SEMESTER VII

BP701T.INSTRUMENTALMETHODSOFANALYSIS(Theory)

45Hours

Scope: This subject deals with the application of instrumental methods in qualitative andquantitativeanalysisofdrugs.Thissubjectisdesignedtoimpartafundamentalknowledge on the principles and instrumentation of spectroscopic and chromatographictechnique.Thisalsoemphasizesontheoreticalandpracticalknowledgeonmodernanalyticalinstruments that areusedfordrugtesting.

Objectives: Upon completionofthecoursethestudentshallbe ableto

1. Understandtheinteractionofmatterwithelectromagneticradiationsanditsapplications indruganalysis
2. Understandthechromatographicseparationandanalysis ofdrugs.
3. Performquantitative&qualitativeanalysisofdrugsusingvariousanalyticalinstruments .

CourseContent:

UNIT–I **10Hours**

UVVisiblespectroscopy

Electronictransitions,chromophores,auxochromes,spectralshifts,solventeffectonabsorptionspectra,BeerandLambert'slaw,Derivationanddeviations.

Instrumentation-Sourcesofradiation,wavelengthselectors,samplecells,detectors-Phototube,Photomultipliertube,Photovoltaiccell,SiliconPhotodiode.

Applications-Spectrophotometrictitrations,Singlecomponentandmulticomponentanalysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and externalconversions,factorsaffectingfluorescence,quenching,instrumentationandapplications

UNIT–II **10Hours**

IRspectroscopy

Introduction,fundamentalmodesofvibrationsinpolyatomicmolecules,samplehandling,factorsaffectingvibrations

Instrumentation-Sourcesofradiation,wavelengthselectors,detectors-Golaycell,Bolometer,Thermocouple,Thermister,Pyroelectricdetector andapplications

FlamePhotometry-Principle,interferences,instrumentationandapplications

Atomicabsorptionspectroscopy-
Principle,interferences,instrumentationandapplications

Nepheloturbidometry- Principle,instrumentationandapplications

UNIT–III **10Hours**

Introductiontochromatography

Adsorptionandpartitioncolumnchromatography-
Methodology,advantages,disadvantagesandapplications.

Thinlayerchromatography-
Introduction,Principle,Methodology,Rfvalues,advantages,disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques,advantages,disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniquesofpaper,gel,capillaryelectrophoresis, applications

UNIT–IV **08Hours**

Gas chromatography - Introduction, theory, instrumentation, derivatization,temperatureprogramming,advantages,disadvantagesandapplications

High performance liquid chromatography (HPLC)-Introduction, theory,instrumentation,advantagesand applications.

UNIT–V **07Hours**

Ionexchange chromatography-Introduction,classification, ionexchange resins,properties,mechanismofionexchangeprocess,factorsaffectingionexchange,methodologyandapplications

Gelchromatography-Introduction,theory,instrumentationandapplications

Affinitychromatography- Introduction,theory,instrumentationandapplications

BP702T.INDUSTRIAL PHARMACYII(Theory)

45Hours

Scope: Thiscourseisdesignedtoimpartfundamentalknowledgeonpharmaceuticalproductdevelopment andtranslationfromlaboratoryto market

Objectives: Upon completionofthecourse,thestudentshallbeableto:

1. Knowtheprocessof pilotplantandscaleupofpharmaceuticaldosageforms
2. Understand theprocess oftechnologytransferfrom lab scaleto commercial batch
3. KnowdifferentLawsandActsthatregulatepharmaceuticalindustry
4. Understandthe approvalprocessandregulatoryrequirementsfordrugproducts

CourseContent:

UNIT-I **10Hours**

Pilotplantscaleuptechniques: Generalconsiderations-including significanceofpersonnelrequirements,spacerequirements,rawmaterials,Pilotplantscaleupconsiderations for solids, liquid orals, semi solids and relevant documentation, SUPACguidelines,Introduction toplatformtechnology

UNIT-II **10Hours**

Technologydevelopmentandtransfer:WHOguidelinesforTechnologyTransfer(TT):Terminology,Technologytransferprotocol,Qualityriskmanagement,TransferfromR&Dtoproduction(Process,packagingandcleaning),GranularityofTTProcess(API,excipients,finishedproducts,packagingmaterials)Documentation,Premisesandequipments,qualificationandvalidation, qualitycontrol,analyticalmethodtransfer,Approvedregulatorybodiesandagencies,Commercialization-practicalaspectsandproblems(casestudies),TTagenciesinIndia-APCTD,NRDC,TIFAC,BCIL,TBSE/SIDBI; TT related documentation-confidentialityagreement,licensing,MoUs,legalissues

UNIT-III **10Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatoryauthorities, Role of Regulatory affairs department, Responsibility of Regulatory AffairsProfessionals

Regulatory requirements for drug approval: Drug Development Teams, Non-ClinicalDrugDevelopment,Pharmacology,DrugMetabolismandToxicology,Generalconsiderations of Investigational New Drug (IND) Application, Investigator's Brochure(IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical ResearchProtocols, Biostatistics in Pharmaceutical Product Development, Data Presentation forFDASubmissions,Management ofClinicalStudies.

UNIT-IV **08Hours**

Qualitymanagementsystems: Quality management&Certifications:ConceptofQuality,TotalQualityManagement,QualitybyDesign(QbD),SixSigmaconcept,Outof Specifications(OOS), Change control,IntroductiontoISO9000seriesofqualitysystemsstandards,ISO14000, NABL,GLP

UNIT-V **07Hours**

IndianRegulatoryRequirements: CentralDrugStandardControlOrganization(CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate ofPharmaceutical Product (COPP), Regulatory requirements and approval procedures forNewDrugs.

Recommended Books:(LatestEditions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April availableathttp,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. InternationalRegulatoryAffairsUpdates,2005.availableathttp ://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A GuideforPrescriptionDrugs,MedicalDevices,andBiologics'SecondEdition.
4. RegulatoryAffairs broughtbylearningplus,inc.availableathttp.//www.cgmp.com/ ra.htm.

BP703T.PHARMACYPRACTICE(Theory)

45Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice ofHospital Pharmacy, the students are required to learn various skills like drug distribution,druginformation,andtherapeuticdrugmonitoringforimprovedpatientcare.Incommunity pharmacy,studentswillbelearningvariousskillssuchasdispensingofdrugs,respondingtominorailmentsbyprovidingsuitablesafemedication,patientcounsellingfor improvedpatient carein thecommunityset up.

Objectives: Upon completionofthecourse,thestudentshallbeableto

1. knowvarious drugdistributionmethodsinahospital
2. appreciate the pharmacystoresmanagementand inventorycontrol
3. monitordrugtherapyofpatientthroughmedicationchartreviewandclinicalreview
4. obtainmedicationhistoryinterviewandcounsel thepatients
5. identifydrugrelatedproblems
6. detectandassessadversedrugreactions
7. interpretselectedlaboratoryresults(asmonitoringparametersintherapeutics)ofspecificdiseasestates
8. knowpharmaceuticalcareservices
9. dopatientcounselingincommunitypharmacy;
10. appreciatetheconceptofRationaldrugtherapy.

UnitI: **10Hours**

a) Hospitalandit'sorganization

Definition,Classificationofhospital-Primary,SecondaryandTertiaryhospitals,Classification based on clinical and non-clinical basis, Organization Structure of aHospital,andMedicalstaffs involvedinthehospitalandtheirfunctions.

b) Hospitalpharmacyanditsorganization

Definition, functions of hospital pharmacy, Organization structure, Location, Layoutandstaffrequirements,andResponsibilitiesandfunctionsofhospitalpharmacists.

c) Adversedrugreaction

Classifications-Excessivepharmacologicaleffects,secondarypharmacologicaleffects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicityfollowingsuddenwithdrawalofdrugs,Druginteraction-beneficialinteractions,adverseinteractions,andpharmacokineticdruginteractions,Methods fordetecting

drug interactions, spontaneous case reports and record linkage studies, and Adversedrugreactionreportingand management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legalrequirementsforestablishmentandmaintenanceofadrugstore,Dispensingofproprietaryproducts, maintenanceof records ofretailandwholesaledrugstore.

UnitII: 10Hours

a) Drugdistribution systemin ahospital

Dispensingofdrugstoinpatients,typesofdrugdistributionsystems,chargingpolicyandlabelling,Dispensingofdrugstoambulatorypatients,andDispensingofcontrolleddrugs.

b) Hospitalformulary

Definition, contents of hospital formulary, Differentiation of hospital formulary andDrug list, preparation and revision, and addition and deletion of drug from hospitalformulary.

c) Therapeuticdrugmonitoring

NeedforTherapeuticDrugMonitoring,FactorstobeconsideredduringtheTherapeuticDrug Monitoring,andIndianscenarioforTherapeuticDrugMonitoring.

d) Medicationadherence

Causesofmedicationnon-adherence,pharmacistroleinthemedicationadherence,andmonitoringofpatientmedication adherence.

e) Patientmedicationhistoryinterview

Needfor the patient medicationhistoryinterview,medicationinterviewforms.

f) Communitypharmacymanagement

Financial,materials,staff,andinfrastructurerequirements.

UnitIII: 10Hours

a) Pharmacyandtherapeuticcommittee

Organization,functions,Policiesofthepharmacyandtherapeuticcommitteeinincludingdrugsintoformulary,inpatientandoutpatientprescription,automaticstoporder,andemergencydruglist preparation

Drug**informationservice:**

DrugandPoisoninformationcentre,Sourcesofdruginformation,Computerisedservices,and storageandretrievalofinformation.

Patientcounseling

Definitionofpatientcounseling;stepsinvolvedinpatientcounseling,andSpecialcasesthatrequirethepharmacist

b) Educationandtrainingprogramin thehospital

Roleofpharmacistintheeducationandtrainingprogram,Internalandexternaltraining program, Services to the nursing homes/clinics, Code of ethics for communitypharmacy,andRoleofpharmacistintheinterdepartmentalcommunicationandcommunityhealth education.

c) Prescribedmedicationorderandcommunicationskills

Prescribedmedicationorder-interpretationandlegalrequirements,andCommunicationskills-communicationwithprescribersandpatients.

UnitIV **8Hours**

a) Budgetpreparationandimplementation

Budgetpreparationandimplementation

b) ClinicalPharmacy

IntroductiontoClinicalPharmacy,Conceptofclinicalpharmacy,functionsandresponsibilitiesofclinicalpharmacist,Drug therapy monitoring-medicationchartreview, clinical review, pharmacist intervention, Ward round participation, Medicationhistoryand Pharmaceutical care.

DosingpatternanddrugtherapybasedonPharmacokinetic &diseasepattern.

c) Overthecounter(OTC)sales

Introductionandsaleofoverthecounter,andRationaluseofcommonoverthecountermedications.

UnitV **7Hours**

a) Drugstore managementandinventorycontrol

Organisation of drug store, types of materials stocked and storage conditions, Purchaseand inventory control:principles, purchase procedure, purchase order,procurementand stocking, Economic order quantity, Reorder quantity level, and Methods used fortheanalysisofthedrugexpenditure

b) Investigationaluseofdrugs

Description,principlesinvolved,classification,control,identification,roleofhospitalpharmacist, advisorycommittee.

c) InterpretationofClinicalLaboratoryTests

Bloodchemistry,hematology,andurinalysis

Recommended Books(LatestEdition):

1. MerchantS.H.and Dr.J.S.Quadry. *Atextbookof hospitalpharmacy*,4thed.Ahmadabad:B.S.ShahPrakakshan; 2001.
2. ParthasarathiG,KarinNyfort-Hansen,Milap CNahata.*AtextbookofClinicalPharmacy Practice- essential concepts and skills,* 1st ed. Chennai: OrientLongmanPrivateLimited; 2004.
3. WilliamE.Hassan.*Hospitalpharmacy*,5thed.Philadelphia:Lea&Febiger;1986.
4. TipnisBajaj.*HospitalPharmacy*,1sted.Maharashtra:CareerPublications;2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society ofHealthSystemPharmacistsInc; 2009.
6. ParmarN.S.*Health EducationandCommunityPharmacy*,18thed.India:CBSPublishers&Distributers ; 2008.

Journals:

1. Therapeuticdrugmonitoring.ISSN:0163-4356
2. Journalofpharmacypractice.ISSN:0974-8326
3. Americanjournalofhealthsystempharmacy.ISSN:1535-2900(online)
4. Pharmacytimes(Monthlymagazine)

BP704T:NOVEL DRUGDELIVERYSYSTEMS(Theory)

45Hours

Scope: Thissubjectisdesignedtoimpartbasicknowledgeonthe areaofnoveldrugdeliverysystems.

Objectives: Upon completionofthecoursestudentshallbeable

1. To understand various approachesfordevelopmentofnovel drugdeliverysystems.
2. To understand the criteria for selection of drugs and polymers for the development ofNovel drugdeliverysystems, theirformulation and evaluation

Coursecontent:

Unit-I **10Hours**

Controlled drug delivery systems: Introduction, terminology/definitions and rationale,advantages, disadvantages, selection of drug candidates.Approaches to design controlledreleaseformulationsbasedondiffusion,dissolutionandionexchangeprinciples.Physicochemicalandbiologicalpropertiesofdrugsrelevanttocontrolledreleaseformulations

Polymers: Introduction,classification,properties,advantagesandapplicationofpolymersin formulationofcontrolledrelease drugdeliverysystems.

Unit-II **10Hours**

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules,microparticles,methodsofmicroencapsulation,applications

MucosalDrugDeliverysystem: Introduction,Principlesofbioadhesion/mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability andformulation considerations ofbuccal deliverysystems

ImplantableDrugDeliverySystems: Introduction,advantagesanddisadvantages,conceptofimplantsand osmoticpump

Unit-III **10Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factorsaffecting permeation,permeationenhancers,basic componentsof TDDS,formulationapproaches

Gastroretentivedrugdeliverysystems: Introduction,advantages,disadvantages,approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesivesystemsandtheirapplications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes ofdrug delivery,FormulationofInhalers(dry powder andmetereddose),nasalsprays,nebulizers

Unit-IV **08Hours**

TargeteddrugDelivery: Conceptsandapproachesadvantagesanddisadvantages,introduction toliposomes,niosomes,nanoparticles,monoclonalantibodiesandtheirapplications

Unit-V **07Hours**

OcularDrugDeliverySystems: Introduction,intraocularbarriersandmethodstoovercome – Preliminarystudy,ocularformulationsandocuserts

IntrauterineDrugDeliverySystems: Introduction,advantagesanddisadvantages,developme ntofintrauterinedevices (IUDs) andapplications

Recommended Books:(LatestEditions)

1. YW.Chien,NovelDrugDeliverySystems,2nd edition,revisedandexpanded,MarcelDe kker,Inc., NewYork,1992.
2. Robinson,J.R.,LeeV.H.L,ControlledDrugDeliverySystems,MarcelDekker,Inc.,Ne wYork,1992.
3. EncyclopediaofControlledDelivery.EdithMathiowitz,PublishedbyWileyInterscien ce Publication,JohnWileyandSons,Inc,New York.Chichester/Weinheim
4. N.K.Jain,ControlledandNovelDrugDelivery,CBSPublishers&Distributors,NewDel hi,First edition1997(reprintin2001).
5. S.P.VyasandR.K.Khar,ControlledDrugDelivery-conceptsandadvances,VallabhPrakashan,NewDelhi,First edition2002.

Journals

1. IndianJournalofPharmaceuticalSciences(IPA)
2. IndianDrugs (IDMA)
3. JournalofControlledRelease(ElsevierSciences)
4. DrugDevelopment andIndustrial Pharmacy(Marcel&Decker)
5. InternationalJournalofPharmaceutics(ElsevierSciences)

BP705P.INSTRUMENTALMETHODSOFANALYSIS(Practical)

4Hours/Week

2 Determinationofabsorptionmaximaandeffectofsolventsonabsorptionmaximaofor ganiccompounds
3 Estimation ofdextrosebycolorimetry
4 Estimation ofsulfanilamide bycolorimetry
5 Simultaneousestimationofibuprofenandparacetamolby UVspectroscopy
6 AssayofparacetamolbyUV-Spectrophotometry
7 Estimation of quinine sulfate byfluorimetry
8 Studyof quenchingof fluorescence
9 Determinationof sodiumbyflame photometry
10 Determination ofpotassiumbyflame photometry
11 Determinationofchloridesandsulphatesbynepheloturbidometry
12 Separationof amino acidsbypaperchromatography
13 Separation of sugarsbythin layerchromatography
14 Separation of plantpigmentsbycolumnchromatography
15 DemonstrationexperimentonHPLC
16 DemonstrationexperimentonGasChromatography

Recommended Books(LatestEditions)

1. InstrumentalMethodsofChemicalAnalysisbyB.KSharma
2. Organic spectroscopybyY.RSharma
3. TextbookofPharmaceutical AnalysisbyKennethA.Connors
4. Vogel'sTextbookofQuantitativeChemicalAnalysisbyA.I. Vogel
5. Practical PharmaceuticalChemistrybyA.H.Beckett andJ.B. Stenlake
6. Organic ChemistrybyI.L.Finar
7. Organic spectroscopybyWilliamKemp
8. QuantitativeAnalysisofDrugsbyD.C.Garrett
9. Quantitative AnalysisofDrugsinPharmaceuticalFormulationsbyP.D.Sethi
10. Spectrophotometric identificationof OrganicCompoundsbySilverstein