NATIONALMEDICALCOMMISSION
PostgraduateMedicalEducationBoard

D11011/1/22/AC/Guidelines/PG 08 **Date:01-08-2022**

GUIDELINES FOR COMPETENCYBASED POSTGRADUATE TRAINING PROGRAMME FOR MD IN PHARMACOLOGY

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Implementation of Revised Competency Based Post Graduate Training Programme for MD in Pharmacology as per the guidelines prepared by the National Medical Commission through Subject Expert Groups{ Date of Bos 21.07.2022 Ref :SBKSMIRC/Dean/Outward No.1301/2021-22, Date of Academic council :29.07.2022 Ref :SVDU/NOTFN/O370/2021-22 dated 30.07.2022}

Preamble

The purpose of the postgraduate (PG) education is to create specialists who wouldprovide high quality education, health care and advance the cause of science throughresearchandtraining.

Pharmacology consists of both experimental and clinical sciences. The experimentalcomponent is essential in understanding the drug action in diseases as well as for theresearch in drug discovery and development. Clinical application of pharmacologyconcepts is essential for rational prescribing practices, rational therapeutics, clinicaltrials,rationaluseofdrugsincludingantimicrobials,pharmacovigilanceandpharmacologyconsults.

The job prospects for a medical pharmacologist have evolved over time along with acongruentriseinthedemandfortrainedpharmacologistsinIndia,bothinacademicsaswell in other areas such as pharmacovigilance centres, regulatory bodies, nationalresearchinstitutes,pharmaceuticalindustryandasscientificwritersorsciencemanagers. Hence, a PG student in Pharmacology should be competent to meet thegrowingchallengesinjobrequirementsatalllevelsinvariousfieldsandorganizations.

Consideringtheemergingtrendsinpharmacology&therapeutics,clinicalapplicationsofthe subject,itsroleinnationalprograms,evolvingintegratedcourseschedules while broadening the subject scope and number of students seeking to join the PG degree inpharmacology,thereishugedemandtostandardizeandupdatePGcurricularcomponentsincludingcompetencies,teachinglearningmethodsandassessmentmethodsintheMDpharmacologycourseinIndia.Thisrequiresintegrationofpharmacologywithothersciencesincludingbasic,para-clinicalandclinicaldisciplines.

A pragmatic approach to postgraduate pharmacology teaching in India is a key steptowards addressing the aforesaid challenges and facilitating a fresh curriculum design.The purpose of this documentis to provide teachers and learnerscomprehensiveguidelines to achieve the defined competencies through various teaching-learning andassessment strategies. This document was prepared by various subject and educationexperts of the national Medical Commission. The subject Expert Group has attemptedto render uniformity without compromising the purpose and content of the document.Compromise in purity of syntax has been made in order to preserve the purpose andcontent. This has necessitated retention of “domains of learning” under the heading“competencies”.

SUBJECTSPECIFICLEARNINGOBJECTIVES(GOALS)

At the end of the MD training programme in Pharmacology, the student should meetthe followinggoals:

1. **Acquisitionofknowledge**

The student should be able to clearly explain concepts and principles of pharmacologyandtherapeutics,drugdevelopmentprocesses,thedrugsandcosmeticsact,rationaluseof drugs, antimicrobial resistance, pharmacovigilance, pharmacy, health economics,clinicaltrialprocessesandrelevantnationalprograms.

2. **AcquisitionofSkills**

Thestudentshouldbeabletodevelopandapplyskillsinpharmacology-basedservices(e.g. rational prescribing), in self-directed learning for evolving educational needs andscientific information, in conduct of research and in managerial assignments in thedepartment/institution.

3. **Teaching andtraining**

The student should be able to effectively teach and assess undergraduate medicalstudents(MBBS)andalliedhealthsciencecourses(Dentistry,Nursing,Physiotherapy)so that they become competent healthcare professionals and are able to contribute totrainingofundergraduates (UG)andpostgraduates.

4. **Research**

The student should be able to conduct a research project (in both basic and clinicalpharmacology)from theplanningto thepublication stage andbe able topursueacademic interests and continue life-long learning to become a more experiencedteacher&mentorinalltheaboveareasandtoeventuallybeabletoguidepostgraduatesintheirthesis,researchworkandallotheracademic activities.

5. **Professionalism, Ethics and Communication skills**

The student should be able to learn and apply principles of professionalism, ethics andeffectivecommunicationinconductofresearch,pharmacology-basedservices,educationalactivities anddaytodaywork.

SUBJECTSPECIFICCOMPETENCIES

The competencies will have a judicious mix of all domains of learning and usually arepredominant in one domain. The postgraduate student during the training programshouldacquirethefollowing competenciestoachievethedefinedfivegoals:

A. PredominantinCognitivedomain

TheMD Pharmacologystudentaftertraininginthecourseshould beableto:

GeneralPharmacology:

1. Demonstrate an understanding of the basic principles of Pharmacology includingmolecularpharmacology.
2. Demonstrate an awareness of the historical journey and contributions of scientistsinthedrugdevelopmentprocess.
3. Describe the process of new drug development including preclinical and clinicalphases.
4. Describe principles of pharmacokinetics of drugs and apply these to prescribemedicinesforindividualization of pharmacological therapy,includinguseofmedicinesinspecialcategories(Pediatrics,Geriatrics,PregnancyandPathologicalstates).

5. Explaintheprinciplesofpharmacodynamicsandapplytheseindifferenttherapeutic situations.
6. Describemechanismsofdrug-druginteractionsandtheir clinicalimportance.
7. Describetheprinciplesofpharmacogenomicsanditsclinicalsignificance.
8. Describepharmacologicalprinciplesunderlyingtheeffectsofdrugsusedindiagnosis,prevention and treatment ofcommonsystemic diseasesin man.
9. Demonstrateanunderstanding ofthefactorsthatmodifydrug action.
10. Define Therapeutic Drug Monitoring (TDM), describe the methods of TDM andimportanceintherapeutic decisionmaking.
11. Describetheprinciplesandimportanceof Pharmacoeconomicsinhealthcaredelivery. Describe the methods in pharmacoeconomic studies and the economicconsiderationsintheuseofmedicinesin individualsandinthecommunity.
12. Describetheprinciples,methodsandimportanceofpharmacoepidemiology,including drugutilizationstudies.
13. Definepharmacovigilance.Describetheimportanceofpharmacovigilanceinensuring patientsafetyandthevariousmethods/proceduresinpharmacovigilance.
14. DescribetheroleofEssentialMedicinesinrationaltherapeutics.Describeprinciplesfor selecting Essential Medicinesfor a defined healthcare deliverysystem.
15. Demonstrateanunderstanding ofprinciplesofrationalprescribing.
16. Demonstrate an understanding of prescription analysis and be able to conductprescriptionanalysisinahealthcarefacility.
17. Demonstrateanunderstandingofantimicrobialresistance,antibiogram,antimicrobial stewardshipprogramandstrategiesforcontainmentofantimicrobialresistance.

SystemicPharmacology:

1. Applyandintegrateknowledgeofpathophysiologyofdiseasesandpharmacological principles underlying the effects of drugs, for the purpose ofdiagnosis,preventionandtreatmentofcommonsystemicdiseasesinmanincludingdisordersof:
    a. Synaptic & neuroeffector junctional sites of the autonomic nervoussystem
    b. Neuromuscular junction
    c. Centralnervoussystem
    d. Cardiovascularsystem
    e. Endocrinesystem
    f. Gastrointestinalsystem
    g. Respiratorysystem
    h. Renovascular system
    i. Hematologicalsystem
    j. Immunologicalsystem
    k. Autacoids

(Note:The above is only anindicativelist).

2. Describe the mechanism of action, pharmacological effects and therapeutic statusofdrugsusedforpreventionandmanagementofmicrobialandparasiticinfections /infestationsandneoplasticdisorders.
3. Describethepathophysiologicalbasisandmanagementofcommonpoisonings.
4. Demonstrateanawarenessabouttherecentadvancesinpharmacologyandtherapeutics.
5. Demonstrate an understanding of the special considerations in pharmacokinetics,mechanismofaction,pharmacologicaleffectsandtherapeuticstatusofdrugsusedfordermatologicalandoculardisorders.

Research:

1. Demonstrateanunderstandingoftheimportanceandethicalconsiderationsofbiomedicalresearchinanimalsandman.
2. Describetheprinciplesandmethodsofbiomedicalresearchinanimalsandman.
3. DescribethecurrentprinciplesofGoodClinicalPractice(GCP)andGoodLaboratoryPractice(GLP)guidelines,as applicable.
4. Demonstrate an understanding of the different tools and methods for literatureresearch.
5. Describeandapplytheprinciplesofbiostatisticsintheevaluationandinterpretation of efficacy and safety studies of drugs in man. Apply and interpretthe various statisticaltoolsinbiomedicalresearch.
6. Demonstrate an understanding of the principles of Good Publication practices asapplicable topublicationofresearchstudies.

7. Describe different methods of drug assays - biological, chemical, immune-assayincluding knowledge of analytical techniques like HPLC, TLC etc. and theirapplicationsintherapeutics.
8. Describethemethodsforscreening/evaluationofanalgesics,antipyretics,anticonvulsants,anti-inflammatorydrugs,antidepressants,antianxietyandantipsychotics,sedatives,muscl erelaxants,antihypertensives,hypocholesterolemic agents, antiarrhythmic drugs, diuretics, adrenergic blockingdrugs,drugsaffectinglearningandmemoryinanimalsandman.(Note:Thisisonlyanindicativelist).
9. Describe the regulatory and ethical issues involved in drug developmentandresearch.

TeachingandAssessment:

1. Demonstrate an awareness about the salient features of Undergraduate MedicalEducationCurriculuminIndia.
2. DemonstrateanawarenessaboutPostgraduateMedicalEducationCurriculumandGuidelinesinIndia.
3. Describetheprinciplesofteaching-learningtechnologyandapplythesetoconductclassroom lectures, self-directed learning (SDL) sessions, Case-Based Learning(CBL), case discussions, integrated teaching, small group discussions, seminars,journalclubandresearchpresentations.
4. Describe the principles of assessment of learning and be able to use the differentmethodsforassessmentofundergraduate studentsinpharmacology.
5. Demonstrateknowledgeabouttheutilityofcomputerassistedlearningandbeabletousethemefficientlytopromotelearningofpharmacology.

Note: The list mentioned above is indicative. A postgraduate student is expected to beknowledgeableaboutallaspectsofthesubjectandbeupdatedaboutthecontemporaryadvancesandresearchinthesubject.

B. PredominantinAffectiveDomain

ThestudentsaftertrainingintheMD(Pharmacology)courseshouldbeableto:

1. Effectively explain to patients, the effects, appropriate use and adverse effectsofdrugs, includingdruginteractionsandtheneedformedicationadherence.
2. Communicate effectively with students, peers, staff, faculty and other membersofthehealthcareteamaboutrationaluseofmedicinesandimprovingsponta neousreportingofadversedrugreactions,withpharmacologicalreasoning
3. Demonstrate respect in interactions with peers, patients and other healthcareprofessionals.
4. Demonstrateprofessionalism,ethicalbehaviorandintegrityinone'swork.
5. Demonstrate ability to generate awareness about the use of generic drugs invariousconditions.
6. Acquire skills for self-directed learning to keep up with advances in the subjectandtoimprovetheskillsandexpertisetowardscontinuousprofessionaldevel opment.

C. PredominantinPsychomotorDomain

a.Mandatory

i. The students after training in the MD (Pharmacology) course should be able to*perform the following procedures independently* or as a part of a team and/orinterprettheresults:

1. Predict,report,monitorandparticipateinthemanagementandcausality assessmentofadversedrugreactionsassociatedwithuseofdrugs,aspernationalprogra m.
2. Demonstrateskills forwritingrationalprescriptionsandprescriptionanalysis.
3. DemonstrateproperuseofequipmentfollowingtheSOPse.g.organbath,analgesiomet er, physiograph, convulsiometer, plethysmograph, equipment fortesting/measuringlearning and memory, affective disorders, muscle relaxants,bloodpressure,ECG,respirationandpain.
4. Preparedrugsolutionsofappropriatestrengthand volume.
5. DetermineEC_{50},ED_{50},pD2and pA_2valuesofdrugs.
6. Demonstrate presentation skills in a classroom setting as well as in academicmeetingsatlocalandnationallevels.
7. Providecriticalappraisalofaresearchpaper.

8. Performexperimentstodemonstrateandinterpretthedoseresponsecurveandeffectofa gonists (inthepresence orabsence ofanantagonist)onsimulations.
9. Performthefollowing:
    - Design protocol for evaluation of a given drug for various phases ofclinicaltrials.
    - PrepareInformedConsentFormandParticipantInformationSheetforclini caltrials/research.
    - AdministerInformedConsentForm
    - Evaluatepromotionaldrugliterature
    - Prepare“Packageinsert”
    - Calculateandinterpretpharmacokineticparametersofadrugfromagiven data
    - Demonstrate skills to prepare material for teaching-learning andassessment.

ii.ThestudentsaftertrainingintheMD(Pharmacology)courseshouldbeableto ***do/performfollowingproceduresundersupervision***:

10. Testandpredictefficacyofdrugsfollowingappropriateguidelinesandregulations e.g. drugs affecting memory and psychomotor functions (e.g. criticalflickerfusiontestsinhumanvolunteers),pain,cardiovascularfunctions,respira toryfunctions etc.
11. Observe and understand basic principles of working of important contemporarydrug analytical techniques, interpret the observations about the drug levels andtheirtherapeuticapplications.
12. Demonstrate skills for contributing toantibioticstewardship program of theinstitutetomanageantimicrobialresistance.
13. Demonstrate Standard Operating Procedures (SOPs) for various methods andtechniquesusedinpharmacologyincludingSOPsinclinicaltrialsandresearch.
14. Administer drugs by various routes (subcutaneous, intravenous, intraperitoneal)insimulations andhybridmodels.
15. Demonstrate acquisition of writing skills for scientific publications and researchprojectsforfundingagenciesandapprovalbyEthicsCommittee.
16. Demonstratescientificwritingskills.

b. Desirable: The students after training in the MD (Pharmacology) course should beableto:

17. Collectbloodsamplesandoralgavagefromexperimentalanimals.
18. Administer drugs by various routes (subcutaneous, intravenous, intraperitoneal)inexperimentalanimals.
19. Perform invivoandinvitroanimal experiments orsimulatedexperiments,interpret the observations and relate these to potential clinical applications of theexperimentaldrug:

    e.g.- effectofmydriaticsandmioticsonrabbiteye,

    - effectofanti-epilepticdrugsusingappropriateanimalmodelsofepilepsy,
    - effectofanalgesicsusing appropriateanimalmodelsofanalgesia,and
    - effect of drugs on learning, memory and motor coordination and effect oflocalanesthetics.

    Theseareexamples,butthelist isnotlimitedto thisonly.
20. Perform experiments to demonstrate and interpret the dose response curve andeffectofagonists(inthepresenceorabsenceofanantagonist)onvariousbiologicaltis sues.

AnimalExperiments:AllanimalexperimentsmustbecompliantwiththeRegulationsofGovernmentofIndia,notifiedfromtimetotime.Amphibian/Dog/Catexperimentsshouldbeconductedbycomputerassistedsimulationmodels/facilities.Otherexperimentscanbeperformed,butaspermissiblebyexisting‘CommitteeforthePurposeofControlandSupervisionofExperimentsonAnimals(CPCSEA)’guidelinesandotherGovernmentregulations.

SYLLABUS

Thecoursecontentsshouldcoverthefollowingbroadtopics:

1. HistoryofPharmacologyandmedicine
2. Basicandmolecularpharmacology
3. DrugreceptorsandPharmacodynamics
4. Pharmacokinetics (Absorption, Distribution, Biotransformation, Excretion &kineticparameters)

5. TherapeuticDrugMonitoring
6. Drugsactingonsynapticandneuroeffectorjunctionalsites
7. Autonomicpharmacology
8. Drugsactingoncentralnervoussystem
9. Drugsmodifyingrenalfunctions
10. Drugsactingoncardiovascularsystemandhemostaticmechanisms
11. ReproductivePharmacology
12. Agentsaffectingcalciumhomeostasis
13. Autacoids and related pharmacological agents (analgesics) and drugsusedinRheumatoidarthritisandGout
14. Drugsacting onGastrointestinalsystem
15. Pharmacologyofdrugs affectingthe respiratorysystem
16. Chemotherapy-Generalprinciplesandvariousantimicrobials
17. Chemotherapyofneoplasticdisease
18. DrugsusedinAutoimmunedisorder andGraftversusHostDisease
19. Dermatologicalpharmacology
20. Ocularpharmacology
21. Use ofdrugsinspecialpopulation
22. Immunomodulators-immunosuppressantsandimmunostimulants
23. Pharmacologyofdrugsusedinendocrine disorders
24. Drug deliverysystems
25. Heavymetalpoisoning
26. Non-metallictoxicants- airpollutants,pesticidesetc.
27. Researchmethodologyandbiostatistics
28. Pharmacogenomics, pharmacovigilance, pharmacoeconomics andpharmacoepidemiology
29. Over the counter drugs, essential medicines, P-drug, commonly usedOver-The-Counter (OTC)drugs,genericdrugs,drugsbannedinIndia
30. Principlesofrationaluse ofdrugsandrationalprescribing
31. Dietarysupplementsandherbalmedicines
32. Pathophysiologicalbasisandmanagementofcommonpoisonings
33. National programmes for infectious and vector borne diseases including theregimes.
34. Professionalism &ethics

35. Clinicalpharmacology

- Functioning oftheDrugsand TherapeuticsCommittee.
- Hospitalformularydevelopment.
- Druginformationservices.
- Medicationerrordetectionandmitigationadvice.
- Antimicrobialresistanceandantibioticstewardship.
- Prescriptionauditing
- Drug counseling - explain to patients, the effects and adverse effects ofdrugs,includingthe needformedicationadherence
- Emergencydrugsusedincrashcart/resuscitation

36. DrugdevelopmentresearchandRegulations

- Principles of Good Clinical Practice (GCP) and Good LaboratoryPractice (GLP)guidelines,andGoodpublicationpractices
- Recentregulatoryguidelinesfor drugs/researchandclinicaltrials
- Drugdevelopmentandresearchandethicalissuesinvolved init
- Research protocol development, research study conduct, experimentalobservations, analysis of data using currently available statisticalsoftware
- Emergencyuseauthorizationfordrugseg., vaccinedevelopment

37. Pharmacometrics-methodsofdrugevaluation.

38. Generalscreening andevaluationof:

- analgesics,antipyretics,anticonvulsants,anti-inflammatorydrugs,antidepressants, antianxiety and antipsychotics, sedatives, muscle relaxants,antihypertensives,hypocholesterolemicagents,anti-arrhythmicdrugs,diuretics,adrenergicblockingdrugs,localanaesthetics,antifertilityagents, antidiabetics,drugsusedinpepticulcerdiseasesanddrugsaffectinglearningandmemoryinanimalsandman.

39. Experimentation

- Bioassaymethods
- Animalexperiments:Ethicalconsiderations,ethicalapproval,applicableRegulatoryGuidelines,humaneanimalresearch(principlesof3Rs)andalternativestoanimalexperimentation.Generalandstatisticalconsiderations

- Anestheticsusedinlaboratoryanimals
- PrinciplesofEC50,ED50,pD2andpA2valuesofdrugs
- Describemethodsofbioassayfor estimationof: Acetylcholine,skeletalneuromuscularjunctionblockers,adrenaline,noradrenaline,histamine,5HT,hormones,insulin,vasopressin/oxytocin,estrogen,progestins,ACTH
- Competitiveantagonism-pA2values
- Immunoassays:Concept,typesofbioassaysandtheirapplication/s
- Animal experiments: Ethical consideration, Ethics Committee and ethicalapproval
- RegulatoryGuidelinesandalternativestoanimalexperimentation.

40. BiochemicalPharmacology
    - Basicprinciplesandapplicationsofsimple analyticalmethods
    - Principlesofquantitativeestimationofdrugs,endogenouscompoundsandpoisons using Colorimetry, Spectrophotometry, flame photometry, HighPerformance Liquid Chromatography (HPLC) and enzyme-linkedimmunosorbentassay(ELISA).
41. Education
    - SalientfeaturesofUndergraduateMedicalEducation CurriculuminIndia.
    - PostgraduateMedicalEducationCurriculumandGuidelinesinIndia.
    - Principlesofteaching -learningmethodsandtechnology
    - Principlesofassessmentoflearners

TEACHINGANDLEARNINGMETHODS

Generalprinciples

Acquisition of competencies being the keystone of doctoral medical education, suchtrainingshouldbeskillsoriented.Learning intheprogram,essentiallyautonomousandself-directed, and emanatingfrom academic andclinical work, shall alsoincludeassistedlearning.Theformalsessionsaremeantto supplement thiscoreeffort.

All students joining the postgraduate courses shall work as full-time (junior) residentsduringtheperiodoftraining,attendingnotlessthan80%ofthetrainingactivitydurin gthe calendar year, and participating in all assignments and facets of the educationalprocess.Theyshallmaintainalogbookforrecordingthetrainingtheyhaveunderg one,anddetailsoftheproceduresdoneduringlaboratoryandclinicalpostingsinrealtime.

Teaching-Learningmethods

Thisshouldincludeajudiciousmixofdemonstrations,symposia,journalclubs,clinicalmeeti ngs, seminars, small group discussions, bed-side teaching, case-based learning,simulation-basedteaching,self-directedlearning,integratedlearning,interdepartmentalmeetingsandanyothercollaborati veactivitywiththeallieddepartments. Methods with exposure to the applied aspects of the subject relevant tobasic/clinicalsciences shouldalsobeused.

Thesuggestedexamplesofteaching-learningmethodsaregivenbelowbutarenotlimited to these. The frequency of various below mentioned teaching-learningmethods can vary based on the subject's requirements, competencies, work loadandoverallworkingschedule ofthedepartment.

A. Lectures:Didacticlecturesshouldbeusedsparingly. Aminimumof10lecturesperyear in the concerned PG department is suggested. Topics to be selected as per subjectrequirements.All postgraduate trainees will be required toattend these lectures.Lecturescancovertopics suchas:

1. Subjectrelatedimportanttopics
2. Recentadvances
3. Researchmethodologyandbiostatistics
4. SalientfeaturesofUndergraduate/postgraduatemedicalcurriculum
5. Teachingandassessmentmethodology
6. Toxicitystudies
7. Screeningforpharmacologicalactivityofdrugs
8. Technicaland ethicalissuesinclinicalresearchandpractice
9. Good laboratorypractice
10. Goodmanufacturingpractice
11. Healtheconomics

No 3, 4, 5 can be done in the course of research/biostatistics and medical educationworkshops intheinstitute.

B. Journalclub:Minimumofoncein1-2weeksissuggested.

Topics will include presentation and critical appraisal of original research paperspublished in peer reviewed indexed journals. The presenter(s) shall be assessed byfacultyandgrades recordedinthelogbook.

C. StudentSeminar: Minimumofonceevery1-2 weeksissuggested.

Important topics should be selected as per subject requirements and allotted for in-depth study by a postgraduate student. A teachershouldbe allocated for eachseminarasfacultymoderatortohelpthestudentpreparethetopicwell.Itshouldaimat comprehensive evidence-based review of the topic. The student should be gradedbythefacultyandpeers.

D. StudentSymposium:Minimumonceevery3months.

A broad topic of significance should be selected, and each part shall be dealt by onepostgraduate student. A teacher moderator should be allocated for each symposiumandmoderatorshouldtrackthegrowthofstudentsduringmoderation.Itshoul daimat complete evidence-based review of the topic. All participating postgraduatesshouldbegradedbythefacultyandpeers.

E. Laboratorywork/ Bedsideclinics: Minimum-onceevery1-2 weeks.

Laboratory work/clinics/bedside teaching shouldbe coordinated and guidedbyfaculty from the department. Various methods like DOAP (Demonstrate, Observe,Assist, Perform), simulations in skill lab, and case-based discussions etc. are to beused. Faculty from the department should participate in moderating the teaching-learningsessions duringclinicalrounds.

F. Interdepartmentalcolloquium

Faculty and students must attend monthly meetings between the Department ofPharmacology and another department or departments on topics of current/commoninterestorclinicalcases.

G. a. Rotationalclinical/community/institutionalpostings

Dependingonlocalinstitutionalpolicyandthesubjectspecialtyneeds,postgraduatetrain eesmaybepostedinrelevantdepartments/units/institutions.Theaim would be to acquire more in-depth knowledge as applicable to the concernedspecialty.Postingswouldbe rotatedbetweenvariousunits/departments.

Thepostingsschedulewithdurationisgivenbelow:

- Medicine -2 weeks
- Anesthesia -2 weeks
- Dermatology -1week
- Medicaloncology -2weeks(ifavailable)
- Microbiology/Infectioncontrolunitordept-2weeks
- Biochemistry -2weeks
- HospitalPharmacy -1week(ifavailable)
- Clinicaltrialunit/Researchunit/ Pharmaceuticalindustry -2-8weeks(asperavailability)
- MedicalEducationUnit(MEU)or DepartmentofMedicalEducation(DOME)-1week(optional)

Gb. Postingunder"District ResidencyProgramme"(DRP):

To consider and approve the tmpte Students admitted in the 2021-22 batch as per the NMC notifications vide letter F.No. NMC23(1)(25)12021/PG/053909 dated 2211212022 and Clarification issued by NMC vide tetter F. N o. N M C/23 (1) (25) 12021 I Med. I 00 1 866 d ated 1 9 I Ot t 2023 Resolution ' with reference to the NMC notifications vide letter F.No. NMC-23(1)(25)t2o21tpcto53g0g dated 2211212022 and Clarification issued by NMC vide letter F.No.NMC/23(1)(25)t2021/Med./001g66 dated 1910112023. the District Residency Program (DRP) shall be implemented for the students admitted in 2021-22 batch onwards. The said notification and clarification from NMC were considered and passed unanimously.

The communication from National Medical Commission vide no. NMC-23 (1) (25) / 2021 / PG / 053909, dated 22.12.2022 regarding Implementation of District Residency Programme, and National Medical Commission vide no. NMC-23(1)(25)/2021/Med./001866, dated 19.01.2023 regarding Clarification on implementation of District Residency Programme, is adopted for execution.

(BOS-Ref :SBKSMIRC/Dean/Outward No.1158/2022-23, Date of Academic council : 11/02/2023)

(BOM-Ref. No.: SVDU/R/2431-A/2022-23, Date of Academic council : 29/05/2023)

Every posting should have its defined learning objectives. It is recommended thatthe departments draw up objectives and guidelines for every posting offered inconjunction with the collaborating department/s or unit/s. This will ensure thatstudents acquire expected competencies and are not considered as an additionalhelpinghandforthedepartment/unitinwhichtheyareposted.ThePGstudentm ustbetaggedalongwiththoseofotherrelevantdepartmentsforbedsidecasediscussion/ba sic science exercises as needed, under the guidance of an assignedfaculty.

Opportunities to present and discuss infectious disease cases through bedsidediscussionandward/grandroundswithspecialists/cliniciansindifferent

hospital settings must be scheduled to address antimicrobial resistance issuesandstrategiestodealwithit.

- With reference to the Notification vide no. MC!-18(1)12020-Med.1121415, dated 16.09.2020, related to 'Postgraduate Medical Education (Amendment) Regulations 2020'; all the postgraduate students pursuing MD / MS in broad specialties in Sumandeep Vidyapeeth Deemed to be University, as a part of course curriculum, shall undergo a compulsory Residential rotational posting in the 3rd or 4th or Sth semester of the Postgraduate programme, for a duration of three months, in the District Hospitals / District Health System, is confirmed and approved for execution.

- (Board of Studies letter no.:SBKS/DEAN/1576/2020,dated 0/10/2021 and Vide Notification of Board of Management Resolution : Ref no. SVDU/R/1271-1/2020-21, dated - 30th December 2020)

- To introduce Basic life support (BLS) and Advanced Cardiac Life Support (ACLS) trainingforalltheFirstyearPostgraduateResidentDoctorsfromacademicyear2017-18

- To introduce New chapter / topic 'Intellectual Property Rights (IPR) foralltheFirstyearPostgraduateResidentDoctorsfromacademicyear2020-2021 of duration of 4hrs (Board of Studies letter no.: SBKS/DEAN/742/2021,dated 05/06/2021 and Vide Notification of Board of Management Resolution Ref no.:SVDU/R/3051-1/2020-21, dated - 29" July 2021)

List of topics :

1. Introduction-ConceptofIntellectualProperty,Historicalviewof Intellectual Property system in India and International Scenario, Evolution of Intellectual Property Laws in India, Legal basis of Intellectual Property Protection, Need for Protecting Intellectual Property, Theories on concept of property - Major IP Laws in India.
2. Types of IPR: Patents, Copyright, Trademark Industrial Designs, TradeSecrets.
3. Patents: Concept of Patent, Criteria of Patentability, Inventions NOT patentable, Process of Obtaining a Patent, Duration of Patents, Rights of Patentee, Limitation of rights, Infringement andEnforcement.
4. Copyrights: Meaning of Copyright, Copyright Vs. Moral rights, Copyrighteligibility,TermofCopyright,RegistrationofCopyright, Infringement andRemedies
5. Trademark: Meaning of Trademark, Criteria for trademark, Procedure for Trademark Registration, Term of protection, Infringement andRemedies.
6. Industrial Designs: Meaning of Industrial Designs, Rights in Industrial Designs: Nature, Acquisition and duration ofrights.
7. Trade Secrets: Meaning of Trade Secrets, Need to protectTrade secrets, Criteria of Protection, Procedure for registration, Infringement.
8. Commercialization of IPR: Traditional IP and Evolving IP, Assignment, Licensing, Cross License, Patent Pool, Negotiations, Defensive Publications, TechnicalDisclosures,

Patent Pooling, Patent Trolling, Brand Management, Brand and Pricing Strategies.

H. Teachingresearchskills

Writing a thesis should be used for inculcating research knowledge and skills. Allpostgraduate students shall conduct a research project of sufficient depth to bepresented to the University as a postgraduate thesis under the supervision of aneligible faculty member of the department as guide and one or more co-guides whomaybefromthe sameorotherdepartments.

Inadditiontothethesisproject,everypostgraduatetraineeshallparticipateinatleastonead ditionalresearchprojectthatmaybestarted oralready ongoinginthedepartment.Itispreferablethatthisprojectwillbeinanareadifferentfromthe thesiswork. For instance, if a clinical research project is taken up as thesis work, theadditional project may deal with community/field/laboratory work. Diversity ofknowledge andskillscantherebybe reinforced.

I. Traininginteachingskills

MedicalEducationUnit(MEU)/DepartmentofMedicaleducation(DOME)shouldtrain PG students in education methodologies and assessment techniques. The PGstudentsshallconductUGclassesinvariouscoursesandafacultyshallobserveandpro videfeedbackonteachingskills tothestudent.

J. Logbook

During the training period, the postgraduate student should maintain a Log Bookindicatingthedurationofthepostings/workdoneinWards,OPDs,Casualtyandother areas of posting. This should indicate the procedures assisted and performed and theteaching sessions attended. The log book entries must be done in real time. The logbookisthusarecordofvariousactivitiesbythestudentlike:(1)Overallparticipation&pe rformance,(2)attendance,(3)participationinsessions,(4)recordofcompletionofpre-determinedactivities,and(5)acquisitionofselectedcompetencies.

The purposeofthe LogBookisto:

a) helpmaintainarecordofthework doneduringtraining,
b) enableFaculty/Consultantstohavedirectinformationabouttheworkdone andintervene,ifnecessary,

c) provide feedback and assess the progress of learning with experiencegainedperiodically.

The Log Book should be used in the internal assessment of the student, should bechecked and assessed periodically by the faculty members imparting the training.The PG students will be required to produce completed log book in original at thetimeoffinalpracticalexamination.ItshouldbesignedbytheHeadoftheDepartment. A proficiency certificate from the Head of Department regarding theclinical competence and skillful performance of procedures by the student will besubmittedbythe PGstudentatthetime oftheexamination.

The PG students shall be trained to reflect and record their reflections in log bookparticularlyofthecriticalincidents.Componentsofgoodteachingpracticesmustbeassessed in all academic activity conducted by the PG student and at least twosessionsdedicatedforassessmentofteachingskillsmustbeconductedeveryyearofthe PG program. The teaching faculty are referred to the MCI Logbook GuidelinesuploadedontheWebsite.

K. Course in Research Methodology: All postgraduate students shall complete anonline course in Research Methodology within six months of the commencementof the batch and generate the online certificate on successful completion of thecourse.

L. Otheraspects

- Thepostgraduatetraineesmustparticipateintheteachingandtrainingprogramofunder graduate students andinternsattendingthedepartment.
- Traineesshallattendaccreditedscientificmeetings(CME,symposia,andconferences)atleastoncea year.
- Departmentshallencouragee-learningactivities.
- ThepostgraduatetraineesmustundergocompulsorytraininginBasicCardiacLifeSupport(BCLS)andAdvanced Cardiac LifeSupport (ACLS).
- The postgraduate trainees mustundergo trainingin information technology anduse ofcomputers.

- Thepostgraduate traineesshouldpreferably undergo trainingin Good ClinicalPractice (GCP)

Duringthetrainingprogram,patientsafetyisofparamountimportance;therefore,relevantclinicalskillsaretobelearntinitiallyonthemodels,latertobeperformed under supervision followed by independent performance. For thispurpose,provisionofskillslaboratoriesinmedicalcollegesismandatory.

ASSESSMENT

FORMATIVEASSESSMENT,i.e.,assessmenttoimprovelearning

Formative assessment should be continual and should assess medical knowledge,patient care, procedural & academic skills, interpersonal skills, professionalism,self-directedlearningandabilitytopracticeinthe system.

GeneralPrinciples

TheInternalAssessmentshouldbeconductedintheoryandpractical/clinicalexamination, should be frequent, cover all domains of learning and used to providefeedbacktoimprovelearning;itshouldalsocoverprofessionalismandcommunicationskills.The InternalAssessmentshouldincludequarterlyassessment.

QuarterlyassessmentduringtheMDtrainingshouldbebasedon:

- Casepresentation,caseworkup, casehandling/management :once a week
- Laboratoryperformance :twice aweek
- Journalclub :once a week
- Seminar :onceafortnight
- Casediscussions :onceafortnight/month
- Interdepartmentalcaseorseminar :onceamonth

Note: Thesesessionsmaybeorganizedandrecordedasaninstitutionalactivityforallpostgraduates.

- AttendanceatScientificmeetings,CMEprogrammes(atleast02each)

Importantinstructions:

- Thefeedbackshould begiventostudentstimelyand frequentlyso thattheygeta chancetoimprove.
- AllteachersoftheDepartmentshouldbeinvolvedinassessment.
- The records andLog book shall be checkedandassessedperiodically by thefacultymembersimpartingthetraining.

Thestudenttobeassessedperiodicallyaspercategorieslistedinpostgraduatestudentappraisalform(AnnexureI).

SUMMATIVE ASSESSMENT, i.e., assessment at the end of

trainingEssentialpre-requisitesforappearing forexaminationinclude:

1. **Log book** of work done during the training period including rotation postings,departmentalpresentations, andinternalassessmentreportsshouldbesubmitted.

2. At least **two presentations** at national level conference. One research paper shouldbe published / accepted in an indexed journal**. (It is suggested that the local orUniversity Review committee assessthe worksentforpublication).**

Thesummativeexaminationwouldbecarriedoutaspertheir RulesgiveninthelatestPOSTGRADUATE MEDICAL EDUCATION REGULATIONS. The theory examinationshallbeheldinadvancebeforetheClinicalandPracticalexamination,sothat the answer books can be assessed and evaluated before the commencement of theclinical/PracticalandOralexamination**.**

Thepostgraduateexaminationshallbeinthreeparts**:**

1. **Thesis**

   Thesis shall be submitted at least six months before the Theory and Clinical /Practicalexamination.Thethesisshallbeexaminedbyaminimumof threeexaminers;oneinternalandtwoexternalexaminers,whoshallnotbetheexaminersfor Theory and Clinical examination. A post graduate student in broad specialtyshall be allowed to appear for the Theory and Practical/Clinical examination onlyaftertheacceptanceoftheThesisbytheexaminers**.**

2. **Theoryexamination**

The examinations shall be organized on the basis of 'Grading'or 'Marking system'to evaluate and to certify post graduate student's level of knowledge, skill andcompetence at the end of the training, as given in the latest POSTGRADUATEMEDICAL EDUCATION REGULATIONS. Obtaining a minimum of 50% marksin'Theory'aswellas'Practical'separatelyshallbemandatoryforpassingexamination asawhole.TheexaminationforM.D./M.Sshallbeheldattheendof3rd academicyear.

There shall be four theory papers (as per PG Regulations).**PaperI:** Basicsciencesasapplied toPharmacology**PaperII:**SystemicPharmacology

PaperIII: ClinicalPharmacology,Experimentation,Research,BiostatisticsandEducation

PaperIV: Recentadvancesinthe Pharmacology

3. **Practical/clinical and Oral/viva voce examinationPracticalexamination**

Practicalexaminationshouldbespreadover**two**daysandincludevariousmajorcomponents ofthesyllabusfocusingmainlyonthepsychomotordomain.

Oral/Vivavoceexaminationon definedareasshouldbeconductedby eachexaminer separately. Oral examination shall be comprehensive enough to test thepostgraduate student's overall knowledge of the subject focusing on psychomotorandaffectivedomain.

PracticalExaminationExercises:

a) longexercises:

- Protocoldesignfor agivenscenario
- Caseauditforagivencase
- Perform experiments or simulated experiments (as per PG Regulations)Theexercisesshouldbeobserved,responseofstudentnotedandassessed.The questionrelatedtothese exercisescanbe asked

b) shortexercises:

- Interpretationofresultsofaprevioustracing-Tableexercise

- Demonstrationofeffectsofdrugs/interpretationofresultsinhuman
- Demonstration of effects of drugs/interpretation of results in small,animals-optional(asperRegulationsnotified)

  Theexercisesshould beobservedandassessed.

c) OSPEexercises: ObjectiveStructuredPracticalExamination(OSPE)

OSPE should have 10-15 stations. Stations should be mixture of observed(observerpresent)andunobservedstations(withoutanobserver).Fewexamplesaregivenbelow:

- Variousdrug deliverysystems
- Calculatingpharmacokineticparameters
- Pharmaceuticalcalculations
- Statisticalexercise
- Pharmacoeconomics
- Criticalappraisalofapublishedpaper
- Abstractwritingofapublishedpaper
- Evaluationofdrug promotionalliterature.
- AdverseDrugReaction(ADR)reportingandcausalityassessment
- Assessmentofpreclinicaltoxicitydata
- Analysisofrationalandirrationalformulations
- SelectingaP-drugandwritingrationalprescriptions
- Analyticalinstruments-useandinterpretation
- Identifyingethicsrelateddilemmas/mistakesinclinicaltrialdocuments

d) Assessmentofteaching/presentationskills

- e.g., presentation of a UG lecture, making Question paper, LearningObjectives
- Discussionondissertation

Recommended

ReadingsBooks:

1. Brunton LL, Hilal-Dandan R, Knollmann BC. Goodman and Gilman's ThePharmacological Basis of Therapeutics, 13th edition, Mc Graw Hill Education,2018.

2. KatzungBG.Basic& Clinical Pharmacology,14th edition,McGrawHillEducation,2018.
3. Papadakis MA, Mcphee SJ. CurrentMedical Diagnosis & Treatment. 60theditionNewYork.McGrawHillEducation.2021.
4. RitterM,FlowerR,HendersonG,LokeYK,MacEwanD,RangHP.Pharmacology.Elsevier,9thedition,2020.
5. Tripathi KD. Essentials of Medical Pharmacology, 8th edition. Jaypee BrothersMedicalPublishers PrivateLtd:NewDelhi2019.
6. M.N.Ghosh.FundamentalsofExperimentalPharmacology.7thEdition.Hilton&Company,2019.
7. BadyalD.PracticalManualofPharmacology.JaypeeBrothersMedicalPublishers;3rd edition2020.
8. Vogel HJ. Drug Discovery and Evaluation: Pharmacological Assays Springer;3rdedition,2007.
9. Sharma S, Velpandian T. Illustrated Reviews Pharmacology. Wolter Kluver,SouthAsianEdition,2019.
10. MedhiB,PrakashA.PracticalManualofExperimental&ClinicalPharmacology.JaypeeBrothersMedicalPublishers,2ndedition,2017.
11. AlldredgeBK, CorelliRL, ErnstME, GuglielmoJr.BJ, JacobsonPA,Kradjan WA,Williams BA.Koda-KimbleandYoung'sAppliedTherapeuticsLippincott WilliamsandWilkins,10thedition,2012.
12. Cheston B Cunha,BurkeA Cunha.Antibioticessentials.Jaypee BrothersMedicalPublishers 17th edition,2021.

Websites:

1. National Guidelines on national programs e.g.https://cdsco.gov.in/opencms/opencms/en/Home
2. MOHFWWebsite https://www.mohfw.gov.in/
3. WHOWebsite https://www.who.int/

Journals:

03-05 internationalJournals and02national(allindexed).

StudentappraisalformforMDinPharmacology											
	Elements	**Lessthan Satisfactory**			**Satisfactory**			**More than satisfactory**			**Comments**
		1	2	3	4	5	6	7	8	9	
1	**Scholastica ptitudeand learning**										
1.1	Has knowledgeappr opriate forleveloftrainin g										
1.2	Participation andcontribution tolearning activity(e.g., Journal Club,Seminars,CM E etc)										
1.3	Conductofresearc handotherscholarl y activityassigned (e.g.,Posters, publicationsetc)										
1.4	Documentation ofacquisition ofcompetence (e.g.,Logbook)										
1.5	Performancein work-basedassess ments										
1.6	Self-directed Learning										
2	**Work related totraining**										
2.1	Practical skills thatareappropriate for theleveloftraining										
2.2	Respectforproce sses andproceduresint he workspace										
2.3	Ability to work withothermembers of theteam										

2.4	Participation andcompliance withthe qualityimprovem entprocessatthe workenvironment										

2.5	Ability to recordanddocumentwork accuratelyandappropriatefor leveloftraining										
3	**Professional attributes**										
3.1	Responsibility andaccountability										
3.2	Contribution togrowth of learningoftheteam										
3.3	Conductthatisethicallyappropriate andrespectful at alltimes										
4	**Space foradditionalcomments**										
5	**Disposition**										
	Has thisassessmentpattern beendiscussedwithnthe trainee?	Yes	No								
	Ifnotexplain										
	Name andSignatureofthe assesse										
	Nameand Signature of theassessor Date										

SubjectExpertGroupmembersforpreparationofREVISEDGuidelinesforcompetency basedpostgraduatetrainingprogrammeforMDinPharmacology

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