Pre Ph.D. (Pharmacy)

Faculty of Pharmacy

DIT University Dehradun

Course Structure
for
Pre Ph.D. (Pharmacy) Course Work
Session: 2017-18

Approved by the Academic Council at its 6th Meeting held on 13.05.2017

Pre Ph.D. (Pharmacy)

Course Category	Course Code	Course Title	L	T	P	Credit
UC	MS621	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

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	MS621	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