

B.P.S. MAHILA VISHWAVIDYALAYA, KHANPUR KALAN

DEPARTMENT OF PHARMACEUTICAL EDUCATION & RESEARCH

**Course Curriculum & Scheme of Examination of Pre- Ph.D. course work in
Pharmaceutical Sciences
(W.E.F 2014-15)**

S. No.	Code	Paper Title	Hours per Week			Total Credits	Max Marks		
			L	T	P		Internal Marks	External Marks	Total Marks
Theory Papers :									
1	PPPL-101	Paper-I(Research Methodology)	3	2	---	4	50	50	100
2	PPPL-103	Paper II (Advances in Pharmaceutical Sciences).	3	2	--	4	50	50	100
Practical/Lab Papers:									
3	PPPP-105	Independent Study*	--	2	6	4	100	----	100
4	PPPP-107	Scientific Communication*		2	6	4	100	---	100
Total Contact Hours/Credits/ Max. Marks			6	8	12	16	300	100	400
			26						

Note: 1. Students must pass separately in internal and external examination (pass percentage 50% separately & 50 % in aggregate).

2.* Assessment/ evaluation of the candidate will be carried out by internal board of examiners comprising of Dean of Faculty, HOD, and concerned subject teacher on the basis of literature review, proposal, presentation and viva voce.

3. Students will be allowed to use scientific calculator only but sharing of the same will not be permitted in the exam.

4. The duration of theory exam will be of 03 hrs.

Paper Code: PPPL-101 Paper I -- Research Methodology

**L -- T -- P
3 - 2 - 0**

**Total Credits: 04
Total Marks: 100**

**External Marks: 50
Internal Marks: 50**

Duration of Exam: 03 hrs

Paper Objectives:

Objective of this subject is to understand the various research methods to pursue the research.

Unit 1

Objectives of research, Types and significance of research, research and scientific methods, research approaches. Importance of knowing how research is done – Research Process – Criteria of good Research.

Necessity of defining the problem, technique involved in defining the Problem.

Research Design: Need for research design, features of a good design, important concepts relating to research design, different research design.

Significance of report writing, different steps in writing report, layout of the research report, precautions for writing research reports.

Unit 2

Sample Design: Objective and principal of experimental design. Experimental design terminology. Completely randomized design. Complex random sampling design.

Blocking design: Latin square design, two and three level of factorial design

Measurement and scaling Techniques: measurement in research, measurement scales and source of errors, tests of second measurement, technique of developing measurement tools, important scaling and scale construction techniques.

Data collection: collection of primary and secondary data through various techniques, selection of appropriate method for data collection, case study method, guideline for developing questionnaire, successful interviewing. Survey V/S experiment.

Unit 3

Processing and analysis of Data, Statistics in Research, measures of central tendency, dispersion, Standard deviation, skewness and kurtosis.

Sampling Fundamentals: Definition, Need, Important sampling distribution, central limit theorem, sampling theories, concept of standard error, estimation, estimation population mean, proportion, sample size and its determination.

Tests of hypothesis and significance: basic concepts, important parametric tests. Hypothesis testing of means, differences between means, comparing two related samples,

testing of proportion, difference between proportions, comparing variance to hypothesised population variance, equality of variances of two normal populations. Hypothesis testing of correlation coefficients, limitations of test of hypothesis.

Unit 4

Tests of significance for large and small samples. Problems based on χ^2 -test for goodness of fit, t test, F-test and analysis of variance (one way and two way classifications). Regression and Correlation: Karl Pearson's coefficient of correlation, Rank correlation coefficient, Regression Lines, Regression equations. Control charts, namely, X,R,C and p charts. Analysis of variance and covariance.

Note: Instruction for Examiner:

The examination in each theory subject shall be of 50 marks. The examiner will set nine questions. Candidate will attempt five questions. First question would be of short answer type question covering all four Units (2.5 Marks per Unit) & it would be compulsory. Two questions will be set from each unit & out of which candidate will attempt one question. Each Question shall be of 10 marks.

Books Recommended:

1. Operations Research Methods and Practices, CK Mustafi
2. Operations Research, Kantiswarup, PK Gupta, Manmohan
3. Business Statistics, Gupta and Gupta
4. Theory and problems of probability and Statistics, MP Spiegel
5. Research Methodology (Methods and Techniques), C.R. Khotari, New Age Publisher.
6. Fundamentals of modern statistical methods, Rand R. Wilcox

Paper Code: PPPL-103 Paper-II Advances in Pharmaceutical sciences

L -- T -- P
3---2---0

Total Credits: 04
Total Marks: 100

External Marks: 50
Internal Marks: 50

Duration of Exam: 03 hrs

Paper Objectives:

Objective of this subject is to give the general overview on the subject Pharmaceutical Sciences.

UNIT I

Central Drug Standard Control Organization (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 Pharmacokinetic 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, biodegradable 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: 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.

UNIT IV

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.

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

Note: Instruction for Examiner:

The examination in each theory subject shall be of 50 marks. The examiner will set nine questions. Candidate will attempt five questions. First question would be of short answer type question covering all four Units (2.5 Marks per Unit) & it would be compulsory. Two questions will be set from each unit & out of which candidate will attempt one question. Each Question shall be of 10 marks.

Books Recommended:

1. Indian Pharmacopoeia, Central Indian Pharmacopoeia Laboratory, Govt. of India, Ministry of Health & Family Welfare, Ghaziabad, Latest Edition.
2. U. S. Pharmacopoeia – NF, The United States Pharmacopoeial Convention, Rockville, USA, Latest Edition.
3. European Pharmacopoeia, Directorate for the Quality of Medicines of the Council of Europe (EDQM), Strasbourg, Europe, Latest Edition.
4. British Pharmacopoeia, The Stationary Office on behalf of the Medicine Health Care Product Regulatory Agency (MHRA), London, Latest Edition.
5. Mendham J, Denney RC, Barnes JD and Thomas M. Vogel's Textbook of Quantitative Chemical Analysis. Pearson Education Limited, Singapore. Latest Edition.
6. Silverstein RM and Webster FX. Spectrometric Identification of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
7. Vogel HG and Vogel WH. Drug Discovery and Evaluation. Springer-Verlag, Berlin. Latest Edition.
8. Kulkarni SK. Handbook of Experimental Pharmacology. Vallabh Prakashan, New Delhi. Latest Edition.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata. Latest Edition.

Paper Code: PPPP-105

Independent Study

L -- T -- P

0 - 2 - --6

Total Credits: 04

Total Marks: 100

Internal Marks: 100

Study of research oriented activities involving problem formulation, literature review, plan of the research work related to the Ph.D. topic. The student is required to present the same in department.

Note: Assessment/ evaluation of the candidate will be carried out by internal board of examiners comprising of Dean of Faculty, HOD, and concerned subject teacher on the basis of literature review, proposal, presentation and viva voce.

Paper Code: PPPP-107

Scientific Communications

L -- T -- P

0 - 2 - --6

Total Credits: 04

Total Marks: 100

Internal Marks: 100

Application of computer and information technology in scientific research: operating system, use of software package such as MS Office, Power Point, Excel, SPSS, etc. application of data base of literature via internet.

Introduction of English Grammar: Word Choice, Sentence Structure, paragraph structure and comprehension.

Types of Scientific Communications, Basic concept of paper writing, Importance of publishing research papers, writing review articles, citation index/impact factor

Publishing Research paper:

- Preliminaries, Format, Choosing Journal
- Title, Running Title
- Authors: Single and Multi authorship
- Writing Abstract
- Introduction section
- Materials and Methods Section
- Result Section
- Figures: Design Principles, Legends, Table components, Graphs: Types, Style,
- Tables v/s Graph
- Discussion Section: Format, Grammar Style, Content.
- Acknowledgements
- References : Different Styles
- Selecting Keywords
- Communication with the Editor, Handling Referees' Comments, Galey Proofs
- Preparing and Delivering of Oral and Poster Presentations

Avoiding Plagiarism, introduction to intellectual property rights i.e. patent and copy right, etc. Preparing documents for MoUs, Confidentiality Agreements.

The research student is required to prepare a concept paper/working paper/review paper by reviewing at least 40-60 research papers/reference books/ etc. The student is required to present the same in department/conference/ seminar/ workshop/ journal.

Note: Evaluation/ assessment in terms of submission of scientific communication/ article in journal or to the concern guide.

Books Recommended:

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.