YENEPOYA
UNIVERSITY
Recognized under Sec 3(A) of the UGC Act 1956

Faculty of Pharmacy

Ph.D. Program
Paper I

Curriculum/Syllabus (Old)

Centre Ph.D. Program
Yenepoya University
Deralakatte, Mangalore -575 018
Karnataka, India

YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Office of the Registrar
University Road
Deralakatte
Mangalore - 575018
Ph: 0824-2204667/68/69/71
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NOTIFICATION – 13/32-ACM/2018 dtd. 03.09.2018

Sub: Amendment to Ph.D Regulations with regard to
(1) Amendments to the Regulations – Rule 03 and 07
(2) Inclusion of Faculty of Pharmacy in Rule 03 to the regulations

Ref: Resolution of the Academic Council at its meeting held on 11.08.2018 vide agenda – 19

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The Board of PG Teaching & Research at its 42nd meeting proposed the following amendments to the regulations governing the Degree of Philosophy in various Faculties of Health & Allied Sciences of Yenepoya (Deemed to be University).

Amendments to the Regulations – Rule 03 and 07

Clause /point No. Title of the clause	Existing	Now Amended
03. ELIGIBILITY FOR ADMISSIONS **ANNEXURE 1 GUIDELINES** **1. GUIDELINES FOR ELIGIBILITY CRITERIA FOR ADMISSION (CLAUSE NO. 3)**	Teacher candidates, who fulfill the qualifications specified in the regulations and are (i) regular teaching faculty (ii) non teaching staff in a department / Constituent college of the Yenepoya University may be permitted to register himself / herself as a part time scholar for Ph.D degree under a Guide recognized by this University.	Candidates who fulfill the qualifications specified in the regulations and are regular (after completion of probation) (i) teaching faculty (ii) non teaching staff in a department / Constituent college of the Yenepoya deemed to be University, may be permitted to register himself / herself as a part time scholar for Ph.D degree under a Guide recognized by this University.

Inclusion of Faculty of Pharmacy in Rule 03 - to the regulation

02. DISCIPLINES	Admission to Ph.D program will be made under the following faculty, covering a wide range of disciplines. 2.1 FACULTY OF MEDICINE 2.2 FACULTY OF DENTISTRY 2.3 FACULTY OF NURSING 2.4 FACULTY OF ALLIED HEALTH AND BASIC SCIENCES All subjects coming under the scope of respective faculties or any other new faculty approved by the University will be included from time to time.	Admission to Ph.D program will be made under the following faculty, covering a wide range of disciplines. 2.1 FACULTY OF MEDICINE 2.2 FACULTY OF DENTISTRY 2.3 FACULTY OF NURSING 2.4 FACULTY OF ALLIED HEALTH AND BASIC SCIENCES 2.5 FACULTY OF PHARMACY All subjects coming under the scope of respective faculties or any other new faculty approved by the University will be included from time to time.

The amended Regulations for the course as approved by the Academic Council and subsequently by the Board of Management for implementation.

(Dr. G. Shreekumar Menon)
REGISTRAR
mj

To:
Dy. Director, MPhil Ph.D Programme

PRE-Ph.D EXAMINATION - PAPER I – SYLLABUS

RESEARCH METHODOLOGY & BIOSTATISTICS

RESEARCH METHODOLOGY

Unit 1. Introduction to Research: General (8 hours)

- Definition, need
- Kinds and purposes of Research: Diagnostic, Descriptive, Exploratory, Explanatory
- Research approaches
- Significance of research & importance
- Criteria of good research
- Research process : components
- Types of Research: Quantitative, Qualitative, Basic and applied

General Topics

- Guidelines for Research ICMR, WHO, Nursing
- Research Ethics – Animal ethics; Human ethics
- Biosafety : Good Lab Practices, Scientific integrity and code of conduct; Plagiarism

Unit 2. Literature survey; Proposal writing (6 hours)

- Types of Literature search – use of library, books & journals – Medlines, internet, getting patents and article reprints as a source of literature survey
- Review of Literature– Formulation of Hypothesis
- Identification and selection of research problems, preparation of research proposal, synopsis.
- Research Proposal writing IP users, Plagiarism
-

Unit 3. Research Design;Study design (6 hours)

- Basic Concepts of Research Design & selection of research design
- Classification and types : Experimental, Pre-experimental, Quasi-Experimental designs and Non - experimental
- Historical design, Descriptive design, case control, cohort, cross sectional, longitudinal

Unit 4. Data Collection Techniques and Interpretation (6 hours)

- Types of Data .
- Data Collection methods: Interview; Observation; Questionnaire
- Developing tools – Validity (internal & external), Reliability of the tools.

Unit 5. Research Reporting

Scientific Writing: **(6 hours)**

- General structure of scientific reports :- IMRAD; Different types of scientific documents - journal articles, books, thesis, conference and project reports
- Components of a research paper - abstract, key words, main text, illustrations, supporting information; Publication process, copyright transfer. Open access terms
- Thesis: Structure and Content;
- Style manuals with examples (Harvard, Vancouver, APA, MLA); Citation styles: reference writing
- Evaluation of research reports/papers- Criteria: novelty, originally, adequacy of information, responsibility, limitations, etc.

Recommended Books:

- How to Write and Publish a Scientific Paper? ; Robert A. Day, Barbara Gastel ; 6th edition; Cambridge : Cambridge University ; 2006.
- Research Methodology Methods and Techniques; C.R. Kothari; 2nd edition; New Age International; 1990 (published in 2009).
- Research Methodology Methods and Statistical Techniques; Santosh Gupta; New Delhi: Deep & Deep Publications ; 2000.
- Research Methodology ; Indrayan
- Research Methodology by C. Rajendra KumarPublisher, APH Publishing Corporation, 2008
- Research Methodology by Mukul Gupta & Deepa GuptaPublisher: PHI Learning Pvt. Ltd, print edition pages: 224, ISBN: 978-81-203-4381-8.
- Research Methodology: A step by step guide for beginners byRanjit Kumar, *Third Edition*, Ranjit Kumar University of Western Australia, *SAGE Publications Ltd*
- Research Methodology by R. Pannerselvam, Publisher:PHI Learning, 2004, Edition: Second Edition, ISBN: 978-81-203-4946-9.
- Research Methods by Ram Ahuja, Rawat Publications, 01-Jan-2001 - Reference
- Introduction to Bio-statistics and Research methods by P.S.S Sundar Rao & J. Richard, Publisher: PHI Learning, 2012, Edition: fifth edition, ISBN: 978-81-203-4520-1
- Nursing Research : Principles & Methods 7th edition by demise E. Polit Cheryl Tatano Beck, Published by CAMINO PALMERO
- Research Design: Qualitative, Quantitative and Mixed Methods Approaches: by Creswell
  Sage South Asia Edition, 3rd Edition2011
- Research Methodology: A guide for researchers in Management and Social Sciences, by Bill Taylor, Gautam Sinha, TaposhGhoshal. , Published By PHI.
- Research Methods in Community Medicine: Surveys, Epidemiological Research, Programme Evaluation, Clinical Trials, Sixth Edition, by J. H. Abramson, Z. H. AbramsonPrint ISBN: 9780470986615, Copyright © 2008 John Wiley & Sons, Ltd
- Developing Research Proposals : by Pam Denicolo& Lucinda Becker; Sage South Asia Edition , Success in Research Series.
- Patient Care Research: by G D Mogli, Jaypee Brothers Medical publishers (P) Ltd
- Research Methods for Business- A Skill Building Approach: by Uma Sekaranand Roger Bougie; 5th Ed, Willey India. Edition.

Pre PhD Course Work
Syllabus Biostatistics
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Unit 1. Basic concepts and descriptive statistics: (8 hours)

- Definition of statistics & biostatistics, population and sample, parameter and statistics; variables – different types, scales of measurement
- Types of data: qualitative and quantitative; tabulation of data - one-way and two-way tables, frequency table; visualisation of data – diagrams and graphs
- Measures of central tendency : Mean, median, mode; partition values – quartiles, percentiles
- Measures of variability: Range, inter-quartile range, standard deviation, mean deviation and coefficient of variation.
- Measures of skewness and kurtosis; Box plot and its application

Unit 2. Sampling techniques and Probability distributions (8 hours)

- Notion of a random variable, probability and probability distribution
- Normal probability distribution , properties of normal probability curve, applications of normality, divergence from normality, checking normality
- Sampling techniques: random sampling- simple random, stratified sampling , systematic sampling, cluster sampling; non random sampling, sample size determination

Unit 3. Testing of hypothesis (10 hours)

- Estimation of population parameters, standard error
- Principles of hypothesis testing: Null and alternate hypothesis, type-I and type - II error, power of the test, test statistic, p - value.
- Parametric tests: Z test, t-test, F-test: applications of these tests
- One way ANOVA , repeated measures ANOVA
- Non-Parametric tests : Chi-Square test, Mann- Whitney test, Wilcoxon Sign rank test, Kruskal - Wallis test.

Unit 4. **(6 hours)**

Correlation &Regression Techniques: Correlation : scatter diagram, types of correlation

- Karl Pearson's Product Moment Correlation Coefficient (r)
- Spearman's Rank-order Correlation Coefficient (rho)
- Linear regression analysis, introduction to logistic regression

Diagnostic tests & reliability tests

- Sensitivity, Specificity, Positive predictive value, Negative predictive value, False positive rate, False negative rate, Odds ratio
- Reliability & Validity, Measures of agreement: kappa statistics, intra-class correlation coefficient (ICC).

NOTE: Statistical software SPSS will be taught along with theory.

Reference Books:

1. Biostatistics: A Foundation for Analysis of Health Sciences- Wayne Daniel; John Wiley and Sons, Inc.; 2009.
2. Basic Statistics: A Primer for the Biomedical Sciences - Olive Jean Dunn & Virginia A. Clark, John Wiley & Sons, 2009
3. Medical Statistics: A Guide to Data Analysis and Critical Appraisal – Jennifer Peat and Belinda Barton, Blackwell publishing, BMJ Books, 2004
4. Introductory Biostatistics : Chap T.Le, Wiley Interscience,2003
5. Statistics at Square One - T. D. V. Swinscow and M.J. Campbell,10th Edition, BMJ Books, 2002
6. Fundamentals of Biostatistics – Bernard Rosner, 7th Edition, Brooks/Cole, 2010

Faculty of Pharmacy

PhD Program
Paper II

Curriculum/Syllabus

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Fax: 0824-2203943

PhD Program
Faculty of Pharmacy

Paper II

The Paper II in the PhD Program is subject specific. The syllabus for the subject is prepared by the Research Guide in consultation with doctoral advisory committee. Accordingly, each candidate shall have separate syllabus based on the research topic.

Candidate wise research topic and syllabus for Paper II is compiled and presented here on.

Vinitha Ramanath Pai, PhD
Deputy Director, MPhil and PhD Program
Yenepoya (Deemed to be University)

Dy.Director M.Phil & Ph. D Pr...
Yenepoya University
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Faculty of Pharmacy Paper II - Syllabus

Sl.No	Name & Reg. No of the Ph.D Scholars	Name of the Topic	Curriculum Page No.
2019-20			
1.	Mr. Abdul Rahamanulla 368/July 2019	Formulation and evaluation of Salacia reticulate Nanoparticle based tablets for the treatment of diabetes mellitus and obesity	11-13
2018-19			
2.	Ms. Sandhya V 357/Jan 2019	Development, Characterization and comparison of Transdermal formulation containing red sandalwood and wild Turmeric for the Treatment of Acne Vulgaris	14-16
3.	Ms. Arfa Nasrine 311 July 2018	Formulation and evaluation of in – situ gel containing silk fibroin and estrogen inhibitors for the targeted treatment of breast cancer	17-19
4.	Ms. Soumya 315 July 2018	Design and evaluation of in situ gels containing Anti - vegf drugs for ophthalmic delivery	
2017-18			
5.	Mr. Thriveni M. 303/Jan 2018	Formulation and study the effect of resveratrol phytosomes alone and in combination with piperine to treat myocardial infarction	20-22
6.	Ms. Sanjana A 273/July 2017	Development and characteristic evaluation of cubosomes containing tacrolimus and dexamethasone	23-24

2019-20

“Paper II- Curriculum/ Syllabus”

Name of the Research Guide: Dr. Mohammed Gulzar Ahmed
Name of the PhD Scholar: Mr. Abdul Rahamanulla

PAPER II -THERORETICAL FOUNDATION

Broad area of work: Formulation and evaluation of Salacia reticulate Nanoparticle based tablets for the treatment of diabetes mellitus and obesity

Total Hours: 65

Unit-I Absorption of Drugs:

1. Structure of cell membrane
2. Gastro-intestinal absorption of drugs, mechanisms of drug absorption,
3. Factors affecting drug absorption: Biological, Physiological, Physico-chemical and Pharmaceutical. Absorption of drugs from non-per oral routes,
4. Methods of determining absorption: *In-vitro, in-situ* and *in-vivo* methods. **9 Hrs**

Unit-II Formulation and processing factors:

1. Introduction: Dissolution, factors affecting dissolution rate.
2. Biopharmaceutical Classification System (BCS),
3. Noyes-Whitney's dissolutions rate law,
4. Study of various approaches to improve dissolution of poorly soluble drug Correlation of in vivo data with in vitro dissolution data.
5. Solubility: Experimental methods. Permeability: *In-vitro and In-vivo* methods.

9 Hrs

Unit- III Drug Product Performance, *In Vivo:*

1. Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability.
2. Methods for assessing bioavailability, bioequivalence studies.
3. Pharmacokinetics: Basic considerations, pharmacokinetic models. **9 Hrs**

Unit IV Product Stability:

1. Degradation kinetics.
2. Mechanisms.
3. Stability testing of drugs and pharmaceuticals.
4. Factors influencing-media effects and pH effects.
5. Accelerated stability studies.
6. Interpretation of kinetic data (API).
7. Solid state stability and shelf life assignment.

8. Stability protocols, reports and ICH guidelines. **11 Hrs**

Unit V Optimization techniques in Pharmaceutical Formulation:

1. Optimization: Concept and parameters of optimization,
2. Optimization techniques in pharmaceutical formulation and processing.
3. Statistical designs, Contour designs and Factorial designs.
4. Response surface method, and application in formulation **10 Hrs**

Unit VII Novel drug delivery system (NDS):

1. Introduction of NDS: Concept and models
2. Introduction: Basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation,
3. Classification of rate-controlled Drug delivery systems (DDS): rate programmed release, activation modulated & feedback regulated DDS advantages and disadvantages, applications. **11 Hrs**

Unit VII Carriers for Drug Delivery:

1. Polymers/ co-polymers : Introduction, classification, characterization,
2. Various Polymerization techniques
3. Application in Controlled release Drug Delivery System (CDDS) and Novel Drug Delivery Systems (NDDS).
4. Biodegradable, natural and synthetic polymers. **6 Hrs**

REFERENCE

1) Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2) Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi
3) Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
4) Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5) Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970

6) Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
7) Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
8) Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of rd Industrial Pharmacy, 3 ed., Varghese Publishers, Mumbai 1991.
9) Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5ed., B.I. Publications Pvt. Ltd, Noida, 2006.
10) Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
11) Modern Pharmaceutics; By Gillbert and S. Banker. Remington's Pharmaceutical Sciences.
12) Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
13) Physical Pharmacy; By Alfred martin
14) Bentley's Textbook of Pharmaceutics – by Rawlins.
15) Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
16) Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

2018-19

“Paper II- Curriculum/ Syllabus”

Paper II - Theoretical Foundation

Broad area of work: Development, characterization and comparison of transdermal formulation containing red sandalwood and wild turmeric for the treatment of acne vulgaris

Total Hours: 65

Unit 1: Study of consolidation parameters **(10 h)**

1. Introduction: Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters
2. Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot.

Unit 2: Drug Product Performance, *In Vivo* **(10 h)**

1. Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability.
2. Methods for assessing bioavailability, bioequivalence studies.
3. Pharmacokinetics: Basic considerations, pharmacokinetic models.

Unit 3: Product Stability **(12 h)**

1. Degradation kinetics.
2. Mechanisms.
3. Stability testing of drugs and pharmaceuticals.
4. Factors influencing-media effects and pH effects.
5. Accelerated stability studies.
6. Interpretation of kinetic data (API).
7. Solid state stability and shelf life assignment.
8. Stability protocols, reports and ICH guidelines.

Unit 4: Optimization techniques in Pharmaceutical Formulation **(12 h)**

1. Optimization: Concept and parameters of optimization,
2. Optimization techniques in pharmaceutical formulation and processing.
3. Statistical designs, Contour designs and Factorial designs.
4. Response surface method and application in formulation

Unit 5: Novel drug delivery system (NDS) **(11 h)**

1. Introduction of NDS : Concept and models
2. Introduction: Basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation,
3. Classification of rate controlled Drug delivery systems (DDS): rate programmed release, activation modulated & feedback regulated DDS advantages and disadvantages, applications.

Unit 6: Nano particulate Drug Delivery Systems **(10 hr)**

1. Introduction of various Nanoparticulates: microspheres, Niosomes, Liposomes, transfersomes, cubosome, pharmacosomes.
2. Design and formulation of Nanoparticles.
3. Evaluation parameters and Applications.

REFERENCE

1) Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 1991

2) Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi

3) Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985

4) Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

5) Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970

6) Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995

7) Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

8) Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of rd Industrial Pharmacy, 3 ed., Varghese Publishers, Mumbai 1991.

9) Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5ed., B.I. Publications Pvt. Ltd, Noida, 2006.

10) Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.

11) Modern Pharmaceutics; By Gillbert and S. Banker.Remington's Pharmaceutical Sciences.

12) Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A. H. Beckett.

13) Bentley's Textbook of Pharmaceutics – by Rawlins.

14) Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

15) Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

16) Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

17) Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.

03/08/24
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Yenepoya Pharmacy College & Research Centre
Deralakatte, Mangaluru-575018

Paper II - Theoretical Foundation

Broad area of the Study: Formulation and evaluation of in – situ gel containing silk fibroin and estrogen inhibitors for the targeted treatment of breast cancer

Unit-I Absorption of Drugs:

1. Structure of cell membrane
2. Gastro-intestinal absorption of drugs, mechanisms of drug absorption,
3. Factors affecting drug absorption: Biological, Physiological, Physico-chemical and Pharmaceutical. Absorption of drugs from non-per oral routes,
4. Methods of determining absorption: *In-vitro, in-situ* and *in-vivo* methods. **9 Hrs**

Unit-II Formulation and processing factors:

1. Introduction: Dissolution, factors affecting dissolution rate.
2. Biopharmaceutical Classification System (BCS),
3. Noyes-Whitney's dissolutions rate law,
4. Study of various approaches to improve dissolution of poorly soluble drug Correlation of in vivo data with in vitro dissolution data.
5. Solubility: Experimental methods. Permeability: *In-vitro, in-situ and In-vivo* methods.

9 Hrs

Unit- III Drug Product Performance, *In Vivo:*

1. Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability.
2. Methods for assessing bioavailability, bioequivalence studies.
3. Pharmacokinetics: Basic considerations, pharmacokinetic models. **9 Hrs**

Unit - IV Product Stability:

1. Degradation kinetics.
2. Mechanisms.
3. Stability testing of drugs and pharmaceuticals.
4. Factors influencing-media effects and pH effects.
5. Accelerated stability studies.
6. Interpretation of kinetic data (API).
7. Solid state stability and shelf life assignment.
8. Stability protocols, reports and ICH guidelines. **11 Hrs**

Unit - V Optimization techniques in Pharmaceutical Formulation:

1. Optimization: Concept and parameters of optimization,
2. Optimization techniques in pharmaceutical formulation and processing.
3. Statistical designs, Contour designs and Factorial designs.
4. Response surface method, and application in formulation **10 Hrs**

Unit -VI Novel drug delivery system (NDS):

1. Introduction of NDS: Concept and models
2. Introduction: Basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation,
3. Classification of rate-controlled Drug delivery systems (DDS): rate programmed release, activation modulated & feedback regulated DDS advantages and disadvantages, applications. **11 Hrs**

Unit -VII Carriers for Drug Delivery:

1. Polymers / co-polymers : Introduction, classification, characterization,
2. Various Polymerization techniques
3. Application in Controlled release Drug Delivery System (CDDS) and Novel Drug Delivery Systems (NDDS).
4. Biodegradable, natural and synthetic polymers. **6Hrs**

REFERENCE:

1) Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
2) Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
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4) Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath,Prism Book
5) Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekker Inc.,New York, 1982. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, LeaandFebiger, Philadelphia, 1970
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9) Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5ed., B.I. Publications Pvt. Ltd, Noida, 2006.
10) Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2 ed., CBS Publishers & distributors, New Delhi, 2005.
11) Modern Pharmaceutics; By Gillbert and S. Banker.Remington's Pharmaceutical Sciences.
12) Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
13) Physical Pharmacy; By Alfred martin
14) Bentley's Textbook of Pharmaceutics – by Rawlins.
15) Good manufacturing practices for Pharmaceuticals: A plan for total qualitycontrol, Second edition; By Sidney H. Willig.
16) Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

04/08/2014

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2017-18

“Paper II- Curriculum/ Syllabus”

Name of the Research Guide : Dr. Mohammed Gulzar Ahmed
Name of the PhD Scholar: Ms. Thriveni M

YENEPOYA (DEEMED TO BE UNIVERSITY)

Guide Name: Dr.Mohammed Gulzar Ahammed **Subject:** Pharmaceutical Science

Pre PhD Syllabus

Paper II

1. **Absorption from the Gastrointestinal Tract:**Gastrointestinal tract, Mechanism of drug absorption, Factors affecting, pH–partition theory. Formulation and physicochemicalfactors: Dissolution rate, Dissolution process, Noyes–Whitneyequation and drug dissolution, Factors affecting the dissolutionrate.**7 Hrs**
2. Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, and Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. **10 Hrs**
3. **Biopharmaceutical Considerations in Drug Product Design and *in Vitro* Drug Product Performance**; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Similarity factors – f2 and f1, Higuchi and Peppas plot. **8 Hrs**
4. **Drug Product Performance, In Vivo:** Bioavailability andBioequivalence: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, cytochrome p450-based drug interactions. **15 Hrs**
5. **Product Stability:** Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. **10 Hrs**
6. **Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and

processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation **15Hrs**

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1) Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger, 1991
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6) Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995
7) Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, MackPublishingCompany, Pennsylvania 1989
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08/08/2024

Principal / Dean
Yenepoya Pharmacy College & Research Centre
Deralakatte, Mangaluru-575018

Gulzar Sir

Name of the Research Guide : Dr. Mohammed Gulzar Ahmed
Name of the PhD Scholar: Ms. Sanjana A

YENEPOYA UNIVERSITY

Name: Sanjana. A **Registration No:** 273/july/2017

Subject: Pharmaceutical Sciences **Faculty:** Faculty of Pharmacy

Pre-PhD Syllabus July 2017 Batch
Paper II

1. Validation: Introduction to Pharmaceutical Validation, Scope &merits of Validation, Validation and calibration of Master plan,ICH & WHO guidelines for calibration and validation of equipment's, Validation of specific dosage form, Types ofvalidation. Government regulation, Manufacturing Process Model,URS, DQ, IQ, OQ & P.Q. of facilities. — 10 Hrs
2. Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot. — 10 Hrs
3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modelling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartments - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems. — 10 Hrs
4. Computers in Pharmaceutical Formulation Research and Development: A General Overview: History, Ethics of Computers in Pharmaceutical Research and Development. Concept of optimization, Optimization parameters, Optimization technology & Screening design. Factorial design for product and process development and their application. Drug carriers Legal Protection of Innovative Uses of Computers in R&D, Computers in Market analysis. — 12 Hrs
5. Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Statistical design, Response surface method, Contour designs.Introduction to Quality-by-Design, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application — 12 Hrs
6. Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines. — 12 Hrs

30/7/17

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
6. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
7. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
8. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
9. Modern Pharmaceutics; By Gillbert and S. Banker.
10. Remington's Pharmaceutical Sciences.
11. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
12. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985
13. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc.,New York, 1982
14. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing,2009.
15. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
16. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
17. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.
18. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
19. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
20. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
21. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.

03/08/2024

Principal / Dean
Yenepoya Pharmacy College & Research Centre
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Pre-PhD coursework

SCHEME OF PH.D. COURSE WORK, EXAMINATION, EVALUATION AND DECLARATION OF RESULTS (CLAUSE NO. 07)

1. The scheme for PhD Course Work Examination to be conducted by the University shall be as follows:
   a) Three written papers (I, II and III) each of three hours duration and each carrying maximum of 100 marks and
   b) Paper IV involving review of Literature and Planning and presentation of the synopsis of the Proposed Research Work with a Tentative Title (200 marks)

Papers	Particulars	No. of Credits	Marks
Paper 1	Research Methodology and Biostatistics	4	100
Paper 2	Theoretical Foundations	4	100
Paper 3	Recent Developments	4	100
Paper 4	Reviewing of Literature and Planning of the Proposed Research Work with a Tentative Title	4	200
	Total	16	500

Ph.D. Course Work Examination

The scheme of marks

Papers	Particulars	No. of Credits	Maximum marks		
			Theory*	Internal assessment	Total
Paper 1	Research Methodology and Biostatistics	4	70	30	100
Paper 2	Theoretical Foundations	4	70	30	100
Paper 3	Recent Developments	4	70	30	100
Paper 4	Reviewing of Literature and Planning of the Proposed Research Work with a Tentative Title	4	-	-	200
	Total	16	-	-	500

**Theory conducted out of 100 marks and brought down to 70*

Paper I Internal assessment calculation

Total marks : 30

Activity	No conducted	Maximum marks /each	Brought down
1. Internal assessment examination	Two	60	20
2. Journal club	Two	50	10
3. Class tests / Class activity	Nine	30	
4. Assignments	Ten	10	
5. Presentation of an E-Poster	One	50	
6. Review article (review of literature)	One	100	

7. Review of "Research proposal for funding agency"	Once	100	
8. Presentation of the review of literature	Once	10	

Ph.D. Course Work Examination

Ph.D. Course Work Examination will be conducted at the end of the course work as follows

Dates of the Pre-Ph.D. examination shall be notified by the Controller of Examinations

PAPERS FOR THE EXAMINATION :

Paper I Research Methodology & Biostatistics duration : 3 hrs Marks 100

Paper II Theoretical Foundations duration : 3 hrs Marks 100

Paper III Recent Developments duration : 3 hrs Marks 100

Paper IV Synopsis preparation and presentation Marks 200

PATTERN OF QUESTION PAPER I :

Paper I Research Methodology (60 marks)

MCQ 15 No.'s X 1 mark

Short essay : 5 No.'s X 5 marks

Long Essay : 2 No.'s X 10 marks

Biostatistics (40 marks)

MCQ : 10 No.'s × 1 mark

Short essay : 4 No.'s × 5 marks

Long Essay : 1 No.'s × 10 marks

Panel of Examiners for Paper I :

Internal Examiner (1) Appointed from Yenepoya (Deemed to be University)

External Examiner (1) Appointed from other Universities

PAPER II:

P**attern of Paper II & III** : Subject related to the field of research (100 marks)

Long Essays : 5 No.'s × 20 marks

Classification of Successful Candidates:

The results of successful candidates at the end of the course work shall be classified on the basis of the Grade Point Average (GPA) obtained in all the papers. The Grade Point (GP) in a paper and the Grade Point Average (GPA) at the end of the course work shall be computed as follows:

The grade points (GP) in a paper shall be assigned on the basis of actual marks scored in that course as per the table below:

% Marks	Less than 55	55	56<60	61<65	66<70	71<75	76<80	81<85	86<90	91<95	96<100
Grade Points	Fails	5.5	6	6.5	7	7.5	8	8.5	9	9.5	10

The Grade Point Weights (GPW) shall then be calculated as the product of the grade points earned in the paper and the credits for the paper. The total GPW for a course is obtained by adding the GPW of all the papers.

The GPA shall then be computed by dividing the total GPW of all the papers of study by the total credits for the course.

A Ph.D. scholar has to obtain a minimum of 55% of marks or its equivalent GPA of 5.5, in the UGC 7 - point scale in the course work in order to be eligible to continue in the programme and submit the dissertation/thesis.

In case the candidate is not successful in the Ph.D. Course Work Examination in the first attempt, he/she may be given one more chance to appear for the paper in which the candidate has failed anytime when the next the examination is scheduled on payment of the requisite fees of Rs. 500/-. If the candidate is not successful in the PhD Course Work Examination, even in the second appearance, his/her provisional registration shall stand cancelled. Registration of the candidate will be confirmed only after they pass the Ph.D. Course Work Examination.