VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)

M.PHARMACY (PHARMACEUTICAL REGULATORY AFFAIRS)

R23COURSESTRUCTUREANDSYLLABUS

EffectivefromAcademicYear2023-24AdmittedBatch

I YEARISemester

CourseCode	CourseTitle	L	T	P	Credits
Professional Core-I	Good Regulatory Practices	3	1	0	4
Professional Core-II	Drug Regulatory Affairs	3	1	0	4
Professional Elective-I	1. IntellectualPropertyRights 2. TotalQualitymanagement 3. PharmaceuticalValidation	3	1	0	4
Professional Elective-II	1. Stability of Drugs and Dosage Forms 2. Pharmaceutical Formulation Technology 3. DocumentationandRegulatoryWriting	3	1	0	4
	ResearchmethodologyandIPR	2	0	0	2
Laboratory- I	RegulatoryPracticeandDocumentationLab	0	0	6	3
Laboratory-II	DrugRegulationandRegistrationLab	0	0	6	3
Audit-I	AuditCourse-I	2	0	0	0
	Seminar&Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

I YEARIISemester

CourseCode	CourseTitle	L	T	P	Credits
ProfessionalCore-III	Regulatoryaspectsof herbalsandbiologicals	3	1	0	4
ProfessionalCore-IV	Regulatoryaspectsofmedical devices	3	1	0	4
ProfessionalElective-III	1. RegulatoryaspectsofFoodsandNutraceuticals 2. PharmaceuticalQualityControlandQuality Assurance 3. NanoBasedDrugDeliverySystems	3	1	0	4
ProfessionalElective-IV	1. ClinicalResearchandPharmacovigilance 2. Nutraceuticals 3. AdvancedDrugDeliverySystems	3	1	0	4
Laboratory-III	Regulatoryaspectsof herbalsandbiologicalslab	0	0	6	3
Laboratory-IV	Regulatoryaspectsofmedicaldeviceslab	0	0	6	3
	Mini project	2	0	0	2
Audit-II	AuditCourse-II	2	0	0	0
	Seminar&Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

IIYEARI Semester

CourseCode	CourseTitle	L	T	P	Credits
ProfessionalElective-V	1. Biostatistics 2. ScaleupandTechnologyTransfer 3. Productionarea,DesignandPackaging Development	3	1	0	4
OpenElective	OpenElective	3	1	0	4
	ComprehensiveVivaVoce	0	0	8	4
	DissertationWorkReview- II	0	0	24	12
	Total	**6**	**2**	**32**	**24**

IIYEARIISemester

CourseCode	CourseTitle	L	T	P	Credits
Dissertation	DissertationWorkReview- III	0	0	24	12
Dissertation	DissertationViva-Voce	0	0	20	10
	Total	**0**	**0**	**44**	**22**

***ForDissertationWorkReview-I,PleasereferR23AcademicRegulations. Audit Courses I & II:**

1. EnglishforResearchPaperWriting
2. DisasterManagement
3. SanskritforTechnologicalLearning
4. Value Education
5. ConstitutionofIndia
6. PedagogyStudies
7. StressManagementbyYoga
8. PersonalityDevelopmentthroughLifeEnlightenmentSkills

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm IYear ISem (Pharmaceutical Regulatory Affairs)

GOOD REGULATORY PRACTICE (Professional Core - I)

Course Objective: This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs) and biological products and understand the rationale behind these requirements and will propose ways and means ofcomplying with them.

Course Outcome: At completion of this course it is expected that students will be able to understand

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- PrepareandimplementthechecklistsandSOPsforvariousGoodRegulatoryPractices.
- ImplementGoodRegulatoryPracticesintheHealthcareandrelatedIndustries.
- Prepareforthereadinessandconductofauditsandinspections.

UNITI
Current Good Manufacturing Practices: Introduction, USCgmp Part 210 and Part 211.EC Principlesof GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

UNITII
Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals ofLaboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI)Standards

UNITIII
Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPsof GALP, TrainingDocumentation,21 CFRPart 11, General checklist of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.

UNITIV
Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self- Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards

UNITV
Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types ofValidation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. TheInternational Conference on Harmonization (ICH) process, ICH guidelinesto establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.

TEXTANDREFERENCEBOOKS:

1. GoodLaboratoryPracticeRegulations,bySandy Weinberg,FourthEditionDrugsandthe Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner,Wiley Publication.
4. HowtopracticeGLPbyPPSharma,VandanaPublications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C. Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6. Drugs&CosmeticsAct,Rules& Amendments

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm IYear ISem (Pharmaceutical Regulatory Affairs)
DRUG REGULATORY AFFAIRS (Professional Core - II)

Course Objectives: The topics which are present in the Drug regulatory affairs arevery much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

CourseOutcomes:

- Studentswillcometoknowthedifferentcompetentregulatoryauthoritiesglobally.
- Studentsbe aware of technical aspectspertainingtothemarketing authoritization application (MAA)
- The regulatory guidelinesand directionsframedby theregulatory authoritieswill behelpful to place the drug products in market for marketing approvals.

UNITI

DrugRegulatoryAspects(India)

1. Indiandrugregulatoryauthorities,CentralandStateregulatorybodies(FDA)
2. DrugsandCosmeticsActandRuleswithlatestAmendments(Selective)
3. Specialemphasis–ScheduleMandY
4. Newdrugs–Importation,Registration,development,ClinicalTrials,BENOC&BEstudies
5. VariousLicenses–Test Lic., Importlic.,fortesting of drugsand API's, Manufacturing Contract andLoan license manufacturing.

UNITII

GoodManufacturingPractices(GMP)

1. IndianGMPcertification,WHOGMPcertification.
2. ICHguidelinesforstabilitytestingandotherrelevantones(Q1-Q10)
3. Exportpermissionsandmanufacturingforsemi-regulatedcountries
4. Understanding oftheplant layouts withspecialemphasis ontheenvironment &safety. (HVAC,Water Systems, Stores Management, Effluent etc.)
5. QualityAssuranceandQualityControl–Basicunderstandingforin-builtquality.

UNITIII

A detailed study ofregulatory aspects that affect drug product design, manufacture and distribution ina developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act;BolarProvisionsandotherFDARegulations.Regulatoryaspectsofpharmaceuticaland bulkdrugmanufacture, regulatory drug analysis.

UNIT IV

Documentationrelatedtomanufacturing,cleaningmethods,retentionsamplesandrecords, qualitycontrol, batch release documents, distribution records, complaints and recalls.
Quality,safetyandlegislationforcosmeticproductsandherbalproducts.

UNITV

GoverningRegulatoryBodiesacrosstheglobe.

CountryAuthoritySubmission

a. U.SFood&DrugAdministrationUSDMF
b. CanadaTherapeuticProductDirectorateDMF
c. Europe
    1) EuropeanMedicinesAgency(EMEA/NationalAuthorities)EDMF
    2) EuropeanDirectorateforQualityofMedicinesCEP/COS&HealthCareProducts.
    3) MHRA–MedicinesandHealthCareProductsRegulatoryAgency

b. ProductFiling
c. RespondingRegulatoryDeficiencies
d. FinalApprovalProcedure

Preparation, reviewand submission of Drug Master Filesto Regulatory Authoritiesasper theirspecific requirements.

TEXTANDREFERENCEBOOKS

1. OriginallawspublishedbyGovt.ofIndia.
2. TextBookofForensicPharmacybyMithalB.M.;VallabhPrakashan,NewDelhi.
3. LawsofDrugsinIndiabyHussain.
4. TextBookofForensicPharmacybyJainN.K.;VallabhPrakashan,NewDelhi.
5. PharmaceuticalRegulatoryAffairs-SelectedTopics,CVSSubramanyam and JThimmasetty, Vallabh Prakashan Delhi – 2013

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

INTELLECTUALPROPERTYRIGHTS (ProfessionalElective-I)

Course Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

CourseOutcome: Theclearinformationaboutthepatentlaws,intellectualpropertyrightsand drug regulation in India and abroad is gained by the students.

UNIT-I
Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non- Obviousness, Utility, enablement and Best mode),

UNIT-II

a. History of Indian Patent Protection, Rationale behind Patent System, Objectives and Advantagesof Patent System, andfuturechallenges. IndianPatentsAct 1970, Definitionsand Key Terminology, Types of Patent applications, Inventions not patentable (section 3 and4).
b. Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
c. Opposition - pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power ofController.
d. PatentfilingprocedureunderPCT,advantages,patentsearchandliterature

UNIT-III

a. Salient featuresof Indian Patents(Amendments) Act 1999, 2002 and 2005. US and European Patent System,
b. Background,SalientFeaturesandImpactofInternationalTreaties/Conventionslike
    1. ParisConvention,Berneconvention
    2. WorldTradeOrganization(WTO)
    3. World IntellectualPropertyOrganization(WIPO)
    4. TradeRelatedAspectsofIntellectualPropertyRights(TRIPS)
    5. PatentCo-operationTreaty(PCT),MadridProtocol

UNIT-IV

a. PCTApplicationprocedureandreviewprocedure
b. NationalphaseapplicationprocedureforUS&EU
c. PatentprosecutionprocedureinUSandEU
d. WIPOanditsroleinIPR
e. Hatch-WaxmanprovisionforIPR

UNIT-V

a. PatentinvalidationprocessinIndia,USandEurope
b. IPRrelatedtocopyright,trademark,tradesecretandgeographicalindication.
c. Patentapplicationwriting
d. Claimconstructionandclaims.

RECOMMENDEDBOOKS:

1. ResearchMethodologyconceptsandcasesbyDepakChawla,NeenaSondhi
2. DraftmanualofPatentPracticeandProcedure-2008,ThePatentOffice,India
3. IntellectualPropertyRightsinPharmaceuticalIndustry,BSubbaRao,PharmamedPress
4. FundamentalsofPatentsandPatenting,VivekanandaMandal,PharmamedPress
5. ManualofPatentOfficePracticeandProcedure-2010
6. OriginalLawsPublishedbyGovt.ofIndia
7. ProtectionofIndustrialPropertyrightsbyP.DasandGokulDas
8. LawandDrugs,LawPublicationsbyS.N.Katju
9. LawsofdrugsinIndia,Hussain
10. Newdrugapprovalprocess, 5th edition,byGuarino
11. CommercialManualonDrugsandCosmetics2004,2nd edition
12. DrugsandCosmeticsact byVijayMalik
13. GoodManufacturingPracticesforPharmaceuticals,S.H.Wiling,Vol.78,MarcelDecker.
14. fda.org,wipo.int,patentlawlinks.com,hc-sc.gc.ca,ich.org,cder.org
15. CurrentgoodmanufacturingpracticesforpharmaceuticalsbyManoharA.Potdar
16. Pharmaceutical Regulatory affairs–selected topics. CVS subhramanyam and JThimma settee. Delhi, Vallabh Prakashan, 2012

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.PharmI Year I Sem(Pharmaceutical Regulatory Affairs)
TOTALQUALITYMANAGEMENT (Professional Elective-I)

Course Objectives: Total quality management constitutes very useful chapter like –good manufacturing practices, GLP, GCP, ICH etc. Which increases the knowledge of students in various quality control & regulatory aspects.

Course Outcomes: Total quality management helps the students to learn the established regulatory guidelines in GMP, GCP, GLP, USFDA,WHO, ISO etc to become a perfect budding pharmacist. It is very useful to students to acquire vast knowledge regarding the quality control aspects of different regulatory bodies as per their requirements throughout the world.

UNIT-I
ConceptsandPhilosophyofTQM,GLP,GMP(orangeguide).

UNIT–II
Drugregulatoryandaccreditingagenciesoftheworld(USFDA,TGA,ICH,WHO,ISOetc.)

UNIT-III
Good manufacturing practices: Organization and personnel, responsibilities, training, hygiene. Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination. Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP). Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.Manufacture of and controls ondosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc., Packaging and labelling control, line clearance, reconciliation of labels, cartons and other packaging materials. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house. Data generation and storage, quality controldocuments,retention samples, records and audits of quality control facilities. Finished products release, quality review, quality audits, batch release document.

UNIT-IV
Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as mutagenicity, carcinogenicity and teratoginicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials. Quality assurance standards as per ISO.

UNIT-V
Globalizationof drugindustry, present statusand scopeof pharmaceuticalindustryinIndia.WHO and NABL certification, ICH guidelinesfor manufacturing and quality assurance of drug formulation.

TEXTANDREFERENCEBOOKS:

1. GuidelinesforDevelopingNationalDrugPolicies;WHOPublications,1998.
2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
3. AGuidetoTotalQualityManagementbyKaushikMaitraandSedhanK.Ghosh.
4. GMPbyMehra.
5. HowtoPracticeGMP byP.P.Sharma.
6. ISO9000andTotalQualityManagementbySadhanK.Ghosh.
7. GoodManufacturingPracticesforPharmaceuticals-APlanforTotalQualityControlbySidney H.Willing&JamesRStoker.(Drugs&Pharm.Sciences)Vol.78;MarcelDekkerInc.
8. OPPI-Quality Assurance,USP.
9. CurrentgoodmanufacturingpracticesforpharmaceuticalsbyManoharA.Potdar
10. Quality assurance and quality management in pharmaceutical industry by Y. Anjaneyulu and marayya
11. TotalQualityManagement,AnintegratedApproachbyD.R.Kiran,BSPublications
12. TotalQualityManagement,3rdeditionbyJoelE.Ross.CRCpress

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)
PHARMACEUTICALVALIDATION(ProfessionalElective-I)

Course Objective: Themain purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. Thesubject covers the complete information about validation, types, methodology and application.

CourseOutcome: Uponcompletionofthesubjectstudentshallbeableto

- Explaintheaspectofvalidation
- Carryoutvalidationofmanufacturingprocesses
- Applytheknowledgeofvalidationtoinstrumentsandequipments

UNIT-I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User RequirementSpecification, Design Qualification, FactoryAcceptanceTest (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT-II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC

QualificationofGlassware:Volumetricflask,pipette,Measuringcylinder,beakersandburette.

UNIT-III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus,tap density tester, Disintegration tester, Dissolution test apparatus.

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT-IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation ofanalyticalmethodusedincleaning.Cleaningof Equipment.CleaningofFacilities.Cleaninginplace (CIP).

UNIT-V

Analyticalmethodvalidation:Generalprinciples,Validationofanalyticalmethodasper ICH guidelines and USP.

- Validatethemanufacturingfacilities

REFERENCEBOOKS:

1. T.Loftus&R.A.Nash,"Pharmaceutical ProcessValidation",DrugsandPharm Sci.Series,Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. TheTheory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. ValidationMasterplanbyTerveeksorDeeks,DavisHarwoodInternationalpublishing.
4. Validationof AsepticPharmaceutical Processes,2ndEdition,byCarleton&Agalloco,(Marcel Dekker).
5. MichaelLevin,PharmaceuticalProcessScale-Up‖,DrugsandPharm.Sci.Series,Vol.157,2nd Ed.,MarcelDekkerInc.,N.Y.
6. ValidationStandardOperatingProcedures: AStepbyStepGuideforAchievingCompliancein thePharmaceutical, Medical Device, andBiotechIndustries, SyedImtiaz Haider
7. Pharmaceutical Equipment Validation:The UltimateQualification Handbook, Phillip A. Cloud, Interpharm Press
8. ValidationofPharmaceuticalProcesses:SterileProducts,FrederickJ.Carlton(Ed.)and JamesAgalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical MethodvalidationandInstrumentPerformanceVerificationbyChurgChan, HeimanLam

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

STABILITYOFDRUGSANDDOSAGEFORMS (Professional Elective-II)

Course Objectives: These topics are designed impart a specialized knowledge to preserve the propertiesof drugsanddosageformsduringmanufacturestorageand shelf life.Theunderstandingof propertiesandevaluationof stabilityduringstorage, bysolutionandsolidstateagainst severalfactors of degradation.

Course Outcomes: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNITI

Drugdecompositionmechanisms:

1. Hydrolysisandacyltransfers:Natureofreaction,structureandutility,stabilizationof Pharmaceutical examples.
2. Oxidation:Natureofoxidation,kineticsofoxidation, oxidationpathways ofpharmaceutical, Interest Inhibition of oxidation
3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNITII

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid-state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.
Physicalstabilitytestingofdosageforms:

1. Solids–tablets,capsules,powderandgranules
2. Dispersesystems
3. Microbialdecomposition
4. Over-view,physicalstabilityofnoveldrugcarriers,liposomes,niosomes,nano-particles.

UNITIII

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.
Analysisof drugsfrom biological samplesincluding,selectionof biological sample,extraction of drugs by variousmethods as LLE, SPE andMembranefiltration. Factors affecting extraction of drugs.

UNITIV

Generalmethodof analysistodeterminethequality of rawmaterialsusedincosmetic industry.Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNITV

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personalhygiene products, Colour cosmetics, Ethnicproducts, Colourmakeup preparation,Lipsticks, Hairsettinglotionsand Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.
Stabilitystudies:Conceptofstabilitystudies.

a) cGMP&ICHguidelinesforAcceleratedstabilityTesting.
b) Interactionofcontainers&closureCompatibilityTesting.

REFERENCEBOOKS:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
4. J. B. Wilkinson and R. J. Moore, Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
5. P.D.Sethi;QuantitativeAnalysisofDrugsinPharmaceuticalFormulations,3rdEdition-1997,
6. Classification of cosmetics rawmaterials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
8. Methodsof samplingandtestforvariouscosmeticsaslaiddownby Bureauof Indian Standards.
9. Drugstability:PrinciplesandpracticesbyJensT.Carstensen
10. StabilityTestingofDrugProductsbyW.Grimm.
11. StabilityofDrugsandDosageFormsbyYoshiokaandStella.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

PHARMACEUTICALFORMULATIONTECHNOLOGY(Professional Elective-II)

Course Objective: Students will know the pre-formulation studies, methodology, different excipients used in solid dosage forms and their evaluation with references to production technologies. The students also know the optimization techniques and their applications in pharmaceutical industries.

Course Outcome: Students shall explain the pre-formulation parameters, apply ICH guidelines and evaluate drug, drug excipients compatibility. Students also explain about formulation and development, use of excipients in tablets, powders, capsules, micro-encapsules and coating techniques. They also learn and apply the statistical designin different formulations.

UNITI

Pre-formulation: Goals of pre-formulation, solid state manipulation and characterization. pH dependent solubility of drug, equilibrium solubility, intrinsic dissolution of drug, particle sizedistribution.

Flow of Powders: Physical properties and importance. Angle of repose, Cars index, compressibility, bulk density, tapped density.

UNITII

Excipients used in various dosage forms like tablets, capsules, emulsions, suspensions, semisolids and sterile products. Knowledge of packing materials. Drug- excipient compatibility- Drug stability, factors affecting stability, stabilization methods.

UNITIII

Tablets: Typesoftablets,granulationmethods,highlightingoperationssuchasmixing,drying, milling, blending, lubrication and compression.

Tabletcoating:Typesofcoating,stepsinvolvedincoatingprocess-pancoatingandfluidbed coating and problems associated with coating.

Hard Gelatin Capsules:Generalprinciples and steps involved in the production ofdrug loadedhard gelatin capsules, filling operation, filling of powders, granules and pellets.

UNITIV

Dissolution: Principles ofdissolution, factors influencing dissolution, official methods andapparatus. Dissolution of immediate release, controlled release and delayed release products.

UNITV

Stabilitytesting: Chemical degradation and preventivemeasures. Various stability testingconditions and use of stabilizers in packing

TEXTBOOKS:

1. Pharmaceutics-TheScienceofDosageformdesignbyMEAulton.
2. PharmaceuticalDosageforms-Tablets(VolI,IIandIII)byLieberman,Lachmanand Schwartz.
3. PharmaceuticalDosageforms-Capsules(VolI,IIandIII)byAvis,LiebermanandLachman.
4. PharmaceuticalDosage forms – Dispersesystems (Vol I, IIand III) by Avis,Liebermanand Lachman.
5. PharmaceuticalDosageForm:BasicsandBeyond,KamleshJ.Wadher,PharmamedPress
6. ModernPharmaceuticsbyGilbertS.BankerandChristopherT. Rhodes.
7. Pharmaceutical statisticsbyBoltonIndustrialPharmacy-SelectedTopics,CVS SubramanyamandJThimmasetty,VallabhaPrakashanDelhi-2013

REFERENCEBOOKS:

1. TheTheoryandPracticeofindustrialPharmacybyLeonLachman,HerbertA.Lieberman.
2. Remington'sScienceandPracticeofPharmacybyA.Gennaro.
3. Ansel'sPharmaceuticalDosageformandDrugdeliverysystembyLoydV.Allen,Jr.Nicholas G.Popovich,HowardC.Ansel.
4. GenericDrugProductDevelopmentbyLeonShargelandIsadoreKanfer.
5. DispensingforPharmaceuticalStudentsbySJCarter.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

DOCUMENTATIONANDREGULATORYWRITING (Professional Elective-II)

CourseObjective:Thiscourseisdesignedtoimpartfundamentalknowledgeondocumentation and general principlesinvolved in regulatory writing and submission to agencies.

CourseOutcomes: Uponcompletionofthecoursethestudentshallbeableto,

- Knowthevariousdocumentspertainingtodrugsinpharmaceuticalindustry
- Understandthebasicsof regulatorycompilation
- Createandassembletheregulationsubmissionasperthe requirementsofagencies
- Followupthesubmissionsandpostapprovaldocumentrequirements

UNITI

Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation,BatchPackaging Records, Printpack specifications, Distribution records, Certificateof Analysis (CoA), Site Master File and Drug Master Files(DMF).

UNITII

Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions;Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). None CTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.

UNITIII

Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits,Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.

UNITIV

Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).

UNIT-V

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Affected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard

TEXTANDREFERENCEBOOKS:

1. ComplianceauditingforPharmaceuticalManufacturers.KarenGinsburyandGilBismuth, Interpharm/CRC,BocaRaton,LondonNewYork,WashingtonD.C.
2. PharmaceuticalManufacturingHandbook,RegulationsandQualitybyShayneCoxGad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. HandbookofmicrobiologicalQualitycontrol.RosamundM.Baird,NormanA.Hodges, StephenP. Denyar. CRC Press. 2000.
4. AcademicWriting,AjaySemalty,PharmamedPress
5. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis(2005).
6. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
7. Understanding, Managing and ImplementingQuality:Frameworks, Techniquesand Cases,By Jiju Antony; David Preece, Routledge, 2002
8. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
9. Corporate Cultureandthe QualityOrganizationBy JamesW. Fairfield- Sonn, Quorum Books, 2001
10. The Quality Management Sourcebook: An International Guideto Materials and ResourcesBy Christine Avery; Diane Zabel, Routledge, 1997
11. TheQualityToolbox,SecondEdition,NancyR.Tague,ASQPublications
12. Juran'sQualityHandbook,SixthEdition,JosephM.JuranandJosephA.DeFeo,ASQ Publications
13. RootCauseAnalysis,TheCoreofProblemSolvingandCorrectiveAction,DukeOkes, 2009, ASQ Publications
14. InternationalMedicalDeviceRegulatorsForum(IMDRF)MedicalDeviceSingleAudit Program (MDSAP)

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.PharmIYearISem (Pharmaceutical Regulatory Affairs)

RESEARCH METHODOLOGY AND IPR

CourseObjectives:

- Tounderstandtheresearchproblem
- Toknowtheliteraturestudies,plagiarismandethics
- Togettheknowledgeabouttechnicalwriting
- Toanalyzethenatureofintellectualpropertyrightsandnewdevelopments
- Toknowthepatent rights

CourseOutcomes: Attheendofthiscourse,studentswillbeableto

- Understandresearchproblemformulation.
- Analyzeresearchrelatedinformation
- Followresearchethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT-I:
Meaning of research problem, Sourcesof research problem, Criteria Characteristicsof a good research problem, Errorsin selecting a research problem, Scope and objectivesof research problem. Approachesof investigation of solutionsforresearch problem,data collection, analysis,interpretation, Necessary instrumentations

UNIT-II:
Effectiveliteraturestudiesapproaches,analysis,Plagiarism,Researchethics

UNIT-III:
Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT-IV:
Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT-V:
PatentRights: ScopeofPatentRights.Licensingandtransferoftechnology.Patentinformation
and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXTBOOKS:

1. StuartMelvilleandWayneGoddard,"Researchmethodology:anintroductionfor science&engineeringstudents'"
2. WayneGoddardandStuartMelville,"ResearchMethodology:AnIntroduction"
3. PharmaceuticalResearchMethodologyandBioStatistics,BSubbaRao,Pharmamed Press
4. IntellectualPropertyRightsinPharmaceuticalIndustry,BSubbaRao,PharmamedPress

REFERENCEBOOKS:

1. RanjitKumar,2ndEdition,"ResearchMethodology:AStepbyStepGuideforbeginners"
2. Halbert,"ResistingIntellectualProperty",Taylor&FrancisLtd,2007.
3. Mayall,"IndustrialDesign",McGrawHill,1992.
4. Niebel,"ProductDesign",McGrawHill,1974.
5. Asimov,"IntroductiontoDesign",PrenticeHall,1962.
6. RobertP.Merges,PeterS.Menell,MarkA.Lemley,"IntellectualPropertyinNew Technological Age", 2016.
7. T.Ramappa,"IntellectualPropertyRightsUnderWTO",S.Chand,2008

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

REGULATORYPRACTICEANDDOCUMENTATION LAB (Laboratory-I)

Listof Experiments:

1. Casestudies(4Nos.)ofeachofGoodPharmaceuticalPractices.
2. DocumentationforinprocessandfinishedproductsQualitycontroltestsforSolid,liquid, Semisolid and Sterile preparations.
3. PreparationofSOPs,Analyticalreports(Stabilityandvalidation)
4. Protocol preparation for documentation of various types of records (BMR, MFR, DR)Labeling comparison between brand & generics.
5. PreparationofregulatorydossierasperIndianCTDformatandsubmissioninSUGAM
6. CasestudiesonresponsewithscientificrationaletoUSFDAWarningLetter
7. PreparationofsubmissionchecklistofIMPDforEUsubmission.
8. ComparisonstudyofmarketingauthorizationproceduresinEU.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year I Sem (Pharmaceutical Regulatory Affairs)

DRUGREGULATION&REGISTRATIONLAB (Laboratory-II)

Listof Experiments:

1. CasestudiesonChangeManagement/Changecontrol.DeviationsandCorrective& Preventive Actions (CAPA)
2. Importofdrugsforresearchanddevelopmentalactivities
3. GMPAuditRequirementsasperCDSCO
4. PreparationofchecklistforregistrationofINDasperICHCTDformat.
5. PreparationofchecklistforregistrationofNDAasperICHCTDformat.
6. PreparationofchecklistforregistrationofANDAasperICHCTDformat.
7. ComparativestudyofDMFsysteminUS,EUandJapan
8. PreparationofregulatorysubmissionusingeCTDsoftware
9. Documentationofrawmaterialsanalysisasperofficialmonographs
10. Preparationofauditchecklistforvariousagencies
11. PreparationofsubmissiontoFDAusingeCTDsoftware
12. PreparationofsubmissiontoEMAusingeCTDsoftware
13. PreparationofsubmissiontoMHRAusingeCTDsoftware

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORYASPECTSOF HERBALSANDBIOLOGICALS (Professional Core-III)

Course Objective: This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products

CourseOutcome:**Uponthecompletionofthecoursethestudentshallbeableto:**

- KnowtheregulatoryRequirementsforBiologicsandVaccines
- Understandtheregulationfornewlydevelopedbiologicsandbiosimilars
- Knowthepre-clinicalandclinicaldevelopmentconsiderationsofbiologics
- UnderstandtheRegulatoryRequirementsof Bloodand/orItsComponentsIncluding BloodProducts and label requirements

UNIT-I
India: Introduction, Applicable Regulations and Guidelines, Principles for Development of Similar Biologics, Data Requirementsfor Preclinical Studies, Data Requirementsfor Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics, Pharmacovigilance. GMP and GDP.

UNIT-II
USA: Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval ofbiologics and biosimilars (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.

UNIT-III
European Union: Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ bio similarity assessment, Plasma master file, TSE/ BSE evaluation, developmentandregulatoryapproval of biologics(Investigationalmedicinal productsand biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labellingandpacking of biologics in EU.

UNIT-IV
Vaccine regulations in India, US and European Union: Clinical evaluation, Marketing authorization, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN (International Haemovigilence Network)

UNIT-V
Herbal Products: Quality, safety and legislation for herbal products in India, USAand EuropeanUnion.

TEXTANDREFERENCEBOOKS:

1. FDA Regulatory Affairs: AGuideforPrescriptionDrugs,Medical Devices, and Biologics,Douglas J. Pisano, David S. Mantus; Informa, 2008
2. BiologicalDrugProducts:DevelopmentandStrategies;WeiWang,ManmohanSingh; wiley, 2013
3. Development of Vaccines: FromDiscovery to Clinical Testing; Manmohan Singh, Indresh K. Srivastava; Wiley, 2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
6. www.ihn-org.com
7. www.isbtweb.org
8. GuidelinesonSimilarBiologics:RegulatoryRequirementsforMarketingAuthorizationinIndia
9. www.cdsco.nic.in
10. www.ema.europa.eu›scientificguidelines›Biologicals
11. www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation(Biologics)

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)

M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORYASPECTSOFMEDICALDEVICES (Professional Core-IV)

Course Objective: This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketingmedical devices and IVDs in regulated countries.

CourseOutcome: Uponcompletionofthecourse,thestudentshallbeabletoknow;

- BasicsofmedicaldevicesandIVDs,processofdevelopment,ethicalandquality considerations.
- HarmonizationinitiativesforapprovalandmarketingofmedicaldevicesandIVDs.
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN.
- ClinicalevaluationandinvestigationofmedicaldevicesandIVDs.

UNIT-I

Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of MedicalDevicesand IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure,Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

UNIT-II

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, GoodClinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality:Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

UNIT-III

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality SystemRequirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

UNIT-IV

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

UNIT-V

ASIAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.

REFERENCEBOOKS:

1. FDAregulatoryaffairs:aguideforprescriptiondrugs,medicaldevices,andbiologicsby Douglas J. Pisano, David Mantus.
2. MedicalDeviceDevelopment:ARegulatoryOverviewbyJonathanS.Kahan
3. MedicalProduct RegulatoryAffairs: Pharmaceuticals, Diagnostics, Medical DevicesbyJohnJ. Tobin and GaryWalsh
4. ComplianceHandbookforPharmaceuticals,MedicalDevicesandBiologicsbyCarmen Medina

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORYASPECTSOFFOODANDNUTRACEUTICALS (ProfessionalElective–III)

Course Objective: This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA andEurope. It prepares the students to learn in detail on Regulatory Aspects for nutraceuticals and food supplements.

CourseOutcome: Uponcompletionofthecourse,thestudentshallbeableto

a. KnowtheregulatoryRequirementsfornutraceuticals
b. Understandtheregulationforregistrationandlabelingof nutraceuticalsandfood supplementsin India, USA and Europe.

UNIT-I

Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

UNIT-II

Global Aspects:WHO guidelines on nutrition. NSF International:Its Roleinthe Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.

UNIT-III

India: Food Safety and Standards Act, Food Safety and Standards Authority ofIndia: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

UNIT-IV

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S

UNIT-V

European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutritionlabelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.

TEXTANDREFERENCEBOOKS:

1. RegulationofFunctionalFoodsandNutraceuticals: AGlobal PerspectivebyClareM. Hasler(Wiley Online Library)
2. Nutraceutical andFunctionalFoodRegulationsintheUnitedStatesandAroundthe World byDebasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324 _EN.pdf
5. HandbookofNutraceuticalsbyYashwantPathak(CRCPress)
6. FoodRegulation:Law,Science,PolicyandPracticebyNealD.Fortin(Wiley)
7. CountrySpecificGuidelinesfromofficialwebsites.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

PHARMACEUTICALQUALITYCONTROLANDQUALITYASSURANCE
(Professional Elective–III)

Course Objectives: This course deals with the various aspects of quality control and quality assurance aspectsof pharmaceutical industries. It coversthe important aspectslike cGMP, QCtests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcome: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

UNITI

a. **Impurity and stability studies:** Definition, classification of impuritiesin drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines.
b. **Impurities in new drug products**: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products
c. **Impurities in residual solvents:** General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents.

UNIT II

a. ConceptsofQualityAssurance,TotalQualityManagement,PhilosophyofGMPandcGMP
b. GuidelinesforQualityAssuranceofHumanBloodProductsandlargevolumeparenterals.

UNIT III

a. Organizationandpersonnel,responsibilities,traininghygiene
b. **Premises**: Location, design, plan Layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
c. **Equipments:** Selection, purchase specifications, maintenance, clean in place, sterilize in place – Raw – materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

UNIT IV

a. Packagingandlabelingcontrols,lineclearanceandotherpackagingmaterials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage.

UNIT V

Manufactureandcontrolsondosageforms

a. Manufacturing documents, Master Formula, Batch Formula, Records, Standard Operating Procedures,
b. In process quality control on various dosage forms sterile and biological products, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

TEXTBOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition General Methodsof AnalysisQuality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
2. QualityAssuranceofPharmaceuticals.ACompendiumofGuidelinesandRelatedMaterial Vol. 1 and Vol. 2, WHO 2007)
3. GMPbyMehra
4. PharmaceuticalProcessValidationbyBerryandNash
5. HowtoPracticeGMP's–P.P.Sharma

REFERENCESBOOKS:

1. BasicTestsforPharmaceuticalSubstances-WHO(1991)
2. TheDrugsandCosmeticAct1940byVijayMalik
3. Q.A.ManualbyD.H.Shah
4. SOPGuidelinesbyD.H.Shah
5. QualityAssuranceGuidebyOPPI
6. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
7. AnalyticalProfilesofdrugsubstancesandExcipients–HarryGBrittan,Volume21–30, Elsevier, 2005.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

NANOBASEDDRUGDELIVERYSYSTEMS (Professional Elective–III)

Course Objective -To develop expertise regarding suitability and evaluation of nanomaterials,able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes – The students should be able to select the right kind of materials, able to developnano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT I
IntroductiontoNanotechnology

a. Definitionofnanotechnology
b. Historyofnanotechnology
c. Uniquepropertiesandclassificationofnanomaterials
d. Roleofsizeandsizedistributionofnanoparticlesproperties.
e. Marketedformulationsbasedonnanotechnologyandsciencebehindthem

UNIT II
SynthesisofNanomaterialsPhysical,chemicalandbiologicalMethodsMethodsforsynthesisof

- Goldnanoparticles
- Magneticnanoparticles
- Polymericnanoparticles
- Self–assemblystructuressuchasliposomes,Niosomes,transferasomes,micelles, aquasomes and nanoemulsions

UNIT III
BiomedicalapplicationsofNanotechnology

a. Nanotechnologyproductsusedforinvitrodiagnostics
b. Improvementstomedicalormolecularimagingusingnanotechnology
c. Targetednanomaterialsfordiagnosticandtherapeuticpurpose

UNIT IV
Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials forcancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNITV
Characterizationincludingtheprinciples,sizereduction,analysisofnanoparticles,size,PDI,size separation, stability, methods of analysis regarding integrity and release ofdrugs

REFERENCEBOOKS:

1. NanomedicineandNanoproducts:Applications,DispositionandToxicologyintheHuman body, Eiki Igarashi, CRC press. 2015
2. NanotechnologyandDrugDeliveryVolume oneandtwo:Nanoplatforms inDrugDelivery, Jose L. Arias, CRC press
3. Nano:TheEssentials:UnderstandingNanoscienceandNanotechnology,T.Pradeep,Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)

5. Nanostructures andNanomaterials:Synthesis,Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano-CarrierSystemsTheories,Methods&Applications,AmitK.Goyal,GoutamRath, Pharmamed Press.
7. Nanochemistry:AClassical ApproachtoNanomaterials–RoyalSocietyforChemistry, Cambridge, UK (2005)
8. Nanocompositescienceandtechnology,pulickel M. Ajayan, LindaS.Schadler,paulV. Braun, Wiley - VCH Verlag, Weiheim (2003)
9. NanoscalematerialsinchemistryEditedbyKennethJ.Klabunde,JohnWiley&Sons,2009
10. NanoparticlesasDrugcarriers,VladimirPTorchiling,ImperialCollegePress,USA,2006
11. IntroductiontoNanoScienceandTechnologies,AnkaneyuluYerramilli,BSPublications. 2016
12. NanoparticlesasDrugcarriers,VladimirPTorchiling,ImperialCollegePress,USA,2006

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VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)

M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

CLINICALRESEARCHANDPHARMACOVIGILANCE(ProfessionalElective-IV)

Course Objectives: This subject will provide a value addition and current requirement forthe students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drugdevelopment and post market surveillance.

CourseOutcomes: Uponcompletionofthecourse,thestudentshallbeableto;

- Explaintheregulatoryrequirementsforconductingclinicaltrial
- Demonstratethetypesof clinicaltrialdesigns
- Explaintheresponsibilitiesofkeyplayersinvolvedinclinicaltrials
- Executesafetymonitoring,reportingandclose-outactivities
- Explaintheprinciplesof Pharmacovigilance
- Detectnewadversedrugreactionsandtheirassessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNITI

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization -Good Clinical Practice(ICH-GCP)guidelinesEthical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNITII

ClinicalTrials:TypesandDesign:

Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNITIII

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNITIV

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNITV

Methods, ADR reporting and tools used in pharmacovigilance: International classification of diseases,InternationalNonproprietarynamesfordrugs,PassiveandActivesurveillance,

Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelinesfor ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluatingmedication safety data.

REFERENCEBOOKS:

1. Central DrugsStandard Control Organization- Good Clinical Practices, Guidelinesfor Clinical Trials on Pharmaceutical Productsin India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press
7. HandbookofclinicalResearch.JuliaLloydandAnnRavenEd.ChurchillLivingstone.
8. PrinciplesofClinicalResearcheditedbyGiovannadiIgnazio,DiGiovannaandHaynes.
9. Textbook ofPharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
10. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm IYear IISem (Pharmaceutical Regulatory Affairs)

NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals invarious diseased conditions and also knowthe role of antioxidant infree radical induced disease conditions and will expose to variousfood laws and regulations.

CourseOutcomes: HelpsthestudenttounderstandtheimportanceofNutraceuticalsinvarious common problems with the concept of free radicals

UNITI

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals,Health problems and diseases thatcan be prevented or cured byNutraceuticals i.e.weightcontrol,diabetes,canceretc.
b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefitsoffollowing used asnutraceuticals/functionalfoods: Spirulina,Soyabean,Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNITII

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical naturemedicinal benefits) of following

a) Carotenoids-αandβ-Carotene,Lycopene,Xanthophylls,lutein
b) Sulfides:Diallylsulfides,Allyltrisulfide.
c) Polyphenolics:Reservetrol
d) Flavonoids-Rutin,Naringin,Quercitin,Anthocyanidins,catechins,Flavones
e) Prebiotates/Probiotics.:Fructooligosaccharides,Lactobacillum
f) Phytoestrogens:Isoflavones,daidzein,Geebustin,lignans
g) Tocopherols

UNITIII

a. Introduction tofree radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b. Measurementoffreeradicals:Lipidperoxidationproducts,lipidhydroperoxide,malondialdehyde.

UNIT IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage.Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, GlutathioneVitamin C, Vitamin E, α- Lipoic acid, melatonin. Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNITV

FoodLawsandRegulations;FDA,FPO,MPO,AGMARK.HACCPandGMPsonFoodSafety. Adulteration of foods.
RegulationsandClaims–CurrentProducts:LabelClaims,NutrientContentClaims,HealthClaims,Dietary Supplements Claims

REFERENCEBOOKS:

1. DieteticsbySriLakshmi
2. Role of dietary fibres and nutraceuticals in preventingdiseases by K. T. Agusti and P. Faizal: BS Publication.
3. AdvancedNutritionalTherapiesbyCooper.K.A.,(1996).
4. TheFoodPharmacybyJeanCarper,Simon&Schuster,UKLtd.,(1988).
5. Prescription forNutritionalHealingbyJamesF.BalchandPhyllisA.Balch2nd Edn.,Avery Publishing Group, NY (1997).
6. G.GibsonandC.WilliamsEditors*2000Functionalfoods*WoodheadPubl.Co. London.
7. Goldberg,I.*FunctionalFoods*.1994.ChapmanandHall,NewYork.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice(GMPs)andShelf LifeTestingin*Essentialsof FunctionalFoods*M. K.Sachmidl and T.P. Labuzaeds. AspenPress.
9. HandbookofNutraceuticalsandFunctionalFoods,ThirdEdition(ModernNutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

ADVANCEDDRUGDELIVERYSYSTEMS (Professional Elective-IV)

CourseObjectives: Thestudentsshall applythepharmacokineticandpharmacodynamicprinciplesin the design of CDDS. They also apply the design, evaluation and applications related to oral, parenteral, transdermal, implants, bio adhesives and targeted drug delivery systems.

Course Outcomes: Students will select the drugs for CDDS design of the formulation fabrication of systems of above drug delivery systems with relevant applications.

UNITI
Fundamentalsof controlled drug delivery systems, pharmacokinetic and pharmacodynamic basisof controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

a. Controlledreleaseoraldrugdeliverysystems
b. Parenteralcontrolledreleasedrugdeliverysystems

UNITII
Design,fabrication,evaluationandapplicationsofthefollowing

a. ImplantableTherapeuticsystems
b. Transdermaldeliverysystems
c. OcularandIntrauterinedeliverysystems
d. Vaccinedelivery:Deliverysystemsusedtopromoteuptake,absorptionenhancers,oral immunization, controlled release microparticles form vaccine development

UNITIII
Biochemicalandmolecularbiologyapproachestocontrolleddrugdeliveryof

a. Bioadhesivedrugdeliverysystems
b. Nasaldrugdeliverysystems
c. DrugdeliverytoColon

UNITIV
Biochemicalandmolecularbiologyapproachestocontrol drugdeliveryof

a. Liposomes
b. Niosomes
c. Microspheres
d. Nanoparticles
e. Resealederythrocytes

UNITV
Drugtargetingtoparticularorgans

a. Deliverytolungs
b. Deliverytothebrainandproblemsinvolved
c. Drugtargetinginneoplasams

TEXTBOOKS:

1. NovelDrugDeliverySystembyYieW.Chien.
2. ControlledDrugDeliverybyJosephR.RobinsonandVincentH.L.Lee.
3. ControlledandNovel DrugDeliverySystemsbyN.K.Jain.
4. TargetedandControlledDrugDelivery(Novelcarriersystems)byS.P.VyasandKhar.
5. ModernPharmaceuticsbyGilbertS.BankerandChristopherT.Rhodes.
6. AdvancesinDrugDelivery,Vol 1,2,3,4byY.MadhusudanRao,A.V.Jithan
7. OralDrugDeliveryTechnology,2nded,byAukunuruJithan

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORYASPECTSOFHERBALSANDBIOLOGICALLAB(Laboratory-III)

Listof Experiments:

1. PreparationofBiologicsLicenseApplications(BLA)
2. PreparationofdocumentsrequiredforVaccineProductApproval
3. ComparisonofclinicaltrialapplicationrequirementsofUS,EUandIndiaof Biologics
4. PreparationofChecklistforRegistrationofBloodandBloodProducts
5. Registrationrequirementcomparisonstudyin5emergingmarkets(WHO)andpreparing check list for market authorization
6. Registrationrequirementcomparisonstudyinemergingmarkets(BRICS)andpreparing check list for market authorization
7. Registrationrequirement comparisonstudyinemergingmarkets(ChinaandSouth Korea) and preparing check list for market authorization
8. Registrationrequirement comparisonstudyinemergingmarkets(ASEAN)andpreparing check list for market authorization
9. Registrationrequirement comparisonstudyinemergingmarkets(GCC)andpreparing check list for market authorization
10. Preparationofdocumentrequiredfortheapprovalof herbal productsofdiversedosage forms(3products) as per regulations requirements

Practicalworkshallbecarriedoutbasedonthetheorysyllabus.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm I Year II Sem (Pharmaceutical Regulatory Affairs)

REGULATORYASPECTSOFMEDICAL DEVICESLAB (Laboratory-IV)

Listof Experiments:

1. Checklistsfor510kandPMAforUSmarket
2. ChecklistforCEmarkingforvariousclassesofdevicesforEU
3. STEDApplicationforClassIIIDevices
4. AuditChecklistforMedicalDeviceFacility
5. ClinicalInvestigationPlanforMedicalDevices
6. Preparationandsubmissionofmedicaldevicesforapproval(3products)
7. GMPofmanufacturingofmedicaldevicesof diversenature(3products)
8. preparationandsubmissionofnutraceuticalsdevicesforapproval(3products)

Practicalworkshallbecarriedoutbasedonthetheorysyllabus

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm IYear IIISem (Pharmaceutical Regulatory Affairs)

BIOSTATISTICS (Professional Elective - V)

Course Objective: The student shall know the introduction, scope of biostatistics and Researchwork, calculation and present of the data.

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts.They also know the correlation and regression & application of different methods, analysis of data

UNITI
Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II
Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III
Measuresof CorrelationandRegression
Probabilityrules:Binomial,PoisonandNormaldistribution.

UNIT IV
Experimentaldesigning,planningofanexperiment,replicationandrandomization.
AnalysisofVariance(ANOVA):1-way,2-Way

UNIT V
Hypothesistesting:Student't'test,Chisquaretest,
Non-ParametricTests: SignTest,SignRankTest,WilcoxonSignRankTest

REFERENCEBOOKS:

1. Statisticsforbusinessandeconomics3rdeditionbyVikasbookspublications
2. Biostatistics&ComputerapplicationsbyGNRaoandNKTiwari
3. Sokal,R.R.andRohlf,F.J.1987.AnIntroductiontoBiostatistics.W.H.Freemanand Company.
4. Bailey,N.T.J.1981.StatisticalMethodsinBiology.EnglishUniversityPress.
5. Mitchell,K.andGlover,T.2001.IntroductiontoBiostatistics.McGrawHill,Publishing Co.
6. ATextbookof ResearchMethodologiesandBiostatisticsforPharmacyStudents,KPR Chowdary, Pharmamed Press.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm II Year I Sem (Pharmaceutical Regulatory Affairs)

SCALEUPANDTECHNOLOGYTRANSFER (Professional Elective-V)

Course Objective: This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

CourseOutcome: Oncompletionofthiscourseitisexpectedthatstudentswillbeableto;

- Managethescaleupprocessinpharmaceuticalindustry.
- Assistintechnologytransfer.
- Toestablishsafetyguidelines,whichpreventindustrialhazards.

UNITI

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentral and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, rawmaterials, physical layout, input, in-processand finished product specifications, problems encountered during transfer of technology

UNIT II

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analyticalmethod validation, cleaning validation and vender qualification.

UNIT III

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapidmixer granulator, cone blender, FBD, tabletcompressionmachine, liquidfilling andsealing machine. Aseptic room validation.

UNIT IV

Process validation: Importance, validation of mixing, granulation, drying, compression, tabletcoating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT V

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

REFERENCEBOOKS:

1. Pharmaceuticalprocessvalidation,JRBerry,Nash,Vol57,MarcelDekker, NY.
2. PharmaceuticalProductionfacilities,designandapplications,byGCCole,TaylorandFrancis.
3. Pharmaceuticalprojectmanagement,T.Kennedy,Vol86,MarcelDekker,NY.
4. Thetheory&PracticeofIndustrialPharmacy,L.Lachman,H.A.Lieberman,VarghesePubl Bombay.
5. Tabletmachineinstrumentsinpharmaceuticals,PRWatt,JohnWiloy.
6. Pharmaceuticaldosageforms,Tablets,Vol1,2,3byLachman,Lieberman,MarcelDekker, NY.
7. Pharmaceuticaldosageforms,Parentralmedications,Vol1,2byK.E.Avis,MarcelDekker,NY.
8. DispersedsystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
9. Subrahmanyam,CVS,PharmaceuticalproductionandManagement,2007,VallabhPrakashan,
10. PharmaceuticalProcessScale-up2ndEd.LevinMichael,CRCpress

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm IIYear ISem (Pharmaceutical RegulatoryAffairs)

PRODUCTIONAREADESIGN&PACKAGINGDEVELOPMENT(ProfessionalElective-V)

Course Objectives: The student shall learn about Industrial area design, Current goodmanufacturing practices. They also learn about packaging components, polymers and metals used in packaging. They also understand about the storage conditions of different formulations and their stability evaluations.

CourseOutcome: At theendof thesemesterstudent willget anideaabout Industrial areadesign and packaging of different formulations and its stability conditions.

UNITI
Production Area Design: Selection of plant location, Design of plant for bulk drugs and formulations (Solids, Semisolids, Injectables, Nutraceuticals etc.), General utilities such as purified water, portable water, water for injection, Air handling units-Relative humidity and Temperature control, Material and personnel movement. Warehouse handling-API, Excipients, packaging materials and solvents.

UNIT II
Current Good Manufacturing Practices: GMP design for buildings & facilities. GMP layout design. Clean room classifications. Segregation & cross contamination control. HVAC (heating, ventilation & air-conditioning) systems. Clean room environment control. Documentation and record keeping: Specifications and testing procedures, Specifications for finished products, Master Formulae, Packaging instructions. Batch processing records, Standard operating procedures.

UNIT III
Pharmaceutical packaging and Design: Introduction, Packaging system, Components ofpackaging, Symbols used on packages and labels. Package development and Design research. Packaging materials- Polymers and Plasters, Glass, Metal and Blister and strip packaging.

UNIT IV
Stability of Packaging: Introduction, Legislation, Regulation, Pharmaceutical Stability Testing in Climatic Cabinets, Pharmaceutical Stability Testing Conditions, Photo-Stability Testing, Review of Pharmaceutical Product Stability, Packaging and the ICH Guidelines.

UNIT V
PackagingofSolids,Semisolids,Parenterals,OphthalmicandAerosols:Introduction,Packaging of Solid and semisolids, Packaging of Sterile Pharmaceuticals, Packaging Components, Inspection of Filled Injectable Products, Storage and Labelling, Packaging of Ophthalmics, Selection of Packaging Materials, Packaging of Aerosols.

REFERENCEBOOKS:

1. Leon Lachman; Lieberman Herbert A.; Kanig, Joseph L. The theory and Practice of Industrial Pharmacy.
2. GilbertBankerandChristopherRhodes.ModernPharmaceutics.
3. Aulton'sPharmaceutics:ThedesignandManufactureofMedicine
4. D.A.Dean,RoyEvans,IanHall.Pharmaceuticalpackagingtechnology.TylorandFrancis.
5. EdwardJ.Bauer,PharmaceuticalPackagingHandbook.BauschandLomb,Rochester,New
6. PharmaceuticalFacilities:Design,LayoutsandValidation,Potdar,PharmamedPress
7. WilmerA.Jenkins,KentonR.Osborn.Packagingdrugsandpharmaceuticals.
8. Remington:TheScienceandPracticeofPharmacy.8.MichaelE.Aulton,KevinTylor
9. PharmaceuticalPackagingTechnology,UKjain,PharmamedPress

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)

ENGLISHFORRESEARCHPAPERWRITING(AuditCourse-I&II)

Prerequisite: None

Courseobjectives: Studentswillbeableto:

- Understandthathowtoimproveyourwritingskillsandlevelof readability
- Learnaboutwhattowriteineachsection
- Understandtheskillsneededwhenwritinga Title Ensurethegoodqualityofpaperat very first-time submission

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
ReviewoftheLiterature,Methods,Results,Discussion,Conclusions,TheFinalCheck.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXTBOOKS/REFERENCES:

1. GoldbortR(2006)WritingforScience,YaleUniversityPress(availableonGoogleBooks)
2. DayR(2006)HowtoWriteandPublishaScientificPaper,CambridgeUniversityPress
3. HighmanN(1998),HandbookofWritingfortheMathematicalSciences,SIAM.Highman's book.
4. AdrianWallwork,EnglishforWritingResearchPapers,SpringerNewYorkDordrecht Heidelberg London, 2011

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)
DISASTERMANAGEMENT (Audit Course-I&II)

Prerequisite: None

CourseObjectives: Studentswillbeableto

- learntodemonstrateacriticalunderstandingofkeyconceptsindisasterriskreductionand humanitarian response.
- criticallyevaluatedisasterriskreductionandhumanitarianresponsepolicyandpracticefrom multiple perspectives.
- developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevancein specific types of disasters and conflict situations.
- criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,
- planning and programming in different countries, particularly their home country or the countries they work in

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

DisasterProneAreasinIndia:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

RepercussionsofDisastersandHazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

DisasterPreparednessandManagement:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

RiskAssessmentDisasterRisk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

DisasterMitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXTBOOKS/REFERENCES:

1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "'New Royal book Company.
2. Sahni, Pardeep Et. Al.(Eds.)," Disaster Mitigation Experiencesand Reflections", Prentice Hall of India, New Delhi.
3. GoelS.L.,DisasterAdministrationandManagementTextandCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)

SANSKRIT FORTECHNICAL KNOWLEDGE (Audit Course-I &II)

Prerequisite: None

CourseObjectives:

- TogetaworkingknowledgeinillustriousSanskrit,thescientificlanguageintheworld
- LearningofSanskrittoimprovebrainfunctioning
- Learning of Sanskrit to develop the logic inmathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

CourseOutcomes: Studentswillbeableto

- UnderstandingbasicSanskritlanguage
- AncientSanskritliteratureaboutscience&technologycanbeunderstood
- BeingalogicallanguagewillhelptodeveloplogicinstudentsUNIT-I:

Alphabetsin Sanskrit,

UNIT-II:
Past/Present/FutureTense,SimpleSentences

UNIT-III:
Order,Introductionofroots,

UNIT-IV:
TechnicalinformationaboutSanskritLiterature

UNIT-V:
TechnicalconceptsofEngineering-Electrical,Mechanical,Architecture,Mathematics

TEXTBOOKS/REFERENCES:

1. “Abhyaspustakam”–Dr.Vishwas,Samskrita-BhartiPublication,NewDelhi
2. “TeachYourselfSanskrit”PrathamaDeeksha-VempatiKutumbshastri,RashtriyaSanskrit Sansthanam, New Delhi Publication
3. “India’sGloriousScientificTradition”SureshSoni,Oceanbooks(P)Ltd.,NewDelhi.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

CourseObjectives: Studentswillbeableto

- Understandvalueofeducationandself-development
- Imbibegoodvaluesin students
- Lettheshouldknowabouttheimportanceof character

Courseoutcomes: Studentswillbeableto

- Knowledgeofself-development
- Learntheimportanceof Humanvalues
- Developingtheoverallpersonality

UNIT-I:
Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:
Importanceof cultivationofvalues.Senseof duty.Devotion,Self-reliance.Confidence,Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:
Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religioustolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:
Character and Competence –Holy books vs Blind faith. Self-management and Good health. Scienceof reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXTBOOKS/REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)
CONSTITUTION OF INDIA (Audit Course-I &II)

Prerequisite: None

CourseObjectives: Studentswillbeableto:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood inthe early years of Indian nationalism.
- To addressthe role of socialism inIndia afterthe commencement of theBolshevikRevolution in 1917 and its impact on the initial drafting of the Indian Constitution.

CourseOutcomes: Studentswillbeableto:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP] under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct elections through adult suffrage in the Indian Constitution.
- DiscussthepassageoftheHinduCodeBillof 1956.

UNIT-I:

HistoryofMakingoftheIndianConstitution: HistoryDraftingCommittee,(Composition& Working), **Philosophy of the Indian Constitution:** Preamble**,** Salient Features.

UNIT-II:

Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:

Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:

Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:

Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXTBOOKS/REFERENCES:

1. TheConstitutionofIndia,1950(BareAct),GovernmentPublication.
2. Dr.S.N.Busi,Dr.B.R.AmbedkarframingofIndianConstitution,1stEdition,2015.
3. M.P.Jain,IndianConstitutionLaw,7thEdn.,LexisNexis,2014.
4. D.D.Basu,IntroductiontotheConstitutionofIndia,LexisNexis,2015.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)

M.Pharm(Pharmaceutical Regulatory Affairs)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

CourseObjectives: Studentswillbeableto:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identifycriticalevidencegapstoguidethedevelopment.

CourseOutcomes: Studentswillbeabletounderstand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What isthe evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. Howcan teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidenceforeffectivepedagogical practices. Pedagogictheory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professionaldevelopment:alignmentwith classroom practicesandfollow-up support, Peersupport, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXTBOOKS/REFERENCES:

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare,31 (2):245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof Curriculum Studies, 36 (3): 361-379.
3. AkyeampongK (2003) Teacher trainingin Ghana- doesit count?Multi-siteteacher education research project (MUSTER) country report 1. London: DFID.
4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. ChavanM(2003)ReadIndia:Amassscale,rapid,'learningtoread'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)

STRESSMANAGEMENT BYYOGA (Audit Course-I&II)

Prerequisite: None

CourseObjectives:

- Toachieveoverallhealthofbodyandmind
- Toovercomestress

CourseOutcomes: Studentswillbeableto:

- Develophealthymindinahealthybodythusimprovingsocialhealthalso
- Improveefficiency

UNIT-I:
DefinitionsofEightpartsofyog. (Ashtanga)

UNIT-II:
YamandNiyam.

UNIT-III:
Do`sandDon't'sinlife.
i) Ahinsa,satya,astheya,bramhacharyaandaparigraha
ii) Shaucha,santosh,tapa,swadhyay,ishwarpranidhan

UNIT-IV:
AsanandPranayam

UNIT-V:
i) Variousyogposesandtheirbenefitsformind&body
ii) Regularizationofbreathingtechniquesanditseffects-Typesof pranayam

TEXTBOOKS/REFERENCES:

1. 'Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2."RajayogaorconqueringtheInternalNature"bySwamiVivekananda,AdvaitaAshrama (PublicationDepartment),Kolkata

VAAGDEVI PHARMACY COLLEGE (AUTONOMOUS)
M.Pharm (Pharmaceutical Regulatory Affairs)

PERSONALITYDEVELOPMENTTHROUGHLIFEENLIGHTENMENTSKILLS
(Audit Course-I &II)

Prerequisite: None

CourseObjectives:

- Tolearntoachievethehighestgoalhappily
- Tobecomeapersonwithstablemind,pleasingpersonalityanddetermination
- Toawakenwisdominstudents

CourseOutcomes: Studentswillbeableto

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- ThepersonwhohasstudiedGeetawillleadthenationandmankindtopeaceandprosperity
- StudyofNeetishatakamwillhelpindevelopingversatilepersonalityofstudents

UNIT-I:

Neetisatakam-Holisticdevelopmentofpersonality

- Verses-19,20,21,22(wisdom)
- Verses-29,31,32(pride&heroism)
- Verses-26,28,63,65(virtue)

UNIT-II:

Neetisatakam-Holisticdevelopmentofpersonality

- Verses-52,53,59(dont's)
- Verses-71,73,75,78(do's)

UNIT-III:

Approachtodaytodayworkandduties.

- ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
- Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
- Chapter18-Verses45,46,48.

UNIT-IV:

Statementsof basicknowledge.

- ShrimadBhagwadGeeta:Chapter2-Verses56,62, 68
- Chapter12-Verses13,14,15,16,17,18
- PersonalityofRolemodel.ShrimadBhagwadGeeta:

UNIT-V:

- Chapter2-Verses17,Chapter3-Verses36,37,42,
- Chapter4-Verses18,38,39
- Chapter18–Verses37,38,63

TEXTBOOKS/REFERENCES:

1. "SrimadBhagavadGita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
2. Bhartrihari'sThreeSatakam(Niti-sringar-vairagya)byP.Gopinath,RashtriyaSanskrit Sansthanam, New Delhi.