COURSE STRUCTURE AND SYLLABUS OF Ph. D. PRE-REGISTRATION COURSE WORKS IN PHARMACEUTICAL SCIENCES
(Duration: 6 months)

Recommended by DRC in Pharmaceutical Sciences held on 10.04.2023 (w.e.f. AY: 2023-24)

Approved by the 128th Meeting of the Academic Council, Dibrugarh University held on 30.06.2023 [vide Resolution No. 06]

COURSE STRUCTURE AND SYLLABUS OF Ph. D. PRE-REGISTRATION COURSE WORKS IN PHARMACEUTICAL SCIENCES

COURSE	COURSE CODE	COURSE TITLE
Course I (4 credit)*	PHD101T	Research Methodology
Course II (4 credit)*	PHD102T	Pharmaceutical Quality Assurance
Course III (Optional) (4 credit)*	PHD103T	Pharmaceutical Research (to be offered by the prospective supervisor concerned)
Course IV (4 credit)*	PHD104A	Assignment (under guidance of the prospective supervisor concerned)
RPE (2 credit)*	RPE	Research and Publication Ethics

***Total Credit: 18**

PhD Pre-Registration Course Work Syllabus

Course I: Research Methodology (PHD101T)

Credit: 4, Hours/ week: 3, Marks: 100 (End Semester: 60, Internal Assessment: 40)

Course Content

Chapter I: Research and Research Design

Objectives and Importance of Research, Types of Research, Concept of Applied and Basic Research, Criteria of good research, Research methods and Methodology.

Research Problems, Identification of Research Problems, and Importance of literature review in defining a problem.

Literature review - primary and secondary sources, reviews, monograph, patents, research databases, web as a source, searching the web, critical literature review, identifying gap areas from literature and research database.

Research Hypothesis; Development of working hypothesis.

Chapter II: Data collection, Processing and Analysis

Collection of data, methods of data collection, sampling methods, data processing and analysis strategies, data processing tools, Computer and its role in data analysis, data analysis with various statistical software, hypothesis testing – Logic and Importance.

Chapter III: Data Interpretation and Report Writing

Importance and Technique of Interpretation, Precaution in Interpretation.

Significance of Report Writing, Different Steps in Writing Report, Layout of the Research Report, Types of Reports, Precautions for Writing Research Reports. Presentation of research finding.

Chapter IV: IPR and Research Publication

IPR- Intellectual property rights and patent law, commercialization, copyright, royalty, trade related aspects of intellectual property rights (TRIPS).

Research publication-IMRAD concept and design of research paper, citation of reference and acknowledgement, Software for paper formatting.

Plagiarism and Self-Plagiarism, Software for detection of Plagiarism.

Journals in Pharmaceutical Sciences, Impact factor and h-index of journals.

Course II: Pharmaceutical Quality Assurance (PHD102T)

Credit: 4, Hours/ week: 3, Marks: 100 (End Semester: 60, Internal Assessment: 40)

Course Content

Chapter 1: Introduction to Good Laboratory Practices

Good Laboratory practices – Introduction, WHO guidelines on GLP, GMP and cGMP

Protocol for conduct of a clinical and nonclinical laboratory studies

Laboratory Ethics – ethical issues, ethical committees (human, animal and biosafety)

Chapter 2: Quality control and Quality Assurances

Quality Control and Quality Assurance– functions, advantages, National/International standards

Quality by Design (QbD) - Principle and Procedure

Concept of Total Quality Management (TQM), ICH Guidelines on TQM

Validation of Pharmaceutical Processes and Equipments

Chapter 3: Biosafety

Biosafety in Laboratory and Levels of Biosafety

Assessment of Biological Hazards

Biological Hazards- prevention and control

Chapter 4: Laboratory Hazards and Safety

Laboratory Hazards – prevention and control

Radiation and fire hazards – prevention and control

Hazards associated with animal handling

Course III: Pharmaceutical Research (PHD103T)

Credit: 4, Hours/ week: 3, Marks: 100 (End Semester: 60, Internal Assessment: 40)

Course Content

To be offered by the prospective supervisor concerned

Course IV: Assignment (PHD104A)

Credit: 4, Marks: 100 (Assignment writing: 80, Viva on the Assignment: 20)

Course Content

Under guidance of the prospective supervisor concerned

Course RPE: Research and Publication Ethics (RPE)

Credit: 2, Hours/ week: 2, Marks: 50 (End Semester: 30, Internal Assessment: 20)

Course Content

THEORY

RPE 01: PHILOSOPHY AND ETHICS
Introduction to Philosophy: definition, nature and Scope, Concept, Branches
Ethics: definition, moral philosophy, nature of moral judgements and reaction
RPE 02: SCIENTIFIC CONDUCT
Ethics with respect to science and research
Intellectual honesty and research integrity
Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP)
Redundant publications: duplicate and overlapping publications, salami slicing
Selective reporting and misrepresentation of data.
RPE 03: PUBLICATION ETHICS
Publication ethics: definition, introduction and importance
Best practices /Standards setting initiatives and guidelines: COPE, WAME, etc.

Conflicts of interest

Publication misconduct: definition, concept, problems that lead to unethical behaviour and vice versa, types

Violation of publication ethics, authorship and contributorship

Identification of publication misconduct, complaints and appeals

Predatory publishers and journals

PRACTICE

RPE 04: OPEN ACCESS PUBLISHING

Open access publications and initiatives

SHEERPA/RoMEO online resource to check publisher copyright & self – archiving policies

Software tool to identify predatory publications developed by SPPU

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

RPE 05: PUBLICATION MISCONDUCT

A. Group Discussions

Subject specific ethical issues, FFP, authorship

Conflicts of interest

Complaints and appeals: examples and fraud from India and abroad

B. Software tools

Use of plagiarism software like Turnitin, Urkund and other open source software tools

RPE 06: DATABASES AND RESEARCH METRICS

A. Databases

Indexing databases

Citation databases: Web of Science, Scopus, etc.

B. Research Metrics

Impact Factor of Journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score

Metrics: h-index, g-index, i10 index, altmetrics

Reference:

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

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

P.Chaddah, (2018) Ethics in Competitive Research: Do not get Scooped; do not get Plagiarized, ISBN: 978-9387480865

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.

Resnik, D.B.(2011) What is ethics in research & why is it important. National institute of Environmental Health Science, 1-10 Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm

Beall, J: (2012) Predatory publishers are corrupting open access. Nature, 489(7415), 179-179. https://doi.org/10.1038/489179a

Indian National Science Academy (INSA), Ethics in Science Education, Research and Governance (2019), ISBN: 978-81-939482-1-7.

htt://www.insaindia.res.in/pdf/Ethics_Book.pdf.