



SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH

(A Deemed to be University Declared under Section 3 of UGC Act, 1956)

Comprising Sri DevarajUrs Medical College

[Constituent Unit of Sri DevarajUrs Educational Trust for Backward Classes (Regd.)]

TAMAKA, KOLAR-563103, KARNATAKA, INDIA

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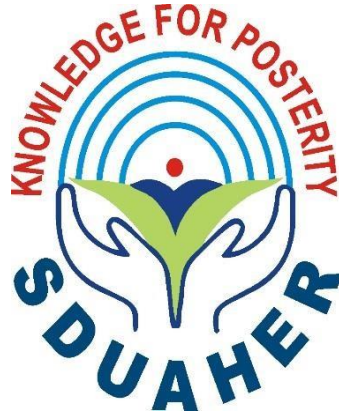
(With effect from 2019-2020 batches)

Competency Based Postgraduate Curriculum for Doctor of Medicine Pharmacology


Dean Faculty Of Medicine
Sri Devaraj Urs Academy of Higher
Education & Research, Tamaka, Kolar.

Approved as per BOM-56-2019, (Resolution No-LVI.06) Dated-20/12/2019

REGULATIONS GOVERNING
POST GRADUATE DEGREE PROGRAMMES
CURRICULUM 2019-2020

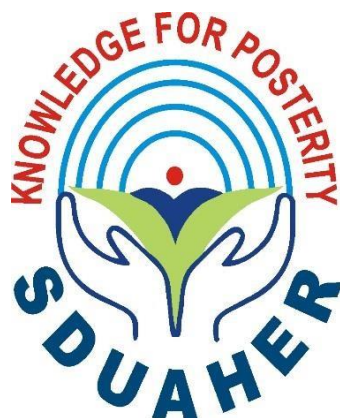


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Comprising Sri Devaraj Urs Medical College
A Deemed To Be University

Declared under section 3 of UGC, Act,1956,
MHRD GOI NO.F,9-36/2006-U.3(A), Dt.25th may 2007
Post box No.62, Tamaka, Kolar-563101, Karnataka, INDIA
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REGULATIONS AND CURRICULA
FOR
POST GRADUATE DEGREE PROGRAMMES
IN
MEDICAL SCIENCES
2019-2020



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Edition Year: 2020

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VISION:

“UNIVERSITY OF EXCELLENCE - KNOWLEDGE FOR POSTERITY”

MISSION:

1. To be a global centre of excellence for Teaching, Training and Research in the field of Higher education.
2. To inculcate scientific temper, research attitude and social accountability amongst faculty and students.
3. To promote with value based education for the overall personality development and leadership qualities to serve the humanity.

OBJECTIVES:

1. To provide need based infrastructure and facilities to students to become responsible professionals with social commitment and accountability.
2. To implement effectively innovative programs in teaching learning and evaluation.
3. To impart scientific and socio cultural temperament among students to forge national identity and needs.
4. To provide instruction and training in Basic and advanced branches of learning.
5. To provide facilities for research for the advancement and dissemination of knowledge.
6. To undertake extra mural studies, consultancy, extension programmes and field outreach services for the development of society.
7. To collaborate with other Universities, Institutions of excellence and research organizations within the country and outside for the purpose of teaching, training and research.
8. To undertake need based activities for the betterment of socially and educationally backward society.

At a glance this logo is abstract, yet it contains the vital ingredients for an institution like Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar.

The institution's medical background, Humanitarian values, Compassion,

Approachability, Social Commitment and the subsequent research towards the most precious thing, the human life, is the core theme.

The graphic form of a person in the centre of a bud represents the humanity. It denotes the growing process of life and its existence. And the two hands safeguarding them show the care and a sense of security. It is also capable of holding something within the vast expanse of knowledge by the University for the People's benefit. Hence, the motto "Knowledge for Posterity" is very appropriate and gives a punch in Red. The four light blue half circles (smaller to bigger) depict the unending quest for knowledge and imparting it to a wider horizon, growing higher and higher.

And finally, the whole unit is embedded in a "D" shaped graphic template as background to give it a corporate identity.

COLORS USED:

Deep Blue: Credible, Confident and Dependable. Represents Peace, Tranquility, Stability, Harmony, Trust, Security, Cleanliness and Loyalty

Light Blue: For Sky and Water (color scheme for 4 half circles)

Red: A dominant color for strengths.

Green: For Nature, Health and Generosity. It is cool quality soothes and has great healing powers



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No. SDUAHER/KLR/ ADMN/1322/2020-21

Date:12/10/2020

NOTIFICATION

Sub: Regulations, curricula and syllabi of Postgraduate medical degree programmes in Preclinical, Paraclinical and clinical subjects- reg

Ref.

- I. Proceedings of the Academic Council meetings**
- II. Proceeding of the Board of Management meetings**
- III. MCI notifications**
- IV. SDUAHER notification:**

Academic Council Meetings		Board of Management Meetings	
19 th	17.11.2014	34 th	19.06.2015
21 st	25.04.2015	36 th	04.12.2015
22 nd	18.11.2015	44 th	23.06.2017
27 th	29.04.2017	45 th	09.11.2017
28 th	04.11.2017	48 th	20.06.2018
30 th	05.05.2018	50 th	22.12.2018
31 st	03.11.2018	54 th	06.07.2019
33 rd	04.06.2019	56 th	20.12.2019
34 th	15.11.2019	59 th	09.10.2020
36 th	30.09.2020		

Agenda discussed:

- Objectives of external postings of Post Graduates
- Internal & External postings of PG's with assessment tools
- Minimum marks to be scored in PG theory examinations
- Topics to be included in Forensic medicine and toxicology in paper 4 for PG students
- Work placed based assessment for PG students
- Introduction of Assessment of AETCOM in formative/summative assessment
- Design and development of E-portfolio for all PG's
- Patient handover as common EPA for all departments
- Preparation of Question paper from question bank using software

- Coding of answer booklet by software enabled barcoding
- Development of CBME in PG programmes
- Quarterly formative assessment as an assessment tool for all PGs
- Start course in MD psychiatry
- Implement E- Portfolio of PG's
- Discontinuation of practice for 5th evaluation in PG exam
- Post graduate training programme MCI-PG Medical Education Regulations 2000, amended upto May 2018
- Approval of EPA's as competency based medical training for PG's
- Work placed based assessment as part of quarterly assessment for PG's
- PLO's for all programmes

V. MCI Notifications

- MCI Notification dated 09-12-2009, vide No.MCI.18(1)/2009-Med.55455
- No. MCI-23(1)/2014/Med/153433 Dated 28-01-2015
- MCI Guidelines 2017(CBME based)
- MCI postgraduate medical education regulations 2000 amended upto 2018 (clause 13.2,gazette notification dated 05/04/2018)
- Basic Programme in Biomedical Research(MCI-23(1)/2019-Med./141602 dated 27-08-2019).
- MCI-12(2)/2019-Med.Misc./189334.- Dated:12th February 2020
- MCI-18(1)/2020-Med./121415.-date 16/09/2020- (District Residency Programme' (DRP)

VI. Office Memorandum No. SDUAHER / KLR/ ADMN /8071/2019- 20 Dated 22/06/2019

VII. SDUAHER / KLR/ ADMN /1571/2019-20 dated 12/09/2019

REGULATIONS FOR POST GRADUATE DEGREE PROGRAMME IN MEDICAL SCIENCES

CHAPTER- I

1. Branches of Study

1.1 Postgraduate Degree Programme

The following programmes may be pursued.

A. M.D. (Doctor of Medicine)

1. Anatomy
2. Physiology
3. Biochemistry
4. Pharmacology
5. Pathology
6. Microbiology
7. Forensic Medicine
8. Community Medicine
9. General Medicine
10. Dermatology, Venereology and Leprosy
11. Anesthesiology
12. Paediatrics
13. Radio-Diagnosis
14. Psychiatry

B. M.S. (Master of Surgery)

1. General Surgery
2. Obstetrics and Gynecology
3. Orthopedics
4. Ophthalmology
5. OTO-Rhino-Laryngology

1.2. Eligibility for Admission

1.2.1 MD / MS Degree Programme: A candidate affiliated to this academy and who has passed final year M.B.B.S. examination after pursuing a study in a medical college recognised by the Medical Council of India, from a recognised Medical College affiliated to any other Academy recognised as equivalent thereto, and has completed one year compulsory rotating internship in a teaching Institution or other Institution recognised by the Medical Council of India, and has obtained permanent registration of any State Medical Council will be eligible for admission.

1.2.2 A Candidate seeking admission should have successfully cleared the qualifying examination - NEET (National Eligibility cum Entrance Test) conducted by NBE (National Board of Examination).

1.3. Obtaining Eligibility Certificate by the Academy before making Admission

No candidate will be admitted for any postgraduate degree programme unless the candidate has obtained and produced the eligibility certificate issued by the Academy. The candidate has to make an application to the Academy with the following documents along with the prescribed fee:

1. S.S.L.C Marks card
2. 10+2 Certificate
3. All MBBS Marks Cards
4. Internship Completion Certificate
5. Attempt / Academic certificate
6. Degree Certificate
7. Transfer Certificate
8. Migration Certificate
9. Study/ Bonafide Certificate
10. Character & Conduct certificate
11. MCI Recognized Certificate by college
12. Karnataka Medical Council/State medical council
13. MCC Allotment Letter
14. NEET Admission Ticket
15. NEET Rank card
16. Caste (SC/ST) /OBC certificate (domicile) & Income Certificate
17. Aadhar card of both candidate and parents / sponsors
18. Bond for SR Ship
19. Remaining years fee bond

NOTE: The NRI/NRI Sponsor students have to submit the documents as per the MCC/DGHS Criteria for NRI status

Candidates should obtain the Eligibility Certificate before the last date for admission as notified by the Academy.

A candidate who has been admitted to postgraduate programme should register his / her name in the Academy within a month of admission after paying the registration fee.

1.4. Intake of Students

The intake of students to each programme will be in accordance with the ordinance in this behalf.

1.5. Duration of Study

a) M.D/M.S Degree Programme

The programme of study will be for a period of 3 years consisting of 6 academic terms.

1.6. Method of training

The training of postgraduate for degree will be residency pattern with graded responsibilities in the management and treatment of patients entrusted to his/her care. The participation of the students in all facets of educational process is essential. Every candidate should participate in seminars, group discussions, grand rounds, case demonstration, clinics, journal review meetings, CPC and clinical meetings. Every candidate should participate in the teaching and training programme of undergraduate students. Training includes involvement in laboratory and experimental work and research studies.

1.6.1. Teaching methodology

1.6.1.1 Includes Didactic lectures, small group discussion such as seminars, journal clubs, symposia, reviews and guest lectures for acquiring theoretical knowledge.

1.6.1.2 Bedside teaching, grand rounds, structured interactive group discussions and clinical demonstrations should be the hallmark of clinical/practical learning with appropriate emphasis on e-learning. Student should have hand-on training in performing various procedures and ability to interpret various tests/investigations.

1.6.1.3 Exposure to newer specialized diagnostic/therapeutic procedures concerning her/his subject should be given.

1.6.4 Self-learning tools like assignments and case-based learning should be promoted.

1.6.2. Clinical postings and Rotation of posting

Basic medical sciences students will be posted to allied and relevant clinical departments or institutions. Students working in clinical departments will be posted to basic medical sciences and allied speciality departments or institutions. It should be done as concurrent studies during the 1st year of training Similarly Inter-unit rotation in the department should be done for a period of up to one year. Rotation in appropriate related subspecialties **should not extend for a period exceeding 06 months.** Postings to other specialty departments will be during the second year.

All postgraduates' students pursuing MD/MS in broad specialities shall undergo a compulsory residential rotation of three months in District Hospital / District Health system as a part of the course curriculum. Such rotation shall take place in the 3rd or 4th or 5th semester of the postgraduates programme. This rotation shall be termed as District residency programme and the postgraduate medical student undergoing training shall be termed as a District Resident.

Satisfactory completion of the District Residency shall be an essential condition before the candidate is allowed to appear in the final examination of the respective postgraduate course. The District Residency Programme Coordinator (DRPC) shall issue certificate of satisfactory completion of DRP and report on the performance of the District Resident on a prescribed format to the concerned Medical College and the Government of State/Union Territory. No. MCI-18(1)/2020-Med./121415. – date 16/09/2020

1.6.3. Clinical meetings:

Clinical meetings will be conducted within the department weekly and also inter departmental meetings will be conducted monthly to discuss uncommon/interesting cases.

1.6.4 Log book:

Each student should maintain a logbook and document day to-day activities like documentation of ward work, teaching and learning activities , clinical case discussion, procedures performed , seminars, journal clubs, symposium ,CPC meets, inter-unit/interdepartmental teaching sessions, mortality meets, workshops, CME/conferences .The Log books will be checked and assessed periodically by the faculty members imparting the training. This will in turn be evaluated/assessed by an external reviewer appointed by the Director of PG Studies biannually during the months of July and January. The log book should be preserved and presented at the time of summative examinations conducted by the Academy.

1.6.5 Research activities:

- 1.6.5.1 The student should know the basic concepts of research methodology plan a research project and be able to retrieve information from the library. The student should have a basic knowledge of statistics.
- 1.6.5.2 A postgraduate student of a postgraduate degree programme in broad specialities should present one poster presentation, read one paper at a national/state conference and publish 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. MCI Notification No.18(1)/2009/medicine/55455 Dated:09-12-2009
- 1.6.5.3 Department should encourage e-learning activities.

1.6.6 Basic Programme in Biomedical Research:

In order to improve the research skills of post-graduate students, the Board of Governors (BoG) has recommended a uniform research methodology programme across the country, the online programme, “Basic programme in Bio-medical Research”, will be offered by ICMR-National Institute of Epidemiology (ICMR-NIE), Chennai (www.nie.gov.in). The programme will explain fundamental concepts in

Research methodology. This programme is being offered through SWAYAM programme of ministry of human resource development through SWAYAM NPTEL (http://swayam.gov.in/nc_details/NPTEL)

1.6.7 Synopsis and Dissertation:

Every candidate will submit to the Registrar of the Academy in the prescribed proforma, a synopsis containing particulars of proposed dissertation work within six months from the date of commencement of the programme on or before the dates notified by the Academy. The synopsis will be sent through the proper channel.

Such synopsis will be reviewed and the dissertation topic will be registered by the Academy. No change in the dissertation topic or guide will be made without prior approval of the Academy.

Every candidate pursuing MD/MS degree programme is required to carry out work on a selected research project under the guidance of a recognized post graduate teacher. The results of such a work will be submitted in the form of a dissertation.

The dissertation is aimed to train a post graduate student in research methods and techniques. It includes identification of a problem, formulation of a hypothesis, search and review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis and comparison of results and drawing conclusions.

The dissertation should be written under the following headings:

- Introduction
- Aims or Objectives of study
- Review of Literature
- Material and Methods
- Results
- Discussion
- Conclusion
- Summary
- References
- Tables
- Annexures

The written text of dissertation will be not less than 50 pages and will not exceed 150 pages excluding references, tables, questionnaires and other annexures. It should be neatly typed in double line spacing on one side of paper (A4 size, 8.27" x 11.69") and bound properly. Spiral binding should be avoided. The dissertation will be certified by the guide, Head of the department and Head of the Institution.

Six hard copies of dissertation and one soft copy thus prepared will be submitted to

the Controller of Examination (CoE), six months before final examination on or before the dates notified by the Academy.

The dissertation will be valued by examiners appointed by the Academy. Approval of dissertation work is an essential precondition for a candidate to appear in the Academy examination.

Guide: The academic qualification and teaching experience required for recognition by this Academy as a guide for dissertation work is as per Medical Council of India, Minimum Qualifications for Teachers in Medical Institutions Regulations, 1998. Teachers in a medical college/institution having a total of eight years teaching experience out of which at least four years teaching experience as Assistant Professor with at least one research publication in indexed journals gained after obtaining post graduate degree will be recognized as post graduate teachers. (No.MCI- 12(2)/2019-Med.Misc./189334.- Dated: 12th February 2020)

Co-guide: may be included provided the work requires substantial contribution from a sister department or from another medical institution recognized for teaching/training by Sri Devaraj Urs Academy /Medical Council of India. The co- guide will be a recognized post graduate teacher of Sri Devaraj Urs Academy.

Change of guide: In the event of a registered guide leaving the college for any reason or in the event of death of guide, guide may be changed with prior permission from the academy.

1.6.8 Journal Club:

Journal club will be conducted once a week. All the PG students are expected to attend and actively participate in discussion and enter the relevant details in the log book. Further, every candidate must make a presentation from the allotted journal(s), selected articles, at least four times a year and a total of 12 presentations in three years. The presentations would be evaluated using check lists and would carry weightage for internal assessment (See checklist - I in Chapter V). A time table with names of the student and the moderator should be announced periodically, (Quarterly).

1.6.9 Subject Seminar:

Subject seminar will be conducted once a week. All the PG students are expected to attend and actively participate in discussion and enter the relevant details in the log book, Further, every candidate must present selected topics at least four times a year and a total of 12 seminar presentations in three years. The presentations would be evaluated using check lists and would carry weightage for internal assessment (See checklist-II in Chapter V). A timetable for the subject with names of the student and the moderator should be announced periodically, (Quarterly).

1.6.10 Student Symposium:

Student Symposium as an additional inter departmental programme will be conducted periodically, once in three months. The evaluation may be similar to that described for subject seminar.

1.6.11 Ward Rounds:

Ward rounds are service or teaching rounds.

- i. *Service Rounds:* Postgraduate students and Interns will do every day for the care of the patients. Newly admitted patients should be worked up by the PGs and presented to the seniors the following day.
- ii. *Teaching Rounds:* Every unit will have 'grand rounds' for teaching purpose. A diary should be maintained for day to day activities by the students. Entries of (i) and (ii) should be made in the Log book.

1.6.12 Clinico-Pathological Conference:

CPC will be conducted once in two months for all post graduate students. Presentation will be done by rotation. If cases are not available due to lack of clinical postmortems, it could be supplemented by published CPCs.

1.6.13 Inter Departmental Meetings:

These will be conducted once a month. These meetings will be attended by post graduate students and relevant entries must be made in the Log Book.

1.6.14 Teaching & Learning Skills:

Post graduate students must teach under graduate students (Eg. medical, nursing) by taking demonstrations, bed side clinics, tutorials, lectures etc.

Assessment is made using a checklist by surgery faculty as well as students. (See model checklist -III in Chapter V). Record of their participation should be documented in the Log book. Training of post graduate students in Educational Science and Technology is recommended.

Further, all postgraduate students are required to attend at least about 35 hours of didactic lecture as notified by the individual departments.

1.6.15 Entrustable Professional Activity:

EPAs are units of professional practice, defined as tasks or responsibilities to be entrusted to the unsupervised execution by a trainee once he or she has attained sufficient specific competence. EPAs are independently executable, observable, and measurable in their process and outcome, and therefore, suitable for entrustment decisions. The Entrustable professional activity (EPA) concept allows faculty to make competency-based decisions on the level of supervision required by trainees. The Academy has identified few such EPA's for all students in various degree programme. These are:

1. EPA 1: Gather a history and perform a physical examination

2. EPA 2: Prioritize a differential diagnosis following a clinical encounter
3. EPA 3: Recommend and interpret common diagnostic and screening tests
4. EPA 4: Obtain informed consent for tests and / or procedures
5. EPA 5: Recognize a patient requiring urgent or emergent care and initiate evaluation and management
6. EPA 6: Give or receive a patient handover to transition care responsibility
7. EPA 7: Undertake complete patient monitoring including the preoperative and post-operative care of the patient.
8. EPA 8: Provide basic and advanced lifesaving support services in emergency situations
9. EPA 9: Collaborate as a member of an inter-professional team
10. EPA 10: Perform general procedures of a physician
11. EPA 11: Enter and discuss orders and prescriptions
12. EPA 12: Prepare a comprehensive discharge summary.
13. EPA 13: Form clinical questions and retrieve evidence to advance patient care.

However in addition to these common EPA's individual departments are advised to develop their own EPA's.

1.7. Continuing Medical Education (CME):

Every PG student must attend at least 2 CME programmes either at state/regional /zonal/national levels.

1.8. Conferences:

Attending conferences is optional. However it has to be encouraged. All students are encouraged to attend conferences (at state/national/international levels) to enable them to make paper/poster presentations, which is a mandatory requirement to fulfill before appearing for final examinations.

1.9. Attendance, Progress and Conduct:

- A candidate pursuing degree programme will work in the concerned department of the institution for the full period as a full time student. No candidate is permitted to run a clinic/laboratory/nursing home while studying postgraduate programme.
- Academic term of 6 months will be taken as a unit for the purpose of calculating attendance. The candidate should have 80% attendance in each academic term of 6 months.

- Every student will attend symposia, seminars, conferences, journal review meetings, grand rounds, CPC, case presentation, clinics and lectures during each year as prescribed by the department and not absent himself / herself from work without valid reasons.
- Every candidate is required to attend a minimum of 80% of the training during each academic term of the post graduate programme. Provided further, leave of any kind will not be counted as part of academic term without prejudice to minimum 80% attendance of training period every term.
- All the candidates joining the Post Graduate training programme will work as 'Full Time Residents' during the period of training and will attend not less than 80% (Eighty percent) of the imparted training during each academic term. Including assignments, full time responsibilities and participation in all facets of the education process.
- Any student who fails to complete the programme in the manner stated above will not be permitted to appear for the Academy Examinations.
- A Postgraduate student of a postgraduate degree programme 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 postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.

Ref: As MCI Notification dated 09-12-2009, vide No.MCI.18 (1)/2009- Med.55455 and Para No.4.

Procedure for defaulters:

Every department will have a committee containing Head of the department and PG guides to review such situations. The defaulting candidate is counseled by the guide and head of the department. In extreme cases of default the departmental committee may recommend that defaulting candidate be withheld from appearing the examination, if she/he fails to fulfill the, requirements in spite of being given adequate chances to set himself or herself right.

2 Monitoring Progress of Studies:

It is essential to monitor the learning progress of each candidate through continuous appraisal and regular assessment. It not only helps teachers to evaluate students, but also students to evaluate themselves. The monitoring will be done by the staff of the department based on participation of students in various teaching / learning activities. It may be structured and assessment be done using checklists that assess various aspects. Checklists are given in Chapter V.

The learning outcomes to be assessed should include:

- Personal Attitudes,
- Acquisition of Knowledge,
- Clinical and operative skills,
- Teaching skills and
- Dissertation.

a. Personal Attitudes:

The essential items are:

- Caring attitudes
- Initiative
- Organisational ability
- Potential to cope with stressful situations and undertake responsibility
- Trustworthiness and reliability
- To understand and communicate intelligibly with patients and others
- To behave in a manner which establishes professional relationships with patients and colleagues
- Ability to work in team
- A critical enquiring approach to the acquisition of knowledge

The methods used mainly consist of observation. It is appreciated that these items require a degree of subjective assessment by the guide, supervisors, self, peers, faculty from the unit and nurses. (Multi source feedback MSF) checklist XII

b. Acquisition of Knowledge:

The methods used comprise of

2.1 Log book: (Check List - XIII Chapter - V)

'Log Book' which records participation in various teaching / learning activities by the students. The number of activities attended and the number in which presentations are made must be recorded. The log book will periodically be validated by the supervisors. Some of the activities are listed. During the training period, the post graduate student should maintain a Log Book indicating various teaching / learning activities, duration of the postings/work done in Wards including super specialty, OPDs and Casualty. This should indicate the specified number of cases for clinical discussion, procedures and operations observed, assisted and performed / presented seminars and review articles from various journals in inter- unit/inter departmental teaching sessions.

The purpose of the Log Book is to:

- Help maintain a record of the work done during training,
- Enable Consultants to have direct information about the work; intervene if necessary,
- Use it to assess the experience gained periodically.

The log book will be used to aid the internal evaluation of the student.

The Log books will be checked and assessed periodically, monthly basis by guide / head of the unit/ head of the department and biannually by external reviewer.

Procedure for defaulters:

Every department will have a committee to review such situations. The "defaulting candidate is counseled by the guide and head of the department. In extreme cases of default the departmental committee will recommend that defaulting candidate be withheld from appearing the examination, if she/he fails to fulfill the requirements in spite of being given adequate chances to set himself or herself right

2.2 Journal Review Meeting (Journal Club):

The ability to do literature search, in depth study, presentation skills, and use of audio-visual aids are to be assessed. The assessment is made by faculty members and peers attending the meeting using a checklist (see Model Checklist -I, in Chapter V)

2.3 Seminars/Symposia:

The topics will be assigned to the student well in advance to facilitate in depth study. The ability to do literature search, in depth study, presentation skills and use of audio-visual aids will be assessed using a checklist (see Model Checklist -II, Chapter V)

2.4 Clinico'-Pathological conferences:

This will be a multidisciplinary case study of an interesting case to train the candidate to solve diagnostic and therapeutic problems by using an analytical approach. The presenter(s) are to be assessed using a check list similar to that used for seminar.

2.5 Surgical Audit:

Periodic morbidity and mortality meeting must be held. Attendance and participation in these must be insisted upon. This may not be included in assessment.

2.6 Clinical skills

Day to Day work: Skills in outpatient and ward work will be assessed periodically. The assessment should include the candidates' sincerity and punctuality, analytical ability and communication skills (see Model Checklist -V, Chapter V). – Mini CEX (Model check list VII, Chapter V)

2.7 Clinical meetings (Clinical Presentations) :

Candidates should periodically present cases to his peers and faculty members. This should be assessed using a check list (see Model checklist V, Chapter V).

2.8 Clinical and Operative skills:

The candidate will be given graded responsibility to enable learning by apprenticeship. The performance is assessed by the guide by DOPS (Model check list VI, Chapter V). Particulars are recorded by the student in the log book.

2.9 Teaching skills:

Post graduates are required to teach undergraduate medical students and paramedical students, if any (*as a part of Post graduate training*). This performance should be based on assessment by the faculty members of the department and from feedback from the undergraduate students (See Model checklist III, Chapter V) - Microteaching Pedagogy (Model check list VIII, Chapter V)

2.10 Dissertation in the Department:

Periodic presentations must be made in the department. Initially the topic selected is to be presented before submission to the Academy for registration and again before finalization for critical evaluation and before final submission of the completed work (See Model Checklist IX & X, Chapter V)

2.11 Periodic tests:

The concerned departments will conduct quarterly tests. The final test will be held three months before the final examination. The tests may include written papers, practical's / clinical and viva voce. Records and marks obtained in such tests will be maintained by the Head of the Department and sent to the Academy, when called for.

2.12 Work diary / Log Book-

Every candidate will maintain a work diary and record his/her participation in the training programmes conducted by the department such as journal reviews, seminars, etc. Special mention must be made of the presentations by the candidate as well as details of clinical or laboratory procedures, if any conducted by the candidate.

2.13 Records:

Monthly and quarterly reviews of records, log books and marks obtained in tests will be maintained by the Head of the Department and will be made available to the Academy, when called for.

3. ASSESSMENT:

3.1 Formative Assessment

It is essential to monitor the learning progress of each candidate through **continuous appraisal and regular assessment**. It not only helps teachers to evaluate students, but also students to evaluate themselves. The monitoring to be done by the staff of the department based on participation of students in various teaching /learning

activities. It may be structured and assessment be done using checklists that assess, various aspects. This includes assessment of patient care, procedural & academic skills, interpersonal skills, professionalism, self-directed learning and ability to practice in the system.

Checklists are given in Chapter-V

Assessment during the MS/MD training should be based on:

Assessment at end of rotation (Quarterly Postgraduate Student's Appraisal Form) by the Unit Head. The student to be assessed periodically as per categories listed in **Postgraduate Student Appraisal Form** (See Model checklist-X, Chapter V).

Multisource Feedback (MSF) - Quarterly

MSFs should be obtained quarterly from:- 2 from faculty of the unit/department; 2 from peers posted in the unit; 2 from interns, 2 from staff nurses from the areas attached to the unit, 2 from patient/patient relative. (Checklist XII - Chapter V)

Periodic assessment -The Quarterly tests may include written papers (theory), practical's / clinical and viva voce.

Quarterly Postgraduate Student's Appraisal Form (See Model checklist-X I, Chapter V).

- Journal based/ recent advances learning
- Patient based or Skill based learning
- Self-directed learning and teaching
- Departmental & interdepartmental learning activity
- External & Outreach activities/ Continuing Medical Education (CME)
- Attendance, Progress and Conduct

A candidate pursuing degree programme should work in the concerned department of the institution for the full period as a full time student. No candidate is permitted to run a clinic/laboratory/nursing home while studying postgraduate programme.

Academic term of 6 months will be taken as a unit for the purpose of calculating attendance. Every student will attend symposia, seminars, conferences, journal review meetings, grand rounds, CPC, case presentation, clinics and lectures during each year as prescribed by the department and not absent himself / herself from work without valid reasons.

Every candidate is required to attend a minimum of 80% of the training during each academic term of the post graduate programme. Provided further, leave of any kind will not be counted as part of academic term without prejudice to minimum 80% attendance of training period every term.

All the candidates joining the Post Graduate training programme will work as 'Full Time Residents' during the period of training and will attend not less than 80% (Eighty percent) of the imparted training during Academic Term of 6 months including assignments, full time responsibilities and participation in all facets of the education process.

Any student who fails to complete the programme in the manner stated above will not be permitted to appear for the Academy Examinations.

A Postgraduate student of a postgraduate degree programme 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 postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.

Ref: As MCI Notification dated 09-12-2009, vide No.MCI.18 (1)/2009-Med.55455 and Para No.4.

Procedure for defaulters:

Every department should have a committee containing Head of the department and PG guides to review such situations. The defaulting candidate is counseled by the guide and head of the department. In extreme cases of default the departmental committee may recommend that defaulting candidate be withheld from appearing the examination, if she/he fails to fulfill the, requirements in spite of being given adequate chances to set himself or herself right.

3.2 Scheme of examinations

Summative assessment

The summative examination would be carried out as per the Rules given in POSTGRADUATE MEDICAL EDUCATION REGULATIONS, 2000 and amended up to 2018. (The Clause 14 under the heading "EXAMINATION" shall be substituted in terms of Gazette Notification published on 05.04.2018).

The examination will be in three parts:

3.2.1 DISSERTATION

Every post graduate student will carry out work on an assigned research project under the guidance of a recognized Post Graduate Teacher, the result of which will be written and submitted in the form of a dissertation. Work for writing the dissertation is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Dissertation will be submitted at

least six months before the Theory and Clinical / Practical examination. The dissertation will be examined by a minimum of three examiners; one internal and two external examiners, who will not be the examiners for Theory and Clinical examination. A candidate will be allowed to appear for the Theory and Practical/Clinical examination only after the acceptance of the dissertation by the examiners.

3.2.2. THEORY

There will be four question papers, each of three hours duration. Each paper will consist of ten questions each question carrying 10 marks, so the total marks for each paper will be 100. Questions on recent advances maybe asked in any or all the papers. The examinations will be organised on the basis of 'Grading' or 'Marking system' to evaluate and to certify candidate's level of knowledge, skill and competence at the end of the training. The Clause 14 under the heading "EXAMINATION" shall be substituted in terms of Gazette Notification published on 05.04.2018 and the same is as under:-

Obtaining a minimum of 40% marks in each theory paper and not less than 50% cumulatively in all the four papers for degree examinations and three papers in diploma examination. Obtaining of 50% marks in Practical examination shall be mandatory for passing the examination as a whole in the said degree/diploma examination as the case may be. Obtaining a minimum of 50% marks in 'Theory' as well as 'Practical' separately will be mandatory for passing examination as a whole. The examination for MS/MD will be held at the end of 3rd academic year.

3.2.3. Clinical / Practical and viva voce Examination

Clinical examination will be conducted to test the knowledge, skills, attitude and competence of the post graduate students for undertaking independent work as a specialist/Teacher, for which post graduate students will examine a minimum one long case and two short cases.

The Oral examination will be thorough and will aim at assessing the post graduate student's knowledge and competence about the subject, investigative procedures, therapeutic technique and other aspects of the specialty, which form a part of the examination.

Assessment may include Objective Structured Clinical Examination (OSCE) Oral/Viva-voce examination needs to assess knowledge on X-rays, instrumentation, operative procedures. Due weightage should be given to Log Book Records and day to-day observation during the training.

ALLOTMENT OF MARKS

THEORY	MARKS ALLOTMENT	MAXIMUM MARKS	
PAPER-I	10 X 10	100	400
PAPER-II	10 X 10	100	
PAPER-III	10 X 10	100	
PAPER-IV	10 X 10	100	

<u>CLINICALS/ PRACTICALS</u>		200
<u>VIVA VOCE</u>	<u>80</u>	100
<u>PEDAGOGY</u>	<u>20</u>	
TOTAL		700

3.2 Examiners:

There will be at least four examiners in each subject. Out of them two will be external examiners and two will be internal examiners. The qualification and teaching experience for appointment as an examiner will be as laid down by the Medical Council of India. No person will be appointed as internal examiner in any subject unless he/she has three years' experience as recognized PG teacher in the concerned subject. For external examiners he/she should have minimum six years of experience as recognized PG teacher in the concerned subject.

3.2.4 Criteria for declaring as pass in Academy Examination:

A candidate should score minimum 40% marks in each theory paper and not less than 50% marks cumulatively in all the papers in postgraduate degree/diploma, to be declared as pass in the examinations. A candidate shall secure not less than 50% marks in each head of passing which shall include (1) Theory, (2) Practical including clinical and viva voce examination. A candidate securing less than 50% of marks as described above shall be declared to have failed in the examination. (No. MCI-23(1)/2014/Med/153433 Dated 28-01-2015) A failed candidate may appear in any sub-subsequent examination upon payment of fresh fee to the Registrar of the University.

3.2.5 Declaration of distinction:

A successful candidate passing the Academy examination in first attempt will be declared to have passed the examination with distinction, if the grand total aggregate marks are 75 percent and above. Distinction will not be awarded for candidates passing the examination in more than one attempt.

3.2.6 Number of Candidates per day.

The maximum number of candidates for practical/clinical and viva-voce examination will be as under: MD / MS Programme: Maximum of 8 per day

4. ELIGIBILITY CRITERIA FOR APPEARING FOR EXAMINATIONS 4.1 ATTENDANCE

All the candidates joining the Post Graduate training programme will work as 'Full Time Residents' during the period of training and will attend not less than 80% (Eighty percent) of the imparted training during Academic Term of 6 months including assignments, full time responsibilities and participation in all facets of the education process.

- Every student will attend all teaching programmes during each year as prescribed by the department and not absent himself / herself from work without valid reasons
- Every candidate is required to attend a minimum of 80% of the training during each academic year of the post graduate programme. Provided further, leave of any kind will not be counted as part of academic term without prejudice to minimum 80% attendance of training period every term.
- Any student who fails to complete the programme in the manner stated above will not be permitted to appear for the Academy Examinations.

4.2. PROGRESS AND CONDUCT

- Every student will attend symposia, seminars, conferences, journal review meetings, grand rounds, CPC, case presentation, clinics and lectures during each term as prescribed by the department and not absent himself / herself from work without valid reasons.
- Every candidate is required to attend a minimum of 80% of the training during each academic term of the post graduate programme. Provided further, leave of any kind will not be counted as part of academic term without prejudice to minimum 80% attendance of training period every term.

4.3. RESEARCH ACTIVITIES-PAPER/POSTER/PUBLICATIONS

- A Postgraduate student of a degree programme in broad speciality 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 postgraduate studies so as to make him eligible to appear at the postgraduate degree examination. Ref: As MCI Notification dated 09-12-2009, vide No.MCI.18 (1)/2009-Med.55455 and Para No.4.
- It is mandatory for all postgraduate students to undergo training in online programme in "Basic Programme in Biomedical Research" Which should be completed by the end of second semester .Not completing the programme will make them ineligible for appearing for the final academy examinations.(MCI-23(1)/2019-Med./141602 dated 27-08-2019).

4.4 DISSERTATION

Every post graduate student will carry out work on an assigned research project under the guidance of a recognised Post Graduate Teacher, the result of which will

be written and submitted in the form of a dissertation. Dissertation will be submitted at least six months before the Theory and Clinical / Practical examination. The dissertation will be examined by a minimum of three examiners; one internal and two external examiners, who will not be the examiners for Theory and Clinical examination. A candidate will be allowed to appear for the Theory and Practical/Clinical examination only after the acceptance of the dissertation by the examiners.

4.5 District Residency Programme

All postgraduates students pursuing MD/MS in broad specialties shall undergo a compulsory residential rotation of three months in District Hospital / District Health system as a part of the course curriculum. Such rotation shall take place in the 3rd or 4th or 5th semester of the postgraduates programme. This rotation shall be termed as District residency programme and the postgraduate medical student undergoing training shall be termed as a District Resident.

Satisfactory completion of the District Residency shall be an essential condition before the candidate is allowed to appear in the final examination of the respective postgraduate course. The District Residency Programme Coordinator (DRPC) shall issue certificate of satisfactory completion of DRP and report on the performance of the District Resident on a prescribed format to the concerned Medical College and the Government of State/Union Territory. No. MCI-18(1)/2020-Med./121415. – date 16/09/2020

Procedure for defaulters:

Every department should have a committee containing Head of the department and PG guides to review such situations. The defaulting candidate is counseled by the guide and head of the department. In extreme cases of default the departmental committee may recommend that defaulting candidate be withheld from appearing the examination, if she/he fails to fulfill the, requirements in spite of being given adequate chances to set himself or herself right.

CHAPTER II
**GOALS AND GENERAL OBJECTIVES OF POSTGRADUATE MEDICAL
EDUCATION PROGRAM**

GOALS:

The goal of postgraduate medical education will be to produce a competent specialist and/or a medical teacher:

- i. Who will recognize the health needs of the community, and carry out professional obligations ethically and in keeping with the objectives of the national health policy;
- ii. Who will have mastered most of the competencies, relating to the specialty, that are required to be practiced at the secondary and the tertiary levels of the health care delivery system;
- iii. Who will be aware of the contemporary advances and developments in the discipline concerned;
- iv. Who will have acquired a spirit of scientific inquiry and is oriented to the principles of research methodology and epidemiology; and
- v. Who will have acquired the basic skills in teaching of the medical and paramedical professionals.

GENERAL OBJECTIVES:

At the end of the postgraduate training in the discipline concerned the student will be able to:

- i. Recognize the importance of the concerned specialty in the context of the health need of the community and the national priorities in the health sector.
- ii. Practice the specialty concerned ethically and in step with the principles of primary health care.
- iii. Demonstrate sufficient understanding of the basic sciences relevant to the concerned specialty.
- iv. Identify social, economic, environmental, biological and emotional determinants of health in a given case, and take them into account while planning therapeutic, rehabilitative, preventive and promotive measures/strategies.
- v. Diagnose and manage majority of the conditions in the specialty concerned on the basis of clinical assessment, and appropriately selected and conducted investigations.
- vi. Plan and advice measures for the prevention and rehabilitation of patients suffering from disease and disability related to the specialty.
- vii. Demonstrate skills in documentation of individual case details as well as morbidity and mortality data relevant to the assigned situation,
- viii. Demonstrate empathy and humane approach towards patients and their families and exhibit interpersonal behavior in accordance with the societal norms and expectations.
- ix. Play the assigned role in the implementation of national health programmes, effectively and responsibly.

- x. Organize and supervise the chosen/assigned health care services demonstrating adequate managerial skills in the clinic/hospital or the field situation.
- xi. Develop skills as a self-directed learner, recognize continuing educational needs; select and use appropriate learning resources.
- xii. Demonstrate competence in basic concepts of research methodology and epidemiology, and be able to critically analyse relevant published research literature.
- xiii. Develop skills in using educational methods and techniques as applicable to the teaching of medical/nursing students, general physicians and paramedical health workers.
- xiv. Function as an effective leader of a health team engaged in health care, research or training.

STATEMENT OF THE COMPETENCIES

Keeping in view the general objectives of postgraduate training, each disciplines will aim at development of specific competencies, which will be defined and spelt out in clear terms. Each department will produce a statement and bring it to the notice of the trainees in the beginning of the programme so that he or she can direct the efforts towards the attainment of these competencies.

COMPONENTS OF THE PG CURRICULUM

The major components of the PG curriculum will be:

- Theoretical knowledge
- Practical/clinical Skills
- Training in Thesis.
- Attitudes, including communication.
- Training in research methodology.

Source: Medical Council of India, Regulations on Postgraduate Medical Education, 2006 and 2008.

COMPETENCY BASED POSTGRADUATE TRAINING PROGRAMME FOR M.D. PHARMACOLOGY

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.

GOAL:

A candidate, who has successfully completed the course in M.D Pharmacology, should become proficient in all aspects concerning drugs, and should have acquired skills and knowledge so as to opt for any of the following fields for his/her future career:

- Teaching profession in a Medical Institution
- Medical Research
- Clinical Pharmacology
- Pharmaceutical Industry

PROGRAM OUTCOMES

At the end of the program, the student shall be able to

- Teach the under graduate medical, dental, nursing and other allied course students the basics of Pharmacology
- Explain concepts and principles of Pharmacology and therapeutics, drug development process and Drugs and Cosmetics Act
- Plan a protocol for conduct of clinical trial of all phases
- Perform Post marketing surveillance (Pharmacovigilance) for approved drugs
- Analyze critically a scientific article published in a journal.
- Perform experiments in animals and interpret the results of the same, conducted in preclinical studies
- Identify the drug interaction in a patient, interpret and assist the clinician in patient care
- Perform literature search, plan and conduct a research project (both basic and clinical) and prepare a manuscript in publishable format

Objectives

At the end of the course, the postgraduate student should be able to:

Knowledge and Intellectual Skills

1. Explain the general principles of drug action, pharmacokinetic parameters and drug interactions in normal individuals, patients and special situations
2. Explain pharmacotherapy of various clinical conditions
3. Explain the principles of various phases of clinical trials
4. Analyze clinical scenarios and critique scientific article
5. Plan and conduct a study and publish an article

Psychomotor Skills

1. Perform assay methods, chemical tests, different in vivo techniques and DNA extraction
2. Plotting the clinical pharmacokinetic graphs using given values and their interpretation

Attitudes and Communication Skills

1. Tutor students during tutorials, small group discussions and lectures
2. Counsel and obtain consent from patients
3. Interaction with peers, students, members of health care team and faculty on rational use of drugs, use of generic drugs and reporting Adverse Drug Reactions (ADRs)
4. Demonstrate ethical behavior and integrity in one's work.

Academic term wise competencies

I year 1-6 months	
Theory	Practical
<p>Routes of administration, Novel routes in drug delivery, Passage of drugs across cell membrane, Membrane transporters Clinical pharmacokinetics: Absorption, distribution, biotransformation and elimination of drugs Mechanism of drug action, Drug interactions, Adverse drug reaction, Preclinical evaluation of drugs, Clinical trial, Gene therapy, Therapeutic drug monitoring, Computer aided drug design, Chronopharmacology, Chirality, Drug induced hepatotoxicity, nephrotoxicity and agranulocytosis Drugs usage in pediatric, geriatric and pregnancy, Essential drug concept and rational drug use</p>	<p>Chemical test: Alkaloids, Glycosides, Iodides, Salicylates, and other drugs Effect of drugs on eye Techniques- Oral feeding in rats, Intraperitoneal injection in rats, Blood drawing from rat tail vein, Straube's test in mouse, Catalepsy in rats, Actophotometer, Analgesimeter-Tail flick method and Hot plate method Elevated Plus Maze, Rota rod apparatus, Pole climbing apparatus</p>

I year 7- 12 months	
Theory	Practical
<p>Carcinogenicity, P-glycoprotein Pharmacometrics, Drug dosage Chemical methods to estimate drug levels, Monoclonal antibodies role in therapeutics, Nanotechnology, Tyrosine kinase inhibitors, Antioxidants in therapy Protein kinase as drug target Introduction to statistics – measures of central tendency, confidence interval, randomization, sample size calculation, P value significance, Parametric tests Non parametric tests, Metaanalysis and systematic review, History and role of neurotransmitters in Autonomic Nervous System, Cholinomimetics, Anti cholinergic drugs, Sympathomimetics, Sympatholytics</p>	<p>Dog Blood Pressure tracings Clinical problems Pharmacokinetic problems Informed consent form writing</p>

II year 13 - 18 months	
Theory	Practical
Management of shock Drugs acting through Na ⁺ and K ⁺ channels Adenosine and its clinical implication Pharmacotherapy of hypertension Pharmacotherapy of Ischemic Heart Disease Pharmacotherapy of Chronic Heart Failure Hypolipidaemic agents Drugs used in arrhythmia Nitric oxide physiology and its role in therapy Pharmacotherapy of bronchial asthma 5HT receptors, action mediated, Drugs modifying them with clinical uses Role of prostaglandins in therapy History of anesthesia Opioids Non Steroid Anti-Inflammatory Drugs	Rat colon - Dose Response Curve Rat colon- Cumulative effect Rat colon – Matching and interpolation assay Rat colon - Bioassay Guinea pig ileum - Dose Response Curve Guinea pig ileum -Bioassay

II year 19 - 24 months	
Theory	Practical
Drugs used in depression Drugs used in psychosis Neurodegenerative disorders CNS neurotransmitters General anaesthetics and pre anaesthetic medication Substance abuse Anti epileptics Memory enhancers Iron metabolism and pharmacotherapy of anaemia Anticoagulants, antiplatelet drugs, thrombolytics Screening methods: Antiinflammatory drugs, Antidiabetic drugs, Antifertility drugs, Antiepileptic drugs, Antipsychotic drugs, Antidepressants, Analgesics	Protocol writing : Hypertension Protocol writing : Glaucoma Protocol writing : Diabetes mellitus Protocol writing : Peptic ulcer Protocol writing : Epilepsy Protocol writing : Hyperlipidemia Protocol writing : Bronchial asthma Protocol writing : Osteoarthritis Protocol writing : Benign Prostatic Hypertrophy Protocol writing : Post operative analgesia in patients undergoing abdominal surgery Critical evaluation of reviewed / published article

III year 24 - 30 months	
Theory	Practical
<p>SERMs, Corticosteroids, GnRH analogues, Anabolic steroids Current trends in management of diabetes mellitus Estrogens and its antagonist in therapy Pharmacotherapy of thyroid disorders Progestin and antagonists, Contraceptives Drugs affecting bone metabolism Management of endocrinal emergencies Peptic ulcer – drugs used in peptic ulcer Drugs modulating the motility of gastrointestinal tract Bacterial drug resistance, Superinfection Beta lactam antibiotics Drugs acting on Gram positive bacteria Anti pseudomonal agents Drugs acting on staphylococcus aureus</p>	<p>Chemical test: Alkaloids, Glycosides, Iodides, Salicylates, Other drugs Effect of drugs on eye Techniques- Oral feeding in rats, intraperitoneal injection in rats, Blood drawing from rat tail vein Straube's test in mouse Catalepsy in rats Actophotometer Analgesiometer- Tail flick method and Hot plate method Elevated plus Maze Rota rod apparatus Pole climbing apparatus</p>

III Year 30 - 36 months	
Theory	Practical
<p>Combination chemotherapy Pharmacotherapy of TB, HIV Current trends in malaria Immunomodulators Anti cancer drugs- hormones and its antagonists, plant products, antibiotics as anticancer drugs Biologic response modifiers Drugs used in dermatological conditions Screening methods :Learning and memory, Antihypertensives, Diuretics, Hypolipidaemic agents, Peptic ulcer, Immunomodulators, Antisialogogues, Anticancer agents, Antitussives and bronchodilators</p>	<p>Rat colon - Dose Response Curve Rat colon- Cumulative effect Rat colon – Matching, interpolation assay Rat colon - Bioassay Guinea pig ileum - Dose Response Curve Guinea pig ileum –Bioassay 10 Clinical problems 12 Pharmacokinetic problems Informed consent form writing Dog Blood Pressure Protocol writing : Hypertension Protocol writing : Glaucoma Protocol writing : Diabetes mellitus Protocol writing : Peptic ulcer Protocol writing : Epilepsy Protocol writing : Hyperlipidemia Protocol writing : Bronchial asthma Protocol writing : Osteoarthritis Protocol writing : Benign Prostatic Hypertrophy</p>

	Protocol writing : Post operative analgesia in patients undergoing abdominal surgery Critical evaluation of reviewed / published article
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Animal Experiments: All animal experiments must be compliant with Govt. of India regulations, notified from time to time. Amphibian/Dog/Cat experiments should be conducted by computer assisted simulation models/ facilities. Other experiments should be performed as permissible by CPCSEA guidelines.

Course contents

THEORY

General Pharmacology

- Basic principles of pharmacodynamics and kinetics, including Molecular Pharmacology, drug delivery systems
- Historical aspects of drug discovery
- Principles of Good Clinical Practice and Good Laboratory Practice
- Pharmacogenetics and Pharmacogenomics (Gene based therapy)
- Pharmacoepidemiology
- Pharmacoeconomics
- Biochemical Pharmacology and bioassays
- Structure activity relationship of important classes of drugs
- 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
- Animal experiments: Ethical consideration, ethical approval
- Regulatory Guidelines (CPCSEA) and alternatives to animal experimentation
- Screening procedures for various drug categories in humans and animals (Sedative, Hypnotics, Antiepileptics, Local Anesthetics, adrenergic blocking drugs, Skeletal Muscle Relaxants, Diuretics, Hypolipidemic agents, Drugs used in arrhythmia, anxiety, inflammation, pyrexia, cough, bronchial asthma, psychosis, depression, Learning and memory, Hypertension, Diabetes mellitus, infertility, Peptic ulcer, vomiting, Prokinetic agents, opioid agonists and antagonists, Oxytocics, Behavioral pharmacology models)

Clinical Pharmacology

- Principles of Clinical Pharmacokinetics and their application in drug treatment
- Development of new drugs and its evaluation in animals and man
- Clinical trials
- Therapeutic Drug Monitoring (TDM)
- Basic principles and applications of simple analytical methods
- Basic principles of analytical techniques including Spectrophotometry, Chromatography and Radio Immunoassay
- Immunoassays: Concept, types of bioassays and their application/s
- 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).
- Adverse drug reaction monitoring / Pharmacovigilance
- Principles of rational drug use and prescription audit
- Essential drugs concept
- Adverse drug interactions
- Drug information and over the counter drugs
- Role of medicinal plants(herbal medicines) and dietary supplements
- Procedures for new drug development including Pharmacometrics (Methods of drug evaluation)
- Special problems related to drug use in different age groups, pregnancy, lactation and disease conditions
- Biostatistics: Basic Principles and their application in drug research
- Research Methodology including literature search
- (The candidate shall get acquainted with various aspects of biomedical research, so as to enable him to undertake and supervise research projects).
- Basic Principles and related aspects.
- Ethical issues related to research on human subjects and animals.

Systemic Pharmacology and Therapeutics

- Autonomic nervous system, drugs acting on Synaptic and Neuroeffector Junctional sites
- Central Nervous system (Sedatives, hypnotics, General Anesthetics, Local Anesthetics, Skeletal Muscle Relaxants, Drugs used in epilepsy, psychosis, depression, Parkinson's disease, other neurodegenerative disorders, opioid agonists and antagonists, drugs of abuse)
- Cardiovascular system (Drugs used in hypertension, angina, arrhythmia, heart failure)
- Respiratory system (Drugs used in bronchial asthma and COPD)
- Gastrointestinal System
- Autacoids and related pharmacological agents (NSAIDs), Drugs used in Rheumatoid arthritis and Gout

- Blood (Drugs used in Dyslipidemia, fibrinolytics, anticoagulants, antiplatelets),
- Drugs modifying renal function (Diuretics and antidiuretics)
- Hormones (Drugs used in diabetes mellitus, hypothalamic and pituitary hormones, thyroid and antithyroid drugs, adrenocorticoid hormones and their antagonists, gonadal hormones and their inhibitors), Reproductive Pharmacology, Agents affecting calcification and bone turnover, Uterus
- Ocular and Dermatological Pharmacology
- Antimicrobial agents including antimicrobial stewardship program, antiparasitics, antiviral drugs, disinfectants, antiseptics, chemotherapy of neoplastic disease, drugs used in autoimmune disorder and Graft versus Host Disease, Immunomodulators - immunosuppressants and immunostimulants
- Toxicology- Drug poisoning and their management, Heavy metal poisoning, non-metallic toxicants- air pollutants, pesticides, Environmental, Occupational and Industrial Toxicology

Recent advances in Pharmacology

PRACTICAL

Objective: A candidate, after passing the M.D. Pharmacology examination should possess skills in testing the effects of drugs on the various experimental systems specified below. The candidate should also be well versed in interpreting and analyzing the observations and data obtained from studies.

Experiments on Laboratory Animals

Small Animals: Methods of testing for local anaesthetics, anti-inflammatory drugs, analgesics, anticonvulsants, psychopharmacological agents

Isolated tissue preparations (DRC and bioassay)

- Rabbit: Jejunum, Heart
- Rat: Colon, Uterus
- Guinea Pig: Ileum

Demonstration of techniques

- Oral feeding in rats
- Intraperitoneal, subcutaneous & intravenous drug administration in rats
- Blood drawing from rat tail vein/rabbit ear marginal vein
- Catalepsy in rats
- Straub's tail test
- Effect of opioids using Analgesiometer
- Effects of drugs on memory and learning using Hebb William's Maze
- Effect of diazepam using Actophotometer
- Effect of pilocarpine on secretions in rats
- Sleeping time
- Effect of mydriatics and miotics on eye
- Computer Assisted Learning software utilization

Chemical Experiments

- Simple tests for detecting the chemical nature of drugs (alkaloids, glycosides, steroids, barbiturates, salicylates)
- Monitoring of drug levels in body fluids (candidates should acquaint with the techniques of monitoring drug levels, using techniques like chromatography, spectrophotometry and immunoassays).

Clinical Pharmacology

• Tests on Human Volunteers

Simple tests for monitoring of effect of drugs like: Bronchodilators

- using peak flow meters
Psychopharmacological agents - Behavioral effects

- Protocol writing for a clinical trial
- Informed consent form writing
- Patient information sheet for research
- Report Serious Adverse Effect (SAE)
- Pharmacovigilance programme of ADR, Causality assessment
- Pharmacokinetic parameters
- Clinical problems
- Critical evaluation of a published article
- Pharmacoeconomics
- Evaluate Promotional drug literature, prepare Drug Information Sheet (WHO Criteria)

ROTATION POSTINGS

A candidate of the M.D Degree Course in Pharmacology needs to be well versed in the applied aspects of pharmacology and therapeutics. Actual postings in the wards of the Clinical departments will help the candidate get acquainted with the patterns of drug use, rational drug therapy, adverse drug reactions and interactions. Such postings will also help him gain confidence in interacting with the clinicians, which will be needed if the student chooses to be a Clinical Pharmacologist in his/her future career. Specific learning objectives (SLO) for the students to learn in different departments are to be followed prepared by the University. The following clinical postings are recommended:

Name of the department	Duration
Medicine	30 days
Pediatrics	30 days
Anesthesiology / ICU	15 days
Dermatology	08 days
Psychiatry	07 days
Microbiology	08 days
Biochemistry	07 days
Genome laboratory	15 days
Casualty [#]	15 days
Industry posting: As per availability for undergoing internship at Biocon India Ltd, Bangalore	Optional * 30 days

- # All discipline PG students are posted on rotation basis
- *As the drug industries are reluctant to impart training.

Total duration of clinical postings is 4 months. These postings shall be during the II year. Monitoring postings in clinical departments would be through daily discussions with the faculty of department of Pharmacology during the afternoon session & maintenance of work diary.

OBJECTIVES OF POSTINGS OF PG STUDENTS

The PG students of Pharmacology are posted in the departments of General Medicine, Pediatrics, Anesthesiology / ICU, Dermatology, Psychiatry, Microbiology, Biochemistry, Genome Lab and Casualty

A) At the end of one month posting in General Medicine the student should be able to

1. Write the management of a poisoning case
2. Critically evaluate and explain drug interactions
3. Select and make a P drug list with respect to rational pharmacotherapy
4. Write a rationale prescription for chronically ill patients (cancer patients/end stage renal and hepatic cirrhosis)
5. Write the case record forms systematically
6. Write the treatment based on cost (Pharmacoeconomics)

Assessment:

1. Long and Short essay questions
2. Patient management problem
3. Subject seminar using checklist
4. To maintain a log book and should be duly scrutinized by faculty in-charge

B) At the end of one month posting in Pediatrics the student should be able to

1. Calculate the correct dose of various drugs for different age groups
2. Write the dose of drugs used in emergency and NICU
3. Write a rationale prescription for pediatric age group
4. Write the management of diarrhea
5. Critically evaluate and explain drug interactions in NICU

Assessment:

1. Long and Short essay questions
2. Patient management problem
3. Subject seminar using checklist
4. To maintain a log book and should be duly scrutinized by faculty in-charge

C) At the end of 15 days posting in Anesthesiology/ ICU the student should be able to

1. Write the dose and route of administration and rationale of pre anesthetic medication
2. Write the advantages and disadvantages of various general anesthetics
3. Critically evaluate and explain drug interactions with general anesthetics

4. Write the drug interactions with skeletal muscle relaxants
5. Write the drugs used as pre-emptive analgesics and their advantages

Assessment:

1. Long and Short essay questions
2. Subject seminar using checklist

D) At the end of 08 days posting in Dermatology the student should be able to

1. Fill the adverse drug reaction form, do causality assessment based on WHO scale
2. Write the management of a case manifesting with adverse drug reactions
3. Write the treatment for fungal and bacterial infections involving skin and mucous membranes
4. Prescribe the steroids rationally

Assessment:

1. Long and Short essay questions
2. Adverse drugs reaction form filling and its evaluation

E) At the end of 07 days posting in Psychiatry the student should be able to

1. Write a prescription for psychiatric conditions - depression, schizophrenia, anxiety
2. Critically evaluate and explain drug interactions of antipsychotics and antidepressants
3. Explain mechanism and advantages of newer antipsychotics and antidepressants
4. Explain the management of drug addiction and drug dependence

Assessment:

1. Long and Short essay questions
2. Patient management problem
3. Subject Seminar using checklist

F) At the end of 07 days posting in Biochemistry the student should be able to

1. Explain the tests used to identify drugs in biological samples (qualitative and quantitative)
2. Explain the principles and use of HPLC, spectrophotometer and colorimeter
3. Interpret blood sugar level, lipid profile, hyperuricemia, thyroid functions, LFT and RFT

Assessment:

1. Long and Short essay questions
2. Subject seminar using checklist

G) At the end of 08 days posting in Microbiology the student should be able to

1. List the common pathogens isolated and their sensitivity pattern and its interpretation
2. Write and explain the life cycle of protozoa and helminthes
3. Explain the principles of ELISA test
4. Explain the procedure for identifying MDR and XDR strains in tuberculosis

5. Prepare a gram stain / Z N stain / hanging drop / KOH mount & interpret the results

Assessment:

1. Long and Short essay questions
2. OSPE : Demonstration of staining the organism and interpreting the findings

H) At the end of 15 days posting in Genome Lab the student should be able to

1. Explain the terminologies used in pharmacogenetics – (DNA, RNA, Proteins and Cytochromes).
2. Explain the use of instruments used in pharmacogenetics (like PCR, DNA sequences; PAGE).
3. Isolate DNA from blood sample.
4. Identify cytochromes involved in drug metabolism using appropriate instruments

Assessment:

1. Long and Short essay questions
2. OSPE: Demonstration of DNA isolation

I) At the end of 15 days posting in Casualty the student should be able to

1. Mention and perform the step wise patient management in poisoning (Organophosphorous, kerosene, scorpion sting, snake bite bee sting, rat poisoning)
2. Record the findings of medico legal case and treat the patients
3. Perform the first aid in road traffic accident patients
4. Treat the emergency conditions like acute gastroenteritis, burns, status epilepticus, pain abdomen
5. Write the referrals to the concerned specialist
6. Monitor the critically ill patients and update to the concerned specialist

Assessment:

1. Long & Short essay questions
2. Patient management problem
3. OSPE: Setting up intravenous infusion of given drug

District Residency Programme (DRP)

All postgraduate students pursuing MD/MS in broad specialities in all Medical Colleges/Institutions under the Indian Medical Council Act, 1956 shall undergo a compulsory residential rotation of three months in District Hospitals / District Health System as a part of the course curriculum. Such rotation shall take place in the 3rd or 4th or 5th semester (Academic term) of the Postgraduate programme. This rotation shall be termed as 'District Residency Programme' (DRP) and the postgraduate medical student undergoing training shall be termed as a 'District Resident'. The DRP will be implemented with the PG (broad specialty) batch joining in 2020.

Pre- and Para-Clinical Specialities: Postgraduate students of pre/para clinical disciplines (namely, Anatomy; Biochemistry; Community Medicine; Forensic Medicine; Microbiology; Pathology; Physiology; and Pharmacology) will be trained

by the District Hospital and Health System teams within the available avenues in coordination with the District Health Officer/Chief Medical Officer. They would be trained in and contribute to the diagnostic/laboratories services, pharmacy services, forensic services, general clinical duties, managerial roles and public health programmes etc., as applicable. They may also be posted in research units / facilities, laboratories and field sites of the Indian Council of Medical Research and other national research organizations.

SCHEDULE OF WORK TIME TABLE

I Year

1st to 3rd month: Search and identification of topic for dissertation in consultation with guide; use of library, Satellite search etc., and preparation of synopsis. Register for online “Basic Course in Biomedical Research.” Attend didactic lectures during first semester for certain topics of importance.

4th to 6th month: Study of methodology of experiments, instruments for experimentation, maintenance of animals, animal lab, analytical chemistry. Submission of synopsis to Academy for registration.

7th to 9th month: Literature survey, preparation of reference cards, collection of relevant literature and journal work.

10th to 12th month: Literature survey, preparation of reference cards, collection of relevant literature and journal work.

Complete online Research Methods course conducted by ICMR-National Institute of Epidemiology (ICMR-NIE), Chennai by the end of 2nd semester.

Apart from this, the students shall attend all the theory classes, practical, student tutorials and other teaching activities. They should also maintain work diary and duly get it signed by Head of the Department.

II Year and III Year

Candidates should do all the experiments mentioned in the course content on weekly basis and also continue the experimental work of the dissertation if any; candidates should participate in seminars, journal clubs on weekly basis and file the seminars done to be presented as a book.

They should undergo training in teaching skills. They should also maintain a daily Log Book of their work in the Department for 3 years.

MONITORING PROGRESS OF P.G STUDENTS

- Work dairy / Log book: Every candidate shall maintain a work diary and record his/her participation in the training programme conducted by the department such as journal reviews, seminars etc. Special mention to be made of the presentations made by the candidate as well as the laboratory experiments conducted. The log book shall be scrutinized and certified by head of department every term (6 months is an Academic term).
- The department will conduct quarterly periodic tests which may include written paper, practical and viva- voce. Timely feedback will be given by faculty regarding their performance. Records and marks obtained in such tests will be maintained by Head of Department and sent to the office of the Principal.

DISSERTATION

- Every candidate is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher. The results of such work shall be submitted in the form of a dissertation.
- The dissertation is aimed to train the candidate in pharmacological research methods and techniques. It includes identification of a problem, formulation of a hypothesis, search and review of relevant literature, getting acquainted with recent advances, designing of research study, collection of data, critical analysis of results and drawing conclusions.
- The dissertation topic has to be registered.
- The dissertation is to be submitted at least six months before the final examination as notified by the Academy to the Registrar (Evaluation).
- The dissertation shall be valued by three examiners. Prior acceptance of the dissertation shall be a precondition for a candidate to appear for the final examination.
- Every candidate should have sent one paper for publication/published one paper and presented atleast one oral paper and one poster in a conference
- Every candidate should complete online Research Methods course conducted by National Institute of Epidemiology of Indian Council of Medical Research by the end of 2nd semester (End of first year)

Evaluation

Theory

There shall be four question papers, each of three hours duration, carrying 100 marks. Each paper shall consist of 10 long essay questions each carrying 10 marks. Questions on recent advances will be asked in paper IV. Details of distribution of topics for each paper will be as follows *:

Type of Question	Number of Questions	Marks for each questions	Total marks
Long Essay	10	10	100

Paper I: General Pharmacology

Paper II: Clinical Pharmacology

Paper III: Systemic Pharmacology

Paper IV: Recent advances in Pharmacology

* The topics assigned to the different papers are generally evaluated under those sections. However a strict division of the subject may not be possible and some overlapping of topics is inevitable. Students should be prepared to answer overlapping topics.

Practical

Practical Examination (Total 200 marks)

Practical to be held on 2 days, along with Viva-Voce.

Experimental Pharmacology I

A. Bioassay 60 marks

3 or 4 point assay using various isolated tissues like rat colon, guinea pig ileum.

B. Effect of drugs on eye 20 marks

(Pilocarpine, Homatropine, Phenylephrine, lignocaine)

Experimental Pharmacology II

Interpretation of Graphs 20 marks

E.g.:

- (i) Recordings of- BP/ RS/ GIT for dog/cat
- (ii) Discussion graphs

Demonstration of Technique 20 marks

Demonstration of any one technique using small animal such as rat/mice/rabbit, Depending on the availability of equipment.

Eg: Oral feeding in rats, intraperitoneal and intravenous drug administration in rats, blood drawing from rat tail vein, catalepsy in rats, sleeping time.

Eg: Straub's tail test, Analgesiometer, Hebb William's Maze, Actophotometer, Effect of pilocarpine in rat eye

Chemical Testing 20 marks

Identification of any one substance by chemical testing for Alkaloids/ Glycosides/Iodides/ Salicylates/ Steroids/Paracetamol/ Doxycycline/Cholorquine, Benzathine Penicillin, Ampicillin of Urine sample for substance of abuse using Spectrophotometer or colorimeter

Clinical Pharmacology I

Discussion in terms of- Rationality/ Appropriateness/ Correctness in Prescribing using a Clinical Case or a Simulated paper case (Clinical problems), Pharmacovigilance, Pharmacoeconomics 15 marks

Clinical Pharmacology II

- **Clinical Trial Protocol Writing/informed consent form writing** 20 marks
- **Pharmacokinetic parameter calculations** 10 marks
- **Critical evaluation of reviewed/ published article in Clinical Pharmacology** 15 marks

Viva Voce (Total 100 marks)

Viva-Voce Examination: 80 Marks

Students will be examined by all the examiners together about students' knowledge and comprehension of the prescribed course contents, analytical approach, expression and interpretation of data, discussion on dissertation.

Pedagogy Exercise: 20 Marks

A topic is given to each candidate along with the Practical Examination question paper on the first day. Student is asked to make a presentation on the topic on the second day for 8 to 10 minutes.

Distribution of marks

M.D. Pharmacology examination	Theory	Practical (200)	Viva-voce (100)	Grand Total
Total	400	300		700
*Passing criteria 50%	200	150		350

***Each paper student has to score 40% to pass and overall 50% in theory.**

Study material

Recommended books

1. Brunton L, Chabner B, Knollman B, Goodman and Gilman's 'The Pharmacological Basis of Therapeutics'. 13th ed. U.S.A: McGraw Hill Publications; 2018.
2. [Katzung BG. Basic and Clinical Pharmacology. 14th ed.](#) U.S.A :McGraw Hill Publications; 2018.
3. Ritter J, Flower R, Henderson G, Loke YK, MacEvan D, Rang H. Rang and Dale's Pharmacology, 9th edition 2019, Elsevier Churchill Livingstone, Elsevier Ltd, Edinburgh.
4. Dollery CT. Therapeutic Drugs. 2nd ed. Edinburgh London: Elsevier Churchill Livingstone; 1999.
5. Vogel GH, Vogel WH. Drug Discovery and Evaluation - Pharmacological assays. 2nd ed. New York: Springer – Verlag Berlin Heidelberg Publication; 2002.
6. Brayfield A. Martindale: The Complete Drug Reference. 39th ed. London: Royal Pharmaceutical Society; 2017.
7. Kulkarni SK. Hand book of Experimental Pharmacology. 4th ed: Vallabh Prakashan; 2012.
8. Perry WLM. Pharmacological Experiments on Isolated Preparations. 2nd ed. Edinburgh London: Churchill Livingstone; 1974.
9. Perry WLM. Pharmacological Experiments on Intact animals. 2nd ed. Edinburgh London: Churchill Livingstone; 1970.
10. Burn JH. Practical Pharmacology. Oxford: Blackwell Scientific Publications; 1956.
11. Gosh MN. Fundamentals of Experimental Pharmacology. 6th ed. Calcutta: Scientific Book Agency; 2015.
12. Smith G. Oxford textbook of Clinical Pharmacology and drug therapy. 3rd ed. New York: Oxford University Press Inc; 2002.
13. Gupta SK. Basic Principles of Clinical Research and Methodology. 1st ed. New Delhi: Jaypee Brothers Medical Publishers; 2007.
14. Gupta SK. Drug Screening methods. 3rd ed: Jaypee Brothers Medical Publishers; 2016.
15. Shargel L. Applied Biopharmaceutics & Pharmacokinetics. 7th ed. USA: McGraw Hill Publications; 2016.
16. Sharma HL, Sharma KK. Principles of Pharmacology. 3rd ed: Paras Medical Publishers; 2017.
17. [Kolesar JM](#), [Burns C](#), [Schwinghammer](#). Pharmacotherapy Principles and Practice. 4th ed. USA: McGraw Hill publication; 2016.

18. R.S. Satoskar, Nirmala N Rege, S.D. Bhandarkar. Pharmacology and Pharmacotherapeutics. 25th Edition, 2017 Single Volume, Elsevier Health Reed Elsevier India Pvt. Ltd. 14th Floor, Building No. 10B, DLF Cyber City, Phase II, Gurgaon (Haryana) India – 122002

Recommended Journals

1. Journal of Pharmacology and Experimental Therapeutics
2. Journal of Pharmacy and Pharmacology
3. Drugs (Monthly Journal published by Adis International)
4. Clinical Pharmacology and Therapeutics
5. Indian Journal of Pharmacology
6. Journal of Pharmacology and Pharmacotherapeutics
7. Annual Review of Pharmacology (last 5 years)
8. Trends in Pharmaceutical sciences
9. Indian Journal of Physiology and Pharmacology
10. New England Journal of Medicine
11. The Lancet
12. Pharmacological Research
13. Pharmacology and Therapeutics

Other Sources

1. Compendium of recommendations of various committee of Health and Development (1943-1975). DGHS, 1985 Central Bureau of Health Intelligence, Directorate General of Health Services, min. of Health and Family Welfare, Govt. of India, NirmanBhawan, New Delhi. P-335
2. National Health Policy, Min. of Health and Family Welfare .NirmanBhawan: New Delhi;2017.
3. Kumar S.The elements of Research, writing and editing, Dept of Urology:JIPMER, Pondicherry;1994
4. Srinivasa DK etal, Medical Education Principles and Practice, 1995. National Teacher Training Centre, JIMPER, Pondicherry
5. Indian Council of Medical Research, “Policy Statement of Ethical consideration involved in Research on Human Subjects”, 2006 , I.C.M.R, New Delhi
6. Code of Medical Ethics framed under section 33 of the Indian Medical Council Act, 1956. Medical Council of India, Kotla Road, New Delhi
7. Francis CM. Medical Ethics.3rd ed. Bangalore: Jaypee Publications; 2008.
8. Indian National Science Academy, Guidelines for care and use of animals in Scientific Research, New Delhi, 1994
9. International Committee of Medical Journal Editors, Uniform requirements for manuscripts submitted to biomedical journals, N Engl J Med 1991;424-8
10. Kirkwood BR, Essentials of Medical Statistics. 2nd ed. Oxford: Blackwell Scientific Publications; 2003.
11. Mahajan BK. Methods in Biostatistics for medical students. 8th ed. New Delhi: Jaypee Brothers Medical Publishers; 2016.

12. Gitanjali RB. A Practical approach to PG dissertation. 2nd ed. New Delhi: Pharma Med Press; 2012.
13. Briggs GG, Freeman RK, Yaffe SJ. Drugs used in Pregnancy and Lactation. 10th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins Health publishers; 2015.
14. Dipiro JT, Talbert RI, Yee GC. Pharmacotherapy: A pathophysiological approach. 10th ed. USA: McGraw Hill Publications; 2017

Entrustable Professional Activity (EPA)

Eight common EPAs*

*Proceedings of 34th Meeting of Academic Council held on 15th November 2019

- EPA 1: Gather a history and perform a physical examination
- EPA 10: Recognize a patient requiring urgent or emergent care and initiate evaluation and management
- EPA 11: Obtain informed consent for tests and/or procedures
- EPA 3: Recommend and interpret common diagnostic and screening tests
- EPA 2: Prioritize a differential diagnosis following a clinical encounter
- EPA: Patient handover
- EPA: Collaborate as a member of inter-professional team
- EPA: Form clinical questions and retrieve evidence to advanced patient care

Five specific EPA to Pharmacology

- Write protocol for conduct of Phase I Clinical trial
- Critical appraisal of a published article
- Identifying the unknown concentration of a given substance using a suitable tissue
- Demonstrate catalepsy in rats
- Obtaining consent from a patient for participation in a clinical trial

Five EPAs specific to Pharmacology

Title of EPA-1	Write protocol for conduct of Phase I Clinical trial
Description of EPA	<p>Postgraduates should be able to plan a protocol for conduct of clinical trial of all phases. Clinical trials are a vital aspect of drug development and approval. Phase 1 study in healthy subjects is to understand the safety and pharmacokinetics of a new compound.</p> <p>Knowledge and skills required include:</p> <ol style="list-style-type: none"> 1. Updated knowledge on changes in the regulatory aspects of clinical trials such as International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)- Good Clinical Practice (GCP) guidelines. 2. Knowledge, understanding, interpretation and application of the data from preclinical studies. 3. Knowledge and application of biomedical research 4. Should be able to write the protocol for phase I clinical trial

Relevant Core Competencies	<ul style="list-style-type: none"> • Clinician- Knowledge, analysis, interpretation of preclinical data • Communicator- Communicate with the peer group • Lifelong learner- Updated information on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)-Good Clinical Practice (GCP) guidelines and biomedical research • Professional - Demonstrates awareness of own limitations, adheres to timeline and considers ethical aspects for conduct of research <p><u>Levels of competence:</u> Level I: Knowledge only; can observe peers at the end of 12 months Level II: Can write under supervision at the end of 24 months Level III: Can write under loose supervision at the end of 30 months Level IV: Can write independently at the end of 32 months Level V: Has expertise to teach others</p> <p>All PGs expected to reach level IV at the end of 3 years</p>
Assessment Methods	<ol style="list-style-type: none"> 1. Documentation of written protocol in practical record 2. Discussion of the same with the moderator and faculty and obtaining feedback 3. Phase I protocol writing exercise in Practical examination (formative and summative)
Title of EPA-2	Critical appraisal of a published article
Description of EPA	<p>Postgraduates should be able to understand and comprehend the articles published in journals. They should be able to identify the merits and limitations of a research article to assess the usefulness and validity of research findings</p> <p>Knowledge and skills required include:</p> <ol style="list-style-type: none"> 1. Choose an appropriate journal article to assess the relevance of a study published 2. Knowledge on the updated guidelines such as Consolidated Standards of Reporting Trials (CONSORT), Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), Quality of Reporting of Meta-Analyses (QUORUM) - Provides a comprehensive framework for assessments of the quality of reporting in meta analyses and systematic reviews, - Assessment tool for appraisal of systematic reviews (AMSTAR), Meta-Analysis Of Observational Studies in Epidemiology (MOOSE) and Animals in Research: Reporting In vivo Experiments (ARRIVE) 3. Interpretation of Introduction, Methodology, Results, Analysis

	<p>and Discussion (IMRAD) for an article.</p> <p>4. Identify and critique on the limitations, conflict of interest, declaration by authors and references</p>
Relevant Core Competencies	<ul style="list-style-type: none"> • Clinician- Knowledge, analysis and interpretation of the articles • Communicator- Communicate with the peer group and faculty • Lifelong learner- Updated information on guidelines on conduct of studies • Professional - Demonstrates awareness of own limitations and publication ethics <p><u>Levels of competence:</u></p> <p>Level I: Knowledge only; can observe peers at the end of 12 months Level II: Can write under supervision at the end of 24 months Level III: Can write under loose supervision at the end of 30 months Level IV: Can write independently at the end of 32 months Level V: Has expertise to teach others</p> <p>All PG expected to reach level IV at the end of 3 years</p>
Assessment Methods	<ol style="list-style-type: none"> 1. Discussion of the published article with the moderator and obtaining feedback 2. Documentation of critique by all faculty in the checklist 3. Critical evaluation of published article in Practical examination (formative and summative)

Title of EPA-3	Identifying the unknown concentration of a given substance using a suitable tissue
Description of EPA	<p>Post graduates should be able to perform bioassay on the animal tissues and calculate the unknown concentration of the drug</p> <p>Knowledge and skills required include:</p> <ol style="list-style-type: none"> 1. Knowledge of anatomy of various organs like heart, small intestine, colon in rat, mice and guinea pig 2. Knowledge on prerequisite of the materials required, procedure for the conduct of the experiment 3. Knowledge and procedure of euthanasia followed by isolation and mounting the tissue 4. Perform bioassay for the given solution of unknown concentration 5. Manage the technical issues faced during experimentation 6. Fix the graph obtained using appropriate fixing solution and interpret the unknown concentration of the drug using

	formula and graphical method
Relevant Core Competencies	<ul style="list-style-type: none"> • Communicator- Communicate with support team and peer regarding the conduct of experiment to resolve the technical issues • Lifelong learner- Updated information of CPCSEA guidelines on animal procurement, handling, conduct of experimentation and MCI guidelines for the use of animals for experimentation. • Professional - Demonstrates the ability to handle the animals with care and minimal pain. Minimum number of animals utilized. <p>Levels of competence: Level I: Knowledge only; can observe at the end of 6 months Level II: Can perform bioassay under supervision at the end of 12 months Level III: Can perform bioassay under loose supervision at the end of 18 months Level IV: Can do independently at the end of 30 months Level V: Has expertise to teach others</p> <p>All PG expected to reach level IV at the end of 3 years</p>
Assessment Methods	<ol style="list-style-type: none"> 1. Documentation of procedure, graph and calculation 2. Direct Observation of Procedural Skills (DOPS) using checklist and feedback by faculty 3. Perform bioassay to determine the concentration of the unknown drug using an appropriate tissue-Practical examination (formative and summative)

Title of EPA-4	Demonstrate catalepsy in rats
Description of EPA	<p>Postgraduates should be able to perform and demonstrate the catalepsy in rats and interpret the results with standard drug.</p> <p>Knowledge and skills required include:</p> <ol style="list-style-type: none"> 1. Knowledge on definition, features, grading and causes of catalepsy in animals. 2. Perform the intraperitoneal injection of drug to induce catalepsy in rat and monitor the features and record the time of onset and recovery 3. Report on the experiment conducted
Relevant Core Competencies	<ul style="list-style-type: none"> • Communicator- Communicate with support team and peer regarding the conduct of experiment to resolve the technical issues • Lifelong learner- Updated information of CPCSEA guidelines on animal procurement, handling, conduct of experimentation and MCI guidelines for the use of animals

	<p>for experimentation.</p> <ul style="list-style-type: none"> Professional - Demonstrates the ability to handle the animals with care and minimal pain. Minimum number of animals utilized <p><u>Level of competence:</u> Level I: Knowledge only; can observe at the end of 6 months Level II: Can perform under supervision at the end of 12 months Level III: Can perform under loose supervision at the end of 24 months Level IV: Can do independently at the end of 30 months Level V: Has expertise to teach others</p> <p>All PG expected to reach level IV at the end of 3 years</p>
Assessment Methods	<ol style="list-style-type: none"> Documentation of procedure and report Direct Observation of Procedural Skills (DOPS) using checklist and feedback by faculty Demonstrates catalepsy in rats for the given drug -Practical examination (formative and summative)

Title of EPA-5	Obtaining consent from a subject/patient for participation in a clinical trial
Description of EPA	<p>Postgraduates should be able to prepare the informed consent form and subject/patient information sheet. Explain the same to them and obtain written informed consent from them.</p> <p>Knowledge and skills required include:</p> <ol style="list-style-type: none"> Knowledge on the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)-Good Clinical Practice and ICMR Ethical guidelines for Biomedical research on human participants Preparation of informed consent form and subject/patient information sheet for the given study protocol Perform the process of obtaining informed consent for a trial from a participant and document
Relevant Core Competencies	<ul style="list-style-type: none"> Clinician- Knowledge and skill to obtain consent Communicator- Communicates the information to the trial participant and obtains written informed consent. Communicates effectively with family members, when applicable Lifelong learner- Updated information on International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)-Good Clinical Practice and ICMR Ethical guidelines for Biomedical research on

	<p>human participants</p> <ul style="list-style-type: none"> Professional - Demonstrates empathy and ethics during the process of obtaining consent. The needs of subject/patient are given priority with due concern. <p><u>Levels of competence:</u> Level I: Knowledge only; can observe at the end of 6 months Level II: Can perform under supervision at the end of 12 months Level III: Can perform under loose supervision at the end of 24 months Level IV: Can do independently at the end of 30 months Level V: Has expertise to teach others</p> <p>All PG expected to reach level IV at the end of 3 years</p>
Assessment Methods	<ol style="list-style-type: none"> 1. Prepare informed consent form and subject/patient information sheet for the given study protocol 2. Documentation of the written informed consent form 3. Direct Observation of Procedural Skills (DOPS) using checklist and feedback by faculty (formative and summative assessment)

