



Operational Manual of MBBS Curriculum 2021

Subject: **Pharmacology & Therapeutics**



Developed By
Research, Publication & Curriculum Development Wing
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Preface

Curriculum is not the sole determinant of the outcome, it is very important as it guides the faculty in preparing their instruction and tells the students what knowledge, skills and attitude they are to develop through the teaching learning process. The ultimate indicators of assessing curriculum in medical education is the quality of health services provided by its graduates with required competencies.

To implement that curriculum all concerned such as teachers, students, deans, administrators, policymakers to be more dynamic, should run smoothly with the time & appropriate pace. This operational manual to implement the curriculum will act as a catalyst, will give momentum in implementing the curriculum. This operational manual will help to implement the curriculum uniformly, effectively, efficiently & smoothly at all the govt. & non govt. medical colleges under all the universities all over the country.

I would like to mention that the curriculum planning process is continuous, dynamic and never-ending as it is not static. If it is to serve best, the needs of the individual student, teacher, educational institution and the community to whom we are ultimately accountable, must be assessed. Before that assessment we should seriously concentrate for the better implementation of the curriculum. Implementation in regards to teaching-learning, integrated teaching, teaching on generic topics on medical humanities, clinical teaching, ambulatory care/OPD based teaching and acquiring identified competencies of each subject. There is a proverb that “Assessment drives Learning”. To ensure students’ learning formative and summative assessments should be taken care of properly. This operational manual on developed MBBS curriculum 2021 will play a vital role in those regards.

I congratulate all who were involved in developing this operational manual implement MBBS curriculum 2021, particularly the Director (Research, Publication & Curriculum Development), DGME, focal persons, teachers, members of the concerned society, seniors, juniors, legendary teachers & heads of the departments of Pharmacology & Therapeutics.

Different Govt. and non Govt. medical colleges. Special appreciation to the Deans, Faculty Medicine of different medical Universities who were requesting to develop this operational manual and will take lead to implement this operational manual. They contributed a lot to complete this activity, a commendable job and deserve special appreciation.

Professor Dr. Md. Titu Miah

Director General

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Acknowledgement

It is easier to change a graveyard than to change a curriculum. Yet then time & society demand for the change of the curriculum. In such a situation MBBS curriculum 2012 was reviewed and updated in 2021 to fulfill the need of the stakeholders. The updated MBBS curriculum 2021 was started to implement from the August 2022. For implementation of that reviewed & updated curriculum operational manual is also the demand of the present time.

For better implementation of integrated teaching, teaching as per identified competencies, teaching on generic topics on medical humanities, planning, designing, constructing assessment tools for formative and summative assessment, this operational manual will act as the road map.

Research, Publication & Curriculum Development (RPCD) of DGME in association with heads of the departments of Pharmacology & Therapeutics of Phase II of different Govt. & non govt. medical colleges & Deans Offices, DGME, ME, FWD, BM&DC took the initiative to develop the operational manual. Concerned stakeholders meetings were held through active participation of different professional groups, focal persons, faculty members, heads of the department of Pharmacology & Therapeutics, of Phase II of different govt. & non govt medical colleges of Bangladesh.

I hope this operational manual will help to serve as guiding principle for the students and as well as for faculty members.

Last but not least, I would like to extend my deep gratefulness to the Director General, DGME, ADG (ME) & ADG (Admin), DGME, all Directors of DGME, faculty members of Pharmacology & Therapeutics of different Govt & non Govt medical colleges and others who shared their expertise, insights, contributed and worked hard to develop this precious document. Efforts given by the focal persons providing their valuable time, opinions & efforts during the development process of this operational manual for Phase II of MBBS curriculum are duly acknowledged.

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Background and Rationale

Curriculum is a study track along which students travel throughout the course of study. In this journey teachers play an important role in regards to teaching learning and assessment. To produce need based, community oriented, competent graduate medical doctors, MBBS curriculum was reviewed and updated in 2021. The updated MBBS curriculum 2021 was started to implement from the August 2022. For better implementation of MBBS curriculum 2021 effectively, uniformly & competently an operational manual of each subject was felt by each of the Faculty of Medicine of all universities. In this regard Director (Research, Publication & Curriculum Development (RPCD) of Directorate General of Medical Education (DGME) has taken the time felt initiative under the gradience of Director General, DGME. Thanks to DG, DGME, Director (RPCD), DGME, focal persons, members of the concerned society, senior, junior and legendary teachers and heads of the department of concerned subject of different government & non government medical colleges to finalise this operational manual. This operational manual will work as the skeleton of the curriculum in a comprehensive manner. This user-friendly document will serve the purposes of the faculty to ensure better teaching-learning and assessment to produce knowledge competent and compassionate physicians in Bangladesh.

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Overview and Assessment of Phase- II: Implementing MBBS Curriculum 2021

Common Information and Activities of Phase II:

1.1. Basic information:

- i) Total duration of Phase II is 12 months including second professional MBBS examination. The course is expected to start on first day of January or July.
- ii) Second professional examination to be started on first working day of November & May.
- iii) Time for integrated teaching, examination preparatory leave of formative & summative assessment is common for all subjects of the phase.
- iv) Assessment:
 - a) There will be in-course (item/term) and end-course (professional) assessment for the students.
 - b) Formative assessment will be done through results of item examination, term examination and class attendance.

1.2. Distribution of teaching-learning hours/days in 2ndPhase:

Subjects	Lecture	Tutorial	Practical and Demonstration	Clinical Case Report	Total teaching hours	Integrated teaching hour for Phase II	Clinical bedside teaching	Formative Exam		Summative exam	
							(in weeks)	Preparatory leave	Exam time	Preparatory leave	Exam time
Pharmacology & Therapeutics	100 hrs	30 hrs	50 hrs	15 hrs	195 hrs	17hrs		10 days	15 days	10 days	30 days
Forensic Medicine & Toxicology	100 hrs	45 hrs	40 hrs visit Mourge, Thana, Court = 12 days	--	185 hrs + 12 days						
General Pathology	35 hrs	40 hrs	07 hrs	--	82 hrs						
General Microbiology	13 hrs	07 hrs	15 hrs		35 hrs						
Medicine & Allied subjects	28 hrs				28 hrs		21 wks				
Surgery & Allied subjects	35 hrs				35 hrs		20 wks				
Total	311 hrs	122 hrs	112 hrs + 12 days	15 hrs	560 hrs + 12 days	17 hrs	41 wks	25 days		40 days	
<i>Time for integrated teaching, examination, preparatory leave of formative & summative assessment is common for all subjects of the phase</i> <i>Related behavioral, professional & ethical issues will be discussed in all teaching learning sessions</i>											

1.3 Common Classes (generic topics):

Following classes shall be conducted as common. These classes will be held from January or July of each session or starting of 2nd phase.

- The duration of each class will be 1½ (one and half) hours and should be completed by 1st three consecutive classes within the time period of first term.
- These classes will be organized by the supervision of Phase II coordinator and concerned departments and Medical Education Unit.
- Sessions will be planned under the supervision of principal, vice principal and delivered by the concerned departments.
- Academic coordinator and Phase coordinator will prepare suitable class schedule so that classes of every subject of the phase II can be conducted harmoniously.

Common Class:

Generic Topics on Medical Humanities in Phase II	Duration of each session	Total time
(i) Communication skill,	1.5 hrs	05 hrs
(ii) Doctor–patient relationship (DPR)	1.5 hrs	
(iii) Physicians’/bedside manner, etiquette and rapport building with patients	1.5 hrs	

1.4. Duration of each term:

- Term I: duration 04 months; either from January to April or July to October.
First Term Final Exam: 1st & 2nd week of May or 1st and 2nd week of November.
- Term II: duration 04 months; 3rd week of May to 2nd week of September or 3rd week of November to 2nd week of March.
Second Term Final Exam: 3rd & 4th week of September or 3rd & 4th week of March.

1.5. Contents of Pharmacology & Therapeutics in Phase II:

Topics will be distributed among the two terms in the following way:

Subjects	Term I	Term II
Pharmacology and Therapeutics	General pharmacology, ANS, Respiratory, Renal, CVS, GIT, Endocrine	CNS, Autacoids, Anti inflammatory drugs, Chemotherapeutics, Clinical pharmacology

	<u>Generic topics:</u> (i) Communication skill, (ii) Doctor–patient relationship (DPR) (iii) Physicians’/bedside manner, etiquette and rapport building with patients. <u>Integrated teaching :</u> 1. Electrocution, lightening & Burn 2. Drowning 3. Death 4. Anesthetic & Surgical death	<u>Integrated teaching :</u> 5. Poisoning 6. Substance abuse 7. Pulmonary Tuberculosis 8. Malaria
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Integrated teaching in phase II :

Forensic medicine	1. Electrocution, lightening & Burn 2. Drowning 3. Death, 4. Anesthetic & Surgical death
Pharmacology	5. Poisoning 6. Substance abuse 7. Pulmonary Tuberculosis 8. Malaria

1.6. In-course assessment:

- 1) Item examination will be oral / written.
- 2) Card final examination (optional if possible) (written).
- 3) Term final examination will be written, oral & practical.

1.7. Pre-requisite for appearing the term examination:

- Students must complete all items of the in-course evaluation card.
- At least 75% attendance of generic, integrated teaching and general (lecture, tutorial, practical) classes.
- Completion of assignment on integrated teaching.

1.8. Leave:

Following leaves will be granted to the students:

- i) **Pre-term:** Total 10 days, 05 days before each term.
- ii) **Post –term:** Total 10 days, 05 days after each term. These leave may be utilized for organizing cultural week, sports, games or any other extra-curricular activities.
- iii) **Preparatory Leave for Professional Examination:** Total 10 days preparatory leave shall be granted to students before 2nd Professional Examination.

1.9. Formative marks:

The academic performances of the students must be properly documented.

Calculation of Formative marks in Pharmacology & Therapeutics:

Total marks = 10; Among 10 marks 04 marks will be taken from marks obtained in 2 term examinations (02 marks from each term), 02 marks will be from Item card examination, 02 marks

will be from class (lecture and tutorial) attendance, 01 mark from attendance of integrated teaching and 01 mark from attendance of generic topic class.

Marks shall be calculated maintaining the following proportion:

i) For each Term:

85- 100	: 2 marks
75-84%	: 1.5 marks
60-74 %	: 01 mark

ii) For Item card:

85- 100	: 2 marks
75-84%	: 1.5 marks
60-74%	: 01 mark

iii) For class attendance:

85% and above	: 2 marks
75% - 84%	: 1 mark

iv) Calculation of marks for attendance of integrated teaching

- Mandatory: 1 mark

v) Calculation of marks for attendance of generic topics

- Mandatory: 1 mark

Lowest marks in two terms = 02

Lowest marks in item card = 01

Lowest marks in class attendance = 01

Marks from attendance of integrated teaching class = 01

And attendance of generic topics class = 01

So, lowest marks of formative assessment are 06 for eligible students in 2nd professional examination:

Without scoring these 06 marks, students are not eligible for 2nd professional examination.

1.10. Pre-requisite for appearing in the 2nd professional examination:

i) Students must pass all the items and term examinations. If a student fails in a term examination, he/she will have to pass the supplementary term examination.

ii) Certificate from the respective Head of Departments regarding students' attendance which must be at least 75% in all classes (lecture, practical, and tutorial, including generic topics and integrated teaching) and 75% attendance must be ensured in clinical ward placement.

iii) Students should obtain at least 60% marks in formative examinations. No student shall be allowed to appear in the professional examinations unless the student passes in all the subjects of the previous (1st) professional examinations

1.11. Summative Examination of Pharmacology & Therapeutics in 2nd Professional Examination:

Marks distribution of Assessment in Pharmacology & Therapeutics:

Total marks =300 (written, practical & Oral)

- Written =100; (Formative assessment marks=10 + Written = 90)
- Written = 90 [MCQ=20 (Multiple True False-10 + SBA-10), and SAQ+SEQ = 70]
- Oral part of examination will be structured (SOE) = 100
- Practical: 100; OSPE =40 (07 question station and one procedure stations, each having 05 marks) + Traditional =55 (Prescription writing 10, P-drug selection =10, Tracing and plotting = 10, Practical notebook =10, Clinical Case report = 15) and Integrated teaching assignment = 05

- Pass marks in examination is 60% of total marks. Student will have to pass in written, oral and practical examination separately.
- The results will be published as per following GPA system with the provision of reflection of marks in the academic transcript

Numerical Grade	Letter Grade	Grade Point
80% and above	A+	5.00
75% to less than 80%	A	4.50
70% to less than 75%	A-	4.00
65% to less than 70%	B+	3.50
60% to less than 65%	B	3.00
less than 60%	F	0.00

1.12 Examination: Distribution of marks of 2nd Professional Examination:

Subjects	Written Exam marks	Structured Oral Exam marks	Practical Exam marks	Formative Exam mark	Total Marks
Pharmacology & Therapeutics	90	100	100	10	300
Forensic Medicine & Toxicology	90	100	100	10	300
Total					600

1.13. Question setting:

Total number of paper setters must be four (4).

SAQ and SEQ written question groups will be four. (A,B,C,D)

Four paper setters for four groups of SAQ, SEQ and MCQ (MT/F + SBA)

1.14. Moderation: Total number of moderators will be two.

Question paper setter and Moderator should be different.

Pharmacology & Therapeutics

2.1. Departmental Objectives:

The objective is to provide a need based integrated “Basic Pharmacology for a safe and effective prescribing” course so that the students on graduation will be competent to:

- Describe the pharmacological effects, mechanisms of action, pharmacokinetic characteristics and adverse reactions of drugs in order to be able to prescribe safely and effectively.
- Describe the basic principles and concepts considered essential for rational (effective, safe, suitable and economic) prescribing and use of medicines in clinical practice.
- Understand the principles of rational prescribing and the basis of utilizing the principles of rational evaluation of therapeutic alternatives.
- Recognize, manage and report the adverse drug reactions (ADRs) and drug interactions.
- Obtain informed consent by providing enough information about disease(s), treatment(s) and alternative options available, in order to allow the patients to make informed decision about their treatment.
- Identify and assess objectively the drug information sources.
- State the Essential Drug List and principles underlying the “Concept of Essential Drugs”, and apply them appropriately in community oriented health care delivery service.
- Recognize the implications of poly pharmacy and other means of irrational prescribing, identify influences favoring irrational prescribing and develop means to resist them.
- Evaluate the ethical and legal issues involved in drug prescribing, development, manufacture and marketing.
- Acquire methods of learning needed for evaluation of existing and new drugs and to follow trends and approaches in pharmacological research.
- Develop attitude for continuous self learning and professional development throughout their practicing life.

2.2. List of competencies to acquire:

A) Knowledge and Understanding

- Basic pharmacodynamics (effects, mechanism), and clinical pharmacokinetics required for safe and effective prescribing.
- Adverse Drug Reactions (ADRs): recognizing, management & reporting

- Basic principles & concepts essential for rational (effective, safe, suitable and economic) prescribing and use of drugs in clinical practice.
- Concept of essential drugs and selection of essential drug list for use in community oriented health care services.
- Drug information sources: access to unbiased drug compendia and use of standard treatment guidelines, formularies to support safe and effective prescribing.
- Ethics of Prescribing: Informed patient consent about disease, treatment given and alternative options available.
- The ethical and legal issues involved in drug prescribing, development and marketing

B) Skill –

- Taking drug history.
- Prescription writing: choosing safe & effective drugs and appropriate dosage formulations.
- Selecting appropriate drugs (P Drug) to support rational prescribing considering efficacy, safety, suitability and cost.
- Recognizing, managing and reporting Adverse Drug Reactions (ADRs) and drug interactions.
- Obtaining accurate information to support safe and effective prescribing.
- Prescribing drugs for special groups: elderly, children, pregnancy, breast feeding mothers, renal &/or hepatic impairment or failure.
- Getting informed consent from patients
- Analyzing new evidence
- Reading, assessing, and critically analyzing clinical trial results
- Practicing evidence-based medicine.
- Assessing the possible benefits and hazards of new therapy.

C) Attitude –

- Continuous self-learning to keep their knowledge & skill up-to-date through continuous professional development.
- Communicating with patients regarding disease, the drug treatment and alternative options to obtain informed consent and respecting patients' own views and wishes in relation to drug treatment.

2:3. Learning Objectives and Course Contents in Pharmacology:

Term I

Learning Objective	Core Contents	Teaching-Learning Strategies	Teaching Hours
A. GENERAL PRINCIPLES OF PHARMACOLOGY At the end of the session students will be able to: • describe the role and scope of pharmacology • understand the principles of drug disposition (kinetics)-absorption, distribution, biotransformation and excretion • understand the basic principles related to cellular and molecular aspects of drug action (dynamics), selectivity, specificity and quantitative aspects of drug action • recognize adverse drug reactions, interactions and problems of drug misuse and abuse • describe the ethical, legal and economic aspects of prescription writing and compliance	A. GENERAL PRINCIPLES OF PHARMACOLOGY Lectures: 01: Introduction to Pharmacology (definition, branches, sources of drugs & Nomenclature of drugs) 02: Drug Administration Routes, drug delivery and formulations for local & systemic effects 03: Drug Absorption Transfer of drugs across cell membrane & specialized barriers, Factors influencing absorption 04: Bio-availability Studies to compare bio-equivalence & to monitor therapy 05: Drug Distribution V _d , Plasma protein & tissue binding, redistribution 06: Drug Biotransformation Where, why and how bio- transformation occurred, hepatic microsomal enzymes, enzyme induction & inhibition, Genetic influence on Drug biotransformation (Pharmacogenetics) 07: Drug Elimination Routes, Renal Excretion & factors influencing renal excretion 08: Clinical Pharmacokinetics V _d , CL, First & Zero order kinetics of Elimination, t _{1/2} , Steady state concentration, loading dose & maintenance dose	Lectures/ Practical/ Tutorials/ Assignments	2hrs
			2hrs
			1hr
			1hr
			1hr
			1hr
			1hr
			1hr
	09: Pharmacodynamics: Specific and non-specific mechanisms Receptors involved Second messenger system		2hrs

• Name the cholinergic agonists and antagonists with their clinical uses and adverse effects. • Understand the physiology of adrenergic neurotransmission, classify the adrenoceptors and identify the drugs affecting adrenergic transmission and adrenoceptors. • Name the adrenergic agonists and antagonists with their clinical uses and adverse effects	Classification – Neuromuscular blockers, Ganglion blocker (names only) 06: Adrenergic neurotransmission Drugs modifying the events Adrenergic NT, Effects of stimulation of adrenoceptors 07: Adrenergic Drugs: Classification, Adrenergic inotropic agents & their role in Therapy, Role of Adrenaline, Noradrenaline, Isoprenaline, Dopamine & Dobutamine in Therapy, Adrenergic vasoconstrictors, nasal decongestants 08: Selective β_2 agonists as Bronchodilators, Drugs used in bronchial asthma 9: α-adrenoceptor antagonist: Name & Role of α_1 antagonist in therapy 10: β- adrenoceptor antagonist Name & Role of β blockers in therapy		1hr 1hr 1hr 1hr
Learning Objectives	Core Contents	Teaching-Learning Strategies	Teaching Hours

RENAL & CARDIOVASCULAR PHARMACOLOGY At the end of the session Students will be able to: • Classify or list drugs which affect the Cardiovascular System • State their pharmacological effects • Explain mechanisms of actions, State kinetics and adverse effects • Correlate these knowledge to form the basis for their rational use in a given clinical situation	RENAL & CARDIOVASCULAR PHARMACOLOGY Lectures : 01: Diuretics Classification of diuretics: based on sites of action and efficacy. Pharmacology of Thiazides, Loop and Potassium sparing diuretics: their role in edema and hypertension 02: Drugs used in hypertension Epidemiology and pathophysiology of hypertension, Objectives of anti-hypertensive therapy, Classification of anti-hypertensive drugs. Pharmacology of Diuretics, beta blockers, Calcium channel blockers, ACE inhibitors, Angiotensin receptor antagonists, alpha blockers, alpha methyl dopa, Vasodilators, Principles of selection of drug in different clinical situations 03: Drugs used in congestive cardiac failure, Pathophysiology of heart failure Objectives of therapy Drugs used in CCF: Diuretics, ACE inhibitors & ARBs, beta blockers, Cardiac glycosides, vasodilators, Phosphodiesterase inhibitors. 04: Anti anginal drugs Pathophysiology of angina, Objectives of therapy, Drugs used in angina: Nitrates, β-blockers, Calcium channel blockers. 05. Anti arrhythmic Drugs Pathophysiology of arrhythmia Pharmacology of anti arrhythmic drugs	Lecture/ Tutorial/ Class Assignments	2hrs 2hrs 2hrs 2hrs
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Learning Objectives	Core Contents	Teaching-Learning Strategies	Teaching Hours
ENDOCRINE PHARMACOLOGY At the end of the session the students will be able to: • List the pancreatic islet hormones and understand their role in the control of blood glucose; state pharmacology of insulin and oral anti-diabetic drugs. • Describe the pharmacology of adrenocorticosteroids • to assess their role in therapy as anti-inflammatory and immunosuppressive drugs, precautions of their uses. • Name the drugs affecting reproductive function • State the clinical uses of hormone in therapy and precautions of uses. • List the thyroid and anti-thyroid drugs, states their uses in thyroid disorder.	Endocrine Pharmacology Lectures: 01: Endocrine Pancreas and control of blood glucose, Islet hormones, control of blood glucose Diabetes mellitus – types, diagnostic criteria, Insulin preparations, mechanism of action, adverse effects Hypoglycemic reactions & management Oral antidiabetic agents, newer drugs, drug selection criteria in different clinical situation	Lectures/ Practicals/ Tutorials/ Assignments	2hrs
	02: Adrenal cortex and drugs used in therapy, Adrenocortical hormones: synthesis & blockers; Control of secretion, mechanism of action, Pharmacological actions, uses and preparations Adverse effects, management of adverse effects, monitoring therapy		2hrs
	03: Reproductive system Hormonal control of female reproductive system Estrogens & anti-estrogens Progesterone & anti-progesterone Hormone replacement therapy (HRT) Drugs used for contraception		1hr
	04: The Uterus Drugs that stimulate uterine contraction (oxytocics) Drugs that inhibit uterine contraction 05: The Thyroid Synthesis, storage & secretion of thyroid, Thyroid functions & regulations Abnormalities of thyroid function Drugs used in thyroid disorder		1hr

Term II

Learning Objectives	Core Contents	Teaching-Learning Strategies	Teaching Hours
Pharmacology of Drugs Acting on CNS At the end of the session students will be able to: • Classify or list of drugs acting on Central Nervous System • Explain the mechanism of action and state kinetics of these drugs • Describe the uses, administration, adverse effects & precautions of drugs used in diseases of CNS	Central Nervous System Lectures: 01: Introduction to CNS Drugs Neurotransmitters of CNS general characteristics of CNS drugs 02: Opioid analgesic Pathophysiology of pain, Pain pathway, endogenous opioids and opioid receptors Opioids: morphine, codeine, pethidine, tramadol, fentanyl used as analgesics compared. Role of morphine in myocardial infarction and pulmonary edema. Other clinical uses of opioids 03: Anxiolytics and hypnotics Pathophysiology of sleep Benzodiazepines and other non-BDZ sedative-hypnotics Centrally acting muscle relaxants 04: Antidepressant drugs Neurochemical basis of depression TCAs, SSRIs, MAOIs and other atypical antidepressants, 05: Antipsychotic drugs Neurochemical basis of psychosis Pharmacology of anti-psychotic drugs: 06: Local anesthetics Drugs, mechanism of action, techniques of local anesthesia, uses and hazards 07: General anesthetics Principles of General Anesthesia Preanesthetic medication, Balanced Anesthesia, Intravenous & Inhalational anesthetics (nitrous oxides, halothane, fluranes) 08: Skeletal muscle relaxants Depolarizing and Non-depolarizing agents 09: Antiparkinsonian Drugs Pathophysiology of Parkinson's diseases Pharmacology of antiparkinsonian drugs 10: Antiepileptics/Anticonvulsants Pathophysiology of epilepsy Pharmacology of antiepileptic drugs	Lecture/ Tutorial/ Class Assignment	1hr 2hrs 2hrs 1hr 2hrs 1hr 2hrs 1hr 1hr 2hrs

Pharmacology Practicals

Learning Objectives	Core Contents	Teaching Hours
GENERAL PRINCIPLES OF PHARMACOLOGY PRACTICALS: At the end of session students will be able to: - Relate the principles and concepts to specific clinical situations • Identify different dosage formulation and their usage • Interpret, explain and analyze experimental data relating to drug disposition	GENERAL PRINCIPLES OF PHARMACOLOGY 1. Prescription writing Format, legal & ethical aspects, drug nomenclature, compliance and Exercise on Prescription Writing	05 hrs
	2. Drug Dosage Formulation Source & Routes of drug administration Drug Formulation & Delivery Techniques Exercise on Drug Dosage Formulations	05 hrs
	3. Clinical Pharmacokinetics Study of Time-Plasma Concentration Curves Determination of $t_{1/2}$, V_d , Cl , K_e , steady-state concentration, Loading & Maintenance dose	04 hrs
	4. Study of Pharmacodynamics i. Study of Dose Response Relationship Construction of Log Dose-Response Curves	04 hrs
	ii. Study of Drug Antagonism Construction of Log Dose-Response Curves in presence of Antagonists 5. Adverse drug Reaction – Exercise on ADRs reporting	04 hrs

• explain the mechanisms of action and describe the uses, administration, kinetics, adverse effects & precautions of used in different clinical conditions • state the principles of rational prescription • correlate this knowledge to form the basis for rational use of drugs in a given clinical situation		• Review of Cholinergic–Anticholinergic drugs • Reviews of Adrenergic–Antiadrenergic drug • Drugs acting on Renal & CVS • Review on Endocrine drugs • Drugs for Bronchial asthma, PUD, • Anticoagulant drugs, • Hemopoietic agents	
	Term II	• Drugs used in Anxiety, sleep disorder • Drugs used in depression, psychosis, epilepsy and parkinsonism • Opioid analgesics •Autacoids & NSAIDs • Chemotherapeutic agents: classification, name, mechanism of action, clinical uses, adverse effects & precaution • Chemotherapy for specific infections: Enteric fever, ARIs, UTIs, Shigellosis, amoebiasis, tuberculosis, malaria, filaria, fungal infections, viral infection, cancer chemotherapy. • RUM: Principles of Rational prescribing & means to resist pressure for irrational prescribing, Essential Drug Concept	10 hours
	Clinical case studies & presentation – 5 clinical Cases- 1.Hypertension, 2.Diabetes mellitus, 3.Peptic ulcer disease, 4.Iron deficiency anemia, 5.Chronic Bronchial asthma		15 hours

2.4. Distributions of teaching /learning hours in pharmacology& therapeutics:

Lecture	Tutorial	Practical	Clinical Case Report	Total teaching hours	Integrated teaching hour for Phase II	Formative Exam		Summative exam	
						Preparatory leave	Exam time	Preparatory leave	Exam time
100 hrs	30 hrs	50 hrs	15 hrs	195 hrs	17hrs	10 days	15 days	10	30 days
(Time for exam. preparatory leave and formative & summative assessment is common for all subjects of the phase)									

2.5. Teaching/learning methods, teaching aids and evaluation:

Teaching Methods			Teaching aids	In course evaluation
Large group teaching	Small group teaching	Self-learning		
Lecture Integrated teaching	Tutorial Practical Demonstration	Assignment Self -study	Computer, Multimedia & other IT materials • White board & markers • Slide projector • Specimens • Projector • Study guide & manuals. • Practical note book	Item examination(oral/ written) • Card final examination (optional) • Term Examination (Written, oral & practical) • Assignment

2.6. Time allocation in different terms:

	Term I	Term II	Total teaching hours
Lectures	50 hrs	50 hrs	100 hrs
Practicals and demonstration	30 hrs	20 hrs	50 hrs
Tutorials	20 hrs	10 hrs	30 hrs
Clinical case report , assignment & presentation		15 hrs	15 hrs
Total	100 hrs	95 hrs	195 hrs
Integrated teaching	17 hrs		

2.7. Academic Calendar for Pharmacology:

		1st Term	E v a l u a t i o n 3 w e e k s	2rd Term	E	Prepara tory leave for summa tive examin ation 10 days	Summa tive examin ation 30 days
Teaching /Learning Method	Teaching hours	16 working weeks		16 working weeks	v a l u a t i o n 3 w e e k s		
Lecture	100 hrs	General pharmacology- 15 hrs, ANS & Respiratory-10 hrs, Renal & CVS-08 hrs, Hemopoietics- 06 hrs, Endocrine-06 hrs, Gastrointestinal- 05 hrs.		CNS -15 hrs, Autacoids, Anti-inflammatory drugs-06 hrs, Chemotherapeutic s- 25hrs, Clinical pharmacology-04 hrs	a t i o n 3 w e e k s		
Practical and demonstration	50 hrs						
Tutorial	30 hrs						
Clinical case report, assignment &presentation	15 hrs						

3. Overview of Assessment in 2nd Professional Examination:

3.1. Summative Assessment of Pharmacology & Therapeutics

3.2. Assessment Systems and Marks Distribution:

Components	Marks	Total Marks
Formative assessment	10	10
WRITTEN EXAMINATION MCQ (Multiple True/False+SBA) SAQ+SEQ	20 70	90
PRACTICAL EXAMINATION Traditional Practical Examination + assignment on integrated teaching + OSPE	55+ 5+ 40	100
ORAL EXAMINATION (Structured) 2 Boards	50+50	100
	Grand Total	300

- There will be separate Answer Script for MCQ

- Pass marks 60 % in each of theoretical, oral, and practical

3.3.Written examination:

3.3 a. Formative assessment marks =10

3.3.b. Calculation of Formative marks:

Total marks: 10; Among 10 marks 04 marks will be taken from marks obtained in 2 term examination (02 marks from each term). 02 marks will be from Item card examination. 02 marks will be from class (lecture and tutorial) attendance. 01 mark from attendance of integrated teaching and 01 mark from attendance of generic topic classes. Lowest marks of formative assessment are 06.

Lowest marks in two terms = 02

Lowest marks in item card = 01

Lowest marks in case of attendance = 01

Marks from attendance of integrated teaching class = 01

And attendance of generic topics class = 01

So, lowest marks of formative assessment for sent up = 06

Without scoring these 06 marks, students are not eligible for 2nd professional examination.

3.3.c. Formative marks calculation score sheet:

Students Roll No.	2 Term final exam (4 marks)	Item card exam (2 marks)	Class Attendance (2 marks)	Generic topic class attendance (1 mark)	Integrated teaching class attendance (1 mark)	Total 10 marks	Remarks

3.3.d. Multiple choice questions (MCQ) (MTF + SBA):

- Time allocation for MCQ is 30 minutes
- Number of questions is 20, Among the 20 questions, 10 questions will be Multiple True/False (MT/F Type) and 10 questions will be Single Best Answer (SBA type).
- Each question will carry one mark.
- No negative marking for MCQ.

In case of Multiple True/False (MTF) type:

- Type of question is multiple choice true/false types
- Each question will carry one stem and five (5) alternatives.
- Each alternative will carry 0.2 marks
- OMR sheet will be supplied for answering MCQ.
- MCQ will be checked centrally by digital process

For Single Best Answer (SBA) type:

- Each question will carry one (1) stem and four (4) alternatives
- Most appropriate answer will be considered as correct answer.
- Single correct answer will carry one (1) mark.
- If answer more than one it will produce no mark
- OMR sheet will be supplied for answering MCQ
- Instruction: Fill up the single circle for the best answer
- **Example of a MCQ (MTF type):**
Fill up the “T” circle for true and “F” circle for false in the OMR sheet provided-

H₁ receptor blockers are useful in the treatment of -

- a) Urticarial rash
- b) Motion sickness
- c) Urinary retention
- d) Peptic ulcer disease
- e) Common cold

- **Example of a MCQ (SBA type):**
Fill up the single circle for the best answer in the OMR sheet provided-

Aspirin is now a days most commonly used for its-

- a) Analgesic action
- b) Anti-inflammatory effect
- c) Anti-platelet effect
- d) Anti pyretic effect

3.3.e. Short answer questions (SAQ) + Structured essay questions (SEQ):

There will be four groups: Group A, B, C, D

Content distribution in written test shall include as follows:

- Group A
 - Introduction to pharmacology
 - General pharmacology
 - Autonomic pharmacology
- Group B
 - Renal and CVS
 - Endocrine pharmacology
 - Hemopoietic agents
- Group C
 - Central nervous system
 - Autacoids, NSAIDs
- Group D
 - Chemotherapeutics
 - GIT pharmacology
 - Respiratory pharmacology
 - Clinical pharmacology

Short Answer Question (SAQ) and Structured essay questions(SEQ):

Total marks = 70 (Group A=17.5; Group B = 17.5; Group C=17.5; Group D = 17.5)

Group A & Group C shall contain 6 questions. Students shall answer 5.

Group B & Group D shall have 5 questions from which students shall answer 4.

In group B & D one question will be mandatory, which will be SEQ type.

In Group A & C: Total questions will be 06 Q. No. (a) to (f): each carrying 3.5 marks are SAQ type of which 5 to be answered.

In Group B Total questions will be five. Among which 04 shall be answered. Q. No.2(a) will be SEQ type carrying 07 marks (mandatory) and other 04 question will SAQ type carrying 3.5 marks, among which 03 shall be answered.

In Group D total questions will be five. Among which 04 shall be answered. Q. No.4(a) will be SEQ type carrying 07 marks (mandatory) and other 04 question will be SAQ type carrying 3.5 marks among which 03 shall be answered.

Each question may contain more than one item and cover the educational domains.

It is suggested that:

50% of the question shall be of recall type

35% of the question shall be of understanding type

15% of the question shall be of PBL or application type

Example of question for SAQ:

Q. Name four emergency routes of drug administration. Write down the four advantages of oral route and four disadvantages of intravenous route. (1+2.5)

Example of question for SEQ:

Q. Describe the pharmacodynamics of morphine. (07)

3.4. Oral Examination (structured):

During preparing structural oral card containing questions instead of preparing specific question, topics will be fixed considering wide range of contents coverage. Rating scale will be used for marking the students concurrently. Each student will be asked question from all topics of the card/set. Equal or average duration of time will be set for every student.

Board A

Introduction to pharmacology
General pharmacology
Autonomic pharmacology
Renal and CVS
Endocrine pharmacology
Hemopoietic agents

Board B

Central nervous system
Autacoids, NSAIDs
Chemotherapeutics
GIT pharmacology
Respiratory pharmacology
Clinical pharmacology

3.4 a. Rating scale for structural oral examination:

Correct and complete = (5)
Correct and partially complete (80%) = 4
Correct and partially incomplete (50-60%) = 3
Partially correct and partially incorrect =2
Completed but incorrect =00
Not known = 00

Board A: Marks 50

Roll no	Introductory pharmacology (1x5) =5	General pharmacology (2x5) =10	Autonomic pharmacology (2x5) =10	Renal, CVS & Hemopoietic agents (3x5) =15	Endocrine pharmacology (2x5) =10	Total

Signature of examiner -----

Board B: Marks 50

Roll no	Central nervous system (3x5) =15	Autacoids, clinical pharmacology (2x5) =10	Chemotherapy (3x5) =15	GIT & Respiratory pharmacology (2x5) =10	Total	

Signature of examiner -----

3.5. PRACTICAL MARKS DISTRIBUTION:

Total = 100

(OSPEmarks= 40 + Traditional marks = 55 + Assignment on integrated teaching = 05)

1. OSPE: Marks-40

Total 08 stations: 05 marks for each station

A. Question Station: 07

Station:1 – Drug Formulations & Drug Delivery System (Tablet, Capsule, Inhaler, Ampule, Suppository, Syrup, Vial, Ointment)/Drug information sources-----5

Station:2 –Drug Interaction -----5

Station:3 – Abbreviation / Prescription criticism -----5

Station:4 –Rational use of drugs5

B. Stations for interpretation & analysis of tracing/Kinetic data

Station: 5 – Bioavailability curves/Dose response curves/Drug antagonism -----5

Station:6 –Calculations (T.I, half life, Vd, CL, Calculations of dose).....-5

Station:7 –Fill up ADR reporting form.....5

C. Procedure Station: 01

Station:8 – Procedure Stations (Eye Drop, Inhaler, Nitroglycerine Spray)5

2. TRADITIONAL: Marks-55

i) Prescription writing.....	10
ii) Selection of P drugs -----	10
iii) Tracing interpretation (Acetylcholine , Adrenaline, Nor-Adrenaline Histamine, Ephedrine) -----	10
iv) Clinical Case Report (5 case reports) : -----	15
v) Practical Note Book-----	10
3. Assignment on integrated teaching -----	05
Total- 100	

3.5.a. Check list for procedure station: INHALER

Each step of procedure carries – 0.5 marks

Total marks=05

Instruction for observer – put tick mark against each step if correctly done / if not done put cross mark

STEPS–

1. Greeting
2. Shake the inhaler & open the cap
3. Hold the aerosol properly usually upside down with the index finger on the back of the metal container
4. Placing the tips tightly around the mouth piece
5. Tilting the head backward slightly
6. Breathing out slowly, emptying the lungs of as much air as possible
7. Press the container twice & ask the patient to take a deep breath in
8. Holding the breath for 10 – 15 secs.
9. Breathing out through the nose
10. Rinsing the mouth with warm water

Roll no.	1	2	3	4	5	6	7	8	9	10	Total

3.5.b.. Tabulation sheet for Oral and Practical:

Roll no.	Oral		Oral Total (100)	Practical			Practical Total (100)	Remarks
	Board A (50)	Board B (50)		OSPE (40)	Traditional practical (55)	Assignment on integrated teaching (5)		

Signature of examiners -----

4. Post Examination Procedure:

Preparation and submission of marks sheet:

After completion of all examinations (Oral & Practical) and examining the answer scripts it is the responsibility of the convener/examiner to send the properly marked and sealed mark sheets to the controller of examination as early as possible.

The following points should be carefully noted before sending the marks to the controller office.

Mark Sheet:

Top of the each mark sheet must be filled up properly (name of the examination, part-oral/practical/written- group/SAQ, total marks,- eg, 2nd prof examination May/November 20-- sub: Pharmacology& Therapeutics written SAQ group A/B/C/D Total marks-17.5)

- * Roll number should be written serially. Marks should be given against each roll number.
- * Examinee who is absent must be mentioned against their roll numbers.
- * Any overwriting on the mark sheet should be avoided.
- * Any pen through/ alteration on the mark sheet must be signed properly.
- * Each page of the mark sheet must be signed by the examiner.

Written marks :

Formative :

- Formative marks should be sent to the Head of the center/ to the Controller of examination in a separate marks sheet. The Head of the center will send the packet to the Controller of examination.

- Marks sheet should be signed by all four (two internal and two external) examiners.

SAQ and SEQ :

- Marks of short answer question and structured essay question of each group should be submitted by all four examiners to controller of examination within three (03) days of completion of oral and practical examination schedule. Group A & B answer script should be checked by Internal examiners and Group C & D answer script should be checked by external examiner.

MCQ:

- OMR sheets should be packed and sealed properly by hall superintendent of written examination and will be submitted to the Head of the center.
- The Head of the center will send the packet of OMR sheet to the Controller of examination.

Practical marks:

Total practical marks will be submitted to the Head of the center / controller of examination in a separate mark sheets signed by four examiners (two internal + two external).

Oral marks :

Mark sheets of oral examination should be signed by all the four (two internal + two external) examiners and will be submitted to the Head of the center / to the controller of examination.

5. Students' In-Course Evaluation Card:**TERM I**

SL No	Title and contents	Marks	Initial of teacher
01.	<u>General Pharmacology</u> • Introduction to Pharmacology and its branches • Sources of Drug, Nomenclature and Dosage Formulation • Drug compendia (BNF, BDNF) • Routes of Drug Administration • Drug development		
02.	<u>Pharmacokinetics</u> • Absorption, Bio-availability, Bioequivalence and • Drug distribution		
03.	<u>Pharmacokinetics</u> • Biotransformation		
04.	<u>Pharmacokinetics</u> • Excretion • Clinical Pharmacokinetics • Volume of distribution, half -life • Clearance, Order of kinetics • Steady State Concentration, • Loading dose, Maintenance dose		
05.	<u>Pharmacodynamics</u> • Specific and Nonspecific Mechanism of Drug Action • Signal Transduction • Dose response relationship and curve • Therapeutic Index and Window • Affinity, Efficacy, Potency, Agonist, Antagonist		
06.	<u>Pharmacodynamics</u> • Adverse drug reactions (ADRs) • Drug Interaction (Pharmacokinetic and Pharmacodynamics) • Pharmacovigilance		

07.	<u>Autonomic Pharmacology</u> • Introduction to ANS • Cholinomimetic drugs , OPC poisoning and management		
08.	•Anticholinergic drugs (Anti muscarinic and Anti nicotinic)		
09.	•Adrenergic agonists •Drugs used in anaphylactic shock, septic and cardiogenic shock)		
10.	•Adrenergic Antagonist •Drugs used in Glaucoma • Respiratory Pharmacology		
11.	<u>Cardiovascular, Renal and Hemopoietic Pharmacology</u> •Drugs used in Hypertension		
12.	• Diuretics		
13.	• Antianginal drugs, Drugs used in heart failure • Antiarrhythmicdrugs		
14.	• Antiplatelet, Anticoagulant, Fibrinolytic drugs		
15.	Lipid regulating drugs and Hematinics		
16..	<u>Endocrine Pharmacology</u> • Drugs used in Diabetes Mellitus		
17.	• Adrenocortical steroids • Drugs used in thyroid disorder		
18.	• Estrogen and Progesterone • Ovulation inducing agents • Hormonal Contraceptives • Drugs acting on Uterus and • Hormone Replacement Therapy		
19.	<u>Gastrointestinal Pharmacology</u> • Drugs used in PUD • Antiemetic and prokinetic drugs		
20.	• Antidiarrheal agents , ORS • Antimotility drugs, IV fluid • Drugs used in constipation • Drugs for Inflammatory bowel disease(IBD) and Irritable bowel syndrome (IBS)		
FIRST TERM EXAMINATION			

TERM II

SL No	Title and contents	Marks	Initial of teacher
01.	<u>Central Nervous System</u> • Introduction to CNS • Drugs used in anxiety and sleep disorder: • Benzodiazepines and Non-Benzodiazepines		
02.	• Antipsychotic and Antiparkinsonian drugs		
03.	• Antiepileptics and Anticonvulsant drugs		
04.	• Antidepressant		
05.	• General Anesthetics		
06.	• Local anesthetics, Skeletal muscle relaxants		
07.	• Opioid Analgesics, • Drug dependence, Tolerance, Addiction & Tachyphylaxis		
08.	<u>Autacoids</u> • Eicosanoids • Prostaglandin analogues • Non-steroidal anti-inflammatory Drugs (NSAIDs)		
09.	Histamine and Antihistamines • Serotonin agonist and antagonists • Drugs used for Migraine		
10.	<u>Antimicrobials</u> • Introduction and Principles of antimicrobial chemotherapy • Classification • Antimicrobial resistance, Superinfection, • Masking of Infections • Post antibiotic effects • Chemoprophylaxis		
11.	Cell wall synthesis inhibitors • Beta lactams and • Non beta lactam antimicrobials		
12.	Protein Synthesis Inhibitors • Aminoglycosides • Tetracyclines • Macrolides • Chloramphenicol • Newer Protein synthesis inhibitors		
13.	Nucleic acid synthesis inhibitor • Sulfonamides & Cotrimoxazole		
14.	• Quinolones & Fluoroquinolones		
15..	• Drugs used in Malaria : Therapy and Prophylaxis • Drugs used in Kala-azar		
16.	• Drugs used in Tuberculosis, Leprosy,		

17.	• Anti-amoebic drugs , • Anthelmintic drugs • Drugs used in Filariasis • Drugs used in Scabies		
18.	• Drugs used in Fungal infection • Drugs used in Viral infection		
19.	Anti-cancer drugs • Classification • Adverse effects • Targeted biological therapy		
20.	Clinical Pharmacology • Essential drug concept • Rational use of medicine • “P” drug concept • Compliance		
SECOND TERM EXAMINATION			

Department of Pharmacology & Therapeutics Clinical Pharmacology Case Report

Name of the Student:

Class Roll no:

Remarks of the Batch Teacher:

Particulars of the Patient:

Personal history:

Patient's name:

Age:

Education:

Occupation:

Socio-economic Status:

Ward/Bed:

Date of Admission:

Date of discharge:

History of past illness (including Drug History):

Description of present illness (History & Clinical Findings):

Investigation done with results:

Provisional diagnosis:

Treatment given:

Drug therapy given:

(mention the exact brand name written in the treatment sheet and their corresponding generic):

Result & Outcome of the treatment:

Make a Summary of the Case Report (Stating personal history, complaints, clinical findings, reports of investigations done, diagnosis made, treatment given & outcome of the treatment)

A. Discussion about therapeutic problem & drug therapy given:

1. Define the therapeutic problem(s) of the case you have reported.

2. Did the drug(s)/treatment given address all the therapeutic problem?

Yes/No

Relate the treatment/drugs given to specific therapeutic problem.

If no, explain why?

3. For each drug given, was their other alternatives?

4. Considering the drug(s) given & the alternatives, whether the choice was MOST appropriate

(consider drug's effectiveness (benefit), Risk & Cost, Route of Administration, Dosage, Frequency & Duration of Therapy and Patient's Factors like age, Pregnancy & Diseases).

B. Comments on Prescription:

1. Was the route of administration, dosage, frequency & duration of therapy properly mentioned?

2. **Was the patient warned about possible adverse effects of each drug & how to avoid them?**

C. Report on Adverse Effects

Was there any reported adverse effects in this case?

If yes, what are the clinical manifestations & how they have been managed?

D. Final Comments:

E. Drug Discussion:

Brief information about the drug(s) used in the therapy (including Generic name/
International Non-proprietary name, Pharmacological effects, Mechanism of action,
Metabolism and Elimination, Important drug-drug and drug-food interactions)

Signature of the student