ACADEMIC REGULATIONS, COURSE STRUCTURE
AND DETAILED SYLLABUS

M.Pharm (INDUSTRIAL PHARMACY)

FOR
MASTER OF PHARMACY TWO YEAR POST GRADUATE COURSE
(Applicable for the batches admitted from 2015-2016)

R15

ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)
Venkatapur, Ghatkesar, Hyderabad – 500 088
Applicable for the students of M. Pharm. (Regular) programme from the Academic Year 2015-16 and onwards

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

1.0 ELIGIBILITY FOR ADMISSIONS

Admission to the above programme shall be made subject to eligibility, qualification and specialization as prescribed by the University from time to time.

Admissions shall be made on the basis of merit/rank obtained by the candidates at the qualifying Entrance Test conducted by the University or on the basis of any other order of merit as approved by the University, subject to reservations as laid down by the Govt. 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 in not less than two and not more than four academic years, failing which he shall forfeit his seat in M. Pharm. programme.

2.2 The student shall register for all 88 credits and secure all the 88 credits.

2.3 The minimum instruction days in each semester are 90.

3.0 COURSES OF STUDY

The following specializations are offered at present for the M. Pharm. programme of study.

1. Industrial Pharmacy
2. Pharmaceutics
3. Pharmacology
4. Pharmaceutical Analysis and Quality Assurance

Course Registration

4.1 A ‘Faculty Advisor or Counselor’ shall be assigned to each student, who will advise him on the Post Graduate Programme (PGP), its Course Structure and Curriculum, Choice/Option for Subjects/Courses, based on his competence, progress, pre-requisites and interest.

4.2 Academic Section of the College invites ‘Registration Forms’ from students with in 15 days from the commencement of class work through ‘ON-LINE SUBMISSIONS’, ensuring ‘DATE and TIME Stamping’. The ON-LINE Registration Requests for any ‘CURRENT SEMESTER’ shall be completed BEFORE the commencement of SEE’s (Semester End Examinations) of the ‘PRECEDING SEMESTER’.
4.3 A Student can apply for ON-LINE Registration, ONLY AFTER obtaining the ‘WRITTEN APPROVAL’ from his Faculty Advisor, which should be submitted to the College Academic Section through the Head of Department (a copy of it being retained with Head of Department, Faculty Advisor and the Student).

4.4 If the Student submits ambiguous choices or multiple options or erroneous entries during ON-LINE Registration for the Subject(s) / Course(s) under a given/specified Course Group/ Category as listed in the Course Structure, only the first mentioned Subject/ Course in that Category will be taken into consideration.

4.5 Subject/ Course Options exercised through ON-LINE Registration are final and CANNOT be changed, nor can they be inter-changed; further, alternate choices will also not be considered. However, if the Subject/ Course that has already been listed for Registration (by the Head of Department) in a Semester could not be offered due to any unforeseen or unexpected reasons, then the Student shall be allowed to have alternate choice - either for a new Subject (subject to offering of such a Subject), or for another existing Subject (subject to availability of seats), which may be considered. Such alternate arrangements will be made by the Head of Department, with due notification and time-framed schedule, within the FIRST WEEK from the commencement of Class-work for that Semester.

5 ATTENDANCE

The programmes are offered on a unit basis with each subject being considered a unit.

5.1 Attendance in all classes (Lectures/Laboratories etc.) is compulsory. The minimum required attendance in each theory / Laboratory etc. is 75% including the days of attendance in sports, games, NCC and NSS activities for appearing for the End Semester examination. A student shall not be permitted to appear for the Semester End Examinations (SEE) if attendance is less than 75%.

5.2 Condonation of shortage of attendance in each subject up to 10% (65% and above and below 75%) in each semester shall be granted by the College Academic Committee on genuine medical grounds and valid reasons on representation by the candidate with supporting evidence.

5.3 Shortage of Attendance below 65% in each subject shall not be condoned.

5.4 Students whose shortage of attendance is not condoned in any subject are not eligible to write their end semester examination of that subject and their registration shall stand cancelled.

5.5 A prescribed fees shall be payable towards condonation of shortage of attendance.

5.6 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.

5.7 A student shall not be promoted to the next semester unless he satisfies the
attendance requirement of the present Semester, as applicable. They may seek readmission into that semester when offered next. If any candidate fulfills the attendance requirement in the present semester, he shall not be eligible for readmission into the same class.

6 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 practicals, on the basis of Internal Evaluation and End Semester Examination.

6.1 For the theory subjects 60 marks shall be awarded for the performance in the Semester End Examination and 40 marks shall be awarded for Continuous Internal Evaluation (CIE). The Continuous Internal Evaluation shall be made based on the average of the marks secured in the two Mid Term-Examinations conducted, one in the middle of the Semester and the other, immediately after the completion of Semester instructions. Each mid-term examination shall be conducted for a total duration of 120 minutes with Part A as compulsory question (10 marks) consisting of 5 sub-questions carrying 2 marks each, and Part B with 3 questions to be answered out of 5 questions, each question carrying 10 marks. The details of the Question Paper pattern for End Examination (Theory) are given below:

• The Semester End Examination will be conducted for 60 marks. It consists of two parts. i) Part-A for 20 marks, ii) Part-B for 40 marks.

• Part-A is a compulsory question consisting of 5 questions, one from each unit and carries 4 marks each.

• Part-B to be answered 5 questions carrying 8 marks each. There will be two questions from each unit and only one should be answered.

6.2 For practical subjects, 60 marks shall be awarded for performance in the Semester End Examinations and 40 marks shall be awarded for day-to-day performance as Internal Marks.

6.3 The practical end semester examination shall be conducted with an external examiner and the laboratory teacher. The external examiner shall be appointed by the Principal from the panel of examiners recommended by Chairman, Board of Studies in respective Branches.

6.4 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 form and shall make an oral presentation before the Departmental Academic Committee consisting 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% of marks to be declared successful. If he fails to fulfill minimum marks, he has to reappear during the supplementary examinations.
6.5 There shall be a Comprehensive Viva-Voce in II year I Semester. The Comprehensive Viva-Voce is intended to assess the students’ understanding of various subjects he has studied during the M. Pharm. course of study. The Head of the Department shall be associated with the conduct of the Comprehensive Viva-Voce through a Committee. The Committee consisting of Head of the Department, one senior faculty member and an external examiner. The external examiner shall be appointed by the Principal from the panel of 3 examiners recommended by Chairman, Board of Studies in respective Branches. There are no internal marks for the Comprehensive Viva-Voce and evaluates for maximum of 100 marks. A candidate has to secure a minimum of 50% of marks to be declared successful. If he fails to fulfill minimum marks, he has to reappear during the supplementary examinations.

6.6 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 Semester End Examination and a minimum aggregate of 50% of the total marks in the Semester End Examination and Continuous Internal Evaluation taken together.

6.7 In case the candidate does not secure the minimum academic requirement in any subject (as specified in 6.6) he has to reappear for the Semester End Examination in that subject.

6.8 A candidate shall be given one chance to re-register for the subjects if the internal marks secured by a candidate is less than 50% and failed in that subject for maximum of two subjects and should register within four weeks of commencement of the class work. In such a case, the candidate must re-register for the subjects and secure the required minimum attendance. The candidate’s attendance in the re-registered subject(s) shall be calculated separately to decide upon his eligibility for writing the Semester End Examination in those subjects. In the event of the student taking another chance, his Continuous Internal Evaluation (internal) marks and Semester End Examination marks obtained in the previous attempt stands cancelled.

6.9 In case the candidate secures less than the required attendance in any subject, he shall not be permitted to write the Semester End Examination in that subject. He shall re-register for the subject when next offered.

7 Examinations and Assessment - The Grading System

7.1 Marks will be awarded to indicate the performance of each student in each Theory Subject, or Lab/Practicals, or Seminar, or Project, etc., based on the % marks obtained in CIE + SEE (Continuous Internal Evaluation + Semester End Examination, both taken together) as specified in Item 6 above, and a corresponding Letter Grade shall be given.

7.2 As a measure of the student’s performance, a 10-point Absolute Grading System using the following Letter Grades (UGC Guidelines) and corresponding percentage of marks shall be followed:
<table>
<thead>
<tr>
<th>% of Marks Secured (Class Intervals)</th>
<th>Letter Grade (UGC Guidelines)</th>
<th>Grade Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>80% and above</td>
<td>O (Outstanding)</td>
<td>10</td>
</tr>
<tr>
<td>(≥ 80%, ≤ 100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 80% but not less than 70%</td>
<td>A+ (Excellent)</td>
<td>9</td>
</tr>
<tr>
<td>(≥ 70%, &lt; 80%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 70% but not less than 60%</td>
<td>A (Very Good)</td>
<td>8</td>
</tr>
<tr>
<td>(≥ 60%, &lt; 70%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 60% but not less than 55%</td>
<td>B+ (Good)</td>
<td>7</td>
</tr>
<tr>
<td>(≥ 55%, &lt; 60%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 55% but not less than 50%</td>
<td>B (Above Average)</td>
<td>6</td>
</tr>
<tr>
<td>(≥ 50%, &lt; 55%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 50%</td>
<td>F (Fail)</td>
<td>0</td>
</tr>
<tr>
<td>(&lt; 50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>Ab</td>
<td>0</td>
</tr>
</tbody>
</table>

7.3 A student obtaining F Grade in any Subject shall be considered ‘failed’ and is be required to reappear as ‘Supplementary Candidate’ in the Semester End Examination (SEE), as and when offered. In such cases, his Internal Marks (CIE Marks) in those Subjects will remain the same as those he obtained earlier.

7.4 A student not appeared for examination then ‘Ab’ Grade will be allocated in any Subject shall be considered ‘failed’ and will be required to reappear as ‘Supplementary Candidate’ in the Semester End Examination (SEE), as and when offered.

7.5 A Letter Grade does not imply any specific Marks percentage and it will be the range of marks percentage.

7.6 In general, a student shall not be permitted to repeat any Subject/ Course (s) only for the sake of ‘Grade Improvement’ or ‘SGPA/ CGPA Improvement’.

7.7 A student earns Grade Point (GP) in each Subject/ Course, on the basis of the Letter Grade obtained by him in that Subject/ Course. The corresponding ‘Credit Points’ (CP) are computed by multiplying the Grade Point with Credits for that particular Subject/ Course.

Credit Points (CP) = Grade Point (GP) x Credits .... For a Course

7.8 The Student passes the Subject/ Course only when he gets $\text{GP} \geq 6$(B Grade or above).

7.9 The Semester Grade Point Average (SGPA) is calculated by dividing the Sum of Credit Points ($\Sigma$CP) secured from ALL Subjects/ Courses registered in a
Semester, by the Total Number of Credits registered during that Semester. SGPA is rounded off to TWO Decimal Places. SGPA is thus computed as

\[
SGPA = \left( \frac{\sum_{i=1}^{N} C_i G_i}{\sum_{i=1}^{N} C_i} \right)
\]

For each Semester,

where ‘i’ is the Subject indicator index (takes into account all Subjects in a Semester), ‘N’ is the no. of Subjects ‘REGISTERED’ for the Semester (as specifically required and listed under the Course Structure of the parent Department), C is the no. of Credits allotted to the ith Subject, and G represents the Grade Points (GP) corresponding to the Letter Grade awarded for that ith Subject.

7.10 The Cumulative Grade Point Average (CGPA) is a measure of the overall cumulative performance of a student over all Semesters considered for registration. The CGPA is the ratio of the Total Credit Points secured by a student in ALL registered Courses in ALL Semesters, and the Total Number of Credits registered in ALL the Semesters. CGPA is rounded off to TWO Decimal Places. CGPA is thus computed from the I Year Second Semester onwards, at the end of each Semester, as per the formula

\[
CGPA = \left( \frac{\sum_{j=1}^{M} C_j G_j}{\sum_{j=1}^{M} C_j} \right)
\]

For all S Semesters registered

(ie., upto and inclusive of S Semesters, \( S \geq 2 \)),

where ‘M’ is the TOTAL no. of Subjects (as specifically required and listed under the Course Structure of the parent Department) the Student has ‘REGISTERED’ from the 1st Semester onwards upto and inclusive of the Semester S (obviously \( M > N \)), ‘j’ is the Subject indicator index (takes into account all Subjects from 1 to S Semesters), C is the no. of Credits allotted to the jth Subject, and G represents the Grade Points (GP) corresponding to the Letter Grade awarded for that jth Subject. After registration and completion of I Year I Semester however, the SGPA of that Semester itself may be taken as the CGPA, as there are no cumulative effects.

7.11 For Calculations listed in Item 7.6 – 7.10, performance in failed Subjects/ Courses (securing F Grade) will also be taken into account, and the Credits of such Subjects/ Courses will also be included in the multiplications and summations.

8. **EVALUATION OF PROJECT/DISSERTATION WORK**

Every candidate shall be required to submit a thesis or dissertation on a topic approved by the Project Review Committee.

8.1 A Project Review Committee (PRC) shall be constituted with Head of the Department as Chairperson, Project Supervisor and one senior faculty member of the Departments offering the M. Pharm. Programme.

8.2 Registration of Project Work: A candidate is permitted to register for the project work after satisfying the attendance requirement of all the subjects, both theory and practical.
8.3 After satisfying 8.2, a candidate has to submit, in consultation with his Project Supervisor, the title, objective and plan of action of his project work to the PRC for approval. Only after obtaining the approval of the PRC the student can initiate the Project work.

8.4 If a candidate wishes to change his supervisor or topic of the project, he can do so with the approval of the PRC. However, the PRC shall examine whether or not the change of topic/supervisor leads to a major change of his initial plans of project proposal. If yes, his date of registration for the project work starts from the date of change of Supervisor or topic as the case may be.

8.5 A candidate shall submit his project status report in two stages at least with a gap of 3 months between them.

8.6 The work on the project shall be initiated at the beginning of the II year and the duration of the project is two semesters. A candidate is permitted to submit Project Thesis only after successful completion of all theory and practical courses 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 Head of the Department and make an oral presentation before the PRC.

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

8.8 For Project work Review I in II Year I Sem. there is an internal marks of 50, the evaluation should be done by the PRC for 25 marks and Supervisor will evaluate for 25 marks. The Supervisor and PRC will examine the Problem Definition, Objectives, Scope of Work, Literature Survey in the same domain. A candidate has to secure a minimum of 50% of marks to be declared successful for Project Work Review I. If he fails to fulfill minimum marks, he has to reappear as per the recommendations of PRC.

8.9 For Project work Review II in II Year II Sem. there is an internal marks of 50, the evaluation should be done by the PRC for 25 marks and Supervisor will evaluate for 25 marks. The PRC will examine the overall progress of the Project Work and decide the Project is eligible for final submission or not. A candidate has to secure a minimum of 50% of marks to be declared successful for Project Work Review II. If he fails to fulfill minimum marks, he has to reappear as per the recommendations of PRC.

8.10 For Project Evaluation (Viva Voce) in II Year II Sem. there is an external marks of 150 and the same evaluated by the External examiner appointed by the Institution. The candidate has to secure minimum of 50% marks in Project Evaluation (Viva-Voce) examination.

8.11 If he fails to fulfill as specified in 8.10, he will reappear for the Viva-Voce examination only after three months. In the reappeared examination also, fails to fulfill, he will not be eligible for the award of the degree.

8.12 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 3 examiners, who are eminent in that field with the help of the concerned guide and senior faculty of the department.
8.13 If the report of the examiner is not favourable, the candidate shall revise and resubmit the Thesis. If the report of the examiner is unfavourable again, the thesis shall be summarily rejected.

8.14 If the report of the examiner is favourable, Project Viva-Voce examination shall be conducted by a board consisting of the Supervisor, Head of the Department and the external examiner who adjudicated the Thesis.

8.15 The Head of the Department shall coordinate and make arrangements for the conduct of Project Viva-Voce examination.

9. **AWARD OF DEGREE AND CLASS**

9.1 A Student who registers for all the specified Subjects/Courses as listed in the Course Structure, satisfies all the Course Requirements, and passes the examinations prescribed in the entire PG Programme (PGP), and secures the required number of 88 Credits (with CGPA ≥ 6.0), shall be declared to have ‘QUALIFIED’ for the award of the M.Pharm. Degree in the chosen Branch of Engineering and Technology with specialization as he admitted.

9.2 **Award of Class**

After a student has satisfied the requirements prescribed for the completion of the programme and is eligible for the award of M.Pharm. Degree, he shall be placed in one of the following three classes based on the CGPA:

<table>
<thead>
<tr>
<th>Class Awarded</th>
<th>CGPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Class with Distinction</td>
<td>≥ 7.75</td>
</tr>
<tr>
<td>First Class</td>
<td>6.75 ≤ CGPA &lt; 7.75</td>
</tr>
<tr>
<td>Second Class</td>
<td>6.00 ≤ CGPA &lt; 6.75</td>
</tr>
</tbody>
</table>

9.3 A student with final CGPA (at the end of the PGP) < 6.00 will not be eligible for the Award of Degree.

10. **WITHHOLDING OF RESULTS**

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

11. **TRANSITORY REGULATIONS**

11.1 If any candidate is detained due to shortage of attendance in one or more subjects, they are eligible for re-registration to maximum of two earlier orequivalentsubjects at a time as and when offered.

11.2 The candidate who fails in any subject will be given two chances to pass the same subject; otherwise, he has to identify an equivalent subject as per R15 Academic Regulations.
12.1 **Credit**: A unit by which the course work is measured. It determines the number of hours of instructions required per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.

12.2 **Credit Point**: It is the product of grade point and number of credits for a course.

12.3 Wherever the words “he”, “him”, “his”, occur in the regulations, they include “she”, “her”.

12.4 The academic regulation should be read as a whole for the purpose of any interpretation.

12.5 In the case of any doubt or ambiguity in the interpretation of the above rules, the Decision of the Academic Council is final.

12.6 The Academic Council may change or amend the academic regulations or syllabi at any time and the changes or amendments made shall be applicable to all the students with effect from the dates notified by the Academic Council.
### MALPRACTICES RULES
### DISCIPLINARY ACTION FOR IMPROPER CONDUCT IN EXAMINATIONS

<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 of the remaining 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 regulations in connection with forfeiture of seat. If the imposter is an outsider, he will be handed over to the police and a case is registered against him.</td>
</tr>
<tr>
<td>4. Smuggles in the Answer book or</td>
<td>Expulsion from the examination hall and</td>
</tr>
<tr>
<td></td>
<td>Using 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>
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<tr>
<td>5.</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 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.</td>
</tr>
<tr>
<td>6.</td>
<td>Leaves the exam hall taking away answer script or intentionally tears of the script or any part thereof inside or outside the examination hall.</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>---</td>
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</tr>
<tr>
<td>8.</td>
<td>Posses any lethal weapon or firearm in the examination hall.</td>
</tr>
<tr>
<td>9.</td>
<td>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</td>
</tr>
<tr>
<td>10.</td>
<td>Comes in a drunken condition to the examination hall.</td>
</tr>
<tr>
<td>11.</td>
<td>Copying detected on the basis of internal evidence, such as, during valuation or during special scrutiny.</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>
</tr>
</tbody>
</table>
**ANURAG GROUP OF INSTITUTIONS**  
**(AUTONOMOUS)**  
**M.PHARMACY (INDUSTRIAL PHARMACY)**  
**(R15) COURSE STRUCTURE AND SYLLABUS**

### I Year – I Semester

<table>
<thead>
<tr>
<th>Category</th>
<th>Course Title</th>
<th>Int. marks</th>
<th>Ext. marks</th>
<th>L</th>
<th>P</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Course I</td>
<td>Biopharmaceutics and Pharmacokinetics</td>
<td>40</td>
<td>60</td>
<td>4</td>
<td>--</td>
<td>4</td>
</tr>
<tr>
<td>Core Course II</td>
<td>Advanced physical Pharmaceutics</td>
<td>40</td>
<td>60</td>
<td>4</td>
<td>--</td>
<td>4</td>
</tr>
<tr>
<td>Core Course III</td>
<td>Industrial Pharmaceutics</td>
<td>40</td>
<td>60</td>
<td>4</td>
<td>--</td>
<td>4</td>
</tr>
</tbody>
</table>
| Core Elective    | 1. Modern Pharmaceutical Analytical Techniques  
|                  | 2. Drug Regulatory Affairs (National & International) | 40         | 60         | 4 | --| 4 |
| Open Elective    | 1. Pharmacoepidemiology, Pharmacoeconomics and Pharmacovigilance  
|                  | 2. Advanced Biostatistics And Research Methods  
|                  | 3. Herbal Cosmetic Technology                | 40         | 60         | 4 | --| 4 |
| Laboratory I     | Modern Pharmaceutical Analytical Techniques Lab | 40         | 60         | --| 4| 4 |
| Laboratory II    | Advanced Physical Pharmaceutics Lab         | 40         | 60         | --| 4| 2 |
| Seminar I        | Seminar                                     | 50         | --         | --| 4| 2 |
| **Total Credits**|                                            |            |            | 20| 12| 28|

### I Year – II Semester

<table>
<thead>
<tr>
<th>Category</th>
<th>Course Title</th>
<th>Int. marks</th>
<th>Ext. marks</th>
<th>L</th>
<th>P</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Course IV</td>
<td>Advanced Drug Delivery Systems</td>
<td>40</td>
<td>60</td>
<td>4</td>
<td>--</td>
<td>4</td>
</tr>
<tr>
<td>Core Course V</td>
<td>Pharmaceutical Industry Management</td>
<td>40</td>
<td>60</td>
<td>4</td>
<td>--</td>
<td>4</td>
</tr>
<tr>
<td>Core Course VI</td>
<td>Advanced Pharmaceutical Technology</td>
<td>40</td>
<td>60</td>
<td>4</td>
<td>--</td>
<td>4</td>
</tr>
</tbody>
</table>
| Core Elective    | 1. Screening Methods & Clinical Research  
|                  | 2. Nutraceuticals                           | 40         | 60         | 4 | --| 4 |
| Open Elective    | 1. Intellectual Property Rights and Regulatory Affairs  
|                  | 2. Stability of Drugs and Dosage Forms  
|                  | 3. Nano Based Drug Delivery Systems         | 40         | 60         | 4 | --| 4 |
| Laboratory III   | Advanced Drug Delivery Systems Lab          | 40         | 60         | --| 4| 4 |
| Laboratory IV    | Advanced Pharmaceutical Technology Lab      | 40         | 60         | --| 4| 2 |
| Seminar II       | Seminar                                     | 50         | --         | --| 4| 2 |
| **Total Credits**|                                            |            |            | 20| 12| 28|

### II Year - I Semester

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BIOPHARMACEUTICS AND PHARMACOKINETICS  
(Core Course I)

Objective: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, non-linear and time dependent pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

UNIT I

a. Biological and metabolic factors affecting bioavailability, complexation, dissolution - techniques of enhancing dissolution.

b. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms.

c. **Bioavailability**: Importance, dose dependency, AUC, rate and extent, assessment, blood and urine samples, single dose and multiple dose studies, *Invitro- Invivo Correlation analysis* and Levels of Correlations.

d. **Bioequivalence**: Importance equivalency concepts, biowaivers, study designs, protocol, transformation of data, Statistical Criteria as per the Regulations.

UNIT II
Pharmacokinetics – Drug Disposition: compartment models: One, two and non-compartmental approaches to pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:


b. Metabolism: Metabolic rate constant, Factors affecting Metabolism

c. Elimination: Over all apparent elimination rate constant, and half life.

All the above under the following conditions:

1. Intravenous infusion
2. Multiple dose injections

d. Non-invasive methods of estimating pharmacokinetics parameters with emphasis on salivary and urinary samples.

e. Concept of clearance: organ, total clearance, hepatic clearance, lung clearance and renal clearance.

UNIT III

UNIT IV

Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. kinetics in GI disease, malabsorption syndrome, liver, cardiac, renal and pulmonary disease states.

UNIT V
Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically
induced dependency.

**Drug Interactions:** Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.
- Numerical problems associated with all units, if any.

**Outcome:** students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for non-linear kinetics.

**TEXT BOOKS**
1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz

**RECOMMENDED BOOKS**
1. Bio-Pharmaceutics and Pharmacokinetics by V.Venkateshwarlu.
4. Drug drug interactions, scientific and regulatory perspectives by Alber P. G
ADVANCED PHYSICAL PHARMACEUTICS
(Core Course II)

Objective: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

UNIT I
Polymer science: Classification, properties and characterization of polymers, phase separation, polymers in solid state, preparation of polymer solution, application of polymers in pharmaceutical formulations. Mechanism of biodegradation of biodegradable polymers including controlled drug delivery systems, Mucoadhesive, Hydrodynamically balanced and Transdermal Systems.

UNIT II
Physics of tablet compression: Basic principles of interactions, compression and consolidation, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, Measurement of compression with strain gauges, compression pressure-QA parameters.

UNIT III

UNIT IV
Viscoelasticity: Theoretical consideration, instrumentation, rheological properties of disperse systems and semisolids. Oscillatory testing, Creep measurement.

UNIT V
Dissolution and solubility: Solubility and solubilization of nonelectrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, Mechanisms of Drug release - dissolution, diffusion (Matrix and Reservoir) and swelling controlled (Peppas Model) and dissolution equipment.

Outcome: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

TEXT BOOKS
2. Theory and Practice of Tablets – Lachman Vol.4

REFERENCE BOOKS
1. Dispersive systems I, II, and III
2. Robinson. Controlled Drug Delivery Systems
Objective: This subject is to make the student achieve different parameters and factors that influence the dosage form design:

UNIT 1
a. **Preformulation studies:** Goals of preformulation, preformulation parameters, methodology, solid state manipulation and characterization, solubility and partition coefficient, drug-excipient compatibility.
b. Advances in Pharmaceutical excipients. Excipients selection
c. Packaging development – selection of primary and secondary packaging materials and testing

UNIT II
**Pharmaceutical unit operations:** A detail study involving machinery and theory of pharmaceutical unit operations like mixing, filtration, drying, and sterilization.

UNIT III
**Formulation development of solid and powder dosage forms:** Improved production techniques for tablets, new materials, processes, equipment improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development and computerization for in process quality control of tablets. Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

UNIT IV
**Formulation development of soft and hard gelatin capsules:** Introduction, production and methods of manufacture, filling equipment and filling operations, formulations, finishing, special techniques, the nature of the capsule shell and capsule, advances in capsule manufacture, processing and control including pharmaceutical aspects, physical stability and packaging.

UNIT V
**Optimization techniques in pharmaceutical formulation and processing:** Introduction, optimization parameters, statistical design, response surface method, contour diagrams, factorial design, partial factorial design, simplex methods, mixture designs, Placket Burhan method, Box Benken method, applications in pharmaceutical formulation.

Outcome:
- Different machinery used for various steps in manufacture of various dosage forms.
- Formulation and evaluation of hard and soft gelatin capsules and their advantages over other dosage forms.

**TEXT BOOKS**
1. Pharmaceutics - The Science of Dosage form design by ME Aulton.

**RECOMMENDED BOOKS:**
1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington’s Science and Practice of Pharmacy by A. Gennaro.
5. Dispensing for Pharmaceutical Students by SJ Carter.
Objective: The course is designed to impart the knowledge in the field of Pharmaceutical Analysis. The various modern analytical techniques like UV-Visible, IR, NMR, Mass, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation. In addition to the theoretical aspects, the basic practical knowledge relevant to the analysis is also imparted.

UNIT I

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation
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
c. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical 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(NO), C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

Outcome: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.
References:

1) Instrumental Methods of Chemical Analysis by B.K Sharma
2) Organic spectroscopy by Y.R Sharma
3) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
4) Vogel’s Text book of Quantitative Chemical Analysis by A.I. Vogel
5) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6) Organic Chemistry by I. L. Finar
7) Organic spectroscopy by William Kemp
8) Quantitative Analysis of Drugs by D. C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10) Spectrophotometric identification of Organic Compounds by Silverstein
11) HPTLC by P.D. Seth
12) Indian Pharmacopoeia 2007
13) High Performance thin layer chromatography for the analysis of medicinal plants by Eike Reich, Anne Schibli
14) Introduction to instrumental analysis by Robert. D. Braun
**ANURAG GROUP OF INSTITUTIONS**

(AUTONOMOUS)

I Year – I Sem M.Pharm (Industrial Pharmacy)

**DRUG REGULATORY AFFAIRS (NATIONAL AND INTERNATIONAL)**

(Core Elective II)

**Objective:** The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

**UNIT I**

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

**UNIT II**

The Drugs and Cosmetics Act, 1940 and Rules there under. Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Drugs (Price Control) Order in force. Loan license (contract manufacture). Certification and licensing procedures.

**UNIT III**

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

**UNIT IV**

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Quality, safety and legislation for cosmetic products and herbal products.

**UNIT V**

**Governing Regulatory Bodies across the globe.**

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product Directorate DMF
c. Europe
   1) European Medicines Agency (EMEA/ National Authorities) EDMF
   2) European Directorate for Quality of Medicines CEP/COS & Health Care Products
d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure
   Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

**Outcome:**

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

**TEXT AND REFERENCE BOOKS**

1. Original laws published by Govt. of India.
3. Laws of Drugs in India by Hussain.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabha Prakashan Delhi - 2013
**Objective:** The student shall know the introduction, scope of biostatistics and research work, calculation and present the data. It also informs the students, how the present research work writing and correlating.

**UNIT I**

**UNIT II**
**Measures of central tendency:** computation of means, median and mode from grouped and ungrouped data.
**Measure of dispersion:** computation of variance, standard deviation, standard error and their coefficients.

**UNIT III**
**Measures of Correlation and Regression:** Experimental designing, planning of an experiment, replication and randomization. Probit analysis.
**Probability rules:** Binomial, Poisson and Normal distribution.
**Hypothesis testing:** Student ‘t’ test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

**UNIT IV**
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 V**
The research report paper writing/ thesis writing Different parts of the research paper
1. Title—Title of project with authors’ name
2. Abstract – Statement of the problem, Background list in brief and purpose and scope
3. Key words
4. Methodology—subject, apparatus, instrumentation and procedure
5. Results—tables, graphs figure and statistical presentation
6. Discussion support or non-support of hypothesis, practical and theoretical implications
7. Conclusion
8. Acknowledgements
9. References
10. Errata
11. Importance of Spell check for entire projects
12. Uses of footnotes

**Outcome:** The student will be known the biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

**Text Books**
1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books publishers
2. Donald H. McBurney -Theresa L. White “Research Methods” ( Cengage learning India Pvt. Ltd)
Reference Books

1. Remington’s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. Statistics for business and economics 3rd edition by Vikas books publications
4. Biostatistics & Computer applications by GN Rao and NK Tiwari
8. Research methods and Quantity methods by G.N.Rao
ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)

I Year – I Sem M.Pharm (Industrial Pharmacy)

PHARMA COEPIDEMIOLOGY, PHARMA COECONOMICS AND PHARMA COVIGILANCE
(Optional Elective –II)

Objective: This course is designed to impart knowledge and skills in epidemiology, economics and vigilance of various diseases. This will enable the students to understand cost effectiveness in the management of disease and ADRS

Unit-I
Pharmacoepidemiology: Definition and scope: Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.
Measurement of outcomes in pharmacoepidemiology: Outcome measures and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.

Unit-II
Concept of risk in pharmacoepidemiology, Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio
Pharmacoepidemiological methods: Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods. Drug utilization review, case reports, case series, surveys of drug use, cross-sectional studies, cohort studies, case control studies, case-cohort studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Unit-III
Sources of data for pharmacoepidemiological studies: Adhoc data sources and automated data systems.
Selected special applications of pharmacoepidemiology: Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit-IV
Pharmaco economic
Definition, history, need of pharmaco economic evaluations: Role in formulary management decisions.
Pharmaco economic evaluation: Outcomes 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: Cost – minimization, cost- benefit, cost – effectiveness, cost utility
Applications of Pharmaco economics: Softwares used and case studies

Unit-V
a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, Mechanism, predisposing factors, causality assessment (different scales used)
c. Reporting, evaluation, monitoring and management of ADRs
d. Role of pharmacist in management of ADRs.

Outcome: At completion of this subject, the students are expected to understand risk of pharmacoepidemiology history and need of pharmaco economics and assessment of pharmacovigilance.
REFERENCES:
ANURAG GROUP OF INSTITUTIONS  
(AUTONOMOUS) 

I Year – I Sem M.Pharm (Industrial Pharmacy)  

HERBAL COSMETICS TECHNOLOGY  
(Optional Elective –III)  

Objective: The topics helps the students to get exposed to processes involved in the manufacturing of herbal cosmetics including the skin and hair care herbal products preparation and their evaluation.

UNIT I  
a) Introduction, historical background and present status of Herbal cosmetics  
b) Processes used in the manufacture of cosmetics - Emulsification, Mixing, compaction, Moulding, Packing, Raw materials used in preparation of herbal cosmetics  
c) Machinery and Equipment for Cosmetics: Cream, Liquid, Powder and emulsion making machinery  
d) Quality, safety and efficacy of Herbal cosmetics  

UNIT II  
Skin care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like Creams, Lotions, Lipsticks, face packs. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT III  
Hair care Products: Method of preparation, pharmaceutical and Pharmacological evaluation procedures for various formulations like hair dyes, creams, Lotions, Jels, oils and Shampoos. Elaborative study of five formulations under each category with regard to their composition and claims for various herbs used in them.

UNIT IV  
A brief account of following herbals or herb extracts or herbal products of cosmetic importance such as Acacia concinna pods, Aloe Vera, Almond oil, Neem, Citrus aurantium peels, Henna, Turmeric, Liquorice, Olive oil, tea tree oil and wheat germ oil with special emphasis on their source, active principles and cosmetic properties.

UNIT V  
a) General Principles of Quality control and standardization of cosmetics - Raw material control, Packaging material control, finished product control, Shelf testing  
b) Natural colorants: Biological Source, coloring principles, chemical nature and usage of the following Annato, Cochineal, Caramel, Henna, Indigo, Madder, Saffron, Turmeric  
c) Flavors and Perfumes: Sandal wood oil, Orange oil, Lemon oil, Vanilla, Palmarosa, geranium oil

Outcome: Students will learn about the raw materials used in herbal cosmetics and get exposed to various preparations of herbal cosmetics.

REFERENCES:  
1. Cosmetics- Formulation, Manufacturing and Quality control – P.P. Sharma  
2. Herbal Cosmetics Hand Book - H. Panda  
3. Herbal Cosmetics by P.K Chattopadhyay  
4. The Complete Technology Book on Herbal Perfumes and Cosmetics by H. Panda
I Year – I Sem M.Pharm (Industrial Pharmacy)  

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB  
(LABORATORY I)

List of experiments

1. Colorimetry / UV / Visible, Spectroscopy, scanning of few compounds for UV-absorption, calculation of Assay / content uniformity / % of drug release (2-3 experiments.)
2. Estimation of multi components formulation by UV of two different methods
3. Experiment base on HPLC (Isocratic and gradient) Techniques – (2 experiments)
4. Incompatibility studies, identification and functional groups – Determination by FTIR (2 experiments)
5. Separation and calculation of Rf values by using paper chromatography, TLC, HPTLC Technique (2-3 experiments)
6. Interpretation of spectra and structure determination of Mass Spectroscopy
7. Separation of protein drug substances by electrophoresis.
8. Workshop on IR and NMR interpretation
ANURAG GROUP OF INSTITUTIONS
(AUTONOMOUS)

I Year – I Sem M.Pharm (Industrial Pharmacy)

ADVANCED PHYSICAL PHARMACEUTICS LAB
(LABORATORY II)

List of experiments

1. Determinates of molecular weight of some selected polymers.
2. Preparation and evaluation of solid dispersions (Immediated release and sustained release)
3. Accelerated stability testing of Aspirin Tablets
4. Stability evaluation of Aspirin at various pH and temperature conditions
5. Determination of 1st order and 2nd order rate constant. Half life by Acid / Alkali hydrolysis
6. Preparation and evaluation of multiple emulsions
7. Preparation and evaluation of β-cyclodextrin complexes of some drugs.
8. Generation of dissolution profiles of few dosage forms and application of the data into various kinetic equations. Calculation of Hixon-crowell dissolution rate constant
9. Preparation and dissolution study of paracetmol tablets and comparison with the marketed product.
10. Study of solubility and dissolution for few drugs and their respective salts.
11. Study of drug release from commercial suspension and emulsion dosage forms
12. Viscosity measurement of Newtonian and Non-Newtonian liquids
13. Evaluation of drug-protein binding analysis
14. Assignment of numerical problems, one compartment and two compartment disposition, method of residuals, AUC and evaluation of pharmacokinetic parameters.
ANURAG GROUP OF INSTITUTIONS
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I Year – II Sem M.Pharm (Industrial Pharmacy)  

ADVANCED DRUG DELIVERY SYSTEMS
(Core Course IV)

Objective: The students shall know the pharmacokinetic and pharmacodynamic on the basis of CDDS. They also know the design evaluation and application related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

UNIT 1
Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems
Controlled release oral drug delivery systems
a. Parenteral controlled release drug delivery systems

UNIT II
Design, fabrication, evaluation and applications of the following
Implantable Therapeutic systems
Transdermal delivery systems
Ocular and Intrauterine delivery systems
Vaccine delivery: Delivery systems used to promote uptake, absorption enhancers, oral immunization; controlled release microparticles form vaccine development

UNIT III
Biochemical and molecular biology approaches to controlled drug delivery of
Bioadhesive drug delivery systems
Nasal drug delivery systems
Drug delivery to Colon

UNIT IV
Biochemical and molecular biology approaches to control drug delivery of
Liposomes
Niosomes
Microspheres
Nanoparticles
Resealed erythrocytes

UNIT V
Drug targeting to particular organs
Delivery to lungs
Delivery to the brain and problems involved
Drug targeting in neoplasms

Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

Text Books
Novel Drug Delivery System by Yie W. Chien.
Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
Controlled and Novel Drug Delivery Systems by N. K. Jain.
Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
Controlled Drug Delivery by N.K Jain.
PHARMACEUTICAL INDUSTRY MANAGEMENT  
(Core Course V)  

Objective: This particular study of the course aimed at achieving, enabling the student effectively manage a given organization in planning, hiring, personnel, selection training and other infrastructures maintenance apart from design, lay-out and handling of the equipment.

UNIT I  
Human Resource management: Human resource planning, job analysis and design, recruitment, Personnel selection, orientation and placement, training and development, supervision, performance appraisal key result area and key performance area remuneration and salaries, Compensation and incentives, industrial relations, motivation.

UNIT II  
Entrepreneurship and Project Management - Quality Assurance Management:  
Total quality management, Organization and personnel, responsibilities, training, hygiene Premises: Location, design, layout, construction, maintenance, and sanitations, environmental control, sterile areas, control contamination, Equipments procedure and documentation for selection, purchase, speciation, installation and maintenance, clean in place, sterilization in place.,

UNIT III  
Production management:  
Production organization, objectives and policies of good manufacturing practices, layout of buildings, services, equipments and their maintenance, materials management, handling and transportation, inventory management and control, production planning and control, selection of vendors, purchase cycle, sales forecasting, budget and cost control.

UNIT IV  
Process validation: Regulatory basis, validation of pharmaceutical equipment and processes, validation of analytical methods.

UNIT V  
Industrial Hazards and Pollution Management:  

Outcome: This subject aims at validation of different process, equipment methods and effective management of waste materials.

References:  
1. Unit operations of Chemical Engineering by Warren L. McCabe, Julian C. Smith, Peter Harriott.  
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.  

Recommended Text Books:  
1. Remington's Science and Practice of Pharmacy by A. Gennaro.  
ANURAG GROUP OF INSTITUTIONS
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I Year – II Sem M.Pharm (Industrial Pharmacy)

ADVANCED PHARMACEUTICAL TECHNOLOGY
(Core Course VI)

Objective: The students shall know about the pilot plant scale up techniques for manufacturing of tablets, capsules, suspensions, emulsions and semisolids. The students also know about the filling of capsules, compression machines and sterilizers for formulation of parenterals and also know about the propellants, DPI, MDI and their quality control. The students also know about the cosmetics and neutraceuticals.

UNIT I
Pilot plant scale-up techniques used in pharmaceutical manufacturing
General considerations, preparation of master manufacturing procedures, product considerations of solid dosage forms, liquid dosage forms, semisolid products, suppositories, Generation of product development report.

UNIT II
Formulation development of parenteral dosage forms
Advances in materials, selection of excipients and production techniques, filling machines, filter selection and validation, sterilizers, aseptic processing.

UNIT III
Pharmaceutical Aerosols
Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosols formulation, manufacture and quality control.

UNIT IV
Formulation development of semi-solid dosage forms
Industrial processing, preparation of oil and aqueous phases, low energy emulsification, and storage of semisolids.

UNIT V
Aseptic processing operation
Introduction, contamination control, microbial environmental monitoring of particulate contamination, microbiological testing of water, microbiological air testing, characterization of aseptic process, theoretical evaluation of aseptic operations Equipment selection and maintenance.

Outcomes: Students will know about the scale up and pilot plant techniques used for all pharmaceutical dosage forms like tablets, capsules, parenterals, aerosols, cosmetics and neutraceuticals.

Text Books
1. Pharmaceutics - The Science of Dosage form design by ME Aulton.
2. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
3. Remington's Science and Practice of Pharmacy by A. Gennaro.
5. Pharmaceutical Dosage forms - Parenterals (Vol I, II and III) by Avis, Lieberman and Lachman.

Recommended Books
1. Bentley’s Text Book of Pharmaceutics by EA Rawlins.
3. Dispensing for Pharmaceutical Students by SJ Carter.
Objective: The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

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, sub-acute 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.

Outcome: The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

Text Books:
5. Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

Reference Books:
1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

UNIT I
Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.

b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II
Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following
Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
Sulfides: Diallylsulfides, Allyl trisulfide.
Polyphenolics: Reservetrol
Flavonoids: Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones
Prebiotates/Probiotics: Fructo oligosaccharides, Lacto bacillus
Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
Tocopherols

UNIT III
a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b) Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT IV
b. Antioxidants: Endogenous antioxidants — enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

UNIT V

Outcome: Helps the student to understand the importance of Neutraceuticals in various common problems with the concept of free radicals.
REFERENCES:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.
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I Year – II Sem M.Pharm (Industrial Pharmacy)

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS
(Open Elective I)

Objective: Various types of Intellectual Property Rights Patentable Subject History of Indian Patent Protection, Patent filing procedure in India, Opposition- pre-grant opposition and post-grant opposition, Patent filing procedure under PCT, advantages, patent search and literature and Salient features of Indian Patents are discussed in detail.

UNIT I
Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non- Obviousness, Utility, enablement and Best mode),

UNIT II
Patent filing procedure in India (Patent Prosecution), Specifications (Provisional and Complete), Claims- types of claims and legal importance of claims, Grant of patent, Rights of Patentee and co-owners
Opposition- pre-grant opposition and post-grant opposition, Anticipation, Infringement, Compulsory Licensing, revocation of patents, and power of Controller.
Patent filing procedure under PCT, advantages, patent search and literature

UNIT III
Paris Convention, Berne convention
World Trade Organization (WTO)
World Intellectual Property Organization (WIPO)
Trade Related Aspects of Intellectual Property Rights (TRIPS)
Patent Co-operation Treaty (PCT), Mandrid Protocol
Regulatory Affairs

Unit IV
National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act and its amendments, overview of schedules, detail study of schedule M and Schedule Y.
USFDA, FDA guidelines on IND, NDA and ANDA approvals, and SUPAC changes and understanding on 505 (b) (2) applications

Unit V
Requirement of GLP Guidance and recommendation on Dissolution and Bio-equivalence requirement. Types of ANDA filing (Para I, II, III, IV filing). Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC)
ICH objectives and Guidelines- stability testing, WHO guidelines, ISOs- Production design, certification. ICH 8(QbD), ICH Q9 and ICHQ10

Outcome: The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students
RECOMMENDED BOOKS:

1. Research Methodology concepts and cases by Depak Chawla, Neena Sondhi
4. Original Laws Published by Govt. of India
5. Protection of Industrial Property rights by P.Das and Gokul Das
6. Law and Drugs, Law Publications by S.N. Katju
7. Laws of drugs in India, Hussain
10. Drugs and Cosmetics act by Vijay Malik
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar
Objective: These topics are designed to impart specialized knowledge to preserve the properties of drugs and dosage forms during manufacture, storage, and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation.

UNIT-I
Drug decomposition mechanisms:
1. Hydrolysis and acyltransfer: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.

UNIT-II
Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:
1. Solids – tablets, capsules, powder and granules
2. Disperse systems
3. Microbial decomposition

UNIT-III
Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.
Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT-IV
General method of analysis to determine the quality of raw materials used in cosmetic industry.. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT-V
Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products.
Stability studies: Concept of stability studies.
   a) cGMP& ICH guidelines for Accelerated stability Testing.
   b) Interaction of containers & closure Compatibility Testing.

Outcome: The students should describe the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.
REFERENCE BOOKS:

6. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
7. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
9. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
10. Drug stability: Principles and practices by Jens T. Carstensen
Objective - To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

UNIT I – Introduction to Nanotechnology
Definition of nanotechnology
History of nanotechnology
Unique properties of nanomaterials
Role of size and size distribution of nanoparticles properties, classification.

UNIT II – Synthesis of Nanomaterials
Physical, chemical and biological Methods
Methods for synthesis of
Gold nanoparticles
Magnetic nanoparticles
Polymeric nanoparticles
Self – assembly structures such as liposomes, micelles, aquasomes and nanoemulsions

UNIT III – Biomedical applications of Nanotechnology
Nanotechnology products used for in vitro diagnostics
Improvements to medical or molecular imaging using nanotechnology
Targeted nanomaterials for diagnostic and therapeutic purpose

Unit IV
Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

Unit V
Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

Outcomes – The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

Recommended Books:
1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicologyin the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L.Arias, CRC press
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
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ADVANCES IN DRUG DELIVERY SYSTEMS LAB  
(LABORATORY III)

List of Experiments

1. Study on diffusion of drugs through various polymeric membranes (2 experiments)
2. Formulation and evaluation of sustained release oral matrix tablet (2 experiments)
3. Formulation and evaluation of sustained release oral reservoir system. (2 experiments)
4. Formulation and evaluation of microspheres / microencapsules (2 experiments)
5. Study of in-vitro dissolution of various SR products in market (2 experiments)
6. Formulation and evaluation of transdermal films (2 experiments)
7. Formulation and evaluation mucoadhesive system (2 experiments)
8. Preparation and evaluation enteric coated pellets / tablets. (2 experiments)
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1 Year – II Sem M.Pharm (Industrial Pharmacy)

ADVANCED PHARMACEUTICAL TECHNOLOGY LAB
(LABORATORY IV)

List of Experiments

1. Preparation of four different types of semisolid forms and evaluation of their performance using in vitro diffusion method
2. Evaluation of test sterility for commercial preparations including sterile water for injection and antibiotic injection.
3. Collecting samples of environment of aseptic room and counting the colonies
4. Validation of one unit operation (eg. Mixing) and development of protocol.
5. Comparative evaluation of different marketed products (tablets) of the same API
6. Dissolution studies of drug in three different bio relevant dissolution media
7. Stability study testing of tablet dosage forms (Any two products)