KARPAGAM ACADEMY OF HIGHER EDUCATION

Deemed to be University

(Established Under Section 3 of UGC Act 1956)

Eachanari Post, Pollachi Main Road, Coimbatore – 641021.

COURSE OF STUDY AND SCHEME OF EXAMINATION

Ph.D COURSE IN PHARMACY

2020-2021

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PART – I COURSE WORK SYLLABUS FOR Ph.D COURSE IN PHARMACY (2020-2021)

SL.NO	TITLE OF THE COURSE	NO. OF SUBJECT	C	EXAM. HRS	MARKS
1	PAPER I	01	4	3	100
2	PAPER II	01	4	3	100
3	PAPER III	01	4	3	100
	TOTAL	03	12	9	300

PART – I COURSE WORK SYLLABUS FOR Ph.D COURSE IN PHARMACY (2020-2021)

SUB.CODE	TITLE OF THE COURSE	CREDITS	EXAM HRS	MARKS
PAPER - I (COMPULSORY)				
20PYR101	Research Methodology and Pedagogy	4	3	100
PAPER - II (COMPULSORY)				
20PYR 201	Research and Publication Ethics	4	3	100
PAPER - III (ANY ONE)				
20PYR 301	Pharmaceutics	4	3	100
20PYR 302	Pharmaceutical Chemistry	4	3	100
20PYR 303	Pharmacology	4	3	100
20PYR 304	Pharmacognosy	4	3	100
20PYR 305	Pharmaceutical Analysis	4	3	100

20PYR101. RESEARCH METHODOLOGY AND PEDAGOGY

Course Objectives:

- To design the impart fundamental knowledge of higher education
- To illustrate the Research Processes and Methodologies that was undergone by the Research scholars
- To Explain the Research Skills like Research strategies, Ethics, Code for Research and IPR
- To Illustrate the techniques of teaching and evaluation
- To demonstrate the Essentials that was needed for the effective communication in English
- To describe the Data collection, Data Presentation Skills and Research Writing skills

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the objectives, role,social focus, curricular focus, administrative focus, drivers of change globalization in Higher Education
2. Restructure the new patterns of decision making
3. Describe the Expectations by employers, rate of knowledge growth, campus demographics and concern for community
4. Illustrate the Research strategies, Ethics, Code of conduct for Research, Health and Safety and also the IPR
5. Describe the Data collection , Modeling , Simulation , Analysis, Prototyping, Presentation Skills , Data Presentation Skills and Research Writing skills
6. Demonstrate the techniques of teaching and evaluation

Course Content

UNIT I

HIGHER EDUCATION AN INTRODUCTION: Historical perspectives, the objectives of higher education, role of higher education-social focus, curricular focus, administrative focus, drivers of change in higher education-globalization, changing demographics, structuring of employment, technological change, demand of accountability, consumerism,. Expectations by employers, rate of knowledge growth, campus demographics, concern for community. Restructuring and new patterns of decision making.

UNIT II

RESEARCH PROCESSES AND METHODOLOGY: Introduction to Research – Research strategies – Ethics – Code of conduct for Research – Health and Safety – IPR – Research Events

– Networks – Outreach Activities – Best Research practices – Quality assurance for Research – Career Management for Researchers – Research seminars – Journal critiques -.

UNIT III

EFFECTIVE RESEARCH SKILLS

Data collection – Modeling – Simulation – Analysis – Prototyping – Presentation Skills – Data Presentation Skills – Research Writing skills (For Articles, Reports, Journals and Thesis) – Creative Skills – Effective Interview Skills – Team Building Skills – Communication and Interpersonal Skills – knowledge Transfer skills – Vivo Voce – Teaching and Information Skills – Effective use of Library – Survey Skills – Planning and Control Methods – Statistical Tools – Patents and Copyrights – Advanced Research Techniques and Tools.

UNIT IV

TECHNIQUES OF TEACHING AND EVALUATION

Large group techniques – lecture, seminar, symposium, panel discussion-project approaches and workshop. Small Group techniques- group discussion simulation, role playing-Buzz techniques, brain storming, case discussion and assignment…system approach in education. Individualized techniques-CAI Keller plan – PSI and programmed learning-methods of evaluation-self evaluation and student evaluation in higher education, question banking, diagnostic testing and remedial teaching.

UNIT V

ESSENTIALS FOR EFFECTIVE COMMUNICATION IN ENGLISH

Improving Vocabulary stock-general and technical vocabulary-British and American vocabulary-homophones & homonyms, idioms and phrases-Different grammatical functions of the same word-Grammar-Tenses, Voice, reported speech, Modals, spoken English structures, formal and informal-letters, project reports, descriptions, circulars, synopsis and summary writing. Listening skills for competitive exams-Reading skills-skimming and scanning – Reading journals, magazines and newspapers for comprehension. Practical use of English – conversation, seminars, individual speeches and group discussions. Reference skills-Using dictionary, thesaurus and encyclopedia effectively. Error shooting for better use of English.

SUGGESTED READING BOOKS

1. Alley, Michael,(1996), 'The Craft of Scientific Writing', 3rd Edition, Springer.
2. Alley, Michael, (2003), 'The Craft of Scientific Presentations", Springer.

REFERENCE BOOKS :

1. Hubbuch, Susan M.,(2005), Writing Research Papers Across the Curriculum, 5th Edition, Thompson.
2. Vedanayagam.E.G (1989),Teaching technology for college teachers New Delhi - Sterling publishers (Pvt) Ltd.
3. Kumar.K.H.(1997), Educational technology, New Delhi- New age international (Pvt) Ltd.
4. Tony Bates.A.N,(2005) Technology, e-learning and distance education, New York, Rout ledge.
5. Agarwal. J.C. (1995), Essential of educational technology; Teaching Learning innovations in education-New Delhi- Vikas publishing house (p) Ltd.,.
6. Crow & Crow. (1998),Educational Psychology", Erusia Publishing House New Delhi.
7. M. Ashraf Rizvi.(2005),Effective technical communication, TataMcGraw Hill Co.Ltd.

Websites:

www.english4engineer.com

www.learn4good.com/language/engineer

20PYR201.RESEARCH AND PUBLICATION ETHICS

Course Objectives:

- To illustrate the Philosophy, Ethics, nature of moral judgments and reaction
- To Explain the Intellectual honesty , research integrity, Fabrication and Plagiarism
- To demonstrate the Publication Ethics, violation of publication ethics and authorship
- To describe the duplicate ,overlapping publication,salami slicing,selective reporting and misrepresentation of date
- To illustrate the Conflicts of interest , publication misconduct and problems that lead to unethical behavior.
- To develop the e-content ,IPR, indexing database,citation database and web of science

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the Philosophy, Ethics, nature of moral judgments.
2. Illustrate the Intellectual honesty , research integrity, Fabrication and Plagiarism
3.Describe the duplicate ,overlapping publication,salami slicing,selective reporting and misrepresentation of date
4. Demonstrate the Publication Ethics, violation of publication ethics and authorship
5. Develop the e-content , IPR, indexing database,citation database and web of science
6. Illustrate the Conflicts of interest , publication misconduct and problems that lead to unethical behavior

Course Content

UNIT I: Philosophy and Ethics

Introduction to Philosophy : Definition, nature and scope, concept, branches – Ethics: Definition, moral philosophy, nature of moral judgments and reaction.

UNIT II: Scientific Conduct

Ethics with respect to science and research – Intellectual honesty and research integrity – scientific misconduct: Falsification – Fabrication – Fabrication and Plagiarism (FFP) – Redundant publications: duplicate and overlapping publication-salami slicing- selective reporting and misrepresentation of date.

Unit III : publication Ethics

Publication Ethics: Definition , introduction and importance- Best practices/ standards setting initiatives and guidelines : COPE, WAME, etc. – Conflicts of interest – publication misconduct: definition , concept , problems that lead to unethical behavior and vice versa, type- violation of publication ethics , authorship and contributing and appeals- predatory publishers and journals.

Unit IV :Publication misconduct

Group discussions : Subject specific ethical issues, FFP, authorship – conflicts of interest- complaints and appeals : examples and fraud from India and abroad.

Unit V : Development of e-content &**IPR**

Database : indexing database- citation database : web of science , scopus, etc.

Research Metrics : impact factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score – Metrics: h-index, g index, g index, I 10 index, altmetrics.

Unit VI : Development of e- content & IPR

Integrated Library Management System (ILMS) : e-journals – e-books – e-shodhsindu – shodhganga – database – e-content development – Learning Management system (LMS) – e-PG – Pathshala – CEC (UG) SWAYAM – MOOCs – NPTEL – NMEICT. IPR : Patent – Copyrights- trademark – Geographical Indication.

PRACTICE:

Open access publishing

Open access publications and initiatives-SHERPA/RoMEO online resource to check polisher copyright & self -archiving policies-software tool to identify predatory publications developed by SPPU-Journal finder / journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

20PYR301. PHARMACEUTICS

Course objective

- To determine the organoleptic properties and physical properties of the different dosage forms
- To explain the Physico- chemical characteristics of new drug molecules with respect to different dosage forms
- To illustrate the Compaction and Compression of tablet Dosage form
- To demonstrate the Controlled & Novel Delivery Systems like microparticles, nano particles , Liposomes &niosomes
- To estimate the bioavailability & bioequivalence concept & methodology
- To determine the dissolution of poorly soluble drugs and invitro dissolution testing models

Course outcome(CO's): On successful completion of the course the student will

1. Evaluate the physico- chemical characteristics of new drug molecules with respect to different dosage forms
2. Measurement of forces within the powder mass, moisture content and strength of tablets
3. Explain the concept of optimization parameters, classical optimization, statistical design and optimization methods.
4. Explain the Oral SR/CR products ,Ocular, Transmucosal, transdermal delivery Colonic delivery, Liposomes and niosomes of different dosage forms
5. Estimate the absorption rate of drugs, bioavailability and Bioequivalence methodologies.
6. Illustrate the In-vitro dissolution testing models and its In-vivo correlation

Course Content

UNIT – I

Preformulation- Introduction- organoleptic properties- purity- particle size- shape- and surface area.Solubilisation- surfactants and its importance- temperature- pH- co-solvency; Techniques for the study of crystal properties and polymorphism. Drug-Excipients compatibility studies. Physico- chemical characteristics of new drug molecules with respect to different dosage forms.

UNIT – II

Compaction and compression- Compactionof powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; Effect of particle size- moisture content- lubrication etc on strength of tablets, Heckul's Plot. Transducers. Concept of optimization- optimization parameters- classical optimization- statistical design- and optimization methods.

UNIT – III

Controlled & novel delivery systems-Concept of CR- Polymers for CR- Parentral SR products- Oral SR/CR products- Ocular- Transmucosal- transdermal delivery- Colonic delivery- nasal delivery,Particulate CR systems – microparticles- nano particles and Liposomes &niosomes

UNIT – IV

Bioavailability & bioequivalence-Basic considerations- Definition- estimating absorption rate of drugs- measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Methods of enhancing bioavailability of drugs- Bioequivalence – concept & methodology

UNIT – V

Dissolution-Theory, factors influencing dissolution, study of various approaches to improve dissolution of poorly soluble drugs- Invitro dissolution testing models- I*nvitro -Invivo* correlation in brief.

TEXT BOOKS:

1. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
2. Remington's Pharmaceutical Sciences; By Mack publishing company- Pennsylvania.

REFERENCE BOOKS :

1. Pharmacokinetics; By Milo Gibaldi- Donald Perrier; Marcel Dekker- Inc.
2. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by
3. ADIS Health Science Press.
4. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
5. Biopharmaceutics; By Swarbrick.

6. Biopharmaceuties and Pharmacokinetics- A Treatise; By D.M.Brahmankar and Sunil
7. B.Jaiswal.-VallabhPrakashanPitampura- Delhi.
8. Clinical Pharmacokinetics- Concepts and Applications; By Malcolm Rowland and
9. Thomas N.Tozer. Lea and Febiger- Philadelphia- 1995.
10. Dissolution- Bioavailability and Bioequivalence; By Abdou.H.M.- Mack Publishing
11. Company- Pennsylvania- 1989.
12. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition-
13. Revised and expanded By Robert. E. Notari- Marcel Dekker Inc- New York and Basel-1987.
14. Encyclopedia of Pharmaceutical Technology- Vol 13- James Swarbrick- James.
15. C.Boylan. Marcel Dekker Inc- New York- 1996.

WEBSITES:

- www.slideshare.net
- www.picscheme.org
- www.ijper.org

20PYR302. PHARMACEUTICAL CHEMISTRY

Course Objectives:

- To describe the Modern concept and principles of Drug design and drug discovery
- To explain pharmacokinetic parameters in drug design and Molecular Docking
- To Illustrate techniques for preparing chiral drugs
- To explain the synthetic strategical analysis and QSAR
- To analyze the recent advances in anticancer research
- To describe the Applications of UV- IR- 1H NMR- 13C NMR- MASS spectroscopic data in structural elucidation

Course Outcomes (CO's): On successful completion of the course the student will

1. Evaluate the drug target interactions, Intracellular signaling pathways and Pharmacokinetic parameters in drug design
2. Describe the Molecular Modeling, Docking, XRD, QSAR methods, Combinatorial Synthesis and Computer-Aided Drug Design.
3. Demonstrate the Techniques in preparing the chiral drugs,Enantioselective synthesis and Stereroselective synthesis
4. Explain the Synthetic strategies like Synthones for carbon-carbon bond formation
5. Illustrate the Pathophysiology of Anti-microbial activities and Recent advances in antimicrobial research.
6. Elucidate the structure of natural- synthetic and semi-synthetic by using the UV, IR, ^{1}H NMR, ^{13}C NMR, MASS spectroscopic data

Course Content

UNIT – I

Drug design & drug discovery- Modern concept and principles of Drug design - Analog design- Receptors and Enzymes as drug targets and their characterization – Drug target interactions - Intracellular signaling pathways - Pharmacokinetic parameters in drug design. Molecular Modeling – Docking - XRD - QSAR methods & Combinatorial Synthesis.Computer-Aided Drug Design (CADD).

UNIT – II

Asymmetric Synthesis- Chirality and the importance of chiral drugs- Techniques for preparing chiral drugs (chirality pool - enzymatic transformation and asymmetric synthesis).Enantioselective synthesis - Stereroselective synthesis.

Moleculardocking:Rigiddocking,flexibledocking,manual docking, Dockingbased screening. Denovodrugdesign.
QuantitativeStructureActivityRelationship(QSAR): SARversusQSAR,History and developmentofQSAR,Typesof physicochemical parameters,experimentalandtheoretical approachesfor thedetermination of physicochemicalparameterssuchasPartition coefficient, Hammet's substituent constantandTaftsstericconstant. Hanschanalysis, Free Wilson analysis, 3D-QSAR approaches likeCOMFAand COMSIA.

UNIT – III

Synthetic strategies - Introduction- Disconnection approach- Synthones for carbon-carbon bond formation.-Difunctional compounds- Selective functional group interconversions (FGI) - Retrosynthetic analysis.

Informatics & Methods in drug design: Introduction toBioinformatics, chemoinformatics. ADME databases, chemical,biochemicalandpharmaceuticaldatabases.

UNIT – IV

Cytotoxic (Anti cancer) activities- Pathophysiology of Cytotoxic (Anticancer) activity-Recent advances in anticancer research - **Antimicrobial activities** - Pathophysiology of Anti microbial activities - Recent advances in antimicrobial research.

UNIT–V

Spectroscopic Analysis- Applications of UV- IR- ^{1}H NMR- ^{13}C NMR-, correlation spectroscopy, DEPT, MASS spectroscopic data in structural elucidation of natural- synthetic and semi-synthetic drugs. **Chromatographic techniques-** Applications ofTLC- HPTLC- HPLC- GCMS- LCMS.

TEXT BOOKS:

1. Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold
2. Organic spectroscopy by William Kemp

REFERENCE BOOKS

1. Burger's medicinal chemistry drug discovery- vol. 1 sixth edition- by Donald J. Abraham. (2007)

2. Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold
3. Introduction to Medicinal Chemistry by G. Patrick.
4. Introduction to principles of drug design by Smith and Williams- Harwood Academy press.
5. Advanced Organic chemistry- Reaction mechanisms and structure- J. march- John Wiley and sons- N.Y
6. Medicinal Chemistry byWilliam O Foye.
7. Text book of pathology by Harsh Mohan- third edition. (1998)
8. Spectrometric Identification of organic compounds by Robert M. Silverstein- Francis X-Webster- sixth edition. (1998)
9. Instrumental methods of analysis by Skoog.
10. Organic spectroscopy by William Kemp

WEBSITES:

- www.rsc.org
- www.acs.org
- www.medicinalchemistry.org

20PYR303 . PHARMACOLOGY

Course Objectives:

- To explain the drug discovery process, Bioassays, statistical designs and statistical models employed in biological standardization.
- To employ the Preclinical , clinical models in the screening of new drugs .
- To explain the Review of Literature and the Regulations in the laboratory animal care
- To Illustrate the various International guidelines like ICH, WHO, OECD and CPCSEA
- To evaluate ED50, LD_{50} and TD values
- To describe the Pathophysiology and drug therapy of various disease disorders

Course Outcomes (CO's): On successful completion of the course the student will

1. Describe the High throughput screening and human genomics of drug discovery
2. Explain the principles of bioassays, experimental models, statistical designs and statistical models employed in biological standardization.
3. Demonstrate the Preclinical and clinical models employed in the screening of new drugs.
4. Explain the alternatives to animal screening procedures like cell-line and patch-clamp technique
5. Describe the Principles of toxicity evaluations like ED_{50},LD_{50} , TD values and bioassay methods
6. Illustrate the Pathophysiology and drug therapy of the various disease disorders

Course Content

UNIT – I

Drug discovery process & Bioassays: Principles- techniques and strategies used in new drug discovery. High throughout screening- human genomics of drug discovery. Basic principles of bioassays- official bioassays- experimental models- statistical designs and statistical models employed in biological standardization

UNIT - II

Preclinical and clinical models employed in the screening of new drugs such as Antifertility agents- sedatives- hypnotics- antiarrhythmic agents- cardiac stimulants- bronchodilators- antihistaminics. Antipsychotic agents- Neurodegenerative diseases- antidepressant drugs; antiparkinsoinan agents; antiepileptics; analgesics and anti-inflammatory agents; antiulcer agents; antiatherosclerotic drugs; antidiabetics; transgenic animals and other genetically prone animal models.

Study of pharmacological screening methods of the following categories of drugs: hypolipidemic- - cardiovascular- hepatoprotective- anticancer- - antioxidant- immunomodulator- antimalarial- antimicrobial- antiallergic and antifertility drugs.
Narcotic and non-narcotic analgesics, Drugs acting on Central Nervous System General anesthetics.

UNIT - III

Regulations for laboratory animal care and ethical requirements.Alternatives to animal screening procedures- cell-line- patch-clamp technique *in-vitro* and *in-vivo* models- molecular biology techniques.

ResearchmethodologyandBio-statistics**:** Selectionofresearchtopic,reviewofliterature, researchhypothesis andstudydesign Pre-clinicaldataanalysisandinterpretationusingStudents‘t’test andOne-wayANOVA. Graphicalrepresentationofdata.

UNIT – IV

Principles of toxicity evaluations- ED_{50}- LD_{50} and TD values.International guidelines (ICH /WHO/OECD/CPCSEA recommendations).Toxicology: Principles of toxicity evaluations, ED_{50}, LD_{50} and TD values, International guidelines (ICH& OECD recommendations). Preclinical studies: General principles and procedures involved in acute, sub-acute, chronic, teratogenicity, mutagenicity and carcinogenicity toxicity studies.

LaboratoryAnimals:StudyofCPCSEA andOECDguidelinesformaintenance,breeding and conductof experiments on laboratory animals, Common lab animals: Descriptionandapplicationsofdifferentspeciesandstrains ofanimals.Populartransgenicandmutantanimals.
Techniques forcollectionofbloodandcommon routesofdrug administrationin laboratoryanimals, Techniques of blood collection andeuthanasia.

UNIT – V

Pathophysiology and drug therapy of the following disorders. Schizophrenia- anxiety- depression- epilepsy- Parkinson’s- Alzheimer’s diseases- migraine hypertension- angina pectoris- arrhythmias- atherosclerosis- myocardial infarction- TB- leprosy- leukemia- solid tumors- lymphomas- psoriasis- respiratory- urinary- g.i. tract infections- endocarditis- fungal and HIV infection- rheumatoid arthritis- glaucoma- menstrual disorders- menopause Pharmacogenomics – basic principles- Chronopharmacology – Principles- molecular pharmacology

Biological Screening methods**:** Bioassays-Basic principles of bioassays, official bioassays, experimental models and statistical designs employed in biological evaluation and standardization. Alternatives to animal screening procedures, cell-line, patch –clamp technique, *In-vitro* models, molecular biology techniques.Enzymatic screening methods: α-glucosidase, α-amylase, DNA polymerase, nucleases, L-asparginase, lipases and peptidases. Preclinicalscreeningmodels**:**forCVSactivity-antihypertensives, diuretics,antiarrhythmic, antidyslepidemic,anti aggregatory, coagulants,andanticoagulants. Preclinicalscreeningmodelsforotherimportantdrugslike antiulcer, antidiabetic,anticancerandantiasthmatics.

TEXT BOOKS:

1. Essentials of Medical Pharmacology by K.D.Tripathi.
2. Pharmacology and Pharmacotherpeutics by Satoskar R.S and Bhandarkar S.D.

REFERENCE BOOKS

1. Lippincott's illustrated Reviews- Pharmacology by Mycek M.J- Gelnet S.B and PerperM.M.
2. Hand book of Experimental Pharmacology by Kulkarni.S.K.
3. Fundamentals of Experimental Pharmacology by M. N. Ghosh.
4. Pharmacology by Rang. M.P. Dale- M.M- Reter J.M.
5. Goodman and Gilman's- The Pharmacological basis of therapeutics by Gillman G- Rall T.W.-Nies
6. A.I.S. and Taylor P.
7. Basic & Clinical Pharmacology by Katzung B.G.
8. Craig C.R. and Stitzel R.R- Modern Pharmacology.
9. Ghosh M. N- Fundamentals of experimental Pharmacology.
10. Katzung B.G- Basic and Clinical Pharmacology- Prentice Hall International.
11. Laurence D.R and Bennet P.N. Clinical Pharmacology Churchill Livingstone.
12. Mycek M.J- Gelnet S.B and Perper M.M- Pharmacology- Lippincott's illustrated Reviews.
13. Rang M.P- Dale M.M- Reter J.M- Pharmacology.
14. Goodman and Gilman's- The Pharmacological basis of Therapeutics.
15. S.K. Kulkarni. Hand book of Experimental Pharmacology.

16. N.Udupa and P.D. Gupta- Concepts in Chronopharmacology.

WEBSITES:

- www.libguides.utep.edu
- www.pharmacology2000.com
- www.pharmacologycorner.com

20PYR304. PHARMACOGNOSY

Course Objectives:

- To evaluate the Preparation of monograph of crude drugs
- To Interperate the data of UV, IR, NMR, 1H NMR, 13C NMR & Mass spectroscopy
- To analyze the Ayurvedic Formulations and crude drugs
- To explain the Principles and procedures of microtomy and advanced histological techniques.
- To describe the Pharmacological screening methods
- To Illustrate the Regulatory requirements for new drugs, Markers constituents and importance in crude drug standardization

Course Outcomes (CO's): On successful completion of the course the student will

1.Explain the pharmacopoeia and other guidelines like European Pharmacopoeia , BP , Ayurvedic Pharmacopoeia of India , Ayurvedic formulary of India and WHO guidelines

2. Apply the chromatographic techniques in separation and identification of natural products
3. Analyze the of Ayurvedic Formulations and crude drugs
4. Describe the Principle and procedure involved in biological test like Presence of Mycobacterium tuberculosis, Living contaminants in vaccines and toxic elements
5. Demonstrate the pharmacological screening of the drugs
6. Explain the Regulatory requirements for new drugs

Course Content:

UNIT – I

Evaluation of Drugs: Concept- considerations- parameters and methods of quality control for medicinal plant materials as per various pharmacopoeia and other guidelines. Preparation of monograph of crude drugs.Comparative study of IP- European Pharmacopoeias- BP / Ayurvedic Pharmacopoeia of India / Ayurvedic formulary of India and WHO guidelines in relation to above.

Application of chromatographic techniques in separation and identification of natural products.Only interpretation of data UV- IR- NMR-^{1}H NMR-^{13}C NMR & Mass spectroscopy for purification and structural elucidation of phytoconstituents.Herbal fingerprint profile of single and multicomponent herbal drugs.Stability testing of natural products.

UNIT - II

Analysis of Ayurvedic Formulations and crude drugs with references to: Identity- purity and quality of crude drugs. Determination of pesticide residues- determination of arsenic and heavy metals- detection of microorganisms- determination of microbial load in crude drugs. Identification of aflatoxins in crude drugs.Quality assurance in herbal drug industry- concept of GMP and ISO-9000.Quality assurance in herbal drug :industry of cGMP, GAP, GMP and GLP in traditionalsystemofmedicine. WHOGuidelinesoncurrentgoodmanufacturingPractices(cGMP)forHerbalMedicines. WHOGuidelinesonGACPforMedicinalPlants.

UNIT–III

Quantitative microscopy including lycopodium spore method as applied to drug evaluation and pollen grain analysis - Principles and procedures of microtomy and advanced histological techniques as applied to Pharmacognosy -Principle and procedure involved in biological test for presence of Mycobacterium tuberculosis, living contaminants in vaccines -determination of toxic elements.

UNIT-IV

Herbal drugs available in the categories of Anti-inflammatory, hypolipidemic, diuretics, cardiovascular, hepatoprotective, anticancer, Expectorant antidiabetic, antiulcerative, antioxidant, immunomodulator, antimalarial, antimicrobial, antiallergic and antifertility andStudy of pharmacological screening methods of the following categories of drugs: Antiinflammatory-hypolipidemic- diuretics- cardiovascular-hepatoprotective- anticancer-antidiabetic-antiulcerative- antioxidant-immunomodulator- antimalarial- antimicrobial-antiallergic, drug acting on CNSand antifertility drugs.

UNIT- V

Regulatory requirements for new drugs: Markers constituents- Definition- importance in crude drug standardization. Examples of Biomarkers.Standardization- quality- efficacy and safety requirements & assessment procedures for herbal medicines as per USFDA/WHO guidelines.

Regulatoryrequirementsforherbalmedicines,
WHOguidelinesonsafetymonitoringofherbalmedicinesin pharmacovigilancesystems
ComparisonofvariousHerbalPharmacopoeias.
Roleofchemical andbiologicalmarkersin standardizationofherbalproducts.

Stabilitytestingofherbalmedicines.Applicationofvariouschromatographictechniques in standardizationofherbalproducts.
Preparationofdocumentsfornewdrugapplicationandexportregistration.
GMPrequirementsandDrugs &CosmeticsActprovisions.

TEXT BOOKS :

1. Vogel- Drug Discovery and Evaluation.

2.AshutoshKar-Pharmacognosy and Pharmacobiotechnology- New Age International Publishers

REFERENCE BOOKS :

1..Dhawan- B.N.-Shrimal- R.C.- Use of Pharmalogical Techniques for the Evaluation of Natural Products- CDRI-Lucknow.

2.Ayurvedic Formulary of India.

3..Ayurvedic Pharmacopoeia of India.

4.. Indian herbal Pharmacopoeia.

5. Indian Pharmacopoeia 2007.

6. European Pharmacopoeia 6th Edn. 2008.

7. Pulok K. Mukherjee- Quality Control of Herbal drugs. An Approach to Evaluation of Botanicals.

8.Quality Control Methods for Medicinal Plant Material- WHO Headquarters- Geneva.

9.Standardization of Botanicals by V. Rajpal- Vol. I & II- Eastern Publishers- New Delhi.

10.Evans- W.C.-Trease& Evans Pharmacognosy- W.B. Saunders & Co. London.

11.WHO guidelines- Methodologies on Research for Drug Development and Evaluation of Traditional Medicines.

12.Willard- H.H.-Merrit- L.L.- Dean- J.A.- Settle P.A.- Instrumental Methods of Analysis- Van Nostrand.

13. Skoog- D.A.- Heller- F.J.-Nieman- T.A.- Principles of Instrumental Analysis- W.B Saunders.

14. Hunson- J.W.- Pharmaceutical Analysis - Modern Methods- part A & B- Marcel Dekker.

15. Schirmer- R.E.- Modern Methods of Pharmaceutical Analysis- Vol. 1- 2- Boca Raton F.L: CRC Press.

16. Mann- C.K. et al.- Instrumental Analysis- Harper & Row.
17. Jaffe- H.H.-Orchin- M.- Theory & Applications of Ultraviolet Spectroscopy- Willy.
18. Silverstein- R.M.- et al.- Spectrometric Identification of Organic Compounds- Willy.
19. Bovey- F.-Jelinski- L-Miran- P.- Nuclear Magnetic Resonance Spectroscopy-Sau: Diego Academic.
20. Stothers- J.B.- Carbon-13 NMR.Spectroscopy- Academic.
21. Gordy- W.- Theory & Applications of Electron Spin Resonance- Willy.
22. Haswell- S.J.- Atomic Absorption Spectroscopy- Elsevier.
23. Ardrey- R.E.- Pharmaceutical Mass Spectra- Pharmaceutical press- London.
24. WHO Monographs on Selected Medicinal Plants- Vol. I & II.
25. WHO Quality Control Methods of Medicinal Plant Materials.
26. WHO- International Pharmacopoeia- Vol. I-V.
27. Wilfried- M.A.-Niessen- Liquid Chromatography-Mass Spectrometry.
28. Harry- G. Brittain- Spectroscopy of Pharmaceutical Solids.
29. Indian Herbal Pharmacopoeia-Vol. 1 & 2.
30. Wallis- T.E.- Practical Pharmacognosy.
31. Gorag- Steroid Analysis in Pharmaceutical Industry.
32. Wagner's- Plant Drug Analysis-A Thin layer Chromatography- Atlas.
33. Bogers- Medicinal and Aromatic plants- Agricultural- Commercial- Ecological- Legal- Pharmacological and Social Aspects.

WEBSITES:

- www-autostream-com
- www-epharmacognosy-com
- www-science20-com

20PYR305 .PHARMACEUTICAL ANALYSIS

Course Objectives:

- To describe the Concepts and Philosophy of TQM- GMP (orange guide)- ISO-9000
- To explain the Selection- purchase specifications- maintenance- sterilization of an area.
- To explain the Manufacturing Documents- Master Formula- Batch Formula Records- Standard operating procedure- Quality audits of manufacturing processes
- To Illustrate the concepts in the Quality control Laboratory
- To describe the Regulatory aspects of Pharmaceuticals and Bulk drug Manufacturing
- To explain the Preparation of drug sample for analysis

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain about orange guide, Location, Design, Plan Layout, Construction, Maintenance and Sanitations
2. Describe about Purchase specifications, Maintenance of stores, Selection of vendors, and Controls on Raw materials.
3. Illustrateabout Manufacturing Documents, Master Formula, Batch Formula Records- Standard operating procedure and Quality audits of manufacturing processes.
4. Explain the Good Laboratory Practices andGood warehousing practice.
5. Describe about the Globalisation of Drug Industry, Export of Drugs and Import Policy
6. Explain about HPLC Method development by using different stationary phases

Course Content

UNIT - I

Concepts and Philosophy of TQM- GMP (orange guide)- ISO-9000. Organisation and personnel- responsibilities- training- hygiene. Location- Design- Plan Layout- Construction- Maintenance and Sanitations. Environmental control- Sterile areas- control of contamination. Selection- purchase specifications- maintenance- sterilization of an area (TP & STP)

Spectroscopy:UV-VISIBLE Spectroscopy: Electromagnetic spectrum. Shifts and their interpretation, instrumentation and applications.INFRARED Spectroscopy: Basic principles, molecular vibrations, vibration frequency and its influencing factors, instrumentation and applications. Interpretation of IR spectra.NMRSpectroscopy: Fundamental principles of NMR, instrumentation and applications. Interpretation of NMR spectra.

Spectrometry: MassSpectrometry: Basic principles and brief outline of instrumentation and applications. Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups.Interpretation of Mass spectra

UNIT – II

Purchase specifications- Maintenance of stores- Selection of vendors- Controls on Raw materials. Manufacture of and controls on dosage forms :. Manufacturing Documents- Master Formula- Batch Formula Records- Standard operating procedure- Quality audits of manufacturing processes and facilities. Standard operating procedures for various operations like cleaning- filling- drying- compression- coating- disinfection- sterilisation- membrane filtration etc.-

UNIT – III

Quality control Laboratory : Responsibilities- Good Laboratory Practices- Routine controls- Instruments- Protocols- Non-clinical testing- Controls on animal house- Application of Computers in Quality control laboratoryFinished product release : Quality review- Quality audits- Batch release document. Warehousing : Good warehousing practice- Materials- Managements. Packaging and labeling controls- line clearance- reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass and plastics. Introduction to cGMP

UNIT – IV

Distribution : Distribution of records- Handling of returned goods- Recovered materials and Reprocessing. Complaints and Recalls : Evaluation of complaints- Recall procedures- Related records and documents. Waste disposal- Scrap disposal procedure and records. Regulatory aspects of Pharmaceuticals and Bulk drug Manufacturing- Regulatory drug analysis. Loan License Auditing – Concepts- Auditing. Recent Amendments to drugs and cosmetics act and other relevant rules- Consumer protection- Environmental protection act- Certification and Licensing procedure. WHO Certification- Globalisation of Drug Industry- Introduction to Export of Drugs and Import Policy. Patent regime.

UNIT – V

Internal and standard addition methods Preparation of drug sample for analysis-Introduction-compatibility with the instrumental method- fundamental theories controlling preparation techniques- Specific sample preparation techniques: soxhlet extraction- Liquid-liquid extraction-solid phase extraction- solid phase micro extraction- protein precipitation methods- Ultra filtration- direct injection- methods- derivatization methods- residual sample preparation-different sample preparation methods for pharmaceutical dosage forms: tablets- capsules-ointments etc- Gas Chromatography: inlets and injectors- GC column characteristics- GC detectors- GC preventive maintenance and troubleshooting- method development process-method validation and QA Processes HPLC: Detectors- PDA- ELSD- Conductivity- UV-Refractive Index- Fluorescence- Mass- HPLC column selection and mobile phases- mobile phase additives. HPLC Method development by using different stationary phases- mechanism of interactions- HPLC preventive maintenance and troubleshooting- case studies. Calibration methods: external, HPTLC and interface.

TEXT BOOKS:

1. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
2. Good Laboratory Practice Regulations- 2nd Edition- Sandy Weinberg- Vo. 69-

REFERENCE BOOKS:

1. Decker Series.
2. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related
3. materials – Vol. I – WHO Publications.
4. A guide to Total Quality Management – KaushikMaitra and SedhanK.Ghosh.
5. How to practice GMPs – P. P. Sharma.
6. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
7. The International Pharmacopoeia Vol. 1-2-3-4 - 3rd Edition- General Methods of
8. Analysis and Quality specification for Pharmaceutical Substances- Excipients and
9. Dosage forms.
10. Controller of Publication- Govt. of India - Indian Pharmacopeia- Vol. I and II -
11. 1996.
12. Burn- Finiey and Godwin : Biological Standardisation- 2nd Edition- Oxford
13. University Press- London.

14. Dr. A. Patani : The Drugs and Cosmetics Act 1940- Eastern Book Company-Lucknow.

WEBSITES:

- www.jpr.info.com
- www.sciencedomain.org
- www.pharmaresearchlibrary.com