Ph D Course Structure
(Those who are admitted on the basis of M Pharm degree, from 2012-13 onwards)

First year: Total credits: 16 (08 in July and 08 in January semester)

July (autumn) Semester

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Subjects</th>
<th>Credits</th>
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<tbody>
<tr>
<td>1</td>
<td>Compulsory Subject</td>
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<tr>
<td></td>
<td>PH-7101 Advanced Chemical and Bioanalytical Techniques</td>
<td>04</td>
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<tr>
<td>2</td>
<td>Elective Subject (Any one)</td>
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<tr>
<td></td>
<td>PH-7102 Advanced Pharmaceutics</td>
<td>04</td>
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<td>PH-7103 Advanced Pharmaceutical Chemistry</td>
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<td>PH-7104 Advanced Pharmacology</td>
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<td>PH-7105 Advanced Pharmacognosy</td>
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<td></td>
<td><strong>Total credits of Semester I</strong></td>
<td><strong>08</strong></td>
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January (spring) Semester

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<tr>
<th>S. No.</th>
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<tbody>
<tr>
<td>1</td>
<td>Compulsory</td>
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<tr>
<td></td>
<td>PH-7201 Advanced Spectral Techniques</td>
<td>04</td>
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<tr>
<td>2</td>
<td>Elective (Any one)</td>
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<tr>
<td></td>
<td>PH-7202 Research Methodology</td>
<td>04</td>
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<td>PH-7203 Drug Regulatory Affairs</td>
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<td></td>
<td><strong>Total credits of Semester II</strong></td>
<td><strong>08</strong></td>
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Second year onwards: 08 credits in each semester

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<tr>
<th>S. No.</th>
<th>Subjects</th>
<th>Credits/Semester</th>
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<tbody>
<tr>
<td>1</td>
<td>PH-7199 - Thesis (Autumn/Odd Semester)</td>
<td>04</td>
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<tr>
<td>2</td>
<td>PH-7299 - Thesis (Spring/Even Semester)</td>
<td>04</td>
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<tr>
<td></td>
<td><strong>Total Credits per Semester</strong></td>
<td><strong>08</strong></td>
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Detailed Syllabus of Ph D Course

July (autumn) semester

Compulsory paper for all candidates:

**PH-7101: Advanced Chemical and Bioanalytical Techniques**  [Contact hours: 03; Credits: 04]

1. Advanced separation techniques: Methods of separation of cells and their organelles, modern centrifugation methods.
2. Electrophoresis techniques for analysis of proteins & nucleic acids: Polyacrylamide gel electrophoresis (PAGE), SDS-PAGE, Western blot, PCR and RT-PCR methods.
3. Chromatographic techniques: Principles, methods, interpretation of data and application of HPLC, GLC, flash chromatography and HPTLC. Advances in tandem LC-MS and GC-MS techniques and their pharmaceutical research applications including case studies.
4. Microscopic techniques: Confocal microscopy, atomic force microscopy (AFM), scanning electron microscopy (SEM) and transmission electron microscopy (TEM) in drug development, advanced microscopic methods for evaluation of natural drugs.
5. Thermal analysis: Differential scanning calorimetry (DSC), Thermogravimetric analysis (TGA) and Differential thermal analysis (DTA).
6. Animal imaging techniques – Magnetic resonance imaging (MRI), Functional MRI, Positron emission tomography (PET) and single-photon emission computer tomography (SPECT). Optogenetic techniques. Doppler methods. Radiotracer techniques for PK and PD evaluation of drugs and metabolites.

**Elective subject (Any one)**

**PH-7102 Advanced Pharmaceutics**  [Contact hours: 03; Credits: 04]

1. The concepts of bioavailability and bioequivalence. In vitro and in vivo methods in establishment of bioequivalence. Case studies of IVIVC.
2. Compartment modeling in pharmacokinetics, significance of different pharmacokinetic parameters, Non-linear pharmacokinetic and reasons thereof. Dose adjustment in disease conditions and in geriatric and pediatric patients.
4. Polymers - Natural and synthetic polymers with respect to their pharmaceutical applications, characterization methods of polymers, polymer drug interactions.
5. Controlled drug delivery - Strategies, oral drug delivery (Gastroretentive and osmotic control systems) targeting through nanoparticles, colon targeting, lung targeting, targeting of cancerous tissues, mucoadhesive and transdermal drug delivery systems.

**PH-7103 Advanced Pharmaceutical Chemistry**  [Contact hours: 03; Credits: 04]

1. Modern concept and principles of drug design, analog design, receptors and enzymes as drug targets and their characterization, drug-target interactions, modern virtual and physical tools for
lead compound identification and optimization: molecular modeling, virtual docking, combinatorial synthesis and high-throughput screening.


3. Advances in QSAR methods (2D, 3D QSAR) – concepts and applications in drug design, case studies.

4. Synthesis, mode of action, structure-activity relationships of newer drugs and agents belonging to the following categories: COX-2 inhibitors, anti-histamines (H1, H2 & H3), oral hypoglycemics, anticonvulsants, fluoroquinolone antibiotics, anticancer & anti-HIV drugs.

5. Structural elucidation, biosynthesis and mode of actions of (a) Steroids: Sex hormones; (b) Alkaloids: Quinine and steroidal alkaloids; (c) Antibiotics: New generation cephalosporins and macrolides; (d) Glycosides: Cardiac glycosides, Triterpenoid glycosides (Panax ginseng); (e) Prostaglandins and their analogs.

**PH-7104 Advanced Pharmacology [Contact hours: 03; Credits: 04]**

1. Chemical transmission and drug action in the CNS, pharmacogenetics, metabolite kinetics.

2. Drug discovery and evaluation through advanced pharmacological methods with emphasis on neuropsychopharmacology.


4. Recent pharmacological anti-addiction strategies for nicotine, methamphetamine, cocaine and alcohol.


6. Clinical pharmacology and pharmacodynamics. Clinical trials (Phase I to IV) - design, documentation and interpretation of clinical data.

7. Applications of PK-PD modeling and related software in drug development.

**PH-7105 Advanced Pharmacognosy [Contact hours: 03; Credits: 04]**

01. Methods of literature survey, abstract services, citation index and journal impact factor.

02. Methods of extraction, isolation and purification of plant constituents – novel solvent extraction methods, modern chromatographic methods (HPLC, HPTLC and GLC).

03. General methods of physicochemical characterization of plant constituents – Melting point, boiling point, optical rotation, case studies involving structural elucidation of phyto-constituents (alkaloids, glycosides, phenolics etc) by spectral methods including IR, NMR and Mass, ORD, CD and XRD.

04. Standardization of herbal drugs by conventional and modern techniques including chemical markers, DNA based molecular markers. Pre-formulation, formulation & standardization of herbal drugs (Traditional and NDDS like phytosomes, nanoparticles etc.). Herbal drug interactions and synergism, Regulatory guidelines for evaluating the safety and efficacy herbal medicines.
05. Methods of biological evaluation of plant drugs and bioassay methods for the following pharmacological categories: antidiabetics, hepatoprotectives, antioxidants, antineoplastics, antivirals, antiseptics, anti-inflammatory and analgesics.

January (spring) semester:

Compulsory paper for all candidates:

PH-7201: Advanced Spectral Techniques [Contact hours: 03; Credits: 04]

1. Overview of spectral methods in drug research, fundamentals of molecular absorption and emission spectroscopic methods, basic and modern principles, instrumentation, methods of data collection, interpretation of spectra and research applications of following optical techniques: Ultraviolet spectroscopy (First and second order derivative UV), fluorescence spectroscopy including fluorescence correlation spectroscopy (FCS), fluorescence polarization (FP), and fluorescence resonance energy transfer (FRET).

2. Theory, instrumentation, data interpretation and pharmaceutical applications of Fourier Transform infrared absorption spectroscopy (FTIR), reflectance FTIR techniques like FTIR-ATR, FTIR-PAS & DRIFTS FTIR.

3. Solution NMR spectroscopy: Principles of proton (H-1), carbon (C-13) and nitrogen (N-15) NMR spectroscopy, interpretation of spectral data and research applications of multidimensional (1D, 2D, 3D and 4D) FTNMR COSY and case studies of drugs, peptides and proteins. Recent advances in protein NMR.

4. Solid state NMR (SSNMR) spectroscopy – theory and concepts, instrumentation, magic angle spinning and cross polarization SSNMR experiments, advantages over liquid state NMR and research applications including case studies involving small and macromolecular (protein) structural characterization.

5. Mass spectrometry: Principles of modern ionization methods and mass analyzers (TOF and FT-ICR), hybrid/tandem mass methods (MS-MS) and applications of MS in the analysis of small drugs and macromolecules.


Elective subject (Any one)

PH-7202: Research Methodology [Contact hours: 03; Credits: 04]

1. Objectives and types of research: Motivation and objectives, research methods vs methodology. Types of research – descriptive vs analytical, applied vs fundamental, quantitative vs qualitative, conceptual vs empirical. Introduction to drug discovery & development research, objectives, flowchart from discovery to post-marketing research, overview of research methodology in various areas of drug discovery and development research.

2. Research formulation – Defining and formulating the research problem, selecting the problem, necessity of defining the problem, importance of literature review in defining a problem, Literature
review - primary and secondary sources, reviews, monographs, patents, research databases, web as a source, searching the web, critical literature review, identifying gap areas from literature review and research databases, development of working hypothesis.

3. **Research design and methods**: Research design – basic principles, need of research design, features of good design, important concepts relating to research design, observation and facts, laws and theories, Prediction and explanation, research databases, development of models, developing a research plan – exploration, description, diagnosis, and experimentation.

4. **Execution of the research, data collection and analysis**: Aspects of method validation, observation and collection of data, methods of data collection, sampling methods, data processing and analysis strategies and tools, data analysis with statistical packages (Sigma STAT, SPSS for Student t-test, ANOVA, etc), hypothesis testing, generalization and interpretation.

5. **Reporting and thesis writing**: Structure and components of scientific reports, types of report, technical reports and thesis. Thesis writing – different steps and software tools (Word processing, etc) in the design and preparation of thesis, layout, structure (chapter plan) and language of typical reports, illustrations and tables, bibliography, referencing and footnotes. Oral presentation – planning, software tools, creating and making effective presentation, use of visual aids, importance of effective communication.

6. **Research ethics, IPR and scholarly publishing**: Ethics – ethical issues, ethical committees (human & animal); IPR - intellectual property rights and patent law, commercialization, copy right, royalty, trade related aspects of intellectual property rights (TRIPS); Scholarly publishing – IMRAD concept and design of research paper, citation and acknowledgement, plagiarism, reproducibility and accountability.

**PH-7203 Drug Regulatory Affairs [Contact hours: 03; Credits: 04]**

1. **Manufacturing**: Introduction, regulatory requirements as per Indian and other regulatory authorities for manufacturing information, formula, process, validation of manufacturing process, equipment, documentation, inspection requirement, regulatory guidelines for active ingredients and formulations. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, microbiological test and evaluation of closures.

2. **Stability testing**: Introduction, scientific and technical background to the design of stability testing regulatory requirements as per Indian and other regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging.

3. **Preclinical aspects of biopharmaceutics, clinical bioavailability, study design, presentation documentation, statistical analysis, current guidelines and developments as per regulatory requirements of Indian and other regulatory authorities.**

4. **Clinical pharmacology and pharmacodynamics**: Clinical study design, documentation, presentation and interpretation. Clinical trials: definition, Phase I, Phase II, Phase III and Phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data, factorial design, guidelines as per Indian and other regulatory authorities.

5. **Intellectual property rights**: Introduction, purpose, guidelines as per Indian and other regulatory authorities.