SEMESTERVIII

BP801T.BIOSTATISITCSANDRESEARCHMETHODOLOGY(Theory)

45Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals withdescriptive statistics,Graphics, Correlation,Regression, logistic regression Probabilitytheory,Samplingtechnique,Parametrictests,NonParametrictests,ANOVA,Introduction to Design of Experiments, Phases of Clinical trials and Observational andExperimentalstudies,SPSS,RandMINITABstatisticalsoftware's,analyzingthestatistical datausingExcel**.**

Objectives: Upon completionofthecoursethestudentshallbeableto

- KnowtheoperationofM.S.Excel,SPSS,RandMINITAB®, DoE(DesignofExperiment)
- Knowthevariousstatisticaltechniquestosolvestatisticalproblems
- Appreciatestatisticaltechniquesinsolvingtheproblems**.**

Coursecontent:

Unit-I **10Hours**

Introduction: Statistics,Biostatistics,Frequencydistribution

Measures of central tendency:Mean, Median, Mode- Pharmaceutical examples**Measures of dispersion**: Dispersion, Range, standard deviation,Pharmaceuticalproblems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticalsexamples

Unit-II **10Hours**

Regression: Curve fittingbythe methodof leastsquares, fittingthelines y=a+bxandx =a+by,Multipleregression,standarderrorofregression– PharmaceuticalExamples**Probability:**Definition of probability, Binomial distribution, Normal distribution,Poisson'sdistribution,properties -problems

Sample,Population,largesample,smallsample,

Nullhypothesis,alternativehypothesis,sampling, essence of sampling, types of sampling, Error-I type,Error-II type, Standarderrorofmean(SEM)-Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One wayandTwoway),Least Significancedifference

Unit-III **10Hours**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallistest,FriedmanTest

Introduction to Research: Need for research, Need for design of Experiments,ExperientialDesign Technique,plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph**Designingthemethodology:**SamplesizedeterminationandPowerofastudy,Reportwritingandpresentationofdata,Protocol,Cohorts studies, Observational studies,Experimental studies,Designingclinical trial,various phases.

Unit-IV **8Hours**

Blockingandconfoundingsystem forTwo-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels**IntroductiontoPracticalcomponentsofIndustrialandClinicalTrialsProblems**:StatisticalAnalysisUsingExcel,SPSS,MINITAB®,DESIGNOFEXPERIMENTS,R-OnlineStatisticalSoftware'stoIndustrialandClinical trialapproach

Unit-V **7Hours**

Design andAnalysisofexperiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design**ResponseSurfacemethodology**:Centralcompositedesign,Historicaldesign, OptimizationTechniques

RecommendedBooks(Latestedition):

1. Pharmaceuticalstatistics-Practicalandclinicalapplications,SanfordBolton,publisherMarcel DekkerInc.NewYork.
2. FundamentalofStatistics –HimalayaPublishingHouse-S.C.Guptha
3. DesignandAnalysisofExperiments–PHI LearningPrivateLimited, R.Pannerselvam,
4. Design and AnalysisofExperiments–WileyStudentsEdition,DouglasandC.Montgomery

BP802TSOCIALAND PREVENTIVEPHARMACY **(Theory)**

Hours:45

Scope:
The purpose of this course is to introduce to students a number of health issues and theirchallenges. This course also introduced a number of national health programmes. Therolesofthe pharmacistinthesecontextsarealso discussed.

Objectives:
Afterthesuccessfulcompletionofthiscourse,thestudentshallbeableto:

- Acquirehighconsciousness/realizationofcurrentissuesrelatedtohealthandpharmaceuticalproblemswithinthe countryandworldwide.
- Have a critical wayofthinkingbasedon current healthcaredevelopment.
- Evaluate alternative ways of solving problems related tohealth andpharmaceuticalissues

Coursecontent:

UnitI: 10Hours

Concept of health and disease: Definition, concepts and evaluation of public health.Understanding the concept of prevention and control of disease, social causes of diseasesandsocial problems of thesick.

Social and health education: Food in relation to nutrition and health, Balanced diet,Nutritionaldeficiencies,Vitamindeficiencies,Malnutrition anditsprevention.

Sociology and health: Socio cultural factors related to health and disease, Impact ofurbanization onhealth anddisease, Povertyand health

Hygieneandhealth:personalhygieneandhealthcare; avoidablehabits

UnitII: 10Hours

Preventive medicine: General principles of prevention and control of diseases such ascholera,SARS,Ebolavirus,influenza,acuterespiratory infections,malaria,chickenguinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer,drugaddiction-drugsubstanceabuse

UnitIII: 10Hours

National health programs, its objectives, functioning and outcome of the following:HIVANDAIDScontrolprogramme,TB,Integrateddiseasesurveillanceprogram(IDSP),Nationalleprosycontrolprogramme,Nationalmentalhealthprogram,National

programme for prevention and control of deafness, Universal immunization programme,Nationalprogrammeforcontrolofblindness,Pulsepolioprogramme.

UnitIV: 08Hours

National health intervention programme for mother and child, National family welfareprogramme, National tobacco control programme, National Malaria Prevention Program,National programme for the health care for the elderly, Social health programme; role ofWHOinIndian nationalprogram

UnitV: 07Hours

Community services in rural, urban and school health: Functions of PHC,Improvementin rural sanitation, national urban health mission, Health promotion and education inschool.

RecommendedBooks(Latestedition)*:*

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition,2010,ISBN: 9789380704104, JAYPEEPublications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by RoyRabindra Nath, Saha Indranil, 4thEdition, 2013, ISBN: 9789350901878, JAYPEEPublications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6thEdition,2014,ISBN: 9789351522331, JAYPEEPublications
4. EssentialsofCommunity Medicine—APracticalApproach,HiremathLalitaD,HiremathDhananjayaA,2ndEdition,2012,ISBN :9789350250440,JAYPEEPublications
5. ParkTextbook ofPreventiveandSocialMedicine,KPark,21stEdition,2011,ISBN-14:9788190128285,BANARSIDASBHANOTPUBLISHERS.
6. CommunityPharmacyPractice,RameshAdepu,BSPpublishers, Hyderabad

Recommended Journals:

1.ResearchinSocialandAdministrativePharmacy,Elsevier,Ireland

BP803ET. Pharmaceutical Marketing Management (Theory)

45Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemists and,technicalpeople, butalsorequires skilled managers who cantake the industry forwardby managing and taking the complex decisions which are imperative for the growth of theindustry. The KnowledgeandKnow-how ofmarketing managementgroomthe peoplefortakingachallenging rolein Sales and Productmanagement.

Course Objective: The course aims to provide an understanding of marketing conceptsandtechniques andtheirapplicationsinthepharmaceuticalindustry.

UnitI **10Hours**

Marketing:

Definition, general concepts and scope of marketing; Distinction between marketing &selling; Marketing environment; Industry and competitive analysis; Analyzing consumerbuyingbehavior; industrial buyingbehavior.

Pharmaceuticalmarket:

Quantitative and qualitative aspects; size and composition of the market; demographicdescriptionsandsocio-psychologicalcharacteristicsoftheconsumer;marketsegmentation&targeting.Consumerprofile;Motivationandprescribinghabitsofthephysician;patients' choice of physicianand retailpharmacist.Analyzing the Market;Roleofmarket research.

UnitII **10Hours**

Productdecision:

Classification, product line and product mix decisions, product lifecycle,productportfolioanalysis;productpositioning;New productdecisions;Productbranding,packagingandlabelingdecisions,Productmanagementinpharmaceuticalindustry.

UnitIII **10Hours**

Promotion:

Methods,determinantsofpromotionalmix,promotionalbudget;Anoverviewofpersonalselling,advertising,directmail,journals,sampling,retailing, medicalexhibition,publicrelations,onlinepromotionaltechniques forOTCProducts.

UnitIV **10Hours**

Pharmaceuticalmarketingchannels:

Designingchannel,channelmembers,selectingtheappropriatechannel,conflictinchannels,physicaldistributionmanagement:Strategicimportance,tasksinphysicaldistributionmanagement.

Professionalsalesrepresentative(PSR):

DutiesofPSR,purposeofdetailing,selectionandtraining,supervising,normsforcustomercalls, motivating,evaluating,compensationandfutureprospectsofthePSR.

UnitV **10Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies,issuesinpricemanagementinpharmaceuticalindustry.AnoverviewofDPCO(DrugPriceControlOrder)andNPPA(NationalPharmaceuticalPricingAuthority).

Emergingconceptsinmarketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing;GlobalMarketing.

Recommended Books:(LatestEditions)

1. PhilipKotlerandKevinLaneKeller:MarketingManagement,PrenticeHallofIndia,NewDelhi
2. Walker,BoydandLarreche:MarketingStrategy-PlanningandImplementation,TataMCGrawHill,NewDelhi.
3. DhruvGrewalandMichaelLevy:Marketing,TataMCGrawHill
4. ArunKumarandNMenakshi:MarketingManagement,VikasPublishing,India
5. RajanSaxena:MarketingManagement; TataMC Graw-Hill(IndiaEdition)
6. Ramaswamy,U.S&Nanakamari,S:MarketingManagemnt:GlobalPerspective,IndianContext,MacmilanIndia,NewDelhi.
7. Shanker,Ravi:ServiceMarketing,ExcellBooks,NewDelhi
8. SubbaRaoChanganti,PharmaceuticalMarketinginIndia(GIFT–Excelseries)ExcelPublications.

BP804ET:PHARMACEUTICALREGULATORYSCIENCE(Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatoryrequirementsforapprovalofnewdrugs, anddrugproductsinregulatedmarkets ofIndia & other countries like US, EU,Japan,Australia,UK etc.Itpreparesthestudentstolearnindetailonthe regulatoryrequirements,documentationrequirements,andregistrationprocedures formarketingthedrugproducts.

Objectives: Upon completionofthesubjectstudentshallbeableto;

1. Know about the processof drugdiscoveryanddevelopment
2. Knowtheregulatoryauthoritiesandagenciesgoverningthemanufactureandsaleofpha rmaceuticals
3. Knowtheregulatoryapprovalprocessandtheirregistrationin Indianandintern ationalmarkets

Coursecontent:

UnitI **10Hours**

NewDrugDiscoveryanddevelopment

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinicalactivities, clinical studies,Innovator andgenerics, Concept of generics, Generic drugproductdevelopment.

UnitII **10Hours**

RegulatoryApprovalProcess

Approvalprocessesandtimelines involved inInvestigationalNew Drug (IND),NewDrug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to anapprovedNDA/ ANDA.

Regulatoryauthorities andagencies

Overview of regulatory authorities of India, United States, European Union,Australia,Japan,Canada(Organizationstructureand typesofapplications)

UnitIII **10Hours**

RegistrationofIndiandrugproductinoverseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug MasterFiles(DMF),CommonTechnicalDocument(CTD),electronicCommonTechnical

Document(eCTD),ASEANCommonTechnicalDocument(ACTD)research.

UnitIV **08Hours**

Clinicaltrials

DevelopingclinicaltrialprotocolsInstitutionalReviewBoard/IndependentEthicscommittee-formationandworkingprocedures,Informedconsentprocessandprocedures,GCPobligationsofInvestigators,sponsors&Monitors,Managing andMonitoringclinical trials,Pharmacovigilance-safetymonitoringinclinical trials

UnitV **07Hours**

RegulatoryConcepts

Basicterminology,guidance,guidelines,regulations,LawsandActs,Orangebook,FederalRegister,CodeofFederalRegulatory, Purplebook

Recommended books(Latestedition):

1. DrugRegulatoryAffairsbySachinItkar,Dr.N.S.Vyawahare,Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry andRobertP. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa HealthcarePublishers.
3. NewDrugApprovalProcess:AcceleratingGlobalRegistrationsByRichardAGuarino,MD,5th edition,DrugsandthePharmaceuticalSciences,Vol.190.
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc.
5. FDARegulatoryAffairs:aguideforprescriptiondrugs,medicaldevices,andbiologics/edited byDouglas J. Pisano,David Mantus.
6. GenericDrugProductDevelopment,SolidOralDosageforms,LeonShargelandIsader Kaufer,Marcel Dekkerseries,Vol.143
7. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFay A.RozovskyandRodneyK.Adams
8. PrinciplesandPracticesof ClinicalResearch, SecondEditionEditedby JohnI.GallinandFrederick P.Ognibene
9. Drugs:FromDiscoveryto Approval,SecondEditionByRickNg

BP805T:PHARMACOVIGILANCE(Theory)

45hours

Scope: This paper will provide an opportunity for the student to learn about development ofpharmacovigilanceasa science, basic terminologies used inpharmacovigilance, globalscenarioofPharmacovigilance,trainstudentsonestablishingpharmacovigilanceprogrammeinan organization, various methods that can be used to generate safety data and signal detection. Thispaperalsodevelopstheskillsof classifyingdrugs,diseasesandadversedrugreactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, andappreciate):

1. Whydrugsafetymonitoringisimportant?
2. Historyanddevelopmentofpharmacovigilance
3. Nationalandinternationalscenarioofpharmacovigilance
4. Dictionaries,codingandterminologiesusedinpharmacovigilance
5. Detectionofnewadversedrugreactionsandtheirassessment
6. Internationalstandardsforclassificationofdiseasesanddrugs
7. Adversedrugreactionreportingsystemsandcommunicationinpharmacovigilance
8. Methodstogeneratesafetydataduringpreclinical,clinicalandpostapprovalphasesofdrugs' life cycle
9. Drugsafetyevaluationinpaediatrics,geriatrics,pregnancyandlactation
10. PharmacovigilanceProgramofIndia(PvPI)requirement for ADRreportinginIndia
11. ICHguidelinesforICSR,PSUR,expeditedreporting,pharmacovigilanceplanning
12. CIOMSrequirementsforADRreporting
13. Writingcasenarrativesofadverseeventsandtheirquality.

CourseContent

UnitI **10Hours**

IntroductiontoPharmacovigilance

- HistoryanddevelopmentofPharmacovigilance
- ImportanceofsafetymonitoringofMedicine
- WHOinternationaldrugmonitoringprogramme
- PharmacovigilanceProgramofIndia(PvPI)

Introductiontoadversedrugreactions

- DefinitionsandclassificationofADRs
- Detectionandreporting
- MethodsinCausalityassessment
- Severityandseriousnessassessment
- Predictabilityandpreventabilityassessment
- Managementofadversedrugreactions

Basicterminologiesusedinpharmacovigilance

- Terminologiesofadversemedicationrelatedevents
- Regulatoryterminologies

Unit II **10hours**

Druganddiseaseclassification

- Anatomical,therapeuticandchemicalclassificationofdrugs
- Internationalclassificationofdiseases
- Dailydefineddoses
- InternationalNonproprietaryNamesfordrugs

Drugdictionariesandcodinginpharmacovigilance

- WHOadversereactionterminologies
- MedDRAandStandardisedMedDRAqueries
- WHOdrugdictionary
- Eudravigilancemedicinalproductdictionary

Informationresourcesinpharmacovigilance

- Basicdruginformationresources
- SpecialisedresourcesforADRs

Establishingpharmacovigilanceprogramme

- Establishinginahospital
- Establishment &operationofdrugsafetydepartment inindustry
- ContractResearchOrganisations(CROs)
- Establishinganationalprogramme

Unit III **10Hours**

Vaccinesafetysurveillance

- VaccinePharmacovigilance
- Vaccinationfailure
- Adverseeventsfollowingimmunization

Pharmacovigilancemethods

- Passivesurveillance–Spontaneousreportsandcaseseries
- Stimulatedreporting
- Activesurveillance–Sentinelsites,drugeventmonitoringandregistries
- Comparativeobservationalstudies– Crosssectionalstudy,casecontrolstudyandcohort study
- Targetedclinicalinvestigations

Communicationinpharmacovigilance

- EffectivecommunicationinPharmacovigilance
- CommunicationinDrugSafetyCrisismanagement
- CommunicatingwithRegulatoryAgencies,BusinessPartners,Healthcarefacilities&Media

UnitIV **8Hours**

Safetydatageneration

- Preclinicalphase
- Clinicalphase
- Postapprovalphase(PMS)

ICHGuidelinesforPharmacovigilance

- OrganizationandobjectivesofICH
- Expeditedreporting
- Individualcasesafetyreports
- Periodicsafetyupdatereports
- Postapprovalexpeditedreporting
- Pharmacovigilanceplanning
- Goodclinicalpracticeinpharmacovigilancestudies

UnitV **7hours**

Pharmacogenomicsofadversedrugreactions

- GeneticsrelatedADRwithexamplefocusingPKparameters.

Drugsafetyevaluationinspecialpopulation

- Paediatrics
- Pregnancyandlactation
- Geriatrics

CIOMS

- CIOMSWorkingGroups
- CIOMSForm

CDSCO(India)andPharmacovigilance

- D&CActandScheduleY
- DifferencesinIndianandglobalpharmacovigilancerequirements

RecommendedBooks(Latestedition):

1. TextbookofPharmacovigilance:SKGupta,JaypeeBrothers,Medical Publishers.
2. PracticalDrugSafetyfromAtoZByBartonCobert,PierreBiron,JonesandBartlettPublishers.
3. Mann'sPharmacovigilance:ElizabethB.Andrews,Nicholas,WileyPublishers.
4. Stephens'DetectionofNewAdverseDrug Reactions:JohnTalbot,PatrickWalle,WileyPublishers.
5. AnIntroductiontoPharmacovigilance:PatrickWaller,WileyPublishers.
6. Cobert'sManualofDrugSafetyandPharmacovigilance:BartonCobert,Jones&Bartlett Publishers.
7. TextbookofPharmacoepidemiologeditedbyBrianL.Strom,StephenEKimmel,SeanHennessy,WileyPublishers.
8. ATextbookofClinicalPharmacyPractice-EssentialConceptsandSkills:G.Parthasarathi,Karin NyfortHansen,MilapC.Nahata
9. NationalFormularyofIndia
10. TextBookofMedicinebyYashpal Munjal

11. TextbookofPharmacovigilance:conceptandpracticebyGPMohantaandPKManna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

BP806ET.QUALITYCONTROLANDSTANDARDIZATIONOFHERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines forevaluation and standardization of herbs and herbal drugs. The subject also provides anopportunity forthestudenttolearncGMP,GAPandGLPintraditionalsystemofmedicines.

Objectives: Upon completionofthesubjectstudentshallbeableto;

1. knowWHO guidelines forqualitycontrol ofherbal drugs
2. knowQualityassurance in herbaldrugindustry
3. knowtheregulatoryapprovalprocessandtheirregistrationinIndianandintern ationalmarkets
4. appreciateEUandICH guidelinesforqualitycontrolofherbaldrugs

UnitI **10 hours**

Basictestsfordrugs–Pharmaceuticalsubstances,Medicinalplantsmaterialsanddosageforms WHO guidelines for quality control of herbal drugs.Evaluationofcommercialcrudedrugsintended foruse

UnitII **10 hours**

QualityassuranceinherbaldrugindustryofcGMP,GAP,GMPandGLPintraditional system of medicine.

WHOGuidelinesoncurrentgoodmanufacturingPractices(cGMP)forHerbalMedicinesWHO Guidelines onGACPforMedicinal Plants.

UnitIII **10 hours**

EU andICHguidelinesfor qualitycontrol ofherbal drugs.
ResearchGuidelinesforEvaluatingtheSafetyand EfficacyofHerbal Medicines

UnitIV **08hours**

Stabilitytestingofherbalmedicines.Applicationofvariouschromatographictechniquesinstand ardizationof herbal products.
Preparationofdocumentsfornewdrugapplicationandexportregistration GMP requirementsandDrugs&CosmeticsAct provisions.

UnitV **07 hours**

Regulatoryrequirements forherbalmedicines.

WHOguidelinesonsafetymonitoringofherbalmedicinesinpharmacovigilancesystemsComparisonofvarious HerbalPharmacopoeias.

Roleofchemical andbiologicalmarkersinstandardizationofherbalproducts

Recommended Books:(LatestEditions

1. PharmacognosybyTreaseandEvans
2. PharmacognosybyKokate,PurohitandGokhale
3. Rangari,V.D.,Text bookofPharmacognosyandPhytochemistryVol.I,CarrierPub.,2006.
4. Aggrawal,S.S.,HerbalDrugTechnology.UniversitiesPress,2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional MedicinalProducts,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation ofBotanicals.BusinessHorizonsPublishers,NewDelhi,India,2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality controlprinciplestoherbaldrugs.InternationalJournalofPhytomedicine1(2009);p.4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World HealthOrganization,Geneva,1998.WHO.GuidelinesfortheAppropriateUseofHerbalMedicines. WHO Regional Publications, Western Pacific Series No 3, WHORegional officefortheWesternPacific,Manila,1998.
9. WHO. TheInternationalPharmacopeia,Vol. 2:QualitySpecifications, 3rdedn.WorldHealthOrganization,Geneva,1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World HealthOrganization,Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and AlternativeMedicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World HealthOrganization,Geneva, 2005.
12. WHO.GuidelinesonGoodAgriculturalandCollectionPractices(GACP)forMedicinalPlants.WorldHealthOrganization,Geneva,2004.

BP807ET.COMPUTERAIDEDDRUGDESIGN(Theory)

45HoursS

cope: This subject is designed to provide detailed knowledge of rational drug designprocessand varioustechniques usedinrational drugdesign process.

Objectives: Upon completionofthecourse,thestudentshallbeabletounderstand

- Design anddiscoveryofleadmolecules
- The role ofdrugdesignin drugdiscoveryprocess
- TheconceptofQSAR anddocking
- Variousstrategiestodevelopnewdruglikemolecules.
- Thedesign ofnewdrugmolecules usingmolecularmodelingsoftware

CourseContent:

UNIT-I **10Hours**

IntroductiontoDrugDiscoveryandDevelopment

Stages ofdrugdiscoveryanddevelopment

LeaddiscoveryandAnalogBased DrugDesign

Rationalapproachestoleaddiscovery basedontraditionalmedicine,Random screening, Non-random screening, serendipitous drug discovery,leaddiscoverybasedondrugmetabolism,leaddiscoverybasedoncli nicalobservation.

Analog BasedDrug Design: Bioisosterism,Classification,Bioisostericreplacement. Anythreecasestudies

UNIT-II **10Hours**

QuantitativeStructureActivityRelationship(QSAR)

SARversusQSAR,HistoryanddevelopmentofQSAR,Typesofphysicochemi cal parameters, experimental and theoretical approaches forthe determination ofphysicochemical parameters such as Partitioncoefficient, Hammet'ssubstituent constant and Tafts steric constant.Hanschanalysis,FreeWilsonanalysis,3D-QSARapproacheslikeCOMFAandCOMSIA.

UNIT-III **10Hours**

MolecularModelingandvirtualscreeningtechniques

VirtualScreeningtechniques: Druglikenessscreening,Conceptofpharm acophoremappingandpharmacophorebasedScreening,

Moleculardocking:Rigiddocking,flexibledocking,manualdocking,Docking based screening.*Denovo* drugdesign.

UNIT-IV **08Hours**

Informatics&Methodsindrugdesign

IntroductiontoBioinformatics,chemoinformatics.ADMEdatabases,chemical,biochemicalandpharmaceuticaldatabases.

UNIT-V **07Hours**

Molecular Modeling: Introduction to molecular mechanics and quantummechanics.Energy Minimization methods and Conformational Analysis,global conformational minimadetermination.

Recommended Books(LatestEditions)

1. RobertGCK, ed.,"DrugAction at theMolecularLevel"UniversityPrak PressBaltimore.
2. MartinYC."QuantitativeDrugDesign"Dekker,NewYork.
3. DelgadoJN,RemersWAeds"Wilson&Gisvolds'sTextBookofOrganicMedicinal&PharmaceuticalChemistry"Lippincott,NewYork.
4. Foye WO"Principles ofMedicinalchemistry'Lea&Febiger.
5. KorolkovasA,BurckhalterJH."EssentialsofMedicinalChemistry"WileyInterscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry"JohnWiley&Sons,NewYork.
7. PatrickGraham,L.,AnIntroductiontoMedicinalChemistry,OxfordUniversityPress.
8. SmithHJ,WilliamsH,eds,"IntroductiontotheprinciplesofDrugDesign"WrightBoston.
9. SilvermanR.B."TheorganicChemistryofDrugDesignandDrugAction"AcademicPress NewYork.

BP808ET:CELLANDMOLECULARBIOLOGY(Elective subject)

45Hours

Scope:

- Cellbiology isabranchof biology thatstudies cells –their physiologicalproperties,theirstructure,the organelles theycontain,interactionswiththeirenvironment,theirlifecycle,division,deathand cellfunction.
- Thisisdonebothonamicroscopicandmolecularlevel.
- Cell biologyresearchencompassesboththegreatdiversityofsingle-celledorganismslike bacteria and protozoa,aswellasthemany specializedcellsinmulti-cellularorganismssuchas humans,plants,andsponges.

Objectives: Upon completionofthesubjectstudentshallbeableto;

- Summarize cellandmolecularbiologyhistory.
- Summarizecellularfunctioningandcomposition.
- Describethechemicalfoundationsofcellbiology.
- SummarizetheDNApropertiesofcellbiology.
- Describeproteinstructureandfunction.
- Describecellularmembranestructureandfunction.
- Describebasicmoleculargeneticmechanisms.
- SummarizetheCellCycle

Coursecontent:

UnitI **10Hours**

a) CellandMolecularBiology:DefinitionstheoryandbasicsandApplications.
b) CellandMolecular Biology:HistoryandSummation.
c) Propertiesofcellsandcellmembrane.
d) ProkaryoticversusEukaryotic
e) CellularReproduction
f) ChemicalFoundations–anIntroductionandReactions(Types)

UnitII **10Hours**

a) DNA andtheFlowofMolecularInformation
b) DNAFunctioning
c) DNAandRNA
d) TypesofRNA
e) TranscriptionandTranslation

UnitIII **10Hours**

a) Proteins: Defined**and**AminoAcids
b) ProteinStructure

c) RegularitiesinProteinPathways
d) CellularProcesses
e) PositiveControlandsignificanceofProteinSynthesis

UnitIV **08Hours**

a) ScienceofGenetics
b) TransgenicsandGenomicAnalysis
c) CellCycleanalysis
d) MitosisandMeiosis
e) CellularActivitiesandCheckpoints

UnitV **07Hours**

a) CellSignals:Introduction
b) ReceptorsforCellSignals
c) SignalingPathways:Overview
d) MisregulationofSignalingPathways
e) Protein-Kinases:Functioning

RecommendedBooks(latestedition):

1. W.B.HugoandA.D.Russel:PharmaceuticalMicrobiology,BlackwellScientificpublications,OxfordLondon.
2. PrescottandDunn.,IndustrialMicrobiology,4th edition,CBSPublishers&Distributors,Delhi.
3. Pelczar,ChanKreig,Microbiology,TataMcGrawHilledn.
4. MalcolmHarris,BalliereTindallandCox:PharmaceuticalMicrobiology.
5. Rose:IndustrialMicrobiology.
6. Probisher,Hinsdilletal:FundamentalsofMicrobiology,9thed.Japan
7. CooperandGunn's:TutorialPharmacy,CBSPublisherandDistribution.
8. Peppler:MicrobialTechnology.
9. Edward:FundamentalsofMicrobiology.
10. N.K.Jain:PharmaceuticalMicrobiology,VallabhPrakashan,Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverlycompany
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles andApplicationsofRecombinantDNA: ASMPress WashingtonD.C.
13. RAGoldshyet.al.,:KubyImmunology.

BP809ET.COSMETICSCIENCE(Theory)

45Hours

UNITI **10Hours**

Classificationofcosmeticandcosmeceuticalproducts

DefinitionofcosmeticsasperIndianandEUregulations,Evolutionofcosmeceuticalsfromcosmetics,cosmetics as quasiandOTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients,preservatives.Classification andapplication

Skin: Basicstructureandfunctionofskin.

Hair: Basicstructureofhair.Hairgrowthcycle.

OralCavity: Commonproblemassociatedwithteethandgums**.**

UNITII **10Hours**

Principlesof formulationandbuildingblocksofskincareproducts:

Facewash, Moisturizingcream,ColdCream,Vanishingcreamandtheiradvantagesanddisadvantages.Application of these products in formulation of cosmecuticals.**Antiperspants&deodorants**-Actives&mechanismofaction.

Principlesof formulationandbuildingblocksofHaircareproducts:

Conditioningshampoo,Hairconditioner,anti-dandruffshampoo.Hairoils.

Chemistry and formulation of Para-phylene diamine based hair dye.Principles of formulation and building blocks of oral care products:Toothpasteforbleedinggums,sensitiveteeth.Teethwhitening,Mouthwash.

UNITIII **10Hours**

Sunprotection,ClassificationofSunscreens andSPF.

Roleofherbsin cosmetics:

Skin Care:Aloe and turmericHaircare:Hennaand amla.

Oralcare:Neemandclove

Analyticalcosmetics:BIS specificationandanalyticalmethodsforshampoo,skin-creamandtoothpaste**.**

UNITIV **08Hours**.

PrinciplesofCosmeticEvaluation:Principlesofsebumeter,corneometer.MeasurementofTEWL,Skin Color,Hairtensilestrength,Haircombingproperties

Soaps,andsyndetbars.Evolutionandskinbenfits.

UNITV **07Hours**

Oilyand dryskin,causesleadingtodryskin, skinmoisturisation.Basic understandingoftheterms Comedogenic,dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causesCosmeticproblemsassociatedwithskin:blemishes,wrinkles,acne,pricklyheatandbodyodor.

AntiperspirantsandDeodorants-Activesandmechanismofaction

References

1) Harry'sCosmeticology,Wilkinson,Moore,SeventhEdition,George Godwin.
2) Cosmetics– Formulations,ManufacturingandQualityControl,P.P.Sharma,4th Edition,VandanaPublications Pvt.Ltd., Delhi.
3) Text bookof cosmelicologybySanju Nanda&RoopK. Khar, TataPublishers.

BP810ET.EXPERIMENTAL PHARMACOLOGY (PHARMACOLOGICALSCREENINGMETHODS)

45Hours

Scope: Thissubjectisdesignedtoimpartthebasicknowledgeofpreclinicalstudiesinexperimentalanimals includingdesign,conductandinterpretationsofresults.

Objectives

Uponcompletionofthecoursethestudentshallbeableto,

- Appreciatetheapplications ofvarious commonlyusedlaboratoryanimals.
- Appreciateanddemonstrate thevariousscreeningmethodsusedinpreclinicalresearch
- Appreciateanddemonstratetheimportanceofbiostatisticsandresearchmethodology
- Designandexecutearesearch hypothesisindependently

Unit–I	**08Hours**
LaboratoryAnimals: Study of CPCSEA and OECD guidelines for maintenance, breedingandconductofexperimentsonlaboratoryanimals,Commonlabanimals: Descriptionandapplicationsofdifferentspeciesandstrainsofanimals. Popular transgenicandmutant animals. Techniquesforcollectionofbloodandcommonroutesofdrugadministration in laboratory animals,Techniquesof blood collectionandeuthanasia.	
Unit–II	**10Hours**
Preclinicalscreening models a. Introduction: Dose selection, calculation and conversions,preparation of drug solution/suspensions, grouping of animals andimportanceofshamnegativeandpositivecontrolgroups.Rationaleforselection of animalspeciesandsexforthestudy. **b. Studyof screeninganimalmodelsfor** Diuretics, nootropics, anti-Parkinson's,antiasthmatics,**Preclinical screening models:** for CNS activity- analgesic,antipyretic,anti-inflammatory,generalanaesthetics,sedativeandhypnotics, antipsychotic, antidepressant, antiepileptic,antiparkinsonism,alzheimer's disease	

Unit–III **Preclinical screening models:** for ANS activity, sympathomimetics,sympatholytics, parasympathomimetics, parasympatholytics, skeletalmusclerelaxants,drugsactingoneye,localanaethetics	**10Hours**
Unit–IV **Preclinicalscreeningmodels:** forCVSactivity-antihypertensives,diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory,coagulants, and anticoagulants Preclinicalscreeningmodelsforotherimportantdrugslike antiulcer,antidiabetic,anticancerand antiasthmatics.	**10Hours**
ResearchmethodologyandBio-statistics Selectionofresearchtopic,reviewofliterature,researchhypothesisandstudydesign Pre-clinicaldataanalysisandinterpretationusingStudents‘t’test and One-wayANOVA.Graphicalrepresentationof data	**05Hours**

RecommendedBooks(latestedition):

1. FundamentalsofexperimentalPharmacology-byM.N.Ghosh
2. HandbookofExperimentalPharmacology-S.K.Kulakarni
3. CPCSEAguidelinesforlaboratoryanimalfacility.
4. DrugdiscoveryandEvaluationbyVogelH.G.
5. DrugScreeningMethodsbySureshKumar GuptaandS. K. Gupta
6. IntroductiontobiostatisticsandresearchmethodsbyPSSSundarRaoandJRichard

BP811ET. ADVANCEDINSTRUMENTATIONTECHNIQUES

45Hours

Scope: This subject deals with the application of instrumental methods in qualitative andquantitative analysis of drugs. This subject is designed to impart advanced knowledge ontheprinciplesandinstrumentationofspectroscopicandchromatographichyphenatedtechniques.Thisalsoemphasizesontheoreticalandpracticalknowledgeonmodernanalyticalinstruments that areusedfordrugtesting.

Objectives: Upon completionofthecoursethestudentshallbeableto

- understandtheadvancedinstrumentsusedanditsapplicationsindruganalysis
- understandthechromatographicseparationandanalysisofdrugs.
- understandthecalibrationofvariousanalyticalinstruments
- knowanalysisof drugsusingvariousanalyticalinstruments.

CourseContent:

UNIT-I **10Hours**

NuclearMagneticResonancespectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemicalshift, coupling constant, Spin - spin coupling, relaxation, instrumentation andapplications

MassSpectrometry-Principles,Fragmentation,Ionizationtechniques– Electronimpact,chemicalionization,MALDI,FAB,Analyzers-TimeofflightandQuadrupole,instrumentation, applications

UNIT-II **10Hours**

ThermalMethods ofAnalysis: Principles, instrumentationand applicationsof ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA),Differential ScanningCalorimetry(DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction,powderdiffraction,structural elucidationandapplications.

UNIT-III **10Hours**

Calibrationandvalidation-asperICHandUSFDAguidelines

CalibrationoffollowingInstruments

Electronicbalance,UV-Visiblespectrophotometer,IRspectrophotometer,

Fluorimeter,FlamePhotometer,HPLCandGC

UNIT-IV **08Hours**

Radio immune assay: Importance, various components, Principle, differentmethods,Limitation andApplicationsofRadioimmuno assay

Extractiontechniques:Generalprincipleandprocedureinvolvedinthesolidphaseextraction andliquid-liquidextraction

UNIT-V **07Hours**

Hyphenatedtechniques-LC-MS/MS,GC-MS/MS,HPTLC-MS.

RecommendedBooks(LatestEditions)

1. InstrumentalMethodsofChemicalAnalysis byB.KSharma
2. Organic spectroscopybyY.RSharma
3. TextbookofPharmaceutical Analysis byKennethA.Connors
4. Vogel'sTextbookofQuantitativeChemicalAnalysisbyA.I.Vogel
5. Practical PharmaceuticalChemistrybyA.H.BeckettandJ.B.Stenlake
6. OrganicChemistrybyI.L.Finar
7. Organic spectroscopybyWilliamKemp
8. QuantitativeAnalysisofDrugsbyD.C.Garrett
9. Quantitative Analysisof Drugs in PharmaceuticalFormulationsbyP.D. Sethi
10. Spectrophotometric identification of OrganicCompoundsbySilverstein

BP812ET.DIETARYSUPPLEMENTSANDNUTRACEUTICALS

No.ofhours:3 Tutorial:1 Credit

point:4Scope:

Thissubjectcoversfoundationaltopicthatareimportantforunderstandingtheneedandrequirementso fdietarysupplementsamongdifferent groupsinthepopulation.

Objective:

This module aims to provide an understanding of the concepts behind the theoreticalapplicationsofdietarysupplements.Bytheendofthecourse,studentsshouldbe ableto:

1. Understandtheneedofsupplementsbythedifferentgroupofpeopletomaintainhealthy life.
2. Understandtheoutcomeofdeficienciesindietarysupplements.
3. Appreciatethecomponentsindietarysupplementsandtheapplication.
4. Appreciatetheregulatoryand commercialaspectsofdietarysupplementsincludinghealthclaims.

UNITI 07 hours

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classificationof Nutraceuticals, Health problems and diseases that can be prevented or cured byNutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis,hypertensionetc.
b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutritioneducationincommunity.
c. Source, Name of marker compounds and their chemical nature, Medicinal uses andhealthbenefitsoffollowingusedasnutraceuticals/functionalfoods:Spirulina,Soyabean, Ginseng, Garlic, Broccoli,Gingko,Flaxseeds

UNITII 15 hours

Phytochemicalsasnutraceuticals:Occurrenceandcharacteristicfeatures(chemicalnaturemedicinal benefits)offollowing

a) Carotenoids-αandβ-Carotene,Lycopene,Xanthophylls,leutin
b) Sulfides:Diallylsulfides,Allyltrisulfide.
c) Polyphenolics:Reservetrol
d) Flavonoids-Rutin,Naringin,Quercitin,Anthocyanidins,catechins,Flavones
e) Prebiotics/Probiotics.:Fructooligosaccharides,Lactobacillum
f) Phytoestrogens:Isoflavones,daidzein,Geebustin,lignans
g) Tocopherols
h) Proteins,vitamins, minerals,cereal, vegetablesandbeveragesasfunctionalfoods: oats,wheatbran,ricebran, sea foods, coffee,teaandthelike.

UNITIII 07 hours

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of freeradicalsincells,damagingreactionsoffreeradicalsonlipids,proteins,Carbohydrates,nu cleicacids.

b) Dietaryfibresandcomplexcarbohydrates asfunctionalfoodingredients..

UNITIV **10 hours**

a) FreeradicalsinDiabetesmellitus, Inflammation, Ischemicreperfusioninjury,Cancer,Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage,muscle damage. Free radicals involvement in other disorders. Free radicals theory ofageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidantdefence,Superoxidedismutase,catalase,Glutathioneperoxidase,GlutathioneVitaminC,VitaminE,α-Lipoicacid,melatonin
Syntheticantioxidants:ButylatedhydroxyToluene,ButylatedhydroxyAnisole.

c) Functionalfoodsforchronicdiseaseprevention

UNITV **06 hours**

a) Effectofprocessing,storageandinteractionsofvariousenvironmentalfactorsonthepotentialofnutraceuticals.

b) RegulatoryAspects;FSSAI,FDA,FPO,MPO,AGMARK.HACCPandGMPsonFoodSafety.Adulterationoffoods.

c) PharmacopoeialSpecificationsfordietarysupplementsandnutraceuticals.

References:

1. DieteticsbySriLakshmi
2. RoleofdietaryfibresandneutraceuticalsinpreventingdiseasesbyK.TAgustiandP.Faizal:BS Punblication.
3. Advanced NutritionalTherapiesbyCooper.K.A., (1996).
4. TheFoodPharmacybyJeanCarper,Simon&Schuster,UKLtd.,(1988).
5. PrescriptionforNutritionalHealingbyJamesF.BalchandPhyllisA.Balch2nd Edn.,AveryPublishingGroup,NY(1997).
6. G.GibsonandC.williamsEditors *2000Functionalfoods*WoodheadPubl.Co.London.
7. Goldberg,I.*FunctionalFoods*.1994.ChapmanandHall,New York.
8. Labuza,T.P.2000FunctionalFoodsandDietarySupplements:Safety,GoodManufacturing Practice(GMPs) and Shelf Life Testing in*Essentials of FunctionalFoods* M.K.Sachmidland T.P.Labuzaeds.AspenPress.
9. HandbookofNutraceuticalsandFunctionalFoods,ThirdEdition(ModernNutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*.Eighthedition.LeaandFebiger

SemesterVIII–Elective course on

PharmaceuticalProductDevelopmentNoofHours:3 Tutorial:1

Creditpoints:4

Unit-I **10Hours**

Introduction to pharmaceutical product development, objectives, regulations related topreformulation,formulationdevelopment,stabilityassessment,manufacturingandquality controltestingofdifferent types ofdosageforms

Unit-II **10Hours**

Anadvancedstudy ofPharmaceuticalExcipientsinpharmaceuticalproductdevelopmentwithaspecialreferencetothefollowingcategories

i. Solventsandsolubilizers
ii. Cyclodextrinsandtheirapplications
iii. Non-ionicsurfactantsandtheirapplications
iv. Polyethyleneglycolsandsorbitols
v. Suspendingandemulsifyingagents
vi. Semisolidexcipients

Unit-III **10Hours**

AnadvancedstudyofPharmaceuticalExcipientsinpharmaceuticalproductdevelopmentwithaspecial referencetothefollowingcategories

i. Tabletandcapsuleexcipients
ii. Directlycompressiblevehicles
iii. Coatmaterials
iv. Excipientsinparenteralandaerosolsproducts
v. ExcipientsforformulationofNDDS

Selectionandapplicationofexcipientsinpharmaceuticalformulationswithspecificindustrialapplications

Unit-IV **08Hours**

Optimizationtechniquesinpharmaceuticalproductdevelopment.Astudy ofvariousoptimizationtechniquesforpharmaceuticalproductdevelopmentwithspecificexamples.Optimization by factorial designs and their applications.A study of QbD and itsapplicationinpharmaceutical productdevelopment.

Unit-V **07Hours**

Selectionandqualitycontroltestingofpackagingmaterialsforpharmaceuticalproductdevelopment-regulatoryconsiderations.