SRI BALAJI VIDYAPEETH

(Deemed - to be - University u/s 3 of UGC Act, 1956)

Pillaiyarkuppam, Puducherry – 607 402

Mahatma Gandhi Medical College & Research Institute
Shri Sathya Sai Medical College & Research Institute

COMPETENCY BASED POSTGRADUATE CURRICULUM
M.D. PHARMACOLOGY
2021

Preface

The promulgation of the much-awaited Competency Based Medical Education (CBME) for post graduate programs by the National Medical Council is a welcome move. Sri BalajiVidyapeeth (SBV), Puducherry, deemed to be University, declared u/s 3 of the UGC Act. and accredited by the NAAC with A grade, takes immense privilege in preparing such an unique document in a comprehensive manner and most importantly the onus is on the Indian setting for the first time, with regard to the competency based medical education for post graduate programs that are being offered in the broad specialty departments. SBV is committed to making cardinal contributions that would be realised by exploring newer vistas. Thus, post graduate medical education in the country could be made to scale greater heights and SBV is poised to show the way in this direction.

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Preface

Following roll out of much awaited Competency-Based Medical Education (CBME) for undergraduate by the Medical Council of India (MCI)(superseded by the Board of Governors) , adoption of CBME for post-graduate by it is welcome move.

The MCI has laid down the syllabus course wise, listing competency to some extent, teaching learning methods and the assessment methods as well. The MCI describes competencies in three domains (knowledge, skill, and attitude). However, the most significant problem in competency-based training is the development of appropriate assessment tools.

The salient feature of this document is defining the program educational objectives (PEO) for its postgraduate program as a whole, defining program outcomes (PO) based on the competencies to be practiced by the specialist, course outcomes (CO) and program specific sub-competencies and their progression in the form of milestones. The compilation of the milestone description leads to the formation of the required syllabus. This allows the mentors to monitor the progress in sub-competency milestone levels. It also defines milestone in five levels, for each sub-competency. Although MCI has described three domains of competencies, the domain 'Attitude' is elaborated into 4 more competencies for ease of assessment. The six competency model (ACGME) for residency education: Medical Knowledge, Patient Care, Practice Based Learning and Improvement, Systems Based Practice, Professionalism, Inter personal and Communication Skills gives better clarity and in-depth explanation. The sub-competency and their milestone levels are mapped into the entrustable professional activities (EPA) that are specific to the individual postgraduate program. To make the program more relevant, PEO, PO, CO and EPAs are mapped with each other. EPA's which are activity based are used for formative assessment and graded. EPA assessment is based on workplace based assessment (WPBA), multisource feedback (MSF) and eportfolio. A great emphasis is given on monitoring the progress in acquisition of knowledge, skill and attitude through various appraisal forms including e-portfolios during three years of residency period.

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Foreword

The ability to use drugs safely and effectively is a defining characteristic of a good medical pharmacologist. This ability is predicated upon an up-to-date knowledge of the ever expanding information of drugs.

The extensive change made to our curriculum of MD Pharmacology reflects enormous progress and profusion of new knowledge regarding drugs across a wide range of therapeutic areas.

Although the content has been revised and refreshed our objective always is to provide a comprehensive emphasis on the principles of clinical pharmacology, prescribing skills, the way the drugs are used in clinical practice, an updated and succinct understanding of the major pathogenic mechanisms in context with the action of drugs and the consequences of their therapeutic uses.

Our curriculum offers a structured approach to the principles of disease management, outlining core principles of drug choices and planning a therapeutic regimen for many common diseases.

It is our intention that our MD Pharmacology curriculum will encourage students to develop a deeper understanding of the principles of drug usage that will help them to become a safe and effective pharmacologist and to carry out basic clinical research and teach. As medical science advances, these principles should underpin the lifelong learning essential for the maintenance of these skills of clinical pharmacologist.

With an MD in Pharmacology, you can teach or conduct research in higher educational institutions, work in the pharmaceutical industry, research and develop new medicines, conduct clinical research, work in regulatory and marketing divisions of industry, employ in hospitals, career in medical editing or develop new chemicals, .

We thank our team wholeheartedly for their spontaneous and unforced enthusiasm in preparing this curriculum.

With a handshake in thought God bless you all.

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This document named Postgraduate Curriculum for the M.D. Pharmacology program has beenpreparedintheaccordancewiththedocumentnotifiedbyBoardofGovernorsinsuppressionof MCI https://www.mciindia.org/CMS/information-desk/for-colleges/pg-curricula-2. This document has been prepared by Dr.Kartik Salwe & Dr.Sudar Codi, Department of Pharmacology, MGMCRI, Puducherry , and compiled by Dr.Manimekalai, Prof & HOD of Pharmacology, ratified by the Board of Studies on 05.05.2020 and approved by Academic Council of Sri Balaji Vidyapeeth, a deemed to be university, accredited 'A' Grade by NAAC.

Board of studies for M.D. Pharmacology

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- Dr.Somasundaram, Prof & HOD of Pharmacology, Sri Lakshminarayana Institute of Medical Sciences, Puducherry

Alumni:

- Dr.Jacob, Professor, St.Believer's Church Medical College, Tiruvala, Kerala.

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Sri Balaji University
Department of Pharmacology
Post- Graduate Program

1. Preamble

The purpose of PG education is to create specialists who would provide high quality health care and advance the cause of science through research & training. Pharmacology consists of both the experimental (basic) and clinical sciences. Experimental pharmacology is essential to understanding of drug action in diseases as well as for the pharmaceutical industry for drug discovery and development. Clinical pharmacology is essential for prescribing practice in medicine, adverse drug reactions, clinical trial and pharmacovigilance. The job prospects for a medical pharmacologist are in academics, pharmaceutical industry/clinical research organization, government research institutions, in regulatory bodies and as scientific writer or science manager.

Accordingly, a post graduate (MD) student in Pharmacology should be competent to meet the job requirements at all these places. The applied nature of the discipline, the move towards integrated course structures, the widening of discipline boundaries and increasing number of students seeking post graduation degree raise issues concerning maintaining and improving competency as along with maintenance of academic standards. These issues also necessitate integration with other biomedical and clinical disciplines. A pragmatic approach to postgraduate pharmacology teaching in India is an important step towards addressing the aforesaid challenges and facilitating a fresh curriculum design.

The purpose of this document is to provide teachers and learners illustrative guidelines to achieve defined outcomes through learning and assessment. This document was prepared by various subject- content specialists. The Reconciliation Board of the Academic Committee has attempted to render uniformity without compromise to purpose and content of the document. Compromise in purity of syntax has been made in order to preserve the purpose and content. This has necessitated retention of “domains of learning” under the heading “competencies”.

2. Program Educational Objectives (PEO)

PEO1: Specialist who can explain clearly concepts and principles of Pharmacology andtherapeutics.

PEO2: Leader and team member who understands health care system and act to provide safe patient care by training the health care professionals with accountability and responsibility.

PEO3: Communicator possessing adequate communication skill to convey required informationin an appropriate manner in various health care setting.

PEO4: Lifelong learner keen on updating oneself regarding the advancement in the field of Pharmacology and therapeutics and able to perform the role of researcher and teacher

PEO5: Professional who understands and follows the principle of bio-ethics / ethics related tohealth care system.

3. Program Outcome (PO)

After three years of residency program postgraduate should be able to

PO1: Able to explain clearly concepts and principles of Pharmacology and therapeutics

PO2: Apply and integrate the knowledge of pathophysiology of diseases and its modulation by drugs

PO3: Acquire Knowledge of the various recent advances in pharmacology pertaining to new drugdevelopment and treatment approach of various disorders.

PO4: Able to effectively teach undergraduate students in medicine (MBBS, Dentistry, Nursing and allied health sciences) so they become competent healthcare professionals and able tocontribute to training of postgraduate trainees.

PO5: Perform major in vivo and in vitro animal experiments with proper animal handling and careaccording to guidelines proposed for animal research.

PO6: Demonstrate the skills in prescription writing, auditing and effectively communicate with the patients, health care team, faculty and peers on the rational use of drugs, adverse drug reactionreporting and medication adherence.

PO7: Demonstrate and apply the knowledge of basics of research methodology, ethics, biostatistics and important guidelines to perform animal and human research and to have the potential ability to pursue further specializations and eventually be competent to guide students.

PO8: Apply skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.

4. Course and Course Objectives (CO):

4.1 Course 1 (C1): General Pharmacology

Objectives: At the end of three years post graduate student should be able to

C1.1 Acquire sound knowledge of general pharmacological principles to explain the mechanisms of action, pharmacokinetics, pharmacodynamics and adverse effects of drugs for various disorders

C1.2 Acquire knowledge on the rational use of drugs

C1.3 Acquire knowledge of the various branches of pharmacology and the principles underlying each

C1.4 Demonstrate the skills in prescription writing, auditing and effectively communicate with the patients, health care team, faculty and peers on the rational use of drugs, adverse drug reaction reporting and medication adherence.

4.2 Course 2 (C2): Clinical & Experimental Pharmacology

Objectives: At the end of three years post graduate student should be able to

C2.1 Acquire knowledge, understand and apply the principles of various national guidelines proposed and the legal and ethical issues involved in doing human and animal research.

C2.2 Describe how to evaluate, analyze and monitor preclinical and clinical data in drug discovery

C2.3 Demonstrate and apply the knowledge of basics of research methodology and biostatistics, develop a research protocol, prepare and take Informed consent form and patient information sheet, conduct the study, record experimental observations, analyse data using currently available statistical software, interpret results and write up a research paper

C2.4 Demonstrate standard operating procedures of various methods and techniques used in clinicaltrials and research.

C2.5 Demonstrate knowledge about computer assisted learning (CAL) software and instrumentationto use them efficiently in promoting learning of pharmacology.

C2.6 Perform major in vivo and in vitro animal experiments with proper animal handling and care

C2.7 Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies

C2.8 Estimate toxic drug levels using chemical and biological tests (alkaloids, glycosides, steroids,barbiturates, salicylates) by commonly used method

C2.9 Evaluate promotional drug literature, prepare “Drug Information Sheet” (WHO criteria), Interpret bioavailability parameters with the help of given pharmacokinetics data, Perform causality assessment and report ADR as per Pharmacovigilance Programme of India (PvPI)

4.3 Course 3 (C3): Systemic Pharmacology

Objectives: At the end of three years post graduate student should be able to

C3.1 Apply and integrate the knowledge of pathophysiology of diseases and its modulation by drugs

C3.2 Understand and apply the concepts of general pharmacology on the treatment of varioussystemic disorders.

C3.3 Understand and apply the principles of various teaching - learning technology in their practice

4.4 Course 4 (C4): Recent advances in Pharmacology

Objectives: At the end of three years post graduate student should be able to

C4.1 Acquire Knowledge of the various recent advances in pharmacology pertaining to new drug development and treatment approach of various disorders.

C4.2 Apply skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.

The PEO, PO and the CO are mapped with each other.**(Table 1)**

Table1. Mapping of PEO, PO and CO

	PEO 1			**PEO2**		**PEO3**	**PEO 4**		**PEO 5**
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO8**
C1	Y			Y		Y			
C2			Y	Y	Y	Y	Y		
C3	Y	Y	Y	Y		Y			
C4		Y	Y	Y				Y	Y

All courses run concurrently for 3 years with a summative assessment at the end of 3 years. The program is competency based and the competencies, sub-competencies and milestones are detailed. Theseare mapped to the Entrustable professional activities (EPA) identified as essential for a specialist. Formative assessment is carried out every three months using appropriate tools, for identifying eligibilityfor transfer of trust.

Competencies, Sub-competencies and Milestone:

At the end of the MD course in Pharmacology, the student should have acquired various competencies i.e. medical knowledge, patient care, interpersonal communication skill, system based practice, practice based learning and implementation and professionalism. Details of each with milestone as level is described below. **(Table 2)**

Table 2. Description of Competencies, Sub-competencies and Milestone

COMPETENCY – 1: Medical Knowledge (MK):

Demonstrate knowledge of established and evolving biomedical, clinical, epidemiological, and social-behavioral sciences, as well as the application of this knowledge to patient care

S,No	MILESTONE	Level 1	Level 2	Level 3	Level 4	Level 5
	SUB COMPETENCY	**Acquire knowledge and recall**	**Understand and explain Concepts**	**Analyze/Correlate /Apply the knowledge for treatment**	**Demonstrates the knowledge**	**Ability to plan and share their knowledge**
MK 1	Describe and apply pharmacological principles to explain the mechanism of action, PK, PD, drug interactions of drugs used in diagnosis, prevention and treatment of diseases	Acquire knowledge and able to recall the general pharmacological principles to explain the mechanism of action, PK, PD, drug interactions of drugs used in diagnosis, prevention and treatment of diseases	Understands the pharmacological principles and explains the concepts underlying the mechanism of action, PK, PD, drug interactions of drugs used in diagnosis, prevention and treatment of diseases	Analyse the knowledge gained and correlates the mechanism of action, PK, PD, drug interactions of various drugs used in diagnosis, prevention and treatment of diseases	Demonstrates the knowledge gained to the peer groups and faculties and ensure right learning of the pharmacological principles to explain the mechanism of action, PK, PD, drug interactions of drugs used in diagnosis, prevention and treatment of diseases	Able to make a lesson plan and educate the undergraduates and paramedics on the pharmacological principles underlying the mechanism of action, PK, PD, drug interactions of drugs used in diagnosis, prevention and treatment of diseases
MK 2	Apply and integrate knowledge of pathophysiology of	Acquire knowledge of the pathophysiology of	Apply and integrate the knowledge of various groups of	Analyze, correlate and arrive at the drugs of choice used	Demonstrates the knowledge gained to the peer groups and	Able to make a lesson plan and educate the

	diseases and its modulation by drugs.	diseases and the drugs used in treatment of various diseases.	drugs based on the pathophysiology of diseases and its modulation by drugs.	in the treatment of a clinical condition based on their pathophysiology.	faculties and ensure right learning of the knowledge of pathophysiology of diseases and its modulation by drugs.	undergraduates and paramedics on Pathophysiology of diseases and its modulation by drugs.
MK 3	Acquire knowledge on various fields of Pharmacology	Acquire knowledge on various fields of Pharmacology	Understand the basic principles behind the functioning of various fields of Pharmacology	Analyze and apply the knowledge of various fields of pharmacology in the treatment of a given condition.	Demonstrates the knowledge gained to the peer groups and faculties and ensure right learning of the principles of various fields of Pharmacology and their clinical application	Able to make a lesson plan and educate the undergraduates and paramedics on principles of various fields of Pharmacology and their clinical application
MK 4	Acquire knowledge about principles of basic and advanced Instruments used in Pharmacology.	Acquire knowledge on various basic and advanced Instruments used in Pharmacology.	Understand the basic principles behind the functioning of basic and advanced Instruments used in Pharmacology.	Analyze and apply the knowledge of basic and advanced Instruments used in Pharmacology for the treatment of a given condition.	Demonstrates the knowledge gained to the peer groups and faculties and ensure right learning of the principles of basic and advanced Instruments used in Pharmacology and their clinical application	Able to make a lesson plan and educate the undergraduates and paramedics on principles of basic and advanced Instruments used in Pharmacology. and their clinical application
MK 5	Acquire knowledge on detoxification and rehabilitation	Acquire knowledge on various drugs used in the treatment of common poison consumption and rehabilitation of patient.	Understand the basic mechanisms of the various drugs used in the treatment of common poison consumption and rehabilitation of patient..	Analyze and apply the knowledge of various drugs used in the treatment of common poison for the treatment of a given condition.	Demonstrates the knowledge gained to the peer groups and faculties and ensure right learning of the various drugs used in the treatment of common poison	Able to make a lesson plan and educate the undergraduates and paramedics on various drugs used in the treatment of common poison

					consumption and rehabilitation of patient..	consumption and rehabilitation of patient..

COMPETENCY - 2:
PATIENT CARE - Provide patient-centered care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.

S.No	MILESTONE	Level 1	Level 2	Level 3	level 4	Level 5
	SUB COMPETENCY	**Acquire knowledge and Understand concept**	**Apply the Concepts with direct Supervision**	**Apply the Concepts with in-direct Supervision**	**Perform Independently**	**Assist others in Learning**
PC 1	Acquire knowledge on essential medicines and generic drugs	Acquire knowledge on essential medicines and generic drugs	Apply the essential medicine concept on the choice of treatment of a given medical condition with direct supervision by faculty	Apply the essential medicine concept on the choice of treatment of a given medical condition in routine activities with indirect supervision by faculty	Apply the essential medicine concept to choose the right choice of treatment of a given medical condition independently	Able to make a lesson plan and educate the undergraduates and paramedics on essential medicine concept and its utility in clinical scenario.
PC 2	Acquire knowledge on rational use of drugs and prescription writing and prescription auditing	Acquire knowledge on the rational use of drugs and its clinical importance	Apply the knowledge of rational use of drugs in writing and auditing a prescription for a given medical condition under direct supervision by faculty	Apply the knowledge of rational use of drugs in writing and auditing a prescription for a given medical condition under indirect supervision by faculty	Write and audit a prescription for a given medical condition independently	Able to educate and train the undergraduates and paramedics on effective prescription writing and auditing

PC 3	Acquire knowledge on pharmaco vigilance and able to predict efficacy and adverse effects associated with use of drugs	Acquire knowledge on pharmacovigila nce and causality assessment to report an adverse drug reaction	Apply the knowledge, perform casualty assessment and report an adverse drug reaction with direct supervision by faculty	Apply the knowledge, perform casualty assessment and report an adverse drug reaction with indirect supervision by faculty	Perform Casualty assessment, report Independently	Able to make a lesson plan and educate the undergraduates and paramedics on Pharmacovigilance and Casualty Assessment
PC 4	Acquire knowledge about antimicrobial stewardship programs and strategies for containment of antibiotic resistance	Acquire knowledge on drugs used for the treatment of infections and the antimicrobial stewardship program	Apply the knowledge on choose the right drugs used for the treatment of infections and participate in the hospital antimicrobial stewardship program under direct supervision by faculty	Apply the knowledge on choose the right drugs used for the treatment of infections and participate in the hospital antimicrobial stewardship program under indirect supervision by faculty	Choose the right choice of drug for the treatment of infections and participate independently to combat antimicrobial resistance	Able to make a lesson plan and educate the undergraduates and paramedics on right choice of drug for treatment of various infections

COMPETENCY - 3: INTERPERSONAL COMMUNICATION SKILLS - Demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals

S. No	**MILESTONE**	**Level 1**	**Level 2**	**Level 3**	**level 4**	**Level 5**
	SUB COMPETENCY	**Acquire knowledge and understand the concepts**	**Demonstrate/ Communicate with direct Supervision**	**Demonstrate/ Communicate with in-direct Supervision**	**Perform/ communicate Independently**	**Assist/train others in Learning**
ICS 1	Demonstrate the Instrument used routinely in Pharmacology	Acquire knowledge on Instruments used routinely in Pharmacology.	Understand the basic principles behind the functioning of Instruments used	Analyze and apply the knowledge of instruments used routinely in	Demonstrates the knowledge gained to the peer groups and faculties and ensure	Able to make a lesson plan and educate the undergraduates and

			routinely in Pharmacology.	Pharmacology for the treatment of a given condition.	right learning of the principles of Instruments used routinely in Pharmacology and their clinical application	paramedics on principles of Instruments used routinely in Pharmacology. and their clinical application
ICS 2	Communicate legal and ethical issues involved in drug development and research to patients and peer groups	Understand the legal and ethical issues involved in drug development and research to patients and peer groups	Communicate legal and ethical issues involved in drug development and research to patients and peer groups with direct supervision by faculty.	Communicate legal and ethical issues involved in drug development and research to patients and peer groups with indirect supervision by faculty.	Communicate legal and ethical issues involved in drug development and research to patients and peer groups independently.	Train others to Communicate legal and ethical issues involved in drug development and research to patients and peer groups
ICS 3	Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence	Understands the importance and learns to explain patients, the effects and side effects of drugs, including the need for medication adherence	Effectively explains to patients, the effects and side effects of drugs, including the need for medication adherence with direct supervision by faculty.	Effectively explains to patients, the effects and side effects of drugs, including the need for medication adherence with indirect supervision by faculty.	Effectively explains to patients, the effects and side effects of drugs, including the need for medication adherence independently.	Train others to Effectively explain to patients, the effects and side effects of drugs, including the need for medication adherence
ICS 4	Communicate effectively with health care team on rational use of drugs and ADR reporting	Learns to Communicate effectively with health care team on rational use of drugs and ADR reporting	Communicates effectively with health care team on rational use of drugs and ADR reporting with direct supervision by faculty.	Communicate effectively with health care team on rational use of drugs and ADR reporting with indirect supervision by faculty.	Communicate effectively with health care team on rational use of drugs and ADR reporting independently.	Train others to Communicate effectively with health care team on rational use of drugs and ADR reporting
ICS 5	Demonstrate ability to generate	Acquire knowledge about the use of	Demonstrate ability to generate	Demonstrate ability to generate	Demonstrate ability to generate	Train others to generate awareness

	awareness about the use of generic drugs in patients.	generic drugs in patients.	awareness about the use of generic drugs in patients with direct supervision by faculty.	awareness about the use of generic drugs in patients with indirect supervision by faculty.	awareness about the use of generic drugs in patients independently.	about the use of generic drugs in patients.

COMPETENCY - 4:
SYSTEM BASED PRACTICE - Demonstrate the ability to follow the standard operating procedures relevant to practices of the organisations for patient care .

S.No	MILESTONE	Level 1	Level 2	Level 3	level 4	Level 5
	SUB COMPETENCY	**Acquire knowledge and understand the concepts**	**Demonstrate/ Develop skills with direct Supervision**	**Demonstrate/ Develop skills with in- direct Supervision**	**Perform/ Prepare Independently**	**Assist/train others in Learning**
SBP1	Acquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines and prepare protocol for clinical trial	Acquire knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines and prepare protocol for clinical trial	Demonstrates knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines and prepare protocol for clinical trial under direct supervision by faculty	Demonstrates knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines and prepare protocol for clinical trial under indirect supervision by faculty	Demonstrates knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines and prepare protocol for clinical trial without supervision by faculty	Trains others in acquiring knowledge and understanding of principles of Good clinical practice (GCP) and Good laboratory practice (GLP) guidelines and prepare protocol for clinical trial
SBP2	Acquire knowledge and Demonstrate the basics of research methodology and biostatistics in clinical and	Acquire knowledge on the basics of research methodology and biostatistics in clinical and	Demonstrate the basics of research methodology and biostatistics in clinical and experimental	Demonstrate the basics of research methodology and biostatistics in clinical and experimental	Demonstrate the basics of research methodology and biostatistics in clinical and experimental	Trains others on the basics of research methodology and biostatistics in clinical and experimental

	experimental research	experimental research	research under direct supervision by faculty	research under indirect supervision by faculty	research without supervision by faculty	research
SBP3	Prepare Informed consent form and participant information sheet for research involving human participants	Acquires knowledge to prepare an informed consent form and participant information sheet for research involving human participants	Prepare Informed consent form and participant information sheet for research involving human participants under direct supervision by faculty	Prepare Informed consent form and participant information sheet for research involving human participants under indirect supervision by faculty	Prepare Informed consent form and participant information sheet for research involving human participants without supervision by faculty	Train others to prepare Informed consent form and participant information sheet for research involving human participants
SBP4	Acquire knowledge on research and ethical guidelines and perform in vivo and in vitro animal research and toxicity studies	Acquire knowledge on the basics of research methodology and ethical guidelines to perform in vivo and in vitro animal research and toxicity studies	Demonstrate the basics of research methodology and ethical guidelines to perform in vivo and in vitro animal research and toxicity studies under direct supervision by faculty	Demonstrate the basics of research methodology and ethical guidelines to perform in vivo and in vitro animal research and toxicity studies under indirect supervision by faculty	Demonstrate the basics of research methodology and ethical guidelines to perform in vivo and in vitro animal research and toxicity studies without supervision by faculty	Trains others on the basics of research methodology and ethical guidelines to perform in vivo and in vitro animal research and toxicity studies

COMPETENCY - 5:
PROBLEM BASED LEARNING Demonstrate the commitment to learn by practice and improve upon their ability.

S. No	MILESTONE	Level 1	Level 2	Level 3	level 4	Level 5
	SUB COMPETENCY	**Acquire knowledge and understand the concepts**	**Demonstrate/ Evaluate with direct Supervision**	**Demonstrate/ Evaluate with indirect Supervision**	**Perform/ Evaluate Independently**	**Assist/train others in Demonstration and evaluation**
PBLI 1	Acquire knowledge and apply the principle of research methodology and biostatistics in the evaluation and interpretation of human and animal pharmacological studies	Acquire knowledge and apply the principle of research methodology and biostatistics in the evaluation and interpretation of human and animal pharmacological studies	Demonstrate the knowledge or evaluate the principle of research methodology and biostatistics in the evaluation and interpretation of human and animal pharmacological studies with direct supervision by faculty	Demonstrate the knowledge or evaluate the principle of research methodology and biostatistics in the evaluation and interpretation of human and animal pharmacological studies with indirect supervision by faculty	Evaluate the principle of research methodology and biostatistics in the evaluation and interpretation of human and animal pharmacological studies independently	Assist others in evaluating and interpretation of the principle of research methodology and biostatistics in human and animal pharmacological studies
PBLI 2	Describe how to evaluate, analyse and monitor preclinical and clinical data in drug discovery and treatment	Acquire knowledge to evaluate, analyse and monitor preclinical and clinical data in drug discovery and treatment	Evaluate, analyse and monitor preclinical and clinical data in drug discovery and treatment with direct supervision by faculty	Evaluate, analyse and monitor preclinical and clinical data in drug discovery and treatment with indirect supervision by faculty	Evaluate, analyse and monitor preclinical and clinical data in drug discovery and treatment independently	Assist others to evaluate, analyse and monitor preclinical and clinical data in drug discovery and treatment
PBLI 3	Describe and demonstrate the principles of teaching - learning methodology used in	Acquire knowledge to Describe the principles of teaching - learning methodology used in	Demonstrate the principles of teaching - learning methodology used in learning	Describe and demonstrate the principles of teaching - learning methodology used in	Describe and demonstrate the principles of teaching - learning methodology used in	Assist others to demonstrate the principles of teaching - learning methodology used in

	learning Pharmacology	learning Pharmacology	Pharmacology with direct supervision by faculty	learning Pharmacology with indirect supervision by faculty	learning Pharmacology independently	learning Pharmacology
PBLI 4	Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology.	Acquire knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology.	Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology with direct supervision by faculty	Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology indirect supervision by faculty	Demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology independently	Train others to demonstrate knowledge about computer assisted learning (CAL) softwares and ability to use them efficiently to promote learning of pharmacology.
PBLI 5	Evaluate promotional drug literature	Acquire knowledge to Evaluate promotional drug literature	Evaluate promotional drug literature with direct supervision by faculty	Evaluate promotional drug literature with indirect supervision by faculty	Evaluate promotional drug literature independently	Assist others to Evaluate promotional drug literature
PBLI 6	Prepare “Drug Information Sheet” (WHO criteria)	Acquire knowledge to Prepare “Drug Information Sheet” (WHO criteria)	Acquire knowledge to Prepare “Drug Information Sheet” (WHO criteria) with direct supervision by faculty	Acquire knowledge to Prepare “Drug Information Sheet” (WHO criteria) with indirect supervision by faculty	Acquire knowledge to Prepare “Drug Information Sheet” (WHO criteria) independently	Assist others to Prepare “Drug Information Sheet” (WHO criteria)
PBLI 7	Interpret bioavailability parameters with the help of given pharmacokinetics data	Acquire knowledge to Interpret bioavailability parameters with the help of given pharmacokineti cs data	Interpret bioavailability parameters with the help of given pharmacokinetics data with direct supervision by faculty	Interpret bioavailability parameters with the help of given pharmacokinetics data with indirect supervision by faculty	Interpret bioavailability parameters with the help of given pharmacokineti cs data independently	Assist others to Interpret bioavailability parameters with the help of given pharmacokinetics data

COMPETENCY - 6:
PROFESSIONALISM - Demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles

S. No	MILESTONE	Level 1	Level 2	Level 3	level 4	Level 5
	SUB COMPETENCY	**Acquire knowledge and understand the concepts**	**Demonstrate with direct Supervision**	**Demonstrate with indirect Supervision**	**Perform Independently**	**Assist/train others in Learning**
P 1	Ability to guide the students to do clinical and experimental research	Acquire knowledge to guide the students to do clinical and experimental research	Demonstrate the ability to guide the students to do clinical and experimental research with direct supervision by faculty	Demonstrate the ability to guide the students to do clinical and experimental research with indirect supervision by faculty	Demonstrate the ability to guide the students to do clinical and experimental research without supervision by faculty	Assumes longterm leadership to guide the students to do clinical and experimental research
P 2	Demonstrate the knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology	Demonstrate the knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology	Demonstrate the knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology	Demonstrate the knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology	Demonstrate the knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology	Demonstrate the knowledge about recent advances and trends in research in the field of pharmacology and clinical pharmacology
P 3	Demonstrate respect in interactions with peers, and other healthcare professionals.	Demonstrate respect in interactions with peers, and other healthcare professionals.	Demonstrate respect in interactions with peers, and other healthcare professionals and accepts constructive feedback	Demonstrate respect in interactions with peers, and other healthcare professionals and modifies one's behaviour,	Trains undergraduates to demonstrate respect in interactions with peers, and other healthcare professionals.	Assumes leadership in departmental activities.
P 4	Demonstrate ethical behaviour and integrity in one’s	Demonstrate ethical behaviour and integrity in one’s	Demonstrate ethical behaviour and integrity in one’s	Demonstrate ethical behaviour and integrity in one’s	Trains undergraduates to demonstrate ethical	Assumes long term leadership to train others on ethical

	work.	work.	work and accepts constructive feedback	work and modifies one's behaviour	behaviour and integrity in one's work.	behaviour and integrity in one's work.
P 5	Acquire skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.	Acquire skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.	Demonstrates the skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development by seminar presentation under direct supervision by faculty	Demonstrates the skills for self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development by seminar presentation under indirect supervision by faculty	Performs self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development independently	Performs long term self-directed learning to keep up with developments in the field and to continuously build to improve on skills, expertise and perpetual professional development.
P 6	Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies.	Acquires presentation skills at academic meetings, publications and writing research projects for funding agencies.	Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies under direct supervision by faculty.	Demonstrate presentation skills at academic meetings, publications and writing research projects for funding agencies under indirect supervision by faculty.	Performs presentation at academic meetings, publications and writing research projects for funding agencies independently.	Assumes longterm leadership in presentation skills at academic meetings, publications and writing research projects for funding agencies.

6. Syllabus

Course 1 General Pharmacology:

1. General Pharmacology

- Routes of drug administration
- Drug delivery system
- Basic and molecular pharmacology
- Drug receptors and Pharmacodynamics
- Pharmacokinetics (Absorption, Distribution, Metabolism and Excretion)
- Biotransformation
- Factors modifying drug action
- Dose response relationship
- Therapeutic drug monitoring
- Adverse drug reactions
- Use of drugs in special population – pregnancy, Perinatal and Paediatrics Pharmacology, Geriatric Pharmacology
- Over the counter drugs
- Dietary supplements and herbal medicines
- Rational use of drugs
- Medication adherence
- Spurious drugs
- Essential medicines concept
- 'P' drug

2. Various fields of Pharmacology

- Pharmacovigilance
- Pharmacogenomics
- Pharmacognosy
- Pharmacoepidemiology
- Chronopharmacology
- Pharmacoeconomics
- Pharmacometrics
- Ethnopharmacology

3. New Drug Development

- Clinical trial Phases
- FDA Guidelines for new drug development
- In silico methods
- High throughput screening
- Computer aided drug designing

Course 2: Clinical & Experimental Pharmacology

1. Experimental Pharmacology:

- Laboratory animals
- Euthanasia
- Animal House Laboratory – CPCSEA Guidelines, OECD guidelines, ARRIVE Guidelines
- Bioassays- Bioassay methods, Animal experiments: Ethical considerations, ethical approval, applicable regulatory Guidelines (CPCSEA), humane animal research (principles of 3Rs) and alternatives to animal experimentation. General and statistical considerations, Anesthetics used in laboratory animals, Principles of EC50, ED50, pD2 and pA2 values of drugs, Describe methods of bioassay for estimation of : Acetylcholine, skeletal neuromuscular junction blockers, adrenaline, noradrenaline, histamine, 5 HT, hormones, insulin, vasopressin/oxytocin, estrogen, progestins, ACTH, Competitive antagonism - pA2 values, Immunoassays: Concept, types of bioassays and their applications, Animal experiments: Ethical consideration, ethical approval, Regulatory Guidelines (CPCSEA) and alternatives to animal experimentation
- Invivo and Invitro animal experiments
- General screening and evaluation of: Analgesics, antipyretics, anticonvulsants, anti- inflammatory drugs, antidepressants, antianxiety and antipsychotics, sedatives, muscle relaxants, antihypertensives, hypocholesterolaemic agents, antiarrhythmics, diuretics, adrenergic blocking drugs, Drugs used in peptic ulcer diseases/Prokinetic agents/ antiemetics, Antitussives, /anti-asthma agents, Local Anaesthetics, Oxytocics, antifertility agents, Antidiabetics, Behavioral pharmacology models and evaluation of drugs affecting learning and memory

2.Biochemical Pharmacology

- Basic principles and applications of simple analytical methods, Principles of quantitative estimation of drugs, endogenous compounds and poisons using Colorimetry,

  Spectrophotometry, flame photometry, High Performance Liquid Chromatography (HPLC)and enzyme-linked immunosorbent assay (ELISA).

3.Clinical Pharmacology

- GCP guidelines
- ICMR guidelines for biomedical research
- Drugs and cosmetic act
- New drug & Clinical trials guidelines

4.Research Methodology for biomedical research

- Literature search & review
- Protocol designing
- Research methodology
- Reference Management
- Basic biostatistics in biomedical research

5. Ethics in animal and human research

- ICMR guidelines for biomedical research
- CPCSEA Guidelines for animal research

Course 3: Systemic Pharmacology

- Autonomic Pharmacology
- Drugs acting on Smooth muscles
- Drugs acting on Synaptic and Neuroeffector Junctional sites
- Drugs acting on Central Nervous System (Sedative, Hypnotics, Antiepileptics, General Anesthetics, Local Anesthetics, Skeletal Muscle Relaxants, Antipsychotic, Antidepressants, Drugs used in Parkinson's disease and other neurodegenerative disorders, opioid agonists and antagonists, Drugs of abuse)
- Drugs modifying renal function
- Drugs acting on cardiovascular system and haemostatic mechanisms (Antihypertensives, Antianginal, Antiarrhythmics, Drugs used in heart failure, Drugs used in Dyslipidemias, Fibrinolytics, Anticoagulants, Antiplatelets)
- Reproductive Pharmacology
- Agents effecting calcification and bone turnover
- Autacoids and related pharmacological agents (NSAIDs) and drugs used in Rheumatoid arthritis and Gout
- Gastrointestinal drugs
- Pharmacology of drugs affecting the respiratory system (drugs used in Bronchial Asthma and COPD)
- Antimicrobial, antiparasitics, disinfectants, antiseptics
- Chemotherapy of neoplastic disease
- Antiviral drugs
- Drugs used in Autoimmune disorder and Graft versus Host Disease
- Dermatological pharmacology
- Ocular pharmacology
- Immunomodulators - immunosuppressants and immunostimulants
- Pharmacology of drugs used in endocrine disorders (drugs used in diabetes mellitus, hypothalamic and pituitary hormones, thyroid and anti-thyroid drugs, adrenal corticoid hormones and their antagonists, gonadal hormones and their inhibitors)
- Drug delivery systems
- Heavy metal poisoning
- Non-metallic toxicants - air pollutants, pesticides etc.

Course 4: Recent advances in Pharmacology

1. **Important Contribution by scientists**
2. **Recent advances in the management of**
    - Bronchial Asthma, COPD, Rheumatoid arthritis, Migraine, Gout. Angina, Hypertension, Congestive Cardiac Failure, Arhythmias, Anticoagulants, Hyperlipidemia, Diabetes, Bone homeostasis, Glaucoma, Dermatological disorders, Antimicrobials, Chemotherapy of tuberculosis, Malaria, Viral Infections, Epilepsy, Parkinsonism, Schizophrenia, Depression, Peptic Ulcer, Inflammatory bowel disease and other disorders.
3. **Newer drugs**

7. Teaching and Learning Methods

Postgraduate Training

Learning in a PG program is primarily self-directed and in Pharmacology and consists of laboratory and academic work. The formal sessions are merely meant to supplement this core effort. Acquisition of practical competencies thus becomes the cornerstone of postgraduate medical educationin Pharmacology.

Formal teaching sessions

• In addition to laboratory work, at least 6-hr of formal teaching per week will be followed.Journal club Once a week

Seminar Once a week

Practical Once a week

Group Discussions Once a week

Case discussions

Once a month Interdepartmental case or seminar Once a month

• Attend accredited scientific meetings (CME, symposia, and conferences).

• A postgraduate student of Pharmacology would be required to present one poster presentation, to read one paper at a national/state conference and to present one research paper which should be published/accepted for publication/sent for publication during the period of his postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.

• Additional sessions on basic sciences, biostatistics, research methodology,teaching methodology, hospital waste management, health economics, medical ethics and legal issues related to experimentationwill be ensured by participation in workshops, conference etc.

• The postgraduate students shall be required to participate in the teaching and training programmeof undergraduate students and interns.

- • **Log book:**Maintenance of log book: **E-portfolio:- It is an electronic portfolio to be maintainedby** the resident to record their activities under the section:
    - EPA,
    - Daily log
    - Patient care
    - Procedure
    - Dissertation
    - Academic activities(Seminar, symposium, case presentation, journal club)
    - Co-curricular activities (Conference, CME, Workshop),
    - Teaching Assignments,
    - Awards and achievements

- Outreach activities.

  - **E-portfolio** shall be checked and assessed periodically by the faculty members. This will enable to monitor progress of the resident, his level of attainment of milestone and impart the training accordingly

- Writing thesis following appropriate research methodology, ethical clearance and good clinical practice guidelines.
- The postgraduate students shall be required to participate in the teaching and training programmeof undergraduate students and interns.
- A postgraduate student of a postgraduate degree course in broad specialities/super specialities would be required to present one poster presentation, to read one paper at a national/state conference and to present one research paper which should be published/accepted for publication/sent for publication during the period of his postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.
- Department should encourage e-learning activities.

The postgraduate student in M.D (Pharmacology) shall undergo a 3 - year (6 terms of 6 monthseach) training that will comprise of the following:

I. **Theory:** (lectures, seminars, group discussion, journal club) (at least 6 hours a week, daily 2hours for 3 days)

II. Practical:

Practical training in the following suggested areas: (8 hours a week, daily 4 hours for 2

days)

• Experimental Pharmacology:

In vitro (including bioassays), *in vivo* (including common methods of drug evaluation)experiments, computer simulations and toxicity tests

• Chemical Pharmacology:

Identification of drug/toxin by using chemical, biological and analytical tests.Quantitativeestimation - Use of colorimeter, spectrophotometer and/or other advanced analytical equipments

• Clinical Pharmacology:

I Evaluation of drugs in healthy volunteers as well as patients

II Critical evaluation of drug literature, pharmacoeconomics, pharmacovigilance andpharmacoepidemiology.

III Thesis on a suitable problem

IV Training in undergraduate teaching

V Computer training

During the training programme, patient safety is of paramount importance;therefore, skills are to be learnt initially on the models, later to be performed under supervision followed by performing independently; using simulation lab.

Rotations:

- Details of 3 years posting in the PG programme (6 terms of 6 months each)

	1st Mon	2nd Mon	3rd Mon	4th Mon	5th Mon	6th Mon	7th Mon	8th Mon	9th Mon	10th Mon	11th Mon	12th Mon
1st year	P	P	P	P	P	I	AP	AP	AP	AP	P	P
2nd year	P	P	P	P	P	I	AP	AP	AP	AP	P	P
3rd year	P	P	P	P	P	P	P	P	P	P	P	P

P– Pharmacology, **I**-Industrial Visit, **AP**-Allied postings

***Allied posts should be done during the course – for 10 weeks**

- Medicine - 2 weeks in 1st year
- Cardiology – 2 weeks in 1st year
- Emergency - 2 weeks in 1st year
- Intensive Care - 2 weeks in 1st year
- Biochemistry – 2 weeks in 2nd year
- Microbiology 2 weeks in 2nd year
- Pathology – 2 weeks in 2nd year
- CIDRF – 2 weeks in 2nd year

8. Assessment

Formative assessment:

Formative assessment is continual and assess medical knowledge, patient care, procedural & academic skills, interpersonal communication skills, system based practice, self-directed learning and professionalism of the activities mentioned every 3/6monthly. EPAs are listed as bellow**(Table 3)** withdescription of each EPA **(Table 4).** Progress of the students is recorded after discussion with the student in Entrustable Professional Activity (EPA) assessment form **Annexure-1.**These EPAs are also mapped with PO and CO. **(Table 5)**

List the of Entrustable Professional Activity

Table 3. List the of Entrustable Professional Activity

EPA No.	GENERAL
1	ADR reporting and participating in National Pharmacovigilance Program
2	Rational Use of Drugs – Essential Medicines List & 'P'drug
3	Drug Compliance – Measuring Medication Adherence
4	Analysing Prescribing pattern using WHO criteria
5	Identifying Drug-Drug Interactions
6	Identifying the right choice of drug based on Pharmacoeconomics
7	Evaluating Drug Promotional Literature
8	Evaluating the Teaching – Learning Methodologies in Pharmacology
9	Performing Bioassay of drugs
10	Performing Herbal Extraction Procedures
11	Performing In vivo small animal experiments
	RESEARCH METHODOLOGY
12	Understanding Basics of Research Methodology & Performing a Clinical or Experimental research
13	Obtaining Informed Consent for participation in the clinical trial
14	Applying basic concepts of Biostatistics in Performing Clinical or Experimental research
15	Design a Protocol for a Clinical or Experimental study
16	Criticise a Journal Article
17	Writing a manuscript for publication

Description of Entrustable Professional Activity with relevant domains of competence, domain critical behavior

Table 4. EPAs, Competency levels and entrustability

EPA 1: ADR reporting and participating in National Pharmacovigilance Program	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • perform casualty assessment • report an ADR • participate and own long term leadership in national Pharmacovigilance program
2. Most relevant domains of competence:	MK, PC, ICS
3. Competencies within each domain critical to entrustment decisions:	MK: 1.3 PC: 2.3 ICS: 3.4
4.Methods of assessment	1. Formative theory exam 2. Workplace assessment by Faculty 3. Multisource feedback- Nurses, Faculty, Peers

Competency	**Pre-Entrustable**	**Entrustable**
MK 1.3	Lack of adequate **knowledge** on Pharmacovigilance program and ADR reporting. Fail to **analyze and apply** the knowledge of pharmacology in identifying ADR. Fails to **explain** the basic methodology for casualty assessment and report ADR reporting. Fails to **Train** the undergraduates and junior residents on Casualty Assessment, ADR reporting and participation in the Pharmacovigilance program	**Demonstrates** adequate knowledge on Pharmacovigilance program and ADR reporting. **Analyze and apply** the knowledge of pharmacology in identifying ADR. **Explains** the basic methodology in identifying and reporting an ADR. **Trains** the undergraduates and junior residents on Casualty Assessment, ADR reporting and participation in the Pharmacovigilance program
PC 1.3	Fail to **analyze and apply** the knowledge of pharmacology in identifying ADR.	**Analyze and apply** the knowledge of pharmacology in identifying ADR. **Follows** methodology forcasualty assessment and report ADR reporting.

	Fails to **follow** methodology for casualty assessment and report ADR reporting. Fails to **perform** causualty assessment perfectly and report ADR following the regulatory guidelines Fails to **follow** the guidelines to monitor the safety of the patient due to the side effect of the drug.	**Performs** casualty assessment perfectly and reports ADR following the regulatory guidelines **Follows** the guidelines to monitor the safety of the patient due to the side effect of the drug.
ICS 3.4	Fails to **communicate** to the patient about the side effect of the drug Fails to **communicate** to the health care team about the ADR. Fails to **actively participate** in the Pharmacovigilance program.	Effectively **communicates** to the patient about the side effect of the drug Effectively **communicates** to the health care team about the ADR. A**ctively participates** and assumes **long term leadership** in the smooth functioning of the Pharmacovigilance Program

EPA 2: Rational Use of Drugs – Essential Medicines List & 'P'drug	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the essential medicines needed for a pharmacy • List the group of drugs available to treat the given condition • Choose the right choice of drug based on efficacy, safety and cost
2. Most relevant domains of competence:	MK, PC, ICS
3. Competencies within each domain critical to entrustment decisions:	MK: 1.2 PC: 2.1, 2.2 ICS: 3.4,3.5
4.Methods of assessment	1. Formative & Summative theory exam 2. Therapeutic Problems 3. Multisource feedback – faculty, students

Competency	Pre-Entrustable	Entrustable
MK 1.2	**Lack of** adequate knowledge on the classification, mechanism of action, adverse effects, dosage, drug interactions and uses of various groups of drugs available to treat a given medical condition. Fails to **understand &explain** the concept of essential medicines list and 'P' drug and its clinical importance.	**Demonstrates** adequate knowledge on the classification, mechanism of action, adverse effects, dosage, drug interactions and uses of various groups of drugs available to treat a given medical condition. **Understands & Explains** the concept of essential medicines list and 'P' drug and its clinical importance.
PC 2.1,2.2	Fail to **analyse and apply** the knowledge in choosing the right drug for a given medical condition based on specific criteria. Fails to **follow** the guidelines to prescribe drugs rationally from the essential medicines list	**Analyses and apply** the knowledge in choosing the right drug for a given medical condition based on specific criteria. **Follows** the guidelines to prescribe drugs rationally from the essential medicines list
ICS 3.4,3.5	Fails to **Train** the undergraduates and junior residents on rational use of drugs - essential medicines list and 'P' drug concept. Fails to **actively follow** the regulations guiding rational use of drugs	**Trains** the undergraduates and junior residents on rational use of drugs - essential medicines list and 'P' drug concept. **Actively follows** the regulations guiding rational use of drugs

EPA 3: Drug Compliance – Measuring Medication Adherence	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Understand the clinical importance of drug compliance • Measuring medication adherence • Communicate effectively the importance of medication adherence to the patient
2. Most relevant domains of competence:	ICS
3. Competencies within each domain critical to entrustment decisions:	ICS: 3.3
4.Methods of assessment	1. Workplace Assessment by Faculty

Competency	Pre-Entrustable	Entrustable
MK 1.2	Fails to **understand** the clinical importance of drug compliance. Fails to **communicate** effectively the importance of medication adherence to the patient Fails to **measure** medication adherence according to Morisky Scale	**Understands** the clinical importance of drug compliance **Communicates** effectively the importance of medication adherence to the patient **Measures** medication adherence according to Morisky Scale
P 6.1	Fails to **Train** the undergraduates to measure medication adherence	**Trains** the undergraduates to measure medication adherence

EPA 4: Analysing Prescribing pattern using WHO criteria	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the available prescribing indicators • Analyse the prescribing pattern and rationality of prescriptions for a given medical condition based on WHO prescribing indicators
2. Most relevant domains of competence:	PC, ICS
3. Competencies within each domain critical to entrustment decisions:	PC: 2.2 ICS: 3.4,3.5
4.Methods of assessment	1. Problem Solving Exercises 2. Formative practical exam

Competency	Pre-Entrustable	Entrustable
PC: 2.2	**Lack of** adequate knowledge on the available prescribing indicators Fail to **analyse** the prescribing pattern and rationality of prescriptions for a given medical condition based on WHO prescribing indicators	**Demonstrates** adequate knowledge on available prescribing indicators **Analyses** the prescribing pattern and rationality of prescriptions for a given medical condition based on WHO prescribing indicators
ICS 3.4,3.5	Fails to **Train** the peer groups to **analyse** the prescribing pattern and rationality of prescriptions for a given medical condition based on WHO prescribing indicators	**Trains** the peer groups to **analyse** the prescribing pattern and rationality of prescriptions for a given medical condition based on WHO prescribing indicators

EPA 5: Identifying Drug-Drug Interactions	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Gain adequate knowledge on the drug-drug interactions • Identify the drug-drug interactions for a given medical conditions and list the ways to combat it
2. Most relevant domains of competence:	MK, PC
3. Competencies within each domain critical to entrustment decisions:	MK: 1.1 PC: 2.2
4.Methods of assessment	1. Formative & Summative practical exam – Problem Solving Exercises

Competency	**Pre-Entrustable**	**Entrustable**
MK 1.2	**Lack of** adequate knowledge on the classification, mechanism of action, adverse effects, dosage, drug interactions and uses of various groups of drugs available to treat a given medical condition. Fails to **understand &explain** the drug interactions and its clinical importance.	**Demonstrates** adequate knowledge on the classification, mechanism of action, adverse effects, dosage, drug interactions and uses of various groups of drugs available to treat a given medical condition. **Understands & Explains** the drug interactions and its clinical importance.
PC 2.1,2.2	Fail to **analyse and apply** the knowledge in identifying the drug-drug interaction for a given medical condition	**Analyses and apply** the knowledge in identifying the drug-drug interaction for a given medical condition

EPA 6: Identifying the right choice of drug based on Pharmacoeconomics	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Perform Pharmacoeconomic analysis and choose the right choice of drug for a patient with given medical condition
2. Most relevant domains of competence:	MK, PC,ICS
3. Competencies within each domain critical to entrustment decisions:	MK: 1.3 PC: 2.2 ICS: 3.4
4.Methods of assessment	1. Formative practical exam – Problem Solving Exercise

Competency	Pre-Entrustable	Entrustable
MK 1.3	**Lack of** adequate knowledge on field of Pharmacoeconomics, various methods to analyse the cost and effectiveness of a drug Fails to **understand &explain** the methods of Pharmacoeconomic analysis	**Demonstrates** adequate knowledge on field of Pharmacoeconomics, various methods to analyse the cost and effectiveness of a drug **Understands & Explains** the methods of Pharmacoeconomic analysis.
PC 2.2	Fail to **analyse and apply** the knowledge of Pharmacoeconomics in choosing the right drug for a given medical condition by various methods	**Analyses and** the knowledge of Pharmacoeconomics in choosing the right drug for a given medical condition by various methods
ICS 3.4	Fails to **Train** the undergraduates to **Analyse and apply** Pharmacoeconomics in choosing the right drug for a given medical condition by various methods	**Trains** the undergraduates to **analyse and apply** Pharmacoeconomics in choosing the right drug for a given medical condition by various methods

EPA 7: Evaluating Drug Promotional Literature	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the essential medicines needed for a pharmacy • List the group of drugs available to treat the given condition • Choose the right choice of drug based on efficacy, safety and cost
2. Most relevant domains of competence:	MK, PBL
3. Competencies within each domain critical to entrustment decisions:	MK: 1.1 PBL: 5.5
4.Methods of assessment	1. Formative Practical exam – Problem Solving Exercise

Competency	Pre-Entrustable	Entrustable
MK 1.2	**Lack of** adequate knowledge on the classification, mechanism of action, adverse effects, dosage, drug interactions and uses of various groups of drugs available to treat a given medical condition. Fails to **understand** the need to evaluate drug promotional literature and its importance.	**Demonstrates** adequate knowledge on the classification, mechanism of action, adverse effects, dosage, drug interactions and uses of various groups of drugs available to treat a given medical condition. **Understands** the need to evaluate drug promotional literature and its importance.
PBL 5.5	Fails to **follow** the methodology to evaluate a given drug promotional literature Fails to **Train** the undergraduates to evaluate a given drug promotional literature	**Follows** the methodology to evaluate a given drug promotional literature **Trains** the undergraduates to evaluate a given drug promotional literature

EPA 8: Evaluating the Teaching–Learning Methodologies in Pharmacology	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the merits and demerits of various teaching learning methods in Pharmacology • Analyse the merits and demerits of various teaching learning methods and choose the right method for a given topic • Gain adequate knowledge about computer assisted learning (CAL) softwares and able to use them efficiently to promote learning of pharmacology
2. Most relevant domains of competence:	PBL, P
3. Competencies within each domain critical to entrustment decisions:	PBL: 3.3, 3.4 P: 6.5
4.Methods of assessment	1. Formative & Summative Practical exam 2. Workplace assessment by Faculty 3. Multisource feedback – Faculty, students

Competency	Pre-Entrustable	Entrustable
PBL: 3.3, 3.4	**Lack of** adequate knowledge on the various teaching learning methods in Pharmacology and their merits and demerits. Fails to **analyse& identify**the right teaching learning method for a given topic **Lack of** adequate knowledge about computer assisted learning (CAL) softwares **Unable** to use CAL efficiently to promote learning of pharmacology	**Demonstrates** adequate knowledge on the various teaching learning methods in Pharmacology and their merits and demerits. **Analyses& identifies**the right teaching learning method for a given topic **Demonstrates** adequate knowledge about computer assisted learning (CAL) softwares **Able**to use them CAL efficiently to promote learning of pharmacology
P 6.5	Fails to **actively follow** the right teaching learning method for a given topic and situation	**Actively follows** the right teaching learning method for a given topic and situation

EPA 9: Performing Bioassay of drugs	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the things required for performing bioassay of drugs • Set up an equipment and validate for performing a bioassay • Handle animals, euthanize them, isolate and mount the tissue • Perform a bioassay
2. Most relevant domains of competence:	MK, SBP,P
3. Competencies within each domain critical to entrustment decisions:	MK: 1.4 SBP: 4.2, 4.4 P: 5.1
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty 3. Multisource feedback – faculty, technician, peer group

Competency	Pre-Entrustable	Entrustable
MK 1.4	**Lack of** knowledge on the commonly used instruments used in bioassay **Lack of** knowledge on the bioassay methods Fails to **understand** the functions of each instrument used in bioassay	**Demonstrates** knowledge on the commonly used instruments used in bioassay **Demonstrates** knowledge on the bioassay methods **Understands** the functions of each instrument used in bioassay

SBP 4.2	Fails to **follow** the guidelines for preparation for setting up the equipment **Unable** to handleanimals and euthanize according to the guidelines Fails to **isolate** and mount the tissue **Unable** toset up and validate the equipment for bioassay Fails to **perform** a bioassay according to specific methodology	Fails to **follow** the guidelines for preparation for setting up the equipment **Able** tohandleanimals and euthanize according to the guidelines Fails to **isolate** and mount the tissue **Able** toset upand validate the equipment for bioassay Fails to **perform** a bioassay according to specific methodology
P 6.1	Fails to **assist** fellow peers in performing a bioassay	**Assist** fellow peers in performing a bioassay

EPA 10: Performing Herbal Extraction Procedures	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the things required for performing herbal extraction procedures • Set up the equipment and validate for performing extraction procedures • Perform extraction procedures
2. Most relevant domains of competence:	PBL,P
3. Competencies within each domain critical to entrustment decisions:	PBL: 4.1, 4.2 P: 5.1
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty 3. Multisource feedback – faculty, technician, peer group

Competency	**Pre-Entrustable**	**Entrustable**
PBL: 4.1, 4.2	**Lack of** knowledge on the commonly used instruments in herbal extraction procedures **Lack of** knowledge on the herbal extraction methods Fails to **follow** the guidelines for preparation & setting up the equipment Fails to **perform** herbal extraction procedures according to specific methodology	**Demonstrates** knowledge on the commonly used instruments in herbal extraction procedures **Demonstrates** knowledge in herbal extraction procedures **Follows** the guidelines for preparation for setting up the equipment **Performs** herbal extraction procedures according to specific methodology
P 6.1	Fails to **assist** fellow peers in performing herbal extraction procedures	**Assist** fellow peers in performing herbal extraction procedures

EPA 11: Performing in-vivo animal experiments	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • List the things required for performing in-vivo animal experiments • Set up an equipment and validate for performing in-vivo animal experiments • Handling animals • Perform in-vivo animal experiments
2. Most relevant domains of competence:	MK, SBP,P
3. Competencies within each domain critical to entrustment decisions:	MK: 1.4 SBP: 4.2, 4.4 P: 6.1
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty 3. Multisource feedback – faculty, technician, peer group

Competency	**Pre-Entrustable**	**Entrustable**
MK 1.4	**Lack of** knowledge on the commonly used instruments for in-vivo animal experiments **Lack of** knowledge on the methodology for performing in-vivo animal experiments Fails to **understand** the functions of each instrument used in in-vivo animal experiments	**Demonstrates** knowledge on the commonly used instruments for in-vivo animal experiments **Demonstrates** knowledge on the methodology for performing in-vivo animal experiments **Understands** the functions of each instrument used in in-vivo animal experiments
SBP 4.2	Fails to **follow** the methodology for performing in-vivo animal experiments **Unable** tohandleanimals according to the guidelines **Unable** toset upand validate the equipment for in-vivo animal experiments Fails to **perform** in-vivo animal experiments according to specific methodology	**Follows** the methodology for performing in-vivo animal experiments **Able** tohandleanimals according to the guidelines **Able** toset upand validate the equipment for in-vivo animal experiments P**erforms** an in-vivo animal experiments according to specific methodology
P 6.1	Fails to **assist** fellow peers in performing an in-vivo animal experiments	**Assists** fellow peers in performing an in-vivo animal experiments

EPA 12: Understanding Basics of Research Methodology & Performing a Clinical or Experimental research	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Acquire knowledge on basics of research methodology for performing clinical and experimental research • Acquire knowledge of guidelines for performing clinical and experimental research • Analyses and applies the knowledge in performing clinical and experimental research • Assist others in performing clinical and experimental research
2. Most relevant domains of competence:	SBP, PBL, P
3. Competencies within each domain critical to entrustment decisions:	SBP: 4.1, 4.2, 4.4 PBL: 5.1 P: 6.1, 6.6
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty

Competency	**Pre-Entrustable**	**Entrustable**
SBP: 4.1, 4.2, 4.4	**Lack of** knowledge of guidelines for performing clinical and experimental research **Lack of** knowledge on the basics of research methodology for performing clinical and experimental research Fails to **Analyses and apply** the knowledge in performing clinical and experimental research	**Demonstrates** knowledge of guidelines for performing clinical and experimental research **Demonstrates** knowledge on the basics of research methodology for performing clinical and experimental research **Understands** the knowledge in performing clinical and experimental research
PBL 5.1	Fails to **follow** the specific guidelines for performing clinical and experimental research Fails to **Analyses and apply**the knowledge on the basics of research methodology for performing clinical and experimental research Fails to **perform** clinical and experimental research according to specific methodology	**Follows** the methodology for performing in-vivo animal experiments **Able** to handle animals according to the guidelines P**erforms** clinical and experimental research according to specific methodology
P 6.1	Fails to **assist** fellow peers in applying basics of research methodology for performing clinical and experimental research	**Assists** fellow peers in applying basics of research methodology for performing clinical and experimental research

EPA 13: Obtaining Informed Consent for participation in the clinical trial	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Acquire knowledge on ethical guidelines for performing clinical research • Analyze and apply the ethical guidelines for the individual study participant while performing clinical research • Obtain informed consent from patient for participation in clinical trial • Assist others in Obtaining informed consent from patient for participation in clinical trial following the guidelines • Assist others in implementing the ethical guidelines while performing clinical research
2. Most relevant domains of competence:	ICS, SBP, P
3. Competencies within each domain critical to entrustment decisions:	ICS: 3.2 SBP: 4.4, 4.5 P: 6.4
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty 3. Multisource feedback – faculty, peers

Competency	**Pre-Entrustable**	**Entrustable**
ICS 3.2	Fail to d**emonstrate** compassion, integrity and respect for patient Fail to **communicate** effectively about the risk involved in participation of the study Fail to **communicate** effectively to the patient about the study procedure Fail to **answer** effectively the questions raised by the patient and ensure them the voluntariness for participation and withdrawal from the study.	D**emonstrates** compassion, integrity and respect for patient **Communicates** effectively about the risk involved in participation of the study C**ommunicates** effectively to the patient about the study procedure A**nswers** effectively the questions raised by the patient and ensure them the voluntariness for participation and withdrawal from the study.

SBP: 4.4, 4.5	**Lack of** knowledge on the ethical guidelines for performing clinical research **Lack of** knowledge on the ethical guidelines for obtaining informed consent Fails to **Analyse and apply** the knowledge for the individual study participant while performing clinical research Fails to **follow** the specific guidelines to obtain informed consent from patient for participation in clinical trial	**Demonstrates** knowledge on the ethical guidelines for performing clinical research **Demonstrates** knowledge on the ethical guidelines for obtaining informed consent **Analyses and applies** the knowledge for the individual study participant while performing clinical research **Follows** the specific guidelines to obtain informed consent from patient for participation in clinical trial
P 6.4	Fail to a**ccept** constructive feedback to improve his or her ability to demonstrate compassion, integrity, and respect for others.	**Accepts** constructive feedback to improve his or her ability to demonstrate compassion, integrity, and respect for others

EPA 14: Applying basic concepts of Biostatistics in Performing Clinical or Experimental research	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Acquire knowledge on basics concepts of biostatistics for performing clinical and experimental research • Analyses and applies the basics concepts of biostatistics for performing clinical and experimental research • Assist others in applying the basics concepts of biostatistics in performing clinical and experimental research
2. Most relevant domains of competence:	SBP, PBL, P
3. Competencies within each domain critical to entrustment decisions:	SBP: 4.2 PBL: 5.1 P: 6.1
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty

Competency	**Pre-Entrustable**	**Entrustable**
SBP: 4.2	**Lack of** knowledge on basics concepts of biostatistics for performing clinical and experimental research Fails to **Understand** the importance of biostatistics in performing clinical and experimental research	**Demonstrates** knowledge on basics concepts of biostatistics for performing clinical and experimental research **Understands** the importance of biostatistics in performing clinical and experimental research

PBL 5.1	Fails to **Analyses and apply** the knowledge of basics concepts of biostatistics in performing clinical and experimental research Fails to **perform** basic biostatisticsinclinical and experimental research Using computer software	**Analyses and apply** the knowledge of basics concepts of biostatistics in performing clinical and experimental research P**erforms** basic biostatistics in clinical and experimental research Using computer software
P 6.1	Fails to **assist** fellow peers in applying basics of biostatistics for performing clinical and experimental research	**Assists** fellow peers in applying basics of biostatistics for performing clinical and experimental research

EPA 15: Design a Protocol for a Clinical or Experimental study	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Analyses and apply the knowledge of research methodology, ethics and biostatistics in performing clinical or experimental study • Design a protocol for a Clinical or Experimental study • Assist others in performing clinical and experimental research
2. Most relevant domains of competence:	SBP, PBL, P
3. Competencies within each domain critical to entrustment decisions:	SBP: 4.1, 4.2, 4.3, 4.4 PBL: 5.1 P: 6.1
4.Methods of assessment	1. Formative & Summative practical exam 2. Workplace assessment by faculty

Competency	**Pre-Entrustable**	**Entrustable**
SBP: 4.1, 4.2, 4.4	**Lack of** knowledge of basics of research methodology, ethical guidelines and basic biostatistics for design a protocol for clinical or experimental study	**Demonstrates** knowledge of basics of research methodology, ethical guidelines and basic biostatistics for design a protocol for clinical or experimental study

PBL 5.1	Fails to **follow** the specific guidelines to design a protocol for clinical or experimental study Fails to **Analyses and apply**the knowledge of basics of research methodology, ethical guidelines and basic biostatistics for design a protocol for clinical or experimental study Fails to **design** a protocol forclinical or experimental study	**Follows** the specific guidelines to design a protocol for clinical or experimental study **Analyses and apply**the knowledge of basics of research methodology, ethical guidelines and basic biostatistics for design a protocol for clinical or experimental study Designsa protocol forclinical or experimental study
P 6.1	Fails to **assist** fellow peers to **design** a protocol forclinical or experimental study	**Assists** fellow peers to **design** a protocol forclinical or experimental study

EPA 16: Criticise a journal article	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Analyses and apply the knowledge of research methodology, ethics and biostatistics to criticise a journal article according to specific guidelines • Assist others to criticise a journal article according to specific guidelines
2. Most relevant domains of competence:	SBP, PBL, P
3. Competencies within each domain critical to entrustment decisions:	SBP: 4.1, 4.2, 4.3, 4.4 PBL: 5.1 P: 6.1
4.Methods of assessment	1. Formative & Summative practical exam

Competency	**Pre-Entrustable**	**Entrustable**
SBP: 4.1, 4.2, 4.4	**Lack of** knowledge of basics of research methodology, ethical guidelines and basic biostatistics to criticise a journal article according to specific guidelines	**Demonstrates** knowledge of basics of research methodology, ethical guidelines and basic biostatistics to criticise a journal article according to specific guidelines
PBL 5.1	Fails to **follow** the specific guidelines to criticise a journal article according to specific guidelines Fails to **Analyses and apply**the knowledge of basics of research methodology, ethical guidelines and basic biostatistics to criticise a journal article according to specific guidelines	**Follows** the specific guidelines to criticise a journal article according to specific guidelines **Analyses and apply**the knowledge of basics of research methodology, ethical guidelines and basic biostatistics to criticise a journal article according to specific guidelines

P 6.1	Fails to **assist** fellow peers tocriticise a journal article according to specific guidelines	**Assists** fellow peers to criticise a journal article according to specific guidelines

EPA 17: Writing a manuscript for publication	
1. Description of the activity: This included a brief rationale and a list of the functions required for the EPA.	At the end of 3 year program, Residents should be able to • Analyses and apply the knowledge of research methodology, ethics and biostatistics to write a manuscript for publication • Assist others to write a manuscript for publication
2. Most relevant domains of competence:	SBP, PBL, P
3. Competencies within each domain critical to entrustment decisions:	SBP: 4.1, 4.2, 4.4 PBL: 5.1 P: 6.1,6.5, 6.6
4.Methods of assessment	1. Workplace assessment by faculty

Competency	**Pre-Entrustable**	**Entrustable**
SBP: 4.1, 4.2, 4.4	**Lack of** knowledge of basics of research methodology, ethical guidelines and basic biostatistics towrite a manuscript for publication according to specific guidelines	**Demonstrates** knowledge of basics ofresearch methodology, ethical guidelines and basic biostatistics to write a manuscript for publication according to specific guidelines
PBL 5.1	Fails to **follow** the specific guidelinesto write a manuscript for publication according to specific guidelines Fails to **Analyses and apply**the knowledge of basics of research methodology, ethical guidelines and basic biostatistics to write a manuscript for publication accordingto specific guidelines	**Follows** the specific guidelines to write a manuscript for publication according to specific guidelines **Analyses and apply**the knowledge ofbasics of research methodology, ethical guidelines and basic biostatistics to write a manuscript for publication according to specific guidelines
P: 6.1,6.5, 6.6	Fails to **assist** fellow peers to write amanuscript for publication according to specific guidelines	**Assists** fellow peers to write a manuscript for publication according to specific guidelines

Table 5.Mapping of PO, CO, EPA, Competency and Sub-competency with level

EPA		Program outcomes								Domains and levels of competency
1	ADR reporting and participating in National Pharmacovigilance Program	1	2	3	4		6			MK: 1.3 PC: 2.3 ICS: 3.4
2	Rational Use of Drugs – Essential Medicines List & 'P'drug	1	2		4		6			MK: 1.2 PC: 2.1, 2.2 ICS: 3.4,3.5
3	Drug Compliance – Measuring Medication Adherence	1	2		4		6			ICS: 3.3
4	Analysing Prescribing pattern using WHO criteria	1	2		4		6			PC: 2.2 ICS: 3.4,3.5
5	Identifying Drug-Drug Interactions	1	2		4		6			MK: 1.1 PC: 2.2
6	Identifying the right choice of drug based on Pharmacoeconomics	1	2		4		6			MK: 1.3 PC: 2.2 ICS: 3.4
7	Evaluating Drug Promotional Literature	1	2		4		6			MK: 1.1 PBL: 5.5
8	Analysing the Teaching – Learning Methodologies in Pharmacology	1	2		4			7		PBL: 3.3, 3.4 P: 6.5
9	Performing Bioassay of drugs				4	5		7		MK: 1.4 SBP: 4.2, 4.4 P: 5.1
10	Performing Herbal Extraction Procedures				4	5		7		PBL: 4.1, 4.2 P: 5.1
11	Performing In vivo small animal experiments				4	5		7		MK: 1.4 SBP: 4.2, 4.4 P: 6.1
12	Understanding Basics of Research Methodology & Performing a Clinical or Experimental research				4			7	8	SBP: 4.1, 4.2, 4.4 PBL: 5.1 P: 6.1, 6.6
13	Obtaining Informed Consent for participation in the clinical trial				4			7	8	ICS: 3.2 SBP: 4.4, 4.5 P: 6.4
14	Applying basic concepts of Biostatistics in Performing Clinical or Experimental research				4			7	8	SBP: 4.2 PBL: 5.1 P: 6.1
15	Design a Protocol for a Clinical or Experimental study				4			7	8	SBP: 4.1, 4.2, 4.3,4.4 PBL: 5.1 P: 6.1
16	Criticise a Journal Article				4			7	8	SBP: 4.1, 4.2, 4.3, 4.4 PBL: 5.1 P: 6.1
17	Writing a manuscript for publication				4			7	8	SBP: 4.1, 4.2, 4.4 PBL: 5.1 P: 6.1,6.5, 6.6

- The Internal Assessment should be conducted in theory and clinical examination every 6 months
- Quarterly assessment during the MD training should be based on following educational activities:

    1. Journal based / recent advances learning
    2. Patient based /Laboratory or Skill based learning
    3. Self directed learning and teaching
    4. Departmental and interdepartmental learning activity
    5. External and Outreach Activities / CMEs

  The student to be assessed periodically as per categories listed in postgraduate student appraisalform **(Annexure-2).**

Summative assessment:

Eligibility for appearing in the final university exam

- Attendance : 75 % in each year
- One poster presentation in International/National/ State level conference.
- One oral presentation International/National/ State level conference.
- Submission of one scientific paper for publication to an indexed journal

Postgraduate Examination shall be in three parts:

1. Thesis

Every post graduate student shall carry out work on an assigned research project under the guidanceof a recognised Post Graduate Teacher, the result of which shall be written up and submitted in theform of a Thesis. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the post graduate student to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least six months before the Theory and Practical examination and will be evaluated by two external members. A post graduate student shall be allowed to appear for the Theory and Practical examination only after the acceptance of the Thesis by the external members.

2. Theory Examination:

There should be four theory papers, as given below:

- **Paper I:** General Pharmacology
- **Paper II:** Clinical & Experimental Pharmacology
- **Paper III:** Systemic Pharmacology
- **Paper IV:** Recent Advances in Pharmacology

Each theory paper will be of 100 marks i.e. 4 papers – 100 marks each (Total 400). Each paper will have10 short essay answer questions of 10 marks each.

3. Practical and viva voce examination

a) Long Experiment:

- Demonstrating effects of drugs/interpretation of results in anesthetized animal
- Table exercise - Examples are given below:
- Calculating pharmacokinetic parameters
- Statistical exercise
- Critical appraisal of a published paper
- Evaluation of drug literature.
- Protocol designing
- ADR reporting and causality assessment
- Assessment of preclinical toxicity data
- Analysis of rational and irrational formulations

b) Short experiment

- Isolated tissue experiment (Bioassay of drugs) (as per Govt regulations) Orinterpretation of results of a previous tracing
- *In vivo* experiment
- Spotting exercises: Various drug delivery systems, inhalers, insulin syringe,
- drip chamber, various tablets, etc.

Oral/Viva voce Examination

- Microteaching (teaching exercise)
- Discussion on dissertation
- Principles of general and systemic pharmacology
- Recent advances in pharmacology & drug therapy

Pass criteria: The examination MS shall be held at the end of 3rd academic year. There will be four evaluations for each theory paper. The examinations shall be organised on the basis of 'Marking system' to evaluate and to certify post graduate student's level of knowledge, skill and competence at the end of the training. Obtaining a minimum of 50% marks in 'Theory' as well as 'Practical' separately shall be mandatory for passing examination as a whole. Student must secure minimum of 40% in each paper and in aggregate 50% overall as far as theory is concerned.

9. Blue Print and Weight of the System

Each paper shall contain the structure as follows:
Ten Long answer question (LAQ) for 10 marks each. (10 x 10 = 100)

Paper I: General Pharmacology

Sl. No	Section	Topics	Weightage	Marks Allotted	No. of Question
1	General Pharmacology	Various routes of drug administration & drug delivery systems	**10%**	**10**	**1**
2	General Pharmacology	Drug receptors and Pharmacodynamics	**10%**	**10**	**1**
3	General Pharmacology	Pharmacokinetics (Absorption, Distribution, Metabolism and Excretion)	**10%**	**10**	**1**
4	General Pharmacology	Factors modifying drug action	**10%**	**10**	**1**
5	General Pharmacology	Dose Response Relationship	**10%**	**10**	**1**
6	General Pharmacology	Adverse drug reactions	**10%**	**10**	**1**
7	General Pharmacological Principles	General Pharmacological Principles ofspecial population groups	**10%**	**10**	**1**
8	Rational Therapeutics	Rational Use of Drugs	**10%**	**10**	**1**
9	New Drug Development	New Drug Development	**10%**	**10**	**1**
10	Fields of Pharmacology	Various branches of Pharmacology and their applications	**10%**	**10**	**1**

Paper II: Clinical & Experimental Pharmacology

Sl. No.	Section	Topics	Weightage	Marks Allotted	No. of Questions
1	Clinical Pharmacology	Guidelines pertaining to conducting human research	10%	10	1
2	Clinical Pharmacology	Evidence based Medicine	10%	10	1
3	Ethics	Ethics in animal and human research	10%	10	1
4	Research Methodology	Basics of Research Methodology pertaining to animal and human research	10%	10	1
5	Biostatistics	Basics of Biostatistics pertaining to animal and human research	10%	10	1
6	Instrumentation	Principles of instruments in human and animal pharmacology	10%	10	1
7	Experimental Pharmacology	Screening methods for evaluation of drugs	10%	10	1
8	Experimental Pharmacology	Guidelines pertaining to conducting animal research	10%	10	1
9	Experimental Pharmacology	Laboratory animal care Bioassay, Euthanasia, Blood collection, In-vivo animal experiments	10%	10	1
10	Experimental Pharmacology	Alternatives to animal experimentation	10%	10	1

Paper III: Systemic Pharmacology

Sl. No.	Section	TOPICS	Weightage	Marks allotted	No. of Questions
1	Autonomic & PeripheralNervous system	Classification, Mechanisim of action, adverse effects and uses of Drugs acting on Autonomic & Peripheral Nervous system	10%	10	1
2	Autacoids	Antihistamines, 5HT agonist & antagonists,	10%	10	1
3	Respiratory system	Antiasthmatics drugs for cough, COPD	10%	10	1
4	Cardiovascular system including diuretics	antianginals, antihypertensives, diuretics, antiarrhythmics, antidiuretics, drugs for CCF	10%	10	1
5	Hematopoietic system	iron, folic acid, coagulants, anticoagulants, fibrinolytics, antifibrinolytics, antiplatelets, hypolipidemics, plasma expanders	10%	10	1
6	Gastrointestinal system	Antiulcer drugs, drugs for vomiting, diahorrea, constipation, indigestion, inflammatory bowel disease	10%	10	1
7	Hormones	Drugs acting on pituitary, thyroid, bone, sex hormones. Antidiabetics, steroids	10%	10	1
8	Central Nervous system	Classification, Mechanisim of action, adverse effects and uses of Drugs acting on CNS	10%	10	1
9	Antimicrobials & Cancerchemotherapy	Antibiotics, drugs for TB, Leprosy, fungal infections,viral infections, protozoalinfections, parasitic infections, cancer	10%	10	1
10	Miscellaneous	Immunomodulators, vaccines, chelating agents, vitamins,drugs for skin disorders	10%	10	1

Paper IV: Recent advances in Pharmacology

Sl. No.	Section	Topics	Weightage	Marks Allotted	No. of Questions
1	History	Important scientific contributions by scientists	10%	10	1
2	Drug Update	FDA approved newer drugs, Banned drugs	10%	10	1
3	Newer Developments inPharmacology	Stem Cell therapy, Monoclonal Antibodies, Genetherapy, JAK STAT Kinase receptors, inhalational insulin delivery etc	10%	10	1
4	Respiratory system	Recent advances in treatmentof respiratory disorders	10%	10	1
5	Cardiovascular system including diuretics	Recent advances in treatment of cardiovascular & blooddisorders	10%	10	1
6	Gastrointestinal system	Recent advances in treatment of gastrointestinal disorders	10%	10	1
7	Hormones	Recent advances in treatment of hormonal disorders	10%	10	1
8	Central Nervous system	Recent advances in treatment of nervous disorders	10%	10	1
9	Antimicrobials & Cancerchemotherapy	Recent advances in treatmentof microbial infections and cancer chemotherapy	10%	10	1
10	Miscellaneous	Recent advances in treatmentof eye, skin disorders, rheumatoid arthritis, gout, migraine.	10%	10	1

10. Model Question Paper

SRI BALAJI VIDYPAEETH

PILLAIYARKUPPAM, PUDUCHERRY-607402

P.G DEGREE EXAMINATION

M.D. - PHARMACOLOGY

Paper I: General Pharmacology

3 Hours **(10 x 10 = 100 marks)**

ANSWER ALL QUESTIONS

(Draw labelled diagram wherever required)

1. Describe the role of liposomes in drug therapy
2. Describe the role of G-protein coupled receptors in drug therapy.
3. Explain Clinical Significance of drug-protein binding with examples
4. Explain genetics as a factor modifying drug action
5. Explain drug antagonism with examples.
6. Discuss the Pharmacovigilance Programme of India
7. Describe pharmacological implications of drug use in pregnant patients.
8. Discuss the Pros and Cons of Essential Medicines Concept
9. Describe Phase '0' Clinical trial.
10. Describe Chronopharmacology and their therapeutic application.

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P.G DEGREE EXAMINATION

M.D. - PHARMACOLOGY

Paper II: Clinical and Experimental Pharmacology

3 Hours **(10X10=100 marks)**

(Draw labelled diagram wherever required)

ANSWER ALL QUESTIONS

1. Discuss the current regulatory requirements for conducting clinical trials in India.
2. Describe the CPCSEA guidelines for animal housing.
3. Describe Informed Consent in biomedical research.
4. Design a protocol to evaluate an antihypertensive in Phase III clinical trial.
5. Describe the tests of statistical significance in research.
6. Describe the principles and application of HPLC.
7. Discuss the methods used to screen a compound with analgesic activity.
8. Discuss the various methods of bioassay and explain how to perform bioassay of histamine inguinea pig ileum
9. Describe blood collection techniques in small animals
10. Describe 'Rs' in preclinical research.

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P.G DEGREE EXAMINATION

M.D. - PHARMACOLOGY

Paper III: Systemic Pharmacology

3 Hours **(10X10=100 marks)**

ANSWER ALL QUESTIONS

(Draw labelled diagram wherever required)

1. Illustrate with suitable diagrams the steps involved in cholinergic and adrenergicneurotransmission
2. Describe the role of Biological response modifiers in rheumatoid arthritis management.
3. Describe the drugs acting on Phosphodiesterase enzyme and comment on their therapeuticapplication
4. Explain the pathophysiology of heart failure and how drugs can modify it.
5. Compare and contrast Conventional and Low molecular Weight Heparin.
6. Discuss the regulation of gastric secretion and how drugs act on it
7. Describe the therapeutic uses of steroids in non endocrinological disorders and their rationalebehind their use
8. Describe the GABA modulators in treatment of epilepsy
9. Describe the molecular targets for treatment of HIV virus infection
10. Explain the role of Immunomodulators in treatment of various diseases

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P.G DEGREE EXAMINATION

M.D. – PHARMACOLOGY

Paper IV : Recent advance in Pharmacology

3 Hours **(10X10=100 marks)**

ANSWER ALL QUESTIONS

(Draw labelled diagram wherever required)

1. Summarise the contributions of Dale to Pharmacology
2. Explain the mechanism of action, adverse effects and uses of Bedaquiline.
3. Discuss the application of nanotechnology in the treatment of various disorders
4. Describe the newer molecular targets in the treatment of COPD
5. Highlight the salient features of JNC VIII report in treatment of hypertension
6. Discuss the newer targets in the management of inflammatory bowel disease
7. Discuss the recent advances in the management of diabetes mellitus
8. Discuss the role of cannabinoid receptors in therapeutics
9. Describe the newer treatment schedule of RNTCP for Tuberculosis.
10. Describe the current status of use of botulinum toxin in therapeutics

11. Recommended Reading

A: Books (Latest editions of the following books are recommended)

1. Good Mann &Gillman'sThe Pharmacological Basis of Therapeutics
2. Basic and Clinical Pharmacology by Katzung
3. Rang & Dale's Pharmacology
4. Clinical Pharmacology by Morris.J. Brown
5. Oxford Handbook of Practical Drug Therapy – Richards & Jeffrey
6. Principles of Pharmacology by David E Golan
7. Essentials of Medical Pharmacology by K.D.Tripathi
8. Principles of Pharmacology by Sharma & Sharma
9. Lippincott Illustrated Reviews: Pharmacology by Karen Whalen
10. Drug Discovery & Evaluation: Methods in Clinical Pharmacology by Gerhard Vogel
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi
12. Fundamentals of Experimental Pharmacology by M.N.Ghosh
13. Drug Screening Methods by S.K.Gupta
14. Research Methodology: Methodology: Methods & Techniques.
15. Mahajan's Methods in Biostatistics for Medical Students & Research Workers

B: Journals

1. Indian Journal of Pharmacology
2. Indian Journal of Physiology and Pharmacology
3. Journal of Pharmacology and Pharmacotherapeutics
4. Fundamental and clinical pharmacology
5. European Journal of Clinical Pharmacology
6. Journal of Ethnopharmacology
7. British Journal of Pharmacology
8. The Lancet

Annexure-1: Entrustable Professional Activities Assessment

Sri Balaji Vidyapeeth

Department Of Pharmacology

Entrustable Professional Activities Assessment Form for MD Residents

Name of the Resident: …… UIN No:…….

Levels of competence:

- **Level I:** Knowledge only; can observe
- **Level II:** Can perform under direct supervision by Faculty
- **Level III**: Can perform under indirect supervision by Faculty
- **Level IV:** Can do independently
- **Level V:** Has expertise to teach others

First Year of the Residency

S.No	EPAs	1st quarter		2nd quarter		3rd quarter		4th quarter	
		Resident	**Faculty**	**Resident**	**Faculty**	**Resident**	**Faculty**	**Resident**	**Faculty**
1	ADR reporting and participating in National Pharmacovigilance Program								
2	Rational Use of Drugs – Essential MedicinesList & 'P'drug								
3	Drug Compliance – Measuring Medication Adherence								
4	Analysing Prescribing pattern using WHOcriteria								
5	Identifying Drug-Drug Interactions								
6	Identifying the right choice of drug basedon Pharmacoeconomics								
7	Evaluating Drug Promotional Literature								
8	Analysing the Teaching – LearningMethodologies in Pharmacology								

9	Performing Bioassay of drugs								
10	Performing Herbal Extraction Procedures								
11	Performing In vivo small animal experiments								
12	Understanding Basicsof Research Methodology & Performing a Clinical or Experimental research								
13	Obtaining Informed Consent for participation in the clinical trial								
14	Applying basic concepts of Biostatistics in Performing Clinical or Experimental research								
15	Design a Protocol for a Clinical or Experimental study								
16	Criticise a Journal Article								
17	Writing a manuscript for publication								

Second year of the residency

S.No	EPAs	1st quarter		2nd quarter		3rd quarter		4th quarter	
		Resident	**Faculty**	**Resident**	**Faculty**	**Resident**	**Faculty**	**Resident**	**Faculty**
1	ADR reporting and participating in National Pharmacovigilance Program								
2	Rational Use of Drugs – Essential MedicinesList & ‘P’drug								
3	Drug Compliance – Measuring Medication Adherence								
4	Analysing Prescribing pattern using WHOcriteria								
5	Identifying Drug-Drug Interactions								
6	Identifying the right choice of drug basedon Pharmacoeconomics								
7	Evaluating Drug Promotional Literature								
8	Analysing the Teaching – LearningMethodologies in Pharmacology								

9	Performing Bioassay of drugs								
10	Performing Herbal Extraction Procedures								
11	Performing In vivosmall animal experiments								
12	Understanding Basicsof Research Methodology & Performing a Clinical or Experimental research								
13	Obtaining Informed Consent for participation in the clinical trial								
14	Applying basic concepts of Biostatistics in Performing Clinical or Experimental research								
15	Design a Protocol for a Clinical or Experimental study								
16	Criticise a Journal Article								
17	Writing a manuscript for publication								

Third year of the residency

S.No	EPAs	1st quarter		2nd quarter		3rd quarter	
		Resident	Faculty	Resident	Faculty	Resident	Faculty
1	ADR reporting and participating in National Pharmacovigilance Program						
2	Rational Use of Drugs – Essential Medicines List & 'P'drug						
3	Drug Compliance – MeasuringMedication Adherence						
4	Analysing Prescribing pattern usingWHO criteria						
5	Identifying Drug-Drug Interactions						
6	Identifying the right choice of drug based on Pharmacoeconomics						
7	Evaluating Drug Promotional Literature						
8	Analysing the Teaching – Learning Methodologies in Pharmacology						
9	Performing Bioassay of drugs						
10	Performing Herbal Extraction Procedures						
11	Performing In vivo small animal experiments						
12	Understanding Basics of Research Methodology & Performing a Clinical or Experimental research						

13	Obtaining Informed Consent for participation in the clinical trial						
14	Applying basic concepts of Biostatisticsin Performing Clinical or Experimental research						
15	Design a Protocol for a Clinical or Experimental study						
16	Criticise a Journal Article						
17	Writing a manuscript for publication						

Annexure 2: Postgraduate Students Appraisal Form

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607402

Mahatma Gandhi Medical College and Research Institute

Department of Pharmacology

Postgraduate Students Appraisal Form

Name of the PG Student: ..... **UNI No:** .....

Period of Training FROM .....TO.....

Sr. No.	Particulars	Not Satisfactory	- Satisfactory	More Than Satisfactory	Remarks
		1 2 3	- 4 5 6	7 8 9	
1.	Journal based / recentadvances learning		-		-
2.	Patient based /Laboratory or Skillbased learning				
3.	Self directed learningand teaching		–		
4.	Departmental and interdepartmental learning activity				
5.	External and Outreach Activities /CMEs		-		-
6.	Thesis / Research work		-		-
7.	E-portfolio Maintenance				

PublicationsYes/ No
Remarks* _____

_____

***REMARKS: Any significant positive or negative attributes of a postgraduate student to be mentioned. For score less than 4 in any category, remediation must be suggested. Individual feedback to postgraduate student is strongly recommended.**

SIGNATURE OF ASSESSE **SIGNATURE OF HOD**

Annexure 3: Multisource feedback

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607402

Department of Pharmacology

Multisource feedback (To be completed by Faculty)

Name of the Resident:…… UIN No.:……

Name of the Faculty: …… Date:……

Sl. No.	Criteria to be assessed	Score		
		Below par (1)	At par (2)	Above par (3)
1.	Teaching Methodology			
2.	Practical Skills			
3.	ADR reporting			
4.	Communication skills			
5.	Methodological skills			
6.	Self directed learning			
7.	Professionalism			
8.	Proper and complete documentation			
9.	Relationship with peers			
10.	Works constructively in the health care system			
		Total score:		
	General Comments:			
	Highlights in performance (strengths)			
	Possible suggested areas for improvement (weakness)			
	Signature:			

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607402

(To be completed by Nurse / Technician / Other Health Professionals)

Name of the Resident: ……. UIN No.:…….

Name of the Respondent: ……. Date: ……

Sl. No.	Criteria to be assessed	Score		
		Belowpar (1)	At par(2)	Above par (3)
1.	Shows ethics in animal care			
2.	Follows guidelines			
3.	Follows methodologies			
4.	Performs experiments with confidence			
5.	Communicates effectively with technicians			
6.	Communicates effectively with nurses in ADR reporting			
7.	Communicates effectively with other health professionals			
8.	Allows them to express their doubts or concern			
9.	Proper and complete documentation			
10.	Works constructively in the health care system			
		Total score:		
	General Comments:			
	Highlights in performance (strengths)			
	Possible suggested areas for improvement (weakness)			
		Signature:		

(To be completed by Peer)

Name of the Resident: …….. UIN No.:…….

Name of the Respondent: …… Date: ……

Sl. No.	Criteria to be assessed	Score		
		Belowpar (1)	**At par(2)**	**Above par (3)**
1.	Shows ethics in animal care			
2.	Follows guidelines			
3.	Follows methodologies			
4.	Performs experiments with confidence			
5.	Communicates effectively with technicians			
6.	Communicates effectively with nurses in ADR reporting			
7.	Communicates effectively with other health professionals			
8.	Allows them to express their doubts or concern			
9.	Proper and complete documentation			
10.	Works constructively in the health care system			
		Total score:		
	General Comments:			
	Highlights in performance (strengths)			
	Possible suggested areas for improvement (weakness)			
		Signature:		

(To be completed by Patient/Relative)

Name of the Resident: …… UIN No.:…….

Name of the Respondent: …… Date: ……..

Sl. No.	Criteria to be assessed	Score		
		Belowpar (1)	**At par (2)**	**Above par (3)**
1.	Shows a caring attitude to patients			
2.	Effectively explains importance of medication adherence, side effects of drugs			
3.	Provides proper drug information			
4.	Communicates effectively with patients			
5.	Effectively answers doubts or concern			
		Total score:		
	General Comments:			
	Highlights in performance (strengths)			
	Possible suggested areas for improvement (weakness)			
		Signature:		

Annexure 4: Work Place Based Assessment

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607 402

Department of Pharmacology

Work Place Based Assessment

Name of the Resident: ……. UIN No.: …….

Name of the Faculty : …… Date: …….

	Below Expectation	**Borderline**	**Meet Expectation**	**Above Expectation**	**Not Observed**
Teaching skill					
Experimental skill					
Methodological skill					
Communication skill					
Clinical judgement					
Professionalism					
Organisational efficiency					
Overall Performance					

Anything good:	Suggestions for improvement:
Agreed upon action:	
Signature of the resident	**Signature of the Assessor**

Annexure 5: Feedback for Journal club

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607402

Department of Pharmacology

Evaluation Sheet For Postgraduate Journal Club

(To Be Marked Individually By Each Faculty)

Name of the Resident: ……..……..…… UIN No.:…….

Name of the Faculty: ……. Date:……..
…….

S. No.	Criteria to be assessed	Score		
		Below par (1)	At par (2)	Above par (3)
1	Relevance of article chosen			
2	Identifies the problem addressed in the paper			
3	Completeness of presentation			
4	Analyses and gives comments on methodology and statistics			
5	Brief summary of results			
6	Comparison of work with other published work			
7	Merits and demerits of the paper			
8	Summary and take home message			
9	Time management			
10	Overall performance – relevant answers to questions, attitude during presentation and confidence			
		Total score:		
	General Comments:			
	Highlights in performance (strengths)			
	Possible suggested areas for improvement (weakness)			
	Signature:			

Annexure 6: Feedback for Seminar

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607 402

Department of Pharmacology

Evaluation Sheet For Postgraduate Seminar

(To be marked individually by each faculty)

Name of the Resident: ……..…… UIN No.:……

Name of the Faculty: ……..…… Date:…….

S. No.	Criteria to be assessed	Score		
		Below par (1)	At par (2)	Above par (3)
1	Introduction of subject and its importance / Objectives			
2	Completeness of presentation			
3	Coherency of presentation			
4	Consulted all relevant literature			
5	Use of audio-visual aids			
6	Understanding of subject			
7	Summary and take home message			
8	Cites appropriate references / suggests further reading			
9	Time management			
10	Overall performance – relevant answers to questions, attitude during presentation and confidence			
		Total score:		
1	General Comments:			
2	Highlights in performance (strengths)			
3	Possible suggested areas for improvement (weakness)			
	Signature:			

Annexure 7: Practical Procedural Skills Assessment

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607 402

Department of Pharmacology

Evaluation Sheet For Postgraduate Practical Work

(To be marked individually by each faculty)

Name of the Resident: …… UIN No.: ……..

Name of the Faculty: …… Date:…….

S. No.	Criteria to be assessed	Score		
		Below par (1)	At par (2)	Above par (3)
1	Animal Handling			
2	Setting up equipment			
3	Procedural skills			
4	Calculational skills			
5	Problem Solving skills			
6	Communication Skills			
7	Documentation skills			
8	Management skills			
9	Teaching skills			
10	Overall performance			
		Total score:		
	General Comments:			
	Highlights in performance (strengths)			
	Possible suggested areas for improvement (weakness)			
	Signature:			

Annexure 8: Patient Information Sheet

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607402

Department of Pharmacology

Information for Participants of the Study

Instructions – This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Tamil which can be understood by the participant.

We welcome you and thank you for having accepted our request to consider whether you can participate in our study. This sheet contains the details of the study, the possible risks, discomfort and benefits for the participants are also given. You can read and understand by yourself; if you wish, we areready to read and explain the same to you.

If you do not understand anything or if you want any more details we are ready to provide the details.

1. What is the title of the Research Project?
2. Who /where this study is being conducted?

This study is being conducted by _____ a Post graduate medical student belonging to _____Department under the guidance of _____

3. What is the purpose of the study?
4. Procedure/Methods of the study (in brief, simple terms) Note: Do not copy paste from the protocol
5. How long you are expected to participate in this study ?
6. Why I am being considered as one of the participant?

Because

7. Should I definitely have to take part in this study?

No. If you do not wish to participate you will not be included in this study. Also you will continue to getthe medical treatment without any prejudice.

8. If I am participating in this study, what are my responsibilities?

You may have follow some simple rules.These are:

9. Are there any benefits for me/Public ?

Yes _____The benefits to be expected from the research to the participant or to others and the post-

trial responsibilities of the investigator.

10. Will there be any discomfort / risks to me?

No risks. But some discomforts may be there like giving few ml of blood for investigation, undergoing some medical examinations, or any other risks expected from the study to the participant.

11. Will my participating in this study, my personal details will be kept confidentially?

Yes, confidentiality will be maintained.

12. Will I be paid for the Study?

Provision of free treatment for research related injury.

13. Can I withdraw from this study at any time during the study period?

Freedom to withdraw from the study at any time during the study period without the loss of benefits thatthe participant would otherwise be entitled.

14. Possible current and future uses of the biological material to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, for which we seek your permission prior to the study inclusion?

15. Possible current and futures uses of the data to be generated from the research and if the data is likely to be used for secondary purposes or would be shared with others, for which we seek yourpermission prior to the study inclusion?

16. Will I be informed of this study's results and the findings?

Yes, on your request for the results of the study and its findings.

17. Address and mobile number of the Principal Investigator (PI) and Co-PI, if any:

18. Address and telephone number of the IHEC office, MGMCRI and Mobile numbers of the IHECMember Secretary / Additional Member Secretary:

Signature of the Participant Signature of the Investigators

Annexure 9: Informed Consent Form

Sri Balaji Vidyapeeth

Pillaiyarkuppam, Puducherry-607 402

Department of Pharmacology

FORM FOR GETTING INFORMED CONSENT FOR THOSE PARTICIPATING IN THERESEARCH PROJECT

Title of the project:

Participant's name: Address:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent to participate in the above study. (I also consent / do not consent to use my stored biological samples for future scientific purposes: Yes/ No
– if applicable)

Signature/thumb impression of the participant: ……. Date: …….

Signature of the witness: …….. Date: …….

Name and address of the witness:

Signature of the investigator: …… Date: …….