



**University of Dhaka**  
**Department of Clinical Pharmacy and Pharmacology**  
**Faculty of Pharmacy**

**Course curriculum of**  
**Master of Pharmacy (MPharm)**

## 1. Introduction to the Department

The Department of Clinical Pharmacy & Pharmacology (CPP) was established in 2003 under the Faculty of Pharmacy of University of Dhaka. Since the inception of this prestigious department, it has been offering all the relevant subjects of Clinical Pharmacy & Pharmacology through different graduate programs. The goal of the department is to provide innovative, inter-professional experiences to develop students and pharmacists as integral members of the health care team which will contribute to the health care system both nationally and globally. One-year M. Pharm. (Master of Pharmacy) degree is the core program of this department and is offered to the students who have completed five (5) year B. Pharm. Professional (Bachelor of Pharmacy Professional) successfully. Besides M. Phil. (Master of Philosophy) and Ph. D. (Doctor of Philosophy) degree programs are also offered to Pharmacy medical graduates. Faculty members of this department are engaged in extensive research with diverse interests. Main research interests include chemistry and pharmacology of both synthetic and natural products, toxicology, rational use of drugs, cancer biology, molecular and genomic sciences, and drug-protein interaction. The primary goals of the research are to generate and disseminate knowledge to advance patient care, medication safety, disease prevention and treatment, health care cost-effectiveness and quality, and Pharmacy education. Besides the research generated new knowledge are applied to develop, evaluate and innovate health care delivery models, Pharmacy education models, and health policy. The department participate in local, state, national, and global health programs that promote and advocate health improvement, wellness, disease prevention and treatment, and access to health care. The department serves as patient advocates, especially for underserved populations and participate as active leaders of the University and the public at large.

## 2. Introduction to the Program

Course of study for a Masters of Pharmacy degree (M. Pharm) in the Department of Clinical Pharmacy & Pharmacology shall extend over a period of one academic year. A student can enroll either in Non-thesis or in Thesis Group where applicable. A student must earn a total of 34 credits or 36 credits for the non-thesis and thesis group respectively for the award of M. Pharm degree. The distribution of credits will be decided by the Department. However, the M. Pharm courses in the Department of Clinical Pharmacy & Pharmacology will be conducted under the following general rules and regulations.

❖ **Title:** Clinical Pharmacy & Pharmacology

❖ **Duration:** The duration of Masters of Pharmacy (M. Pharm.) program will be of 1 (one) academic year to be distributed as follows:

Classes	24 Weeks
Time for preparation of final examination	04 weeks
Course final examination	04 weeks
Submission of thesis/project/practical examination/seminar/viva voce	16 weeks
Publication of results	04 weeks
Total	52 weeks

- ❖ **Eligibility for Admission:** Students who have completed five (5) years Bachelor of Pharmacy Professional (B. Pharm. Professional) degree from the Department of Pharmacy of University of Dhaka will only be eligible for admission to Masters of Pharmacy (M. Pharm) courses under the Department of Clinical Pharmacy & Pharmacology.
- ❖ **General Objective of the Program:** The vision of the Department of Clinical Pharmacy & Pharmacology is to become a center of excellence in Clinical Pharmacy and pharmacology education, research, consultancy and provision of public services that meet the national, regional and global expectations. The mission of the department is to produce highly trained professionals who are able to provide quality health care and consultancy services and carry out research.

### 3. Structure of Curriculum

The Master Degree in Clinical Pharmacy & Pharmacology is awarded by the Department of Clinical Pharmacy & Pharmacology of University of Dhaka (DU) upon the fulfillment of the following requirements:

1. Compliance with the CPP Master Degree regulations approved by the academic council.
2. Successful completion of required credit hours in one of the following groups:

**Thesis Group:**

SL No.	Course Code	Course Name	Marks	Credit	Credit Hour
1	CPP 601	Advanced Clinical Pharmacy	100	4	60
2	CPP 602	Advanced Pharmacology	100	4	60
3	CPP 603	Drug Use Management	100	4	60
4	CPP 604	Molecular Toxicology	100	4	60
5	CPP 605	Molecular Pharmacology	100	4	60
6	CPP 606	Advanced Clinical Research	100	4	60
7	CPP 607	Thesis Work	200	8	120
8	CPP 608	Presentation	50	2	30
9	CPP 609	Viva Voce	50	2	30
		Total	900	36	540

**Non-Thesis Group:**

SL No.	Course Code	Course Name	Marks	Credit	Credit Hour
1	CPP 601	Advanced Clinical Pharmacy	100	4	60
2	CPP 602	Advanced Pharmacology	100	4	60
3	CPP 603	Drug Use Management	100	4	60
4	CPP 604	Molecular Toxicology	100	4	60
5	CPP 605	Molecular Pharmacology	100	4	60
6	CPP 606	Advanced Clinical Research	100	4	60
7	CPP 601L	Advanced Clinical Pharmacy- Lab	25	1	15
8	CPP 602L	Advanced Pharmacology- Lab	25	1	15
9	CPP 603L	Drug Use Management- Lab	25	1	15
10	CPP 604L	Molecular Toxicology- Lab	25	1	15
11	CPP 605L	Molecular Pharmacology- Lab	25	1	15
12	CPP 606L	Advanced Clinical Research- Lab	25	1	15
13	CPP 610	Research/Protocol Design and Proposal writing and Presentation	50	2	30
14	CPP 611	Viva Voce	50	2	30
		Total	850	34	510

#### 4. Assessment System

❖ Mark Distributions:

#### Thesis Group:

SL No.	Course Code	Course Name	Marks			
			Class Assessment	In-course Exam.	Final Exam.	Total Marks
1	PHP 601	Advanced Clinical Pharmacy	10	20	70	100
2	PHP 602	Advanced Pharmacology	10	20	70	100
3	PHP 603	Drug Use Management	10	20	70	100
4	PHP 604	Molecular Toxicology	10	20	70	100
5	PHP 605	Molecular Pharmacology	10	20	70	100
6	PHP 606	Advanced Clinical Research	10	20	70	100
7	PHP 607	Thesis Work			200	200
8	PHP 608	Presentation			50	50
9	PHP 609	Viva Voce			50	50
		Total				900

#### Non-Thesis Group:

SL No.	Course Code	Course Name	Marks			
			Class Assessment	In-course Exam.	Final Exam.	Total Marks
1	PHP 601	Advanced Clinical Pharmacy	10	20	70	100
2	PHP 602	Advanced Pharmacology	10	20	70	100
3	PHP 603	Drug Use Management	10	20	70	100
4	PHP 604	Molecular Toxicology	10	20	70	100
5	PHP 605	Molecular Pharmacology	10	20	70	100
6	PHP 606	Advanced Clinical Research	10	20	70	100
7	PHP 601L	Advanced Clinical Pharmacy- Lab			25	25
8	PHP 602L	Advanced Pharmacology- Lab			25	25
9	PHP 603L	Drug Use Management- Lab			25	25
10	PHP 604L	Molecular Toxicology- Lab			25	25
11	PHP 605L	Molecular Pharmacology- Lab			25	25
12	PHP 606L	Advanced Clinical Research- Lab			25	25
13	PHP 610	Research/Protocol Design and Proposal writing and Presentation			50	50
14	PHP 611	Viva Voce			50	50
		Total				850

❖ Examination System:

The performance of a student in a given course will be evaluated in the following way:

**Class Assessment:**

- (i) Course instructor should assign a topic relevant to the course work to each individual student
- (ii) The student can either submit a written information on that topic or give a seminar in the classroom
- (iii) Course instructor should decide the form of the assignment and announce the results in 2 weeks after receiving the assignments.
- (iv) The course-coordinator will decide which faculty will participate in class assessment. But at least two faculties will participate in class assessment and the average will be used to prepare final grade.
- (v) Marks for class assessment must be submitted by the course teacher to the Chairman of the Examination Committee and to the Controller of Examinations before the final examination.

**In-course Assessment:**

- (i) In-course assessment should be done by taking class tests.
- (ii) The Chairman of the department will announce the dates of in-course examinations at the beginning of the course. The in-course assessment will be of one hour duration for 4 credit course and of half an hour duration for a 2 credit course. The concerned teacher will be responsible to assess the students sitting in his/her course. There will be 2 in course tests and average of the two should be considered to finalize the grade.
- (iii) Maximum duration of in-course tests will be one class hour.
- (iv) Questions for in-course tests will include four (4) descriptive questions while each bears five (5) marks.
- (v) Course teachers must announce results in 4 weeks of holding the examination. Answer scripts must be shown to the students.
- (vi) Marks for in-course assessment must be submitted by the course teacher to the Chairman of the Examination Committee and to the Controller of Examinations before the final examination.
- (vii) No make-up test will be arranged for a student who fails to appear in in-course test/tests. Absence in any in-course test will be counted as zero for calculating the average in in-course test for that course. However, a student can apply to the Chairman/Chairperson of the department for make-up test if recommended by the respective course teacher. The Chairperson/Chairman will only place the application before the academic committee if the particular student has met with an accident or his/her parents have expired or he/she has gone through a surgical procedure or any other such situation which the Academic Committee feels can be considered. The make-up test must be held during the course period.

**Course Final Examination (Theory and Practical Courses):**

- (i) Students having 75% or more attendance on average (collegiate) are eligible to appear in the final examination.

- (ii) Students having 60-74% attendance are considered to be non-collegiate and will be eligible to sit for the final examination on payment of fine Tk. 7,000/- (Seven thousand).
- (iii) Students having attendance less than 60% will not be allowed to sit for the final examination but may seek readmission in the program.
- (iv) The year final examinations will be conducted centrally by the Controller of Examinations as per existing rules.
- (v) The duration of theoretical course final examinations will be as follows:

Credits	Duration of Examination (hours)
4 Credit Courses	4
3 Credit Courses	3
2 Credit Courses	2.5

- (vi) Duration of practical examinations will be between 4 - 6 hours irrespective of credit hours.
- (vii) For final examination, the question paper should include eighteen (18) questions out of which fourteen (14) should be answered while each question bears five (5) marks.
- (viii) For theoretical course final examinations, there will be two examiners: course teacher will be the first examiner and the second examiner will be from within the department or from any other department of Dhaka University relevant to the subject. In case a suitable examiner is not found from Dhaka University, a teacher from outside Dhaka University may be appointed as second examiner with prior permission from the Vice-Chancellor. Evaluation will be made under the existing rules.
- (ix) The assessment of thesis or laboratory works will be made by observing overall performance of the student at work, viva voce, presentation and evaluation of practical and/or research result reports.
- (x) At the beginning of each academic session, an examination committee is to be constituted for that session by the department. The Chairman of the Examination Committee will act as a course co-ordinator for that session. The examination committee will have a Chairman, two internal members and an external member.
- (xi) Third Examination: Under double-examiner system and in case of difference of above 20% of marks, there will be a 3rd examiner. Marks of nearest two examiners (theory and thesis) will be average out as final marks.
- (xii) Examination of practical courses for non-thesis students will be conducted as per existing rules of the University.

Course Final Examination (Attendance+ Class lab reports+ Final exam)	100% (20%+ 20%+60%)
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### Evaluation of Thesis:

(i) Thesis will be evaluated as per existing rules of the university with two external examiners from outside the respective Department.

(ii) Oral examination of the MS thesis students will be conducted by the members of Examination Committee as per existing rules of the university.

- ❖ **Grading System:** Grades and grade points will be awarded on the basis of marks obtained in the written, oral and practical examinations according to the following schemes:

Marks Obtained (%)	Grade	Grade Point
80-100	A <sup>+</sup>	4.00
75-79	A	3.75
70-74	A <sup>-</sup>	3.50
65-69	B <sup>+</sup>	3.25
60-64	B	3.00
55-59	B <sup>-</sup>	2.75
50-54	C <sup>+</sup>	2.50
45-49	C	2.25
40-44	D	2.00
Less than 40	F	0.00
	I	Incomplete
	W	Withdrawn

Only 'D' or higher grade will be counted as credits earned by a student.

A student obtaining 'F' grade in any course (theory and practical) will not be awarded degree. Student with 'F' grade in any course, shall be allowed to improve twice/two times only with the following batches.

**GPA:** Grade point average (GPA) is the weighted average of the grade points obtained by the students in all the courses completed by the student in a year. GPA will be calculated according to the following formula:

$$GPA = \frac{\sum(\text{Grade points in a course credits for the course})}{\text{Total Credits taken}}$$

*cGPA* = cumulative GPA for different years.



❖ **Requirements for Masters of Pharmacy Degree:**

- (i) A minimum GPA of 2.50 on a scale of 4.00 must be obtained in order to be awarded Masters of Pharmacy (M. Pharm) degree.
- (ii) A student failing to complete the M. Pharm course in a year may seek readmission with the next available batch of students, provided he/she applies within one month of publication of the result of the concerned year.
- (iii) A readmitted student will be allowed to retain his/her in- course/class assessment/tutorial marks earned in previous year.
- (iv) A readmitted student may be allowed to take up thesis work as decided by the Departmental Academic Committee.
- (v) The transcripts of successful readmitted student will bear the letter 'R' after GPA with a foot note explaining 'R' means Readmission.

**Course Number : CPP 601**

**Course Title : Advanced Clinical Pharmacy**

**Credit hours : 4**

**Introduction:**

In healthcare system, the use of medicines is the most common intervention to alleviate the condition of the patients. However, the use of medicines is occurred with a number of unintentional effects which may deteriorate the symptoms profoundly. As a result, meticulous application of medicine is prescribed over the patients. Drug selection and prescribing is increasingly complex and demanding a multi-disciplinary approach that involves pharmacists along with doctors, nurses and other member of healthcare team. Clearly, the clinical pharmacist's role in providing clinical services are expanding and require a dynamic attention with therapeutic knowledge. Therefore, the course content is relevant to current medicinal practice for the selected disorders. This course addresses the needs of the students by presenting contemporary drug therapy that can be used to prepare and update the pharmacy students with unique skill and knowledge of advanced drug therapy.

**Specific Objectives:**

1. The healthcare system continues to change at a dynamic rate which require a high demand of safe and effective use of drugs. The course content displays a major blending of drug therapy and clinical management of different disorders which will provide graduate student a better understanding of this diseases and their current therapy approaches.
2. To promote safe, appropriate and cost-effective prescribing that respects patient choice, the course is designed to help the students understand and address many of these issues
3. The content of this course is addressed to grasp the advent of new drug therapy, effective patient counseling, racial and gender differences in drug responses as well as drug information sources.
4. The students will be enriched about several diseases and their management therapy such as cardiovascular, neurological, psychological, rheumatoid and malignant disorders which require a great attention in respect of social and cost-economic impact. The burden of this diseases greatly influences the quality of life of the patients.

**Course Content:**

**(1) Gastrointestinal disorders**

Etiology, epidemiology, pathophysiology, clinical manifestations, principles of management and treatment of peptic ulcer disease, inflammatory bowel disease- ulcerative colitis, Crohn's diseases, constipation and diarrhea, GERD, Oral rehydration therapy, ORS, drug therapy for traveler's diarrhea and relevant case studies.

**(2) Neurologic disorders**

(a) Parkinson's disease: biochemical basis, epidemiology, etiology, pathophysiology, clinical findings, treatment and management, psychotherapy, physical therapy and prognosis; (b) Alzheimer's disease: etiology, pathophysiology, cholinergic, amyloid and tau hypothesis, prevention, role of green tea, management and treatment and prognosis (c) Cerebrovascular disorders: classification, risk factors, etiology, pathophysiology of ischemic and hemorrhagic stroke, prevention, life style modification and drug treatment; (d) Pain management: pathophysiology, acute versus chronic pain, factors influencing pain perception, evaluation of pain, clinical pain syndromes, principles of pain management etc.

### **(3) Psychiatric disorders**

(a) Etiology, epidemiology, pathophysiology, clinical manifestations, principles of management and treatment of anxiety, mood disorders, sleep disorders, paraphlexic disorders and drug abuse; (b) Schizophrenia: Risk factors, etiology, pathophysiology, dopamine hypothesis, treatment and management with antipsychotics and other related drugs

### **(4) Urological disorders**

Etiology, epidemiology, pathophysiology, clinical manifestations, principles of management and treatment of (a) Acute and chronic renal diseases; (b) Benign prostatic hyperplasia; (c) Glomerulonephritis; (d) Nephrotic syndromes and relevant case studies.

### **(5) Skin disorders**

(a) Eczema and psoriasis: pathophysiology, clinical features, clinical types and treatment; (b) Pressure sores and leg ulcers: pathophysiology, etiology, clinical sign and symptoms, investigations and treatment; (c) Drug induced skin disorders: causes, diagnosis, sign and symptoms, treatment options, relevant case studies.

### **(6) Endocrine disorders**

Epidemiology, etiology, pathophysiology, clinical manifestations, investigations and treatment options, management of thyroid and parathyroid disorders, relevant case studies.

### **(7) Neoplastic disorders**

(a) Acute and chronic leukemia: classification, clinical presentation, drug therapy, induction and consolidation therapy, CNS therapy, maintenance therapy and prognosis; (b) Breast cancer: etiology, pathophysiology, detection and diagnosis, treatment, metastatic breast cancer and its treatment; (c) Lung cancer: etiology and epidemiology, subtypes, diagnosing and staging, treatment of lung carcinoma, major toxicities of the antineoplastic agents; (d) Malignant lymphomas and solid tumors and relevant case studies.

### **(8) Infectious disorders**

(a) Infective endocarditis: anatomy, pathophysiology, etiology, bacteremia, diagnosis and clinical features, treatment, complications and prevention; (b) Central nervous system infections: etiology, epidemiology, common pathogens, pathogenesis, diagnosis and clinical features, complications and treatments, neonatal meningitis, childhood and adult meningitis, controversies in antibiotic therapy; (c) Surgical infections and antibiotic prophylaxis; (d) Fungal infections.

### **(9) Patient counseling, education and chronic disease monitoring**

Format of counseling, counseling area, documentation of counseling, benefits and outcomes, counseling on non-prescription and prescription drugs, patient education, patients learning and behavior, components and types of patient education, monitoring in the community pharmacy, documentation and patient monitoring.

### **Learning outcomes:**

1. The course is intended to learn the etiology, pathophysiology, epidemiology, treatment and management of GI, cardiovascular, neoplasia, neurological, psychiatric, endocrine, infectious, urological and skin disorders.
2. Advance drug therapy and their possible side effects, management of the adverse effects of the related drug candidates used in the above disorders will be focused.

3. Students will acquire the knowledge of how to counsel with patients, monitoring and evaluation of disease prognosis, documentation, patient education with chronic disorders.
4. In the context of safe and effective medicine use, the prime target of a pharmacist impedes with medication non-adherence due to high cost treatment strategies. The course will provide the students to make a worthwhile cost-effective approach for each patient.

<b>Class schedule</b>	<b>: 60 Classes</b>
(1) Gastrointestinal disorders	: 7
(2) Neurologic disorders	: 7
(3) Psychiatric disorders	: 7
(4) Urological disorders	: 6
(5) Skin disorders	: 6
(6) Endocrine disorders	: 6
(7) Neoplastic disorders	: 9
(8) Infectious disorders	: 6
(9) Patient counseling, education and chronic disease monitoring	: 6

**Assessment:** As per the rule of the University of Dhaka.

**References:**

1. Clinical Pharmacy and Therapeutics. E. T. Herfindal, D. R. Gourley and L. L. Hart, Fifth Edition, Williams & Wilkins publications, 1992
2. Clinical Pharmacy and Therapeutics. Roger Walker and Cate Whittlesea, Fifth Edition, Churchill Livingstone, Elsevier publications, 2012
3. Davidson's Principles and Practices of Medicines. N. R. Colledge, B. R. Walker and S. H. Ralston, Twenty third Edition, Churchill Livingstone, Elsevier publications, 2018
4. Clinical Pharmacology and Therapeutics. J. M. Ritter, L. D. Lewis, T. G. K. Mant and A. Ferro, Fifth Edition, Hodder Arnold Publications, UK, 2008
5. Oxford Handbook of Clinical Pharmacy, P. Wiffen, M. Mitchell, M. Snelling and N. Stoner, Third Edition, Oxford University Press, 2017

**Course Number : CPP 602**

**Course Title : Advanced Pharmacology**

**Credit Hours : 4**

**Course Introduction:**

Advanced pharmacology course covers the principles of drug action for several important classes of drugs. A basic knowledge on understanding of the pharmacological basis of drug receptor interaction will be helpful for the students to learn pharmacology in advanced level.

**Specific Objectives:**

The specific objectives and learning outcomes of this course will be -

- To explore the underlying mechanism or mode of action, therapeutic uses and adverse reactions of the pharmacotherapeutic agents that modulates the structure and function of ion-channels and enzymes.
- To study molecular and cellular mechanisms of neuropharmacological agents.
- To understand the therapeutic potentials and applications of various immunotherapeutic agents and to explore how they modulate the functions of the immune system.
- To discuss the wide range of therapeutic agents that are used against various types and forms of cancer, their mode of action, molecular mechanisms of resistance and therapeutic options in the event of relapse and metastasis.
- To discuss the therapeutic application of Pharmacogenetics and Pharmacogenomics.
- To learn about the pharmacological management of various types of ophthalmic disorders.

**Course contents:**

**(1) Pharmacology of ion channels and enzymes**

Transduction mechanisms as targets of drug action, voltage sensitive ion channels-structure and function, K<sup>+</sup> channels, ion channel mutations and their consequence, voltage sensitive Ca<sup>+2</sup> channels and the pharmacology of their inhibitors, agonists at β-adrenoceptors modulating cardiac ion-channels, pharmacology of Na<sup>+</sup>/K<sup>+</sup>ATPase and gap junction.

**(2) Neuropharmacology**

Molecular and cellular mechanisms, ion channels and neurotransmitters, synaptic potentials and transmission, chemical synaptic potential, principles of neuropharmacology, key neurotransmitters, amino acid transmitters: glutamate, GABA, glycine; catecholamine: dopamine, noradrenaline, 5-HT; Acetylcholine and receptors, glutamate receptors, GABA and its reception, catecholamine receptor, Serotonin receptors, the opiate receptors, Antiepileptic drugs, Neurodegenerative disorders: therapeutic approaches of stroke, Parkinson's disease, Alzheimer's disease, Huntington's disease.

**(3) Immunopharmacology**

Pharmacological aspects of clinical conditions involving immunological mechanism including hypersensitivity, autoimmunity, immunodeficiency and immunomodulators; Fc receptors and their modulation for as a therapeutic approach for the treatment of infection, autoimmune disorders and malignant disorders, monoclonal antibody therapy for malignancies; immunotherapeutics including vaccines, plasma-derived immunoglobulins, immunostimulants in cancer therapy; and immunopharmacology of probiotics and prebiotics.

#### **(4) Cancer biology and therapy**

Introduction to biology of cancer, modes of treatment: radiotherapy, chemotherapy, biological therapy including immunology, Other chemotherapeutic targets including vascular targets, abnormal tumor physiology, anticancer drugs and their mechanism, molecular mechanisms of resistance. Relapses, metastasis, carcinogenesis and genetic predisposition, diagnostic tests and prognostic factors.

#### **(5) Pharmacogenetics and Pharmacogenomics**

Introduction, definition, SNPs and other polymorphisms. RFLP and direct sequencing as methods of studying polymorphisms. Pharmacogenetics of cytochrome p 450. e.g. CYP2D6, CYP2C9, CYP2C19, CYP3A4, CYP2A6. Role of NAT2 and CYP2E1 in tuberculosis. Role of different polymorphisms in Lung diseases. Methods of studying prominent SNP using any software. Pharmacogenetics of cancer, psychiatric disease, receptor etc.

#### **(6) Ocular Pharmacology**

Definition, types, causes, signs and symptoms, prevention, treatment of various ocular diseases: cataract, glaucoma, color blindness, chalazion, blurry vision, burning eyes, black eyes, dry eye, blepharitis, Bell's palsy, astigmatism, amblyopia, acanthamoeba, Eales' disease, age-related macular degeneration, diabetic retinopathy and ocular angiogenesis.

#### **(7) Hypolipidaemic drugs and plasma expanders**

Definition, lipid transport, hyperlipoproteinaemia, classification of drugs: HMG-CoA reductase inhibitors (statins), bile acid sequestrants, fibric acid derivatives, nicotinic acid, use of hypolipidaemic drugs: treatment based on LDL-C level, treatment of HDL-C level, treatment of raised TG level, desirable properties of a plasma expanders, indications and contraindications of plasma expanders.

#### **Learning outcomes**

- Students will understand the mechanism or mode of action, therapeutic uses and adverse reactions of the pharmacotherapeutic agents.
- They will learn the molecular and cellular mechanisms of neuropharmacological agents.
- They will understand the therapeutic potentials and applications of various immunotherapeutic agents.
- Students will be able to discuss the wide range of therapeutic agents that are used against various types and forms of cancer, their mode of action, molecular mechanisms of resistance and therapeutic options in the event of relapse and metastasis.
- They will learn the therapeutic application of Pharmacogenetics and Pharmacogenomics.

**Class schedule** : **60 Hours**

(1) Pharmacology of ion channels and enzymes	: 8
(2) Neuropharmacology	: 10
(3) Immunopharmacology	: 10
(4) Cancer biology and therapy	: 10
(5) Pharmacogenetics and Pharmacogenomics	: 8
(6) Ocular Pharmacology	: 6
(7) Hypolipidaemic drugs and plasma expanders	: 8

**Assessment:** As per the rule of the University of Dhaka.

**References:**

1. The Pharmacological Basis of Therapeutics, 12th edition, 2011. Edited By - Laurence L. Brunton, Bruce A. Chabner and Björn C. Knollmann. McGraw-Hill.
2. Principles of Immunopharmacology, 3rd edition, 2011. By - Frans P Nijkamp. Springer.
3. Cellular and Molecular Immunology, 9th edition, 2017. By - Abul Abbas Andrew H. and LichtmanShiv Pillai. Elsevier.
4. Pharmacology and Pharmacotherapeutics, 24th Edition, 2015. By - RS Satoskar, Nirmala Rege and SD Bhandarka. Elsevier India.
5. Basic and Clinical Pharmacology, 14th Edition. By - Bertram G. Katzung. Lange.
6. Rang & Dale's Pharmacology, 8th Edition, 2016. By - James Ritter Rod FlowerGraeme Henderson Humphrey Rang. Churchill Livingstone.
7. Essentials of Medical Pharmacology, 7th edition, ---KD Tripathi

**Course Number : CPP 603**

**Course Title : Drug Use Management**

**Credit hours : 4**

**Course Description:**

The World Health Organization (WHO) defines rational use of drugs as ‘patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community’ and this is one of the basic requirements of promoting health. Contributing factors towards inappropriate use of drugs include faulty and inadequate training & education of health care providers, communication gap between health professional & patient, lack of diagnostic facilities, lack of patient’s knowledge, demand from the patient, lack of standard treatment guidelines, defective drug supply system & ineffective drug regulation, promotional activities of pharmaceutical industries. The course is designed as an intensive learning experience that will foster the development of a basic set of skills to qualitatively address and intervene a healthcare problem; develop and implement an effective public education & health promotion campaign; develop standard treatment guidelines. This course also encompasses key concepts and skills of pharmacoepidemiology; pharmacoeconomics and pharmacovigilance which are also required to monitor and evaluate a healthcare system.

The overall aim of the course is to promote health and improve the quality of life.

**Specific Objectives:**

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

- Define rational use of drugs and determine the factors influencing the role of dispensers to promote drug use management
- Identify nature of inappropriate drug utilization with a background knowledge of effective public education and standard treatment guidelines for changing specific medication use patterns
- Know the steps to implement a drug use indicator study with basic concepts of sampling
- Understand the concepts of pharmacoeconomics and pharmacovigilance
- Describe different types of studies involved in pharmacoepidemiology

**Course Content:**

**1. Introduction of Drug Use Management**

(a) Problems of Irrational Use of Drugs: Background, Definition of rational use of drugs, Factors effecting irrational use of drugs, Impact of irrational use of drugs, Drug use patterns in developed and developing countries, Changing drug use patterns, Learning about drug use problems, Changing drug use problems, Quantitative methods for learning about drug use; (b) Role of Dispensers in Promoting Drug Use Management: Introduction, Definition of dispenser, Dispensing process, Proper and improper dispensing, Impact of improper dispensing, Dispensing practices to enhance rational use of drug, Method to improve complain with therapy, Public vs private sector dispensing.

**2. Drug Use Indicator Study and Sampling Process**

Introduction, Major drug use indicators: Prescribing indicators, Patient care indicators study, Sampling Issues, Different sampling methods, Non-probability sampling methods, Probability sampling methods, Sample size, Practical aspects of sampling, Undertaking the survey, Data collection and entry, Case studies, Different types of forms, Field visits to identify data sources.



### **3. Health Problems Associated with Drug Use and Abuse**

(a) Injection related injuries: Injection related infections, Complication of injection related infections, Infectious diseases, Non-infectious disorders, other common medical problems; (b) Chemical dependence and addiction: Definition, mechanisms of tolerance, mechanisms of physical dependence, mechanisms of psychologic dependence, mechanisms of addiction. Variables affecting the development of addiction; (c) Drugs of abuse: commonly prescribed therapeutics, drugs related to therapeutics, drugs of abuse affecting other receptors; (d) Treatment for addiction and dependence: detoxification, social treatments, pharmacologic treatment, conclusion and future directions.

### **4. Effective Public Education**

Introduction, Patients role, Concept of disease etiology, Concept of cure, Concepts about the therapeutic values of drugs, Effect of promotion and marketing on the use of drugs, Social marketing, Global public education initiatives related to drug use, Developing a public education strategy, Effective communication systems, Public education campaigns on drug use, Examples of public education forms.

### **5. Standard Treatment Guidelines**

Introduction, Importance of standard treatment guidelines, Standard treatment intherapeutic process, Advantages of standard treatment, Key features of standard treatment, Development of standard treatments, Implementation of standard treatments, Standard treatment guidelines in different Countries, Case studies, Standard treatment guidelines for health centers, Relevance to common drugs use decisions, Case studies.

### **6. Pharmacoepidemiology**

Principles of epidemiology, aims of epidemiology, Epidemiologic methods: Observational studies, Experimental studies, Descriptive epidemiology, Analytical epidemiology, Experimental epidemiology, Pharmacoepidemiology versus epidemiology, History of pharmacoepidemiology, Impact of pharmacoepidemiology on drug policy, studying drug interactions.

### **7. Pharmacovigilance**

Key Definitions and importance, Generic and specific aims, Need and objectives, Passive vs active pharmacovigilance, Prescription-Event Monitoring (PEM), Designing a pharmacovigilance system, Data collection, Data analysis and reporting, Taking actions for improvement, Pharmacovigilance center, Post-marketing surveillance, Spontaneous Reporting, Pharmacovigilance for Special Populations (including pregnant and lactating mothers and pediatric and geriatric patients) and Special Product Classes.

### **8. Pharmacoeconomics**

Introduction, terms used in pharmacoeconomics, types of health economic analysis, Cost-benefit analysis, Cost effectiveness analysis, Cost utility analysis, Costs and consequences discounting, Decision analysis, Risk management of unwanted drug effects, Medication non-adherence, Incentives and Disincentives.

#### **Learning outcomes**

- Students will be able to learn about rational use of drugs and determine the factors influencing drug use.
- They will be able to identify nature of inappropriate drug utilization and standard treatment guidelines for changing specific medication use patterns

- They will get the idea about the steps of implementation of drug use indicators in health settings.
- Students will be updated on the understanding of pharmacoeconomics and pharmacovigilance.
- They will be able to describe different types of studies involved in pharmacoepidemiology.

<b>Class schedule</b>	<b>: 60 Classes</b>
1. Introduction of Drug Use Management	: 8
2. Drug Use Indicator Study and Sampling Process	: 8
3. Health Problems Associated with Drug Use and Abuse	: 8
4. Effective Public Education	: 6
5. Standard Treatment Guidelines	: 6
6. Pharmacoepidemiology	: 10
7. Pharmacovigilance	: 8
8. Pharmacoeconomics	: 6

**Assessment:** As per the rule of the University of Dhaka

#### References

1. Management of common health problems of drug users. WHO Regional Office for South-East Asia, 2008. Web access: <http://www.who.int/iris/handle/10665/205435>. ISBN 9789290222927
2. Park Textbook of Preventive and Social Medicine 23rd edition, by K. Park, 2015
3. Clinical Pharmacy and Therapeutics 5th edition by Roger Walker & Cate Whittlesea, 2012.
4. Principles of Pharmacology: The Pathophysiologic Base of Drug Therapy---David E. Golan, Armen H. Tashjian, Ehrin J. Armstrong
5. Mann's Pharmacovigilance 3rd Edition, by Elizabeth B. Andrews and Nicholas Moore, Willey Blackwell, 2014.
6. Textbook of Pharmacovigilance, Edition 1/e, by SK Gupta, ISBN 9789350252062, 2011.
7. A practical handbook on the pharmacovigilance of antiretroviral medicines, WHO, 2013.

**Course Code : CPP 604**  
**Course title : Molecular Toxicology**  
**Credit hours : 4**

### **Introduction to the Course**

Toxicology is a discipline related with biology, chemistry, pharmacology and medicine. It involves the study of the adverse effects of chemical substances on living organisms and the practice of diagnosing and treating exposures to toxins and toxicants. The relationship between dose and its effects on the exposed organism is of high significance in toxicology. In another word, toxicology deals with the symptoms, mechanisms, treatments and detection of poisoning.

### **Specific objectives**

The prime objective and intended learning outcomes of this course will be to help students understand the various aspects, scopes and application of advanced toxicology so that they can understand and learn specifically and comprehensively regarding -

1. The basic concept of advanced toxicology.
2. The molecular mechanisms of toxicity and various aspects of toxicity.
3. The spectrum of toxicity effects produced by reactive intermediates, heavy metals and to give idea about the clinical treatment and remedial measures for such toxicity.
4. Various types and forms of clinically relevant system/organ specific toxicity.

### **Course Contents**

#### **(1) Principle and Mechanism of Toxicity**

(a) Principle: Introduction to toxicology, classification of toxic agents, characteristics of exposure, spectrum of undesired effects, interaction of chemicals, tolerance, dose response, variation in toxic responses, descriptive animal toxicity tests. (b) Mechanism: Delivery from the site of exposure to the target, reaction of the ultimate toxicant with the target molecule, cellular dysfunction and resultant toxicities, repair or dysrepair

#### **(2) Toxicity study in animal models**

Introduction, experimental administration of toxicants, chemical and physical properties, exposure and environmental fate, in vitro and other short-term tests, ecological effects, risk analysis, the future of toxicity testing.

#### **(3) Biotransformation of Xenobiotics**

General Principles, xenobiotic biotransformation by phase I enzymes, phase II enzyme reactions, the cytochrome p450 system-its function, mechanism of action and regulation, glutathione and glutathione-S-transferase-its function, mechanism of action and regulation, superoxide dismutase; mechanism of action and regulation, mechanism of action of different antioxidants.

#### **(4) Toxicokinetics**

Definition, toxic exposure, absorption, distribution, elimination, toxication and detoxication, molecular mechanism of toxicity: nonspecific macromolecular damage, reactive species, inflammatory and immune-mediated mechanism, enzyme-mediated toxicity, receptor-mediated toxicity, teratogenesis.

### **(5) Chemical carcinogenesis and Genetic toxicology**

(a) Chemical carcinogenesis: Definitions, Carcinogenesis by chemicals, mechanisms of chemical carcinogenesis, DNA repair and chemical carcinogenesis, chemical carcinogens and the natural history of neoplastic development, chemical carcinogenesis in humans, the prevention of human cancer induced by chemicals, identification of potential carcinogenic agents, evaluation of carcinogenic potential, relation (extrapolation) of bioassay data to human risk, statistical estimates of human risk from bioassay data by using mathematical models, regulation of carcinogenic risk at the federal level, risk-benefit considerations in the regulation of actual and potential carcinogenic environmental hazards. (b) Genetic toxicology: Definition of genetic toxicology, history of genetic toxicology, health impact of genetic alterations, cancer and genetic risk assessments, mechanisms of induction of genetic alterations, assays for detecting genetic alterations, human population monitoring, new approaches for genetic toxicology.

### **(6) Target organ toxicity**

Blood and cardiovascular toxicity, immunotoxicity, neurotoxicity, hepatic and renal toxicity, reproductive toxicity, respiratory toxicity, ocular toxicity, skin toxicity and endocrine toxicity.

### **(7) Heavy metal and organometallic toxicity**

Host factors influencing the toxicity of metals, metal-binding proteins, complexation and chelation therapy, major toxic metals with multiple effects, essential metals with potential for toxicity, metals related to medical therapy, minor toxic metals, Insecticides, botanical insecticides, herbicides, fungicides, fumigants, rodenticides

### **(8) Environmental toxicology**

(a) Air pollution: Air pollution in perspective, assessing risks associated with air pollution, epidemiologic evidence of health effects, pollutants of outdoor ambient air, adverse health effect. (b) Ecotoxicology: Introduction to ecotoxicology, chemical movement, fate and exposure, biomarkers, endocrine and developmental disruptors, terrestrial and aquatic ecotoxicology, good laboratory practices in terrestrial and aquatic ecotoxicology, modeling and geographic information systems, ecologic risk assessment, environmental toxicology and human health.

### **(9) Clinical and occupational toxicology**

(a) Clinical toxicology: History of clinical toxicology, clinical strategy for treatment of the poisoned patient, case examples of specific poisonings. (b) Occupational toxicology: Workplaces, exposures, and standards, occupational diseases, toxicologic evaluation of occupational agents, exposure monitoring.

### **Learning outcomes**

- Students will get the basic concept on advanced toxicology.
- They will learn about the molecular mechanisms of toxicity.
- Students are intended to learn the spectrum of toxic effects produced by toxicants and remedial measures for such toxicity.
- They will acquire knowledge on various organ specific toxicity.

<b>Class schedule</b>	<b>: 60 Classes</b>
(1) Principle and Mechanism of Toxicity	: 6
(2) Toxicity study in animal models	: 8
(3) Biotransformation of Xenobiotics	: 8
(4) Toxicokinetics	: 6
(5) Chemical carcinogenesis and Genetic toxicology	: 8
(6) Target organ toxicity	: 6
(7) Heavy metal and organometallic toxicity	: 8
(8) Environmental toxicology	: 5
(9) Clinical and occupational toxicology	: 5

**Assessment:** As per the rule of the University of Dhaka

**Reference:**

1. Casarett and Doull's Toxicology, The Basic Science of Poisons. Sixth Edition. Curtis D. Klaassen, Ph.D. McGraw-Hill Medical publishing division.
2. A textbook of modern toxicology, Third Edition. Ernest Hodgson Ph.D. A John Wiley & Sons, Inc., Publication.
3. Introduction to Toxicology, Third Edition, by John Timbrell.
4. Toxicological Chemistry and Biochemistry, Third Edition, by Stanley E. Manahan.
5. Principles of Toxicology, Second Edition, by Phillip L. Williams, PhD, Robert C. James, PhD and Stephen M. Roberts, PhD.

**Course Number : CPP 605**

**Course Title : Molecular Pharmacology**

**Credit hours : 4**

**Introduction:**

This subject utilizes a drug target-based approach rather than the traditional organ/system-based viewpoint and reflects the current advances and research trends towards in silico drug design based on gene and derived protein structure. During the past few decades there have been significant advances and developments in the discipline of molecular pharmacology - an area of pharmacology that is concerned with the study of drugs and their targets at the molecular or chemical level. With the completion of the human genome project, the numbers of genes for each major drug target-family could be determined and fully appreciated. As would be expected, the cloning of the human genome resulted in the identification of many potentially new drug targets. Thus, study of molecular pharmacology would enable the development of novel approaches to explore the complex signal transduction characteristics of pharmacologically important drug targets-proteins.

**Specific Objectives:**

1. The course is designed to explore drug targets at the molecular or chemical level.
2. This course covers advancement of bioscience from a cellular and molecular perspective, with particular attention to the mechanisms of drug action.
3. The course content will update students about latest developments on cellular signaling and appropriate assay platform.

**Course Content:**

**(1) Introduction molecular pharmacology**

Introduction to molecular pharmacology, drug-receptor interactions, the nature of drug targets: GPCRs, ion channels, nuclear receptors, neurotransmitter transporters, future drug targets, molecular pharmacology and drug discovery.

**(2) Molecular drug targets: topology, organization and functions**

(a) G Protein-coupled Receptors: classification, molecular structure and activation of GPCRs, heterotrimeric G-proteins, signal transduction pathways, GPCR desensitization and down-regulation, GPCR oligomerization, constitutive GPCR activity and biased signaling; (b) Ion channels: structure of voltage-gated sodium, potassium and calcium channels, mechanism of their opening and closing, role in neurotransmission and muscle construction; structure of ligand-gated ion channels and their functions; (c) Transporter proteins: transporter families of pharmacological interest, Na<sup>+</sup>/K<sup>+</sup> ATPase pump, ABC transporters.

**(3) Control of cell cycle and cellular proliferation**

Timely regulated expression of cyclins and cell cycle progression, programmed cell death, apoptotic biochemical pathways, necrosis, role of Mitochondria in the necrotic process, drugs and apoptosis, proapoptotic drugs, drugs that inhibit apoptosis.

**(4) Oncogenic signaling pathways and therapeutic potentials**

Hallmarks of cancer; Oncogenes and tumor suppressing genes and molecular signaling that modulates their expression; Signaling pathways involved in human cancers (growth factor, cytoplasmic tyrosine kinase and developmental signaling pathways including Notch, Wnt, Hedgehog, and TGF-β) and potential therapeutic targets; Cross-talk between oncogenic signaling and their

implication in cancer therapy; tumor microenvironment and their role in promoting drug resistance, epithelial-to-mesenchymal transition (EMT) and cancer stemness.

#### **(5) Molecular mechanism of complex genetic diseases**

Mutation and human diseases, types of genetic inheritance, single gene genetic inheritance: cystic fibrosis, sickle cell anemia, Huntington's disease, beta-thalassemia, haemophilia, gaucher disease; Multifactorial genetic inheritance: obesity, diabetes, arthritis, coronary artery disease, high blood pressure; Chromosome abnormalities: down syndrome; Mitochondrial genetic inheritance: epilepsy, dementia.

#### **(6) Recombinant Proteins and Immunotherapeutics**

Introduction to immunotherapeutics, historical background, basis of immunotherapeutics, types of immunotherapeutics, humanisation of antibody therapy, immunotherapeutics in clinical practice, advantages and disadvantages of immunotherapy, the future of immunotherapeutics.

#### **(7) Molecular cloning of drug targets and gene manipulation**

The relevance of recombinant DNA technology to pharmacology/drug discovery, the cloning of drug targets, cloning using peptide sequences, cloning using a specific antibody, cloning using a functional assay, cloning using polymerase chain reaction, structural information from DNA cloning of drug targets, pharmacologic profile of the 'cloned' and the 'native' drug target, reverse pharmacology for orphan drug targets, CRISPR/Cas mediated genome edition, site directed mutagenesis, cutting and joining of DNA molecules, transformation and transfection.

#### **(8) Assays and techniques in molecular pharmacology**

Basic techniques of cell culture, generation of cell lines, basic components of cell culture environment, methods and approaches for successful cell culture, microscopy of living cells: general imaging methodology, imaging of fluorescently labeled cells, immunofluorescence, epifluorescence and confocal microscopy, cryopreservation of cells, Western blotting, Northern blotting, Southern blotting, cell proliferation assay, immunostaining, Resonance energy transfer methods: BRET and FRET to study drug-protein or protein-protein interactions, enzyme linked immunosorbent assay, radioligand binding assays, flow cytometry, cell proliferation assays.

#### **Learning outcomes:**

1. The course focuses on functional relationships between drugs and their targets.
2. This course addresses the understanding drug action from a cellular and molecular perspective.
3. This subject has designed to address the latest development of drug signaling in addition with some current molecular-based techniques.

<b>Class schedule</b>	<b>: 60 classes</b>
(1) Introduction molecular pharmacology	: 6
(2) Molecular drug targets: topology, organization and functions	: 10
(3) Control of cell cycle and cellular proliferation	: 7
(4) Oncogenic signaling pathways and therapeutic potentials	: 7
(5) Molecular mechanism of complex genetic diseases	: 6
(6) Recombinant Proteins and Immunotherapeutics	: 6
(7) Molecular cloning of drug targets and gene manipulation	: 8
(8) Assays and techniques in molecular pharmacology	: 10

**References:**

6. Molecular Pharmacology: From DNA to Drug Discovery, 1<sup>st</sup> Edition, 2013, Authors: John Dickenson, Fiona Freeman, Chris Lloyd Mills, Shiva Sivasubramaniam, Christian Thode, John Wiley & Sons, Ltd.
7. General and Molecular Pharmacology: Principles of Drug Action, 4<sup>th</sup> Edition, 2015. Edited by-Francesco Clementi, Guido Fumagalli, John Wiley & Sons, Ltd.
8. The Molecular Basis of Cancer, 4th Edition, 2015. Edited by - John Mendelsohn, Joe W. Gray, Peter M. Howley, Mark A. Israel and Craig B. Thompson. Elsevier-Saunders.
9. Oncology at a Glance, 1st Edition, 2013. Graham G. Dark. Wiley-Blackwell.
10. Principles and Techniques of Biochemistry and Molecular Biology, 2010, Authors: Keith Wilson, John Walker-Cambridge University Press



**Course Number : CPP 606**

**Course Title : Advanced Clinical Research**

**Credit hours : 4**

**Introduction:**

Clinical drug research forms the experimental basis for efficacy and safety assessment of new therapeutic agents in man. In other words, it allows us to obtain relevant information on how to effectively and safely use a drug in an individual patient. Clinical research is a of key importance for developing and validating new concepts in clinical pharmacology and therapeutics, using already existing and new biologically active agents. Increasingly, it is also conducted to compare different treatment regimens in order to reveal that one is superior to another. In recent years clinical drug research has advanced strongly with the availability of new pharmacokinetic, pharmacodynamic and clinical methods and sophisticated ethical and quality assurance standards, automated and on-line data management. This course is a 'Fundamentals of Clinical Research' in the literal sense of the word. It provides the students with relevant information about every aspect of drug research in human, from the initial research idea to the ultimate publication and with every step in between.

**Specific Objectives:**

4. The course is designed to cover the all aspects of the planning and implementation of the clinical study and of the analysis, interpretation and publication of results. Therefore, students will get the actual knowledge of acquainting with latest research methodology.
5. The course content will give space to the ethical implications of methodological issues in clinical research.
6. A detailed coverage on legal issues, patenting, regulatory bodies and WHO guidelines has been incorporated in order to face the global challenges for clinical research.
7. The course is intended to learn the basic study design, writing protocols and analyzing the data with suitable methods.

**Course Content:**

**(1) Introduction to clinical research and clinical trials**

Definition and history of clinical research-earliest clinical research, Greek and Roman influence, Middle ages, Seventeenth to Twentieth century and beyond, Definition of clinical trial, clinical trial phases, importance of clinical trial, problems in timing of a trial, study protocol.

**(2) Codes, declarations and other ethical guidance**

Ethical framework for biomedical research, The Nuremberg Code, The Declaration of Helsinki, The Belmont report, Regulations for the protection of humans in research in US, International ethical guidance from the council of international organizations, The European community directives on Data protection and clinical trials, Bioethics commissions and research ethics.

**(3) Regulatory Approval and Patent**

(A) Regulatory bodies: Origins of US FDA and its amendments, Drug amendments act of 1962, FDA modernization and Phase IV clinical trials, History of European Medicines Agency, International Conference on Harmonisation, Outline of regulatory approval in the United States, Investigational new drugs, IND and common technical documents, Institutional review board, Timeline of FDA approval, Target product profile, Accelerated approval, Refuse of file, Clinical hold, FDA approval letter, FDA feedbacks, process of administering clinical trials. (B) Patents: History of patenting,

outline of the patenting process, types of documents, organization of information in patent, timeline for patenting, provisional patent applications, sources of law for patenting.

#### **(4) The drug development process and Phases of clinical research**

(a) The pre-clinical development process: Overview, The research stages, Identification of lead compounds, Molecular modeling, Drug selection: in vitro assays and experimental models, Biological drugs, Pharmacokinetic studies, The development stages: Scaling up from laboratory to industrial preparations, choice of dosage form, toxicological studies; (b) The phases of clinical development: Introduction, Phase I, II and Phase III trials, Registration Dossier, Phase IV trials, Project management, The phases of clinical development for Oncology compounds, Accelerating clinical development etc.

#### **(5) Basic study designs**

Fundamental points, Experimental and observational studies, Prospective and retrospective studies, Randomized control trials, Nonrandomized control trials, Cross-over designs, Cohort studies, case-control studies, Withdrawal studies, Factorial designs, The randomization process, Fixed allocation randomization-Simple, blocked and stratified, Adaptive randomization procedures-baseline adaptive, response adaptive process, Blindness-unblind, single-blind, double-blind and triple blind, protecting the double blind design-matching of drugs, coding of drugs, official unblinding, inadvertent unblinding.

#### **(6) Data management and statistical analysis**

Hypothesis testing, sample size and power, data collection, problems in data collection, site education and training, data monitoring, data editing, clinical databases, data entry, data quality control/assurance, statistical analysis plan, statistical approach to analysis.

#### **(7) Good clinical research practice**

Key trial activities, Ethical conduct, research protocol, risk identification, Benefit-risk assessment, Review by IEC/IRB, protocol compliance, informed consent, counting review of risk-benefit assessment, investigations qualifications, staff qualifications, records, confidentiality/privacy, Good manufacturing practice, quality systems.

#### **(8) Assessing Adverse events and Health-related Quality of Life**

Clinical trials in the assessment of adverse events, Determinants of adverse events, classification of adverse events, ascertainment, dimensions, length of follow up, analyzing adverse events, reporting of adverse events, Identification of SAE's, Definition of HRQL, Uses of HRQL, methodological issues-trial design, study populations, intervention, selection of instrument, modes of administration, frequency of assessment, Interpretation of HRQL.

#### **Learning outcomes:**

1. The course will address the traditional methods of clinical research, beginning from the history to the traditional designs with a focus on clinical trials.
2. It will provide the students with general concepts on ethics and regulatory issues, patenting guidelines and respective authority to conduct a clinical research.
3. The students will get the knowledge of writing study protocols, designing a study, data safety and management issues, monitoring boards and meta-analysis.
4. Understanding the basic practices of clinical research, students will acquire the steps of pre-clinical research to develop a potential lead compound to a drug candidates.

<b>Class schedule</b>	<b>: 60 classes</b>
(1) Introduction to clinical research and clinical trials	: 6
(2) Codes, declarations and other ethical guidance	: 8
(3) Regulatory Approval and Patent	: 8
(4) The drug development process and Phases of clinical research	: 8
(5) Basic study designs	: 10
(6) Data management and statistical analysis	: 6
(7) Good clinical research practice	: 6
(8) Assessing Adverse events and Health-related Quality of Life	: 8

**Assessment:** As per the rule of the University of Dhaka

**References:**

11. Principles and Practice of Clinical Research. J. I. Gallin and F. P. Ognibene, Second Edition, Academic press, Elsevier publications, 2007
12. Fundamentals of Clinical Trials. L. M. Friedman, C. D. Furberg and D. L. DeMets. Fourth Edition, Springer publications, 2010
13. The Oxford Textbook of Clinical Research Ethics. Emanuel et. al., Oxford university press, 2008
14. Clinical Trials-Study design, endpoints and biomarkers, drug safety and FDA and ICH guidelines, Tom Brody, Second edition, Academic press, Elsevier publications, 2016
15. Handbook for Good Clinical Research Practice (GCP). WHO guidelines, 2005
16. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations. A. Bacchieri and G. D. Cioppa, Springer publication, 2007
17. General and Molecular Pharmacology. F. Clementi and G. Fumagalli, Fourth edition, Wiley Publication, 2015
18. A Guide to Clinical Drug Research. A. Cohen and J. Posner, Second edition, Kluwer Academic Publishers, 2000