UNIVERSITY OF PUNE, PUNE

STRUCTURE and SYLLABUS

For

Ph.D. COURSE WORK

Under

FACULTY OF PHARMACEUTICAL SCIENCES

CONTENTS

01 . Objective of the Ph.D Course Work (Faculty ; Pharmaceutical Sciences)

The Faculty of Pharmaceutical Sciences, University of Pune, 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 the 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.

02. Rules and Regulations

- The Ph.D course work is mandatory for all the candidates who are registered on or after 11th July 2009 (As per University of Pune circular PGS/Ph.D/1060 Dated 29th August 2011).
- 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 (Appendix 'B')** , the candidate will be allowed to submit his/her thesis to the University of Pune.

03. Ph.D Course Work Structure (Faculty : Pharmaceutical Sciences)

- The Ph.D. course work shall be offered with **credit system**.
- The course work will be for a **minimum period of one semester** and shall be treated as pre Ph.D. preparation
- The course work will have total **20 credits** of minimum six months duration.
- **5 credits** for Research Methodology which includes research methodology, quantitative methods, computer application, tools and techniques including instrumentation, communications skills, seminar presentation and review of published research
- **l0 credits** for subject specific (2 subjects of specialization) course work.
- **5 credits** for field work, seminar and other academic activities.

.Sr.No	**Particulars of the course**	**Learning Hours**	**Examination Type**	**Examination Scheme**			**Credits**
				Continuous Assessment (01)	**Continuous Assessment (02)**	**Average Total (01 + 02)**	
01	Research Methodology	10	Theory	50	50	50	05
02	Subject specialization **- 01**	10	Theory	50	50	50	05
03	Subject specialization **- 02**	10	Theory	50	50	50	05
04	Seminar	5	Viva - voce	50	50	50	05
TOTAL				**200**	**200**	**200**	**20**

04. Evaluation/Assessment methods for Ph.D course work

(Faculty : Pharmaceutical Sciences)

- The Head, Place of Research will conduct the **Two (02)** continuous assessment exams 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 of the results for the Ph.D course work.
- The continuous assessment exams will be for Research methodology, Subject specialization (02) and Seminars.
- The faculty member responsible for the evaluation of the course work should be an **Recognised P.G. teacher/ Ph.D guide** from the University of Pune.
- The research centre will have to conduct two continuous assessment exams and the average percentage of the marks of the two exams will have to be converted into the **final grade**.
- The candidate should pass in all the subjects (Including seminar) of the Ph.D course work
- The **Grade 'B'** is passing grade. The candidate acquiring Min 'B' grade shall be declared to Pass the course work.
- If the candidate is declared "Pass" in all the subjects (Including seminar) of the course work he/she should assign grade on the final marksheet (**Appendix 'A)**
- The candidate should be given **credit points** according to his/her **learning hours** for the specific subjects of the Ph.D course work**.**

05. Scheme for Award of Grades/Marks for Ph.D course work

(Faculty : Pharmaceutical Sciences)

I. AWARD OF GRADE (For Theory based Exams).

Sr.No	Range of Marks (%)	Grade
01	>75 %	O
02	74 % - 65 %	A
03	64% - 50 %	B
04	Below 50%	C **(Detained and repeat the Course work)**

II. Evaluation Criteria for Seminars

Sr.No	Particulars	Marks
01	Literature survey	15
02	Presentation Skills	20
03	Defence	15
Total		**50**

III. AWARD OF GRADE (For evaluation of Seminar)

Sr.No	Range of Marks	Grade
01	40 - 50	O
02	30 - 39	A
03	25 - 29	B
04	Below 25 marks	C **(Detained and repeat the course work)**

IV. AWARD OF FINAL GRADE

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

Appendix 'A'

06. Sample Mark sheet for Ph.D Course work

University of Pune,Pune

Name of the Research Center :

Name of the candidate:

Subject:

Faculty:

Statement of the Marks

Sr.No	Name of the Subject	Min Marks Required (Out of 50)	Marks Obtained (Out of 50)	% Marks	Grade Obtained	No of Credits Earned
01	Research Methodolgy	25				
02	Faculty specific topic – 01	25				
03	Faculty specific topic – 02	25				
04	Seminar	25				
	TOTAL					

Seal of the Institute **(Name and Signature Head Place of Research)**

Date:

Place:

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

Appendix 'B'

07. 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 Pharmaceutical Sciences conducted at our recognized research centre. He/She has successfully completed the Ph.D. course work as prescribed by the University of Pune. The details are as under.

Grade Obtained	No. of Credits earned	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*****.**

Syllabus for Ph.D course work - Research Methodology

Contact Hours : 10

No. of Credits : 05

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:**

   Use of word processing, spreadsheet and database software. Plotting of graphs. Internet and its application: E-mail, WWW, Web browsing, acquiring technical skills, drawing inferences from data,Introduction to Statistics – Probability Theories - Conditional Probability, Poisson distribution, Binomial Distribution and Properties of Normal Distributions, Estimates of Means and Proportions; Chi Square Test,Association of Attributes t Test –Anova, Standard deviation Coefficient of variations.Co relation 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 Communication.

Ph. D course work Pharmaceutics - I

Contact Hrs. - 10
No. of Credits - 05

(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 in surfactant 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.

Contact Hrs. - 10
No. of Credits - 05

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(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.

Syllabus for Ph.D in Pharmaceutical Chemistry under faculty of Pharmaceutical Sciences

Subject 1: Pharmaceutical Chemistry

Learning Hours: 10 **No. of Credits: 05**

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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.

Subject 2: Pharmaceutical Analysis

Learning Hours: 10 **No. of Credits: 05**

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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.

Syllabus for Ph.D. course work – Advanced Pharmacology I

Contact Hours: 10

No. of Credits: 05

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01 Detailed study of guidelines for maintenance, breeding techniques and experimentation using laboratory animals:

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

02 Recent advances in Transgenic and Knockout animals.

03 Organization of screening: Pharmacological activity of new substances and safety assessment tests.

04Toxicity studies: acute, subacute (Repeated dose), subchronic and chronic toxicity.

05 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.

06 Introduction to Pharmacogenomics, Proteomics and Array technology

Syllabus for Ph.D. course work – Advanced Pharmacology II

Contact Hours: 10

No. of Credits: 05

Fundamentals of Molecular mechanism of drug action:
01 Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidyl inositol. Ion channels and their modulators.

02 Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiestrase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

03 Recent trends on different classes of receptors and drugs acting on them:

a. Angiotensin receptors
b. Excitatory amino acid receptors
c. Kinin receptors
d. Adrenoceptors
e. Low molecular weight heparins, hirudins and GP II/IIIa receptor antagonists
f. Imidazole receptors
g. Cholinergic receptors
h. Dopamine receptors
i. Serotonin receptors
j. Hormone receptors
k. GABA and Benzodiazepine receptors
l. Opiod receptors
m. Purinergic receptors
n. Glutamate receptors

04 Ion channel and their modulators: calcium, potassium, sodium and chloride channels.

05 Apoptosis: basic functions, mechanisms and role of caspases. pharmacological and clinical implications.

06 Adhesion therapy and cardiac and vascular remodeling.

07 Basic Concepts of Chronopharmacology and their implications to Drug Therapy.

08 Immunopharmacology: antibody dependent and cellular cytotoxicity. Monoclonal antibodies and its importance.

09 Gene therapy: Concept of gene therapy and recent development in the treatment of various hereditary diseases. Human genome mapping and its potential in drug research.

10 Techniques for the study of Molecular Pharmacology: Western Blotting, Immunostaining, RT-PCR, Cloning, RIA, Cell Cultures etc.

Syllabus for Ph.D course work - Pharmacognosy – I

(Natural product Drug discovery)

Contact Hours : 10

No. of Credits : 05

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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.

Syllabus for Ph.D course work - Pharmacognosy – I

(Herbal Drug Formulation and Evaluation)

Contact Hours : 10

No. of Credits : 05

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1. **Overview of Novel herbal formulations** :

   Phytosomes, Liposomes, Microspheres, novel vesicular herbal formulations etc

2. **Standardization of herbal drugs/formulations :**

   Conventional methods, Modern techniques (Role of genetic markers, RAPD, DNA fingerprinting technique etc)

3. **WHO Guidelines for assessment of crude drugs**

   Evaluation of identity, purity, and quality of crude drugs.

   Determination of pesticide residue

   Determination of Micro-organisms

   Dtermination of Arsenic and heavy metals

4. **Herbal Drug Regulatory affairs**

   Role and importance of national and international regulatory bodies in assessment of quality of herbal drugs and formulations.