Ph.D. Coursework Syllabus

(Academic Year 2022-23)

Faculty of Pharmacy

JIS University
81, Nilgunj Road, Agarpara
Kolkata 700109
West Bengal
India

Syllabus for Ph.D. Coursework

Sl	Course code	Course	Credit points	Full marks	Course type#	Total credits	Total marks
UNIVERSITY PAPER (COMMON)							
1	RPD1001	RESEARCH METHODOLOGY	4	100	C		
2	RPD1002	RESEARCH AND PUBLICATION ETHICS	2	50	C		
FACULTY PAPER (COMMON)							
3	RPH1001	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	4	100	C		
FACULTY PAPER (OPTIONAL)						**14**	**350**
4	RPH1002	PHARMACOLOGY	4	100	M		
5	RPH1003	PHARMACEUTICS	4	100	M		
6	RPH1004	PHARMACEUTICAL CHEMISTRY	4	100	M		
7	RPH1005	PHARMACOGNOSY	4	100	M		
8	RPH1006	QUALITY ASSURANCE	4	100	M		

 # C = COMMON COURSE; M = MAJOR COURSE

COURSE NAME: RESEARCH METHODOLOGY

COURSE CODE: RPD1001 **CREDIT POINTS: 4**

Content:

I. Research-Definition, Objectives of Research, What Makes People do Research? Qualities of a good Researcher, Limitations of Research, Views of Researchers, Scientific method of Research, Importance of Research, Illustrations of Research.

II. Process of Research. Research Methods, Research Methods versus Research Methodology. Fundamental or Basic Research and Examples, Applied Research and Examples, Differences between Basic Research and Applied research. Difference between Approach and Validity, Reliability versus Unbiased and objective, Research structured enquiry, Research Design.

III. Normal, Revolutionary, Quantitative, and Qualitative Research Methods. Learning from Qualitative and Quantitative Research. Data Collection, Generation of Data using Qualitative Methods: (Individual Interviews, Focus groups, Observations, Self-Study, Action Research), Sources of Quantitative Data, Analyzing Quantitative Data, Pros and Cons of Qualitative research, Comparing Quantitative and Qualitative Research, Example and Distinction, Important Difference, Qualitative research, Descriptive Versus Analytical, Conceptual Versus Empirical, Decision-oriented versus Conclusion-oriented,

IV. Process of literature Survey, Advantages and Pitfalls. The Internet as a Medium for Research, Availability of Scientific Research Information, Problems Encounter, Features of Conducting Research through Internet, New Challenges to Researchers, Potential Advantages of Online Questionnaire, Potential Difficulties, Preservation of References, Assessing the Current Status.

V. Ethics in Research, Computer Ethics, Some areas of Research Ethics, Essential information required for authority, Author Responsibilities, What is not acceptable? What are Plagiarism and Self-Plagiarism, Other Types of Ethical Violations, How Journals Detect and Handle Problem Papers? Example, Reasons for possible Plagiarism, appropriate authorship.

VI. Seminar, Oral Report, Quotation, Points to be Remembered in Preparing an Oral Report, Write-up of the oral presentation, Art of writing and layout of Research Paper or Article or Ph. D. Thesis. Main Text, End Matters, Content of work.

References:

1. Ander May, R., Meyer, V., Van Rys, J., Kemper, D., & Sebranek, P. (2016). The College Writer: A Guide to Thinking, Writing, and Researching, MIT Press.

2. Gustavii, B. (2014). How to Write and Illustrate a Scientific Paper. New York, NY: Cambridge.

3. Kothari, C.K. (2015). Research Methodology – Methods and Techniques. New Age International, New Delhi.

4. Krishnswamy, K.N., Shivkumar, AppaIyer, &Mathiranjan M. (2013). Management Research Methodology: Integration of Principles, Methods, and Techniques. Pearson Education, New Delhi.

5. G. Vijaylakshmi and C. Sivapragasam (2008). Research Methods: Tips and Techniques. MJP Publishers, Chennai.

COURSE NAME: RESEARCH AND PUBLICATION ETHICS

COURSE CODE: RPD1002 CREDIT POINTS: 2

I. PHILOSOPHY AND ETHICS

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

II. SCIENTIFIC CONDUCT

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

III. PUBLICATION ETHICS

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 behavior 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

IV. OPEN ACCESS PUBLISHING

1. Open access publications and initiatives
2. SHERPA/RoME0 online resource to check publisher copyright & self-archiving policies
3. Software tool to identify predatory publications developed by SPPU

V. Journal finder / journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

VI. PUBLICATION MISCONDUCT

1. Subject specific ethical issues, FFP, authorship
2. Conflicts of interest
3. Complaints and appeals: examples and fraud from India and abroad
4. Use of plagiarism software like Turnitin, Urkund and other opensource software tools

VII. DATABASES AND RESEARCH METRICS

1. Indexing databases
2. Citation databases: Web of Science, Scopus, etc.

VIII. Impact Factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score Metrics: h-index, g index, il 0 index, altimetric

References:

1. Bird, A. (2006). Philosophy of Science. Routledge.

2. MacIntyre, Alasdair (1967). A Short History of Ethics. London.

3. P. Chaddah (2018). Ethics in Competitive Research: Do not get scooped; do not get plagiarized.

4. National Academy of Sciences, National Academy of Engineering, and Institute of Medicine (2009). On Being a Scientist: A Guide to Responsible Conduct in Research (Third Edition). National Academies Press.

5. Resnik, D. B. (2011). What is Ethics in Research & Why is it Important. National Institute of Environmental Health Sciences.

6. Beall, J. (2012). Predatory Publishers Are Corrupting Open Access. Nature, 489(7415), 179–179.

7. Indian National Science Academy (INSA) (2019). Ethics in Science Education, Research and Governance.

COURSE NAME: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

COURSE CODE: RPH1001 CREDIT POINTS: 4

Content:

I. **a) UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UVVisible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analyzed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

II. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

III. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, isotopic peaks and Applications of Mass spectroscopy.

IV. **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography

b) High Performance Thin Layer Chromatography

c) Ion exchange chromatography

d) Column chromatography

e) Gas chromatography

f) High Performance Liquid chromatography

g) Ultra High-Performance Liquid chromatography

h) Affinity chromatography

i) Gel Chromatography

V. **Electrophoresis:** Principle, Instrumentation, working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis

b) Gel electrophoresis

c) Capillary electrophoresis

d) Zone electrophoresis

e) Moving boundary electrophoresis

f) Iso electric focusing

X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

VI. **a) Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.

b) Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power compensation and designs), Modulated DSC, Hyper DSC, experimental

parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

c) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).

d) TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

COURSE NAME: PHARMACEUTICS

COURSE CODE: RPH1002 CREDIT POINTS: 4

1. **New Drug Delivery Systems**
    - **a.** Gastro-Retentive Drug Delivery Systems
    - **b.** Occular Drug Delivery Systems
    - **c.** Targeted Drug Delivery Systems: Tumor targeting and Brain specific delivery.
    - **d.** Pulmonary Drug Delivery Systems
    - **e.** Nucleic acid based therapeutic delivery system
2. **BA/BE Studies:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs
3. **Nanotechnology Based Formulation Development:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.
4. Thermodynamic Approach to Drug-Excipient Interactions: Natural gum VS
5. Exploration of Natural Gum as Pharmaceutical Adjuvants
6. Standardization of Ayurvedic Drug/Polyherbal Formulations

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 Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

Journals as reference:

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

COURSE NAME: PHARMACEUTICAL CHEMISTRY

COURSE CODE: RPH1003 **CREDIT POINTS: 4**

1. In silico design, synthesis (conventional, microwave, development of combinatorial solution phase synthetic techniques) and evaluation of novel candidate compounds with special reference to heterocyclic moieties and small peptides in the field of antimicrobial, antiprotozoal, antiviral, anti-HIV, anticancer, analgesic, antihistaminic, anticonvulsant, cardiovascular, antidiabetic and other activities.
2. Natural products-chemistry/pharmacology/structure standardization/ using spectroscopic methods (UV-VIS/IR/NMR/MS etc.)
3. Studies on synthetic nutraceuticals
4. Molecular modelling, docking, QSAR and solution phase ADME studies using CADD based software.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, 6 th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5 th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7 th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4 th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3 rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3 rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

COURSE NAME: PHARMACOLOGY

COURSE CODE: RPH1004 CREDIT POINTS: 4

1. Anti-tumor & immunomodulatory studies of compounds from synthetic and natural sources.
2. General pharmacological screening of new moieties from synthetic and natural sources.
3. Toxicological studies of bioactive molecules (natural and synthetic sources)
4. Neuropharmacological studies of bioactive molecules
5. Studies of bioactive molecules on experimentally induced urolithiasis, nephropathy, neuropathy and diabetes in animal models.
6. Biochemical; and Molecular Pharmacological studies of bioactive molecules.

References:

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3 rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Ed, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

COURSE NAME: QUALITY ASSURANCE

COURSE CODE: RPH1005 CREDIT POINTS: 4

1. **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

4. **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

5. Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

Reference:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.

3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.

4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.

5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.

10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.

13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

14. Packaging of Pharmaceuticals. 15. Schedule M and Schedule N.

COURSE NAME: PHARMACOGNOSY

COURSE CODE: RPH1006 **CREDIT POINTS: 4**

1. Validation of traditional systems of medicine
2. Validated methodologies for development of new herbal formulations.
3. Microcomputerized identification of indigenous drugs & development of standards
4. Development of Drug molecules from natural sources and their enhancement by biotechnological approaches.
5. Exploring natural resources for novel drug delivery systems

Reference:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4 th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition