DEPARTMENT OF PHARMACEUTICAL SCIENCES
MAHARSHI DAYANAND UNIVERSITY, ROHTAK

PH. D. COURSE WORK IN PHARMACEUTICAL SCIENCES

PROGRAM SPECIFIC OUTCOMES

PSO1 Develop the deep methodological skill and an understanding of contemporary research in their respective area of emphasis, and be able to implement innovative research practices under guidance of their faculty advisor and in concert with their research team.

PSO2 Apply contemporary research in their respective area of emphasis to industry contexts and be able to engage in innovative practices informed by such research pertinent to pharmaceutical sciences and their area of emphasis in diverse contexts.

PSO3 Provide teaching assistance to Pharm.D. students, master's students and fellow Ph.D. students who are less advanced than they are in their respective doctoral programs.

PSO4 Launch an independent research agenda in their respective area of emphasis under the guidance of their faculty advisor.

PSO5 Complete and orally defend an acceptable dissertation based on original investigation and supervised by their dissertation committee showing mastery of an area of emphasis within pharmaceutical sciences, capacity for independent research, and a scholarly result.

SCHEME OF EXAMINATIONS

Teaching Load

Paper Code	Nomenclature	Load
17PHARMPC1	Paper I -- Research Methodology	6 hrs / wk
17PHARMPC2	Paper – II (Communication Skills and Computer Applications)	6 hrs / wk
17PHARMPC3	Paper – III (Pharmaceutical sciences)	6 hrs / wk
17PHARMPC4	Practical	6 hrs/week
	Total	**24 hrs / wk**

Total = 24 hours / week

Distribution of Marks :

Paper Code	Nomenclature	Marks
17PHARMPC1	Paper I -- Research Methodology	100
17PHARMPC2	Paper – II (Communication Skills and Computer Applications)	100
17PHARMPC3	Paper – III (Pharmaceutical sciences)	100
17PHARMPC4	Practical	100
	Total	**400**

Total = 400 marks

Note:

1. **In Paper I, II and III (Theory), there shall be 20 marks for Internal Assessment and 80 marks Main Theory Examination.**
2. Internal Assessment of 20 marks shall comprise of 10 marks for 01 assignment and 10 marks for 01 presentation, to be evaluated by the concerned subject teacher.
3. **For Practicals (common for Paper I, II & III), there shall be 01 presentation (by each candidate), of 100 marks, in the Main Practical Examination.** A committee comprising of Dean of Faculty, HOD, and concerned subject teacher shall evaluate the presentation in the Main Examination.
4. A candidate shall be declared pass if he/she obtains 50 % marks individually in each subject (theory & practical separately) and 50 % marks in aggregate.

SYLLABUS FOR PH.D COURSE WORK IN PHARMACEUTICAL SCIENCES

Paper I -- Research Methodology

Course outcomes

After completion of the course, student is able to

CO1 Understand the principles of statistics
CO2 Interpret the raw data by using statistics
CO3 Understand the applications of the different research design.

Theory : (6 hrs / week) (Max. marks = 80; Duration of examination = 03 hours)

1. Meaning, objectives and types of research. Research approaches
2. Research Methods – Library, Field and Laboratory methods.
3. Research Methodology and steps involved in a research process – formulating the research problem, extensive literature survey, developing the hypothesis, preparing the research design, determining sample design, collecting the data, execution of the project, analysis of data, hypothesis testing, generalizations and interpretation, and preparation of the report or presentation of the results.
4. Statistics: Introduction, its rule and usages; Collection, organization, graphics and pictorial representation of data, measures of central tendencies and dispersion, coefficient of variation. Probability: Basic concept; Common probability distribution related to normal distribution.
5. Sampling: Simple random and other sampling procedure. Distribution of sample mean and proportion. Estimation and Hypothesis testing: Point and interval estimation including fiducial limits. Concept of hypothesis testing and type of errors. Student –t and chi square tests. Sample size and power.
6. Correlation and regression: Graphical presentation of two continuous variables; Person's product moment correlation coefficient, its statistical significance. Multiple and partial correlation. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model.
7. Optimization techniques in experimentation.

Paper-II Communication Skills and Computer Applications

Course outcomes

After completion of the course, student is able to

CO1 Understand the different types of scientific communications
CO2 Importance of the publication in the research
CO3 Understand the process involved in the publication

Theory : (6 hrs / wk) (Max. marks = 80; Duration of examination = 03 hours)

1. Basics of Communication skill.
2. Types of Scientific Communication.
3. Importance of publishing research paper.
4. Presenting and Publishing paper:
    a. Preliminaries, format, choosing Journal
    b. Title, Running Title
    c. Author : Single and Multi authorship
    d. Writing Abstract
    e. Selecting Keywords
    f. Introduction section
    g. Materials and Methods selection
    h. Result section
    i. Figures: Design Principles, Legends, table components, Graphs: Types, Style, Table v/sGraphs
    j. Discussion Section : Format, Grammar Style, Content
    k. Acknowledgements
    l. References : Different Styles
    m. Communication with the Editor, Handling Referees' Comments, Gallery Proofs
6. Writing Review Articles
7. Preparing Posters for Scientific Presentation
8. Preparing and Delivering of Oral Presentation
9. Writing Practical Reports
10. Avoiding Plagiarism
11. Research Grant Funding Agencies, Preparing for application to grant Providing agencies
12. Patent drafting and submission
13. Preparing documents for Technology Transfers, MoUs, confidentially Agreements
14. Detailed study of MS Word, MS Powerpoint, and MS Excel. Concepts of Internet and Primary search engines in research.

Reference Books:

1) Study and Communication Skills for the Biosciences by *Stuart Johnson and Jon Scott, Oxford* University Press
2) Write and Publish a Scientific Paper by *Robert A. Day* Oryx Press
3) Scientific Easy when you know how by *Jennifer Peat* BMJ Books
4) Research Projects and Research Proposals A Guide for Scientists Seeking Funding by *Paul G. Chapin* University Press

Paper-III (Pharmaceutical sciences)

Course outcomes

After completion of the course, student is able to

CO1 Understand the discovery and development of the new drug
CO2 Understand the different types of the drug delivery system.
CO3 Understand the use of the different animal models in the area of drug development.

Theory : (6 hrs / wk) (Max. marks = 80; Duration of examination = 03 hours)

1. **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.
2. **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.
3. **Drug Design:** Approaches to drug design, method of variation, 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.
4. **Extraction:** Different techniques adopted for the extraction of phytoconstituents like Maceration, percolation, sonication, soxhlet assisted extraction, ultrasound assisted extraction, super critical carbon dioxide extraction and Microwave assisted extraction.
5. Common animal models for selected categories of drugs: anti-hypertensive, anti-inflammatory, anti-diabetic, anti-ulcer, anti-oxidants.

<u>Practicals</u> : (6 hrs / wk) (Max. marks = 100)

Course outcomes

After completion of the course, student is able to

CO1 Understand the different types of regulatory guidelines used in the new drug approval process
CO2 Understand the basic applications of the statistical analysis
CO3 Understand the use of the animal models.

Practicals

The students shall be assigned a number of practical exercises / small projects / presentations on the theory topics as presented above.