Pre Ph.D.(Pharmacy)

Faculty of Pharmacy

DIT University Dehradun

Course Structure
for
Pre Ph.D. (Pharmacy) Course Work
Session: 2019-20

Amended by the BoS and approved by the Academic Council at its 11th Meeting held on 29.04.2019

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Course Category	Course Code	Course Title	L	T	P	Credit
UC	MB901	Research Methodology	4	0	0	4
DE		Elective 1	4	0	0	4
DE		Elective 2	4	0	0	4
DC	DS001	Seminar	1	0	0	1

List of Electives(select any two)					
PH 741	Drug Regulatory Affairs	4	0	0	4
PH742	Targeted Drug Delivery Systems	4	0	0	4
PH743	Advance Pharmaceutics	4	0	0	4
PH744	Pharmacological Screening methods	4	0	0	4
PH745	Advanced Molecular Pharmacology	4	0	0	4
PH 746	Herbal Drug Manufacturing Technology	4	0	0	4
PH 747	Standardization and Pharmacological screening of herbal preparations	4	0	0	4

Note : Apart from above listed Elective courses, Research Scholar may choose any course across departments being offered at PG level, if it is required/suggested by the Research Committee.

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Subject Code	MB901	Subject Title	Research Methodology						
LTP	4 0 0	Credit	4	Subject Category	UC	Year	1st	Semester	I / II

UNIT – I

Fundamentals of Research: Defining research, Objectives of research, types, research process, deductive and inductive reasoning;

Identifying and formulating a research problem, Literature review: Search for existing literature (World Wide Web, Online data bases), Review the literature selected (Case studies, review articles and Meta-analysis), Develop a theoretical and conceptual framework, Writing up the review,

Definition of variables: Concepts, indicators and variables, Types of variables, Types of measurement scales, Constructing the Hypothesis- Null(Research) and alternative, one-tailed and two-tailed testing, errors in testing. Ethical and Moral Issues in Research, Plagiarism, tools to avoid plagiarism – Intellectual Property Rights – Copy right laws – Patent rights

UNIT – II

Research Design: Design of Experiments: Research Designs -Exploratory, Descriptive and Experimental, Experimental designs- Types of Experimental Designs

UNIT – III

Sampling, Sampling distribution, and Data Collection: Sampling distribution, Normal and binomial distribution, Reasons for sampling, sampling technique, sampling errors. Sources of Data-Primary Data, Secondary Data, Data Collection methods

UNIT – IV

Statistical Data Analysis: Descriptive and inferential statistical analysis. Testing of hypothesis with Z-test, T-test and its variants, Chi-square test, ANOVA, Correlation, Regression Analysis, Introduction to data analysis data using SPSS20.0

UNIT – V

Research Report: Writing a research report- Developing an outline, Formats of Report writing, Key elements- Objective, Introduction, Design or Rationale of work, Experimental Methods, Procedures, Measurements, Results, Discussion, Conclusion, Referencing and various formats for reference writing of books and research papers, Writing a Research Proposal.

Books Recommended:

1. Ganesan R, Research Methodology for Engineers , MJP Publishers, Chennai. 2011
2. C.R.Kothari, "Research Methodology", 5th edition, New Age Publication,
3. Cooper, "Business Research Methods", 9th edition, Tata McGraw hills publication
4. Walpole R.A., Myers R.H., Myers S.L. and Ye, King: Probability & Statistics for Engineers and Scientists, Pearson Prentice Hall, Pearson Education, Inc. 2007.
5. Anderson B.H., Dursaton, and Poole M.: Thesis and assignment writing, Wiley Eastern 1997.
6. Bordens K.S. and Abbott, B.b.: Research Design and Methods, McGraw Hill, 2008.
7. Morris R Cohen: An Introduction to logic and Scientific Method (Allied Publishers) – P 197-222; 391–403

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Subject Code	PH741	Subject Title	Drug Regulatory Affairs						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

This course is designed to impart knowledge and skills necessary for implementation of various regulatory aspects including the patent filing of any invention & also knowledge on conducting holistic research as per the GLP guidelines

Course Objective:

The course is designed with following objectives

Upon completion of this course it is expected that the scholars will able to implement the various regulatory principles in their professional practices and they can conduct scientific research as per GLP guidelines.

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit I

i) Indian Patent Act

ii) Indian Patent Filing, Drafting, Writing Claims and various Forms for Filing.

Unit II

i) Regulatory Regulations for MHRA, USFDA, CDSCO

Unit III

Good Laboratory Practices (GLP), Schedule M, Inter Regulatory Prospects on Bioavailability and Bioequivalence

Unit IV

i) Clinical Ethical Regulatory Issues of Nanotechnology and Nanoparticles

ii) Regulatory Issues on Pharmaceutical Excipient Techniques

Unit V

U.S. Patent Act

Text Book: Title, Author, Publication House, Edition, Year

Learning Outcome

Upon completion of this course the students will be able to:

Upon completion of this course it is expected that the scholars will able to implement the various regulatory principles in their professional practices and they can conduct scientific research as per GLP guidelines.

Recommended Books (Latest edition):

I. GLP Regulations, 2nd Edition, Revised and Expanded by Sandy Weingberg.
II. GMP Practices in Pharmaceuticals, Sidney H. WilligandJanes R Stokes
III. Preparing for FDA preapproval Inspection: Martin D. Hynes
IV. Drugs and Cosmetic Act (Schedule M)
V. Gennaro A.R., Remington- The science and practice of pharmacy, Lippircott, Williams & Wilkins.
VI. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.
VII. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.
VIII. Guarino R.A., New Drug Approval Process, Marcel Dekker.
IX. Sharma P.P., How to practice GMP, VandanaPrakashan, New Delhi.
X. Sharma P.P., how to practice GLP, VandanaPrakashan, New Delhi,
XI. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.
XII. Weinlerg S., Good Laboratory Practices, Marcel Dekker.
XIII. The Patent Act, 1970
XIV. The Trade Marks Act, 1999.
XV. The Copyright Act, 1958.
XVI. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.
XVII. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.
XVIII. Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Anthoriter of different countries.
XIX. Introduction to the pharmaceutical regulatory process.Ira R. Berry

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Subject Code	PH742	Subject Title	Targeted Drug Delivery System						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

The course is designed to provide a knowledge on various drug targeted drug delivery system for effective delivery of therapeutics and nano formulations approaches for targeting drug to brain and cell specific region

Course Objective:

The course is designed with following objectives

The research scholar will acquire a knowledge& basic concept for designing various nano formulations and factors to be considered while targeting a therapeutic molecule to brain & cell region

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit I

An overview on DSS & Targeted DDS: Approaches, Approval, Mechanism & Research Updates

i) Drug Targeting to Brain: Concepts, Approaches, Approval, Mechanism & Research Updates

ii) Recent Brain Targeting Concept: Nose to Brain; Ear to Brain

Unit II

i) Cell Specific Delivery: Concepts, Various Approaches and Recent Advances

ii) Strategies for Specific Drug Targeting to Tumour Cells and Tumour Vasculature

iii) Drug Delivery Applications of Nanoparticles and Nanotoxicology

Unit III

i) Recent advances in Transmucosal Drug Delivery; Buccal; Soft Palatal, Trans-Labial

ii) Ocular Drug Delivery

Unit IV

Targeted GI Delivery and Colon Targeting Specific Drug Delivery and Trans-Ungual

Unit V

i) Self Emulsifying Drug Delivery System (SEDDS): Improving Absorption of poorly soluble drugs using SEDDS and Nano Self Emulsifying Drug Delivery System(NSEDDS)

ii) Case Study On:

a) Development and Evaluation of SEDDS

b) Modified Release Solid Oral Dosage Forms

Learning Outcome

Upon completion of this course the students will be able to:

The research scholar will acquire a knowledge& basic concept for designing various nano formulations and factors to be considered while targeting a therapeutic molecule to brain & cell region

Recommended Books (Latest edition):

i) Sterile Product facility design and Project Management; 2nd Edition, JeffeneNodum, CRC Press

ii) Modified Release Drug Delivery Techniques; Michaeal J. Rathbone (Marcel Dekker Inc.)

iii) Pharmaceutical Skin Permeation Enhancement; Kenneth A. Waters and Jonathan Hadgrats

iv) Physical Characterization of Pharmaceutical Solids; Harry G. Orittam

v) Pharmaceutical Experimental Design; Gareth A. Lewis.

vi) Surfactants polymer in drug delivery; Martin Malmsten

vii) Drug delivery Nanoparticles formulation and characterization; Yashwant Pathak, Informa Publication

viii) Dermatokinetics: S.N Murthy

ix) Pharmaceutical Gene Delivery System; Alian Rolland

x) Pharmaceutical Extrution technology edited by IsaachGhebreSellossie

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xi) Compliance Handbook of pharmaceuticals, medical devices and biologics.Edited by Carmen Medina
xii) Liposome technology (vol 1,2,3); Gregory Gregoriadis
xiii) Pharmaceutical Manufacturing Encyclopedia; Marshall Sittig
xiv) Pharmaceutical technology controlled drug release(vol:1,2,3)M.Rubinstein
xv) Prodrug topical and ocular delivery; Kenneth B.Sloan
xvi) Microencapsulation method and industrial application; Simon Benita
xvii) Oral mucosal drug delivery system. Michail,J.rathbone

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Subject Code	PH743	Subject Title	Advance Pharmaceutics						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

The subject provides detailed knowledge on various physical and chemical factors and their role in designing effective therapeutic formulations to impart better therapeutic value

Course Objective:

The course is designed with following objectives

The scholars will be able to apply various knowledge acquired related to designing suitable formulations by considering various physic chemical factors of various excipients and their impact on their formulation stability and they can able to apply the knowledge for preparing various pharmaceutical dosage forms

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit I

i) Basic Concepts of Solubility and Dissolution of Pharmaceutical Solids

ii) Theoretical Estimation of Solubility

iii) Thermodynamics of Solutions; Solubility by Combination of Approaches

iv) Various Techniques for Solubilization, Experimental Methods of Determination of Solubility and its Conditions

Unit II

i) Polymorphism and Transformation of Solids, Amorphous Drugs and Solid Dispersion;
Analytical Techniques for Solid State Characterization; Salts Screening and Selection;
Excipient Compatibility

ii) Theory of Diffusion and Pharmaceutical Applications

Unit III

Polymers, Biopolymers and its properties, characterization and its applications

Unit IV

i) Oral Drug Absorption, Evaluation and Prediction

ii) Biopharmaceutical and Pharmacokinetic Evaluation of Drug molecules and Dosage Form

Unit V

i) FDA Guidelines for Bioequivalence Study for NDDS

ii) Developing predictive in-vitro test &In-vivo Evaluation for Oral Dosage Forms, Performance and In-Vitro/In-Vivo Correlation techniques and Approaches

Learning Outcome

Upon completion of this course the students will be able to:

The scholars will be able to apply various knowledge acquired related to designing suitable formulations by considering various physic chemical factors of various excipients and their impact on their formulation stability and they can able to apply the knowledge for preparing various pharmaceutical dosage forms

Recommended Books (Latest edition):

i) Developing Oral Solid Dosage Forms; Pharmaceutical Theory and Practice- Yihokiu,
Academic Press

ii) Foundation of Pharmacokinetic ACDO RESCIGNO Kulwer Academic Publishers

iii) Handbook of Pharmaceutical Manufacturing Formulation (Volumes I, II, III, IV, V,VI);
Sarfaraz K. Niazi, CRC Press.

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iv) Handbook of Stability Testing in Pharmaceutical Development, Springer Publisher, Kim Huynh-Ba
v) Handbook of PreformulationSarfaraz K. Niazi, Informa Health Care
vi) PharmaceuticalPreformulation and Formulation; Mark Gibson, HIS Health Gr
vii) Pharmaceutical Product Development IVIVC, Dueshina Murthy ChilukasiInforma Health Care
viii) Pharmaceutical Dissolution Testing, Jennifer Dressman, Taylor and Francis
ix) Physical Pharmacy; David Attwood, PhP Pharmaceutical Press
x) Spectroscopy of Pharmaceutical Solid; Janes S Warbrick, Taylor and Francis Group
xi) Pharmaceutical Excipients Characterization by IR, Raman, NMR; David EiBugey and W. Paul Findlay
xii) Polymorphism in Pharmaceutical Solid; Harry G Brittain
xiii) Bioadhesive Drug Delivery: Fundamental, Novel approaches and development: Mathioneitzes
xiv) Drug Delivery to Oral Cavity Molecules to Market; Tapash. K. Ghosh and Willian R. Pfister

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Subject Code	PH744	Subject Title	Pharmacological Screening methods						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

This subject is intended to impart the advanced knowledge on various screening principle and methods aspects of drugs acting on various systems of body and in addition, emphasis on the advances in toxicological screening using cell line technique.

Course Objective:

The course is designed with following objectives

The research scholar will acquire a knowledge& advances in screening of various active using experimental animals and in-depth knowledge pertaining to toxicological screening of molecules using cell lines as per the regulatory guidelines.

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit I

Laboratory animal handling and breeding techniques, CPCSEA guidelines, alternatives to animal studies, RRR concept.Animal research regulation and guidelines in USA, New Zealand, Canada, Europe and UK.

Unit II

Principles & types of bioassay, Bioassay of biological like vaccine and sera, immunoglobulin etc.

Unit III

Determination of LD50, Acute, sub-acute and chronic toxicity studies, Therapeutic index, OECD guidelines. Cell line toxicity.

Unit IV

Screening methods for evaluation of hepatoprotective, antihypertensive, antidepressant, antipsychotic, anti-inflammatory, analgesic, anticancer and anti-diabetic activity and drugs used for the treatment of brain disease and GI disorders.

Unit V

New drug discovery, Clinical evaluation of new drugs, Phases & types of clinical trials, protocol design, Ethics in human research, Pharmacovigilance.

GLP, GCP guidelines,CRF, IRB/IEC, inclusion criteria and exclusion criteria in Clinical research and recent amendment and advancement.

Learning Outcome

Upon completion of this course the students will be able to:

The research scholar will acquire a knowledge& advances in screening of various active using experimental animals and in-depth knowledge pertaining to toxicological screening of molecules using cell lines as per the regulatory guidelines.

Recommended Books (Latest edition):

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn. 2. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springerverlag, Berlin Heideleberg.

3. Handbook of experimental pharmacology by S.K. Kulkarni, VallabhPrakashan, Delhi.

4. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.

5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes.
6. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
7. Good clinical practice - Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.
8. https://www.animalethics.org.au/legislation/international
9. www.who.int/tdr/publications/documents/glp-handbook.pdf
10. https://www.ich.org/.../ICH.../Guidelines
11. www.oecd.org

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Subject Code	PH745	Subject Title	Advanced Molecular Pharmacology						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

The subject provides in depth knowledge on basic and advance concept of drug molecular mechanisms. Approaches for gene therapy and stem cell therapy used for the treatment of different diseases.

Course Objective:

The course is designed with following objectives

The research scholar will acquire a knowledge & research advances in molecular mechanism of drug molecule and concept and therapeutic management in multi-drug resistance disease like tuberculosis, leprosy etc.

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit I

Molecular mechanism of drug action: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol, enzymes, nuclear transcription factors, Ionic channels and their modulators.

Unit II

Ion channel and their modulators: calcium, potassium, sodium and chloride channels

Unit III

Recent trends on different classes of receptors as follows and drugs acting on them Dopamine receptors, Serotonin receptors, GABA and Benzodiazepine receptors, Opioid receptors, Glutamate receptors and Histamine receptor.

Unit IV

Endogenous bioactive molecules: Cytokines, nitric oxide, phosphodiestrase enzyme, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, Angiotensin, Bradykinin, endogenous opioids.

Unit V

Gene and stem cell Therapies: Basic concepts and clinical potentials of gene therapy and stem cell therapy, Impact of human genome sequence on the discovery of newer pharmacological agents. Ethical issues related to stem cells and human cloning.

Multi-drug resistance mechanism and causes in virus, bacteria, fungus and parasitic diseases, its Pharmacoepidemiology and recent research advancement in therapeutic management.

Learning Outcome

Upon completion of this course the students will be able to:

The research scholar will acquire a knowledge & research advances in molecular mechanism of drug molecule and concept and therapeutic management in multi-drug resistance disease like tuberculosis, leprosy etc.

Recommended Books (Latest edition):

1. The Pharmacological basis of therapeutics, 11ed. – Goodman and Gilman's., Mc Graw Hill
2. Pharmacotherapy; A pathophysiological Approach, Josef T. Dipiro& Robert L. Talbert ,7th. Ed., 2005, Mc Graw Hill
3. Pharmacology – Rang and Dale, 2015.
4. Fundamentals of experimental pharmacology by M.N.Ghosh., Hiltton Kolkata, 2007
5. Principles of drug action. The Basis of Pharmacology by Avram Goldstein, Lewis Aronow Harper and Row, New York, 1968.
6. Clinical pharmacology by Molmon and Morrelli.2009
7. P.I. Good, A Managers Guide to Design and Conduct of Clinical trials, Wiley-Liss, Hobokem, U.S.A., 2002.
8. B.R. Glick and J.J. Paternak, Molecular Biotechnology: Principles and Applications of DNA Recombinant Technology. ASM Press, Washington, U.S.A., 1994.

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Subject Code	PH746	Subject Title	Herbal Drug Manufacturing						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

This course will help to understand the technologies used in industry and commercial purpose to explore the potentials of drugs of natural origin. It will also help to integrate the Indian system of traditional medicine with modern system of medicine.

Course Objective:

The course is designed with following objectives

1. Understand the requirements of setting up herbal drug industry
2. Learn requirements of regulatory authorities in maintaining quality of herbal products.
3. Know process and procedure in patenting knowledge, molecule and product derived from natural resources.

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit-1

Herbal drug industry: Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Current challenges in upgrading and modernization of herbal formulations.Entrepreneurship Development, Project selection, project report, technical knowledge, Capital venture, plant design, layout and construction. Pilot plant scale –up techniques, case studies of herbal extracts. Formulation and production management of herbals.

Unit – 2

Regulatory requirements for setting herbal drug industry: Quality assurance in herbal/natural drug products. Concepts of TQM, GMP, GLP, ISO-9000, AYUSH and WHO guidelines.

Unit-3

Development and evaluation of polyherbal formulations; tablets, capsule, phytosomes, novel formulations, etc. Approaches in delivery of phytoconstituents and their evaluation.

Unit-4

Analytical Evaluation of Herbal Drugs: LC-IR, LC-MS, LC-GC, GC-MS, phytoequivalence, hyphenation, Radioimmunoassay, etc

Unit-5

Recent advances in plant tissue culture; soma clonal variation, In vitro selection of plants tolerant to abiotic stress, In vitro selection of salt-tolerant plants, Characterization of salt- or drought-tolerant plants during in vitro selection, Transgenesis for abiotic stress tolerance, In vitro tissue culture as a tool for physiological and biochemical studies in plants,

Learning Outcome

Upon completion of this course the students will be able to:

1. Understand the requirements of setting up herbal drug industry
2. Learn requirements of regulatory authorities in maintaining quality of herbal products.
3. Know process and procedure in patenting knowledge, molecule and product derived from natural resources.

Recommended Books (Latest edition):

I. Herbal drug industry by R.D. Choudhary (1996), Eastern Publisher, New Delhi.

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II. GMP for Botanicals - Regulatory and Quality issues on Phytomedicine by Pulok K Mukharjee (2003), Ist Edition, Business horizons Robert Verpoorte, New Delhi.

III. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.

IV. PDR for Herbal Medicines (2000), Medicinal Economic Company, New Jersey.

V. Indian Herbal Pharmacopoeia (2002), IDMA, Mumbai.

VI. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (1996), NiraliPrakashan, New Delhi.

VII. Text book of Pharmacognosy and Phytochemistry by Vinod D. RangarI (2002), Part I & II, Career Publication, Nasik, India.

VIII. Plant drug analysis by H.Wagner and S.Bladt, Springer, Berlin.

IX. Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol.I, Eastern Publisher, New Delhi.

X. Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants by J.B.Harborne, (1999), IInd Edition, Taylor and Francis Ltd, UK.

XI. Herbal Medicine. Expanded Commission E Monographs by M.Blumenthal, (2004), IST Edition,

XII. Drug Formulation Manual by D.P.S.Kohli and D.H.Shah (1998), Eastern Publisher, New Delhi.

XIII. New Delivery Systems for Controlled Drug from Naturally Occuring Materials (ACS Symposium Series) , by Nicholas Parris, LinShiu Liu, Cunixian Song, V Prasad Shastri, 27 Nov 2008

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Subject Code	PH747	Subject Title	Standardization and Pharmacological Screening of Herbal Preparations						
LTP	4:0:0	Credit	4	Subject Category	DE	Year	1st	Semester	I

Course Outline:

This course is designed to impart the knowledge, skills on preclinical screening of herbal drugs by using traditional and advanced methods. The course also provides basic information required for possible exploration of drugs for clinical use.

Course Objective:

The course is designed with following objectives

1. Appraise the regulations and ethical requirement for the usage of experimental animals.
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
3. Describe the various newer screening methods involved in the drug discovery process
4. Appreciate and correlate the preclinical data to humans

Course Pre/Co- requisite (if any) : Nil

Detailed Syllabus

Unit-1

Standardization of herbal drugs:

Active principal identification, need for standardization, standardization of polyherbal formulations, pharmacopoeial standards, parameters for standardization; quality control of herbal drugs, DNA fingerprintings, genetic markers.

Unit-2

Screening of Herbal Medicines for Potential Toxicities:

Toxicity of herbs, Goals of toxicity testing of herbal drugs, Pre-clinical toxicity testing of herbs, Cell-based cytotoxicity tests, Herbal toxicokinetics, Toxicogenomic screening tools, High throughput next generation sequencing, Animal tests, General tests, Chronic toxicity/carcinogenity,

Unit-3

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Reproductive Pharmacology: Aphrodisiacs and antifertility agents

Analgesics, antiinflammatory and antipyretic agents.

Gastrointestinal drugs: anti ulcer, anti -emetic, anti- diarrheal and laxatives.

Unit-4

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antianginal, and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents, anti-cancer agents and hepatoprotective screening methods.

Unit- 5

Clinical evaluation of herbal preparations: Status of research on alternative medicine clinical trials, current guidelines and regulatory authority directives for clinical research on alternative medicine, clinical trial guidelines, search for information, design of protocol, testing of the acceptability, submission of clinical trial protocol for regulatory and ethical approval, testing of subject acceptance of clinical trials on herbal products and clinical investigator acceptance.

Learning Outcome

Upon completion of this course the students will be able to:

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1. Appraise the regulations and ethical requirement for the usage of experimental animals.
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
3. Describe the various newer screening methods involved in the drug discovery process
4. Appreciate and correlate the preclinical data to humans

Recommended Books (Latest edition):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author), Ajay Prakash (Author)