S1 PhD Course I- Research Methodology

SEMESTER		SUBJECT			
I		Research Methodology			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
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Objective: To inculcate an understanding of research methodology in pharmaceutical sciences and study various aspects guidelines, regulations and ethics associated with it.

1. To identify research problems, its implementation and evaluation. To survey various research funding agencies for research projects.
2. Concepts of basic research and a brief overview of research problem.
3. To understand design of experiment, general model of process and introduce risk assessment and uncertainty associated with experimental modeling.
4. To study in detail concepts of mathematical modeling and types involved in the processes of formulation of model based on simulation
5. To study different statistical methods, to analyze, process and introduce softwares used in data analysis.
6. To inculcate an understanding of research deliverables in the form of various publications, thesis writing and presentations.
7. To learn principles of ethical considerations involving research and issues related to plagiarism.
8. To learn about the IPR and patenting.

Pre assessment: Determination of entry level knowledge of research student about research methodology in pharmaceutical sciences based on quizzes, question & answers

Module 1	Introduction to Research	1 credit
Objectives	1. Identification of and orientation to the research problem 2. To understand needs of the society, country and world as a whole 3. To identify the research area and orientation to research area 4. To know various research funding agencies in Pharmacy. 5. To learn about the sources of information related to research area. 6. To study and understand research publications in the identified research area 7. To learn planning, execution and implementation of the schedule. 8. To learn handling and maintenance of various instruments.	
Contents	Topics Covered	15
	1. Research Introduction to research, idea about the fundamental research, and selection of the research projects based on the needs of the society, country and world contributing to scientific advancements and technical applications, objectives and scope of work, the steps involved in research. **2. Literature review** Important methods and sources to search for literature (Primary and secondary sources), referencing and search from Journals and Patents, Literature search using internet and web based interfaces, suitable search engines, advanced search techniques & data bases. Review and compilation of the collected matter. **3. Funding & Scholarships**	(2) (3) (3)

	Agencies funding research in pharmaceutical sciences and scholarships for research. 4. **Research Plan & Schedule** Developing research plan and schedule, designing experiments, writing experimental protocols including animal studies protocols taking prior sanction from Ethical Committees for the same**,** activity chart to plan the research work in the permitted time. 5. **Implementation and Documentation** Collecting the requisites of the experiments to be performed in advance, to follow the program strictly as per the schedule, maintaining the r¬¬¬¬¬ecords of all the experiments, incorporating new modifications in the experiments to contribute towards the betterment of technology, maintenance of equipments/instruments and log books for all the instruments, to come out with innovative ideas.	(3) (4)
Assigned writing & Exercise activities	Research student will identify the research problem of interest, collect literature, plan the work, execute the schedule, implement innovative ideas, gather and analyze data and present it in the form of review articles or/and present seminar.	
Assigned Reading	1. B.D. John, A.L. Brown and R.R. Cocking (1999). How People Learn: brain, mind, experience and school. Washington, DC: National Academy Press. 2. J.R. Fraenkel, N.E. Wallen, (2008) How to Design and Evaluate Research in Education*, 7th Ed*. Boston: McGraw-Hill. 3. K.E. David, (2009) Curriculum Development for Medical Education: *A Six-Step Approach,* 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4. 4. N. Peter, (2009) Leadership: Theory and Practice.*3rd Ed.* Thousand Oaks: Sage Publications.	

	5. G. Bordage, B. Dawson, (2003) Experimental study design and grant writing in eight steps and 28 questions. *Medical Education, 37*(4): 376-385. 6. B.J. Avolio, F.O. Walumbwa, T.J. Weber, (2009) Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*: 421-449. 7. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.	
Module 2	**Design of Experiments (DOE) & Mathematical Modeling**	**1credit**
Objectives	• To learn various methods of design of experiments • To acquaint research students with various Statistical Techniques • To emphasize the use of these techniques to design experiments and to analyze generated data • • To identify, analyze and solve problems related to biostatistics using statistical softwares.	
Contents	**Topics Covered**	15
	I – Experimental Modeling a. Definition of experimental design, single factor experiments blocking and nuisance factors, guidelines for designing experiments b. General model of process: Input factors / variables, output parameters / controllable / uncontrollable variables, dependent / independent variables. c. Introduction to risk assessment, reliability, sustainability and uncertainity d. Optimization Techniques ,Optimization using factorial designs, Composite design to estimate curvature	(5)

	II – Statistical Techniques & their Application in data analysis **a. Basics of Probability Distribution** **b. Statistical Computing & Data Management** Data management principles and concepts using relational database software **c. Principles of Statistical Inference** Key concepts of estimation, Point Estimates and Interval Estimates, Concept of mean, median and mode. Standard deviation and relative standard deviation, Construction of Normal-theory confidence intervals, Theory of estimation including hypothesis tests; methods of inference based on likelihood theory, writing the hypothesis, Students t- test ,Introduction to distribution-free statistical methods. **d. Linear Models and Experimental Design** Method of least squares; regression models and correlation and related statistical inference; multiple regressions with matrix algebra; model construction and interpretation. ANNOVA (one way and two way), planned versus posteriori comparisons, two way analysis of variance. **III-Mathematical modeling** Concepts of modeling, processes of formulation of model based on simulation, variables and measurement	(1) (2) (2) (5)
Assigned writing & Exercise activities	Student will compile and analyze the data obtained using various statistical methods and experimental designs and present in the form of written project report and or seminar.	
Assigned Reading	1. Stanford Bolton, Charles Bon (2004) Pharmaceutical Statistics, Practical and Clinical Applications (Fourth revised. ed) Marcel Dekker, Inc. 2. Dowdy, S., and Wearden, S. (1991) Statistics for Research	

	(2nd ed.), New York: John Wiley. 3. Freund, R. J., and Wilson, W. J. (1997) Statistical Methods (rev. ed.), San Diego, CA, Academic Press. 4. Miller, R. G., Efron, B., Brown, B. W., and Moses, L. E. (eds.) (1980) Biostatistics Casebook, NewYork: John Wiley. 5. Steel, R. G. D., and Torrie, J. H. (1980) Principles and Procedures of Statistics: A Biometrical Approach (2nd ed.), New York: McGraw-Hill. 6. Woolson, R. F. (1987) Statistical Methods for the Analysis of Biomedical Data, New York: John Wiley. 7. Wackerly DD, Mendenhall W, Scheaffer RL. (2008) Mathematical Statistics with Applications, 7th edition, , Duxbury Press, USA. 8. Piantadosi S. (2005) Clinical Trials a Methodological Perspective, 2nd edition. John Wiley & Sons. 9. Senn S. (2002) Cross-over trials in clinical research, 2nd edition. Wiley. 10. Jennison C. and B.W. Turnbull.(1999) Group sequential methods with applications to clinical trials. Chapman & Hall. 11. Relevant articles from Journals.	

Module 3	Regulatory Pharmaceutical Guidelines	1 credit
Objectives	1. To create a thorough understanding of important regulatory concepts in Pharmacy 2. To encourage learning and development in Drug Regulatory Affairs and documentation. 3. To acquaint research students with various philosophies of drug regulatory controls, practical input of international bodies and national agencies.	
Contents	Topics Covered	15
	1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA).	(2)

	2. Drug Approval Process as per US FDA guidelines- CDER, INDA, NDA, ANDA' . Clinical Trials and its various Phases. 3. Schedule Y and Good Clinical Practices (GCP') and GLP' . 4. The Concept of CTD Application and E-submission 5. Indian GMP Certification and WHO GMP Certification 6. Attempt towards harmonization of Global regulatory requirements –ICH guidelines - (Q1 – Q10) with special emphasis on stability testing, Quality by design (QbD) and validation guidelines. 7. OECD guidelines 8. Country-based regulatory guidelines	(3) (3) (1) (1) (3) (1) (1)
Assigned writing & Exercise Activities	Students will search the various guidelines available and will present the same followed by group discussion.	
Assigned Reading	1. Guarino, R.A. (1987) New Drug Approval Process, Marcel Dekker, New York. 2. John J. Tobin and Gary Walsh (2008) Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices, John Wiley & Sons. 3. Douglas J. Pisano and David S., Mantus. (2008) Regulatory Affairs: Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition , Informa Healthcare. 4. Helene I. Dumitriu, (1997) Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series), Vol 1. 5. *www.drugscontrol.org/* 6. http://www.fda.gov/Drugs 7. *www.**mhra**.gov.uk* 8. http://www.ich.org/u 9. *www.**oecd**.org/*	

Module 4	Research Deliverables	1 credit
Objectives	• To develop professional approach in writing of the scientific articles. • To develop skills of presenting research work at National and International levels. • To access claim on IPR	
Contents	Topics Covered	15
	Various Forms of Publication: Thesis, Research Paper, Review article, Poster, Presentation, Patent **I – Thesis writing** (3) Introduction, Literature Review or State-of-the-Art, Research Approach (methodology), Results or findings, Discussions, Conclusions, References, Appendices, Scope for future work **II – Research & Review articles** The sources, format for manuscript writing, different formats for reference writing for books & research papers, impact factor for journals, documentation, organization, Processing and analysis of data, acknowledging of reference material, bibliography, and end note. (3) Issues related to plagiarism, copyright laws. **III – Presentation of the Research papers** Introduction to presentation tools, features and functions, creating presentation, customizing presentation, making presentation using Microsoft Power Point, or a similar tool. Collecting a research paper of interest and group discussion. (3) **IV – IPR and Patenting** (6) 1. To study the basics of patent, inventions and component of patent. 2. Patenting in India & outside India.	

	3. TRIPS 4. WIPO 5. PCT filing	
Assigned Reading	1. Alley, Michael. (1996) The Craft of Scientific Writing. 3rd Ed. Springer Science & Business Media, Inc., New York, N.Y. ISBN -10 0-387-94766-3 2. Hult, Christine A. (1996) Researching and Writing in the Sciences and Technology. Allyn and Bacon, Boston, MA. ISBN 0-205-16840-X 3. McMillan, V.E. (2006) Writing Papers in the Biological Sciences. 2nd Ed. Bedford Books, Boston ISBN0-312-11504 4. Rodney Ryder (2002) Intellectual property and the Internet , Lexisnexis-Butterworths, New Delhi. 5. Patent System and Related issues at a glance (1990) New Delhi, National working group on Patent Law. 6. Martin J. Adelman et. al. (1998) Cases and Materials on Patent law, New York ,West Publishing Co. 7. P. Narayanan (1985) Patent Law, 2nd Edition, Calcutta, Eastern Law House. 8. Brain C. Reid. (1993) 2nd Edition, A practical guide to patent law, London, Sweet and Maxwell. 9. Ramappa, T. (2000) Intellectual Property Rights under WTO: Tasks before India, New Delhi, Wheeler Publishing. 10. J.R. Fraenkel, N.E. Wallen (2008) How to Design and Evaluate Research in Education, 7th Ed. Boston: McGraw-Hill.	