Post Graduate Diploma in Clinical Research
(PGDCR)

Two semesters full time course

S. B. Gardi Institute of Pharmacy
Department of Pharmaceutical Sciences
Saurashtra University
Rajkot - 360 005

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Post graduate diploma in clinical Research
(PGDCR) SYLLABUS

Semester – I

Interdisciplinary paper – I

Patent and Intellectual property rights Theory

Paper code: PGDCR-101

(Four hours per week, 4 credits)

UNIT-I

The Indian Patents Act 1970 and Indian patents (Amendments) Act 2005 and issue related to Patents, Importance, parts of patent, type of patent, provisional application, Oppositions, Patent infringement, Patent search engines

UNIT-II

Introduction to INTELLECTUAL PROPERTY RIGHTS (IPR) and patent

OVERVIEW OF INTELLECTUAL PROPERTY, meaning of Intellectual Property?, types of intellectual creations

COPYRIGHT

Introduction, Area covered by copyright, types of rights covered by copyright, economic rights, moral rights, need of protection of copyright

RELATED RIGHTS

Introduction, distinction between related rights and copyright , the rights granted to the beneficiaries of related rights, need for protection of related rights?

TRADEMARKS

Introduction, kind of signs used as trademarks, types of trademark, function of a trademark, protecting trademark, protection provided by a trademark,

GEOGRAPHICAL INDICATIONS

Introduction, difference between a geographical indication and a trademark, protecting geographical indication, need for protection of geographical indications

INDUSTRIAL DESIGNS

Introduction, protecting industrial designs, protection provided by industrial designs, territorial restrictions to industrial design protection, need for protection of industrial designs?

UNIT III

PATENTS

What is a patent?, kind of inventions protected by patent, protecting inventions, granting process of a patent, rights provided by patent, patent protection.

NEW PLANT VARIETIES

Introduction, protecting new varieties of plants, protection obtained by a breeder

UNFAIR COMPETITION

Unfair competition, relationship between unfair competition and intellectual property laws

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

Infringement of intellectual property rights, Enforcement Measures,

EMERGING ISSUES IN INTELLECTUAL PROPERTY,

Protection of biotechnological inventions, traditional knowledge, the issue of genetic resources relate to IP

UNIT-IV

1. Paris conventional, World Trade Organization, WIPO and GATT.
2. US Patent System and European Patent System

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Semester – I

Interdisciplinary paper-II

Research Methodology Theory

PGDCR-102

(Four hours per week, 4 credits)

UNIT-I

1. Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research
2. Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey.
3. Selecting a problem and preparing Research proposals

UNIT-II

The Research Report Paper writing/ thesis writing

Different parts of the Research paper

1. Title –Title of project with authors name
2. Abstract- Statement of the problem, Background list in brief and purpose and scope.
3. Key Words.
4. Methology-subject, apparatus, instrumentation & procedure.
5. Results- tables, graphs, figures & statistical presentation
6. Discussion support or non support of hypothesis, practical & theoretical Implications
7. Conclusion
8. Acknowledgements.
9. References
10. Errata
11. Importance of Spell check for entire project
12. Uses of footnotes

UNIT-III

Presentation (especially for oral presentation)

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

Recommended Books: -

1. Research In Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
2. Practical Introduction o copyright.- Gavin Mcfarlane

3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furmess
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
14. Manual for the preparation of industrial feasibility studies

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Semester – I

Subject of Specialization paper – I (Core Subject-I)

Basics of Clinical Research Theory

PGDCR-103

(Four hours per week, 4 credits)

Unit I

Introduction to Drug Discovery and drug Development
Basic pharmacology and clinical research : Basic conceptual knowledge about receptors, drugs, preclinical studies, pharmacodynamic, pharmacokinetic (ADME), drug interactions, clinical research,
Introduction to pharmacoeconomics.

Unit II

Clinical trials

New drug discovery process- purpose, main steps involved in new drug discovery process, timelines of each steps, advantages and purposes of each steps, ethics in clinical research, unethical trials, thalidomide tragedy, Phase-I, II, III, IV trials.
-Introduction and designing
-Various phases of clinical trials
-Post Marketing surveillance – methods
-Principles of sampling
-Inclusion and exclusion criteria
-Methods of allocation and randomization
-Informed consent process in brief
-Monitoring treatment outcome
-Termination of trial
-Safety monitoring in clinical trials

Unit III

(1) Pre clinical toxicology: General principles, Systemic toxicology (Single dose and repeat dose toxicity studies), Carcinogenicity, Mutagenicity, Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity, animal toxicity requirements.

Unit IV

(2) Basic terminology used in clinical research: Types of clinical trials, single blinding, double blinding, open access, randomized trials and their examples, interventional study, ethics committee and its members, cross over design, etc…and Institution Ethics Committee / Independent Ethics Committee
Data Management in clinical Research

TEXT BOOKS and REFERENCES:

(1) Basic and Clinical Pharmacology, Prentice hall, International, Katzung, B.G.
(2) Clinical Pharmacology, Scientific book agency, Laurence, DR and Bennet PN.
(3) Clinical pharmacokinetics, Pub. Springer Verlab, Dr. D.R Krishna, V. Klotz
(4) Remington Pharmaceutical Sciences, Lippincott, Williams and Wilkins
(5) Drug interaction, Kven Stockley. Hamsten
(6) Drug interaction, Basic Bussiness Publ, Bombay, J.K. Mehra
(7) Clinical pharmacology and drug therapy Grahame smith and Aronson,
(8) Text Book of Therapeutics Drug and Disease Management Hardbound. Richard A Helms,
(9) Clinical Pharmacy and therapeutics Herfindal E T and Hirschman JL, Williams and Wilkins,

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Semester – I

Subject of Specialization paper – II (Core Subject-II)

Pharmacokinetics Theory

PGDCR-104

(Four hours per week, 4 credits)

Unit I:

Clinical Pharmacokinetics: Introduction to clinical pharmacokinetics, Steady-state pharmacokinetic. Linear and non-linear pharmacokinetics.

Absorption: Definition, Mechanism of absorption, Factors influencing the absorption.

Distribution: Definition, Binding of drugs, Physiological barriers, Drug disposition, Factors affecting the distribution.

Metabolism: Definition, Phase-I and Phase-II metabolism with examples.

Excretion: Definition, Clearance, Renal clearance, Hepatic clearance, Factors affecting the excretion of drugs.

Unit II:

Drug Interactions: Definition, Epidemiology, Mechanism of drug interactions, Drug-food interactions.

Adverse Drug Reaction: Epidemiology, Definition and Classification, Predisposing factors, Types of ADRs and their mechanism, Detection and Monitoring of ADR, Identification of ADR.

Therapeutic Drug Monitoring : Introduction, When and why TDM is required? Necessity of the TDM, Indications for TDM, Protocol for TDM, TDM of selected drugs used in the following disease conditions: cardiovascular disease, CNS conditions etc.

Text Books and References:

(1) Applied Therapeutics, The clinical uses of Drugs applied therapeutics INC
(2) Text book of Biopharmaceutics, Dr. Brahmankar
(3) Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

(4) International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

(5) Principles of Pharmacology –The Pathophysiologic Basic –Golan David E.

(6) Pharmacological Basis of Therapeutics-Goodman and Gilman

(7) Pharmacology-Rang and Dale

(8) Essentials of Pharmacotherapeutics-F.S. Barar

(9) Principles of Pharmacology – Paul L. Munson

(10) Pharmacology and Pharmacotherapeutics-R.S.Satoskar

(11) Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

(12) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

(13) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

(14) Clinical Pharmacy and Therapeutics: Roger walker and Clive Edwards,Churchill Livingstone Edinburgh

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Semester – I

Subject of Specialization paper – III (Core Subject-III)

Clinical trials: Design and regulations Theory

PGDCR-105

(Four hours per week, 4 credits)

Unit I

Types of clinical trials

Unit II

Design and organization of phase-I, phase-II, phase-III, phase-IV trials

Unit III

Various regulatory requirements in clinical trials, Schedule Y, ICMR guidelines etc.

Documents in clinical study

Investigator Brochure (IB), Protocol & Amendment in Protocol , Case Report Form (CRF), Informed Consent Form (ICF) , Content of Clinical Trial Report

Essential Documents in Clinical Trial

Good Clinical Practice: ICH guidelines

Indian GCP guidelines (CDCSO guidelines)

ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y

Unit IV

Study of various clinical trials (completed or ongoing)

Clinical Trial Application in India

Import & Export of Drug in India

Investigational New Drug application (IND)

Abbreviated New Drug Application (ANDA)

New Drug Application (NDA)

Reference books:

(1) Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

(2)International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

(3)Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

(4)Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

(5)Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

(6)Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh

(7)Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.

(8)Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.

(9)Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.

(10) Comprehensive Pharmacy Review- Shargel Leon

(11) Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers

(12) A textbook of Clinical pharmacy practice- Parthasarthi G.

(13) Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004

(14) Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002

(15) Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002

(16) Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006

(17) Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002

(18) Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication **7.** Bert Spilker. Guide to Clinical Trials. **8.** Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009

(19) Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006

(20) Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

(21) Various Guidelines like: ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996. ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects. Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices– Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.
Schedule Y

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Semester – I

Multidisciplinary / Elective paper

Biostatistics and experimental Design Theory

PGDCR-106

(Four hours per week, 4 credits)

UNIT-I

Biostatistics in clinical trials: Introduction, Probability, Regression, Biostatistics and Various statistical methods i.e. null hypothesis, t- Test, Regression analysis, ANOVA, Chi-square etc Parametric and Non-parametric tests

UNIT- II

Optimization Techniques

Design of experiments, Factorial designs

Grid search technique, Response surface methodology, contour plots, etc.

Semester – II

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Semester – II

Interdisciplinary paper - III
Methods in Biological Evaluation of Drugs Theory
PGDCR-201
(Four hours per week, 4 credits)

Unit-I

1 Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.

2 Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED_{50} and LD_{50} determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies.

Biological evaluation of drugs--Screening and evaluation (including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study) techniques of the following:

Unit -II

1. Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
2. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.

Unit -III

Drugs used in Peptic Ulcer, Respiratory disorders, and Endocrine disorders. Anti fertility agents and diuretics.

Books recommended (Latest Edition):

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

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Semester – II

Subject of Specialization paper – IV (Core Subject-IV)

Bio-availability and Bio-equivalence (BA/BE) studies Theory

PGDCR-202

(Four hours per week, 4 credits)

Unit-I

Bioavailability studies

Introduction, Defination, objectives, factors affecting bioavailability, types: absolute vs relative, single vs multiple dose studies, healthy voluntiers vs patient studies, measurement of bioavailability, drug dissolution rate and Bioavailability, invitro-invivo correlation, methods for enhancement of bioavailability

Unit-II

Bioequivalence

Introduction, Defination, Bases for Determining Bioequivalence

Design and Evaluation of Bioequivalence Studies

Analytical Methods, Reference Standard, Extended-Release Formulations, Combination Drug Products,

Study Designs

Fasting Study, Food Intervention Study, Multiple-Dose (Steady-State) Study

Crossover Designs, Replicated Crossover Design, Evaluation of the Data, Pharmacokinetic Evaluation of the Data, Statistical Evaluation of the Data, Analysis of Variance (ANOVA), Two One-Sided Tests Procedure, Example Bioequivalence, Study Submission and Drug Review Process, Waivers of *In-Vivo* Bioequivalence Studies (Biowaivers) Dissolution Profile Comparison, The Biopharmaceutics Classification System (BCS), Solubility, Permeability, Dissolution, Drug Products for Which Bioavailability or Bioequivalence May Be Self-Evident, Generic Biologics, Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution, Approved Drug Products with Therapeutic Equivalence Evaluations (*Orange Book*),

Reference books:

(1) Applied Biopharmaceutics & Pharmacokinetics, 5th Edition by Leon Shargel, Susanna Wu-Pong, Andrew B.C. Yu
(2) Biopharmaceutics by Bramhankar
(3) Basic and Clinical Pharmacology, Prentice hall, International, Katzung, B.G.
(4) Clinical Pharmacology, Scientific book agency, Laurence, DR and Bennet PN.
(5) Clinical pharmacokinetics, Pub. Springer Verlab, Dr. D.R Krishna, V. Klotz
(6) Remington Pharmaceutical Sciences, Lippincott, Williams and Wilkins
(7) Drug interaction, Kven Stockley. Hamsten

(8) Drug interaction, Basic Bussiness Publ, Bombay, J.K. Mehra
(9) Clinical pharmacology and drug therapy Grahame smith and Aronson,
(10) Text Book of Therapeutics Drug and Disease Management Hardbound. Richard A Helms,
(11) Clinical Pharmacy and therapeutics Herfindal E T and Hirschman JL, Williams and Wilkins,
(12) Applied Therapeutics, The clinical uses of Drugs applied therapeutics
(13) Hospital and Clinical Pharmacy, Nirali Prakashan, Dr. A.R. Paradker.

(12) Central Drugs Standard Control Organization. Guidelines

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Semester – II

Subject of Specialization paper – V (Core Subject-V)

Pharmacovigilance and Pharmacoepidemiology Theory

PGDCR-203

(Four hours per week, 4 credits)

Unit-I

Pharmacovigilance

Scope, definition and aims of pharmacovigilance Adverse drug reactions – Classification, mechanism, predisposing factors and causality assessment. Role of clinical pharmacist in Reporting, evaluation, monitoring, prevention and management of ADR

Adverse drug reaction reporting and monitoring

Drug induced diseases

Unit-II

II Pharmacoepidemiology

Definations: epidemiology,
Disease distribution, disease determination, disease frequency, ,
Aims of epidemiology,
Difference between epidemiology and clinical medicines,
Epidemiological approach,
Measurements in epidemiology, (rates, ratios, and proportions)
Measurement of mortality: international death certificate, limitations and use of mortality data, mortality rates and ratios, crude death rates, specific death rates, case fatality ratio, proportional mortality ratio, survival rate, standardize rates, direct standardization, indirect standardization,
Measurement of morbidity: Incidence, Prevalence, uses of prevalence, relationship between incidence and prevalence,
Epidemiological methods:

(1) Descriptive epidemiology:

Time distributions:

(1) Short term fluctuations: Types of Epidemics- single exposure/point source exposure epidemics, continuous exposure epidemics, propagated epidemics, slow epidemics
(2) Periodic fluctuations
(3) Long term fluctuations

Place Distributions:

-International variance, National variance, Rural-Urban variations, Local distributions.

Person distributions:

(2) Analytical epidemiology:

Case control study:

Selection of cases, selection of controls, matching, measurements of exposure, analysis, odds ratio, bias in case control study., advantages, disadvantages and some examples of case control study

Cohort study :

Concept, framework, prospective and retrospective cohort study, combination of prospective and retrospective cohort study, elements of cohort study, relative risk, attributable risk, advantages, disadvantages and examples of cohort study.

(3) Experimental epidemiology:

Randomized controlled trials: Protocol, selecting reference and populations, randomization, manipulation, follo-ups, assessment, study designs in randomized trials like parallel and cross over study, Types of randomized controlled trials: clinical trial, preventive trials, risk factor trials, cessational trials, trial of aeitiological agents,

Non-randomized trials: uncontrolled trials, natural experiments, before and after comparison studies

Ethical principles in pre-clinical studies and clinical trials, History, its Principles

Roles & Responsibility of various clinical trial personnel as per ICH GCP and ICMR guidelines like Sponsor, Investigator, Monitor, Auditors

Reference books:

(1) International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

(2) Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

(3) Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

(4) Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

(5) Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh

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(7) Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.

(8) Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.

(9) Comprehensive Pharmacy Review- Shargel Leon

(10) Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers

(11) A textbook of Clinical pharmacy practice- Parthasarthi G.

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Semester – II

Subject of Specialization paper – VI (Core Subject-VI)

Dissertation

PGDCR-204

(12 credits)

Introduction to Dissertation work,
Practical training/dissertation work.