ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

M. Pharm (HOSPITAL AND CLINICAL PHARMACY)

FOR
MASTER PHARMACY TWO YEAR POST GRADUATE COURSE
(Applicable for the batches admitted from 2012-2013)

ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)
SCHOOL OF PHARMACY
Venkatapur, Ghatkesar, Hyderabad – 500088
Academic Regulations for M. Pharm (Regular) Degree Course
(Effective for the students admitted into I year from the Academic Year 2012-2013 onwards)

The M.Pharm Degree of Jawaharlal Nehru Technological University Hyderabad shall be conferred on candidates who are admitted to the program and fulfill all the requirements for the award of the degree.

1.0 ELIGIBILITY FOR ADMISSIONS:
Admission to the above program shall be made subject to the eligibility, qualifications and specialization prescribed by the university from time to time.

Admissions shall be made on the basis of merit rank obtained by the qualifying candidate at an Entrance Test conducted by the University or on the basis of any other order of merit approved by the University, subject to reservations prescribed by the university from time to time.

2.0 AWARD OF M.PHARM DEGREE:
2.1 A student shall be declared eligible for the award of the M.Pharm degree, if he pursues a course of study and completes it successfully for not less than two academic years and not more than four academic years.
2.2 A Student, who fails to fulfil all the academic requirements for the award of the degree within four academic years from the year of his admission, shall forfeit his seat in M.Pharm course.
2.3 The minimum instruction period for each semester is 90 clear instruction days.

3.0 COURSE OF STUDY
The following specializations are offered at present for the M.Pharm Course of study.
1. Hospital and Clinical Pharmacy
2. Pharmaceutics
3. Industrial Pharmacy
4. Pharmacology
5. Pharmaceutical Analysis and Quality Assurance

4.0 ATTENDANCE:
The programs are offered on a unit basis with each subject being considered as an unit.
4.1 A candidate shall be deemed to have eligibility to write end semester examinations in a subject if he has put in at least 75% of attendance in the subject.
4.2 Shortage of attendance up to 10% in any subject (i.e. 65% and above and below 75%) may be condoned by the college Academic council on genuine and valid reasons on representation by the candidate with supporting evidence.

4.3 A candidate shall get minimum required attendance at least in three (3) theory subjects in the present semester to get promoted to the next semester. In order to qualify for the award of the M.Pharm Degree, The candidate shall complete all the academic requirements of the subjects, as per the course structure.

4.4 Shortage of attendance below 65% shall in no case be condoned

4.5 A stipulated fee shall be payable towards condonation of shortage of attendance.

5.0 EVALUATION:

The performance of the candidate in each semester shall be evaluated subject-wise, with a maximum of 100 marks for theory and 100 marks for practical’s, on the basis of internal evaluation and End semester Examination. For the theory subjects 60 marks shall be awarded based on the performance in the End semester Examination, 30 marks shall be awarded based on the internal evaluation and 10 marks for assignment.

5.1 For theory subjects, during the semester there shall be 2 midterm examinations. Each midterm examination consists of one subjective paper and one assignment. The subjective paper is for 30 marks with duration of 2 hours. Subjective paper of each semester shall contain 2 parts Section-A & Section-B. Section-A comprises of five (5) short answer type of questions. The student has to answer all the questions from section-A. Each question carries two marks. A total of ten marks are allocated to section-A. Each question carries two marks. A total of ten marks are allocated to section-A. Section-B consists of five (5) essay type of questions from which the student has to answer three questions. Each question carry not more than seven (7) marks. A total of 20 marks are allocated for section-B. The questions in the first midterm examination includes the topics of first 2.5 units while the questions in the second midterm examination includes the topics of remaining 2.5 units. The assignments should be submitted before the conduct of respective midterm examinations.

The total marks secured by the student are out of 40 marks (30marks from midterm examination and 10 marks from assignment) in an internal examination for a subject. The average of marks secured in two midterm examinations shall be taken as final marks. If he/she is absent for any test / assignment, he/she are awarded zero marks for that test / assignment.

5.2 For practical subjects, 60 marks shall be awarded based on the performance in the End Semester Examinations, 40 marks shall be awarded based on the day-to-day performance as internal marks.
5.3 There shall be two seminar presentations during I year I semester and II Semester. For seminar, a student under the supervision of a faculty member, shall collect the literature on a topic and critically review the literature and submit it to the department in a report from and shall make an oral presentation before the departmental committee. The departmental committee consists of Head of the department, supervisor and two other senior faculty members of the department. For each seminar there will be only internal evaluation of 50 marks. A candidate has to secure a minimum of 50% to be declared successful.

5.4 There shall be a Comprehensive Viva-Voce in II year I Semester. The comprehensive Viva-Voce will be conducted by a committee consisting of Head of the Department and two Senior Faculty members of the Department. The comprehensive Viva-Voce is aimed to assess the students’ understanding in various subjects he/she studies during the M.Pharm course of study. The Comprehensive viva-voce valued for 100 marks by the Committee. There are no internal marks for the Comprehensive viva-Voce.

5.5 A candidate shall be deemed to have secured the minimum academic requirement in a subject if he secures a minimum of 40% of marks in the End Examination and a minimum aggregate of 50% of the total marks in the End Semester Examination and Internal Evaluation taken together.

5.6 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 4.3) he has to reappear for the End Examination in that subject. A candidate shall be given one chance to re-register for each subject provided the internal marks secured by a candidate are less than 50% and he has failed in the end examination. In such case candidate must re-register subject(s) and secure required minimum attendance. Attendance in the re-registered subject(s) has to be calculated separately to become eligible to write the end examination in the re-registered subject(s). The attendance of re-registered subject(s) shall be calculated separately to decide upon the eligibility for writing the end examination in those subject(s). In the event of taking another chance, the internal marks and end examination marks obtained in the previous attempt are nullified.

5.7 In case the candidate secures less than the required attendance in any subject(s), he shall not be permitted to appear for the End Examination in that subject(s). He shall re-register the subject when next offered.

5.8 Laboratory examination for M.Pharm courses must be conducted with two Examiners, one of them being Laboratory Class Teacher and second examiner shall be other Laboratory Teacher.
6.0 EVALUATION OF PROJECT/DISSERTATION WORK:

Every candidate shall be required to submit thesis or dissertation after taking up a topic approved by the project review committee.

6.1 A Project Review Committee (PRC) shall be constituted with Principal as chair person, Heads of all the departments which are offering the M.Pharm programs and two other senior faculty members.

6.2 Registration of Project work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects (theory and practical subjects).

6.3 After satisfying 6.2, a candidate has to submit, in consultation with his project supervisor, the title, objective and plan of action of his project work to the Departmental Committee for its approval. Only after obtaining the approval of Departmental Committee the student can initiate the Project work.

6.4 If a candidate wishes to change his supervisor or topic of the project he can do so with the approval of Departmental Committee. However, the Departmental Committee shall examine whether the change of topic/supervisor leads to a major change of his initial plans of project proposal. If so, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

6.5 A candidate shall submit status report (in a bound-form) in two stages at least with a gap of 3 months between them.

6.6 The work on the project shall be initiated in the beginning of the second year and the duration of the project is for two semesters. A candidate is permitted to submit project thesis only after successful completion of theory and practical course with the approval of PRC not earlier than 40 weeks from the date of registration of the project work. For the approval of PRC the candidate shall submit the draft copy of thesis to the Principal (through Head of the Department) and shall make an oral presentation before the PRC.

6.7 Three copies of the Project Thesis certified by the supervisor shall be submitted to the College/School/Institute.

6.8 The thesis shall be adjudicated by one examiner selected by the Institution. For this, Chairmen, BOS of the respective departments shall submit a panel of 5 examiners, who are eminent in that field with the help of the concerned guide and senior faculty of the department.

6.9 If the report of the examiner is not favourable, the candidate shall revise and resubmit the thesis, in the time frame as prescribed by PRC. If the report of the examiner is unfavourable again the thesis shall be summarily rejected.
6.10 If the report of the examiner is favourable, viva-voce examination shall be conducted by a board consisting of the supervisor, Head of the Department and the examiner who adjudicated the Thesis.

The Board shall jointly report candidates work as:

A. EXCELLENT’
B. GOOD
C. SATISFACTORY
D. UNSATISFACTORY

Head of the Department shall coordinate and make arrangements for the conduct of viva-voce examination. If the report of the viva-voce is unsatisfactory, the candidate will retake the viva-voce examination after three months. If he fails to get a satisfactory report at the second viva-voce examination, he will not be eligible for the award of the degree.

7.0 AWARD OF DEGREE AND CLASS
After a student has satisfied the requirement prescribed for the completion of the program and is eligible for the award of M.Pharm Degree he shall be placed in one of the following three classes.

<table>
<thead>
<tr>
<th>Classes Awarded</th>
<th>% of marks to be secured</th>
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</thead>
<tbody>
<tr>
<td>First Class with Distinction</td>
<td>70% and above</td>
</tr>
<tr>
<td>First Class</td>
<td>Below 70% but not less than 60%</td>
</tr>
<tr>
<td>Second Class</td>
<td>Below 60% but not less than 50%</td>
</tr>
</tbody>
</table>

(The marks in internal evaluation and end examination shall be shown separately in the marks memorandum)

8.0 WITH-HOLDING OF RESULTS:

If the candidate has not paid any dues to the institution or if any case of indiscipline is pending against him, the result of the candidate will be withheld and he will not be allowed into next higher semester. The issue of the degree is liable to be withheld in such cases.

9.0 TRANSITORY REGULATIONS:
Candidate who have discontinued or have been detained for want of attendance or who have failed after having undergone the course are eligible for admission to the same or equivalent subjects as and when subjects are offered, subject to 5.5 and 2.0
10.0 GENERAL:

10.1 The academic regulations should be read as a whole for purpose of any interpretation.
10.2 In case of any doubt or ambiguity in the interpretation of the above rules, the decision of the Academic Council is final.
10.3 The institution may change or amend the academic regulations and syllabus at any time and the changes and amendments made shall be applicable to all the students with effect from the date notified by the institution.
10.4 Wherever the word he, him or his occur, it will also include she, her and hers. There shall be no transfers within the constituent colleges of Jawaharlal Nehru Technological University.
<table>
<thead>
<tr>
<th>Nature of Malpractices/Improper conduct</th>
<th>Punishment</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the candidate:</td>
<td></td>
</tr>
<tr>
<td>1. (a) Possesses or keeps accessible in examination hall, any paper, note book, programmable calculators, cell phones, pager, palm, computers or any other form of material concerned with or related to the subject of the examination (theory or practical) in which he is appearing but has not made use of (material shall include any marks on the body of the candidate which can be used as an aid in the subject of the examination)</td>
<td>Expulsion from the examination hall and cancellation of the performance in that subject only</td>
</tr>
<tr>
<td>(b) Gives assistance or guidance or receives it from any other candidate orally or by any other body language methods or communicates through cell phones with any candidate or persons in or outside the exam hall in respect of any matter.</td>
<td>Expulsion from the examination hall and cancellation of the performance in that subject only of all the candidates involved. In case of an outsider, he will be handed over to the police and a case is registered against him.</td>
</tr>
<tr>
<td>2. Has copied in the examination hall from any paper, book, programmable calculators, palm computers or any other form of material relevant to the subject of the examination (theory or practical) in which the candidate is appearing.</td>
<td>Expulsion from the examination hall and cancellation of the performance in that subject and all other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted to appear for the remaining examinations of the subjects of that semester/year. The hall ticket of the candidate is to be cancelled and sent to the controller of examinations, AGI.</td>
</tr>
<tr>
<td>3. Impersonates any other candidate in connection with the examination.</td>
<td>The candidate who has impersonated shall be expelled from examination hall. The candidate is also debarred and forfeits the seat. The performance of the original candidate who has been impersonated, shall be cancelled in all the subjects of the examination(including practical’s and project work) already appeared and shall not be allowed to appear for examinations</td>
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<tr>
<td>4.</td>
<td>Smuggles in the Answer book or additional sheet or takes out or arranges to send out the question paper during the examination or answer book or additional sheet, during or after the examination.</td>
</tr>
<tr>
<td>5.</td>
<td>Uses objectionable, abusive or offensive language in the answer paper or in letters to the examiners or writes to the examiner requesting him to award pass marks.</td>
</tr>
<tr>
<td>6.</td>
<td>Refuses to obey the orders of the Chief Superintendent/Assistant-Superintendent/ any officer on duty or misbehaves or creates disturbance of any kind in and around the examination hall or organizes a walk out or instigates others to walk out, or threatens the officer-in-charge or any person on duty in or outside the examination hall of any injury to his person or to any office relations whether by words, either spoken or written or by signs or by visible representation, assaults the officer-in-charge, or any person on duty in</td>
</tr>
</tbody>
</table>
or outside the examination hall or any of his relations, or indulges in any other act of misconduct or mischief which result in damage to or destruction of property in the examination hall or any part of the college campus or engages in any other act which in the opinion of the officer on duty amounts to use of unfair means or misconduct or has the tendency to disrupt the orderly conduct of the examination.

| 7. | Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall. | Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred for two consecutive semesters from class work and all semester examinations. The continuation of the course by the candidate is subject to the academic regulation in connection with forfeiture of seat. |
| 8. | Posses any lethal weapon or firearm in the examination hall. | Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. |
| 9. | If student of the college, who is not a candidate for the particular examination or any person not connected with college indulges in any malpractice or improper conduct mentioned in clause 6 to 8 | Student of the college’s expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year. The candidate is also debarred and forfeits the seat. |

Person(s) who do not belong to the
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<tbody>
<tr>
<td>10.</td>
<td>Comes in a drunken condition to the examination hall.</td>
<td>College will be handed over to police and, a police case will be registered against them. Expulsion from the examination hall and cancellation of performance in that subject and all the other subjects the candidates has already appeared including practical examinations and project work and shall not be permitted for the remaining examinations of the subjects of that semester/year.</td>
</tr>
<tr>
<td>11.</td>
<td>Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.</td>
<td>Cancellation of the performance in that subject and all other subjects the candidate has appeared including practical examinations and project work of the semester/year examinations.</td>
</tr>
<tr>
<td>12.</td>
<td>If any malpractice is detected which is not covered in the above clauses 1 to 11 shall be reported to the Malpractices committee, AGI for further action to award suitable punishment.</td>
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</table>
# M. Pharm. (Hospital and Clinical Pharmacy)

## Course Structure and Syllabus

### I Year I Semester

<table>
<thead>
<tr>
<th>Subject Code</th>
<th>Group</th>
<th>Subject</th>
<th>L</th>
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<th>Credits</th>
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<tbody>
<tr>
<td>A41001</td>
<td>HCPT</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>3</td>
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<td>3</td>
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<tr>
<td>A41002</td>
<td>HCPT</td>
<td>Advanced Biostatistics and Research Methods</td>
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<td>A41012</td>
<td>HCPT</td>
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<tr>
<td>A41013</td>
<td>HCPT</td>
<td>Advanced Clinical Pharmacy</td>
<td>3</td>
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<tr>
<td>A41014</td>
<td>HCPT</td>
<td>Community Patient Care/Community Pharmacy</td>
<td>3</td>
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<tr>
<td>A41210</td>
<td>Lab</td>
<td>Pathophysiology and Applied Pharmacotherapeutics – I Lab</td>
<td>0</td>
<td>3</td>
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<tr>
<td>A41211</td>
<td>Lab</td>
<td>Advanced Clinical Pharmacy- Lab</td>
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**Total Credits (5 Theory + 2 Labs + Seminar): 21**

### II Semester

<table>
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<tr>
<th>Subject Code</th>
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<th>Credits</th>
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<tr>
<td>A42001</td>
<td>HCPT</td>
<td>Intellectual Property Rights &amp; Drug Regulatory Affairs</td>
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<td>A42002</td>
<td>HCPT</td>
<td>Screening methods and clinical research</td>
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<td>A42013</td>
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<tr>
<td>A42014</td>
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<tr>
<td>A42210</td>
<td>Lab</td>
<td>Pathophysiology and Applied Pharmacotherapeutics – II Lab</td>
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<tr>
<td>A42211</td>
<td>Lab</td>
<td>Hospital Pharmacy – Lab</td>
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<tr>
<td>A42212</td>
<td>Seminar</td>
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**Total Credits (5 Theory + 2 Labs + Seminar): 21**
## II YEAR I SEMESTER

<table>
<thead>
<tr>
<th>Subject Code</th>
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<th>Subject Name</th>
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<tr>
<td>A43210</td>
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<tr>
<td>A43211</td>
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<td>Project Seminar - I</td>
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<tr>
<td>A43212</td>
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<td>Project Work</td>
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<td><strong>Total Credits</strong></td>
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## II YEAR II SEMESTER

<table>
<thead>
<tr>
<th>Subject Code</th>
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<th>Credits</th>
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<tbody>
<tr>
<td>A44207</td>
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<tr>
<td>A44208</td>
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<td>Project Seminar - II</td>
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<td></td>
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<td></td>
<td></td>
<td><strong>22</strong></td>
</tr>
</tbody>
</table>
I Year – I Sem. M.Pharmacy (HCP)

(A41001) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Unit I
a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection
d. Counter – current extraction, solid phase extraction techniques, gel filtration

Unit II
b. HPLC: Principles and instrumentation, solvents and columns used, detection and applications

Unit III
a. UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

Unit IV
Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, GC/MS, interpretation of spectra and applications for identification and structure determination
Unit V
NMR: Theory, instrumentation, chemical shift, shielding and
deshielding effects, splitting of signals, spin-spin coupling, proton
exchange reactions, coupling constant(J), nuclear overhauser
effect(NOE), $^{13}$C NMR spectra and its applications, 2D-NMR, COSY
and applications in pharmacy

Text Books:
& Co.
India: Wiley India .
Delhi: Pearson.
CBS Publishers.
Compounds . 6th ed. New Delhi: John Wiley.
Chromatography. New Delhi: CBS publishers.
12. India. Ministry of Health and Family Welfare, Indian Pharmacopoeia
Indian Pharmacopoeia Commission.
Unit-I : 
Developing a research question, Resources for research question, 
Literature Review: Traditional Qualitative Review 
Meta-Analysis—A Quantitative Review 
Preparation of Research Proposal 
Variables—Definition of Variable, Types of variables—Dependent and 
Independent variables, Confounded variables, Measurement of variables, 
Types of measurement scales and their comparison. Reliability and Validity of 
Measurements.

Unit-II : 
Validity, Types of validity—Internal validity, Construct validity, External 
validity, Threats to validity. 
Control: Subject as own control (Within Subject control), Statistical control.

Unit-III: 
Non-experimental Research: 
Part 1—Observational, Archival and Case-Study Research: The Hermeneutic 
Approach. 
Observational Research: Naturalistic Observation, Participant-Observer 
Research. 
Archival Research: Archival Data Collection and Compilation. 
Case Studies: Characteristic of Case Studies. 

Non-experimental Research: Survey Research—Designing of Questionnaire, 
Methods of Administration, Response Rates. Types of Samples—Haphazard 
Samples, Purposive Samples, Convenience Samples and Probability Samples.

Unit-IV : 
True Experiments: Single-Factor Designs, Factors, Levels, Conditions, and 
Treatments. Within-Subject Designs.

True Experiments Part-2—Factorial Designs—Main Effects, Interactions, A 
Mixed Factorial Design.

Unit V : 
Single-Subject Experiments: Advantages and Disadvantages. 
Quasi Experiments: The differences between Quasi and True Experiments. 
Design without Control Groups—Interrupted Time Series Designs and 
Repeated Treatment Designs.
Text Books

Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice.

**Unit-I Cardiovascular**
- Acute Coronary Syndrome
- Hypertension
- Congestive Cardiac Failure
- Ischaemic Heart Disease (Angina Pectoris, Myocardial Infarction)
- Arrhythmias
- Hyperlipidarmia
- Cardiopulmonary Arrest
- Shock
- Cardiomyopathy

**Unit-II Respiratory System**
- Introduction to pulmonary function tests
- Asthma
- Chronic Obstructive Pulmonary Disease
- Drug Induced Pulmonary Diseases
- Hydrogen Ion Hemostasis & Blood Gases (external and internal respiration).

**Unit-III Haematological Diseases & Nephrology**
- Anaemia’s
- Thalassemia
- Drug Induced Haematological Diseases
- Venous Thromboembolism
- Acute Renal Failure / Chronic Renal Failure
- Renal Dialysis and Transplantation
- Drug Dosing In Renal Failure / Impairment
- Drug Induced Renal Diseases
- End-Stage Renal Disease
- Diuretic Therapy
- Potassium Depletion
- Hyperkaelemia
- Alakalosis
Unit-IV Gastroentrology & Rheumatology
- Gastro – Oesophageal Reflux Disease
- Peptic Ulcer Disease
- Inflammatory Bowel Disease
- Hepatitis, Viral
- Jaundice & Cirrhosis
- Diarrhoea & Constipation
- Drug Induced Liver Disease
- Gout & Hyperuricemia
- Rheumatoid Arthritis
- Osteoarthritis
- Spondylitis
- NAFLD

Unit-V Endocrinology & Dermatology
- Adrenal Gland Disorders
- Diabetic Mellitus
- Thyroid Disorders
- Osteoporosis
- Acne Vulgaris
- Psoriasis
- Scabies
- Eczema
- Drug Induced Skin Disorders
- Vetiligo

Text Books
11. Relevant review articles from recent medical and pharmaceutical Journals.
(A41013) ADVANCED CLINICAL PHARMACY

Unit-I  **Introduction to clinical pharmacy**
- Definition, Scope, History and Development of clinical pharmacy

Unit-II  **Professional Activities of a Clinical Pharmacist**
- Ward Round Participation
- Medication History Interview
- Drug Therapy Monitoring (Medication Chart Review, Clinical Review, Therapeutic Drug Monitoring & Pharmacist Interventions)
- Adverse Drug Reaction Management
- Drug Information & Poison Information
- Patient Counseling
- PharmaHCPtical Care
- Drug Utilization evaluation (DUE) & Review (DUR)
- Quality Assurance of Clinical Pharmacy Services

Unit-III

A) **Patient Data Analysis**
- The patient’s case history, its structure & use in evaluation of drug therapy, presentation of cases.
- Communication skills, including patient counseling techniques, medication history interview, teaching skills.
- Understanding common medical abbreviations & terminologies used in clinical practices.

B) Clinical Laboratory Tests used in the evaluation of diseases states & interpretation of test results.
- Haemotological, Liver function, Renal function, Thyroid function tests.
- Medical imaging techniques
- Tests associated with cardiac disorders
• Fluid & Electrolyte balance
• Common tests in urine, sputum, faeces, CSF.
• Sensitivity screening for common pathogenic microorganisms, its significance, resistance in disease states & selection of appropriate anti-microbial regimens.
• Pulmonary function tests.

Unit-IV

A) Drug & Poison Information

• Introduction to Drug information, resources available,
• Systematic approach in answering drug information serve queries
• Critical evaluation of drug information and literature
• Preparation of written and verbal reports
• Establishing a drug information center
• Poisons information-organisation and information resources
• Poisons management in drug dependence and drug abuses (opiates, cocaine, amphetamines, alcohols, benzodiazepines, barbiturates, tobacco). Role of emetics, anti-emetics and respiratory stimulants.

B) Evidence Based Medicine

• Formulating Clinical Questions
• Searching for the best evidence
• Critical Appraisal of the evidence
• Applying evidence to patients
• Evaluation

Unit-V

A) Medication Error and Medication Adherence

• Categories and causes of medication error
• Performance indicators of the medication use process
• Categories of medication non-adherence
• Role of pharmacists at medication error and medication adherence

B) Pharmacovigilance

• Scope, Definition and Aims of Pharmacovigilance
• Adverse Drug Reactions – Classification, Mechanism, Predisposing Factors, Causality Assessment [different scaled used].
• Reporting, evaluation, monitoring, preventing & management of ADR’s
• Role of pharmacist in management of ADR’s

Text Books
6. Relevant review articles from recent medical and pharmaceutical literature.
Unit-I

Introduction to the concept of community pharmacy – its activities and professional responsibilities

a) The role of community pharmacy and its relationships to other local health care providers
b) Prescribed medication order- Interpretation and legal requirements
c) Over the counter (OTC) sales
d) OTC medication list and counseling, Rational use of common OTC medications
   (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhal preparations)

Unit-II

Health Education and Community Pharmacy: Family planning, first aid, communicable disease prevention, smoking cessation, screening programs.

Unit-III

a) Services to nursing homes/clinics.
b) Community Pharmacy Management: Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy.
c) Code of ethics for community pharmacy
d) Poly pharmacy and its implications

Unit-IV

A) Communication skills – Principles and elements of communication skills, non-verbal communication in pharmacy, barriers in communication, listening skills, questioning skills, explaining Skills.
   Patient counseling in community pharmacy
B) Education and training staff, training and continuing education for pharmacists, pharmacy students, Medical staff and students, nursing skills , explaining skills and ethics in communication

Unit-V
A) Public Health Policy and Health Care System – National & International
B) Concept of Rational Use of Drugs – Importance of rational drug use, pharmacists role, drug use indication, guidelines for rational prescribing.
C) Code of ethics for community pharmacists

Text Books


5. Relevant review articles from recent medical and pharmaceutical literature

(A41210) PATHOPHYSIOLOGY AND APPLIED PHARMACOTHERAPEUTICS-I LAB

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following departments:

1. Cardiology
2. Respiratory System
3. Haematological Diseases & Nephrology
4. Gastroenterology & Rheumatology
5. Endocrinology & Dermatology

Assignments

The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.
I Year – I Sem. M.Pharmacy (HCP)

(A41211) ADVANCED CLINICAL PHARMACY – LAB

Patient medication history interview, answering drug information questions, patient medication counselling, participation in ward rounds. Case studies related to laboratory investigations covering the topics dealt in theory class.

1. Answering drug information questions (4)
   (Queries related to Dosage, administration, contraindications, adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety)
2. Patient medication counselling – (3) Common diseases like Diabetes, Hypertension, Asthma, COPD, Acute Renal Failure, chronic Renal Failure.
3. Case studies related to laboratory investigations (4) – LFT, Hematology, Thyroid, Renal, Cardiac Enzymes.
4. Patient medication history interview (2)
5. Medication order review (2)
6. Detection and assessment of adverse drug reaction and their documentation (3)

Assignments

Drug information,
Patient medication history interview
Patient medication counseling
Problem solving in clinical Pharmacokinetics
Literature evaluation pertaining to therapeutic range used in therapeutic monitoring of any two drugs frequently subjected for TDM.
Critical appraisal of two recently published articles in the biomedical literature, which deals with a drug or therapeutic issue.
I Year – II Sem. M.Pharmacy (HCP)

(A42001) INTELLECTUAL PROPERTY RIGHTS AND DRUG REGULATORY AFFAIRS

Intellectual Property Management:

**Unit I**: Types of IP, definition, scope, objectives Patents, types, contents of patent, claims and types of claims, key terminology used in patents (Application, examiner, prior art, priority, specifications, provisional and non-provisional applications, claims, applicant, assignee, inventor, anticipation, obviousness, infringement and invalidation).

**Unit II**: Filing process, provisional and non-provisional applications, PCT filing process, Advantages, Patentability requirement: (Novelty, Utility, non-obviousness, enablement and best mode), Understanding on infringement, invalidation and litigations


Regulatory Affairs:

**Unit IV**: National drug regulatory requirements, national drug policy, Drugs and Cosmetics Act and its amendments, overview of schedules, details of schedule M, Schedule Y. US FDA, orange book, FDA guidelines on IND, new drug approvals (NDA), ANDA approvals, SUPAC changes and understanding on 505 (b) (2) applications.

**Unit V**: Office of generic drugs, recommendations on dissolution and bio-equivalence requirements, types of ANDA filing (P I, II, III and IV) PIV ANDA filing and process involved till the approval Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC exclusivity) European regulatory agency, types of filing process (Centralized, de-centralized, RMS countries), SPCs, SPC exclusivities, data exclusivities, WHO, WIPO, ICH objectives and guidelines.
Text Books:

5. P.Das and Gokul Das., Protection of Industrial Property rights.
7. Original Laws Published by Govt. of India
8. Hussain Laws of drugs in India,
10. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org
Unit I
Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

Unit II
Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

Unit III
Toxicity tests: OECD guidelines, determination of LD50, acute, subacute and chronic toxicity studies.

Unit IV
Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation cardiac, psychopharmacological, anti-inflammatory, analgesic and anti diabetic.

Unit V
Clinical evaluation of new drugs, Phases of clinical trial, protocol design, Ethics in human research.

Pharmacovigilance: Definition, collection of data, reporting, assessment of
Post marketing surveillance, periodic safety update reports, Risk-benefit assessment

Text Books:
Advanced Pharmacology – II

(A42012) Clinical Pharmacokinetics and Therapeutic Drug Monitoring

1. Introduction to Clinical pharmacokinetics.
   a. Primary pharmacokinetic parameters
   b. Interrelationship between primary pharmacokinetic parameters and their effect on plasma concentration-time profile
   c. Therapeutics Dosage regimens for special populations
   d. Physiologic variables Affecting drug clearance

2. Design of dosage regimens:
   Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. Pharmacokinetics of Drug Interaction:
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. Therapeutic Drug monitoring:
   a. Introduction
   b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
   c. Indications for TDM. Protocol for TDM.
   d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. Dosage adjustment in Renal and hepatic Disease.
   a. Renal impairment
   b. Pharmacokinetic considerations in renal impairment
   c. General approach for dosage adjustment in Renal disease.
   d. Measurement of Glomerular Filtration rate and creatinine clearance.
   e. Dosage adjustment for uremic patients.
   f. Extracorporeal removal of drugs.
   g. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
   h. Effect of Hepatic disease on pharmacokinetics.
Text Books


7. Relevant review articles from recent medical and pharmaceutical literature


Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice.

**Unit-I**

**Neurology & Psychiatry**
- Epilepsy,
- Parkinson’s Disease
- Multiple sclerosis
- Headache: Migrane & Tension Type
- Pain Management
- Stroke
- Alzheimer’s Disease
- Anxiety Disorders
- Bipolar Disorders
- Depressive Disorder
- Schizophrenia, Psychosis
- Sleep Disorders
- Substance – Related Disorders

**Unit-II**

**Oncology (Blood cancer and Solid tumors)**
- Basic Principles in Cancer Therapy, General Introduction To Cancer Chemotherapy Agents
- Atiangiogenic agents
- Chemotherapy of Brest Cancer
- Chemotherapy of Lung Cancer
- Chemotherapy of Head / Neck Cancer
- Leukemia
- Management of Chemotherapy – Nausea/ Vomiting
- Pallative Care
- Colorectal Cancer
- Lyphomas
- Prostate Cancer
Unit-III
Infectious Diseases
- Antimicrobial Regimen Selection
- Central Nervous System Infections – Meningitis
- Endocarditis
- Fungal Infections, Invasive
- Gastrointestinal Infections
- HIV/AIDS
- Influenza
- Intraabdominal Infections
- Respiratory Tract Infections – Upper & Lower
- Gastroenteritis
- Sepsis & Septic Shock
- STD’s
- Surgical Prophylaxis
- Tuberculosis
- Urinary Tract Infections & Prostatitis

Unit-IV
Gynecologic & Obstetric Disorders / Ophthalmology/ Eye Disorders
- Menopause/ Hormone Replacement Therapy In Women
- Pregnancy & Lactation : Therapeutic Considerations
- Contraception.
- Conjunctivitis
- Glaucoma
- Eye infections

Unit-V
Nutritional Disorder & Immunology
- Assessment & Nutritional Requirement
- Enteral Nutritrion
- Obesity
- Total Parenteral Nutrition
- Immune Disease – Pathogenesis, Mechanism of action of drugs
- Orphan diseases(Sjogren's Syndrome, Paget Disease Extramammary, progeria)
Glucocorticoids – Anti-inflammatory, Anti-allergic & Immunosuppressive actions in tissue as well as organ transplantation
Vaccines, Toxioids and other immunobiologics

Text Books
I Year – II Sem. M.Pharmacy (HCP)

(A42014) HOSPITAL PHARMACY

Unit-I Introduction:
The role of hospital pharmacy department and its relationship to other hospital departments and staff.

Unit-II Hospital Drug Policy:
a) Pharmacy and therapeutic committee (PTC)
b) Hospital Formulary
c) e-Medicine

Unit-III  a) Hospital Committee
- Infection committee
- Research and ethical committee
b) Developing therapeutic guidelines
c) Hospital pharmacy communication - Newsletter.

Unit-IV Pharmacoepidemiology:
i. Definition & Scope – Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

ii. Measurement of outcomes in pharmacoepidemiology – outcome measure and drug use measures, prevalence, incidence and incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.

iii. Concept of risk in pharmacoepidemiology
   - Measurement of risk,
   - Attributable risk and relative risk
   - Time-risk relationship and odds ratio

iv. 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 &
Record Linkage system
v. Sources of data for pharmacoepidemiology studies
Ad Hoc data sources and automated data systems
vi. Selected special applications of pharmacoepidemiology
Studies of vaccine safety
Hospital pharmacoepidemiology
Pharmacoepidemiology and risk management
Drug induced birth defects

Unit-V Pharmacoconomics
Definition, history, needs of pharmacoeconomic evaluations – Role in formulary management decisions
Pharmacoeconomic evaluation - Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Case- minimization, Cost- benefit, Cost-effectiveness, Cost-Utility, Health Insurance - Medical Insurance.
Applications of Pharmacoconomics – Software and case studies

Text Books


The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

The cases may be selected from the following diseases:

1. Neurology & Psychiatry
2. Oncology
3. Infectious Diseases
4. Gynecologic & Obstetric Disorders/ Ophthalmology
5. Nutritional Disorder & Immunology

Assignments
The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.
I Year – II Sem. M.Pharmacy (HCP)

(A42211) Hospital Pharmacy – Lab

The student is expected to perform ABC and VED analysis on the given data on drugs used in the hospital, participate in activity session involving issues regarding pharmacy and therapeutic committee, prepare a model monograph for a drug formulary, critically analyse the given data on hospital pharmacy budget, work flow patterns etc., perform patient medication interview and counselling and present drug profiles one new drugs.

ASSIGNMENTS

The student is expected to perform the following and report.

- Comparison of prescription handling in two community pharmacies.
- Audit of OTC sales over a 24 hour period in a local community pharmacy.
- Role of community pharmacists in health education, family planning, first aid, smoking cessation screening programmes, immunisation, etc.
- Code of ethics for community pharmacies.
- Summary of the advice and recommendations which should be provided to the customers at a community pharmacy.
- Select a new drug, which has recently been marketed in India for the first time.

Prepare a report for a hospital’s Drug and Therapeutic Committee, and make a case either for or against the addition of this new drug on to the hospital’s formulary. Issues, which you may need to cover, include the drug’s pharmacology, its clinical use, the opinions of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.

- Examine and report on the drug distribution methods used in a local hospital.
- Examine and report on the purchase and inventory of drugs in a local hospital.