



**OFFICE OF THE REGISTRAR :: DIBRUGARH UNIVERSITY :: DIBRUGARH**

Ref. No. DU/DR-A/Syllabus-Ph.D.(Pharm. Sc.)/23/850

Date: 17.08.2023

**NOTIFICATION**

As recommended by the meeting of the Departmental Research Committee (DRC) in Pharmaceutical Sciences, Dibrugarh University, held on 10.04.2023, the 128<sup>th</sup> Meeting of the Academic Council, Dibrugarh University held on 30.06.2023 vide Resolution No. 06 has approved the *revised Course Structure and Syllabus of Ph. D. Course Work in Pharmaceutical Sciences* with effect from the academic session 2023-2024.

A copy of the Syllabus is attached herewith.

Issued with due approval.

*Alagankha*  
17/08/2023  
Deputy Registrar (Academic)  
Dibrugarh University.

*phelie*

Copy to:

1. The Hon'ble Vice-Chancellor, Dibrugarh University for kind information.
2. The Deans, Dibrugarh University, for kind of information.
3. The Registrar i/c, Dibrugarh University for kind of information.
4. The Head, Department of Pharmaceutical Sciences, Dibrugarh University, for information.
5. The Controller of Examinations i/c, Dibrugarh University for information.
6. The Programmer, Dibrugarh University, with a request to upload the notification and syllabus in the Dibrugarh University Website.
7. File.

*Alagankha*  
17/08/2023  
Deputy Registrar (Academic)  
Dibrugarh University

*phelie*



**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 128<sup>th</sup> 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**

| <b>COURSE</b>                           | <b>COURSE CODE</b> | <b>COURSE TITLE</b>  |
|---|--------------------|--|
| Course I<br>(4 credit)*                 | PHD101T            | Research Methodology   |
| Course II<br>(4 credit)*                | PHD102T            | Pharmaceutical Quality Assurance   |
| Course III<br>(Optional)<br>(4 credit)* | PHD103T            | Pharmaceutical Research<br>(to be offered by the prospective supervisor concerned) |
| Course IV<br>(4 credit)*                | PHD104A            | Assignment<br>(under guidance of the prospective supervisor concerned)             |
| RPE<br>(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

MacIntyre, 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.

[http://www.insaindia.res.in/pdf/Ethics\\_Book.pdf](http://www.insaindia.res.in/pdf/Ethics_Book.pdf).



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