Maharashtra Cosmopolitan Education Society's

DR. P. A. INAMDAR UNIVERSITY

Pune, Maharashtra (India)

(Established under Maharashtra Act No XXXVII of 2022)

Syllabus of Ph. D. Course Work

for

Faculty of Pharmaceutical Sciences

(EFFECTIVE FROM ACADEMIC YEAR 2023-2024)

1. OBJECTIVES OF THE Ph. D. COURSE WORK

(SUBJECT:PHARMACEUTICAL SCIENCES)

The Faculty of Pharmaceutical Sciences, Dr. P.A. Inamdar University, Pune has a mission to develop high quality scientific specialists having strong base of principles of Pharmaceutical sciences and the scientific methods, deep understanding of their chosen areas of specialization, the motivation to learn continually, interact with multi-disciplinary groups and to handle new challenges offered by the front-end technologies.

The Ph. D. course work is designed to impart knowledge and consolidate concepts and intellectual skills through courses and seminars which help the scholars to develop the capacity for free and objective enquiry, courage and integrity, awareness and sensitivity to the needs and aspirations of society. The course work provides the candidates an enabling research experience thus helping them to enter their professional life with right perspective and knowledge related to their respective fields of specialization.

2. Rules And Regulations

- The Ph. D course work is mandatory for all the candidates who are registered for Ph. D. programme (Dr P.A. Inamdar University, Pune Ph.D. Regulation, 2023).
- Admitted candidates shall be required to undertake course work organized by the Research Centre as the case may be.
- If found necessary, course work may be carried out by doctoral candidates in sister departments/institutes either within or outside the University for which due credit will be given to them.
- Only on the successful completion of the Ph. D course work and on producing the certificate by Head, Place of Research, the candidate will be allowed to submit his/her thesis to the Dr P.A. Inamdar University, Pune.

3. Evaluation/Assessment Methods For Ph.D Course Work

(SUBJECT: PHARMACEUTICAL SCIENCES)

- The Head, Place of Research will conduct the continuous assessment exam during the course work at the research centre.
- The Head, Place of Research will be responsible for appointing the examiners, setting up the question papers, conducting the exams, evaluation of answer sheets and declaration ofthe results for the Ph. D course work.
- The continuous assessment exam will be for all courses.
- The faculty member responsible for the evaluation of the course work should be a recognized P.G. teacher/ Ph. D. guide from the Dr PA Inamdar University, Pune.
- The research centre will have to conduct the continuous assessment exam and the percentage of the marks of the exam will have to be converted into the final grade.
- The candidate should pass in all the subjects of the Ph. D. course work
- The Grade ‘B’ is passing grade. The candidate acquiring minimum “B” grade shall bedeclared to “Pass” the course work.
- If the candidate is declared “Pass” in all the subjects of the course work he/she shouldassign grade on the final marksheet.
- The candidate should be given credit points according to his/her learning hours for thespecific subjects of the Ph. D. course work.

4. Scheme For Award of Grades/Marks for Ph. D. Course Work

(SUBJECT: PHARMACEUTICAL SCIENCES)

Award of grade for theory based exam:

Sr. No.	Range of marks (%)	Grade
1	>75 %	O
2	74 % - 65 %	A
3	64% - 50 %	B
4	Below 50%	C (Detained and repeat course work)

Award of final grade

% Marks Obtained	Grade	Result
50 % and above	P	Pass
Less than 50 %	F	Fail

5. Sample Marksheet

Dr P.A. Inamdar University, Pune

- Name of the Research Center :
- Name of the Candidate:
- Subject:
- Faculty:

Statement of the Marks

Sr. No.	Name of the subject	Marks allotted	Marks obtained	% Marks	Grade obtained	Credits
1	Research Methodology and Statistics	50				4
2	Subject specialization	50				4
3	A subject covering Tutorials/Assignments(Presentations , Publication of review related to research topics)	25				2
4	Research and Publications ethics	25				2
	Total	150				12

Seal of the Institute Name and Signature

(Head, Place of Research)

Date:

Note: The Head, Place of Research should issue this certificate on institute's letter head only

6. Sample Research Centre Certificate

Certificate

This is to certify that Mr/Ms/Mrs……..(Surname)……(First name)

……(Second name) has undergone Ph. D. course work in the subject

…….. under the faculty of Science and Technology conducted at our recognized research centre. He /She has successfully completed the Ph.D. course work as prescribed by the Dr P.A. Inamdar University, Pune. The details are as under.

Grade obtained	Credits	Result

Name and Signature Research guide Name and Signature Head Place of Research

Seal of the Institute

Note: The Head, Place of Research should issue this certificate on institute's letter head only.

Paper I : Research Methodology and Biostatistics

1. Scientific Research:

Research: Definition, Characteristics, types, need of research. Identification of the problem, assessing the status of the problem, formulating the objectives, preparing design (experimental or otherwise), Actual investigation.

2. Literature survey:

References, Abstraction of a research paper, Possible ways of getting oneself abreast of current literature

3. Documentation and scientific writing

Results and Conclusions, Preparation of manuscript for Publication of Research paper, Presenting a paper in scientific seminar, Thesis writing. Structure and Components of Research Report, Types of Report: research papers, thesis, Research Project Reports, Pictures and Graphs, citation styles, writing a review of paper, Bibliography

4. Computer applications and Statistics:

Excel spreadsheet and database software. Plotting of graphs, Introduction to Statistics , Normal and bionomial Distributions, Estimates of Central distribution including mean, median and mode, Sampling, t Test , F Test , z Test, ANOVA, chi square test, Standard deviation Coefficient of variance. Correlation and Regression Analysis.

5. Communication skills

Meaning and importance of communication, Objectives of Communication. Need for Communication. Types of communication, Written & Verbal communication,

language as a tool for communication. Developing effective messages: Thinking about purpose, knowing the audience, structuring the message, selecting proper channel. Scope & Significance. Forms of Technical Communicati

Paper II: Choose any ONE Specialization subject

II (a) Pharmaceutical Product Development

1. Preformulation studies: Preformulation studies of drug substances, proteins and peptides.Preformulation work sheet.
2. Complexation: Metal and organic molecular complexes, inclusion compounds with reference to cyclodextrins, methods of analysis.
3. Solubilization: Solubility and solubilization of nonelectrolyte, drug solubilization insurfactant systems,use of co-solvents, solid-state manipulations and drug derivitization.
4. Optimization: Statistical methods and factorial design, Quality By Design.
5. Stability : Stability of dosage forms as per ICH guidelines
6. Solid State Pharmaceutics

Molecular Level : Crystallinity , crystal habit, polymorphism, amorphous state, solvates, hydrates,analytical techniques for characterization(DSC, PXRD, SEM, FTIR), molecular modeling in solid state characterization- case studies and regulatory perspective

Particle level : Particle size, particle shape, porosity, surface area, compaction, particle engineering in pharmaceuticals and relevance in doses form designing

Bulk level : Bulk density, compressibility, flow properties, compaction and consolidation cohesivity, electrostatistics, aggregation, agglomeration, role in formulation development and processing.

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II (b) Biopharmaceutics and Pharmacokinetics

1. ADME, Pharmacokinetic characterization of drugs: Absorption rate constants (Wagner-Nelson, Loo- Reigelman methods), limitations, lag-time, pharmacokinetics in presence of lag-time; Flip-flop model.
2. Protein and tissue binding, factors effecting protein binding, kinetics of protein binding, determination of rate constants and different plots (direct, scatchard and reciprocal); Significance volume of distribution, implications and in vitro methodologies
3. Chronopharmacokinetics, Drug toxicity and forensic, pharmacokinetics; Case study; Pharmacokinetics in elderly; Drug dosage in children, obese patient; First dose size; Kinetics of maternal-fetal drug transfer; Pharmacokinetics- pharmacologic/clinical response; Distribution kinetics; Metabolic kinetics; Dose and time dependencies; Turnover concepts; Small volume of distribution;Dialysis.
4. Drug disposition, renal clearance, mechanism of clearance , clearance ratio, determination of clearance, hepatic clearance, % drug metabolized, relationship between blood flow, intrinsic clearance, and hepatic clearance.
5. Pharmacokinetics of multiple dosing, dosage regimen design based on mean average, minimum and maximum, plasma/serum concentrations, limited fluctuation methods; Repeated one point method;Dosage adjustment in disease patients.

II (c) Pharmaceutical Chemistry

1. Pharmaceutical Organic Chemistry

Methods of determining reaction mechanisms (kinetic and non-kinetic methods); Energy profile diagrams, reaction intermediates, crossover experiments and isotopic labelling; Order of reactions, reversible, consecutive and parallel reactions, solvent, ionic strength and salt effects; Multi-component reactions of pharmaceutical importance such as Biginelli reaction, Hantzsch reaction, Ugi reaction, Passerini reaction and Strecker synthesis.

2. Pharmaceutical Medicinal Chemistry

General principles, Identification and study of targets for development of various therapeutic agents, Rational approach for drug design, Computer aided drug design, Study of recently developed drugs and molecules in development pipeline.

II (d) Pharmaceutical Analysis

1. Principles, methods, interpretation of data and pharmaceutical applications of various analytical techniques like UV-Visible, IR, NMR spectroscopy; Mass spectrometry; GC, HPLC, HPTLC, Flash Chromatography and hyphenation.
2. Assay of drugs and metabolites in pharmaceuticals and biological fluids.
3. Analytical and bioanalytical methods validation using ICH Guidelines.

II (e) Advanced Pharmacology

1. Detailed study of guidelines for maintenance, breeding techniques and experimentation usinglaboratory animals:

a) CPCSEA
b) OECD
c) ICH
d) GLP
e) ICMR
f) Guidelines according to official

2. Advances in Transgenic and Knockout animals.

3. Organization of screening: Pharmacological activity of new substances and safety assessmenttests.

4.Toxicity studies: acute, subacute (Repeated dose), subchronic and chronic

toxicity

5. Alternatives to animal experimentation:

a) Animal cell lines and their uses
b) Radioligand binding assay
c) Patch clamp and ELISA
d) Stem cell research etc.

6. Introduction to Pharmacogenomics, Proteomics and Array technology

II (f) Pharmacognosy

1. Introduction, use of natural products in traditional medicines, potential of natural products, Natural products in drug discovery and development.
2. Recent development in the research on Natural medicinal products: -
   Introduction, Biological and Pharmacological activities, Isolation and characterization studies of different class of Phytoconstituents (Alkaloids, Glycosides, Steroids, Saponins etc).
3. Natural product drug discovery from different sources (Marine , Microbial, Mineral etc) : Introduction, recent development, methods of extraction and isolation, applications etc
4. Extraction and Isolation techniques:
   Introduction, Principle and Applications of different extraction & isolation methods viz Soxhlet extraction, microwave extraction, supercritical fluid extraction, solid phase extraction,Column chromatography, Flash chromatography etc.

Paper III: Research and Publications Ethics (RPE)

1. Philosophy and Ethics: Introduction to philosophy: Definition, nature and scope, concept, branches ; Ethics: Definition, moral philosophy, nature of moral judgment and reactions.

2. Scientific Conduct: Ethics with respect to science and research, Unethical Practices Nearly Identical to research misconduct, . Intellectual honesty and research integrity, Scientific misconducts: Falsification, Fabrication and Plagiarism (FFP), idea, data, method and text plagiarism , Redundant publications: duplicate and overlapping publications, salami slicing; Selective reporting and misrepresentation of data.

3. Publication Ethics: Publication Ethics: Definition, introduction and importance, citations styles, objectivity, relevance, and transparency of the paper, Best Practices/ standards settings initiatives and guidelines: COPE, WAME, etc ; Conflicts of interest with copyrights and patents; Publication misconduct: Definition, concept, problems that lead to unethical behavior and vice versa, types ; Violation of publication ethics, authorship and contributorship ; Dominant laws regarding research ethics ; Infringement and enforcement of Copyright and Patents

4. Open Access Publishing: Open Access Publications and Initiatives ; SHERPA/ RoMEO online resource to check publisher copyright and self – archiving policies ; Software tool to identify predatory publications developed by SPPU ; Journal finder/ journal suggestions tools viz JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

5. Publication Misconduct: Subject specific ethical issues, FFP, authorship ; Conflicts of interest; Complaints and appeals: examples and fraud from India and abroad ; Peer review process

6.Software Tools : Use of plagiarism software like Turnitin, Urkund,cross check, plagscan, Crossref and other open source software tools.

7. Database and Research Metrics: Databases ; Indexing databases ; Citation Databases: Web of Science, Scopus, etc.; Open databases

8. Research Metrics: Impact factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score; Metrics: h – index, g index, i 10 index, altmetrics.