



**NIPER GUWAHATI**

# **SYLLABUS**

## **M.Pharm. Pharmacy Practice**

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH  
GUWAHATI**

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# M.Pharm. Pharmacy Practice

Course No.	Course Name	Credits
<b>Semester-I</b>		
PP-510	Hospital and Community Pharmacy Practice	1
PP-520	Clinical Pharmacy Practice	2
PP-530	Clinical and Applied Therapeutics – I	3
GE-510	Biostatistics	2
GE-511	Seminar / Presentation	1
LG-511	Clinical Placement	4
LG-512	Computer Applications	1
<b>Elective</b>		2
<b>TOTAL CREDITS</b>		<b>16</b>
<b>Semester-II</b>		
PP-610	Clinical Research	2
PP-620	Pharmacovigilance, Pharmacoepidemiology & Pharmacoeconomics	2
PP-630	Clinical and Applied Therapeutics – II	2
PP-640	Evidence-Based Medicine	2
GE-611	Seminar / Presentation / Journal Club	1
LG-611	Clinical Placement	3
<b>Elective</b>		2
<b>TOTAL CREDITS</b>		<b>14</b>
<b>Semester-III</b>		
Project (22 weeks)		
TH-598	Synopsis	5
TH-599	Presentation	3
<b>TOTAL CREDITS</b>		<b>8</b>
<b>Semester-IV</b>		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
<b>TOTAL CREDITS</b>		<b>12</b>
<b>GRAND TOTAL CREDITS (I to IV Semesters)</b>		<b>50</b>

# M.Pharm. Pharmacy Practice

## SEMESTER-I

### PP-510:- Hospital & Community Pharmacy Practice (1 Credit)

- 1. Introduction to Hospitals:** Definition, classification, and organizational structure of Hospitals. Quality management system in hospitals and NABH accreditation.
- 2. Hospital Pharmacy:** Definition, organizational structure, infrastructural requirements, legal requirements, budget requirements, and management of hospital pharmacy. Roles and responsibilities of hospital pharmacist including the dispensing of controlled and investigational medications.
- 3. Hospital Committees:** Pharmacy & Therapeutic Committee, Pharmacovigilance Committee, Infection Control Committee, Antibiotic Stewardship Committee, Opioid Stewardship Committee, and Research & Ethics Committee. Roles and responsibilities of the hospital pharmacist in these committees.
- 4. Hospital Guidelines and Process:** Developing hospital formulary, preparation of emergency medication list, developing therapeutic guidelines, drug procurement process, methods of inventory control, economic order quantity, drug distribution process, and waste management process.
- 5. Hospital Pharmacist Involvement in Counselling, Education and Training:** Patient counselling, training of pharmacy technicians, training and continuing education for pharmacists, and training of pharmacy, medical, and nursing students & staff.
- 6. Community Pharmacy:** Definition, organizational structure, infrastructural requirements, legal requirements, budget requirements, and management of community pharmacy. Roles and responsibilities of the community pharmacist.
- 7. Medication Management:** Rational use of OTC medications, medication counselling, home medicines review, and identifying & acting upon prescription-related problems and medication-related problems.
- 8. Communication Skills:** Verbal and non-verbal communication skills, reading, writing, listening, and critical thinking skills towards patients and other healthcare professionals.

### Recommended Books:

1. A Practical Guide to Contemporary Pharmacy Practice and Compounding, by Judith E. Thomson, Wolters Kluwer.
2. Introduction to Hospital and Health-System Pharmacy Practice, by David A. Holdford and Thomas R. Brown, American Society of Health-System Pharmacists.
3. Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practitioners, by Robert S. Beardsley, Wolters Kluwer.
4. Hospital Pharmacy, by Martin Stephens, Pharmaceutical Press.
5. Community Pharmacy Practice, by Ramesh Adepu, BSP Publishers.
6. Relevant research & review articles from recent medical and pharmaceutical literature.

1. **Clinical Pharmacy:** Definition, origin, evolution, and scope of clinical pharmacy in India and abroad. Concept of Pharmaceutical care process.
2. **Clinical Pharmacy Setup in Hospital:** Requirements for the establishment of a clinical pharmacy department and drug & poison information center in the hospital. Databases & software used in providing clinical pharmacy services.
3. **Clinical Pharmacy Services:** Ward round participation, drug & poison information, pediatric dosage calculation, patient medication history interview, treatment chart review, identifying medication-related problems, pharmacist intervention, detection, reporting and monitoring of adverse drug reactions (Pharmacovigilance), adverse events following immunization (Vaccine Pharmacovigilance), adverse events related to blood transfusion (Hemovigilance) and adverse events with the use of medical devices (Materiovigilance), patient counselling, patient referrals, and monitoring of patient medication adherence. Documentation and quality assurance of clinical pharmacy services.
4. **Lab Data Interpretation:** Hematological tests, renal function tests, pulmonary function tests, liver function tests, thyroid function tests, cardiac biomarkers, fluid and electrolyte balance, acid-base balance, microbiological culture sensitivity tests, and therapeutic drug monitoring & dosage adjustments of narrow therapeutic index medications (digoxin, theophylline, phenytoin, phenobarbitone, carbamazepine and gentamicin), insulin, and anticoagulants.
5. **Precision Medicine:** Principles of precision medicine and the clinical impact of individual molecular and lifestyle variability. Pharmacogenomics: Basics of pharmacogenomics i.e., the importance of studying genetic variation, and differentiation between a polymorphism & a mutation. Different types of polymorphism and the nomenclature used to describe them. Pharmacogenomics in practice: the role of the pharmacist.

**Recommended Books**

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills, by Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata, Universities Press.
2. Oxford American Handbook of Clinical Pharmacy, by Michelle Mccarthy, Denise R. Kockler, Oxford University Press.
3. Standards of Practice for Clinical Pharmacy Services - The Society of Hospital Pharmacists of Australia.
4. Basic Skills in Interpreting Laboratory Data, by Mary Lee, American Society of Health System Pharmacists.
5. Laboratory Tests and Diagnostic Procedures, Cynthia C. Chernecky, Barbara J. Berger, Saunders
6. Concepts in Pharmacogenomics, by Martin M. Zdanowicz, American Society of Health System Pharmacists.
7. Relevant research & review articles from recent medical and pharmaceutical literature.

*Etiopathogenesis and pharmacotherapy of diseases are associated with the following systems:*

- 1. Cardiovascular System:** Hypertension, heart failure, angina pectoris, acute coronary syndrome, electrophysiology of heart & arrhythmias, and dyslipidemia.
- 2. Respiratory System:** Asthma, chronic obstructive pulmonary disease (COPD), Asthma-COPD overlap syndrome, and drug-induced pulmonary disorders.
- 3. Endocrine System:** Metabolic syndrome, diabetes mellitus (type 1, type 2, gestational, and maturity-onset diabetes of the young), and thyroid disorders.
- 4. Nephrology:** Acute kidney injury, chronic renal failure, drug-induced renal disorders, and hemodialysis & peritoneal dialysis.
- 5. Ophthalmology:** Glaucoma, and conjunctivitis - viral & bacterial.
- 6. Infectious Diseases:** Rational use of antibiotics and surgical prophylaxis. Malaria, tuberculosis, HIV & opportunistic infections, meningitis, Japanese encephalitis, gastroenteritis, endocarditis, septicemia, dengue fever, respiratory tract infections, urinary tract infections, protozoal infections, fungal infections, and viral infections.

**Recommended Books**

1. Koda-Kimble and Young's Applied Therapeutics: The Clinical use of Drugs, by Brian K. Alldredge, Robin L. Corelli, Michael E. Ernst and B. Joseph Guglielmo, Lippincott Williams and Wilkins.
2. Pharmacotherapy: A Pathophysiologic Approach, by Joseph DiPiro, Robert Talbert, Gary Yee, Gary Matzke, Barbara Wells and L. Michael Posey, McGraw-Hill Education.
3. Clinical Pharmacy and Therapeutics, by Eric T. Herfindal and Joseph L. Hirschman, Lippincott Williams and Wilkins.
4. Clinical Pharmacy and Therapeutics, by Robert Walker and Cate Whittlesea, Churchill Livingstone.
5. Goodman and Gilman's The Pharmacological Basis of Therapeutics, by Laurence Brunton, Bjorn Knollman and Randa Hilal-Dandan, McGraw Hill.
6. Harrison's Principles of Internal Medicine, J. Larry Jameson, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, Dan L. Longo and Joseph Loscalzo - McGraw Hill.
7. Relevant research & review articles from recent medical and pharmaceutical literature.

**GE-510:- Biostatistics****(2 Credits)**

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.
2. **Probability:** Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. **Sampling:** Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. **Estimation and Hypothesis testing:** Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student-t and Chi square tests. Sample size and power.
5. **Experimental design and analysis of variance:** Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. **Correlation and regression:** Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation.
8. **Statistical techniques in pharmaceuticals:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

**Recommended Books:**

1. Fundamentals of Biostatistics by Bernard Rosner.
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon
3. Statistical Misconceptions by Huck GE-520 Fundamentals of Intellectual Property (IP) and Technology.

**GE-511:- Seminar / Presentation****(1 Credit)**

*Each student has to present a seminar before the end of the semester on any of the following topics*

1. Latest developments in Pharmacy Practice.
2. Novel therapies approved.
3. Novel diseases and their pathogenesis.
4. Current public health issues.

**LG-511:- Clinical Placement****(4 Credits)**

1. Choice of patients for case studies: Relevance to pharmacists' involvement
2. Ability to pick the right cases/problems/issues, which should be relevant to pharmaceutical care.
3. Patient profiles (Six per semester)
4. Case presentations adopting Pharmaceutical Care Plan Model (Two per semester)
5. Group discussions for 'real' patient issues (six per semester)
6. Pharmacy posting (20 hours per semester)
7. Communication skills with healthcare professionals, patients and caregivers/relatives (level of improvement): Gathering additional information e.g. medication history, allergies, previous medical history, self-medication, use of OTC preparations and knowledge about these and other information relevant to therapy; Counseling ability in view of patients' wish to be so counseled.

**LG-512:- Computer Applications****(1 Credit)**

**Computer Applications in Pharmaceutical Sciences:** Introduction to computer, basic unit & function, hardware & software, operating systems, word processing, spreadsheet, graphic programs, dBase, and windows. Steps involved in software and application development. Computer languages with emphasis on FORTRAN language and programming. Hands-on experience in pharmaceutical database/software systems. Use of computers in information retrieval systems.

# M.Pharm. Pharmacy Practice

## SEMESTER-II

### PP-610:- Clinical Research

(2 Credits)

- 1. Drug Development Process:** Introduction and various approaches to the drug development process, planning & execution of clinical trials, various phases of clinical trials, submission of investigational new drug application to regulatory authorities for the conduct of clinical trials, submission of new drug application to regulatory authorities for market authorization, ethics committee & ethical issues in human biomedical research, data and safety monitoring board, and ICH-GCP, ICMR & CDSCO guidelines for the conduct of clinical trials.
- 2. Types and Designs Used in Clinical Research:** Experimental - Randomized controlled trials (adaptive design, and methods of randomization, blinding, allocation & assessment), quasi-experimental & observational studies, and bioavailability & bioequivalence studies.
- 3. Clinical Trial Study Team:** Roles and responsibilities of the principal investigator, co-investigator, clinical research coordinator, clinical research associate, clinical/contract research organization, sponsor, and monitor.
- 4. Clinical Trial Documents:** Guidelines for the preparation of protocol, investigator's brochure, informed consent form, case record form, contracts & agreements, and dairy cards.
- 5. Clinical Trials Start-up Activities:** Sample size calculation, site feasibility studies, site & investigator selection, pre-study visit, investigators meeting, clinical trial agreement execution, and ethics committee documents preparation & submission.
- 6. Clinical Trial Procedures:** Procurement & storage of investigational products, site initiation visit, preparation & maintenance of master file, investigator site file and pharmacy file, electronic data capture systems, follow-up clinical trial monitoring, close-out, and archival of documents.
- 7. Quality Assurance and Quality Control in Clinical Trials:** Types of audits, audit criteria, audit process, responsibilities of stakeholders in the audit process, audit follow-up & documentation, audit resolution & preparation for FDA inspections, and fraud & misconduct management.
- 8. Clinical Trials Data Management:** Data management plan, data entry, data cleaning, data transfer, data mining, database lock, and warehousing. Experience in advanced statistical programs like SAS, R, and SPSS.

### Recommended Books:

1. Principles of Clinical Research, by Giovanna di Ignazio and Gareth Hayes, Routledge.
2. Textbook of Clinical Trials, David Machin, Simon Day and Sylvan Green, Wiley.
3. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India, by Central Drugs Standard Control Organization.
4. Guideline for Good Clinical Practice, by The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
5. Ethical Guidelines for Biomedical Research on Human Subjects, by Indian Council of Medical Research.
6. Relevant research & review articles from recent medical and pharmaceutical literature.



**PP-620:- Pharmacovigilance, Pharmacoepidemiology & Pharmacoeconomics****(2 Credits)**

- 1. Introduction to Pharmacovigilance:** Definition, history & development, need, and national & international scenario of pharmacovigilance. Basic terminologies used in pharmacovigilance
- 2. Pharmacovigilance Methods:** Passive surveillance – spontaneous reporting; intensified reporting; and active surveillance – targeted reporting, cohort event monitoring, and electronic health record mining. Signal detection, risk assessment and risk management in pharmacovigilance.
- 3. Introduction to Pharmacoepidemiology:** Definition, scope, origin & evolution, need, aims, and applications of pharmacoepidemiology.
- 4. Measures in Pharmacoepidemiology:** Outcome measures: Incidence proportion, incidence rate, prevalence; Medication use measures: ATC classification, defined daily doses, prescribed daily doses; Risk measures: Odds ratio, hazard ratio, relative risk, relative risk reduction, absolute risk reduction, attributable risk, number needed to treat, and number needed to harm.
- 5. Pharmacoepidemiological Methods** (*Includes theoretical and practical aspects of various pharmacoepidemiological methods with the help of case studies for individual methods*): Descriptive study designs: Case reports, case series, and surveys; Observational study designs: Cohort studies, case-control studies, nested case-control studies, case-cohort studies, cross-sectional studies, medication utilization review, post-marketing surveillance and record linkage systems; Experimental study designs: Randomized controlled trials.
- 6. Introduction to Pharmacoeconomics:** Definition, origin & evolution, need, aims, and applications of pharmacoeconomics. Role of pharmacoeconomics in formulary management decisions.
- 7. Measures in Pharmacoeconomics:** Cost measures: Direct cost, indirect cost, and intangible cost; Outcome measures: Clinical outcomes, economic outcomes, and humanistic outcomes; health-related quality of life, quality-adjusted life years, disability-adjusted life years, timing adjustment, decision analysis, sensitivity analysis, and Markov model.
- 8. Pharmacoeconomic Methods** (*Includes theoretical and practical aspects of various pharmacoeconomic methods with the help of case studies for individual methods*): Cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis, cost of illness, and cost consequences analysis. Software used in the pharmacoeconomic analysis.

**Recommended Books:**

1. Pharmacoepidemiology, by Brian L. Strom, Stephen E. Kimmel and Sean Hennessy, Wiley Blackwell.
2. Understanding Pharmacoepidemiology, Yang Yi and Strum DW, McGraw-Hill.
3. Pharmacoepidemiology and Pharmacoeconomics Concepts and Practice, by K.G. Revikumar, PharmaMed Press/BSP Books.
4. Essentials of Pharmacoeconomics, by Karen Rascati, Lippincott Williams & Wilkins.
5. Decision Modelling for Health Economic Evaluation, by Andrew Briggs, Karl Claxton, Mark Sculpher, Oxford University Press.
6. Understanding Health Outcomes and Pharmacoeconomics, George E. MacKinnon III, Jones and Bartlett Publishers.

7. Relevant research & review articles from recent medical and pharmaceutical literature.

**PP-630:- Clinical and Applied Therapeutics – II****(2 Credits)**

*Etiopathogenesis and pharmacotherapy of diseases are associated with the following systems:*

1. **Gastrointestinal System:** Peptic ulcer disease, gastro-oesophageal reflux disease, inflammatory bowel disease, liver disorders: alcoholic liver disease, viral hepatitis including jaundice, and drug-induced liver disorders.
2. **Nervous System:** Epilepsy, Parkinson's disease, Alzheimer's disease, and stroke.
3. **Psychiatric Disorders:** Schizophrenia, depression, anxiety disorders, sleep disorders, and drug-induced psychiatric disorders.
4. **Musculoskeletal Disorders:** Rheumatoid arthritis, osteoarthritis, osteoporosis, gout, spondylitis, and systemic lupus erythematosus.
5. **Oncology:** Basic principles of cancer chemotherapy. Management of breast cancer, head & neck cancer, cervical cancer, gastric cancer, and lung cancer. Management of chemotherapy-induced nausea and vomiting. Targeted or precision oncology drugs.
6. General prescribing guidelines for pediatric patients, geriatric patients, and pregnancy & breastfeeding.

**Recommended Books:**

1. Koda-Kimble and Young's Applied Therapeutics: The Clinical use of Drugs, by Brian K. Alldredge, Robin L. Corelli, Michael E. Ernst and B. Joseph Guglielmo, Lippincott Williams and Wilkins.
2. Pharmacotherapy: A Pathophysiologic Approach, by Joseph DiPiro, Robert Talbert, Gary Yee, Gary Matzke, Barbara Wells and L. Michael Posey, McGraw-Hill Education.
3. Clinical Pharmacy and Therapeutics, by Eric T. Herfindal and Joseph L. Hirschman, Lippincott Williams and Wilkins.
4. Clinical Pharmacy and Therapeutics, by Robert Walker and Cate Whittlesea, Churchill Livingstone.
5. Goodman and Gilman's The Pharmacological Basis of Therapeutics, by Laurence Brunton, Bjorn Knollman and RandaHilal-Dandan, McGraw Hill.
6. Harrison's Principles of Internal Medicine, J. Larry Jameson, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, Dan L. Longo and Joseph Loscalzo - McGraw Hill.
7. Relevant research & review articles from recent medical and pharmaceutical literature.

**PP-640:- Evidence-Based Medicine****(2 Credits)**

- 1. Introduction to Evidence-Based Medicine:** Definition, need, and steps involved in evidence-based medicine. Levels of evidence in healthcare decision-making.
- 2. Literature Search and Finding the Current Best Evidence:** Framing the search question by using PICO model; advanced search of various databases for primary literature by using Medical Subject Headings (MeSH), Boolean operators and filters; search of secondary sources like guidelines, evidence-based summaries, and structured abstracts.
- 3. Literature Review:** Various sections of research paper and their importance; reading a scientific paper; and interpretation of results & findings of the research.
- 4. Understanding Terminologies and Concepts:** Confounding, predictive value, prognostic factor, likelihood ratio, sensitivity, specificity, internal validity, external validity, per protocol analysis, intention to treat analysis, missing values, outliers, confidence interval, p-value, patient expected event rate, survival curve, Kaplan-Meier product limit theorem, Kappa statistic, and statistical significance vs. clinical significance.
- 5. Critical Appraisal of Literature:** Critical appraisal of validity, impact, and applicability of primary literature; use of various tools and checklists for assessing the methodological quality, biases, and authenticity of primary literature.
- 6. Evidence Synthesis:** Generating the highest level of evidence by conducting a systematic review and meta-analysis – steps involved in conducting a systematic review, data extraction, data analysis, forest plot, funnel plot, heterogeneity, test for interaction, risk of bias assessment, publication bias, software used in the meta-analysis, and PRISMA & MOOSE guidelines.

**Recommended Books:**

1. Evidence-Based Medicine: How to Practice and Teach EBM, by Sharon Straus, Paul Glasziou, W. Scott Richardson, R. Brian Haynes, Elsevier
2. How to Read a Paper: The Basics of Evidence-Based Medicine, by Trisha Greenhalgh, Wiley-Blackwell.
3. Essential Evidence-Based Medicine
4. (Essential Medical Texts for Students and Trainees), by Dan Mayer, Cambridge University Press.
5. The Pharmacist's Guide to Evidence-Based Medicine for Clinical Decision Making, by Patrick J. Bryant and Heather A. Pace, American Society of Health-System Pharmacists.
6. Introduction to Meta-Analysis, by Michael Borenstein, Larry V. Hedges, Julian P.T. Higgins and Hannah R. Rothstein, Wiley.
7. Research Synthesis and Meta-Analysis: A Step-by-Step Approach, by Harris Cooper, SAGE Publications.
8. Cochrane Handbook for Systematic Reviews of Interventions, Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ and Welch VA, Cochrane.
9. Relevant research & review articles from recent medical and pharmaceutical literature.

**GE-611:- Seminar / Presentation / Journal Club****(1 Credit)**

*Each student has to present a seminar before the end of the semester on any of the following topics:*

1. Latest developments in Pharmacy Practice.
2. Novel therapies approved.
3. Novel diseases and their pathogenesis.
4. Current public health issues.
5. Journal club on the latest publications.

**LG-611:- Clinical Placement****(3 Credits)**

1. Choice of patients for case studies: Relevance to pharmacists' involvement
2. Ability to pick the right cases/problems/issues, which should be relevant to pharmaceutical care.
3. Patient profiles (Six per semester)
4. Case presentations adopting Pharmaceutical Care Plan Model (Two per semester).
5. Group discussions for 'real' patient issues (six per semester)
6. Pharmacy posting (20 hours per semester)
7. Communication skills with healthcare professionals, patients and care givers/relatives (level of improvement): Gathering additional information e.g. medication history, allergies, previous medical history, self-medication, use of OTC preparations and knowledge about these and other information relevant to therapy; Counseling ability in view of patients' wish to be so counseled.