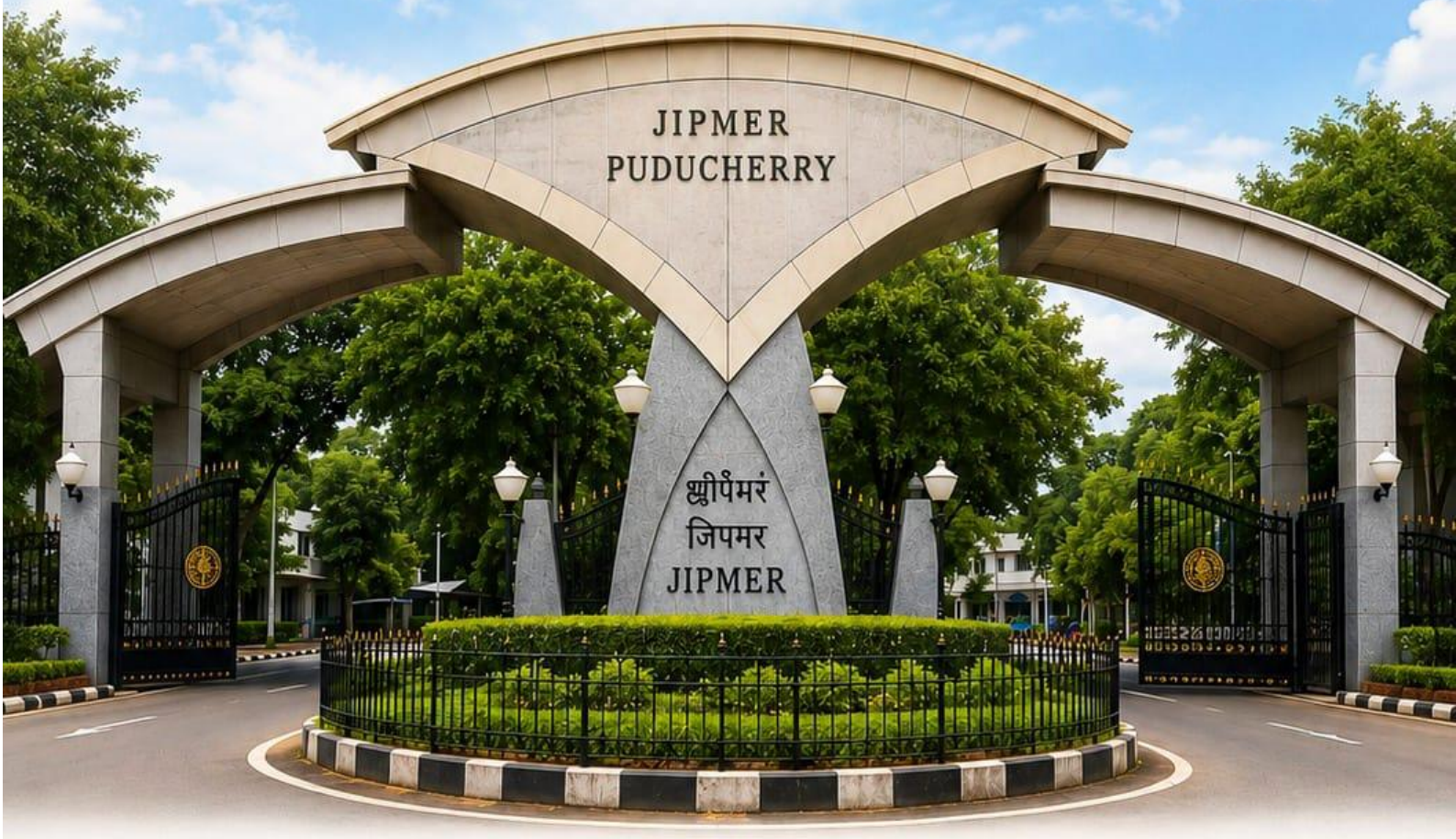
# CURRICULUM

# POSTGRADUATE

## MD Pharmacology

From July 2026 session




JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION AND RESEARCH (JIPMER),
PUDUCHERRY – 605 006.

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This curriculum was approved at the 19th meeting of the Standing Academic Committee held on 28th January 2026 and ratified at the 22nd meeting of the Governing Body and will be applicable for students joining MD Pharmacology from the July 2026 session.

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## GOAL OF THE COURSE

To create pharmacologists who can teach Pharmacology for undergraduate students, facilitate drug discovery and development, conduct research relevant to the societal needs and provide patient care services.

## TERMINOLOGY

### Key-capabilities

They refer to the practices carried out by the specialists as part of their professional services. They represent the services required from them, by patients, students, other medical/paramedical staff or the society in general. Thus, they refer to the specific tasks that the postgraduate will be expected to do after he completes the course.

For the purpose of training, the tasks are broken down into units that have distinct cognitive concepts, unless they are predominantly procedural, or attitude based.

### Core ideas in practice of Key-capabilities

They refer to the ideas that underlie the practice of the specialists. They include ideas and concepts about structure and functioning of organs and organ systems in health and diseases, classification of diseases, equipment, tests, drugs etc.

## COURSE CONTENT

1. Key-capabilities in the practice of Pharmacology (outline below, details in Annexure 1 (Part A))
2. Core ideas in the practice of key-capabilities (outline below, details in Annexure 1 (Part B))
3. Peripheral postings, details in Annexure 1(Part C) and under 'Educational strategy'

**(Please refer Annexure 1 for details)**

**OUTLINE**

| **KEY CAPABILITIES** | |
|---|---|
| 1 | Clinical Pharmacology skills |
| 2 | Skills in drug development process |
| 3 | Skills in analytical techniques |
| 4 | Animal experimentation skills |
| 5 | Skills in pharmacokinetics and BA/BE studies |
| 6 | Evaluating drug quality as per pharmacopoeia standards |
| 7 | Teaching/Learning skills |
| 8 | Skills in bioethics, GCP and Regulatory guidelines |
| 9 | Skills in Research methodology & statistics |
| 10 | Scientific communication skills |
| 11 | Pharmacoeconomics |
| 12 | Drug Inventory management |
| Learning objectives for key-capabilities | |

## LEARNING RESOURCES

### General Pharmacology & Allied Sciences

• Brunton LL, Knollmann BC. Goodman and Gilman's The Pharmacological basis of therapeutics. (14thedition/latest). McGraw Hill Education;2022

• James M Ritter, Rod Flower, Graeme Henderson, Yoon Kong Loke, David MacEwan, Ema Robinson, et al: Rang & Dale's Pharmacology; 10th edition/latest: Elsevier (2023)

• Murray P. Ducharme, Leon Shargel: Shargel and Yu's Applied biopharmaceuticals and pharmacokinetics. (8th edition/latest) McGraw Hill (2022).

• Hartmut Derendorf, Stephan Schmidt: Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics Concepts & Applications. (5th edition / latest) Wolters Kluwer (2019).

• Katzung BG, Todd W Vanderah: Basic and Clinical Pharmacology (15thediti on/latest). McGraw-Hill Education; (2021).

• Forman JC & Johansen TJ, Alasdair J. Gibb: Textbook of receptor pharmacology. (3rd edition/latest). CRC Press (2011).

• David Grahame Grahame-Smith, J. K. Aronson: Oxford Textbook of Clinical Pharmacology and Drug Therapy. (3rd edition/latest). Oxford (2002)

• Morris J. Brown, Pankaj Sharma, Fraz A. Mir, Peter N. Bennett: Clinical Pharmacology: (12th edition/latest) Elsevier (2018)

• Craig W. Stevens: Brenner and Stevens' Pharmacology: (6th edition/latest) Elsevier (2022)

• David E Golan: Principles of Pharmacology: (4th edition / latest) Wolters Kluwer (2016)

### Clinical Pharmacology & Therapeutics

• Joseph Loscalzo, Anthony Fauci, Dennis Kasper, Stephen Hauser, Dan Longo, J. Larry Jameson: Harrison 's Principles of Internal Medicine. (21st edition/latest) McGraw Hill volume I & II (2022)

• Shiew-Mei Huang, Juan J.L. Lertora, Paolo Vicini, Arthur J. Atkinson Jr : Atkinson's Principles of Clinical Pharmacology(4th edition/latest). Science Direct (2021)

• Richard A. Helms, David J. Quan: Textbook of Therapeutics Drugs and Disease Management. (8th edition/latest) Lippincott Williams & Wilkins (2006).

• Joseph T. DiPiro, Gary C. Yee, Stuart T. Haines, Thomas D. Nolin, Vicki L. Ellingrod, L. Michael Posey: DiPiro's Pharmacotherapy – A pathophysiological approach. (12th edition / latest) McGraw Hill (2023).

• Caroline S. Zeind, Michael G. Carvalho: Applied therapeutics - The Clinical Use of Drugs. (11th edition / latest) Wolters Kluwer (2017).

• Avery 's Drug Treatment. (4th edition / latest) Eds. Speight TM & Holford NHG. AdisInternational Ltd (2012)

• Chow SC & Liu JP: Design and analysis of clinical trials – concepts & methodologies. (3rd edition / latest) Wiley (2013)

**Research Methodology & Statistics**

• Geoffrey R. Norman (Author), David L. Streiner: Biostatistics: The Bare Essentials: (3rd edition / latest) McGraw Hill (2008)

• David Bowers: Medical Statistics from Scratch: An Introduction for Health Professionals, (4th Edition/latest): Wiley (2019)

• Michael J. Campbell: Statistics at Square One: (12th Edition/latest) : Wiley Blackwell (2021)

• R.Raveendran, B.Gitanjali, and S.Manikandan; A Practical Approach to PG Dissertation. (2nd edition/latest) BSP Books (2019)

**Experimental Pharmacology**

• Franz J Hock: Vogel's Drug discovery and evaluation – Pharmacological assays. (4th Edition/latest). Springer (2015).

• Ghosh MN. Fundamentals of experimental pharmacology. (7th edition/latest) Hilton And Company (2019).

• Ashutosh Kar: Pharmacognosy and Pharmacobiotechnology. (3rd edition/latest) New Age International Publishers – 2017.

• N.S. Parmar (Author), Shiv Prakash: Screening Methods in Pharmacology; (1st Edition/latest) Alpha Sciences (2006)

• S K Gupta: Drug Screening Methods: (3rd Edition/latest). Jaypee (2016)

• Marsha Ford, Kathleen A. Delaney, Louis Ling, Timothy Erickson: Clinical Toxicology (2001)

• Anthony C. Moffat, M. David Osselton, B. Widdop, Jo Watts: Clarke ‘s Analysis of Drugs and Poisons. (4th edition/latest) volume 1 & 2. Pharmaceutical Press (2011)

• Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch: Practical HPLC Method Development: (2nd edition/latest). Wiley (1997)

**JOURNALS TO BE REFERRED**

- Annual Review of Pharmacology and Toxicology
- Annals of Pharmacotherapy
- Drugs
- Clinical Pharmacology and Therapeutics
- Drug and Therapeutics Bulletin
- British Journal of Pharmacology
- British Journal of Clinical Pharmacology
- Fundamental and Clinical pharmacology
- Journal of Pharmacology and Experimental Therapeutics
- European Journal of Clinical Pharmacology
- Pharmacogenomics Journal
- Pharmacogenetics and Genomics
- Pharmacological Reviews
- Trends in Pharmacological Sciences
- Journal of Ethnopharmacology
- Journal of Pharmacology and Pharmacotherapeutics
- Nature review Drug Discovery
- Science
- Indian Journal of Pharmacology
- Pharmacology Research & Perspectives

## EDUCATIONAL STRATEGY:

**Academic Discussion**

| Academic activity | Day | Timings |
|---|---|---|
| Subject reviews | Saturday | 11 am to 1.00 pm |
| Journal club | Tuesday | 9 am to 10.30 am |
| Clinical case presentation | Tuesday | 9 am to 10.30 am |
| Pedagogy | Saturday | 11 am to 1.00 pm |
| Podium / Professional opinion presentation | Tuesday | 9 am to 10.30 am |
| Debate | Saturday | 11 am to 1.00 pm |
| What's new in the journal this month? | Tuesday | 9 am to 10.30 am |
| PG Modules | Tuesday/ Saturday | 9 am to 10.30 am / 11 am to 1.00 pm |

**Postings:**

The postgraduate residents will be posted in different workplaces of the department and other allied departments on rotation at frequent intervals throughout the course. He/she will achieve the objectives of the posting in all these workplaces.

- Therapeutic drug monitoring (TDM) lab, Department of Pharmacology
- Clinical pharmacology lab, Dept. of Clinical Pharmacology
- ADR Monitoring centre, Dept. of Clinical Pharmacology
- Drug analysis lab, Dept. of Pharmacy
- Internship/Training in Pharmaceutical industry (Optional)

**Posting (in months):**

| Semester | Therapeutic drug monitoring (TDM) | Drug Analysis Lab (DAL) | Clinical Pharmacology (ADR Monitoring and Clinical pharmacology lab) |
|---|---|---|---|
| 1 | | | |
| 2 | 2 | | 2 |
| 3 | 2 | 2 | 2 |
| 4 | 2 | 2 | 2 |
| 5 | 2 | 2 | |
| 6 | | | |

**Posting & Objectives:**

| Posting | Objectives |
|---|---|
| Therapeutic drug monitoring (TDM) | Describe the principle involved in HPLC/UPLC method of estimation of drug levels<br>Identify the parts and describe the function of HPLC/UPLC instrument<br>Independently run and determine the concentration of drug in plasma<br>Do trouble shooting as required<br>Interpret the results & be able to guide management of patient care<br>Reporting of results in HIS |
| Drug Analysis Lab (DAL) | Describe the principle involved in HPLC/UV Spectrophotometer method of estimation of drug levels<br>Identify the parts and describe the function of HPLC/ UV Spectrophotometer instrument<br>Independently run and determine the purity of the drug<br>Do trouble shooting as required<br>Interpret the results & be able to establish quality standards |
| Clinical Pharmacology | Identify the parts and functions of each instrument in Clinical Pharmacology lab<br>Independently use and troubleshoot each instrument appropriately for its function<br>Interpret the results<br>Perform pharmacodynamic exercises with all equipment in Clinical Pharmacology lab<br>Design clinical trial protocol for phase I, II, III, IV trials<br>Perform simple, block and stratified randomization |

| | |
|---|---|
| | Follow GCP, recent regulatory and ethical guidelines while doing clinical research<br>Screen healthy volunteers for phase 1 study<br>Design and conduct a single dose pharmacokinetic study<br>Write SOP for a given activity. |
| ADR Monitoring centre | Promote awareness of ADR monitoring service in JIPMER<br>Respond to spontaneous reporting of ADR and filling up of ADR form<br>Do active surveillance to study a drug/ADR in hospital setting<br>Do assessments of ADRs<br>Report ADRs to Vigibase using the software |
| Internship/Training in Pharmaceutical industry* | To gain practical experience in different domains of pharmaceutical industry practices (Research & development, Clinical product development, Pharmacovigilance, Data analytics, Medical writing, etc., )<br>*Internship/Training in Pharmaceutical industry for a period of 2-3 weeks may be allowed for interested residents. |

**Dissertation**

- A research project should be undertaken and dissertation must be submitted as per Postgraduate Research Monitoring Committee (PGRMC) guidelines of JIPMER.
- Two hard copies of the dissertation, prepared from the research project, should be submitted to the Dean (Academics) JIPMER, at two and half years of the course to become eligible to appear for the final examination at the end of the course, as per the guidelines of JIPMER.
- Six monthly interim presentations of the dissertations will be done to monitor the progress of the research work and take corrective measures when faced with difficulties.
- **Please refer to Postgraduate Dissertation Regulations and Postgraduate Examination Regulations document for further details**

## WORKPLACE OBSERVATION

### Logbook

1. A consolidated record of the number of experiments, done independently and with assistance, of each procedure type is entered. Each entry is made with date and is to be certified by faculty.

2. Detailed work-up of cases selected every month from postings will be maintained by the resident and entered in the logbook.

3. Record of academic activities (at department, institute or outside institute level) to be entered in the logbook are as following

i. Presentation in departmental seminars

ii. Presentations in journal clubs presented (with Title, Journal & Article reference)

iii. Conferences attended – National/International

iv. Papers presented at conferences with title, name of the conference, date of presentation (with abstract book)

v. Papers published in journal (with article reference)

vi. Peripheral postings : Feedback forms/score sheet filled by faculties in other departments during the peripheral posting

4. Record of co-scholastic activities, if any

### Workplace observation scheme

**(Please refer Annexure 3 for sample forms)**

The day to day activities in practice and learning by the resident will be observed and recorded in the "workplace observation form", at pre-decided time instances.

Assessment of logbook is to be done at the same time instances, and entry made in the 'workplace observation form' by the faculty.

Feedback, as part of formative assessment is given to residents, by faculty, during these time instances

**ASSESSMENT**
**Marks**

| Exam | Marks | Description |
|---|---|---|
| Theory exit examination | 400 marks | This is the written exam at the end of the course. Four theory examination papers as given in the curriculum document of the course. |
| Practical exit exam | 400 marks | This is the practical examination at the end of the course. The detailed scheme is given in the curriculum document of the course. |
| Internal Assessment | Internal assessment Theory: 50 marks | Two exams should be conducted - one at the end of first year and the other at the end of second year.<br><br>Portions for the examination and pattern of the examination must be notified to the students at least one month in advance.<br>The pattern of the internal assessment test will be similar to one paper of the theory exit examination.<br><br>Two faculty members will evaluate the paper of each candidate in a blinded manner and the average of the 2 scores will be taken as the final score for the internal assessment. If a resident misses one of the tests due to medical reasons (medical certificate from a faculty member of the treating department and duly forwarded by the HoD to the Dean (Academic)), he/she can be permitted to appear in the test that is held for the next batch 6 months later. This can be permitted only once in the course period. If a resident does not attend an internal assessment test, or if he/she fails to attend the rescheduled test due to medical reasons, the score will be considered as 0 for the test. No retests or re-evaluation will be permitted under any circumstances.<br><br>The internal assessment marks should be communicated to the students within two months of conducting the exams.<br><br>Internal assessment test marks will be added to the final aggregate to the tune of 100 marks (theory and practical). There is no cut off of internal assessment test scores for determining eligibility to appear in the exit examination or to decide pass/fail solely based on the internal assessment test scores.<br><br>However, when a student secures less than 50% marks in the internal assessment or when any |

| | | |
|---|---|---|
| | | concern is formally raised by the student with the Dean office, a review board with at least 3 faculty members should be constituted to review the student's performance with the student, recommend appropriate remedial measures, document the remedial plan, and submit a signed copy of the document to the Dean's Office.<br><br>Additional periodic assessments can be held as part of formative assessment. Scores of these tests will not be considered for internal assessment and will not be considered for replacing scores of any of the internal assessment tests.<br><br>Information to be provided to the Dean Office, before the final examination.<br>1. Dates of internal assessment examinations conducted<br>2. Names of faculty members involved in assessment against each date<br>3. Marks obtained by students in theory, practical and workplace-based observation in each exam session<br>4. Internal assessment marks for each student for Theory, Practical and Workplace based assessment. An average of the two theory and practical tests will be used to calculate scores for 50 and 25 marks respectively. Cumulative workplace-based assessment scores will be determined for 25 marks.<br>5. Copy of review documentations for periods of low performance of a student, if any, with remedial measures suggested by the departmental committee. |
| Internal Assessment (Practical and Workplace-based assessment) | Internal assessment Practical: 25 marks<br><br>Internal assessment Workplace-based assessment: 25 | For practical examinations, all members of the faculty of the department, from Assistant Professor to the senior-most faculty, shall participate in internal assessment on a rotating basis. The assessment shall be planned such that multiple faculty members are engaged for each student and different faculty members are engaged for the two assessments, wherever feasible. The pattern prescribed in the curriculum document shall be followed for practical assessments and the score shall be adjusted for 25 marks.<br><br>Workplace-based assessment marks are given based on practice of the profession and affective domain attributes in the workplace and in the learning environment.<br>Workplace observation proforma should be |

| | | |
|---|---|---|
| | marks | provided to students at the time of joining the department.<br>The method of workplace observation should be explained to the students at the beginning of the course. |
| Dissertation | 100 marks | Dissertation marks will be calculated by the average of the scores provided by 2 external examiners.<br>Approval of the dissertation with more than 50% scores awarded by the external examiners will be one of the eligibility criteria for appearing for the exit examination of the discipline. |
| Total | 1000 marks | **Criteria for PASS:**<br>1. (a) A candidate will need to pass the final Theory Exit Exam and Practical Exit Exam independently. (b) A minimum of 50% marks in 'Theory Exit exam' (a minimum of 40% in each of the four papers) and 50% in 'Practical Exit exam' separately shall be mandatory<br>2. A candidate should also score 50% or above in the final aggregate marks (500 out of 1000) to pass in the degree course.<br>If a student secures a pass score in theory and practical examination but fails in the aggregate score, he/she can re-appear in the exit examination of the subsequent session. There is no provision to improve internal assessment or dissertation scores. |
| **Please refer to Postgraduate Examination Regulations document for further details** | | |

**Syllabus for Exams**

**Sessional & Send up exam schedule & portions (provisional, to obtain final schedule from Department)**

**First Sessional Examination**

To be held at the end of the first year

Theory Paper (UG Paper I & II)

Practical Examination (CAL, Demonstration of simple lab techniques (OSPE) & Analytical experiments – Identification of drug poisoning, barbiturates & alkaloids, paper & thin layer chromatography, study of bioavailability, estimation of sodium salicylate concentration)

**Second Sessional Examination**

**To be held in the mid of the second year**

Theory Papers (Paper I – General Pharmacology & Allied Sciences & Paper III – Experimental Pharmacology, Drug Evaluation, Research Methodology, and Biostatistics)

Practical Examination (Bioassay, Drug assay, Statistics, Protocol writing, Pedagogy, Podium presentation, Critical appraisal, Demonstration of simple lab techniques (OSPE), Pharmacokinetic/Pharmacoeconomics exercise, Viva)

**Third Sessional Examination**

To be held at the beginning of the third year

Theory Paper (Paper II – Systemic Pharmacology & Paper IV – Clinical Pharmacology & Recent advances in Pharmacology)

Practical Examination (Bioassay, Drug assay, Statistics, Protocol writing, Pedagogy, Podium presentation, Critical appraisal, Demonstration of simple lab techniques (OSPE), Pharmacokinetic/Pharmacoeconomics exercise, Viva)

**Send up Examination**

Theory Paper (Papers I, II, III, IV)

Practical Examination (Bioassay, Drug assay, Statistics, Protocol writing, Pedagogy, Podium presentation, Critical appraisal, Demonstration of simple lab techniques (OSPE), Pharmacokinetic/Pharmacoeconomics exercise, Viva)

**Theory Exit Exam**

Written exam is conducted in the following four papers,

Paper – I General Pharmacology and allied sciences

Paper – II Systemic Pharmacology

Paper - III Experimental Pharmacology, Drug Evaluation, Research methodology and Biostatistics

Paper - IV Clinical Pharmacology and Recent advances in Pharmacology

**Practical Exit Exam (To be conducted over two days)**

Bioassay – 100marks

Drug assay- 60 marks

Demonstration of simple lab techniques (OSPE) / Calculation of Pharmacokinetic parameters / Pharmacoeconomic exercise – 40 marks

Protocol writing – 25 marks

Pedagogy – 15 marks

Podium presentation / Professional opinion– 10 marks

Critical appraisal of research paper– 25 marks

Statistical exercises – 25 marks

Viva – 100 marks

**Broad Topics for Theory Question Paper Setting**

*Paper 1 - General Pharmacology and Allied Sciences*

1. **Allied Sciences** – 3 questions

   i. Physiology / Pathophysiology, molecular biology, genetics and bioinformatics

   ii. Biochemistry, Immunology, hematology

   iii. Microbiology – life cycle of virus / parasites, antimicrobial susceptibility testing

   iv. Biotechnology, computer applications

2. **Pharmacokinetics** – 2 questions
   i. Basic Pharmacokinetics
      a. Compartment models
      b. Dose optimization – loading dose, maintenance dose

      ii. Population Pharmacokinetics (PKPD Modelling)

      iii. BA/BE studies

3. **Pharmacodynamics** – 2 questions
   i. Types, structure, location and functions of major types of receptors
   ii. Receptor theory, quantifying the affinity and response of agonist, antagonist and partial agonist
   iii. Membrane transporters
4. **Pharmacovigilance** – 1 question
   i. Types of ADR, causality assessment
   ii. Spontaneous reporting, Pharmacovigilance Program of India

iii. Data mining, Signal detection

iv. Monitoring of ADR – Postmarketing surveillance, Regulatory requirements – Periodic safety update reports (PSUR), Prescription event monitoring (PEM)

5. **Miscellaneous topics** – 2 question

i. Rational use of medicines and antibiotics, EML, P drug concept, drug utilization studies

ii. Adherence, fixed dose drug combinations, drug interactions,

iii. Drug promotion

*Paper 2 - Systemic Pharmacology*

Autonomic nervous sytem – 1 question

Cardiovascular system – 1 question

Blood and autacoids – 1 question

Central nervous system – 1 question

Anaesthetics, Antipsychotics and antidepressants – 1 question

Endocrine – 1 question

GIT, RS & Dermatological disorders – 1 question

Chemotherapy Part 1 (Antibacterials) – 1 question

Chemotherapy Part 2 – 1 question

Heavy metal poisoning, drug overdosing, ANS, CVS, Blood & autacoids, CNS, Endocrine – 1 question from any one of these without overlap

*Paper 3 - Experimental Pharmacology, Drug Evaluation, Research Methodology and Statistics*

1. **Experimental Pharmacology** – 3 questions

i. Experimental animals, handling of small laboratory animals, animal house

ii. Basic experimental techniques – in-vitro / isolated tissue, ex-vivo and in-vivo

iii. Newer experimental techniques – radioligand binding, patch clamp, organ / cell culture

iv. Animal ethics, CCSEA guidelines, euthanasia, alternatives to animal experimentation

2. **Drug Evaluation** – 3 questions

iv. Animal models for evaluation of drugs – 2 questions

c. CVS, GIT, RS, Blood and chemotherapy – 1 question

d. CNS, endocrine and genitourinary – 1 question

ii. Toxicity studies (acute, subacute and chronic)

iii. Special toxicity testing – mutagenicity, carcinogenicity, reproductive organs toxicity, ophthalmic, dermal and pulmonary toxicity studies

3. **Research methodology and statistics** – 4 questions

i. Research methodology – 2 questions

ii. Statistics – 1 question

iii. Research ethics (human) and publication ethics – 1 question

*Paper 4 - Clinical Pharmacology and Recent Advances*

1. **Core Clinical Pharmacology** – 2 questions

i. Pharmacoepidemiology

ii. Pharmacoeconomics

iii. Medication safety

iv. Medication use in children, pregnancy, elderly and disease states (renal / hepatic disease)

2. **Clinical trials** – 3 questions

i. Design and conduct of different phases and types of clinical trials

ii. Regulatory approval – US FDA, EMA, India

3. **Therapeutics** – 2 questions

i. Treatment of common diseases

ii. Application of pharmacological principles in therapeutics

iii. (Latest) standard treatment guidelines of common diseases

4. **Recent advances** – 2 questions
    i. New drugs
    ii. New devices, newer methods / strategies for treatment, technological improvements
5. **Critical thinking in clinical pharmacology** – 1 question
    i. Debating a dilemma
    ii. Articulating pros and cons
    iii. Identifying novel creative ways to solve a therapeutic problem

# MODEL THEORY QUESTION PAPERS

## M.D. DEGREE EXAMINATIONS - PHARMACOLOGY

### Paper I- General Pharmacology and Allied Sciences

**Time: Three Hours** **Maximum Marks: 10*10=100**

**Answer ALL Questions**

1 Explain the two-state receptor model with a schematic diagram. Explain how agonist and antagonist affect this model.

2. Describe the structure, types, location and functions of potassium channels. Explain how drugs affect these channels.

3. Define receptor desensitisation with an example. Explain how receptor desensitisation affects the action of agonist and antagonist.

4. Explain the design, timing of sample collection and conduct of bioavailability / bioequivalence studies.

5. Enumerate the drugs with delayed onset of action. Explain the mechanisms underlying this effect with an example for each.

6. Explain the objectives, timelines for submission and content of a periodic safety update report (PSUR). How are these reports analysed?

7. Illustrate the drug use evaluation (DUE) cycle with a neat diagram and explain the steps with an example.

8. Mention the physiological body fluid compartments. State the contribution of each compartment to the body weight. Explain how changes in these compartments affect drug action and kinetics.

9. Explain how gene silencing can be accomplished with drugs.

10. Think critically and suggest novel and creative ways to overcome the challenges in substituting animal meat with cell cultivated meat for consumption.

**M.D. DEGREE EXAMINATIONS - PHARMACOLOGY**
**Paper II- Systemic Pharmacology**

**Time: Three hours** **Maximum Marks: 10*10=100**

**Answer ALL Questions**

1. Define auto receptors and heteroreceptors with an example. Explain how drugs modulate these receptors.

2. Mention the groups of drugs that are considered as four pillars in the management of heart failure. Explain how each group is beneficial in heart failure.

3. Should fortification of iron in food (wheat, rice) be continued? Support the answer with reasons and evidence.

4. What is meant by sequential nephron blockade and braking effect of diuretics? What are the clinical implications of these phenomena?

5. Enumerate the drugs that inhibit the degradation of neurotransmitters in the central nervous system. Explain their mechanism of action and uses.

6. Describe the role of serotonin in major depression and explain the action of various groups of drugs affecting serotonin that are used in major depression.

7. Which is the preferred reliever for treatment of bronchial asthma? Why is it the preferred? Explain the two different tracks for treatment of bronchial asthma.

8. Debate the points, for and against the argument “sodium glucose cotransporter 2 (SGLT2) inhibitors are the statins of the 21st century.

9. Enumerate the reserve antibiotics and explain the antimicrobial stewardship program.

10. Illustrate the phases of a cell cycle with a diagram. Explain the mechanism of action of the various cell cycle specific anticancer agents.

## M.D. DEGREE EXAMINATIONS - PHARMACOLOGY

### Paper Ill-Experimental Pharmacology, Drug Evaluation, Research Methodology and Biostatistics

**Time: Three hours** **Maximum Marks: 10*10=100**

**Answer ALL Questions**

1. Explain the animal models for evaluation of an antihypertensive agent.

2. Explain the acute toxicity testing of a new chemical entity.

3. Describe the various animal models for evaluation of a new compound with antidepressant effect.

4. Explain the principle, experimental setup, configurations and applications of patch clamp technique.

5. Explain the principles, instrumentation and applications of spectrophotometer.

6. Explain the recommended methods for euthanasia of small laboratory animals.

7. Differentiate:

a. PubMed and PubMed Central

b. Allocation concealment and blinding

8. Explain the criteria, principle, assumptions and interpretation of Chi square test. What should be done if assumptions are violated?

9. When is deception in research justified? Explain how consent should be obtained for such studies.

10. Substantiate the points, for and against the idea of issuing an unique identification number for all medical researchers globally and linking their publications to this number.

**M.D. DEGREE EXAMINATIONS – PHARMACOLOGY**

**Paper IV-Clinical Pharmacology and Recent Advances in Pharmacology**

**Time: Three hours** **Maximum Marks: 10*10=100**

**Answer ALL Questions**

1.Explain the objectives, design, conduct and advantages of phase 0 clinical trials.

2.What is meant by prescription event monitoring? Explain how it is conducted.

3.Explain the different types of cost with an example. Describe the various methods for calculation of cost.

4.How do biosimilars differ from generic drugs? Explain the regulatory requirements for approval of a biosimilar in India.

5.Define master protocols. Explain the types of master protocols with an illustration for each.

6.Enumerate the factors that can increase the risk for medication errors. Suggest strategies to overcome these.

7. Explain the standard treatment guidelines for malaria. Mention the current recommendation for malaria vaccine.

8. Explain the recommended regimens for eradications of Helicobacter pylori (H pylori) infection. Describe the newer regimens for H pylori infection.

9. Explain the pharmacological actions and uses of:

a) Neurokinin 3 receptor antagonist.

b) Hypoxia inducible factor prolyl hydroxylase (HIF PH) inhibitor.

10. Think critically and suggest novel and creative ways to improve the number of patient led clinical trials conducted in India.

# Annexure 1 (Part A)

**Levels of performance:** 1-knows; 2-can do with strict supervision; 3- can do with loose supervision; 4-can do independently; 5-can teach

| No. | Key capabilities | Minimum expected performance at months | | | | | |
|---|---|---|---|---|---|---|---|
| | | 6 | 12 | 18 | 24 | 30 | 36 |
| 1 | **Clinical Pharmacology skills** | | | | | | |
| | **Rational use of medicines**<br>**Identify irrational use of medicines and to devise strategies to improve rational use of medicines.** | **1** | **2** | **2** | **3** | **3** | **4** |
| | Devise strategies to detect irrational use of medicines using WHO core indicators and follow steps of evidence based medicine | **1** | **2** | **2** | **3** | **3** | **4** |
| | **Antimicrobial stewardship**<br>**Coordinate in the AMSP activities for the hospital and work with faculty of other departments** | 1 | 2 | **2** | **3** | **3** | **4** |
| | **Pharmacovigilance activities**<br>**Actively involved in ADR reporting in vigiflow and causality assessment of ADRs** | 1 | 2 | **2** | **3** | **4** | **4** |
| | **Clinical trials**<br>**Train in designing, conduct and reporting of different phases of clinical trials such as phase 0, 1, 2, 3** | | 1 | **2** | **3** | **3** | **3** |
| | **Clinical pharmacology experiments**<br>**Perform cardiovascular system assessment by using periscope for arterial stiffness measurement.**<br>**Perform respiratory system assessment by spirometry**<br>**Perform cardiopulmonary exercise testing.** | | **1** | **2** | **2** | **3** | **3** |
| | **Medication adherence**<br>**To measure medication adherence and identify the various factors affecting it** | **1** | **2** | **2** | **3** | **3** | **4** |
| 2 | **Skills in drug development process** | | | | | | |
| | Perform molecular docking using software | | **1** | **2** | **2** | **3** | **3** |
| 3 | **Skills in analytical techniques** | | | | | | |
| | Quantify the drug concentration in the given solution using colorimeter | **1** | **2** | **2** | **3** | **4** | **5** |
| | Perform assays for quantifying the unknown drug concentration in the given solution using UV-Visible spectrophotometry | **1** | **2** | **2** | **3** | **4** | **5** |
| | Detect the presence of drug in the given test sample using Paper/Thin layer chromatography techniques | **1** | **2** | **2** | **3** | **4** | **5** |
| | Detect the presence of common poisonous drug in the given test sample using chemical assays | | | | | | |
| | Monitor the therapeutic concentration of antiepileptics in blood using High Pressure Liquid chromatography (HPLC) | | **1** | **2** | **2** | **3** | **3** |
| | Monitor the therapeutic concentration of immunosuppressants in blood using Liquid chromatography-mass spectrophotometry (LC-MS/MS) | | **1** | **2** | **2** | **3** | **3** |
| | Extract the nucleic acids using molecular techniques and quantify them using spectrophotometer | | **1** | **2** | **2** | **3** | **3** |

| No. | Key capabilities | Minimum expected performance at months | | | | | |
|---|---|---|---|---|---|---|---|
| | | 6 | 12 | 18 | 24 | 30 | 36 |
| | Perform advanced molecular techniques like genotyping and gene expression using Real Time - Polymerase Chain Reaction (RT PCR) | | 1 | 2 | 2 | 2 | 2 |
| 4 | **Animal experimentation skills** | | | | | | |
| | Design a protocol for conducting animal research | 1 | 1 | 2 | 3 | 2 | 2 |
| | Demonstrate the handling of small laboratory animals (mice, rats, rabbits and guinea pigs) | 1 | 1 | 2 | 3 | 4 | 4 |
| | Collect blood from various routes in small laboratory animals (mice, rats and rabbit) | | 1 | 2 | 3 | 4 | 4 |
| | Administer drugs in small laboratory animals by various routes (oral, subcutaneous, intraperitoneal and intravenous) | | 1 | 2 | 3 | 4 | 4 |
| | Evaluate the effect of drugs in various animal models (depression, convulsion, ulcer, inflammatory, pain models and others) | | 1 | 2 | 3 | 4 | 4 |
| | Perform bioassay to quantify biological substances (acetylcholine, histamine) on isolated tissue specimen | | 1 | 2 | 3 | 4 | 4 |
| | Demonstrate anaesthetic techniques in small laboratory animals | | | | | | |
| | Demonstrate euthanasia in small laboratory animals | | | | | | |
| 5 | **Skills in pharmacokinetics and BA/BE studies** | | | | | | |
| | Derive basic pharmacokinetic parameters from a given dataset (parameters – area under curve, half-life, clearance, volume of distribution) | | 2 | 3 | 3 | 4 | 4 |
| | Design a protocol on bioavailability & bioequivalence studies | | 1 | 2 | 2 | 3 | 3 |
| 6 | **Evaluating drug quality as per pharmacopoeial standards** | | | | | | |
| | Determine the purity of drugs by HPLC techniques | 1 | 2 | 2 | 3 | 3 | 4 |
| | Determine the purity of drugs by UV-Visible spectrophotometry | 1 | 2 | 3 | 3 | 4 | 4 |
| | Perform the disintegration & dissolution experiments for solid oral dosage forms using appropriate apparatus | 1 | 2 | 3 | 3 | 4 | 4 |
| 7 | **Teaching/Learning skills** | | | | | | |
| | Plan and conduct a teaching and learning session for second year MBBS students (small group teaching, tutorials, group discussion, problem-based learning) | 1 | 1 | 2 | 2 | 3 | 4 |
| | Critically analyse an article and present the same | | 2 | 3 | 3 | 4 | 5 |
| | Prepare and present subject reviews (a brief narrative review on a topic of interest) and submit it for publication | | 2 | 3 | 3 | 4 | 5 |
| | Discuss interesting clinical cases and make a presentation | | 2 | 3 | 3 | 4 | 5 |
| | Deliver podium presentation and professional opinion on the given topic | | 2 | 3 | 3 | 4 | 5 |
| | Demonstrate the Computer assisted learning (CAL) experiments for undergraduate teaching | 1 | 2 | 3 | | | |
| 8 | **Skills in bioethics, GCP and Regulatory guidelines** | | | | | | |

| No. | Key capabilities | Minimum expected performance at months | | | | | |
|---|---|---|---|---|---|---|---|
| | | 6 | 12 | 18 | 24 | 30 | 36 |
| | Prepare the documents for obtaining ethical approval for human studies from Institute Ethics Committee (IEC) | 2 | 3 | 3 | 4 | 4 | 5 |
| | Prepare the form B documents for Institute Animal Ethics Committee (IAEC) | 2 | 3 | 3 | 4 | 4 | 5 |
| | Prepare the informed consent documents in accordance with GCP/ NDCT 2019/ ICMR guidelines 2017 | 2 | 3 | 3 | 4 | 4 | 5 |
| | Describe ICH- GCP/ D&C Act/Rules/ NDCT 2019/ ICMR guidelines 2017/ CCSEA/OECD | | 2 | 3 | 3 | 4 | 5 |
| 9 | **Skills in Research methodology & statistics** | | | | | | |
| | Understand and plan various components of research methodology (study designs, conduct of study, data collection) | 1 | 2 | 3 | 3 | 4 | 4 |
| | Identify the variables, types of data and scale of measurement | 2 | 3 | 4 | 5 | | |
| | Select an appropriate test for a given set of data | 2 | 3 | 4 | 5 | | |
| | Calculate the adequate sample size for various research using software (P&S and OpenEpi) | | 2 | 3 | 3 | 4 | 4 |
| | Analyse the study data using statistical softwares like SPSS, R and GraphPad Prism | | 2 | 3 | 3 | 4 | 4 |
| 10 | **Scientific communication skills** | | | | | | |
| | Perform all the steps in dissertation writing, poster presentation and oral presentation | | | | | 3 | 4 |
| | Prepare a manuscript adhering to reporting guidelines (ARRIVE 2.0, STROBE, CONSORT, CASP, RECORD - PE, MOOSE, PRISMA and other relevant reporting guidelines) | | | 2 | 3 | 4 | 5 |
| | Manage citations using referencing softwares (e.g., Zotero, Mendeley) | 1 | 2 | 3 | 4 | 4 | 5 |
| | Learn the process of publishing an article in a journal | | | | | 3 | 4 |
| 11 | **Pharmacoeconomics** | | | | | | |
| | Calculate the cost of effective treatment using formulas for cost effectiveness analysis and cost minimization analysis.<br>Calculate Incremental Cost Effectiveness Ratio (ICER), ACER and QALY<br>Perform decision tree analysis for a given case scenario | | | 2 | 2 | 3 | 4 |
| 12 | **Drug Inventory management** | | | | | | |
| | Formulate and regularly update the drug inventory of a hospital using inventory management techniques | | | | 2 | 3 | 4 |

## LEARNING OBJECTIVES FOR KEY-CAPABILITIES

### 1. Clinical Pharmacology skills

**Rational use of medicines**

Conduct prescription audit by WHO prescribing indicators

Follow steps of evidence based medicine in therapeutics

Perform Prescription Event Monitoring

Prepare drug information sheet as per WHO criteria

Evaluate promotional drug literature

**Antimicrobial stewardship (AMS)**

Describe the role of pharmacologist in AMSP

Contribute to AMSP in hospital

**Pharmacovigilance activities**

Identification and collection of ADR in ADR forms

Perform causality assessment by WHO/Naranjo scale

Perform severity assessment of ADR

Understand signal detection and disproportionality analysis

Demonstrate knowledge of ATC and MedDRA, CTCAE Classification

Demonstrate knowledge of Hemovigilance and Materiovigilance activities

**Clinical Trials**

Understand the phases of clinical trial

Draft protocol for various phases of clinical trials

Demonstrate SAE reporting and compensation in clinical trials

### 2. Clinical pharmacology experiments

Demonstrate a cardiac Stress Testing using treadmill and evaluate the effect of the given drug on BP and heart rate before and after the test.

Perform a Body Composition analysis of a volunteer using Bioelectrical Impedance.

Perform psychomotor assessment of a healthy volunteer and evaluate the effect on given test drug.

Perform Lung function test of a healthy volunteer and evaluate the effect on given test drug.

Demonstrate muscle strength using Hand grip dynamometer

Perform arterial stiffness assessment using periscope.

**3. Essential medicines**

Demonstrate Knowledge about WHO/National list of Essential Medicines

Describe the criteria for selection of drugs as Essential Medicines

Prepare an Essential Medicine list for the Institute/Hospital

**4. Medication adherence**

Identify medication errors and strategies to minimise them

Assess medication adherence using assessment scales

**5. Skills in drug development process**

Describe the drug development pathway

Explain the methods involved in drug development process

*In silico* methods

(CADD, QSAR, Molecular docking techniques)

*In vitro* methods

*In vivo* methods

**6. Skills in analytical techniques**

Prepare drug solutions of appropriate strength and volume for analytical and other assays.

Describe the principle and determine the unknown concentration of drugs in a given sample by Colorimetry

Describe the principle and determine the unknown concentration of drugs in a given sample by UV-Visible spectrophotometry

Describe the principle and determine the unknown concentration of drugs in a given sample by Paper/Thin layer chromatography

Describe the principle and determine the unknown concentration of drugs in a given sample by High Pressure Liquid chromatography

Describe the principle and determine the unknown concentration of drugs in a given sample by Liquid chromatography-mass spectrophotometry

Perform nucleic acid (DNA and RNA) extraction and quantification of the extracted material

Demonstrate the working of lab instruments like pH meter, weighing balance, micropipette, vortex mixer, sonicator and sample evaporator

Describe the working of the enzyme-linked immunosorbent assay (ELISA) and demonstrate the procedure

Describe the principle and demonstrate the working of PCR

Preparation of mobile phase solutions, standard and sample preparation for chromatography

Interpretation of therapeutic drug monitoring results

Perform reporting of results in the hospital information system

Understand and perform quality control of various assays

Demonstrate knowledge of validation of assays according to ICH and FDA bioanalytical guidelines

**7.Animal experimentation skills**

**Animal handling techniques:**

Demonstrate handling of the small laboratory animals like mice and rats by different techniques (e.g. scruff method).

Differentiate and identify the gender of mice and rats.

Differentiate rat pups and mice

**Blood collection in small laboratory animals:**

Perform the blood sampling in mice and rats using techniques like tail snip method, tail vein collection, retro-orbital plexus and terminal methods like cardiac puncture.

**Administration of drugs in small laboratory animals**

Administer drugs in mice and rats by oral, subcutaneous, intraperitoneal routes, and other parenteral routes

**Evaluation of various drugs in small laboratory animal models**

Evaluation of analgesics by Eddy's hot plate method

Evaluation of analgesics in acetic acid induced writhing model

Demonstrate the effect of analgesics by tail flick and tail clip method

Demonstrate the effect of drugs on motor activity using actophotometer

Demonstrate the effect of diazepam and haloperidol on grip strength in mice

Demonstrate the effect of drugs on motor coordination in mice using Rota-rod apparatus in mice

Evaluation of antiepileptic activity of diazepam and phenytoin by Maximal electroshock method and **PTZ**

Evaluation of antidepressants by forced swim test

Demonstrate the effect of antidepressants by tail suspension test

Evaluation of antiulcer agents in NSAID induced rat model

**Bioassay**

Perform Dose – response curve of acetylcholine using discarded chick-ileum/ guinea pig ileum

Calculation of EC50 of acetylcholine

Perform matching assay of acetylcholine in

Perform three-point assay of acetylcholine on discarded chick-ileum

Perform bracketing assay of acetylcholine on discarded chick-ileum

Demonstration of antagonism of atropine on acetylcholine of discarded chick-ileum

**8. Skills in pharmacokinetic and BA/BE studies**

Determination of pharmacokinetic parameters

Determination of elimination rate constant, clearance, peak concentration (Cmax), trough concentration (Cmin), average steady state concentration (Css, avg), half-life (t1/2), area under the curve (AUC), area under the moment curve (AUMC), volume of distribution (Vd), mean residence time (MRT) by manual calculation, Microsoft excel and relevant softwares

Calculation of loading dose and maintenance dose for given drug/antibiotic in a scenario

Calculating bioavailability of two compounds by graphical method and establishing bioequivalence

Demonstrate understanding of the order of kinetics of elimination and its clinical implication

Application of pharmacokinetic principles in dosage adjustment in patients with hepatic and renal failure

**9. Evaluating drug quality as per pharmacopoeia standards**

Purity determination of drugs by UV-Vis spectrophotometry

Purity determination of drugs by HPLC

Purity determination of drugs by titration

Evaluate solid oral dosage forms for disintegration & dissolution properties

**10. Teaching/Learning**

Demonstrate skills to prepare material for teaching-learning and assessment.

Demonstrate the acquisition of teaching-learning skills (symposia, journal clubs, clinical meetings, seminars, small group discussions, bed-side teaching, case-based learning, simulation-based teaching, self-directed learning, integrated learning,)

Demonstrate presentation skills in a classroom setting as well as at local and national levels conferences

## 11. Skills in bioethics, GCP and other regulatory guidelines

### Ethics

Preparation of documents for obtaining ethical approval

Describe the composition of ethics committee

Review of proposals for ethical clearance (observational & interventional studies)

Preparation and review of informed consent documents as per ICMR guidelines for biomedical research

Review protocol and SAE (Serious Adverse Event) ad recommended as per GCP (Good Clinical practice) and NDCT (New Drugs and Clinical Trials) Rules, 2019

Fill a Form-B form for submission to IAEC

### Guidelines and regulatory documents

ICH-GCP International Council for Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) guidelines

CCSEA guidelines - Committee for Control and Supervision of Experiments on Animals

NDCT 2019 - New Drugs and Clinical Trials Rules

Drugs and Cosmetics Act 1940 & Rules 1945

OECD guidelines - Organization for Economic Cooperation and Development

## 12. Skills in research methodology & statistics

### Research methodology

Recognition of knowledge gap and lacunae in current practice

Formulation of question to address knowledge gap and lacunae

Identification of sources of knowledge to answer the question

Interpretation and critique of evidence

Determination of validity and risk of bias in evidence

Application and potential integration of evidence into practice

Formulation of research study design to answer question

Execution of research protocol

Analysis and interpretation of research findings

Dissemination of research findings in conference presentation

Dissemination of research findings in journal publication

**Biostatistics**

Identification of variables, data and scale of measurement

Selection of appropriate test for a given set of data

Demonstrate data analysis using statistical softwares like SPSS, R etc

**13. Protocol writing skills**

Design protocol for screening of investigational compounds in various in vitro and in vivo models

Design protocol for various phases of clinical trials

**14. Scientific communication skills**

**Critiquing a research paper**

Appraise a published article in terms of scientific and ethical principles

**Manuscript preparation and submission to journal for publication**

Disseminate research findings in conference presentation

Disseminate research findings in journal publication

# Annexure 1(Part B)

**Core ideas in the practice of key capabilities:**

| No. | CORE IDEAS IN THE PRACTICE OF KEY CAPABILITIES |
|---|---|
| 1 | General Pharmacology |
| 2 | Systemic Pharmacology |
| 3 | Experimental Pharmacology<br>Animal experiments<br>TDM<br>Genomics<br>DAL |
| 4 | Drug Discovery and Development |
| 5 | Guidelines, Regulations and Classifications (Older versions should be replaced by updated versions, as they become available) |
| 6 | Pharmacokinetics |
| 7 | Pharmacoeconomics |
| 8 | Pharmacovigilance |
| 9 | Pharmacoepidemiology |
| 10 | Research methodology |
| 11 | Biostatistics |
| 12 | Scientific Communication |
| 13 | Teaching Learning |
| 14 | Soft skills |

**Core ideas in the practice of key capabilities:**

| | |
|---|---|
| **1** | **General Pharmacology** |
| | Drug Invention and the Pharmaceutical Industry<br>Pharmacokinetics: The Dynamics of Drug Absorption, Distribution, Metabolism, and Elimination<br>Pharmacodynamics: Molecular Mechanisms of Drug Action<br>Drug Toxicity and Poisoning<br>Drug interactions<br>Membrane Transporters and Drug Response<br>Drug Metabolism<br>Pharmacogenetics |
| **2** | **Systemic Pharmacology** |
| | **Neuropharmacology**<br>Neurotransmission, Muscarinic Receptor Agonists and Antagonists, Nicotine and Agents Acting at the Neuromuscular<br>Junction and Autonomic Ganglia, Adrenergic Agonists and Antagonists, 5-Hydroxytryptamine (Serotonin) and Dopamine, Drug Therapy of Depression and Anxiety Disorders, Pharmacotherapy of Psychosis and Mania, Pharmacotherapy of the Epilepsies, Treatment of Central Nervous System<br>Degenerative Disorders, Hypnotics and Sedatives, Opioids, Analgesia, and Pain Management, General Anaesthetics and Therapeutic Gases, Local Anaesthetics, Ethanol, Drug Use Disorders and Addiction |
| | **Modulation of Pulmonary, Renal, and Cardiovascular Function**<br>Drugs Affecting Renal Excretory Function, Renin and Angiotensin, Treatment of Ischemic Heart Disease, Treatment of Hypertension, Therapy of Heart Failure, Antiarrhythmic Drugs, Treatment of Pulmonary Arterial Hypertension, Blood Coagulation and Anticoagulant, Fibrinolytic, and Antiplatelet Drugs, Drug Therapy for Dyslipidaemias |
| | **Inflammation, Immunomodulation,**<br>**and Haematopoiesis**<br>Introduction to Immunity and Inflammation, Immunosuppressants and Tolerogens, Immune Globulins and Vaccines, Lipid-Derived Autacoids: Eicosanoids and<br>Platelet-Activating Factor, Pharmacotherapy of Inflammation, Fever, Pain, and Gout, Histamine, Bradykinin, and Their Antagonists, Pulmonary Pharmacology, Hematopoietic Agents: Growth Factors,<br>Minerals, and Vitamins |

| | |
|---|---|
| | **Hormones and Hormone Antagonists**<br><br>The Hypothalamic-Pituitary Axis, Thyroid and Antithyroid Drugs, Oestrogens, Progestins, and the Female Reproductive Tract, Androgens and the Male Reproductive Tract, Adrenocorticotropic Hormone, Adrenal Steroids, and the Adrenal Cortex, Endocrine Pancreas and Pharmacotherapy of<br>Diabetes Mellitus and Hypoglycaemia, Agents Affecting Mineral Ion Homeostasis and Bone Turnover |
| | **Gastrointestinal Pharmacology**<br>Pharmacotherapy for Gastric Acidity, Peptic Ulcers, and Gastroesophageal Reflux Disease, Gastrointestinal Motility and Water Flux, Emesis, and Biliary and Pancreatic Disease, Pharmacotherapy of Inflammatory Bowel Disease |
| | **Chemotherapy of Infectious Diseases**<br>General Principles of Antimicrobial Therapy, Chemotherapy of Malaria, Chemotherapy of Protozoal Infections: Amebiasis, Giardiasis, Trichomoniasis, Trypanosomiasis, Leishmaniasis, and Other Protozoal Infections, Chemotherapy of Helminth Infections, Sulfonamides, Trimethoprim-Sulfamethoxazole, Quinolones, and Agents for Urinary Tract Infections, Penicillins, Cephalosporins, and Other β-Lactam Antibiotics, Aminoglycosides, Protein Synthesis Inhibitors and Miscellaneous<br>Antibacterial Agents, Chemotherapy of Tuberculosis, *Mycobacterium avium*<br>Complex Disease, and Leprosy, Antifungal Agents, Antiviral Agents (Nonretroviral), Treatment of Viral Hepatitis (HBV/HCV), Antiretroviral Agents and Treatment of HIV Infection |
| | **Pharmacotherapy of Neoplastic Disease**<br>General Principles in the Pharmacotherapy of Cancer, Cytotoxic Drugs, Pathway-Targeted Therapies: Monoclonal Antibodies, Protein Kinase Inhibitors, and Various Small Molecules, Hormones and Related Agents in the Therapy of Cancer |
| | **Special Systems Pharmacology**<br>Ocular Pharmacology, Dermatological Pharmacology, Environmental Toxicology: Carcinogens and Heavy Metals |

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| 3. | **Experimental Pharmacology** |
| | **Animal Pharmacology** |
| | Tools for drug screening- Cassette dosing, Virtual screening, microassays, cell free assays, receptor screens, nano screens<br>Animal experiments: Ethical considerations, ethical approval, CCSEA, applicable Regulatory Guidelines, humane animal research (principles of 3Rs) and alternatives to animal experimentation, commonly used experimental animals, Animal care, sex determination, Dose calculation for experimental animals, anaesthesia and euthanasia of experimental animals<br>Animal toxicity studies.<br>Screening models for<br>-Cardiovascular system: antihypertensive agents, antianginal agents, antiarrhythmic agents, antiplatelet agents, hypocholesterolaemic agents<br>-Central and peripheral nervous system: anti stroke agents, antiepileptic agents, antidepressants, antipsychotic agents, antianxiety agents, anti-parkinsonian agents, drugs affecting learning and memory, muscle relaxants, sedative and hypnotic agents, local anaesthetic agents, sympathetic and parasympathetic agents<br>-Respiratory system: antiasthmatic agents<br>-Gastrointestinal system: antiulcer agents, anti-emetic agents, drugs affecting gut motility, agents for liver fibrosis<br>-Endocrine system: hormones of pituitary, thyroid, parathyroid, adrenal cortex, ovary and testes, antidiabetic agents, antifertility agents, agents for sexual dysfunction<br>-Anti-inflammatory agents, Analgesics, Antipyretic agents, Antimigraine agents, Anticancer agents, Anti-obesity agents, Antiviral agents, Diuretic agents, Anti-glaucoma agents, Herbal drugs<br>Bioassay-principles, types of bioassay, physiological salt solution, lever and magnification, tissues used in bioassay, error in bioassay, application of bioassay |
| | **Analytical Pharmacology** |
| | **Therapeutic Drug Monitoring (TDM)**<br>Criteria for performing TDM in drugs<br>Precautions for sample collection<br>Type of tube used for sample collection/ type of sample<br>Storage of samples for future analysis/ stability at various temperatures of storage<br>Preparation of reference standards and internal standards<br>Primary vs secondary reference standard<br>Storage conditions for standard solutions<br>Preparation of mobile phase for UPLC<br>Sample extraction techniques<br>Methods of sample processing<br>Parts of UPLC<br>HPLC conditions: Pump, column, detector type, wavelength, run time for assay, temperature<br>Stationary phase/ column<br>Linearity of standard curve<br>Normal therapeutic reference range for various age groups<br>Drug interactions leading to toxicity or clinical failure |

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|---|---|
| | Symptoms of toxicity<br>Conditions where dosage adjustment is required<br>Factors that can lead to false increase/ decrease in levels<br>Management of toxicity<br>Management of clinical failure<br>Pharmacokinetics/ pharmacodynamics of the drug of interest<br>Other methods of measuring drug levels other than UPLC<br>Validation of assays as per FDA bioanalytical validation guidance for industry<br>Quality control of assays |
| | **Genomics**<br>Basics of molecular biology<br>Human gene nomenclature and nomenclature of sequence variants<br>Basics of Pharmacogenomics<br>Hardy - Weinberg Equilibrium<br>Organization of a pharmacogenomic laboratory and good laboratory practice<br>Genotype - Phenotype association studies, methods and clinical importance<br>Pharmacogenomics In Drug Discovery And Development<br>Polymerase chain reaction and Restriction enzymes<br>Real time polymerase chain reaction<br>DNA extraction from blood by phenol chloroform method and kit method<br>DNA purification from blood or body fluids using kit based method<br>Thermocycler programming |
| | **Drug Analysis Lab (DAL)**<br>Quality testing procedures for dosage forms as recommended in Indian Pharmacopoeia (IP), British Pharmacopoeia (BP) and US Pharmacopoeia (USP)<br>Quality testing procedures for individual drugs IP, BP and USP<br>Principles of Purity determination of drugs and related substances by HPLC, UV-Vis spectrophotometry and titration<br>Principles of instrumentation<br>Principles of Quality control and validation of assays |
| **4.** | **Drug Discovery & Development** |
| | Computer assisted drug designing (CADD)<br>Bioinformatics<br>Proteomics<br>Metabolomics<br>High throughput screening<br>Contract Research Organisation, Academic Research Organisations<br>Good Clinical Practice (GCP)<br>Good Laboratory Practice (GLP)<br>Emergency use authorization for drugs eg., vaccine development<br>Clinical Trial -Designs, Phases, Placebo and controls, Bias in clinical trials, Blinding, Randomisation and sampling in clinical trials, DSMB, Ethics committee, vaccine trials |

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|---|---|
| **5.** | **Guidelines, Regulations and Classifications (Older versions should be replaced by updated versions, as they become available)** |
| | International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH - GCP) E6<br>Indian GCP |
| | Drugs & Cosmetic Act 1940, Rules 1945 |
| | New Drugs and Clinical Trial Rules (NDCT) 2019 for conduct of Clinical Trials in India |
| | The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979 |
| | Declaration of Helsinki, October 2013 |
| | ICMR - National Ethical Guidelines for Medical and Health Research involving Human participants 2017 |
| | ICMR guidelines for Good Clinical Laboratory Practices (GCLP) 2021 |
| | WHO - Good Clinical Practices guidelines (GLP) |
| | Organisation for Economic Co-operation and Development (OECD) Guidelines for Toxicity Testing |
| | CCSEA guidelines for conduct of Experiment on Animals in India |
| | Standard Treatment Guidelines for common diseases - ICMR , AHA, NICE, WHO, GINA & PMDT |
| **6.** | **Pharmacokinetics** |
| | Clinical pharmacokinetics<br>Plasma concentration vs time curve<br>Pharmacokinetic parameters- half-life, volume of distribution, clearance, elimination rate constant<br>Calculation of pharmacokinetic parameters<br>Pharmacometrics |

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| | Order of elimination kinetics- First order, zero order, mixed order kinetics<br>Kinetic homogeneity<br>Pharmacokinetic models- one compartment, two compartment models<br>Non compartmental analysis<br>Physiologically based pharmacokinetic models<br>Population pharmacokinetics<br>PK/PD correlation |
| **7.** | **Pharmacoeconomics** |
| | Definition<br>Types of Pharmacoeconomic studies<br>Critiquing pharmacoeconomic research article<br>Cost minimisation Analysis<br>Cost Benefit Analysis<br>Cost Effectiveness Analysis<br>Cost Utility Analysis<br>Health-Related Quality of Life (HRQoL)<br>Decision tree analysis<br>Markov chain modelling<br>Applications of Pharmacoeconomics |
| **8.** | **Pharmacovigilance** |
| | Basics of drug Safety and PV<br>Key PV Terminology (Side Effect, Drug Safety, and Risk Terms)<br>MedDRA (Hierarchy, Searching, Terms, Exporting, Assessing, Important Medical Events)<br>Signal Detection (Detection, Validation, Prioritization, and Action)<br>Signal management and disproportionality analysis<br>Causality Assessment<br>Severity and preventability assessment<br>Risk management systems<br>WHO- Uppsala Drug monitoring system, Vigibase, Vigiflow<br>Pharmacovigilance Program of India<br>Others: Materiovigilance, Biovigilance and Hemovigilance |
| **9.** | **Pharmacoepidemiology** |
| | Definition<br>Pharmacoepidemiologic study designs<br>Sources of Pharmacoepidemiology study data<br>Molecular Pharmacoepidemiology<br>Drug utilisation research (DUR)- Definition, need for DUR, Types of drug utilisation study, Sources of drug utilisation data, ATC drug classification system, Concept of defined daily dose (DDD) and prescribed daily dose (PDD)<br>Applications of Pharmacoepidemiology |

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| **10.** | **Research methodology** |
| | Good clinical practice guidelines<br>Good laboratory practices<br>Different study designs- descriptive studies, case control, cohort, cross sectional<br>Clinical trial designs<br>Phases of clinical trials- phase 0, phase 1, phase 2, phase 3 and phase 4<br>Randomised control analysis<br>Types of randomisation<br>Controls in clinical trials<br>Placebo/ nocebo<br>Blinding in clinical trials<br>Bias in clinical research<br>Institutional ethics committee (IEC)<br>Non-inferiority/superiority/ equivalence trials<br>Platform/ Umbrella/ Basket trials |
| **11.** | **Biostatistics** |
| | Descriptive statistics (Types of data, variables, plots, scale of measurements, measures of central tendency and spread)<br>Incidence/ prevalence estimation<br>Charts interpretation (charts and histograms)<br>Inferential statistics (hypothesis testing – Student's T test, ANOVA test, chi-square test, Wilcoxon signed rank test and Mann – Whitney U test)<br>Concept of p-value and confidence intervals<br>Difference between statistical and clinical significance<br>Type I and II errors<br>Sensitivity, specificity, positive and negative predictive values interpretation<br>Hazard ratio and relative risk estimation<br>Time-to-event data and Kaplan-Meier survival curve description<br>Sample size calculation, randomization techniques, interim analysis, intent to treat analysis appraisal |
| **12.** | **Scientific communication** |
| | Dissertation writing- PICOT format of title, formulating research question and hypothesis, Introduction, background, Aims and objectives, Primary and secondary end points, research methodology, Statistical analysis, results, discussion, ethical considerations, confidentiality statement, conclusion<br>Submission of manuscript to journal for publication |

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| **13.** | **Teaching Learning** |
| | Principles of teaching-learning technology: specific learning objectives (SLO), lesson plan, set induction<br>Teaching learning methods- demonstrations, symposia, journal clubs, clinical meetings, seminars, small group discussions, bed-side teaching, case-based learning, simulation-based teaching, self-directed learning, integrated learning, interdepartmental meetings etc<br>Teaching aids<br>Microteaching<br>Salient features of Undergraduate Medical Education Curriculum in India<br>Principles of assessment of learning<br>Knowledge about the utility of computer assisted learning |
| **14** | **Soft Skills** |
| | Work Ethics, Group management, Team work,<br>Organization of works, Self-motivation<br>Effective communication, Leadership skills<br>Problem solving, negotiation and conflict resolution.<br>Self-directed learning<br>Ethical behaviour and integrity |

# Annexure 1 (Part C)

**Learning Objectives -Peripheral Posting of MD Pharmacology Residents**

Will be attended by Junior Residents in 2nd, 3rd , 4th and 5th Semester

Total Duration- 6 Months (Each posting for 2 months)

**Background:**

The resident will be attending this peripheral only after they pass a test in related theory exam conducted by the parent department. This will help them to achieve the objectives of this posting optimally. Residents should maintain a log of all the procedures and experiments done and the sessions attended in the posting.

**At the end of the posting to Pharmacovigilance centre, the student should be able to**

1. Promote awareness of ADR monitoring service in JIPMER
2. Respond to spontaneous reporting of ADR and filling up of ADR form
3. Do active surveillance to study a drug/ADR in hospital setting
4. Do assessments of ADRs
5. Report ADRs to Vigibase using the software

**At the end of the posting Clinical pharmacology, the student should be able to**

1. Identify the parts and functions of each instrument in Clinical Pharmacology lab
2. Independently use and troubleshoot each instrument appropriately for its function
3. Interpret the results
4. Perform pharmacodynamic exercises with all equipment in Clinical Pharmacology lab
5. Design clinical trial protocol for phase I, II, III, IV trials
6. Perform simple, block and stratified randomization
7. Follow GCP, recent regulatory and ethical guidelines while doing clinical research
8. Screen healthy volunteers for phase 1 study
9. Design and conduct a single dose pharmacokinetic study
10. Write SOP for a given activity.

**At the end of the Drug analysis lab posting, the student should be able to**

1. Describe the principle involved in HPLC/UV Spectrophotometer method of estimation of drug levels

2. Identify the parts and describe the function of HPLC/ UV Spectrophotometer instrument

3. Independently run and determine the purity of the drug

4. Do trouble shooting as required

5. Interpret the results & be able to establish quality standards

# Annexure 2

## Drug analysis lab & TDM posting

The following assays done using spectrophotometry/ HPLC/UPLC/ LCMS during the drug analysis lab/TDM posting to be documented

| SL.NO. | DRUG NAME | METHOD | Procedure (Observed/Assisted/Performed) | Signature of in charge |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |
| 5 | | | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
| 12 | | | | |
| 13 | | | | |
| 14 | | | | |
| 15 | | | | |
| 16 | | | | |
| 17 | | | | |
| 18 | | | | |
| 19 | | | | |
| 20 | | | | |

The ADRs reported during the pharmacovigilance posting in Clinical Pharmacology

| Details | Number |
|---|---|
| ADRs collected by active surveillance | |
| Spontaneous reports of ADRs collected | |
| No of ADRs analysed and reported to Vigibase | |
| Total | |

**The experiment performed during Clinical Pharmacology posting.,**

| Name of equipment | Number of experiments - Observed | Number of experiments - Performed Independently |
|---|---|---|
| Periscope | | |
| Cardiopulmonary Exercise Test | | |
| Spirometer | | |
| Ambulatory blood pressure monitor | | |
| Hand dynamometer | | |

# Annexure 3

# Workplace assessment form

Place of posting: Reporting time: on time/late

Number of leaves taken: authorised: Unauthorised absenteeism, if any

Duration of posting: From ……. To …….

| | Scores | 0 | 1 | 2 | 3 |
|---|---|---|---|---|---|
| | **Score 0-** Not attempting to meet expectations.<br>**Score 1-** Attempting to, but yet to meet expectations.<br>**Score 2- M**eets expectations.<br>**Score 3-** Proficient, independently exhibits responsibility and standards beyond minimum expectations | | | | |
| | **Work experience during the posting**<br>Adequately performs literature search for the assigned activity | | | | |
| | Ability to elicit history for the assigned cases (in case of ADR, toxicity, quality issues with drugs, therapy response, drug interaction) | | | | |
| | Skills in performing the assigned analytical work | | | | |
| | **Documentation**<br>Completeness of the records during the posting<br>Documentation in log book and observation note<br>Maintains Meticulousness and Comprehensiveness of Records- in File and Digital data management | | | | |
| | **Paradigms of teaching**<br>a) Ability to handle large group classes for various undergraduate courses.<br>b) Ability to handle small group teaching | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | c) Ability to present seminars/ journal clubs. | | | | |
| | **Attends and participates in state/national conferences, and workshops and presents poster/paper** | | | | |
| | **Displays adequacy of literature search and justifies rationale for topics presented during departmental activities** | | | | |
| | **Maintains Meticulousness and Comprehensiveness of all documents, research materials, attendance of students etc.,** | | | | |
| | **Team-based work and Leadership**<br>a) Coordinates with Seniors and Colleagues<br>b) Shows interest in teaching juniors. | | | | |
| | Accepts feedback, does self-reflection, and receives critical comments from faculty when expressed. | | | | |
| | **Total marks**<br>**(Maximum possible marks-30)** | | | | |
| | **Log Book Scoring (20 marks)** | | | | |
| | **Signature of Faculty** | | | | |