1st Semester		Contact Hrs.			Marks			Credits
Code	**Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA8-101	Dosage Form Design	3	1	0	40	60	100	4
MPHA8-102	Clinical Research - I	3	1	0	40	60	100	4
MPHA8-103	Clinical Studies – I	3	1	0	40	60	100	4
MPHA8-104	Seminar/Assignments	0	0	8	100	0	100	4
MPHA8-105	Clinical Research Lab.-I	0	0	8	60	40	100	4
Total		**9**	**3**	**16**	**280**	**220**	**500**	**20**

2nd Semester		Contact Hrs.			Marks			Credits
Code	**Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA8-206	Epidemiology: The Basic Science of Public Health	3	1	0	40	60	100	4
MPHA8-207	Clinical Research - II	3	1	0	40	60	100	4
MPHA8-208	Clinical Studies – II	2	2	0	40	60	100	4
MPHA8-209	Seminar/Assignments	0	0	8	100	0	100	4
MPHA8-210	Clinical Research Lab.-II	0	0	8	60	40	100	4
Total		**8**	**4**	**16**	**280**	**220**	**500**	**20**

3rd Semester		Contact Hrs.			Marks			Credits
Code	**Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA8-311	Research Methodology & Biostatistics	3	1	0	40	60	100	4
MPHA8-312	Clinical Research - III	3	1	0	40	60	100	4
MPHA8-313	Research Work/Minor Project	0	0	14	100	0	100	7
MPHA8-314	Seminar/Assignments	0	0	8	100	0	100	4
MPHA8-315	Journal Club	0	0	2	100	0	100	1
Total		**6**	**2**	**24**	**380**	**120**	**500**	**20**

4th Semester		Contact Hrs.			Marks			Credits
Code	**Name**	**L**	**T**	**P**	**Thesis Evaluation**	**Viva-Voce**	**Total**	
MPHA8-416	Dissertation/Major Project	0	0	40	100	200	300	20
Total		**0**	**0**	**40**	**100**	**200**	**300**	**20**

The candidate can carry out Dissertation/Major Project workin-house/internally or outside/externally and shall submit a report which will be evaluated by external expert at the end of academic year.

Total Marks: 1800 **Total Credits: 80**

DOSAGE FORM DESIGN

Subject Code: MPHA8-101 **L T P C** **Contact Hrs.: 45**
3 1 0 4

1. **Introduction:** Definitions and brief – (pharmacology, pharmacokinetics, pharmacodynamics, drug, phrmacotherapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts.
2. **Routes of Drug Administration:** Local routes (topical, deeper tissues and arterial supply etc.), systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.)
3. **Sources of Drugs:** Natural sources and synthetic sources.
   Pharmacokinetics: Brief of absorption, distribution, metabolism and excretion
   Pharmacodynamics: Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction.
4. **Dosage Forms of Drug:** Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injectable, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) and novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices).
5. **Factors Modifying Drug Action:** Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc.

Recommended Books:

1. Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower and Graeme Henderson, 'Rang & Dale's Pharmacology', 8th Edn., Elsevier.
2. Laurence Brunton, Bruce Chabner, Bjorn Knollman, 'Goodman and Gilman's The Pharmacological Basis of Therapeutics', 12th Edn., McGraw Hill.
3. K.D. Tripathi, 'Essentials of Medical Pharmacology', 7th Edn., Jaypee.
4. 'Remington', 22nd Edn., Pharmaceutical Press.
5. Cooper and Gunn's, 'Dispensing for Pharmaceutical Students', 12th Edn., CBS Publishers.
6. Suresh P. Vyas & Roop K. Khar, 'Controlled Drug Delivery', 2nd Edn., Vallabh Prakashan.
7. Herbert A. Lieberman & Leon Lachman, 'Pharmaceutical Dosage Form', Vol-1, 2, 3, 2nd Edn., Informa Healthcare.

CLINICAL RESEARCH - I

Subject Code: MPHA8-102 **L T P C** **Contact Hrs.: 45**
3 1 0 4

1. **Drug Discovery & Development:** Introduction to drug development process, drug design-ligand based, structure based, active site identification, rational drug discovery &high throughput screening,
2. **Introduction to Preclinical Study Guidelines**: Introduction to ICH Guidelines for Quality, Safety and Efficacy.

3. **History & Origin of Clinical Research:** Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines; The Belmont Report; The Nuremberg Code, Principles of ICH-GCP;
4. **Guidelines:** Biomedical Research and Human Participant- Schedule Y, ICMR, Indian Good Clinical Practices.
5. **Clinical Trial Application Requirements for**
   - **Investigational New Drug (IND):** Classifications, IND application submission check list, FDA IND review check list, IND application process, Information for sponsors-investigator submitting IND, IND forms and instructions.
   - **New Drug Application (NDA)**: Pre NDA meeting, NDA submission Check list, FDA NDA review check list.
   - **Abbreviated New Drug Application (ANDA):** ANDA content, ANDA Submission check list, FDA ANDA review check list, ANDA process for generic drugs, guidance documents for ANDAs, ANDA forms and electronic submissions.
   - **Orphan Drugs Application:** Submission check list, FDA orphan drug review check list, FDA documents.

Recommended Books:

1. Sandy Welnberg, 'Guideline for Drug Regulatory Submissions'.
2. Alan A. Chalmers, 'International Pharmaceutical Registration'.
3. Felicity Smith, Sally Anne Francis, Ellen Schathecutle, 'International Research in Health Care'.
4. Graham D. Ogg, 'Quality Management in Clinical Trial Research', e-book.
5. '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**.
6. Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, David M. Reboussin, Christopher B. Granger, 'Fundamentals of Clinical Trials', 4th Edn., Springer.
7. N.G. Rick, 'Drugs from Discovery to Approval', 3rd Edn., Wiley-Blackwell.

CLINICAL RESEARCH - I

Subject Code: MPHA8-103 **L T P C** **Contact Hrs.: 45**
3 1 0 4

Course Objectives: Understand the clinical studies and other aspects of highly prevalent disease including,

- Definition
- Clinical features
- Clinical terminologies
- Case reports/case study of any one representative case report/study in relation to following diseases &
- How to design clinical trial/Research protocols in relation to following diseases.

1. **Psychological and Mood Disorders:** Schizophrenia and Depression.
2. **Neurodegenerative disorders:** Alzheimer's & Parkinson's disease.
3. **Atherosclerosis, Hypertension & Renal diseases.**
4. **Coronary artery diseases & Congestive Heart Failure** including surgical treatments & stents.

5. Cerebrovascular diseases: Stroke.

Recommended Books:

1. Goodman and Gillman's, 'The Pharmacological Basis of Therapeutics'.
2. David E. Golan, Armen H. Tashjian Jr., Ehrin J. Armstrong, April W. Armstrong, Wolters, 'Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy', Kluwer-Lippincott Williams & Wilkins Publishers.
3. B.G. Katzung, 'Basic and Clinical Pharmacology'.
4. Graham Smith, 'Oxford Textbook of Clinical Pharmacology'.
5. 'Dipiro Pharmacology, Pathophysiological Approach'.
6. 'Green Pathophysiology for Pharmacists'.

SEMINAR/ASSIGNMENTS

Subject Code: MPHA8-104 **L T P C**
0 0 8 4

The candidate needs to prepare seminar from syllabus and present in front of class room gathering. At least five assignments to be submitted as per the given instruction of teachers and shall be submitted accordingly.

CLINICAL RESEARCH LAB.-I

Subject Code: MPHA8-105 **L T P C**
0 0 8 4

1. **MS-Excel:** Introduction to MS Office; Word; Power point; Publisher; and Excel
2. **Soft Skills:** Introduction and definition, motivation, SWOT analysis, goal setting, business etiquettes, business dressing, business communication, understanding body language and gestures, listening skill, giving and accepting feedback, group discussion.
3. **Clinical Data Management:** Overview, regulation, data management plan, data acquisition and CRF designing, database designing and implementation, data entry and verification and data analysis and use of statistics in treatment of clinical data.
4. **Introduction to Scientific Writing and Reports:** Importance of research papers and reports and their role in scientific developments to be given. Basic information on the structure and contents of individual sections to be given by experts.

Recommended Books:

1. June Jamrich Parsons, Dan Oja., 'Practical Computer Literacy', 3rd Edn., CENGAGE Learning.
2. Simon Cook, 'Clinical Studies Management'.
3. Duolao Wand, 'Clinical Trials', e-books.
4. Josef Kolman, Paul Meng, 'Good Clinical Practice'.
5. Graham D. Ogg, 'Quality Management in Clinical Trial Research'. E-book.

EPIDEMIOLOGY: THE BASIC SCIENCE OF PUBLIC HEALTH

Subject Code: MPHA8-206 **L T P C** **Contact Hrs.: 45**
3 1 0 4

1. **Epidemiology**: Introduction and history of Epidemiology, Pioneers of epidemiology (history), Examples of Research areas using Epidemiology, Definitions, Person, place, time and population perspective.
2. **Prevalence:** Prevalent vs incident cases, Prevalence, Risks, Rates, Odds.
3. **Study Designs:** Experimental study design [part 1, part 2 & part 3]; Cohort study design, Case control study design, Cross-sectional studies, Ecologic studies.
4. **Measures of Association and Confidence Intervals:** Measures of Association, Odds Ratio, Interpreting Measures of Association, Confidence Intervals, Confidence Intervals examples
5. **Causality:** Introduction to causality, Bradford Hill criteria, Additional resources (study materials).

Recommended Books:

1. Editor Brian L Storm, 'Pharmacoepidemiology', 4th Edn., John Wiley and Sons, Ltd.
2. Brian Haynes, David L. Sachett, Lippinkot, 'Clinical Epidemiology - How to do Clinical Practice Research', 3rd Edn.
3. B. Waning, M. Montagne, W.W. McCloskey, 'Pharmacoepidemiology: Principles and Practice', **2001.**
4. K.G. Revikumar, 'Harmacoepidemiology and Pharmacoeconomics Concepts and Practice', Paperback, **2016**.
5. Brian L. Strom, Stephen E. Kimmel, 'Textbook of Pharmacoepidemiology', 1st Edn,.

CLINICAL RESEARCH - II

Subject Code: MPHA8-207 **L T P C** **Contact Hrs.: 45**
3 1 0 4

1. **Clinical Trials: Types and Phases:** Types of trials: Prevention Trials, diagnostic trial, Treatment trial, Observational studies, Quality of life trials etc.; **Micro-dosing -** Phase 0 and importance in relation to clinical research; Phases of clinical trials- Phase 1, Phase 2, Phase 3, Phase 4.
2. **Bioavailability/Bioequivalence Studies:** Basic Definitions, Requirements of Bioavailability and Bioequivalence study, Study Design, Bio statistical procedure, Bio-analytical method and Method validation, submission of study to the regulatory, Bioequivalence and Pharmacokinetics.
3. **Guidelines of Bioavailability (BA)/Bioequivalence (BE) Studies:**
   - **USFDA Guideline-** Introduction, Background, Methods to document BA and BE, Comparison of BA measures in BE studies, Documentation of BA and BE, Special topics, General pharmacokinetic study design and data handling.
   - **Overview of International BABE Guidelines:** Therapeutic Goods Administration **(**TGA) guideline, Therapeutic Product Directorate **(**TPD) guideline, European Agency for Evaluation of medicinal Products (EMEA) guideline.
4. **Conduct of Bioequivalence Study:** Role of different departments involve in bioequivalence study (Business development, Screening department, Clinical department, Bio-analytical department etc), life span of bioavailability and bioequivalence study (BABE study), day to day activity during the study

5. **Operations in BABE:** Role of quality assurance & quality control in BA/BE studies, role of medical writing in BA/BE studies, waiver of BA/BE studies, Role of project management and business development in BA/BE studies, Form 44.

Recommended Books:

1. David Machin, Simon Day and Sylvan, 'Textbook of Clinical Trials'.
2. Giovanna di Ignazio, Di Giovanna and Haynes, 'Principles of Clinical Research'.
3. 'Ethical Guidelines for Biomedical Research on Human Subjects 2000', Indian Council of Medical Research, New Delhi.
4. Duolao Wand, Ameet Bakhai Remedica, 'Clinical Trials' – e-books.
5. Duolao Wang & Ameet Bakhai, 'Clinical Trials: A Practical Guide to Design, Analysis & Reporting'.
6. Peter G. Welling, Francis L.S. Tse, Shrikant V. Dighe, 'Pharmaceutical Bioequivalence', 1st Edn., Informa Healthcare.
7. Sarfaraz K. Niazi, 'Handbook of Bioequivalence Testing'.

CLINICAL STUDIES - II

Subject Code: MPHA8-208 **L T P C** **Contact Hrs.: 45**

2 2 0 4

Course Objectives: Understand the clinical studies and other aspects of highly prevalent disease including,

- Definition
- Clinical features
- Clinical terminologies
- Case reports/case studies of any one representative case report/study in relation to following diseases &
- How to design clinical trial/Research protocols in relation to following diseases.

1. **Diabetes mellitus**
2. **Arthritis- Rheumatoid arthritis, osteoarthritis**
3. **Inflammatory Bowel Disease and Irritable Bowel Syndrome**
4. **Malignancies & AIDS**
5. **Common infections** like Tuberculosis & Malaria

Recommended Books:

1. Dan Longo, Anthony Fauci, Dennis Kasper, Stephen Hauser, J. Jameson, Joseph Loscalzo, 'Harrison's Principles of Internal Medicine', 18th Edn., McGraw Hill.
2. Brian R. Walker, Nicki R. Colledge, Stuart H. Ralston, Ian Penman, 'Davidson's Principles and Practice of Medicine', 22nd Edn., Churchill Livingstone, Elsevier.
3. Murray Longmore, Ian Wilkinson, Andrew Baldwin, and Elizabeth Wallin, 'Oxford Handbook of Clinical Medicine', 9th Edn., Oxford Medical Handbooks.

Follow the links for Case Studies:

www.ohsu.edu/xd/research/about/integrity/irb/upload/UP-Case-Studies.pdf
www.fcrindia.org/case-studies
https://www.firmaclinicalresearch.com/case-studies/
www.crc.gov.my/.../05_Final_Edited_Ethics_Ethical_problems_in_clinical_trial.pdf
https://www2.rsna.org/.../Graham%20Case%20Studies%20Multicntr%20Clin%20Trial...
https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/.../UCM535780.pd...

www.cliantha.in/pdf/case-study/Biosimilars-Case-Studies.pdf

SEMINAR/ASSIGNMENTS

Subject Code: MPHA8-209 **L T P C**
0 0 8 4

The candidate needs to prepare seminar from syllabus and present in front of class room gathering. At least five assignments to be submitted as per the given instruction of teachers and shall be submitted accordingly.

CLINICAL RESEARCH LAB.-II

Subject Code: MPHA8-210 **L T P C**
0 0 8 4

Clinical Exercises:

- Case studies solutions
- Technical and soft skill presentations
- Term search
- Development of Clinical research documents
  - ✓ SOPs development
  - ✓ CRFs & ICFs Preparation
  - ✓ Dummy clinical research and bioequivalence protocols etc.
- Role played by clinical research stake holders like Clinical research associate, investigator, project manager, volunteer, clinical research coordinator, auditor etc.

Industrial/Hospital/Laboratory Exposure:

- Visits and overview of the facility, infrastructure, flow of activity, visiting different areas like screening room, medical examination room, phlebotomy room, dining area, baggage and body area, clinical pharmacological unit, dosing area, investigator`s cabin, drug store, plasma separation and storage room.
- On site exposure which includes observation of actual in-process activities like blood collection, plasma separation, screening of volunteers, informed consent process.
- A visit to Analytical Department and Central Laboratory to have know-how of the tests/investigations conducted and other procedures performed in respective departments.

Recommended Books:

1. Julia Lloyd and Ann Raven Ed. Churchill Livingstone, ‘Handbook of Clinical Research’.
2. Duolao Wang & Ameet Bakhai, ‘Clinical Trials: A Practical Guide to Design, Analysis & Reporting’.
3. David Machin & Michael Campbell, ‘The Design for Studies for Medical Research’.

Follow the links for Case Studies:

1. www.ohsu.edu/xd/research/about/integrity/irb/upload/UP-Case-Studies.pdf
2. www.fcrindia.org/case-studies
3. https://www.firmaclinicalresearch.com/case-studies/
4. www.crc.gov.my/.../05_Final_Edited_Ethics_Ethical_problems_in_clinical_trial.pdf
5. https://www2.rsna.org/.../Graham%20Case%20Studies%20Multicntr%20Clin%20Trial...
6. https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/.../UCM535780.pd...
7. www.cliantha.in/pdf/case-study/Biosimilars-Case-Studies.pdf.

RESEARCH METHODOLOGY & BIOSTATISTICS

Subject Code: MPHA8-311 **L T P C** **Contact Hrs.: 45**
3 1 0 4

1. **General Research Methodology**: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.
2. **Introduction to Biostatistics & its Role in Clinical Research**: Population & Sample, Parameter & Statistic, Types of variables, Measures of Central Tendency-Mean, different types of mean, Median, Mode, Histograms, Scatter Plots, Construction & Labeling of graphs, Normal & Binomial Distribution, Research Hypothesis testing, Sample size calculation & Power, p-value, Confidence Interval, Randomization methods, Blinding in Clinical research.
3. **Medical Research:** History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.
4. **Patents Regulations & Intellectual Property Rights (IPR):** Patent Laws, trade related aspects of intellectual property rights (TRIPS), patent extension rules, implications; copyright, trademarks, patents: requirement, objectives, patent implications, recent scenario and case studies.
5. **Declaration of Helsinki:** History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Recommended Books:

1. Todd A. Durham & J. Rick Turner, 'Introduction to Statistics in Pharmaceutical Clinical Trials'.
2. Sanford Bolton, 'Phramaceutical Statistics; Practical and Clinical Application'.
3. Sisanne Prouscha, 'Practical Guide to - Clinical Data Management'.
4. 'Universal's Concise Commentary, The Patents Act, 1970', 1st Edn., Universal Law Publishing.
5. C.V.S. Subrahmanyam, 'Pharmaceutical Regulatory Affairs', 1st Edn., Vallabh Prakashan.
6. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

CLINICAL RESEARCH – III

Subject Code: MPHA8-312 **L T P C** **Contact Hrs.: 45**
3 1 0 4

1. **Regulatory Submissions**: Drugs Controller General of India (DCGI)/Central Drugs Standard Control Organization (CDSCO) submissions, e-CTD (Common Technical Document). USFDA & EMA Guidelines.
2. **Designs of Clinical Trials & Clinical Trial Study Team:** Experimental Study- RCT and Non-RCT, Observation Study: Cohort, Case Control, Cross sectional; Clinical Trial Study Team: Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

3. **Informed Consent Process & Operation of Institutional Review Board (IRB)/ Independent Ethics Committee (IEC):** Structure and content of an Informed Consent Process Ethical principles governing informed consent process; Defining Scope of IRB/IEC Authority**,** Responsibilities of IRB/IEC, Composition of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with IRB, IRB/IEC Records.
4. **Pharmacovigilance Overview:** Introduction, history, Definitions of Adverse Event (AE), Adverse Drug Reaction (ADR), Serious Adverse Event (SAE), Serious unexpected and Related events (SUR), Suspected-unexpected serious Adverse reaction (SUSAR), Reporter's Causality, Company's Causality and Listedness, Methods of ADR Reporting, PRAC and Pharmacovigilance Guidelines (GVP modules), Pharmacovigilance centers in India, CDSCO Indian PV Guidelines-National Pharmacovigilance Program (NPP).
5. **Management of Pharmacovigilance Reports:**
   a. **Individual Case Safety Reports (ICSRs):** Definition of ICSRs, Types of ICSRs and Various Sources of ICSRs, Processing of ICSRs: Triage, Initiation, Medical Regulatory Assessment, Narrative writing, Quality Check and Submission of ICSRs to Health Authorities. Introduction to various safety databases: Argus, Aris G and VigiFlow.
   b. **Periodic/Aggregate Safety Reports:** Overview of Periodic Benefit Risk Evaluation Reports (PBRERs), PRAC Reports, Ad-hoc Reports, RMPs (Risk Management Plan) and Addendum to Clinical Overview (ACO).

Recommended Books:

1. Alan A. Chalmers, 'International Pharmaceutical Registration'.
2. Sandy Weiberg, 'Guideline for Drug Regulatory Submissions'.
3. Duolao Wang & Ameet Bakhai, 'Clinical Trials: A Practical Guide to Design, Analysis & Reporting'.
4. Susan S. Ellenberg, Thomas R. Flemming, David L. Demets, 'Data Monitoring Committees in Clinical Trials', e-book.
5. Shayne C. Gad, 'Drug Safety Evaluation'.
6. David Machin & Michael Campbell, 'The Design for Studies for Medical Research'.
7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4231554.
8. https://gmch.gov.in/e-study/.../ADRs%20&%20Pharmacovigilance%20lecture.pdf.
9. https://www.pmda.go.jp/files/000215600.pdf.
10. www.ema.europe.eu/ema/

RESEARCH WORK/MINOR PROJECT

Subject Code: MPHA8-313 **L T P C**
0 0 14 7

The student will be assigned with minor project or Research work pertaining to clinical research. Final report should be submitted following its presentation.

SEMINAR/ASSIGNMENTS

Subject Code: MPHA8-314 **L T P C**
0 0 8 4

The student needs to prepare seminar from syllabus and present in front of class room gathering. At least five assignments to be submitted as per the given instruction of teachers and shall be submitted accordingly.

JOURNAL CLUB

Subject Code: MPHA8-315 **L T P C**
0 0 2 1

Student shall present clinical research papers to be given in the classroom.