UTTARANCHAL UNIVERSITY

# UTTARANCHALUNIVERSITY

**ArcadiaGrant, P.O.Chandanwari, Premnagar, Dehradun,**
**Uttarakhand-248007, INDIA**

## Detailed Course Structure &Syllabus
## of
## Pre-PhD Course Work in Pharmaceutical Sciences

Course Structure & Syllabus

# Pre-PhD Course Workin Pharmaceutical Sciences

## Batch 2022 Onwards

## Course Structure & Syllabus

# Pre-PhD Course Workin Pharmaceutical Sciences

The Course Work shall consist of five subjects of total 13(4+2+2+3+2) Credit with the following scheme pattern

**Scheme of Pre-Ph.D. Course Work**
**Discipline: Pharmaceutical Sciences**

| Course Code | Subject | Credit points | Evaluation Scheme | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Period | | | Sessional | | | Examination | |
| | | | L | T | P | CT-I | CT-II | Total | ESE | Sub Total |
| **RM-101T** | **Research Methodology** | **4** | **4** | **0** | **0** | **20** | **20** | **40** | **60** | **100** |
| RM-102 | Computer & Stats Application in Research | 2 | 2 | 0 | 0 | 20 | 20 | 40 | 60 | 100 |
| RPE-103 | Research & Publication Ethics | 2 | 2 | 0 | 0 | 20 | 20 | 40 | 60 | 100 |
| DS-104 PS<br>DS-104 PS | Discipline Specific Electives*<br>Core Theory (Any One)<br>PHARMACEUTICAL SCIENCES PAPER I<br>PHARMACEUTICAL SCIENCES PAPER II | 3 | 3 | 0 | 0 | 20 | 20 | 40 | 60 | 100 |
| RS-105 | Seminar Presentation | 2 | 0 | 0 | 4 | 20 | 20 | 40 | 60 | 100 |
| | **Total** | **13** | **11** | **0** | **4** | **100** | **100** | **200** | **300** | **500** |

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| Programme Name | **Pre-Ph.D. Course Work** | Programme Code | 23- |
|---|---|---|---|
| Course Code | RM-101 | Credit | 4 |
| Year/Sem | 1/1 | L-T-P | 4-0-0 |
| Course Name | Research Methodology | | |

**Objectives of the Course:**

1. To Equip the Students with the Concept and Methodology of Research.
2. To provide knowledge about type of research, preparation of reports and thesis, designing of Research using Scientific Methods.

**UNIT I (**Total Topics- 7 and Hrs-12)

Introduction to Research: Definition, Nature and significance, Role and Objectives; Types of Research: exploratory, descriptive, experimental and diagnostic research, social and legal research and traditional, analytical, empirical & fundamental research, Doctrinal and non-doctrinal research methods; Various Research Designs; Scientific Research Process: Overview, Problem identification and formulation of research statement.

**UNIT II(**Total Topics- 7 and Hrs- 12)

Data Collection: sources, primary and secondary methods, significance of Primary and Secondary Data, questionnaire Vs. schedules; Data Processing: Editing, Coding Organization and Presentation; Attitude Measurement and scaling: Measurement Scales, Sources of Errors in Measurement, Techniques of Developing Measurement Tools, Classification and Testing (Reliability, Verification and Validity) Scales, Designing Questionnaires and Interviews.

**UNIT- III (**Total Topics- 5 and Hrs- 10)

Sampling, Sampling Methods, Sampling Plans, Sampling Error, Sampling Distributions: Theory and Design of Sample Survey, Census Vs Sample Enumerations, Objectives and Principles of Sampling, Types of Sampling, Sampling and Non-Sampling Errors, Concept of Permutation, Combination & Probability for research analysis.

**UNIT-IV(**Total Topics- 5 and Hrs- 10)

Interpretations and Report Writing: Meaning of Interpretation, Techniques of Interpretation, Precautions in Interpretation, Significance of Report Writing, Steps in Report Writing, Layout of Report and Precautions in Writing Research Reports. Limitations of RM: Ethics in Research, Philosophical Issues in Research.

**CO1.** Acquire in-depth knowledge of various fundamentals, theories and principles related to the research and apply the acquired knowledge in carrying out research studies in the area of interest.

**CO2.** Identify, formulate and critically investigate research problems by applying research-oriented knowledge and analyze relevant data to reach certain conclusions in the form of alternative solutions to these problems.

**CO3.** Apply the acquired knowledge and skills to develop minds to think out of the box while carrying out research operations to conclude something.

**CO4.** Apply parametric and non-parametric statistical tests to verify the developed hypothesis to suggest innovative solutions to the problem being investigated.

**Reference Books**


1. William G. Zikmund, "Business Research Methods", Orlando: Dryden Press.
2. C. William Emory and Cooper R. Donald, "Business Research Methods", Boston, Irwin.
3. Fred N Kerlinger, "Foundations of Behavioural Research", New Delhi: Surjeet Publications.
4. Naresh Malhotra, Marketing Research: An Applied Orientation, Pearson publication David Nachmias and ChavaNachmias, "Research Methods in the Social Sciences", New York: St.Marlia's Press.
5. Bhattacharya, D. K. (2004) Research Methodology, New Delhi, Excel Books.

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| | | | |
|---|---|---|---|
| Programme Name | **Pre-Ph.D. Course Work** | Programme Code | 23- |
| Course Code | RM-102 | Credit | 2 |
| Year/Sem | 1/1 | L-T-P | 2-0-0 |
| Course Name | Computer & Stats Application in Research | | |
| **Objectives of the Course:** | | | |

1. To appraise computational skills for research application.
2. To assess statistical method for research analysis.

**UNIT I**

Characteristics of Computers, Evolution of computers, computer memory, computer generations, Basic computer organization; System software, Application software, introduction to operating system, single user, multi-user, multi-tasking single tasking, application of computer for business and research, MS-windows, Linux .Application of Internet in research : INFLIBNET, Use of Internet, sights (DOAJ), Use of E Journals, Use of E library, use of EBSCO HOST online database of Academic Libraries. Subject/field specific tools on www.freeware.com

**UNIT II**

Computer Application in Research,. Basic concept of Computer, Use of Internet for Research Purpose: E-mail, WWW, Web browsing, technical skills, drawing inferences from data, Research publishing tools-MS Word, Adobe acrobat, Graphics tool-MS Excel, Presentation tool-MS Power, Data Analysis Software and Analysis Techniques point. Creating presentation and adding effects, Introduction to Data analysis software-SPSS: Definition, objectives and features, data analysis using SPSS.

**UNIT- III**

Statistical methods for research application in analysis of data,Measurement in Research , data interpretation, Measures of Central Tendency, Measures of Dispersion, Measures of Asymmetry (Skewness), std deviation, Measures of Relationship, Simple Regression Analysis, Correlation and Regression, Partial Correlation.

**UNIT-IV**

Statistical Tools-Hypothesis and Hypothesis Testing: Parametric & Non-Parametric Tests, Important Parametric Tests ,Hypothesis Testing of Correlation Coefficients ,U Test, Chi Square Test, ,T-Test.Analysis of Variance (ANOVA) , The Basic Principle of ANOVA ,ANOVA Technique, Setting up Analysis of Variance Table, Short-cut Method for One-way ANOVA, Coding Method, Two-way ANOVA .

**Course Outcomes:**

**CO1.** Acquire knowledge of concept of computer with application in Research.
**CO2.** Apply acquired knowledge of computer for presentation skills.
**CO3.** Acquire knowledge of statistical methods for Research.
**CO4.** Apply acquired knowledge to describe the inductive nature of quantitative data analysis.

**Reference Books**

1. C. R. Kothari, "Research Methodology: Methods and techniques", New Delhi: Vishwa Prakashan.
2. Brymann, Alan and Carmer, D. (1995) Qualitative data analysis for social scientist, New York, Routledge Publication.
3.Jain, Satish: "Introduction to Computer Science and basic Programming." BPB Publications, New Delhi, 1990. • Rajaraman, V., "Fundamental of Computers", Prentice Hall of India, New Delhi, 1996.

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|---|---|---|---|
| Programme Name | **Pre-Ph.D. Course Work** | Programme Code | 23- |
| Course Code | RM-103 | Credit | 2 |
| Year/Sem | 1/1 | L-T-P | 2-0-0 |
| Course Name | Research& Publication Ethics | | |

**Objectives of the Course:**

1. 1. Its objectives to provide knowledge about ethics and code of research publication with concept of plagiarism.

**UNIT I (**Total Topics- 2 and Hrs-8)

1. Introduction to philosophy: definition, nature and scope, concept, branches
2. Ethics: definition, moral philosophy, nature of moral judgments and reactions

**UNIT II(**Total Topics- 5 and Hrs- 5)

1. Ethics with respect to science and research
2. Intellectual honesty and research integrity
3. Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP)
4. Redundant publications: duplicate and overlapping publications, salami slicing
5. Selective reporting and misrepresentation of data

**UNIT- III**

1. Publication ethics: definition, introduction and importance
2. Best practices/ standards setting initiatives and guidelines: COPE, WAME,etc.
3. Conflicts of interest
4. Publication misconduct: definition, concept, problems that lead to unethical behaviour and vice versa, types
5. Violation of publication ethics, authorship and contributorship
6. Identification of publication misconduct, complaints and appeals
7. Predatory publishers and journals

**UNIT-IV (**Total Topics-4and Hrs-4)

**Practice Open Access Publishing**

1. Open access publications and initiatives
2. SHERPA/RoMEO online resource to check publisher copyright & self-archiving policies
3. Software tool to identify predatory publications developed by SPPU
4. Journal finder/ Journal suggestion tools viz. JANE, Elsevier Journal finder, Springer Journal Suggester, etc.

**Course Outcomes:**

**CO1**. Recognize the basics of philosophy of science & ethics, research integrity, publication ethics and theories of research ethics.

**CO2**. Familiarize with important issues in research ethics, research integrity, scientific misconduct and misinterpretation of data.

**CO.3** Analyze the best practices for publications, publication ethics and identify the predatory publishers & journals.

**CO4**. Demonstrate &use plagiarism software tools, open-source software tools, citation databases and research metrics.

**CO5**. Publish credible & scholarly publications in reputed peer-reviewed journals.

**Reference Books**

1. **References-**

Research and Publication Ethics, Dr Sumanta Dutta, Bharti Publications,2021
Research and Publication Ethics, Dr Santosh kumar Yadav, Anne Publications,2020

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|---|---|---|---|
| Programme Name | Pre-Ph.D Course Work | Programme Code | 23 |
| Course Code | DS-104 PS | Credit | 3 |
| Year/Sem | 1/1 | L-T-P | 3- 0- 0 |
| Course Name | PHARMACEUTICAL SCIENCES PAPER I | | |
| **Objectives of the Course:**<br>After completion of course student is able to know,<br>•the stage of development during which the physicochemical properties of the drug substance. | | | |

•provides the foundation for development of a robust dosage form.

**UNIT-I**

**a. Pre-formulation Studies:** Introduction, pre-formulation testing criteria, regulatory requirements, testing systems, solid-state characterization, transport across biological membranes

**b. Optimization:** Introduction to statistical methods and factorial design, quality by design

**Pharmaceutical Process Validation**: Basic concept, regulatory basis of validation , benefits of validation, types of process validation related to prospective retrospective and concurrent process validation , revalidation of validation process and scale-up and post approval changes (SUPAC), analytical Validation

**UNIT II**

Definition, need for patenting, types of patents, conditions to be satisfied by an invention to be patentable, introduction to patent search.

Parts of patents, filling of patents, the essential elements of patent, guidelines for preparation of laboratory note book, non-obviousness in patent

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

Brief introduction to trademark protection and WHO Patents, IPR's and its types, major bodies regulating Indian pharmaceutical sector

**UNIT- III**

**Polymer:** Polymer classification, physiochemical properties and polymer solutions, biodegradable and non-biodegradable polymers, application of polymers in controlled release of drugs, transport of small molecules in polymers, ionic polymers as drug carriers, polymer drug interactions

**Stereochemistry:** Optical isomerisim: chirality and molecular symmetry; stereochemical designation of chiral centre(s) (R& S); chiral axis; resolution of racemic mixture-techniques including chiral chromatography, geometric Isomerisim: cis, trans; E, Z ,conformational analysis: boat-chair conformations; staggered, gauche, eclipsed conformations

**UNIT-IV**

**Natural Products:** Drugs of natural origin: from plants, micro-organisms, animal source, marine products, biosynthesis of natural products, approaches of structure elucidation: degradation and synthetic approaches; spectral analysis (UV, IR, NMR, Mass), hyphenated techniques: GC-MS, LC-MS, chemical modifications of natural products; opiod analgesics, antineoplastic agents, anti-malarials

Techniques of Quantitative Estimation of Drugs for Determination of Purity

**UNIT-V**

**Molecular Aspects of Drug Action:** Receptor occupancy, types of drug targets, main families of receptors and ion channels, signal transduction mechanisms coupling receptors to cellular function

**In-vitro Experimentation Techniques:** Animal cell lines and their uses, radioligand binding assay, patch clamp, ELISA

**Molecular Techniques**: PCR, blotting, immunostaining, cloning, RIA


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**References: Books must be available in the Library / Central Library**


1. Ernest EI and Samuel H. Stereochemistry of Organic Compounds. John Wiley and Sons, New York.
2. Lehr RE and Marchand AP. Orbital Symmetry: A Problem Solving Approach. Academic Press, New York.
3. March J. Advanced Organic Chemistry: Reactions, Mechanisms and Structures. John Wiley and Sons, New York.
4. Lehr RE and Marchand AP. Orbital Symmetry: A problem solving approach. Academic Press, New York.

5. Mitscher LA and Baker WR. Wiley and Sons 6. A Search for Novel Chemotherapy Against Tuberculosis Amongst Natural Products. Pure and Applied Chemistry (1998), Vol. 70, No.2, pp 365-371.
6. Wermuth CG. The Practice of Medicinal Chemistry. Academic Press, Jordon Hill, Oxford.

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|---|---|---|---|
| Programme Name | Pre-Ph.D Course Work | Programme Code | 23 |
| Course Code | DS-104 PS | Credit | 3 |
| Year/Sem | 1/1 | L-T-P | 3 - 0 - 0 |
| Course Name | PHARMACEUTICAL SCIENCES PAPER II | | |

**Objectives of the Course:**
Upon completion of the course the student shall be able to
1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship (SAR) of different class of drugs

4. Observe the effect of drugs on animals by simulated experiments

**UNIT-I**

Central Drug Standard Control Organisation (CDSCO) : Functions and responsibilities Investigational New Drug : Need of an IND, Content and Format of an IND application, Submission of an IND, FDA review of IND. The New Drug Application: Overview, Law regulations and Guidance, new drug development and approval, NDA development preclinical investigation, new drug application (phase I, phase II, phase IV and post marketing surveillance), contents of the NDA (chemistry, manufacturing, testing, packaging, labelling, controls, preclinical, clinical data), Human Pharmaco-kinetic and bioavailability testing requirements, Common technical document (CTD) for NDA, Submission, review and maintenance of NDA.

**UNIT II**

Oral Controlled drug delivery systems: Design and fabrication of diffusion controlled, dissolution controlled, osmotic, gastro-retentive delivery systems, biodegrable polymeric delivery systems. Controlled drug delivery polymers, roles of polymers in drug delivery, pharmacokinetic/ pharmacodynamic basis of oral controlled drug delivery.

**UNIT- III**

**Drug Design:** Analogue synthesis versus rational drug design, discovery of lead compounds, pharmacophore identification, structure modifications of lead compound (prototype), physicochemical alterations, pro-drug approach, quantitative structure activity relationship, computer aided drug design, molecular modelling, combinatorial chemistry and high throughput screening, biochemical and physiological approaches.

**Lead compound**: Search & Optimization: Search of lead compound from natural products and other sources, selection of test compounds. Methods of lead optimization – synthesis of analogs, variation of substituents, extension of structure, ring versus chain structures, bioisosterism, ring contraction and expansion. Hansch analysis, Free-Wilson analysis, Craig plot, Topliss scheme, CoMFA analysis.

**UNIT-IV**

**Natural Products:** Drugs of natural origin: from plants, micro-organisms, animal source, marine products, biosynthesis of natural products, approaches of structure elucidation: degradation and synthetic approaches; spectral analysis (UV, IR, NMR, Mass), hyphenated techniques: GC-MS, LC-MS, chemical modifications of natural products; opiod analgesics, antineoplastic agents, anti-malarials

**Extraction:** Different techniques adopted for the extraction of phytoconstituents like Maceration, percolation, sonication, soxhlet assisted extraction, and ultrasound assisted extraction, super critical carbon dioxide extraction and Microwave assisted extraction.

**UNIT-V**

Molecular Aspects of Drug Action: Receptor occupancy, types of drug targets, main families of receptors and ion channels, signal transduction mechanisms coupling receptors to cellular function

Common animal models for selected categories of drugs: anti-hypertensive, anti-inflammatory, anti-diabetic, anti-ulcer.

**Antioxidants:** Reactive oxygen intermediates , antioxidants and their therapeutic implications

**Toxicity Studies** :Acute, sub-acute, sub-chronic, chronic toxicity


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1. J.R. Robinson & V.H.L. Lee (Eds), Controlled Drug Delivery, Fundament and applications, Vol. 29&Vol. 31, Marcel Dekker, N.Y.
2. Y.W. Chien (Ed.), Transdermal Controlled Systemic Medications, Marcel Dekker, N.Y.
3. N.K. Jain, Controlled and novel drug delivery, CBs, New Delhi. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
4. N.K. Jain, Advances in Controlled and novel drug delivery, CBS, New Delhi.
5. J.I. Wells, Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester (UK)
6. S.P.Vyas and R.K.Khar, Controlled Drug Delivery, concept and advances

7. J.G. Wagner, Pharmacokinetics for the Pharmaceutical Scientist.
8. L. Shargel, and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT.
9. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, N.Y.

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|---|---|---|---|
| Programme Name | **Pre-Ph.D. Course Work** | Programme Code | 23- |
| Course Code | RS- 105 | Credit | 2 |
| Year/Sem | 1/1 | L-T-P | 0-0-4 |
| Course Name | Seminar Presentation | | |

**Objectives of the Course:**
Main objective of this course is to develop presentation skills in the scholars and knowledge about review of literature so that they can review properly for utilisation in their research work.

**Seminar** Presentation-Candidate/Research Scholarhas togo through the review of literature in the

concerned field of research. Review of literature guidelines will be given by the concerned faculty/Dean of Department/School/College. Research Scholar has to prepare presentation on review of literature in the concerned field/ topic assigned by the department (DRC) periodically during course work. There will be minimum 3 presentations of review of literature during pre-Ph.D. course work.

- First presentation will be required in DRC/FRC for review of literature with concerned Department focus on area of research. It will be evaluated and assessment sheet will be sent from Department to Dean Research & Studies office.
- Similarly second presentation will be required by research scholar with extension of first presentation and more number of references would be added.

Internal & end term examination marks will be as per scheme. Each presentation is to be assessed by the department as per instructions from Dean-Research & Studies.

Final presentation would be required at the time of end term/sem. examination on proposed synopsis. General guidelines would be issued by Dean-Research for seminar presentation.

**Course outcomes**

**CO1.** Research Scholar would be able to develop & explore the review of literature in concerned area.

**CO2.** Analyze review of literature critically for finding the research gap.

**CO3.** Apply acquired knowledge in making systematic seminar presentations.

**CO4.** Apply acquired knowledge for improving development of all-round research.