EXAMINATION RULES, BYE LAWS AND SYLLABUS

FOR

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PhD COURSE WORK IN DIFFERENT DISCIPLINES OF PHARMACY AND PhD IN PHARMACEUTICAL MEDICINE

(REVISED AND APPROVED IN BRS- 20-05-2016)

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH (SPER)
(FORMERLY: FACULTY OF PHARMACY)
JAMIA HAMDARD, NEW DELHI

(Total-48 pages)

Faculty of Pharmacy
Jamia Hamdard,
New Delhi – 110062

Course work for Ph. D. Programme Bye Laws

(To be effective from the academic session 2016 and applicable to all Ph.D. Students)

1. Programme : Course work for Ph.D.
2. Duration : One semester
3. Medium of Instruction and Examination : English
4. Course Structure

The course work will be assigned credit, generally, during one semester minimum 12 credits are required to be earned for a theory modules of 4 credits each. This practically means 12 (hr) x 15 (15 wk/semester) = 180 hr of teaching/contact classes. Practically, it comes to 4hrs of contact classes per week for each module for a semester of roughly 15 weeks in a 5-day per week classes of a semester. A candidate is required to complete three courses.

The course distribution is as follows

A. **Compulsory module** (one course of 4 credits) Research methodology, Communication skills, Copy right and Ethical issues in Research.

B. **Core module from elective courses** (one course of 4 credits)
The elective course modules will be selected by the students in consultation with supervisor. Supervisor may decide selection of courses depending on the research topic. The department will design 3-4 courses of 4 credits each (48 hrs/ semester).

C. **Crossed Interdisciplinary module** (one course of 4 credits)

- A student will be free to select one course from the modules offered by the other Department/Faculty. This course generally should not have any significant overlapping with the research area of the student. For example, a student registered in Science may choose a course in Human Rights or Islamic Studies.

(2) (9)

Scheme of the examination

Department of Pharmacology

Paper Code	Title of paper	Marks	L-P/S	Credit
		Semester		
Ph.D. 101 (compulsory)	Research Methodology, communication skills, copy rights and Ethical issues in Research	100	4-0	4
	(One course of 4 credits):			
PCOL-PhD-102	Basic Pharmacology	100	2-4	4
PCOL-PhD-103	Cardiovascular Pharmacology	100	2-4	4
PCOL-PhD-104	Neuro Pharmacology	100	2-4	4
PCOL-PhD-105	Endocrinology (Metabolic Disorder)	100	2-4	4
PCOL-PhD-106	Pharmacovigilance	100	2-4	4
	Interdisciplinary (one course from the PhD course offered by other Dept.)	100		4

Department of Pharmaceutical Medicine

Paper Code	Title of paper	Marks	L-T/S	Credit
		Semester		
Ph.D. 101 (compulsory)	Research Methodology, communication skills, copy rights and Ethical issues in Research	100	4-0	4
	(One course of 4 credits):			
PM-PhD-102	Drug Discovery and Development	100	2-4	4
PM-PhD-103	Clinical Pharmacology	100	2-4	4
PM-PhD-104	Clinical Pharmacokinetics and bioequivalence studies	100	2-4	4
	Interdisciplinary (one course from the PhD course offered by other Dept.)	100		4

Department of Pharmaceutics

Paper Code	Title of paper	Marks	L-T/S	Credit
		Semester		
Ph.D. 101 (compulsory)	Research Methodology, communication skills, copy rights and Ethical issues in Research	100	4-0	4
	(One course of 4 credits):			
PCEU-PhD-102	Quality Assurance in Pharmaceutical Industries	100	3-1	4
PCEU-PhD-103	Pharmaceutical Regulatory Affairs	100	3-1	4
PCEU-PhD-104	Novel Drug Delivery Systems	100	3-1	4
PCEU-PhD-105	Nanotechnology in Pharmaceutical Sciences	100	3-1	4
	Interdisciplinary (one course from the PhD course offered by other Dept.)	100		4

10

Department of Pharmaceutical Chemistry

Paper Code	Title of paper	Marks	L-T /S	Credit
		Semester		
Ph.D. 101 (compulsory)	Research Methodology, communication skills, copy rights and Ethical issues in Research	100	4-0	4
	(One course of 4 credits):			
PCHE-PhD-102	Advance Organic Chemistry	100	3-1	4
PCHE-PhD-103	Spectroscopic Methods	100	3-1	4
PCHE-PhD-104	Drug Design and Molecular Modeling	100	3-1	4
PCHE-PhD-105	Chemistry of Natural Products	100	3-1	4
	Interdisciplinary (one course from the PhD course offered by other Dept.)	100		4

Department of Pharmacognosy & Phytochemistry

Paper Code	Title of paper	Marks	L-T/S	Credit
		Semester		
Ph.D. 101 (compulsory)	Research Methodology, communication skills, copy rights and Ethical issues in Research	100	4-0	4
	(One course of 4 credits):			
PCOG-PhD-102	Drug Discovery from Natural Sources	100	3-1	4
PCOG-PhD-103	Quality Control and Phytochemical Techniques	100	3-1	4
PCOG-PhD-104	Plant Biotechnology	100	3-1	4
PCOG-PhD-105	Bioprocess and Bio-catalysis	100	3-1	4
PCOG-PhD-106	Biological Evaluation (in-vitro)	100	3-1	4
	Interdisciplinary (one course from the PhD course offered by other Dept.)	100		4

- L = Lecture, P= Practical, T = Tutorial, S= Seminar

Grading Systems The grade awarded to a student in any particular course will be based on his/her performance in the end semester examination. The letter grades and their equivalent numerical points are listed below:

Percentage marks	**Letter grade**	**Grade point**	**Description of performance**
≥ 80	A^{++}	10	Outstanding
75- <80	A^{+}	9	Excellent
70-<75	A	8	Very good
60-<70	B	7	Good
55-<60	C	6	Average

Earned Credits (EC)

The credits for the course in which a student has obtained C (minimum passing grade for a course) or a higher grade will be counted as credits earned by him/her. Any course in which a student has below C grade will not be counted towards his/her earned credits.

Evaluation of performance

SGPA (Semester Grade Point Average) may be awarded on successful completion of the semester.

Calculation of SGPA

$$SGPA = \frac{\sum (\text{Earned Credit} \times \text{Grade Points})}{\sum (\text{Course credits Registered})}$$

For Example

Subject code	Subject Credits	Marks	Grade Awarded	Grade Point	Points Secured
Ph.D. 101	4	59	C	6	24
Ph.D. 102 A/B/C	4	76	A^+	9	36
Ph.D. 103	4	70	A	8	32
Total	**12**				**92**

Total Credits = 12
Points secured = 92
SGPA = 92/12 = 7.66

5. Completion of a credit course includes attendance in lectures (minimum 75%), appearing for the examination and receiving a qualifying grade. A uniform qualifying grade is 55% marks in each paper. In case a student fails to receive a qualifying grade/marks in the course, he/she will be offered an opportunity to reappear in the examination next year.
6. All students registered for Ph.D. programme including under MoU are required to complete the course work at Jamia Hamdard. However, permission may be granted to undertake the course work at their Institution subject to approval by Hon'ble Vice Chancellor.
7. The examination of the course modules may be coordinated by the Dean of the respective Faculty.
8. Foreign students may also be required to complete the course work.

5 12

Syllabus of PhD Course work in all disciplines of Pharmacy

The following courses are to be taught by the departments in their respective Discipline.

Pharmaceutics

1- Common Paper (PhD-101)
2- Quality Assurance in Pharmaceutical Industries (PCEU-PhD-102)
3- Pharmaceutical Regulatory Affairs (PCEU-PhD-103)
4- Novel Drug Delivery Systems (PCEU-PhD-104)
5- Nanotechnology in Pharmaceutical Sciences (PCEU-PhD-105)

Pharmacology

1- Common Paper (PhD- 101)
2- Basic Pharmacology (PCOL –PhD- 102)
3- Cardiovascular Pharmacology (PCOL –PhD- 103)
4- Neuropharmacology (PCOL –PhD- 104)
5- Endocrinology (PCOL –PhD- 105)
6- Pharmacovigilance (PCOL –PhD- 106)

Pharmaceutical Chemistry

1- Common Paper (PhD-101)
2- Advance Organic Chemistry (PCHE- PhD- 102)
3- Spectroscopic Methods (PCHE- PhD- 103)
4- Drug Design and Molecular Modeling (PCHE- PhD- 104)
5- Chemistry of Natural products (PCHE- PhD- 105)

Pharmacognosy and Phytochemistry

1- Common Paper (PhD-101)
2- Drug Discovery from Natural Sources (PCOG- PhD- 102)
3- Quality Control and Phytochemical Techniques(PCOG- PhD- 103)
4- Plant Biotechnology (PCOG- PhD- 104)
5- Bioprocess and Bio-catalysis(PCOG- PhD- 105)
6- Biological Evaluation (*in-vitro*) (PCOG- PhD- 106)

The HOD are requested to get the consent of the PhD students of their department to opt the PhD courses in consultation with their guides. A candidate will have to opt the following papers compulsorily,

1- Common Papers, PhD 101 (common to all PhD students)
2- One core papers of the Deptt. as listed above in under each Deptt.
3- One inter-disciplinary paper

This information ... has to be submitted to the undersigned latest by 25th June 2012

7

PhD-101 (common to all PhD students)

Jamia Hamdard, New Delhi
Ph.D. Programme
Compulsory module I: Paper code 101
Research Methodology, Communication Skills Copyright and Ethical Issues in Research

Total credit : 4 (Minimum 48 hr teaching, class room or contact sessions in a Semester)

Marks : 100

Unit-1

Section A: Research Aptitude

- Research Meaning, characteristics and types, career options after research degree
- Identifying a research problem
- Steps of research
- What are different types of research paper, their formats of presentation and publications?
- Thesis writing: its characteristics and format

Section B: Data Management

- Types sources, acquisition and interpretation of data
- Quantitative and qualitative analysis of data

Unit 2

- Graphical representation and mapping of data

Section C: Application of Information and Communication Technology (ICT) in research

- ICT: meaning, advantages, disadvantages and uses
- General abbreviations and terminology of ICT
- Basics of internet and emailing
- Use of internet in research works

Unit 3

- Literature survey of the previous works and searches for articles online and in the library

Section D: Communications Skills

- Review of an article in the relevant field and preparation of a short report
- Scientific presentations (oral and poster)
- Development of communication skills in presentation of scientific seminars, eye to eye contact, facing to audience, question & answer sessions etc.
- One seminar paper preparation in power point (which includes text, graphs, picture, tables, reference etc.)
- Art of scientific writing: Steps to better writing, flow method, organization of material and style, drawing figures, graphs, table, footnotes, references etc. in a research paper
- Use of internet networks in research activities in searching material, paper downloading, submission of papers in different textual templates.

Unit 4

Sections E: Copyright and ethical of research

- Introduction to IPR, patent laws, process of patenting a research finding, copyright cyber laws
- Ethical issues in research: Ethical involving use of animal and human subjects, professional ethical publication ethics
- Protection of environment and biodiversity

PhD-10

Semester I

Paper I (Compulsory module 1 for all PhD programmes)
Paper code. PhD-101

RESEARCH METHODOLOGY, COMMUNICATION SKILLS, COPYRIGHT AND ETHICAL ISSUES IN RESEARCH

Total credits: 4 (Minimum 48 hrs including theory, practicals, tutorials)

UNIT I

Section A: Research aptitude

- Research meaning, characteristics and types, career option after research degree
- Identifying a research problem
- Steps of research
- What are different types of research paper, their formats of presentation and publications?
- Thesis writing: its characteristics and format

Section B: Data Management

- Types, sources, acquisition and interpretation of data
- Quantitative and qualitative analysis of data
- Graphical representation and mapping of data

UNIT II

Section C: Application of information and communication technology (ICT) in research

- ICT: Meaning, advantages, disadvantages and uses
- General abbreviations and terminology of ICT
- Basics of internet and E-mailing
- Uses of internet in research works
- Literature survey of the previous works and searches for articles online and in the library

UNIT III

Section D: Communication Skills

- Review of article in the relevant field and preparation of a short report
- Scientific presentations (oral and poster)
- Development of communication skills in presentation of scientific seminars, eye to eye contact, facing to audience, question and answer sessions etc.
- One seminar paper presentation in power point (which includes text, graphs, picture, tables, reference etc.)
- Art of scientific writing: Steps to better writing, flow method, organization of material and style, drawing figures, graphs, tables, foot notes, reference etc. in a research paper.
- Use of internet networks in research activities in searching material, paper downloading, submission of paper in different textual templates.

UNIT IV

Section E: Copyright and ethics of research

- Introduction to IPR, patent laws, processing of patenting a research finding, copyright cyber laws
- Ethical issues in research :Ethical involving use of animal and human subjects, professional ethical publication ethics
- Protection of environment and biodiversity

Dept. of Pharmaceutics

PCEU-PhD-102

QUALITY ASSURANCE IN PHARMACEUTICAL INDUSTRIES

Total Credit: 4 (Minimum 48 Hr teaching, classroom/contact sessions/Tutorials in a semester)

Unit I

Basic concepts of Quality: Quality objectives, Quality assurance and Total Quality management

Quality Assurance in development and Production: Preformulation studies, development process of medicinal products, pre-approval inspection, production, testing, Process analytical technology (PAT), quality assurance in production, quality by Design (QbD), production hygiene,.

Quality of analytical methodologies: Parameters for quality analysis (specificity, sensitivity, linearity, precision, accuracy, ruggedness and system suitability), stability indicating methods.

Unit II

GMPs: Main principles for pharmaceutical products (fundamentals of validation, DQ, IQ, OQ, PQ, Calibration of instruments, Validation of microbiological and analytical methods). GMPs for starting raw materials (Active pharmaceutical ingredients, pharmaceutical excipients), GMPs for specific pharmaceutical products (sterile, biological, investigational products for clinical trials, herbal medicines, radiopharmaceuticals), Guidelines for area classification and air handling units.

Unit III

Inspections and sampling operations of pharmaceutical products: Inspection planning, Inspection manual, inspection errors, sampling plans, sampling procedures in pharmaceutical industries.

Statistical Quality Control: Shewhart Control Charts and applications in quality control of pharmaceuticals, LCL, UCL, control limits etc.

Unit IV

Good Laboratory Practice (GLP): General Provisions, Organizational structure, Organization of personnel, facilities, sample control, Instrumentation, maintenance and calibration of equipments, Standard Operating Procedures (SOPs), standard test procedures (STPs), product identification system, maintenance of records, reference standards, animal care.

Quality Audits: Raw materials, finished products and analytical procedures, SOPs.

References:

1. FDA, Food and Drug Administration. Guidance for Industry. PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance. U.S. Department of Health and Human Services, 1994.
2. Institute of Medicine of the National Academies. The US Commitment to global health. Available at: http://www.nap.edu/. Accessed November 15, 2010.
3. International Pharmacy Federation (FIP) United Nations Educational, Scientific and Cultural Organization (UNESCO), World Health Organization Pharmacy

Education Task Force. Action plan. Available at: http://www.fip.org/. Accessed October 1, 2010.
4. R. Weinekötter, Compact and efficient continuous mixing processes for production of food and pharmaceutical powders, Trends Food Sci. Tech. 20 (2009) S48–S50.
5. O. Berntsson, L.-G. Danielsson, B. Lagerholm, S. Folestad, Quantitative in-line monitoring of powder blending by near infrared reflection spectroscopy, Powder Technol. 123 (2002) 185–193.
6. E.H. Hardy, J. Hoferer, G. Kasper, The mixing state of fine powders measured by magnetic resonance imaging, Powder Technol. 17 (2007) 12–22.
7. World Health Organisation Expert Committee on Specifications for Pharmaceutical Preparations. WHO Orgun. Tech. Rep. Ser. 418, Annexes 1 and 2. Geneva (1969).

PCEL-PhD-103

PHARMACEUTICAL REGULATORY AFFAIRS

Total Credit: 4 (Minimum 48 Hr teaching, classroom/contact sessions/Tutorials in a semester)

Unit I

Overview of the drug regulatory aspects in various countries- e.g. India, US, European and China- Similarities and differences

Central Drugs Standard Control Organisation (CDSCO): Functions and Responsibilities.

Unit II

Good Regulatory Practices (GRP): Definition; GRP and pharmaceutical industry, Quality and quantity of data, authenticity of data, Dossier structure; obligatory and optional studies, development and registration strategy, Role of GRP after registration of pharmaceuticals, GRP with regards to licensing authorities and supervisory bodies.

Unit III

ICH Guidelines: Quality topics, safety topics, efficacy topics, multidisciplinary, ICH global cooperation, MedDRA

WHO Guidelines: WHO certification scheme on the quality of pharmaceutical products moving in the international commerce, exchange of information, Who International Drug monitoring.

Unit IV

Investigational New Drug: Need of an IND, Content and format of an IND application, Submission of an IND and its review, FDA review of an IND.

The New Drug Application: Overview, laws regulations and guidance, new drug development and approval, NDA development preclinical investigation, new drug application (phase I, phase II, phase III, phase IV and Post marketing surveillance), Contents of the NDA as per Schedule-Y (chemistry, manufacturing, testing, packaging, labeling, controls, pre-clinical, clinical data), Human Pharmacokinetic and bioavailability testing requirements, Common technical document (CTD) for NDA, Submission, review and maintenance of NDA. Hybrid NDA(505(b)2).

Generic Drug Development: Generic drugs, Need of generics, Birth of Generics: The Hatch Waxman Act of 1984, Abbreviated New Drug Application (ANDA), Similarity and Comparison of NDA and ANDA application requirements, Format, submission requirements, Submission to the FDA, Application review by the FDA, Orange book, Bioequivalence testing requirements, requirement of biosimilars, biowaivers, FDA Bioequivalence limits, Para certifications, FDA approval process, Method of preparation of DMF.

References:

1. Investigational New Drug Applications. Code of Federal Regulations, Title 21 (Food and Drugs), part 312. Government Printing Office. April 1, 1995.

2. Guidance for Industry. Content and Format of Investigational New Drug Applications (INDs) for Phase II Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products. Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). Government Printing Office. November 1995.
3. IND Process and Review Procedures. Manual of Policies and Procedures 6030. Center for Drug Evaluation and Research. Revised 6/20/96
4. Approved Drug Products with Therapeutic Equivalence Evaluations, 23rd Edition, 2003. US Government Printing Office
5. Achilladelis B, Antonakis N. The dynamics of technological innovation: the case of the pharmaceutical industry. Research Policy 2001; 30:535–88.
6. Verband Forschender Arznemittelhersteller e.V. [German Association of Research-based Pharmaceutical Companies]. The Pharmaceutical Industry in Germany---Statistics 2008; 2008.
7. Grabowski H. Are the economics of pharmaceutical research and development changing? Productivity, patents and political pressures. PharmacoEconomics 2004; 22:15–24.
8. Mooney KG. Challenges faced by the pharmaceutical industry: training graduates for employment in pharmaceutical R&D. European Journal of Pharmaceutical Sciences 2001; 12:353–9.
9. Schweitzer SO. Pharmaceutical economics and policy. New York: Oxford University Press; 2007.
10. Henry D, Lexchin J. The pharmaceutical industry as a medicines provider. The Lancet 2002; 360(9345):1590–5.
11. Resnik DB. The distribution of biomedical research resources and international justice. Developing World Bioethics 2004;4(1):42–57.
12. Danzon PM, Nicholson S, PereiraF N.S. Productivity in pharmaceutical-biotechnology R&D: the role of experience and alliances. Journal of Health Economics 2005; 24(2):317–39.
13. Epstein RJ. Growth of the Asian health-care market: Global implications for the pharmaceutical industry. Nature Reviews Drug Discovery 2007; 6(10):785–92.

PCEU-PhD-104

PCEU-PhD-104

NOVEL DRUG DELIVERY SYSTEMS

Total Credit: 4 (Minimum 48 Hr teaching, classroom/contact sessions/Tutorials in a semester)

Unit I

Oral Controlled drug delivery systems: Design and fabrication of diffusion controlled, dissolution controlled, osmotic, gastroretentive delivery systems, device mediated controlled drug delivery systems, orally disintegrating systems, biodegradable polymeric delivery systems. Controlled drug delivery polymers, role of polymers in drug delivery, pharmacokinetic/pharmacodynamic basis of oral controlled drug delivery.

Unit II

Transdermal Drug Delivery Systems: Introduction, Skin as a route of drug administration, Types of Transdermal drug delivery systems (TDDS), Preformulation issues, Permeation enhancement techniques, Formulation Design and fabrication, Physiochemical characterization, *In vitro/ ex vivo* skin permeation studies, Mechanism of skin permeation, Skin irritancy test, *in-vivo* pharmacokinetics evaluation, *in vitro-in vivo* correlation, *in vivo* pharmacodynamic evaluation, and stability aspects.

Unit III

Ophthalmic drug delivery systems: Introduction to ophthalmic drug delivery, pharmacokinetic consideration, Novel approaches to ocular drug delivery and evaluations

Mucosal drug delivery systems: Introduction, mucosa as a route of drug administration, types of mucoadhesive drug delivery systems, design and fabrication of mucosal drug delivery systems, *in vitro* and *in vivo* evaluation.

Unit IV

Intelligent drug delivery systems: Magnetically modulated, ultrasonically modulated, electrically regulated, photo-responsve, temperature sensitive, pH sensitive, inflammation responsive, glucose sensitive polymers, urea responsive delivery.

Biochemical and molecular biology approaches to controlled drug delivery: Microparticulate drug carriers, liposomes and stealth liposomes, microspheres, selective endocytosis of macromolecular drug carriers, antibodies for drug delivery, resealed erythrocytes, niosomes.

Miscellaneous forms of new drug delivery systems: Design and fabrication of parenteral, implantable and other forms of drug delivery such as carrier or vector mediated delivery systems for biological macromolecules.

References

1 Robinson J.R. & Vincet H.L. Lee.,1987. Controlled drug delivery, fundamentals and Applications. Vol. 29, 2nd ed. Marcel Dekker, Inc. New York.

2. Edith Methiowitz-Encyclopaedia of Controlled Drug Delivery.,2002. Vol 1 & 2, John Wiley & Sons, Inc.

4. S.P. Vyas and Roop K Khar., 2002.Targetted and Controlled Drug Delivery Novel Carrier Systems, CBS Publishers. New Delhi.

5. Ranade V.V, M.A. Hollinger. 2004. 2nd ed. Drug Delivery systems. CRC press, New York.
6. N.K. Jain, 2001.Controlled Drug Delivery, CBS Publisher, New Delhi
7. A.K. Mitra., 1998. Ophthalmic Drug Delivery System. Vol. 58, Marcel Dekker, New York.
8. Yie W. Chien., 1982. Novel Drug Delivery System, 2nd Ed, Marcel Dekker Inc. New York.

PCEU-PhD-105

PCEU-PhD-105

NANOTECHNOLOGY IN PHARMACEUTICAL SCIENCES

Total Credit: 4 (Minimum 48 Hr teaching, classroom/contact sessions/Tutorials in a semester)

Unit I

Introduction of Nanoparticulate Drug Delivery: Needs and requirements. Use of Nanotechnology in herbo-mineral products of the traditional systems of medicine, Nanotoxicology and Safety evaluation of nano-formulations, Applications of nanoparticulate drug delivery systems in certain relevant therapeutic areas.

Polymeric Nanoparticles as Drug Carriers and Controlled Release Devices: Nanoparticle drug release mechanisms, site specific targeting with nanoparticles, importance of size and surface properties.

Unit II

Drug Nanocrystals/Nanosuspensions for the Delivery of Poorly soluble drugs: Physicochemical properties, production methods, application routes.

Nanocapsules: Preparation, characterization drug release mechanisms and therapeutic applications.

Polymeric Nanoparticles for Delivery in the Gastro-Intestinal Tract: Anatomical and physiological considerations of gastro-intestinal tract for Delivery; Preparation of polymeric nanoparticles, drug delivery in the oral cavity, nanoparticles for delivery of drugs and vaccines in the small intestine, nanoparticles for colon-specific delivery, toxicology and regulatory Aspects

Unit III

Polymer Micelles as Drug Carriers: Polymer micelle structures, drug loading and release, pharmacokinetic and bio-distribution, drug delivery applications.

Polymeric Vesicles and Niosomes as drug carriers: Polymeric Vesicle drug delivery applications, Responsive release, Non-ionic Surfactant Vesicles (Niosomes), Niosome delivery applications.

Microemulsions as Drug Delivery Vehicles: Self-emulsifying drug delivery systems (SEDDS) design and formulation aspects, routes of administration.

Unit IV

Lipidic Core Nanocapsules: Lipidic Nanocapsule formulation and structure, Electrical and biological properties, Pharmacokinetic studies and Biodistribution, drug encapsulation and release.

Lipoproteins: The Structure of lipoproteins, Chylomicron, VLDL, LDL, HDL and Cholesterol-rich Emulsions (LDE) as Pharmaceutical Carriers.

Solid Lipid Nanoparticles: Ingredients and production methods, SLN structure and characterization, The "Frozen Emulsion Model" and alternative SLN models, Nanostructured Lipid Carriers (NLC), Drug localization and release, administration routes.

References

1. Vladimir P Torchilin., 2006. Northeastern University, USA, Nanoparticulates as drug Carriers, Imperial College Press.
2. Thassu. . D., Deleers, M., Pathak, Y., 2007. Nanoparticulate Drug Delivery Systems. Informa Health Care. Vol 166. New York, London.
3. S.P. Vyas and Roop K Khar., 2002. Targetted and Controlled Drug Delivery: Novel Carrier Systems, CBS Publishers, New Delhi.
4. Torchilin, V.,2008. Fundamental biochemical technology, multifunctional pharmaceutical nanocarriers. Vol 4 springer, Boston USA.

Dept. of Pharmacology

(20)

Basic Pharmacology Paper code : PCOL-PhD-102

(Ph.D. Pharmacology)

Topics

Evaluation strategies for new drugs

Unit 1
Drug Receptor interaction studies

Estimation of pD_2 values of two agonists and determination of relative affinity

Estimation of pA_2 values of two antagonists and determination relative potency

Unit 2
Blind screening of drugs

Design of screening

Blind Screening of a CNS depressant

Blind Screening of a CNS stimulant

Unit 3
Clinical trials and Schedule Y

Unit 4
Determinants of inter-individual variation in response to drugs

Estimation of NTs Neurotransmitters (Hist, 5HT)

PCOL-PHD-103

THEORY : SYLLABUS FOR Ph.D. COURSE WORK

SUBJECT : CARDIOVASCULAR PHARMACOLOGY

Paper Code: ~~Ph.D. 103~~ (Ph.D. Pharmacology)

Unit 1

Genetics of human obesity

Effect of environment factors on obesity

Current treatment modalities of obesity

Animal models of obesity

Unit 2

Hypertension: Definition, new concepts and approaches for the treatment of hypertension

Treatment of myocardial ischaemia

Atherosclerosis: Definition, pathogenesis and approaches for the treatment of atherosclerosis

Unit 3

PRACTICAL

To measure the heart rate and the blood pressure (systolic and diastolic BP) in Wistar rats using rat tail cuff method by non-invasive blood pressure (NIBP) recorder.

To induce obesity by feeding high fat diet (20 gm/day/rat, p.o.) for a period of 4 weeks in Wistar rats and measure the body weight gain and body mass index (BMI).

To measure serum apolipoprotein-A and B levels in above model of obesity in Wistar rats.

To measure the fat pad weight (perirenal, epidydimal/uterine, mesenteric) and organs weight (Hear, Liver, Kidney).

Unit 4

To induce obesity by goldthioglucose (single i.p. dose of 300 mg/kg) in Swiss albino mice of either sex, 4 weeks old and measure the body weight, body mass index (BMI) after animals attaining 12 weeks of age.

To measure the obesity biomarker (e.g. leptin, insulin etc.) in above models.
To measure serum apolipoprotein-A and B levels in above model of obesity in Swiss mice.

Paper No = PCOL-PhD-104

PCOL-PhD-104

Neuropharmacology

~~Paper Code 102 C:~~ (Ph.D. Pharmacology)

Unit 1

Molecular mechanisms, markers (biochemical and / or neuroimaging and genetics of:
Epileptogenesis
Alzheimer's disease
Neuronal apoptotic pathways and its significance to neurological diseases
Molecular mechanisms of addiction & treatment strategies

Unit 2
Microdialysis and its applications to Neuropharmacology
Primary neuronal cell cultures
Applications of immunohistochemistry and Confocal microscopy to Neuropharmacology

Unit 3
Practical
Behavioral animal models for screening of drug affecting the following:
Anxiety-like behaviors (Vogel's conflict test, Elevated plus maze)
Depression-like behaviors (Forced swim test, Tail Suspension test)
Learning & Memory (Active/Passive Avoidance, Spontaneous Alternation)
Drugs of abuse (Conditioned place preference)
Locomotor activity (Videopath analyzer)
Motor coordination (rota rod, grip strength test)

Unit 4
HPLC analysis of biogenic amines and their metabolites in brain
Release of neurotransmitters by brain microdialysis

RECOMMENDED READING

- Molecular Pharmacology and Neuroscience textbooks
- Current reviews on the area published in reputed pharmacology/neuorsciences journals in Science direct, Wiley, Bentham science journals etc.

PCoL-PhD-105

Endocrinology (Metabolic Disorder)
~~Paper Code : Ph.D. 102 D~~ (Ph.D. Pharmacology)

Unit 1

Diabetes and Insulin resistance

Newer drugs in treatment of diabetes (DPP-IV modifiers, Incretin / GLP-1 based therapies)

Diabetic Dyslipidemia

Diabetic Cardiomyopathy

Diabetic Nephropathy

Unit 2

Diabetic Retinopathy

Diabetic Neuropathy

Diabetes and memory

Recent advances in the pathophysiology of diabetes

Unit 3

(Practical)

Development of Diabetic model (Type I and Type II)

Estimation of HbA level

Estimation of Insulin in ELISA and by HPLC

DPP IV Assay by ELISA and Flourometry

Estimation of C-reactive protein

Unit 4

Evaluation of Lipid

Evaluation of Adenosine Deaminase activity

Evaluation of OGTT and Insulin Tolerance test

Estimation of microalbumin in urine

Estimation of renin

Paper No: PCOL-PhD-106

PCOL-PhD-106

CLINICAL PHARMACY AND PHARMACOVIGILANCE

~~Paper Code: Ph.D. 102E~~ (Ph.D. Pharmacology)

Unit 1

Clinical Pharmacy Practice, pharmaceutical care and research methods in pharmacy: Concepts of clinical pharmacy practice and managed health care, critical literature appraisal, planning and design of research projects in clinical pharmacy and health services research.

Practical: The instructor and student will pick and prepare a peer-reviewed article (e.g. from journals, study sections) for class discussion that demonstrates of involves innovative epidemiology content or methods.

Prescribing and prescription monitoring: Influences on, and psychology of prescribing, types of prescription, prescription writing, application of evidence based practice in prescribing, framework for practice budgets and cost- effective prescribing, medication errors, concept of audit, monitoring and evaluation of prescribing practice.

Practical: Identification of at least two therapeutic areas in which student intend to do monitoring of treatment charts and prescriptions reviewing. Students are required to identify personal learning outcomes relevant to their chosen therapeutic areas, prescribing and modifying therapy for identified disease conditions.

Pharmacoepidemiology: Introduction to epidemiology, core epidemiologic function, descriptive and analytic epidemiology, data collection, organizing data, types of variables, frequency distributions, measures of central tendency and spread, measures of risks, summarizing and displaying public health data, softwares employed in pharmacoepidemiology.

Practical: The student will be exposed to one basic statistics software and introduced to regression methods. Emphasis will be on modeling driven by actual data from studies in a variety of areas from health. The primary practice will be for multiple linear regression, logistic regression, and Poisson regression. A main goal is to determine what approach to use among the liner and nonlinear models.

Unit 2

Healtheconomics: Economics concept in individual consumer decision making, health care market, concept of health care insurance, Government involvement in healthcare, pharmacoeconomics and comparing different pharmacoeconomic methodologics, Approach and steps for conducting pharmacoeconomic evaluations.

Practical: The students will be taught how to calculate individual cost of drug, direct cost, indirect cost and total cost of prescription, Cost minimization, Cost Effectiveness & Cost Benefit Analyses using simulated case studies.

Post-Marketing Safety Surveillance: An overview of post-marketing safety surveilance (PMSS) in the context of America (FDA), European medical evaluation agency Japan, Asia-pacific and international (ICH-E2C) regulatory requirement. Historical overview of PMSS, the role of epidemiological methods in identifying signals and quantifying, assessing, and preventing

adverse drug reactions (ADR). Initiative of World health organization in global monitoring. Medical/legal issues, benefits and limitations of safety surveillance systems, labeling changes, the ability to refute false signals, and social and ethical obligations inherent in the conduct of PMSS

Practical: Case study will be provided to undertake causality assessments using different type of causality assessment scales (Naranjo's cale, WHO probability scale, European ABO system and Bayesian system)

Good Pharmacovigilance Operations: The mechanics and operations of a pharmacovigilance processing center including organizational structure and the business environment, safety database design and structure, MeDDRA coding, Medicinal Product Dictionary, human resource management, process excellence, continuous quality improvement, and data exchange agreements. Preparation of regulatory documents (such as CIOMS forms and Periodic Safety Update reports) and regulatory inspections and pharmacovigilance QA. Introduction to pharmacovigilance softwares.

Practical: Student will be exposed to one functional pharmacovigilance centre and demonstrated onsite functioning of pharmacovigilance centre and softwares used there. (4 hrs.)

Unit 3

Quantative methods in Pharmacovigilance: Understanding of interpretation of data for decison-making applied statistical principles, quantitative measures of benefit, and exposure estimation. Signaling and surveillance will be covered, along with the interpretation of clinical, post marketing and epidemiologic studies, business metrics, and compliance science. (1 hrs.)

Practical: Students will examine case studies and practice benefit-risk assessment, review methods for quantitative benefit-risk analysis and discuss their practical application in decision making.

The Regulatory and Legal Basis of Pharmacovigilance: Regulatory and legal aspects related to medical devices, over-the-counter products, and drug-device combinations. Partnership agreements, pharmacovigilance aspects of due diligence and licensing and acquisitions, and product liability issues.

Unit 4

Pharmacovigilance in special cases and health care reform: Pharmacovigilance in Pediatrics, Pregnancy, Elderly, Vaccines and Complimentary & alternative medicine. Introduction to concept of health care reform, Government and private sector initiative in national and international scenario. Pharmacy profession and health care reform.

Practical: Case study from the area of special cases will be provided to undertake causality assessments using different type of causality assessment scales (Naranjo's scale, WHO probability scale, European ABO system and Bayesian system)

Drug Monitoring methods: Introduction to therapeutic drug monitoring (TDM), Monitoring free drug concentrations, overview of analytical techniques for measuring concentrations in biological fluid, basic principles of pharmacokinetics and TDM, clinical utility of TDM, post analytical issues (handing individual differences, interferences and pitfalls), Prediction techniques for dose optimisation, Pharmacoeconomics of TDM.

Practical: Estimation of concentration of at least two drugs in biological fluid. This include running of at least one standard curve, one precision and accuracy batch and determination of spiked unknown concentration for each drug.

Books recommended

McCarthy RL and Schefermeyer KW. Introduction to healthcare delivery: A primer for Pharmacist

Strom BL and Kimmel EL. Text book of pharmacoepidemiology. John Wiley & sons Ltd.

Mann R D and Andrew E B. Pharmacovigilance. John Wiley & sons Ltd.

Dasgupta A. Handbook of Drug Monitoring Methods. Humana Press Inc.

Dept. of Pharmaceutical Chemistry

(28)

PCHE-PDD 10 2

ADVANCED ORGANIC CHEMISTRY

Total Credits: 3 (Minimum 45 hrs. Teaching programme / Contact session / Tutorials in Semester)

Unit I

Chemistry of protecting groups: Protection of alcohols, carbonyl, and carboxylic, amino and phenolic groups.

Unit II

Reactions of synthetic importance: Benzilic acid rearrangement, Hoffman's rearrangement, Birch reduction, Fischer indole synthesis, Wagner-Meerwein rearrangement, Pachman reaction, Friedel craft acylation.

Reagents in Organic Synthesis: Pyridinium chloride, Organo-lithium reagent, Fetizon's reagent (Ag_2CO_3 / celite), Osmium tetraoxide (OSO_4), pyridinium chloro-chromate (PCC); 2, 2'-Dipyridyl disulphide; palladium diacetate, Fenton's Reagent.

Unit III

Green Chemistry: Principles, Metrics, Perspectives of Pharmaceutical Industries, green discoveries, greener reactions, catalysis, alternative reaction media, greener technology, sustainable synthesis of Pharmaceuticals, Importance of Green Chemistry in Drug Discovery.

Unit IV

Assymetric Synthesis: Prochirality, Substrate and product sclectivities, Aspects of Stereo and Reterosynthetic methods, Concept of Asymmetric synthesis, determination of enantiomeric purity, stereoselective C-C bond formation.

Recommended Books:

1. M. F. Deorge, Wilson & Gisvold's, A text book or Organic Medicinal & Pharmaceutical Chemistry, 12th ed., J. Lippincott. Co. Philadhelphia USA.
2. G. L. Patrick, An Introduction to Medicinal Chemistry. 2nd ed., Oxford University Press, New York, USA.
3. J. March, Advance Organic Chemistry- reaction mechanism and structures, John Wiley & Sons. New York, USA.
4. V. K. Ahluwalia, R. Aggarwal. Organic Synthesis: Special Techniques, Narosa Publishing House, New Delhi.

5. V. K. Ahluwalia, M. Kidwai, New Trends in Green Chemistry, Anamaya Publishers, New Delhi, 2006.

6. J. H. Clark, D. J Macquarrie, Handbook of Green Chemistry and Technology, Wiley-Blackwell, 2002.

7. R. E. Gawley, Principle of Assymetric Synthesis, Elsevier.

8. S. G. Dutta, A new look at Stereochemistry: Concept and Mechanism, Macmillan Publishers, New Delhi.

9. B. P. Mundy, M. G. Ellered, F. G. Favarrio, Name Reactions and Reagents in Organic synthesis, 2nd ed., John Wiley & Sons, New York, USA.

30

SPECTROSCOPIC METHODS PCHE-PhD-103

Total Credits: 3 (Minimum 45 hrs. Teaching Programme / Contact session / Tutorials in Semester)

Unit I

Infrared Spectroscopy:

- Features of IR
- FT-IR: Theory and its Applications
- Interpretation of IR spectrum of drugs mentioned in IP (Paracetamol, Isoniazid, Aspirin, Phenytoin, Benzylpenicillin)

Unit II

Nuclear Magnetic Resonance Spectroscopy:

- ^{1}H-NMR, ^{13}C-NMR and 2D- NMR(COSY) and DEPT
- Interpretation of ^{1}H-NMR and ^{13}C NMR spectrum of Ethyl acetate, Ethyl Benzene, Ibuprofen, Paracetamol, Phenyl Ethyl acetate, Isoniazid

Unit III

Mass Spectroscopy:

- Interpretation of Mass spectrum of Papaverine, Nicotine, Ephedrine, Hygrine, Quercitin, Caffeine.
- Tandem mass spectrometry
- Applications of LCMS, GCMS

Unit IV

Ultraviolet Spectroscopy:

- Types of transitions
- Qualitative and quantitative analysis
- Woodward's rule
- UV absorption of flavonoids, Coumarins, Carotene

Recommended Books:

1. R. M. Silverstein, F. X. Webster, Spectroscopic Identifications of Organic Compounds, 6th ed., New York.
2. W. Kemp, Organic Spectroscopy, 3rd ed., Macmillan Humsphire, U. K.
3. D. H. Williams, I. Fleming, Spectroscopic Methods in Organic Chemistry, Tata Mc-Graw Hill, Publisher, New Delhi.
4. D. L. Pavia, G. M. Lampman, G. S. Kriz, Introduction to Spectroscopy, 3rd ed., Harcourt college Publishers, Philadelphia, USA.
5. Jagmohan, Organic Spectroscopy: Principles and Applications, Alpha Science International Ltd.
6. Y. R. Sharma, Elementary Organic Spectroscopy- Principle and Chemical Applicaions, S. Chand. Group Publisher, Delhi.
7. P. S. Kalsi, Spectroscopy of Organic Compounds, 6th ed., New Age Publications.
8. H. H. Willard, L. L. Merritt, J. A. Dean, International Methods of Analysis, Van Nostrend Reinold, New York, USA.

DRUG DESIGN & MOLECULAR MODELING PCHE-PhD-104

Total Credits: 3 (Minimum 45 hrs. Teaching Programme / Contact session / Tutorials in Semester)

Unit I

Methods and recent development in computer aided drug design and its limitations.

Unit II

Docking: Molecular, Rigid, Flexible and manual.

Introduction to Molecular modeling and its application in Drug Discovery.

Molecular graphics and applications.

Unit III

QSAR (Hammett equation, Hansch equation, Craig Plot, Topliss Scheme), Types of QSAR (1D, 2D, 3D), Descriptors (Electronic and Steric parameters), Selection of Descriptors for QSAR.

Unit IV

Identification of pharmacophore, Concept of conformational analysis and its role in designing of drugs.

Recommended Books:

1. E. J. Ariens: Drug design, Academic Press, New York.
2. R. F. Doerge, Wilson and Gisvold's, Text Book of Organic Medicinal and Pharmaceutical Chemistry, 12th ed., J. Lippincott Co. Philadelphia, USA.
3. S. N. Pandeya, A Text Book of Medicinal Chemistry, Vol. II, 3rd ed., S. G. Publishers, Varanasi.
4. A. Kar, Medicinal Chemistry, 5th ed., New Age International Publishers.
5. V. Alagarsamy, Text Book of Medicinal Chemistry, Vol. II, Elsevier.

Paper No= PCHE-PHD-105

PCHE-PHD-105

CHEMISTRY OF NATURAL PRODUCTS

Total Credits: 3 (Minimum 45 hrs. Teaching Programme / Contact session / Tutorials in Semester)

Unit I

General classes of natural products, isolation including extraction strategy, structural elucidation along with spectral characterization of alkaloids, terpenoids, steroids, flavanoids and other phenolic compounds.

Unit II

Identification, characterization techniques such as chemical and various spectroscopic methods of medicinally active principle (Atropine, Ephedrine, Ergotamine).

Unit III

Synthetic method of some important natural compounds: Coumarins, Quercetin, Rutin, Lupeol.

Unit IV

Chemistry of medicinally useful naturally occurring compounds:

- Anticancer: Vinca alkaloids, Podophyllotoxin
- Antidiabetic: Insulin
- Antioxidants: Rutin, Kaempferol

Recommended Books:

1. I. L. Finar, Organic Chemistry, Vol. I & II, Book Society and Longman Group, London.
2. S. N. Pandeya, A Text Book of Chemistry of Natural Products, 1st ed., S. G. Publisher, Varanasi.
3. K. B. G. Torsell, Natural Products Chemistry, John Wiley & Sons, New York, USA.
4. G. A. Cordell, Introduction to Alkaloid, John Wiley & Sons, New York, USA.
5. M. E. Wolff, Burger's Medicinal Chemistry and Drug Discovery: Principle and Practice, John Wiley & Sons, New York, USA.

Dept. of Pharmacognosy & Phytochemistry

35

Department of Pharmacognosy and Phytochemistry

Faculty of Pharmacy; Jamia Hamdard

Syllabus for PhD Examination

PCOG-PHD-102

4 hr/week

Drug Discovery from Natural Sources

UNIT 1:

- Different approaches for the discovery of new drugs from natural sources.
- Problems associated with drug discovery and its sources.
- New strategies and better methods for the extraction, isolation and characterization of natural products.
- Plant selection criteria along with the issue related to biodiversity and IPR, plant collection, prioritization, analytical techniques, structural elucidation, biological testing, new sources of natural products and biosynthesis.
- Composite extracts and isolated compounds
- Importance of finding and designing new molecules
- Information resources on natural products

UNIT 2:

- Bioactivity directed fractionation of natural drugs
- High throughput and Medium throughput screening of natural products.
- Herbal and Modern drug interaction.

UNIT 3:

Single phytoconstituents as therapeutics- including history, isolation, test and assays: Podophyllotoxins, Paciltaxel, Silymarin, Reserpine, Artimisinin, Digitoxin, Curcumin, Quinine, Ephedrine, Morphine, Camptothecine, Vincristine and Vinblastine.

36

Paper No- PCOG-PhD-103

PCOG-PhD-103

4 hr/week

Quality Control and Phytochemical Techniques

UNIT 1: SHA

Advanced extraction, Isolation and Characterization techniques

Supercritical fluids extraction (SFE), microwave assisted extraction, ultrasound assisted extraction, solid phase micro extraction, centrifugally accelerated chromatography, preparative HPLC and MPLC/ flash chromatography for isolation of lead molecules, NMR, LC-MS.

UNIT 2: SHA

Quality control of herbal medicinal products

- Overview of Pharmacoepeial monographs of API, UPI,USP, EP, IP and BP;
- General monographs on quality and other issue related publications
- Guiding monographs of WHO, ESCOP and ICMR
- Quality control and use of excipients in traditional medicines and stability studies of herbal medicinal products. Determination o f contaminants (microbial load, aflatoxins, pesticide residues and heavy metals)

UNIT 3: VA

Assay methods: Methodology to use standards and finding other sources to generate the PRS.

- Phytochemical Reference Standards (PRS), Source and preparation of PRS
- Fingerprint techniques: UV, HPTLC, HPLC, IR, GC, GC-MS and RIA
- Analytical method development for the markers and Validation assays

UNIT 4: VA

Bioassays and molecular analysis

- Molecular, enzyme and cell based assays for bioevaluation. Gene expression
- Safety evaluation of botanicals
- ELISA, Flowcytometry, PCR, DNA Fingerprints- RAPD, AFLP, ISSR.
- Determination of IC/ EC 50 value. Pharmacokinetics of botanicals using chromatography.

Paper No = PCOG-PhD-104

4 hrs/week

PCOG-PhD-104

PLANT BIOTECHNOLOGY

Unit 1

- Historical background, Tissue culture media and role of each ingredient.
- Types of cultures, significance of tissue culture in micro-propagation of MAP.
- Application of PTC in production of secondary plant metabolites with specific reference to production of biologically active constituents.
- An overview of plant tissue culture industries and their products.

Unit 2

- Transformation, rhizogenesis and hairy root culture.
- Role of microbes in genetic modification of plant cells and organs.
- Various techniques of increasing the production of secondary metabolites in cultured cells
- Metabolomics.

Unit 3

- Immobilization techniques and their use in secondary metabolite production.
- Optimized protocols for in-vitro production of paclitaxel, shikonine, rosamarinic acid and gensenosides.

Unit 4

- Principles of plant conservation biotechnology, its method, techniques and procedure.
- Molecular approach to assess plant diversity.
- Biotechnology in creation, conservation and sustainable utilization of elite germplasm.

Paper No = PCOG-PhD-105

PCOG-PhD-105

PhD in Pharmaceutical Biotechnology

Paper 1

BIOPROCESS & BIOCATALYSIS

Total: 45 hr, 3 hr per week

Unit 1: Fermentation media screening & optimization studies; Scale up studies; isolation, screening, development of microbial strains; growth kinetics.

Unit 2: Solid state & submerged fermentation process; bioreactor for SSF; applications of SSF.

Unit 3: Down streaming of extra cellular & intracellular secondary metabolites like menaquinone , Lovastatin, Pravastatin and Astaxanthin & proteins like nattokinase and asparaginase.

Unit 4: Biotransformation of natural products like ferulic acid, eugenol and glycyrrhizin, withaferin by enzyme & microbial immobilizations; study of enzyme kinetics and the role of enzyme reactors.

Paper No = PCOG-PhD-106

PCOG-PhD-106

PhD in Pharmaceutical Biotechnology

Paper :

Biological evaluation (in-vitro)

Total: 45 hr, 3 hr per week

Unit 1: Animal cell culture media; Development and maintenance of cell lines; Screening of cytotoxic, anti-diabetic and hepato-protective drugs under in-vitro conditions; Molecular target based and enzyme based bioassays.

Unit 2: Analysis of nucleic acid & proteins; gene targets & silencing; protein engineering.

Unit 3: Formulation of protein & peptide drugs; stability and quality control of protein & peptide formulations, Drug Targeting.

Unit 4: Production and Purification of biopharmaceuticals like insulin, growth hormones, therapeutic monoclonal antibodies & viral vaccines.

40

REVISED SYLLABUS

FOR

COURSE WORK OF PhD PHARMACEUTICAL MEDICINE

(Applicable from 2016)

Faculty of Pharmacy

Jamia Hamdard

New Delhi 110062

(91)

Paper Code PM-PhD-102

DRUG DISCOVERY AND DEVELOPMENT

(Core module 1 for PhD Pharmaceutical Medicine)

Total credits: 4 (Minimum 48 hrs including theory, tutorials, practicals/seminars)

UNIT I ***Drug discovery and development process*** ***15hrs***

- An overview of whole process of drug discovery starting from target identification, validation and selection to designing lead candidates, pre-clinical and clinical drug development.
- Role of combinatorial chemistry, high throughput screening, genomics, proteomics, biotechnology and bioinformatics in drug development
- Pre-clinical toxicity testing as per OECD guidelines and Schedule Y

UNIT II ***Clinical Trials*** ***15 hrs***

- Types and phases of clinical trials and clinical trial documents including Investigator's brochure, SOPs, ICFs, CRFs etc.
- Clinical Project management: Volunteer recruitment, inclusion and exclusion criteria; within-trial decisions e.g. code-breaking, premature termination; monitoring; emergency coverage etc.
- Design of clinical trials in special disease conditions including Angina pectoris, Epilepsy, AIDS, Asthma etc.

UNIT III ***Ethical considerations in clinical drug evaluation*** ***8hrs***

- Scope and role of ethics committees, registration of ethics committees, clinical trial registries
- Ethical issues in vulnerable population, compensation to subjects for clinical trial related injuries.

UNIT IV ***Regulatory Affairs*** ***10hrs***

- Background to and general principles of medicines regulations, Practical inputs of international bodies e.g. WHO, CIOMS and national agencies
- Comparative regulation of countries: USA, EU, Japan, India and other geographies etc., GCP guidelines: ICH and Indian
- Process of IND, NDA and ANDA submission
- Regulations of traditional and herbal remedies

42

20/5/16 20/5/16 20 May 2016

Paper Code PM-PhD-103

CLINICAL PHARMACOLOGY

(Core module 2 for PhD Pharmaceutical Medicine)

Total credits: 4 (Minimum 48 hrs including theory, tutorials, seminars)

UNIT I ***Patient centred therapeutics*** ***10 hrs***

- Special considerations for clinical studies and prescribing in children, elderly, pregnant and breast-feeding women
- Therapeutic drug monitoring

UNIT II ***Essential medicines and Drug utilization studies*** ***10 hrs***

- Concept of essential medicines, WHO and Indian list of essential medicines
- Drug utilization studies and its impact on rational drug use
- Basic concepts of GLP and GCLP

UNIT III ***Pharmacogenomics, Pharmacoeconomics, Pharmacoepidemiology*** ***15hrs***

- Pharmacogenomics and personalised medicine, determinants of inter-individual/ genetic variation in response to drugs, methods and applications
- Pharmacoeconomics: basic concepts, importance and methods of analysis
- Pharmacoepidemiology: its significance and methods

UNIT IV ***Biomarkers in clinical drug development*** ***13hrs***

- An introduction to biomarkers, different types of biomarkers, use of biomarkers and surrogate end points, biomarker development
- Biomarkers related to diseases of the cardiovascular and central nervous system

43

20/5/16

20/5/16

20 May 2016

Paper Code PM-PhD-104

CLINICAL PHARMACOKINETICS AND BIOEQUIVALENCE STUDIES

(Core module 3 for PhD Pharmaceutical Medicine)

Total credits: 4 (Minimum 48 hrs including theory, tutorials, practicals/seminars).

UNIT I **Basics of *Clinical Pharmacokinetics and Generic drugs*** ***10 hrs***

- Introduction to ADME, concepts of half-life, volume of distribution, clearance
- Generic drugs: genesis and legislations
- PK-PD modelling
- Concept of follow-on biologics, biosimilars and biobetters

UNIT II ***Practical aspects of clinical BA/ BE studies*** ***15hrs***

- Bioavailability and bioequivalence studies, approaches and challenges to establish bioequivalence
- Protocol designing, reporting and statistical considerations in design and analysis of bioequivalence studies.
- Complete process of conducting BA/BE study from volunteer recruitment and screening process, obtaining informed consent to study initiation, randomization and blinding techniques, dosing process, compliance assessment, run-in and wash-out periods, withdrawal and dropout of a study subject and compensation guidelines in such cases etc.

UNIT III ***Bioequivalence regulatory requirements*** ***8hrs***

- Bioequivalence regulatory requirements in India and comparison to large generic markets such as US, Europe, Brazil, Australia etc.
- Management and documentation of SAE as per Indian regulatory guidelines and compensation guidelines

UNIT IV ***Drug safety & Pharmacovigilance*** ***15 hrs***

- Assessment and classification of adverse events and adverse drug reactions, evidence for association and causality, causality assessment methods & scales
- Pharmacovigilance methods and software, periodic safety update reports

44

20/5/16.

20/5/16.

20 May 2016

MINUTES OF THE MEETING OF BOARD OF RESEARCH STUDIES HELD ON
MAY 20, 2016 IN FACULTY OF PHARMACY

A meeting of the Board of Research Studies of Faculty of Pharmacy was held on 20/5/2016 at 9:30am in the office of the Dean, Faculty of Pharmacy. The following members were present:

Prof. Asgar Ali	Chairman
Dr. Raj Kumar Shirumalla	External Expert Member
Prof. C. L. Kaul	Special Invitee
Prof. S. Raisuddin	Advisor (Research)
Prof. S. H. Ansari (Head, Dept. of Pharmacognosy & Phytochemistry)	Member
Prof. Anees A. Siddiqui (Head, Dept. of Pharmaceutical Chemistry)	Member
Prof. Farhan J. Ahmad (Head, Dept. of Pharmaceutics)	Member
Prof. Nilanjan Saha (Head, Dept. of Pharmacology)	Member
Prof. Nadeem Siddiqui	Member
Prof. Mohd. Amir	Member
Prof. Divya Vohora (In-charge, Pharmaceutical Medicine)	Member
Dr. Gita Chawla	Member
Dr. Kiran Dubey	Member

The Chairman welcomed the members of the Board of Research Studies and informed them about the recent achievement of Faculty of Pharmacy securing third position in the NIRF ranking recently released by Ministry of HRD, research programmes and publications of research papers. Prof. Arvind Bansal couldn't attend the meeting due to pre-occupation.

Agenda Item- 1: To approve the synopsis and title of the research work being carried out by the research scholars for their PhD degree in different Departments of Pharmacy and Ph.D. in Pharmaceutical Medicine.

BRS examined and discussed the DC approved research topics of the proposed research work of the candidates of different departments in Pharmacy (the changes suggested by the members if any, are mentioned in attached **Annexure I, II, III & IV**).

BRS approved that date of registration will be from the date of fee deposit or joining in the Department whichever is later after the offer of the PhD admission.

45

Agenda Item-2: To approve the revised PhD course work syllabus and bye-laws of Ph.D. in Pharmaceutical Medicine and Ph.D. in other disciplines of Pharmacy

The matter of adopting common Ph.D. course work bye-laws of Faculty of Pharmacy for Ph.D. in Pharmaceutical Medicine was discussed by the BRS members. Previously, Ph.D. in Pharmaceutical Medicine was following separate bye-laws and was undergoing two semesters of course work while all other departments in Faculty of Pharmacy were following common bye-laws having one semester of course work as per the requirements for Ph.D. in line with UGC regulations 2009. In order to maintain uniformity of Ph. D. Pharmaceutical Medicine with other PhD programs of Faculty of Pharmacy, it was decided to reduce its duration of course work from two semesters to one semester. The same was recommended in the DC meeting dated 22nd March 2016. The revised bye-laws for PhD Pharmaceutical Medicine were therefore incorporated in the revised common bye-laws of Faculty of Pharmacy. The BRS recommended that there will be three papers (4 credits for each paper i.e. total 4X3=12 credits) i.e. one compulsory paper on "Research Methodology, Communication skills, Copyrights and Ethical issues in Research", one core/elective paper of the department and one elective paper from cross-disciplinary area from another Department or Faculty.

In other discipline of Faculty of Pharmacy, common bye-laws for Ph.D. course work were also revised. BRS approved to remove the sessional examinations (in line with the course work of other Faculties of the University) and include only end semester examination of 100 marks for all three papers (one paper on "Research Methodology, Communication skills, Copyrights and Ethical issues in Research", one core/ elective paper and one interdisciplinary paper from other Department or Faculty).

The revised Ph.D. course work bye-laws of various disciplines of Faculty of Pharmacy and Pharmaceutical Medicine in the Faculty are given as **Annexure V**.

The syllabus of Ph.D. course work of Pharmaceutical Medicine was also revised and included choice-based core modules in line with other Ph.D. programs. The revised syllabus was approved by the BRS and will be applicable from the current batch of students (**Annexure-VI**).

Agenda Item-3: Recognition of Prof. R. C. Jiloha and Dr. Anjali Kumar as co- supervisor for Ph.D. thesis of Pharmaceutical Medicine in Faculty of Pharmacy (CV enclosed, **Annexures VII and VIII**).

BRS examined the bio-data of Prof. R. C. Jiloha and Dr. Anjali Kumar and keeping in view their experience in clinical practice and contribution in the project work of the candidates, the members of the BRS unanimously recognized them as **co-supervisor** for Ph.D. program in Pharmaceutical Medicine in Faculty of Pharmacy.

Agenda Item-4 To report the minutes of the DC meetings held in different departments of Faculty of Pharmacy

The minutes of DCof different departments viz Pharmacognosy and Phytochemistry (DC held on 8th April 2016), Pharmaceutical Medicine (DC held on 22nd March 2016), Pharmacology (DC held on 20th Jan 2016), Pharmaceutics (DC held on 6th Jan 2016) and Pharmaceutical Chem (DC held on 24th Feb & 19th May 2016) were reported in BRS and

approved for thesis submission as recommended by the respective DC subjected to fulfilment of all applicable criteria at the time of submission of thesis. It is pertinent to apprise that as per PhD bylaws 2009- page No 15 " The Candidate may be allowed to submit the thesis, if DC is satisfied with the performance of the student (pre thesis submission presentation) and the candidate has met all the requirements of tenure, attendance, publications, seminar, PhD Course work and plagiarism etc". However, the other items recommended by the DC of respective departments, but not placed before BRS separately shall have to be reported in the forthcoming BRS i.e. Change in research topic, (major/minor), change in name of supervisor/co-supervisor, Extension in span period etc. (All attached, **Annexure IX**)

Agenda Item-5: Any other item with the permission of the Chair

A. **To consider the request of Mr. Ankit Srivastava, MOU candidate, regarding permission to undertake their (AcSIR) Ph.D. course work at CSIR-IGIB**

Mr. Ankit Srivastava, a MOU candidate from CSIR-IGIB, registered in the Department of Pharmacology, Jamia Hamdard had given an application to Advisor (Research) on 29/7/2015 regarding permission to undertake Ph.D. course work at CSIR-IGIB. He has completed the Ph.D. course work of Academy of CSIR (AcSIR) and submitted his credit details and grades. He has completed 14 credits including 9 papers on various subjects including paper on research methodology (**Annexure X**).

In candidates supposed to for common discussion held on 1.11.??

BRS reviewed the details of the courses and equivalence was considered for the course work completed by the candidate at Institute of Genomics and Integrative Biology. The course work of AcSIR was unanimously approved by the committee to suffice the course work requirements of the candidate registered in Jamia Hamdard.

B. **To approve the panel (lists) of external examiners for Ph.D. thesis evaluation and viva-voce examinations for Ms. Rachna Arora/Gulati (Pharmaceutical Medicine), Ms Shehla Najib (Pharmacognosy & Phytochemistry), Mr. Rikeshwer Prasad Dewangan (Pharmaceutical Chemistry) and Mr. Rahmat Ali (Pharmaceutical Chemistry)**

In a letter dated 17/5/16 by the Controller of Examination regarding preparing additional panel of examiners for the thesis work of 4 candidates of various disciplines of Faculty of Pharmacy as the pool of examiners proposed by the Faculty were not appropriate with regard to the specialized area of thesis work of a particular scholar.

In this regard, HOD/ Supervisors of the candidates provided additional names of examiners in the area of the Ph.D. work of the respective candidates showing the evidence of published work. BRS reviewed the panel and approved the same for the respective candidates and also for future use for the work of other Ph.D. scholars working in similar area (**Annexure XI**).

47

3. To approve the minor correction of typographic error in the title of the following candidates (Annexure XII):

S. No.	Name of the candidate	Title of research	Corrected title of research approved in this BRS	Remarks
1.	Neelam Kaushal	Bone mineral density and associated risk factors in North Indian urban population in tertiary care setting a cross-sectional retrospective study	Bone mineral density and associated risk factors in North Indian urban population in tertiary care setting: A cross-sectional retrospective study	BRS approved (the addition of colon ":" and capital "A") as minor change.
2.	Sobiya Zafar	Nonocarrier approach for combinatorial delivery of docetaxel and a neutraceutical agent in solid tumor management	Nanocarrier approach for combinatorial delivery of docetaxel and a nutraceutical agent in solid tumor management	BRS approved the spelling correction (of "nanocarrier" and "nutraceutical") as minor change

Meeting ended with thanks to the Chair.

Submitted for approval please.

Prof. Asgar Ali
Dean, Faculty of Pharmacy

Hon'ble Vice Chancellor

11/7/16

48