RK University (Pre-registration coursework for PhD program)

Program – PhD (Pharmacy)

Concerned Dean – Dr. T. R. Desai (email – trdesai@rku.ac.in)

Sr. No.	Subject	Contents	Method of evaluation	Credits
1.	Research methodology	As per syllabus mention below	Written examination (3 hrs)	4
2.	1. Pharmaceutical Biostatistics & Patent 2. Pharmaceutical Toxicology 3. Pharmacoepidemiology and Pharmacovigilance 4. Modern Analytical Techniques	Research topic specific	Written examination (3 hrs)	4
3.	Review work	Review of literature for the PhD research topic	Presentation + Detailed report in hard copy	3
Total				11

Notes –

1. The admission process of PhD program will comprise of 2 stages viz. (a) admission to PhD program (b) final registration in PhD program.
2. A successful PhD candidate (RAT examination) will be admitted to PhD program after paying admission fees (Rs. 60000/-) and upon allocation of a PhD guide by RK University.
3. An admitted PhD candidate will have to submit synopsis and presentation of his/her actual research project (in consultation with the PhD guide approved and allocated by RK university) before Doctoral Research Committee (DRC) within 6 months from date of admission(date will be declared by university).
4. An admitted PhD candidate will be registered after earning minimum of 11 credits as per above mentioned course-work structure.
5. The candidate will acquire credit of a subject on passing the examination that will be conducted at the end of 6 months (date will be declared by university).
6. On acquiring required credits, an admitted candidate will be issued a certificate of registration (along with project title) by RK University.

Course Title	Research Methodology

Detailed syllabus

A Research:

Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) and objectives of research, phases of research.

B Research Design:

Review of Research Literature: Purpose and use of literature review, locating relevant information, use of library & electronic databases, preparation & presentation of literature review, research article reviews, theoretical models and frame work. Identification of gaps in research, formulation of research problem, definition of research objectives.

C Documentation:

a. ―How‖ of documentation

b. Techniques of documentation

c. Importance of documentation

d. Use of computer packages in documentation

D Research Publication:

Thesis, Research paper, Review Article & Technical Reports: Organization of thesis and reports, formatting issues, citation methods, references, effective oral presentation of research. Quality indices of research publication: impact factor, immediacy factor, H- index and other citation indices.

E Presentation (especially for oral presentation):

Importance and types of different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage fright, volume of pitch, speed, pause & language, Visual aids & seating, Questionnaire etc.

F Cost analysis of the project:

Cost incurred on raw materials, Procedure, instrumentations and clinical trials.

G Sources for procurement of research grants:

International agencies, government and private bodies.

H Industrial-institution interaction:

Industrial projects, their feasibility reports, interaction with industries.

I Research Ethics and Morals:

Issues related to plagiarism, collaborative models and ethics, acknowledgements. Intellectual Property Rights: copy rights, copy left: patents, Industrial designs, Trademarks.

Reference Books:

1. Research Methodology, Methods & Techniques, C.R. Kothari, Viswa Prakashan, 2nd Edition, 2009.
2. Research Methods- A Process of Inquiry, Graziano, A.M., Raulin, M.L, Pearson Publications, 7th Edition, 2009.
3. How to Write a Thesis:, Murray, R. Tata McGraw Hill, 2nd Edition, 2010.
4. Writing For Academic Journals, Murray, R., McGraw Hill International, 2009.
5. Writing for Publication, Henson, K.T., Allyn &Bacon, 2005.
6. What is this thing called Science, Chalmers, A.F., Queensland University Press, 1999.
7. Methods &Techniques of Social Research, Bhandarkar & Wilkinson, Himalaya publications, 2009.
8. Doing your Research project, Bell J., Open University Press, Berkshire, 4th Edition, 2005.
9. A Handbook of Academic Writing, Murray, R. and Moore, S., Tata McGraw Hill International, 2006

Course Title	Pharmaceutical Biostatistics & Patent

Detailed syllabus

A.

Biostatistics introduction, its role and uses, collection, organization, graphic & pictorial representation of data, measurement of central tendencies & dispersion; degree of freedom, standard deviation, standard error, Coefficient of variation, Probability, Sample and Sampling methods.

B.

Estimation and Hypothesis testing, null Hypothesis, confidence level, Point & interval estimation, concept of hypothesis testing & types of error, Student t' test, Chi-Square test.

C.

Linear regression and correlation, analysis of variance (one way & two way), Factorial design.

D.

Brief review of non parametric tests, experimental design in clinical trials, statistical test for bioequivalence, Dose-Response study, statistical quality control; validation, optimization techniques & screening design, significance of coefficient of correlation, non- linear regression, application of software for statistical calculations.

E.

Patents definition, need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, Important patent related websites.

F.

Brief introduction to trademark protection and WTO patents, Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application.

Course Title	Pharmaceutical Toxicology

Detailed syllabus

Section- I

- **Introduction to Pharmaceutical toxicology:**
- History and introduction of Pharmaceutical toxicology
- Classifications of toxicity
- Principles of Toxicology: toxicokinetic and toxicodynamic, routes of exposure, Dose-Response Relationship

- **Cellular and molecular toxicology**
- Cell signaling and receptor mediated toxicity-Ion channels: Receptors linked to protein kinases and phosphatases, intracellular receptors.
- Calcium mediated toxicity: Excitory amino acid toxicity.
- Cytokines toxicity: Steroid hormone induced toxicity.
- Apoptosis, necrosis and comparison
- Toxicogeneomics and microarray: Early predictions, impact to reduce attrition in drug development.
- New assays: New procedures of evaluation, phototoxicity, coment assay, modified assay, transgenic bioassays, neonatal bioassays, validation procedures, uses and limitations.
- In-vitro bioassays:Predictive and mechanistic toxicology, different cell lines their use and limitations.

- **Toxicity and therapetuic management:**
- Organophosphorus compounds, Carbamates and Organochloro compounds, Aluminum phosphide.
- Paralytic agents like Curare
- Alcohols
- Tobacco and Marijuana
- Pulmonary/Inhalation toxicants: Carbon monoxide, Carbon dioxide
- Occupational and industrial toxicology
- Toxicology of heavy metals
- Snake toxins Anti-Snake Venom

4. Mutagenicity:

- Mechanisms of mutagenesis, types of mutations; DNA repair mechanism.

5. Drug abuse and dependence

Section- II

6. Adverse drug reactions, drug-drug and drug-food interactions.

7. Overdosage and its management:

CNS: Antidepressants, Opiod and non-opiod analgesics, Sedatives, Hypnotics & Anxiolytics, Antiepileptic drugs and lithium

CVS: Anti-Hypertensive (Calcium Channel Blockers, Beta Blockers, ACE inhibitors), Digoxin, NO, anti-coagulants

Endocrine: Hypoglycemic Agents, glucocorticoids and androgens

GIT: H2 blockers, PPIs, antacids,

Respiratory system: Bronchodilators

Chemotherapy: Anti-cancer agents, beta-lactum antibiotics, aminoglycoside antibiotics, Chloramphenicol, tetracycline, anti TB agents, anti-viral agents.

8. Interpretaion of various data for determination of hematological, liver, heart, kidney toxicities.

9. Management of toxicities by:

- Hemodialysis / Hemoperfusion
- Gastric Lavage and Methods of toxin elimination
- Activated charcoal and Antidotes

10. OECD guideline for

- Acute Toxicity
- Sub-acute toxicity
- Chronic/Carcinogenicity toxicity

- **11. ScheduleY:** Design non-clinical toxicity studies

Single dose and repeat dose toxicity studies:Factors influencing such studies such as species, sex, size, route, dose level.

Reproductive toxicology assessment of male reproductive toxicity:

Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; alterations in reproductive endocrionology; relationship between maternal and developmental toxicity.

Carcinogenesis and mutagenesis

Dermal toxicity studies

Occular toxicity studeies etc.

Determniation of LD50

References:

- Text book of Forensic Medicine and Toxicology by V.V. Pillay, 15th Edition, Paras Medical Publishing, Hyderabad.
- Fundamentals of Forensic Medicine and Toxicologyby R. Basu, Publishers-Books and Allied (P) Ltd, Kolkata.
- Guharaj Forensic Medicine, 2ndEdition by P.V. Guharaj, Edited by M.R. Chandran, Orient Longman, Hyderabad.
- Molecular Toxicology by P. David Josephy
- Pharmacotherapetuics by Rang and Dale
- Essential of pharmacotherapeutics by KD Triphati
- Advances in Molecular Toxicology by James C. Fishbein
- Cellular and Molecular Toxicology and In Vitro Toxicology by Daniel Acosta
- Lehninger Principles of Biochemistry (5th Edition) by M.M. Cox and DL Nelson
- Clinical Pharmacology by Lawrence
- Basic and Clinical Pharmacology by Katzung
- ScheduleY
- OECD Guideline

Course Title	Pharmacoepidemiology and Pharmacovigilance

Detailed syllabus

Section- I

PHARMACOEPIDEMIOLOGY

Definition and scope:

- Origin and evaluation of pharmacoepidemiology
- Need for pharmacoepidemiology,
- Aims and applications.

Measurement of outcomes in pharmacoepidemiology

- Outcome measure and drug use measures
- Prevalence, incidence and incidence rate.
- Monetary units, number of prescriptions,
- Units of drugs dispensed,
- Defined daily doses and prescribed daily doses
- Medication adherence measurement

Concept of risk in pharmacoepidemiology

- Measurement of risk, attributable risk and relative risk, time-risk relationship andodds ratio

Pharmacoepidemiological methods

- Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods
- Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record
  linkage system.

Sources of data for pharmacoepidemiological studies

- Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

- Studies of vaccine safety, hospital pharmacoepidemiology,pharmacoepidemiology and risk management, drug induced birth defects.

Section- II

PHARMACOVIGILANCE

Introduction to pharmacovigilance

- History and development of pharmacovigilance
- Importance of safety monitoring / Why pharmacovigilance

National and international scenario

- Pharmacovigilance in India
- Pharmacovigilance global perspective
- WHO international drug monitoring programme

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs
- Critical evaluation of medication safety literature

Pharmacovigilance methods

- Passive surveillance - Spontaneous reports and case series
- Stimulated reporting
- Active surveillance - Sentinel sites, drug event monitoring and registries
- Comparative observational studies -Cross sectional study, case control study and cohort study
- Targeted clinical investigations
- Vaccine safety surveillance

Adverse drug reaction reporting

- Introduction to reporting systems
- Spontaneous reporting system
- Reporting to regulatory authorities
- Guidelines for reporting ADRs in biomedical literature

Signal detection,Risk assessmentand management

- Identification of new adverse drug reactions
- Signal detection in pre and post marketing period
- Prioritization and risk assessment
- Risk management

Drug dictionaries and coding in pharmacovigilance

- WHO adversereaction terminologies
- MedDRA and StandardisedMedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

References:

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.

b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.

c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.

d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathietal, Orient OrientLangramPvt.Ltd. ISSBN8125026

e. Pharmacoepidemiology- Brain storm

f. Essentials of community medicine- K Park

Course Title	Modern Analytical Techniques
Detailed syllabus	
1	UV-VISIBLE SPECTROSCOPY : Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.
2	INFRARED SPECTROPHOTOMETRY: Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications
3	MASS SPECTROMETRY: Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.
4	NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications
5	CHROMATOGRAPHIC TECHNIQUES: (a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation. (b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC. (c) Principles, elution techniques, applications of ion exchange and ion Pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

Text Books:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.

Reference Books:

1. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
2. Organic Spectroscopy – William Kemp, 3rd Edition.
3. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
4. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th edition.
5. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
6. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
7. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
8. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
9. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
10. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer, Franklin Book
11. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
12. Clarke's Analysis of Drugs and Poisons, A.C.Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press
13. Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.