPR manikin or dummy.
- 11. Demonstrate the importance of vector control in preventing the spread of dengue fever
- 12. Understanding pre-recorded heart and lung sounds

**Note:** A basic life support (BLS) workshop shall be mandatory to attend as part of Physiology-II practical. The Institute/University may issue a certificate after successful completion of workshop.

# A minimum of 10 practicals should be conducted Recommended Readings

- 9. Barrett, K. E., Barman, S. M., Brooks, H. L., & Yuan, J. X. J. (2019). *Ganong's review of medical physiology* (26th ed.). McGraw-Hill Education.
- 10. Costanzo, L. S. (2024). BRS physiology (7th ed.). Wolters Kluwer
- 11. Firdaus, M. (2021). Firdaus review of physiology: Included BCQs and viva (21st ed.). Riaz Medical Publishers.
- 12. Hall, J. E. (2021). Guyton and Hall textbook of medical physiology (14th international ed.). Elsevier.
- 13. Sembulingam, K., & Sembulingam, P. (2022). Essentials of medical physiology (9th ed.). Jaypee Brothers Medical Publishers
- 14. Sherwood, L. (2016). Human physiology: From cells to systems (9th ed.). Cengage Learning.

- 15. Wecker, L., & Ingram, S. L. (2024). *Brody's human pharmacology: Mechanism-based therapeutics* (7th ed.). Elsevier.
- **16.** Widmaier, E. P., Raff, H., & Strang, K. T. (2023). Vander's human physiology: The mechanisms of body function (16th ed.). McGraw-Hill Education.

### Pathology

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Define and differentiate core pathological terms (e.g., ischemia, necrosis, neoplasia) and explain the mechanisms of inflammation, cellular injury, adaptation, and repair.
- 2. Describe the pathogenesis, morphological changes, and clinical implications of common diseases affecting major organ systems (cardiovascular, nervous, gastrointestinal, endocrine/metabolic).
- **3.** Compare benign and malignant tumors, interpret the hallmarks of cancer, and apply the TNM classification system.
- **4.** Correlate pathological changes with disease manifestations in key conditions (e.g., myocardial infarction, diabetes, peptic ulcers, neurodegenerative disorders).

#### **Contents**

### 1. General Pathology

Introduction to Pathology, Definition, scope, and branches of pathology. Cellular adaptations (atrophy, hypertrophy, hyperplasia, metaplasia, dysplasia).

- 2. Cellular Injury and Death. Causes of cell injury (hypoxia, ischemia, toxins, infections). Mechanisms: Reversible vs. irreversible injury, necrosis, apoptosis. Cellular accumulations (lipids, proteins, pigments).
- **3. Inflammation and Repair**. Acute/chronic inflammation, chemical mediators. Wound healing, fibrosis, granulomas.

### 4. Systemic Pathology

- a) **Cardiovascular Pathology.** Ischemic heart disease (angina, myocardial infarction), Hypertension, heart failure, arrhythmias.
- b) **Neurological Pathology.** Neurodegenerative disorders (Parkinson's, Alzheimer's), epilepsy, stroke.
- c) Gastrointestinal Pathology. Peptic ulcer disease (gastric/duodenal ulcers). Inflammatory bowel disease, liver cirrhosis.
- d) Endocrine/Metabolic Pathology. Diabetes mellitus (types, complications) and Gout.
- 5. **Definitions:** Benign vs. malignant, carcinoma vs. sarcoma. Hallmarks of cancer, metastasis. TNM staging, grading. Definitions of common tumors, examples: Lipoma, adenoma, melanoma, leukemia, and lymphoma etc.

#### **Practical**

### By the end of the course, students will be able to:

- 1. Interpret a histopathology report showing features of chronic inflammation with comparative analysis of acute inflammatory response.
- 2. Interpret a pathology report of a benign vs. malignant neoplasm with reference to histological differentiation and invasion markers.
- 3. Interpret a lymph node biopsy report showing granulomatous inflammation, identifying diagnostic clues and pathological relevance.
- 4. Interpret a histopathology report suggestive of dysplasia and explain its relevance in pre-cancerous lesions.

- 5. Interpret a tumor staging and grading report (TNM system) and explain its clinical pathological implications.
- 6. Interpret a pathology report describing fatty change in liver tissue with reference to reversible cellular injury.
- 7. Interpret a pathological hematology report suggestive of anemia and compare it with a normal profile.
- 8. Interpret a gastric biopsy report in peptic ulcer disease with emphasis on inflammatory and structural changes.
- 9. Interpret a liver biopsy report showing features of cirrhosis with reference to fibrosis and nodular regeneration.
- 10. Interpret a breast lump biopsy report by differentiating fibroadenoma from invasive ductal carcinoma.
- 11. Interpret a prostate biopsy report in suspected prostatic hyperplasia or adenocarcinoma.
- 12. Interpret an oral mucosal biopsy report showing leukoplakia or squamous cell carcinoma.
- 13. Interpret a pathological report in a case of suspected gout and its comparison with normal reference parameters

Note: A minimum of 10 practicals should be conducted

### **Recommended Readings**

- 1. Cross, S. S. (2018). Underwood's pathology: A clinical approach (6th ed.). Elsevier
- 2. Goldblum, J. R., Lamps, L. W., McKenney, J. K., & Myers, J. L. (2018). Rosai and Ackerman's surgical pathology (11th ed.). Elsevier.
- 3. Greene, R. J., & Harris, N. D. (2008). *Pathology and therapeutics for pharmacists* (3rd ed.). Pharmaceutical Press.
- 4. Kumar, V., Abbas, A. K., & Aster, J. C. (2020). Robbins and Cotran pathologic basis of disease (10th ed.). Elsevier.
- 5. Kumar, V., Abbas, A. K., Aster, J. C. (2017). *Robbins basic pathology* (10th ed.). Elsevier Health Sciences Division
- 6. Reisner, H. M., & Rubin, E. (2014). *Essentials of Rubin's pathology* (6th ed.). Wolters Kluwer Health/Lippincott Williams & Wilkins.
- 7. Sattar, H. A. (2014). Fundamentals of pathology: Medical course and step 1 review (2nd ed.). Pathoma
- 8. World Health Organization. (2019). WHO classification of tumours (5th ed.). International Agency for Research on Cancer.

# Anatomy & Histology

# Course Learning Outcomes:

At the end of this course the student will be able to:

- 1. Identify and describe the anatomy of the thoracic region, including the skeletal, respiratory, and cardiovascular structures
- 2. Understand and explain the positions, structures, and functions of the major abdominal organs and related systems.
- 3. Demonstrate knowledge of the structures and functions of the urinary system, limbs, and nervous system, including the spinal cord, brain, cranial nerves, eye, and ear.
- 4. Explain histological techniques and their pharmacological relevance in the context of tissue analysis and drug interactions.

### **Contents**

### 1. The Thorax

The thoracic cage, the thoracic vertebrae, the ribs, sternum, diaphragm, lobes and fissures of lungs, trachea, bronchi, pharynx, larynx

### 2. The Heart

Anterior and posterior aspects of the heart, the coronary arteries and veins, heart chambers, mediastinum

### 3. The Abdominal Cavity

- a. Positions of liver, spleen, gall bladder, pancreas, stomach and kidney in the abdominal cavity.
- b. Gross anatomy of stomach, intestine, liver, spleen, gall bladder, pancreas, and kidney
- c. The portal system of veins, the biliary duct system

# 4. The Urinary System

Gross anatomy of the ureter, the bladder, the urethra, scrotum, testis

### 5. Upper and Lower Limb

Gross anatomy of the bones and joints of upper and lower limbs

### 6. Nervous System

Gross anatomy of spinal cord and brain, names of the cranial nerves and their specific functions.

# 7. Eye and Ear

Gross anatomy of eye and ear

### 8. Histology

- a. Overview of histological techniques like tissue fixation, embedding, sectioning, staining, and microscopy.
- b. Pharmacological relevance of histology

#### **Practical**

By the end of this course, students will be able to:

- 1. Understand thoracic anatomy including the thoracic cage, diaphragm, and lung structures etc.
- 2. Study the cardiac morphology encompassing external and internal structures of the heart and associated vasculature.
- 3. Identify the abdominal organ positions and structures of the liver, spleen, gall bladder, pancreas, stomach, and kidneys using anatomical models.
- 4. Examine urinary system components including kidney, ureter, bladder, and urethra.
- 5. Study male and female reproductive system anatomy.
- 6. Analyze the bones and joints of upper limbs
- 7. Analyze the bones and joints of lower limbs
- 8. Examine brain structures including lobes, ventricles, and brainstem.
- 9. Study spinal cord anatomy with regional differentiation, vertebrae, and grey/white matter.
- 10. Identify the anatomical structure of human eye and ear
- 11. Perform tissue Fixation of rat liver and kidney specimen using 10% neutral buffered formalin for subsequent histopathological analysis.
- 12. Identify key microscopic features of common histological findings in tissues as different types of epithelial tissues, connective tissues. (Loose and dense connective tissues), cartilages, bone (Compact and spongy bone), digestive system (Esophagus, stomach, small intestine), liver, lymphatic system (Lymph nodes, spleen, thymus), excretory system. (Kidneys /glomerulus, ureters and urinary bladder), respiratory system (Bronchi and alveolus), endocrine system (pituitary gland, thyroid gland, adrenal gland), reproductive system (seminiferous tubules/ testes, ovary, mature follicle).

# Note:

The practicals shall be conducted using detailed anatomical models.

• A minimum of 10 practicals should be conducted.

### **Recommended Readings**

- 1. Agur, A. M. R., & Dalley, A. F., II. (2024). *Moore's Essential Clinical Anatomy* (7th ed.). Lippincott Williams & Wilkins.
- 2. Chung, K. W., Chung, H. M., & Halliday, N. L. (2015). *Gross anatomy* (8th ed.). Lippincott Williams & Wilkins
- 3. Dalley, A. F., II, & Agur, A. M. R. (2023). *Moore's Clinically Oriented Anatomy* (9th ed.). Lippincott Williams & Wilkins.
- 4. Drake, R. L., Vogl, A. W., & Mitchell, A. W. M. (2023). *Gray's Anatomy for Students* (5th ed.). Elsevier.
- 5. Ellis, H., & Mahadevan, V. (2010). *Clinical anatomy: Applied anatomy for students and junior doctors* (10th ed.). Wiley-Blackwell.
- 6. Gartner, L. P., & Lee, L. M. J. (2023). *Gartner & Hiatt's Atlas and Text of Histology* (8th ed.). Lippincott Williams & Wilkins.
- 7. Morton, D. A., Foreman, K. B., & Albertine, K. H. (2011). *The big picture: Gross anatomy*. McGraw-Hill.
- 8. Ross, M. H., & Pawlina, W. (2023). *Histology: A Text and Atlas with Correlated Cell and Molecular Biology* (9th ed.). Lippincott Williams & Wilkins.
- 9. Standring, S. (Ed.). (2020). *Gray's anatomy: The anatomical basis of clinical practice* (42nd ed.). Elsevier.

# Pharmacology & Therapeutics-1A

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze fundamental principles of General Pharmacology, including pharmacokinetic and pharmacodynamic parameters, and apply this understanding to evaluate individual drug pharmacology.
- 2. Classify molecular drug targets including receptor types, secondary messengers, and signaling pathways, and demonstrate their therapeutic implications through specific drug examples.
- **3.** Evaluate pharmacological mechanisms of autonomic nervous system drugs and justify their clinical applications in professional healthcare scenarios.
- **4.** Demonstrate comprehensive knowledge of gastrointestinal drug pharmacology and implement this understanding in appropriate clinical decision-making contexts.
- **5.** Explore the emerging field of pharmacomicrobiomics and its potential impact on personalized therapeutics, focusing on how gut microbiota can influence drug metabolism and therapeutic outcomes.

#### **Contents**

# 1. General Pharmacology

- a) Introduction to Pharmacology. Historical milestones in pharmacology, Drug sources.
- b) Routes of drug administration, advantages and disadvantages
- c) Pharmacokinetics: Absorption (Mechanism/membrane permeability, bioavailability), distribution (mechanism, volume of distribution (Vd), plasma protein binding), metabolism (phase 1 and phase II reactions, enzyme induction/inhibition) and elimination (clearance (Cl), half-life) of drugs along with factors affecting them.
- d) Pharmacodynamics: Drug receptor interactions (Agonist, antagonist, partial agonist, inverse agonist). Receptor internalization and receptors co-localization. Definitions: Spare receptors,

orphan receptors, Median lethal dose (LD<sub>50</sub>), Median effective dose (ED<sub>50</sub>), and Therapeutic Index. Efficacy vs Potency, drug tolerance and dependence, dose-response relationships.

# 2. Molecular And Cellular Pharmacology

- a) Types of receptors: (Ligand-gated and voltage-gated ion channels, G-protein coupled receptors, Enzyme-linked receptors, and nuclear receptors).
- b) Secondary messengers

# 3. Drugs Acting on Autonomic Nervous System (ANS):

- a) Sympathetic agonists and antagonists
- b) Parasympathetic agonists (Direct and indirect acting), and antagonists
- c) Ganglion stimulants and Ganglion blockers
- d) Neuromuscular Blockers

# 4. Drugs Acting on Gastrointestinal Tract:

- a) Emetic and anti-emetics
- b) Laxatives, cathartics, and constipation therapy
- c) Anti-diarrheal agents
- d) Treatment of Peptic & duodenal ulcer
- e) Drug treatment of chronic inflammatory bowel diseases
- f) Drugs affecting bile flow and Cholelithiasis

### 6. Pharmaco-microbiomics

a) Introduction to pharmaco-microbiomics and relationship with precision medicine

#### Note:

- 1. Briefly introduce banned/obsolete drugs, focusing on withdrawal reasons and key examples.
- 2. Emphasize class-wide drug actions and highlight only major individual drug differences.
- 3. Include newly approved clinically relevant drugs while excluding therapeutically insignificant ones.
- 4. Select prototype drugs from latest authoritative textbooks representing class characteristics.
- 5. Avoid repetitive teaching provide overviews for previously covered drug classes.

### **Practical**

By the end of this course, students will be able to:

- 1. Understand purpose of pharmacological experiments, research methods in pharmacology and experimental design
- 2. Develop proper laboratory animal handling techniques for rats, mice, and guinea pigs following institutional ethical guidelines.
- 3. Prepare Ringer's solution for physiological studies
- 4. Prepare Tyrode's solution for intestinal smooth muscle experiments
- 5. Prepare Kreb's solution for isolated tissue experiments
- 6. Demonstrate stimulant drug effects (acetylcholine, barium chloride) on rabbit intestine
- 7. Demonstrate depressant drug effects (atropine) on rabbit intestine
- 8. Analyze high potassium (80 mM)-induced contractions in rabbit intestine
- 9. Analyze low potassium (20 mM)-induced contractions in rabbit intestine
- 10. Induce and observe castor oil-induced diarrhea in mice
- 11. Evaluate loperamide's antidiarrheal effects on castor oil-induced diarrhea in mice
- 12. Investigate phenylephrine's effects on rabbit eye (pupil size/iris muscles)
- 13. Investigate homatropine's effects on rabbit eye (cycloplegia/mydriasis)
- 14. Investigate pilocarpine's effects on rabbit eye (miosis/ciliary muscle contraction)

**Note**: A minimum of 10 practicals will be conducted.

# Pharmacology & Therapeutics-IB

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze pharmacogenomic principles and their clinical applications, evaluate ethical implications, and interpret the FDA Table of Pharmacogenetic Associations in therapeutic decision-making.
- **2.** Evaluate cardiovascular drug mechanisms, co-relate international treatment guidelines (ACC/AHA/ESH), and implement evidence-based pharmacological interventions in clinical practice.
- **3.** Demonstrate endocrine drug pharmacology, integrate AACE diabetes management algorithms, and design appropriate therapeutic regimens for endocrine disorders.
- **4.** Explain respiratory drug actions and utilize this knowledge to optimize treatment strategies for pulmonary conditions in clinical settings.

#### Contents

# 1. Pharmacogenomics and Pharmacogenetics

- a) Overview: DNA and its structure, chromosome, Gene, pharmacogenes, allele, genotype, phenotype, gene-drug interaction, genetic polymorphism and its types, Cytochrome P450 enzyme polymorphism, pharmacogenetics, pharmacogenomics
- b) Clinical applications of Pharmacogenomics (Concepts of personalized medicine and precision medicine, targeted therapy and its selection, predicting drug response, optimizing drug dosing, prevention of adverse drug reactions, understanding genetic mechanisms for antibiotic resistance).
- c) Gene therapy and Gene editing along with their clinical applications.
- d) Overview of FDA Table of Pharmacogenetic Associations.
- e) Ethical considerations in Pharmacogenomics

### 2. Drugs Acting on Cardio-Vascular System

- a) Anti-hypertensive drugs
- b) Diuretics
- c) Anti-anginal drugs
- d) Treatment of congestive heart failure
- e) Anti-arrhythmic drugs
- f) Anti-hyperlipidemic agents.
- g) Coagulants and Anti-coagulants
- h) Overview of Pharmacological treatment guidelines from European Society of Hypertension and International Society of Hypertension.
- Overview of Medical Therapy to Prevent Cardiovascular Events and Manage Symptoms in Clinical Practice Guidelines from American Heart Association/American College of Cardiology.

### 3. Drugs Affecting Endocrine Function

- a) Therapeutic agents for: Type 1 and Type 2 Diabetes Mellitus, Latent Autoimmune Diabetes in Adults (LADA), Maturity-Onset Diabetes of the Young (MODY), Includes: Insulin preparations and oral antidiabetic drugs.
- b) Corticosteroids
- c) Thyroid hormone and anti-thyroid drugs
- d) Overview of comprehensive Type 2 Diabetes Management Algorithms from American Association of Clinical Endocrinology

**4. Drugs Acting on Respiratory System**: Anti-asthmatics, Antitussives, Pulmonary surfactants, Drugs for Pulmonary Hypertension and cystic fibrosis

# Note:

- 1. Briefly introduce banned/obsolete drugs, focusing on withdrawal reasons and key examples.
- 2. Emphasize class-wide drug actions and highlight only major individual drug differences.
- Include newly approved clinically relevant drugs while excluding therapeutically insignificant ones.
- 4. Select prototype drugs from latest authoritative textbooks representing class characteristics.
- 5. Avoid repetitive teaching provide overviews for previously covered drug classes.
- 6. There should be emphasis on therapeutics and while consulting clinical practice guidelines, emphasis should be on pharmacological and/or therapeutic treatment guidelines. Latest and updated guidelines should be discussed. Appropriate references and links are given in list of references along with teaching tips at end of each relevant reference.
- 7. Instructors are encouraged to discuss a few selected examples form each section of FDA table of Pharmacogenetic Association to explain gene-drug interactions to students.

#### **Practical**

By the end of the course, student will be able to:

- 1. Demonstrate humane euthanasia procedures for rodents using AVMA-approved methods
- 2. Perform terminal blood collection via cardiac puncture in anesthetized rats with aseptic technique
- 3. Separate plasma and serum from human blood samples using standardized centrifugation protocols
- 4. Administer intraperitoneal injections in rodents using sterile syringes and proper restraint
- 5. Execute accurate oral dosing in rats/mice using calibrated gavage needles with safety monitoring
- 6. Practice intramuscular and subcutaneous injection techniques in rodents with dose verification
- 7. Perform effects of acetylcholine on frog heart.
- 8. Examine effects of atropine on frog heart.
- 9. Evaluate diuretic effects of furosemide in rats.
- 10. Perform diuretic effects of Hydrochlorothiazide in rats
- 11. Evaluate glibenclamide-induced hypoglycemia through OGTT in rats with glucose monitoring
- 12. Analyze metformin's glucose-lowering effects using OGTT in mice with controlled conditions
- 13. Understand WMA Helsinki Declaration principles for ethical human research participation
- 14. Understand OECD test guidelines for humane animal use in pharmacological research

**Note:** A minimum of 10 practicals will be conducted.

# Pharmacology & Therapeutics-IIA

#### **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze the pharmacology of antimicrobial and anticancer agents, interpret WHO and DRAP treatment guidelines, and apply this knowledge to optimize therapeutic regimens in clinical practice.
- 2. Evaluate the mechanisms of anti-inflammatory and anti-rheumatic drugs, implement ACR guidelines for gout and rheumatoid arthritis management, and design evidence-based treatment plans.
- **3.** Demonstrate knowledge of monoclonal antibodies and immunomodulators, and utilize these therapies according to current clinical protocols in autoimmune and neoplastic disorders.

#### **Contents**

# 1. Chemotherapy

- a) Basic principles of chemotherapy
- b) Anti-bacterials:
  - i. Cell wall synthesis inhibitors (β-lactam antibiotics and glycopeptide antibiotics)
  - ii. Protein synthesis inhibitors
  - iii. DNA gyrase inhibitors
  - iv. Anti-folate drugs
  - v. Antimycobacterial drugs
- c) Anti-fungals
- d) Anti-virals
- e) Anti-protozoals
- f) Cancer chemotherapeutic drugs
- g) Overview of the guidelines on responsible use of antimicrobials in human health by Drug Regulatory Authority of Pakistan

# 2. Anti-Inflammatory and Anti-Rheumatic Drugs:

- a) Nonsteroidal anti-inflammatory drugs
- b) Disease modifying anti-rheumatic drugs
- c) Non-opioid analgesics
- d) Drugs used in the treatment of gout.
- e) Overview of the guidelines for the management of Gout and Rheumatoid Arthritis from American College of Rheumatology

# 3. Immunopharmacology

Pharmacology of immuno-suppressants, stimulants, and biosimilars:

- a) Anti-inflammatory monoclonal antibodies: cytokine inhibitors, T-cell activation inhibitors
- b) Asthma therapy: anti-IgE monoclonal antibodies
- c) Anti-tumor monoclonal antibodies
- d) Other monoclonal antibodies: Against Rabies and Tetanus toxins, Intravenous Immunoglobulin (IVIg)
- e) Immunomodulation therapy: Interferons

#### Note:

- 1. Briefly introduce banned/obsolete drugs, focusing on withdrawal reasons and key examples.
- 2. Emphasize class-wide drug actions and highlight only major individual drug differences.
- 3. Include newly approved clinically relevant drugs while excluding therapeutically insignificant ones.
- 4. Select prototype drugs from latest authoritative textbooks representing class characteristics.
- 5. Avoid repetitive teaching provide overviews for previously covered drug classes.
- 6. There should be emphasis on therapeutics and while consulting clinical practice guidelines, emphasis should be on pharmacological and/or therapeutic treatment guidelines. Latest and updated guidelines should be discussed. Appropriate references and links are given in list of references along with teaching tips at end of each relevant reference.

#### **Practical**

By the end of this course, student will be able to:

- 1. Evaluate the analgesic effect of diclofenac using the acetic acid-induced writhing test in mice.
- 2. Assess the analgesic effect of pentazocine using the acetic acid-induced writhing test in mice.
- 3. Examine the analgesic effect of diclofenac using the hot plate method in mice.
- 4. Investigate the analgesic effect of pentazocine using the hot plate method in mice.

- 5. Determine the analyseic effect of diclofenac using the tail immersion test in mice.
- 6. Analyze the anti-inflammatory activity of aspirin through protein denaturation assay.
- 7. Measure the antioxidant activity of diclofenac using DPPH (2,2-Diphenyl-1-picrylhydrazyl) assay.
- 8. Evaluate the anti-inflammatory activity of naproxen in a carrageenan-induced paw edema model in rats.
- 9. Discuss clinical case studies involving monoclonal antibodies for rabies treatment.
- 10. Review clinical case studies of monoclonal antibodies against tetanus toxins.
- 11. Examine clinical case studies of IVIg application for immune modulation.
- 12. Analyze clinical case studies of anti-IgE monoclonal antibodies in asthma treatment.
- 13. Assess patient case studies to evaluate appropriate antibiotic prescription practices in clinical settings.

Note: A minimum of 10 practicals will be conducted

# Pharmacology & Therapeutics-IIB

# **Course Learning Outcomes:**

At the end of this course the student will be able to:

- 1. Analyze the pharmacology of CNS-acting drugs, interpret clinical guidelines from the European Federation of Neurological Societies, British Association of Pharmacology, and American Psychiatric Association (APA), and apply this knowledge to optimize neuropharmacological therapy in clinical practice.
- 2. Evaluate toxicological principles, select appropriate antidotes for drug poisoning and envenomation cases, and demonstrate expertise in chelation therapy pharmacology.
- 3. Implement artificial intelligence applications in pharmacological research, including machine learning for drug discovery and AI-driven pharmacological data analysis, to enhance therapeutic decision-making.

#### **Contents**

# 1. Drugs Acting on Central Nervous System:

- b. Sedatives & Hypnotic
- c. Anxiolytics, antidepressants and antimanic drugs, Overview of the Practice Guideline for the Treatment of Patients with Major Depressive Disorder from American Psychiatric Association
- d. Antipsychotics, Overview of the Evidence-based guidelines for treating bipolar disorder from British Association of Psychopharmacology.
- e. Antiepileptics, Overview of the Pharmacological recommendations in guidelines of European Federation of Neurological Societies for the management of status epilepticus in adults from.
- f. Antiparkinsonian and drug used in other neurodegenerative diseases, Overview of the guidelines on Therapeutic Management of Parkinson's disease from European Federation of Neurological Societies.
- g. Opioid analgesics
- h. Brief concepts of psychedelics and psychedelic pharmacy
- i. Neurosteroids
- j. Anesthetics: General and local

### 2. Toxicology

a) Brief and Basic concepts of Genotoxicity and DNA repair, Carcinogenicity, Reproductive toxicity, Teratogenicity, Occupational toxicology, Forensic toxicology, Environmental toxicology, Exposome Pharmacology, Mitochondrial toxicity, and toxicogenomics

- b) Antidotes of drug poisoning
- c) Anti-venoms
- d) Pharmacology of chelators: Dimercaprol, Edetate Calcium disodium, Pencillamine, Unithol, Defroxamine, Deferasirox, Prussian blue.

# 3. Applications of Artificial Intelligence in Pharmacology

- a) Use of AI to predict drug-target interactions.
- b) Use of AI to find new uses of existing drugs
- c) Use of AI to predict drug Absorption, Distribution, Metabolism, and Excretion properties.
- d) Use of AI In developing personalized medicine
- e) Use of AI to improve the accuracy of molecular docking by predicting binding affinities
- f) AI powered smart inhalers

#### Note:

- 1. Briefly introduce banned/obsolete drugs, focusing on withdrawal reasons and key examples.
- 2. Emphasize class-wide drug actions and highlight only major individual drug differences.
- 3. Include newly approved clinically relevant drugs while excluding therapeutically insignificant ones.
- 4. Select prototype drugs from latest authoritative textbooks representing class characteristics.
- 5. Avoid repetitive teaching provide overviews for previously covered drug classes.
- 6. There should be emphasis on therapeutics and while consulting clinical practice guidelines, emphasis should be on pharmacological and/or therapeutic treatment guidelines. Latest and updated guidelines should be discussed. Appropriate references and links are given in list of references along with teaching tips at end of each relevant reference.

# **Practical**

By the end of this course, students will be able to:

- 1. Evaluate anesthetic effects of ketamine/xylazine mixture via intraperitoneal administration in rats
- 2. Assess hypnotic activity of phenobarbital in mice using sleep latency tests
- 3. Determine hypnotic effects of diazepam in mice through sleep latency tests.
- 4. Measure antidepressant activity of imipramine using tail suspension test in mice
- 5. Analyze antidepressant effects of escitalopram using tail suspension test in mice
- 6. Investigate anticonvulsant properties of diazepam against strychnine-induced seizures in mice
- 7. Examine anticonvulsant effects of phenobarbital using strychnine seizure model in mice
- 8. Test anticonvulsant efficacy of diazepam against picrotoxin-induced seizures in mice Use of Artificial intelligence tools to determine drug-target interaction
- 9. AI tool: STITCH

### http://stitch.embl.de/

- a. Open the STITCH website, which is a database for searching drug-target interactions.
- b. Search for a specific drug of interest (e.g., aspirin, paracetamol etc.).
- c. Choose the *Homo sapiens* as organism
- d. Review the list of potential biological targets (proteins, enzymes, receptors) associated with the drug.
- e. Discuss how these interactions could be linked to the drug's therapeutic effects and side effects.
- f. Perform the procedure using at least 5 different drugs
- 10. AI tool: PharmGKB

- https://www.pharmgkb.org/
- a. Access the PharmGKB website and search for a drug known to have genetic variation-based dosing guidelines (e.g., Warfarin, Clopidogrel, Tamoxifen, Cisplatin, Abacavir etc.).
- b. Explore the drug's pharmacogenomic information, focusing on how genetic factors influence drug metabolism and response.
- c. Discuss how genetic polymorphisms can predict a patient's response to the drug (e.g., fast vs. slow metabolizers).
- d. Analyze how genetic data can be used to tailor drug therapy for individuals (personalized medicine).
- 11. Follow OECD Test Guideline 420 for acute oral toxicity studies
- 12. Follow OECD Test Guideline 452 for chronic toxicity testing
- 13. Follow OECD Test Guideline 414 for prenatal developmental toxicity studies

Note: A minimum of 10 practicals will be conducted

# Recommended Readings for Pharmacology & Therapeutics

- 1. American Psychiatric Association. (2010). Practice guideline for the treatment of patients with major depressive disorder (3rd ed.). American Psychiatric Association. https://psychiatryonline.org/pb/assets/raw/sitewide/practice\_guidelines/guidelines/mdd.pdf Teaching tip: Discuss Figure 1 and 2, table 6, 7, 8, and 11 with students
- 2. Brunton, L. L., & Knollmann, B. C. (2023). Goodman & Gilman's: The pharmacological basis of therapeutics (14th ed.). McGraw-Hill Education.
- 3. Cantley, L., Hunter, T., Sever, R., & Thorner, J. (2013). Signal transduction: Principles, pathways, and processes (1st ed.). Cold Spring Harbor Laboratory Press.
- 4. Cecchin, E., & Stocco, G. (2021). Pharmacogenomics and personalized medicine. MDPI AG.
- 5. Cullis, P. (2015). The personalized medicine revolution: How diagnosing and treating disease are about to change forever. Greystone Books.
- 6. Dawkins, R. (2006). The selfish gene (30th anniversary ed.). OUP Oxford.
- 7. Doudna, J. A., & Sternberg, S. H. (2017). A crack in creation: Gene editing and the unthinkable power to control evolution. HarperCollins.
- 8. Feng, X., & Xie, H. G. (2016). Applying pharmacogenomics in therapeutics. CRC Press.
- 9. Ferreira, J. J., Katzenschlager, R., Bloem, B. R., et al. (2013). Summary of the recommendations of the EFNS/MDS-ES review on therapeutic management of Parkinson's disease. *European Journal of Neurology*, 20(1), 5–15. https://doi.org/10.1111/j.1468-1331.2012.03866.x

# Teaching tip: Discuss table 2 to table 5 with students

10. FitzGerald, J. D., Dalbeth, N., Mikuls, T., et al. (2020). 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care & Research*, 72(6), 744–760. https://doi.org/10.1002/acr.24180

# Teaching tip: Discuss table 1 to table 8 with students

11. Fraenkel, L., Bathon, J. M., England, B. R. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*, 73(7), 924–939. https://doi.org/10.1002/acr.24596

#### Teaching tip: Discuss table 1 to 6 with students

- 12. Ganie, S. A., Ali, A., Rehman, M. U., & Arafah, A. (2023). *Pharmacogenomics: From discovery to clinical implementation*. Academic Press.
- 13. Goodwin, G. M., Haddad, P. M., Ferrier, I. N., et al. (2016). Evidence-based guidelines for treating bipolar disorder: Revised third edition recommendations from the British Association for Psychopharmacology. *Journal of Psychopharmacology*, 30(6), 495–553. https://doi.org/10.1177/0269881116636545

## Teaching tip: Discuss table 4, 5, 6, and 7 with students

- 14. Hasanzad, M. (2022). Precision medicine in clinical practice. Springer Nature Singapore.
- 15. Katzung, B. G., & Vanderah, T. W. (2024). Basic & clinical pharmacology (16th ed.). McGraw Hill.
- Kreutz, R., Brunström, M., Burnier, M., et al. (2024). European Society of Hypertension clinical practice guidelines for the management of arterial hypertension. *European Journal of Internal Medicine*, 126, 1–15. https://doi.org/10.1016/j.ejim.2024.05.033

# Teaching tip: Discuss Figure 5 to Figure 8 with students.

- 17. Lodish, H. F., Berk, A. J., & Kaiser, C. A. (2016). *Molecular cell biology* (8th ed.). W. H. Freeman and Company.
- 18. Meierkord, H., Boon, P., Engelsen, B., et al. (2010). EFNS guideline on the management of status epilepticus in adults. *European Journal of Neurology*, *17*(3), 348–355. https://doi.org/10.1111/j.1468-1331.2009.02917.x
- 19. Primorac, D., Höppner, W., & Bach-Rojecky, L. (2024). *Pharmacogenomics in clinical practice*. Springer International Publishing.
- 20. Raymon, L. P. (2017). USMLE Step 1: Pharmacology (Version 4.0). Becker Professional Education.
- 21. Ritter, J. M., Flower, R. J., Henderson, G., Loke, Y. K., MacEwan, D., Robinson, E., & Fullerton, J. (2023). Rang & Dale's pharmacology (10th ed.). Elsevier.
- 22. Ritter, J., Lewis, L., Mant, T., & Ferro, A. (2008). A textbook of clinical pharmacology and therapeutics (5th ed.). CRC Press. https://doi.org/10.1201/b13234
- 23. Samson, S. L., et al. (2023). American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. *Endocrine Practice*, 29(5), 305–340. https://doi.org/10.1016/j.eprac.2023.02.001

# Teaching tip: Discuss algorithm Figure 1 to algorithm figure 7 with students

- 24. Sanoudou, D. (2012). Clinical applications of pharmacogenetics. IntechOpen.
- 25. Snustad, D. P., & Simmons, M. J. (2015). Principles of genetics. Wiley.
- 26. Tripathi, K. D. (2018). Essentials of medical pharmacology (8th ed.). Jaypee Brothers Medical Publishers.
- 27. U.S. Food and Drug Administration. (n.d.). *Table of pharmacogenetic associations*. https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations
- 28. Unger, T., Borghi, C., Charchar, F., et al. (2020). 2020 International Society of Hypertension Global Hypertension Practice Guidelines. *Hypertension*, *75*(6), 1334–1357. https://doi.org/10.1161/HYPERTENSIONAHA.120.15026

#### Teaching tip: Discuss figure 1 to figure 4 with students

29. Virani, S. S., Newby, L. K., Arnold, S. V., et al. (2023). 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: A report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*, 148(9), e9–e119. https://doi.org/10.1161/CIR.00000000000001168

# Teaching tip: Discuss tables of section 4.3.1 till section 4.3.7 with students

- 30. Wardle, E. N. (2010). *Guide to signal pathways in immune cells* (1st ed.). Humana. https://doi.org/10.1007/978-1-60327-538-5
- 31. Wecker, L., & Ingram, S. L. (2024). Brody's human pharmacology: Mechanism-based therapeutics (7th ed.). Elsevier.
- 32. Whalen, K. (2019). *Lippincott® illustrated reviews: Pharmacology* (7th ed., C. Feild & R. Radhakrishnan, Eds.). Lippincott Williams & Wilkins.

# Clinical Pharmacology

# **Course Learning Outcomes**

- 1. Explain how pregnancy alters the pharmacokinetics and pharmacodynamics of drugs, and evaluate the risks of teratogenicity when selecting drug therapies.
- 2. Describe the pharmacokinetic and pharmacodynamic differences in infants and children, and apply this knowledge to ensure rational and safe pediatric drug use.
- 3. Analyze the considerations for drug use during lactation, including the potential for drug transfer through breast milk and its effects on infants.
- 4. Discuss age-related changes in drug absorption, distribution, metabolism, and excretion, and adjust drug therapy appropriately in geriatric patients.
- 5. Evaluate how co-morbid conditions such as hepatic impairment, renal dysfunction, and diabetes affect drug response, and modify treatment regimens accordingly.

#### **Contents**

# 1. Clinical Pharmacology in pregnancy

- a) Effects of pregnancy on the Pharmacokinetics of drugs
- b) Effects of pregnancy on the Pharmacodynamics of drugs
- c) Teratogenic drug actions

# 2. Pediatric Clinical Pharmacology

- a) Pharmacokinetic considerations in infants and children
- b) Pharmacodynamic considerations in infants and children
- c) Drug use during lactation

### 3. Geriatric Clinical Pharmacology

- a) Pharmacokinetic changes associated with aging
- b) Pharmacodynamic changes associated with aging

# 4. Overview of the effects of co-morbidities on drug response

- a) Effects of hepatic and renal diseases on drug response
- b) Effects of diabetes and environmental factors on drug response

#### **Recommended Readings**

- 1. Brunton, L. L., & Knollmann, B. C. (Eds.). (2023). Goodman & Gilman's: The pharmacological basis of therapeutics (14th ed.). McGraw-Hill Education.
- 2. Cicalese, P. A. (2020). Pharmacotherapy for complex patients: A case-based approach. Springer.
- 3. Katzung, B. G., & Vanderah, T. W. (Eds.). (2024). Basic & clinical pharmacology (16th ed.). McGraw Hill.
- 4. Nahata, M. C., & Hipple, T. F. (2009). Pediatric drug formulations (6th ed.). American Pharmacists
- 5. Association.
- 6. Noble, S. (2022). Drugs in pregnancy and lactation: A reference guide to fetal and neonatal risk (12th ed.). Wolters Kluwer.
- 7. Rowe, J. W., & Fulmer, T. (Eds.). (2018). Clinical geriatrics (3rd ed.). Wiley-Blackwell.
- 8. Shargel, L., Wu-Pong, S., & Yu, A. B. C. (2012). Applied biopharmaceutics and pharmacokinetics (7th ed.). McGraw-Hill Education.
- 9. Talbert, R. L., DiPiro, J. T., Yee, G. C., Matzke, G. R., Wells, B. G., & Posey, L. M. (2022). Pharmacotherapy: A pathophysiologic approach (11th ed.). McGraw-Hill Education.

#### **Practical**

By the end of this course students will be able to discuss and analyze following real-life Clinical Pharmacology cases:

### A. Pregnancy

- 1. Case Discussion: UTI in a pregnant woman during first trimester
  - Discuss selection of antibiotics considering fetal safety and teratogenic risks.
- 2. Case Discussion: Nausea and vomiting in early pregnancy
  - Evaluate pharmacological treatment options, focusing on safety during organogenesis.
- 3. Case Discussion: Hypertension in a pregnant woman at 24 weeks gestation, Eclampsia & Preeclampsia
  - Identify antihypertensive drugs that are safe in mid-pregnancy and avoid teratogenic or fetotoxic agents, Management of Eclampsia & Preeclampsia.
- 4. Case Discussion: Gestational diabetes diagnosed at 28 weeks of pregnancy
  - Discuss appropriate glycemic targets and selection of safe antidiabetic agents during pregnancy.

### B. Lactation

- 5. Case Discussion: Mother with postpartum infection needing antibiotic therapy
  - Analyze which antibiotics are safe during breastfeeding and how to minimize infant drug exposure.
- 6. Case Discussion: Postpartum mother on antidepressants
  - Discuss antidepressant safety during lactation and the risk-benefit analysis for mother and infant.

#### C. Pediatrics

- 7. Case Discussion: Febrile seizures in a 2-year-old child
  - Evaluate appropriate antipyretic and anticonvulsant use, considering age-specific dosing and safety.
- 8. Case Discussion: Asthma exacerbation in a 6-year-old child
  - Discuss age-appropriate bronchodilator and steroid use in acute and maintenance therapy.
- 9. Case Discussion: Antibiotic use in acute otitis media in children
  - Identify appropriate empirical antibiotic therapy and the importance of avoiding overuse.

#### D. Geriatrics

- 10. Case Discussion: Polypharmacy in a 72-year-old patient with diabetes, hypertension, and osteoarthritis
  - Discuss risk of drug interactions, inappropriate medications, and strategies to reduce pill burden.
- 11. Case Discussion: Fall risk in an elderly patient on benzodiazepines
  - Identify safer alternatives and discuss age-related pharmacodynamic changes increasing fall risk.

#### E. Dose calculation for special patients

12. Case Discussion: Dose calculation in special population i.e Renal Failure, Liver Failure, pediatrics, geriatrics etc.

#### F. Comorbidities and Drug Safety

- 13. Case Discussion: NSAID use in a patient with chronic kidney disease
  - Discuss renal safety profile of NSAIDs and suggest safer analgesic alternatives.
- 14. Case Discussion: Antibiotic prescribing in a diabetic patient with foot infection

• Explore antibiotic selection, tissue penetration, and risks related to impaired immunity.

Note: A minimum of 10 practicals should be conducted

# General Courses Reviewed by the NCRC

## Quantitative Reasoning - I

### 1. ALGEBRA

- a. Solution of Linear and Quadratic Equations. Equations reducible to Quadratic Form. Solution of simultaneous Equations.
- b. Arithmetic, Geometric and Harmonic Progressions: Arithmetic, Geometric and Harmonic Means.
- c. Permutations and Combinations:
- d. Binomial Theorem: Simple application.

# 2. TRIGONOMETRY

Measurement of angles in Radian and Degrees. Definitions of circular functions. Derivation of circular function for simple cases.

### 3. ANALYTICAL GEOMETRY

Coordinates of point in a plane. Distance between two points in a plane. Locus, Equations of straight line, Equation of Parabola, Circle and Ellips.

### 4. DIFFERENTIAL CALCULUS

Functions, variations in functions, limits, differential coefficient, differentiation of algebraic, trigonometric, exponential and logarithmic functions, partial derivatives. Maxima and minima values. Points of inflexion.

### 5. INTEGRAL CALCULUS

Concept of integration Rules of integration. Integration of algebraic, exponential, logarithmic and trigonometric functions by using different techniques, and numerical integration

### **Recommended Readings**

- 1. Bali N, Gupta P, Gandhi C. A Textbook of Pharmaceutical Mathematics. 2nd Ed. Laxmi Publications; 2008.
- 2. Edvards CH, Penney DE. Calculus and Analytic Geometry. 5th Ed. Prentice Hall Inc; 1999.
- 3. Hoel PG, PortSC, Stone CJ. Introduction to Statistical Theory. 1st Ed. Brooks Cole; 1972.

### Quantitative Reasoning - II

# 1. DESCRIPTION OF STATISTICS:

Descriptive Statistics: What is Statistics? Importance of Statistics. What is Biostatistics? Application of Statistics in Biological and Pharmaceutical Sciences. How are samples selected?

# 2. ORGANIZING and DISPLAYING DATA:

Vriables, Quantitative and Qualitative Variables, Univariate Data, Bivariate Data, Random Variables, Frequency Table, Diagrams, Pictograms, Simple Bar Charts, Multiple Bar Charts, Histograms.

### 3. SUMMARIZING DATA and VARIATION:

The Mean, the Median, the Mode, the Mean Deviation, the Variance and Standard Deviation, Coefficient of Variation.

### 4. **CURVE FITTING:**

Fitting a Straight Line. Fitting Parabolic or High Degree Curve.

#### 5. **PROBABILITY:**

Definitions, Probability Rules, Probability Distributions (Binomial & Normal Distributions).

# 6. SIMPLE REGRESSION AND CORRELATION:

Introduction. Simple Linear Regression Model. Correlation co-efficient.

# 7. TEST OF HYPOTHESIS AND SIGNIFICANCE:

Statistical Hypothesis. Level of Significance. Test of Significance. Confidence Intervals, Test involving Binomial and Normal Distributions.

# 8. STUDENT "t", "F" and Chi-Square Distributions:

Test of Significance based on "t", "F" and Chi-Square distributions.

### 9. ANALYSIS OF VARIANCE:

One-way Classification, Two-way Classification, Partitioning of Sum of Squares and Degrees of Freedom, Multiple Compression Tests such as LSD, The analysis of Variance Models.

# 10. STATISTICAL PACKAGE:

An understanding of data analysis by using different statistical tests using various statistical software's like SPSS, Minitab, Statistica etc.

# Recommended readings

- 1. Daniel WW. Bio-Statistics: Foundation for Analysis in Health Science. 9th Ed. Wiley Publishers; 2009.
- 2. Nilton JS. Statistical Methods in Biological and health Sciences. 3rd Ed. McGrew Hill; 1998.
- 3. Hoel PG, PortSC, Stone CJ. Introduction to Statistical Theory. 1st Ed. Brooks Cole; 1972.
- 4. Samuels M. Statistics for the life sciences. 3rd Ed. Dellen Publishers co; 2002. 5. Zar JH. Biostatistical analysis. 4th Ed. Francis Hall; 1999.