**INSTITUTE OF CHEMICAL TECHNOLOGY**

**Ordinances, Regulations and Syllabi relating to the**

**Degree of Master of Technology (Pharmaceutical Technology)**

**1. Introduction**

The Institute is revamping its academic structure especially for the masters courses by way of introducing the compulsory industrial training for a period of six months (to be taken in the third semester of the program). The number of credits in the first two semesters has also been increased and a research component has been included. The total credits in the first two semesters now stand at 27 each instead of earlier 21. All the courses will continue to be credit based and the evaluation will be grade based.

The Departmental administrative committee and academic program committee periodically proposed the program outcomes having consistency with the graduate attributes available with NBA. The committee critically analysed information obtained from graduated students, employers and immediately passed out students. The program outcomes are as follows:

|  |  |
| --- | --- |
| SR. NO. | PROGRAM OUTCOMES (POS) |
| 1 | The graduates will be able to apply knowledge of basic sciences (Mathematics, Physics, Chemistry and Biology) and technology courses in getting solutions to issues pertaining to chemical and allied industries. |
| 2 | The graduates should be able to systematically break up complex problems in realizable steps and solve them. |
| 3 | The graduates will be able to design a system or a component of a system or provide a technical solution for a specific task within realistic constraints |
| 4 | The graduates will be able to design and conduct experiments as well as analyze and interpret data. The graduates should be able to systematically break up complex problems in realizable steps and solve them. |
| 5 | The graduate will be able to use modern tools, software, equipment etc. to analyze and obtain solution to the problems. |
| 6 | The graduates will be able to study the impact of process industry on the global, economic, and societal context |
| 7 | The graduates should practice their profession considering environmental protection and sustainability |
| 8 | Graduates are expected to practice professional skills in an ethical manner  |
| 9 | The graduates should have competence to undertake designated task on individual or team basis as per the requirement. |
| 10 | The graduates will be able to communicate effectively their points of view |
| 11 | The graduates will acquire attitude for life- long learning |
| 12 | The graduates should actively participate in project and financial management |

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| --- | --- |
| SR. NO. | PROGRAM SPECIFIC OUTCOMES (PSOs) |
| 13 | Graduates will be acquainted with the latest development in different fields so as to enable them to take up higher studies, research & developmental work |
| 14 | Graduates will be introduced to managerial subjects, so as to enable them to take up further studies in management subjects & function effectively as managers |

Credit system is a systematic way of describing an educational programme by attaching credits to its components. The definition of credits may be based on different parameters, such as student workload, learning outcomes and contact hours. It is a student-centric system based on the **student workload** required to achieve the objectives of a programme. It should facilitate academic recognition of the courses and mobility of the students. Credits assignment is based on the principle that Credits can only be obtained after successful completion of the work required and appropriate assessment of the learning outcomes achieved. As per the AICTE norms 2L/week of lectures are 2 credits, while 2h/week of practical//seminar/literature review/research work are 1 credit. This has been taken as the basis during the working of the proposed syllabus.

**Student workload** consists of the time required to complete all prescribed learning activities such as attendance at lectures/practical, seminars, projects, etc. Credits are allocated to all the educational components of a study programme and indicate the quantity of work each component requires to achieve its specific objectives.

Evaluation is an important component of any teaching-learning process. The Institute gives emphasis on continuous evaluation with considerable freedom to the teacher in deciding the mode of evaluation of the students. The performance of the student is documented by a **grade** at the end of the semester. The grading scale ranks the students on a statistical basis. Therefore, statistical data on student performance is a prerequisite for applying the grading system.

**2. Course Credits**

In general a certain quantum of work measured in terms of **credits** is laid down as the requirement for a particular degree. The student acquires credits by passing courses every semester, the amount of credit associated with a course being dependent upon the number of hours of instruction per week in that course.

There are mainly two types of courses in the Institute - lecture courses and laboratory courses. Lecture courses consist of lecture (L) and tutorial (T) hours. Laboratory courses consist of practical (P) hours. The credit (C) for a course is dependent on the number of hours of instruction per week in that course, as given below:

1. 1h/week of lecture (L) or tutorial (T) = 1 credit
2. 2h/week of Practicals (P) = 1 credit
3. Credit (C) for a theory course = No. of hours of lectures per week +

 No. of hours of tutorials per week = L + T

1. Credits (C) for a Laboratory course/Seminar/research work =

 ½ x No. of hours per week

Credits will be assigned to In-plant, Seminar, Projects and other mandatory course requirements also and these will be mentioned in the respective syllabi. There may be some non-credit requirements. A student is required to earn credits as mentioned in the syllabus.

**3. Evaluation**

**3.1 The** weightages of different modes of assessments shall be as under.

|  |  |  |  |
| --- | --- | --- | --- |
|  | In-Semester evaluation | End-Semester- Exam | Components of continuous mode |
| Continuous mode | Mid Semester- Exam |
| Theory | 20% | 30% | 50% | Quizzes, class tests (open or closed book), home assignments, group assignments, *viva-voce* assignments, discussions |
| Practical | 50% | - | 50% | Attendance, *viva -voce*, journal, assignments, project, experiments, tests |
| Seminar/ Research work  |  |  | 100% | Continuous evaluation not applicable, End semester evaluation will be based on written report evaluation and presentation in front of the external examiner within the Department |

**3.2. In-Semester Evaluation:**

(a) It is expected that the teacher would conduct at least two assessments (in any form as quizzes, tests, home work, group work etc) under the continuous mode in a Semester.

(b) The teacher will announce at the beginning of the respective course the method of conducting the tests under the continuous mode and the assignment of marks

(c) In-semester performance of all students should be displayed and sent to the academic office by the teacher at least 15 days before the end-semester examination.

(d) For the theory courses, there will be one mid-semester test for each course to be held as per the schedule fixed in the Academic Calendar.

(e) For mid –semester examinations in theory papers, duration of examination will be 1 hour for 3 credit courses and 2 hours for 4 credit courses

**3.3. End-Semester examination:**

1. The semester end examination will cover the full syllabus of the course and will be conducted as per the Institutional time table at the end of each semester.
2. For end –semester examinations in theory papers, duration of examination will be 1 hour for 3 credit courses and 2 hours for 4 credit courses
3. For the end semester evaluation of seminar/research work, student will be expected to submit a written report and also make a presentation. The evaluation will be based on the quality of the written report and presentation.

**3.4 Passes and Fail**

(a)The candidates whoobtain 40% and more marks of the total marks of a course head shall be deemed to have **passed** the respective course head.

(b) The candidates whoobtain marks less than 40% of the total marks of a course head shall be deemed to have **failed** in the respective course head **(Grade FF).**

**3.5Grades:**

 (a) The performance of a student shall be documented by a **Letter grade.** Each letter grade has a **Grade point** associated with it. The Grades and Grade points shall be assigned to each head of passing and both will be indicated in the mark-list of the semester examination.

(c) The total marks (in-semester + end-semester) of a candidate in a subject head are converted into a letter grade, based on the relative (and some times the absolute) performance of the student.

|  |  |
| --- | --- |
| **Letter Grade**  | **Grade Point**  |
| AA | 10 |
| AB | 9 |
| BB | 8 |
| BC | 7 |
| CC | 6.5 |
| CD | 6 |
| DD | 5.5 |
| EE | 5 |

(d) For granting class, a grade point of 6.0 and above will be considered equivalent to First class.

 (c) The grades to be allotted in the case of students who fail or do not appear at the end-semester examination shall be as under.

|  |  |  |
| --- | --- | --- |
| **Letter Grade** | **Grade Point** | **Explanation** |
| FF | 0 | The candidate fails in course head. The candidate will be allowed to take end-semester repeat or subsequent examinations as per rule. |
| XX |  | The candidate has not kept term for the course head due to attendance less than requisite.Further see 3.5(g) below.In the above cases, the candidate has to repeat the respective course by paying the fees. |
| I | 0 | The candidate has kept term for the course head, has taken all the internal examinations with satisfactory performance, but has failed to take the end-semester examination or repeat examination due to genuine reasons. The candidate will be allowed to take end-semester repeat or subsequent examinations as per rule.  |
| FR | 0 | The candidate has exhausted all the permissible chances to clear the end-semester examinations.The candidate has to register for the respective semester again for all the subject heads or will be out of the respective degree course as per the rules.  |
| DR | 0 | (i) The candidate hasn't participated in academic programme.(ii) The candidate has taken a drop for the subject head; - provided he/she intimates the same (i or ii) at least 7 days in advance of the commencement of the end-semester examination for the respective year. |

 (d) Grades **FF** and **I** are place-holders only and do not enter into CPI/SPI calculations directly. These grades get converted to one of the regular grades after the end-semester examination.

 (e) A candidate with an **FR** grade is not eligible for any repeat examination in that course and has to re-register for that semester by paying the appropriate fees.

 (f) **I** grade will not be continued beyond the permissible number of end-semester/repeat examinations.

 (g) **‘XX' Grade:** The grade **XX** in a course is awarded if – (i) candidate does not maintain the minimum 75% attendance in the Lecture/Tutorial/Practical classes, (ii) candidate receives less than 20% of the combined marks assigned for continuous assessment and mid-semester examination, and (iii) candidate indulges in a misconduct/uses unfair means in the examination, assignments, etc., of a nature serious enough to invite disciplinary action in the opinion of the teacher.

 (**Note:** Award of the **XX** grade in the case of g(iii) above shall be done by Disciplinary Action Committee (DAC)).

 (h) The names/roll numbers of students to be awarded the **XX** grade should be communicated by the teacher to the Academic office as per academic calendar before the last date of submission of the application for end-semester examination.

**3.6. Awarding the grades**

 The grading scale ranks the students on a statistical basis on the basis of the overall performance of the students of a given class in the given course head. Therefore, statistical data on students’ performance is a prerequisite for applying the grading system. While assigning grades in a given course head, it is essential to know the **average marks(AM)** obtained by the students *who have passedthe subject head* and the **highest marks(HM)** obtained in the *same subject head*.

**3.6.1.** If the **average marks(AM)** obtained by the students *who have passedthe subject head* is <60%, the interval AM shall be awarded grade CC and the other grades shall be decided as follows:

 (i) AA, AB, BB, and BC grades shall be decided between the AM and HM by dividing the range in equal intervals.

 (ii) CD, DD and EE grades shall be decided between the AM and minimum marks required for passing the head (i.e. 40%) by dividing the range in equal intervals.

**3.6.2.** If the **average marks(AM)** obtained by the students *who have passedthe subject head* is such that **60% ≤ AM < 70%,** the interval AM shall be awarded grade BC and the other grades shall be decided as follows:

(i) AA, AB, BB grades shall be decided between the AM and HM by dividing the range in equal intervals.

(ii) CC, CD, DD and EE grades shall be decided between the AM and minimum marks required for passing the head (i.e. 40%) by dividing the range in equal intervals.

**3.6.3.** If the **average marks(AM)** obtained by the students *who have passedthe subject head* is **≥ 70%,** the interval AM shall be awarded grade BB and the other grades shall be decided as follows:

 (i) AA and AB grades shall be decided between the AM and HM by dividing the range in equal intervals.

 (ii) BC CC, CD, DD and EE grades shall be decided between the AM and minimum marks required for passing the head (i.e. 40%) by dividing the range in equal intervals.

**4. SPI and CPI**

 (a) **Semester Performance Index (SPI):** The performance of a student in a semester is indicated by **Semester Performance Index (SPI),** which is a weighted average of the grade points obtained in all the courses taken by the student in the semester and scaled to a maximum of 10. (SPI is to be calculated upto two decimal places.)

A Semester Grade Point Average (SGPA)will be computed for each semester as follows:



Where

‘n’ is the number of courses for the semester,

‘ci’ is the number of credits allotted to a particular course, and

‘gi’ is the grade-points awarded to the student for the course based on his performance as per the above table.

SGPA will be rounded off to the second place of decimal and recorded as such.

 (b) **Cumulative Performance Index (CPI):** An up to date assessment of the overall performance of a student from the time he entered the Institute is obtained by calculating **Cumulative Performance Index (CPI)** of a student. The CPI is weighted average of the grade points obtained in all the courses registered by the student since he entered the Institute. CPI is also calculated at the end of every semester (upto two decimal places).

Starting from the first semester at the end of each semester (S), a Cumulative Grade Point Average (CGPA) will be computed as follows:



Where

 ‘m’ is the total number of courses from the first semester onwards up to and including the semester S,

‘ci’ is the number of credits allotted to a particular course, and

‘gi’ is the grade-points awarded to the student for the course based on his performance as per the above table.

 CGPA will be rounded off to the second place of decimal and recorded as such.

 (c) The CGPA, SGPA and the grades obtained in all the subjects in a semester will be communicated to every student at the end of every semester / beginning of the next semester.

(d) **When** a student gets the grade ‘FF’, or I’ in any subject head during a semester, the SGPA and CGPA from that semester onwards will be tentatively calculated, taking only ‘zero’ grade point for each such ‘FF’ or ‘I’ grade. When the ‘FF’ grade(s) has / have been substituted by better grades after the repeat examination or subsequent semester examination, the SGPA and CGPA will be recomputed and recorded.

**5. Repeat End-Semester Examination**

**5.1.** For those candidates who fail in a subject head or are eligible for appearing at the repeat examination, **Repeat End-Semester Examination** will be conducted within one month from the declaration of the results of regular end-semester examination, as per **Regulation R.14**.

**5.2.** The marks obtained by candidates in the in-semester examinations (continuous assessment and Mid-Semester Examination) will be carried forward in such cases.

**5.3. Grading the performance in the Repeat Examination:**  The grades will be assigned as per 3.5 and 3.6 above. However, for a candidate taking any repeat examination or subsequent regular semester examination or performance improvement examination shall be awarded **one grade lower** than that decided on the basis of the actual marks obtained; provided ‘EE’ grade obtained in such an examination shall remain ‘EE’. For reference see the table below.

|  |  |  |
| --- | --- | --- |
| **Grade obtained in repeat or subsequent end-semester examination** | **Grade to be assigned** | **Grade point**  |
| AA | AB | 9.0 |
| AB  | BB | 8.0 |
| BB | BC | 7.0 |
| BC | CC | 6.5 |
| CC | CD | 6.0 |
| CD | DD | 5.5 |
| DD | EE | 5.0 |
| EE | EE | 5.0 |

**5.4. Revaluation of end-semester and repeat examination: Candidate’s performance in these examinations will be displayed on proper notice board and after 3 days of such display the marks will be sent to the Academic Office. No revaluation of these examinations will be allowed.**

**6. Passing of a Semester examination**

A candidate shall be declared as **‘PASSED’** any semester examination if he/she has

 (a) Cleared all heads of passing by securing grades EE or higher in all the heads;

 (b) Passed all the heads of passing such as project, seminar, training, etc as per the rules;

 (c) Satisfactorily completed all the mandatory requirements of the course;

 (d) paid all the Institute dues;

 (e) No case of indiscipline pending against him/her.

**7. Eligibility for the Award of a Degree**

A candidate shall be declared eligible for the award of a degree, if he/she has cleared all the semester examinations as given in (6) above.

**8. Allowed to keep terms (ATKT)**

8.1 A candidate who has I grade in one or more heads of passing of an odd semester of an academic year shall be allowed to keep terms for the respective even semester.

8.2. A candidate shall be allowed to keep terms for the subsequent academic year if he/she has FF or I grades in not more than two heads of passing from all the heads of passing of the two terms of the previous academic year taken together. Such a candidate shall be declared as **FAILED, ATKT**.

**9. Repeating a course**

**9.1** A student is required to repeat the course under the following situations:

 (a) A student who gets an **XX, FR, or DR** grade in a course; or

 (b) A student has exhausted all permissible chances to clear the course.

**9.2** A candidate from first year who remains absent for the regular end-semester examination of a semester and the corresponding repeat examination for **ALL SUBJECTS** shall have to take fresh admission for the corresponding year; unless the candidate has dropped out / terminated from the course.

**9.3** If a candidate at the Second, fails to pass any semester examination in not more than 4 consecutive examinations, including the repeat examinations, from the date of registering for the respective year, the candidate shall have to take readmission for the corresponding year again in which the failure has occurred, provided the course is not changed.

**10. Improvement of performance**

 A candidate will be allowed to appear at the **entire examination** after the regular end-semester examination as per the respective rules to improve the performance. In such a case if the result of the examination repeated –

1. Is better than the previous one, the previous result shall be declared null and void; and
2. Is worse than the previous one, the result of the subsequent examination shall not be declared.
3. However, awarding of final grade will be made under the provision of sub clause 5.3 above.

**11. Exit rules for poorly performing students**

 A candidate shall be excluded from a course under the following conditions:

(a) If he/she fails to pass any semester examination of the any year of the course in not more than four consecutive attempts (Examination conducted by Institute) from the date of joining the course.

(b) If he/she does not keep two consecutive terms without giving any reasonable justification (as prescribed by the institute) for doing so.

(c) If a candidate fails tofulfill all the requirements of his/her respective degree within the prescribed period from the date of taking admission to the course, the candidate shall be excluded from the course.

**12. Miscellaneous**

(a) Although CPI will be given in the Semester grade report, the final degree certificate will not mention any **Class** whatsoever.

(b) Not withstanding anything said above if a course is revised /restructured then transient provisions applicable at the time of revision /restructuring shall be applicable.

**Syllabus Structure- M Tech., Pharmaceutical Technology**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Subject** | **Credit** | **Hr/Week** | **Marks** |
| **L** | **T** | **P** | **Continuous****Assessment** | **Mid-semester****Examination** | **Final****Examination** | **Total** |
|  |
| **SEMESTER I** |
| **PYT 2106** | Core I: Physical Methods of Analysis | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
| **PHT 2021** | Core II: Advanced Pharmaceutical Technology | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
| **PHT 2019** | Core III: Industrial Pharmacy | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
|  |  Elective I | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
|  |  Elective II | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
| **PHP 2505** | Instrumental Methods of Analysis Laboratory  | 3 |  |  | 6 | 25 |  | 25 | 50 |
| **PHP 2510** | Seminar and Critical Review of one research publication | 3 | --- | --- | 6 |  |  | 30 (Report)20 (Presentation) | 50 |
| **PHP 2511** | Research Project I | 6 | --- | --- | 12 |  |  | 60 (Report)40 (Presentation) | 100 |
|  | TOTAL: | 27 | 10 | 5 | 24 |  |  |  | 450 |
|  |
| **SEMESTER II** |
| **PHT 2020** |  Core IV: Drug Delivery Technology | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
| **PHT 2206** |  Core V: Advanced PharmaceuticalChemistry | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
| **PHT 2022** | Core VI: Active Pharmaceutical Ingredients Technology | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
|  | Elective III | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
|  | Elective IV | 3 | 2 | 1 | 0 | 10 | 15 | 25 | 50 |
| **PHP 2509** | Pharmaceutical Technology Laboratory | 3 |  |  | 6 | 25 |  | 25 | 50 |
| **PHP 2512** |  Research Project II | 9 | --- | --- | 18 |  |  | 90 (Report)60 (Presentation) | 150 |
|  | TOTAL: | 27 | 10 | 5 | 24 |  |  |  | 450 |
|  |
| **SEMESTERS III**  |
| PHP 2513 - Industrial Training of duration of minimum of 15 weeks to maximum of 6 months as per approval of research supervisor and Head of the Department with total assigned credit as 30 and marks as 450 |
| **SEMESTER IV** |
| PHP 2514- Research Project, Thesis and Open defense with total assigned credit as 30 and marks as 450 |

**List of Electives**

1. PHT 2101- Research Methodology
2. PHT 2001-Biopharmaceuticcs and Pharmacokinetics
3. PHT 2002-Intellectual property Rights and Patent Filing
4. PHT 2003-Advanced Biochemistry
5. PHT 2004-Drug Metabolism
6. PHT 2005-Molecular Biology
7. PHT 2007-Packaging Technology
8. PHT 2012-Medicinal Natural Products
9. PHT 2014-Chiral Synthesis
10. PHT 2016-Quality Assurance and Validation
11. PHT 2023-Technological of Fine and Speciality Chemicals
12. PHT 2305 - Clinical Research Management
13. PHT 2011- Advances in Receptor Pharmacology

**\*Core subjects of M.Pharm and other M.Tech courses can be taken as electives**

SEMESTER I

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Course Code: PYT 2106** | **Course Title: Physical Methods of Analysis** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: I** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  |  |  |
| **List of Courses where this course will be prerequisite** |
|  |  |  |
| **Description of relevance of this course in the M. Pharm /M. Tech. Program** |
|  |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | **Fourier Transform Infrared Spectroscopy**: Molecular Vibrations, Frequency shifts associated with structural changes; Basic theory of FTIR spectroscopy, inteferogram, digitization of interferogram, data points collection; Instrumentation and advantages of FTIR spectrophotometry; Qualitative and quantitative analysis using infrared spectrophotometry. |  |
| **2** | **Ultraviolet and Visible Spectrophotometry**: Electronic transition, spectrum, shift of bands with solvents, isolated double bonds, conjugated dienes, carbonyl compounds, aromatic and heteroaromatic compounds; Application in pollution control and chemical industry. |  |
| **3** | **Nuclear Magnetic Resonance:**Basic principle of NMR phenomenon, relaxation processes, spin-spin interaction, chemical shifts, interpretation of NMR spectra, correlation-hydrogen bonds to carbon and other nuclei; Instrumentation-Continuous and pulsed NMR, carbon- 13NMR. |  |
| **4** | **X-ray Diffraction:**Crystal geometry and structural determination; Bragg law of X-ray diffraction, powder method; X-ray spectrometers-wide and small angle diffractrometers; Chemical analysis by X-ray diffraction. |  |
| **5** | **Particle Size Analysis:**Particle size, sampling, conventional techniques of particle size measurement, light scattering particle size measurement by light scattering techniques; Dynamic light scattering (DLS), fibre optic dynamic light scattering (FDLS). |  |
| **6** | **Chromatography:**Basic theory of separation, efficiency, resolution; Liquid chromatography, high performances liquid chromatography; Gas chromatography-columns and detectors; Qualitative and quantitative analysis. |  |
| **7** | **Mass spectroscopy:**Basic principle, ionization of a molecule on electron impact, fragmentation processes in organic compounds, interpretation of mass spectra, molecular weight, molecular formula; Instrumentation-different types of ionization sources and magnetic analyzer. |  |
|  |  |  |
| **List of Text Books/ Reference Books** |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| **Course Outcomes (students will be able to…..)** |
|  |  |  |
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| --- | --- | --- | --- |
|  | **Course Code: PHT 2021** | **Course Title:** Advanced Pharmaceutical Technology | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: I** | **Total contact hours: 45** | **2** | **1** | **0** |
| **Note: Depth to which the topics to be dealt with**.The topics to be dealt with an objective of giving exposure that would develop an appreciation and insight in the minds of the students with informed handling of operations , on site problem solving and process development towards adaptability on large scale. |
| **List of Prerequisite Courses** |
|  | Courses: Organic Chemistry, Physical Chemistry, Pharmaceutical Chemistry, Catalysis, Chemical Reaction Engineering, Energy and Material Balance.Good background of organic and synthetic chemistry,. Synthetic methods often used in manufacture of active pharmaceutical ingredients. Basic course in reaction engineering, concepts of plug flow and CSTR, Basic course in physical Chemistry, Kinetics, Basic course in Physics with concepts in heat conducting,radiation. Basic course in Fluid flow and heat transferThermodynamics of phase Equilibria, |  |
| **List of Courses where this course will be prerequisite** |
|  | - |  |
|  |  |  |
| **Description of relevance of this course in the M. Tech. Program** |
| The emphasis in the M.Tech. program is manufacture of quality products especially API as per the regulatory requirements in the premises approved by the regulatory agencies. The student needs to understand intricacies of process parameters and their effects on the process out come. The student is expected to handle and manage process parameters and unit operation for assurance of quality. Another task is development of new process chemistry and development keeping in mind safety and environmental consideration. Generation of data for scale up. The course content is designed, with combination of different relevant topics to make it relevant to M.Tech. Program. |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Theory of mass transfer with chemical reaction ( only film theory) (regimes and examples). | 1+1 |
| **2** | Isothermal ideal reactor design: Batch reactor, PFR, CSTR design for irreversible reactions.  | 3+2 |
| **3** | Isothermal non-ideal flow in reactors; RTD, Estimation of dispersion/backmixing, dispersed plug flow and tanks in series model, Macro, micro and meso mixing inreactors. Comparative flow characteristics and power number, pump no. with respect to turbine, impeller and paddles.  | 4+2 |
| **4** | Forced and natural convective heat transfer, analogies of momentum and heat transfer  | 4+2 |
| **5** | Development of rate equations for solid catalysed fluid phasereactions; Estimation of kinetic parameters External/internal mass and heat transfer resistances in catalyst particles. | 3+2 |
| **6** | Membrane processess: Membrane types, Principles of various membrane processes like Reverse Osmosis, pervaporation, gas separation, Ultrafiltration, and Design equations and module design. Concentration polarisation. | 5+2 |
| **7** | Scale up methods: introduction to scale up methods, principle of similarity, pilot plants and models.  | 5+2 |
| **8** | Flow Chemistry: Concept, fundamentals of flow chemistry - engineering aspects and its influnce On the out come. Various types of reaction conducted in flow models  | 5+2 |
| **List of Text Books/ Reference Books** |
| 1 | O. Levenspiel, Chemical Reaction Engineering,3rd Edition, Wiley Estern New York, 1999.J.M. Smith, Chemical Engineering Kinetics, 3rd Edition, McGraw Hill, New York, 19811990,  |  |
| 2 | H. Scott Foggler, Elements of Chemical Reaction Engineering, 4th Edition, Prentice Hall , 2008.L.K. Doraiswamy, M.M. Sharma, Heterogeneous Reactions vol. I and II,G. Astarita, Mass Transfer with Chemical Reaction, G.F. Froment, K.B. Bischoff, Chemical Reactor Analysis and Design, 2nd Edition, John Wiley NewYork |  |
| 3 | C. O. Bennet and J. O. Myers, Momentum, Heat and Mass Transfer McGraw Hill, 1995.R.B. Bird, W.E. Stewart, E.N. Lightfoot, Transport Phenomena,, John Wiley, & Sons 2007. |  |
| 3 | C.J. Geankoplis, Transport Processes and Separation Process Principles,C.J. King, Separation Processess,Tata McGraw Hill NewDelhi, 1982.J. D. Seader, E.J. Henley and D.K. Roper; Separation Process Principles, 3rd Edition, John Wiley and Sons 2010.  |  |
| 4 | D.J. Jordon, Chemical Process Development (Part 1 and 2) Interscience Publishers, 1988. Johnstone and Thring , Pilot plants Models and scale up in Chemical Engineering. McGraw Hill, New York, 1962,  |  |
| 5 | Flow Chemistry: Recent review articles and papers dealing with Active Pharmaceutical Ingradients and comple and multi step synthesis in flow format.  |  |
| **Course Outcomes (students will be able to…..)** |
| 1 |  Ability to explain the basis of heat transfer coefficient based on analogies of momentum and heat transfer.  |  |
| 2 | Would be able to understand and analyse flow pattern influencing mass and heat transfer resulting in variation in chemical recationout come. |  |
| 3 | Capability to generate data at the lab scale required for scale-up. |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Course Code: PHT 2019** | **Course Title: Industrial Pharmacy** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: I** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Technology of liquid and topicals, validation and regulatory requirements of B. Tech syllabus of ICT or equivalent |  |
| **List of Courses where this course will be prerequisite** |
|  |  |  |
| **Description of relevance of this course in the M. Tech. Program** |
| This course is designed to impart fundamental knowledge on pharmaceuticalproduct development and translation from laboratory to market |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | **Pharmaceutical Product development**Product life cycle management, Pharmaceutical product design and development, ICH perspectives, Strategies in product development, Design of Experiments, Preformulation studies, Formulation development and scale-up, Process validation and post approval changes | **6+3** |
| **2** | **Unit operations for pharmaceutical development**Equipment design and operation, mixing, milling, drying , filtration etc. | **4+2** |
| **3** | **Facility design**Personnel & Material flows considered, Floors, walls, and ceilings, Temperature and humidity controls, Air control, HEPA, Schedule M, layout setup, factory site, factory buildings, operation areas, facilities, GMP in solid dosage forms, liquids, parenterals. | **6+3** |
| **4** | **Scale-up considerations**Large scale manufacturing of monophasic and biphasic liquids, semisolids and solids | **8+4** |
| **5** | **Regulatory requirements** Generic Drug Product development, Hatch-Waxman Act, Regulatory requirements for product approvals: Clinical research process, IND, NDA, ANDA, SUPAC, Post marketing surveillance.FDA Approval Process: Data procession for Global submission, Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) Format, and CMC Regulatory Compliance, FDA Medical Device Regulation. | **6+3** |
| **List of Text Books/ Reference Books** |
| 1 | Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7thApril available at http,//en.wikipedia.org/wiki/Regulatory\_ Affairs. |  |
| 2 | International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php |  |
| 3 | Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics’ Second Edition. |  |
| 4 | Regulatory Affairs brought by learning plus, inc. available athttp.//www.cgmp.com/ra.htm |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Know the process of pilot plant and scale up of pharmaceutical dosage forms |  |
| 2 | Understand the process of technology transfer from lab scale to commercial batch |  |
| 3 | Know different Laws and Acts that regulate pharmaceutical industry |  |
| 4 | Understand the approval process and regulatory requirements for drug products |  |

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|  | **Course Code: PHP 2505** | **Course Title:** Instrumental Methods of Analysis Laboratory | **Credits = 3** |
| **L** | **T** | **P** |
| **Semester: I** | **Total contact hours: 90** | **0** | **0** | **6** |
| **List of Prerequisite Courses** |
|  | Pharmaceutical Analysis theory and Lab at Undergraduate level |  |
|  | Pharmaceutical Formulation theory at Undergraduate level |  |
| **List of Courses where this course will be prerequisite** |
|  | Pharmaceutics, Pharmacology, Pharmaceutical Chemistry and Pharmacognosy Lab in following Sem.-II and the research work  |  |
|  |  |  |
| **Description of relevance of this course in the M. Tech. Program** |
| Analysis by instrumental methods is important for all industrial synthesis as well as formulations. Monitoring of processes, raw materials and finished products require instrumental analytical techniques.  |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
|  | UV/Visible Spectroscopy1. Calibration of UV spectrophotometer
2. Study effect of solvent on wavelength maxima of drugs.
3. Find Beer’s law limit of drugs in a suitable solvent.
4. Standard calibration curve by UV spectroscopy at
5. λ max
6. λ max + 10 nm
7. λ max – 10 nm
8. Determination of pKa by U.V. spectroscopy.
9. Multicomponent analysis by UV-Spectrophotometry
10. Absorbance corrected for interference method
11. Simultaneous equation method
12. Absorbance ratio method
13. Area under curve method
14. First derivative spectrophotometric method
 | **24** |
|  | Analysis of drugs from formulations focusing on separation of drug from the formulation excipients | **12** |
|  | IR Spectroscopy1. Calibration of IR spectrophotometer
2. Sample preparation for I.R. spectroscopy (solid/liquids) and interpretation of IR bands for important functional groups.
 | **12** |
|  | DSC analysis of drugs in crystalline and amorphous forms. | **12** |
|  | Chromatography: 1. HPLC calibration of HPLC column and determination of response factor by HPLC
2. GC Instrumental handling and few analyses of the API intermediates
3. TLC mobile phase selection of a various combination of compounds and reaction monitoring.
4. Preparative TLC analysis.
5. pH stability evaluation of a drug by TLC.
6. Separation of components by column chromatography.
 | **18** |
|  | Structural Interpretation by Spectroscopy: 1. Basic interpretations of simple Mass spectra and NMR.
2. Structural elucidation workshop: Interpretation of 1H NMR, 13C NMR, IR and Mass spectrometry of simple compounds (maximum 12 carbon atoms).
 | **12** |
| **List of Text Books/ Reference Books** |
|  | M. Orchin and H.H. Jaffe - Theory and applications of Ultraviolet spectroscopy. (John Wiley and Sons. N.Y). |  |
|  | Silverstein, Basseler, Morril- Spectrometric identification of organic compounds (John Wiley and Sons. N.Y). |  |
|  | Willard, Merritt, Dean - Instrumental methods of analysis (CBS Publishers and Distributors, Delhi). |  |
|  | J.R. Dyer - Application of absorption Spectroscopy of Organic Compounds (Prentice Hall, London). |  |
|  | C.N.R. Rao - Chemical Applications of Infrared spectroscopy. (Academic Press, N.Y.). |  |
|  | L.M. Jackmann and B.D. Sternhell - Application of NMR spectroscopy in organic chemistry (Pergamon Press, London.). |  |
|  | F.W. McLafferty and F. Turecek- Interpretation of Mass Spectra. |  |
|  | R.J. Hamilton and P. A. Sewell- Introduction to High Performance Liquid Chromatography. (Chapman and Hall, London). |  |
|  | J.W. Munson- Pharmaceutical Analysis: Modern methods -Part A and Part B (Marcel Dekker, Inc., New York) |  |
|  | Introduction to Spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.  |  |
|  | Analytical chemistry: A Modern Approach to Analytical Science, 2nd edition by Kellner, Mermet, Otto, Valcarcel Wiley ECH. |  |
|  | Ewing’s Analytical Instrumentation Handbook, 3rd edition, edited by Jack, Cazes, Marcel Dekker. |  |
|  | P.D. Sethi - Quantitative Analysis of Drugs in Pharmaceutical Formulations (VBS Publishers, Delhi). |  |
|  | Pharmacopoeia of India (latest edition). |  |
|  | United State Pharmacopoeia (latest edition). |  |
|  | British Pharmacopoeia (latest edition). |  |
|  | A.H. Beckett, J.B. Stenlake - Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers Delhi) |  |
|  | F. D. Snell and C. T. Snell- Colorimetric Methods of analysis (Van Nostrand Reinhold Company, N.Y.). |  |
|  | Journals: Journal of planar chromatography; Actachromatographica. J. Analytical Chemistry. |  |
| **Course Outcomes (students will be able to…..)** |
|  | Analyze bulk drugs and formulations.  |  |
|  | Perform calibration of analytical instruments. |  |
|  | Develop chromatographic mobile phases  |  |
|  | Separate the components of the mixtures and either quantify or isolate preparatively |  |
|  | Interpret the outcomes of the analytical techniques logically to deduce the structure of the compound and/or conclude about the quality/ purity.  |  |

**SEMESTER II**

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|  | **Course Code: PHT 2020** | **Course Title: Drug Delivery Technology** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: II** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Drug delivery systems of B. Tech syllabus of ICT or equivalent |  |
| **List of Courses where this course will be prerequisite** |
|  |  |  |
| **Description of relevance of this course in the M. Tech. Program** |
| To train the students on technological aspects of drug delivery systems |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| Technological considerations in development of the following |
| **1** | **Oral drug delivery systems**Oral controlled release drug delivery, Gastro-retentive drug delivery, Osmotic drug delivery, Ion exchange controlled drug delivery, Pulsatile drug delivery, Pelletization, Hydrodynamically balanced DDS including recent advances  | **7+3** |
| **2** | **Nano drug delivery systems**Colloidal DDS: Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, sub-micron emulsions, liposomes, niosomes, and other vesicular DDS, nanoparticles, their design and development into final dosage forms, issues and consideration | **6+3** |
| **3** | **Mucosal drug delivery systems**Bioadhesion and bioadhesive polymers, Formulation considerations for mucosal administration | **6+2** |
| **4** | **Pulmonary drug delivery systems**Design of Pressurized aerosols, Inhaler (dry powder and metered dose), Devices for administration and evaluation | **3+2** |
| **5** | **Transdermal drug delivery system**Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to manufacturing equipment, components and evaluation. Iontophoretic and Sonophoretic DDS. | **5+3** |
| **6** | **Miscellaneous**Injectables: Preformulation factors and essential requirements, vehicles, additives, Formulations of injections sterile powders, large volume parenterals, and lyophilization.Ophthalmic drug delivery system: Design of controlled release ophthalmic DDS including gels, inserts, novel DDS and evaluation. | **3+2** |
| **List of Text Books/ Reference Books** |
| 1 | Handbook of Pharmaceutical Controlled Release Technology, edited by Donald Wise Marcel Dekker, 2000. |  |
| 2 | Bioadhesive Drug Delivery Systems Fundamentals, Novel Approaches, and Development Series Volume: 98 Edited By: Edith Mathiowitz; Don E. Chickering; Claus-Michael Lehr 1999. |  |
| 3 | Nasal Systematic Drug Delvery Series Volume: 39 Yie W. Chien; Kenneth S. E. Su; Shyi-Feu Chang 1989. |  |
| 4 | Transdermal Drug Delivery by Richard H. Guy (Editor), Jonathan Hadgraft (Editor), Michiko Elizabeth BarroYusa Marcel Dekker; 2nd edition (January 2003) |  |
| 5 | Ophthalmic Drug Delivery Systems, edited by AshimMitra, Marcel Dekker, 1993. |  |
| 6 | Novel Drug Delivery Systems Second Edition, Revised and Expanded Series Volume: 50 Yie W. Chien, 1991 |  |
| 7 | Controlled Release Veterinary Drug Delivery by Michael J. Rathbone (Editor), Robert Gurny (Editor)Elservier Science; 1st edition (July 1, 200) |  |
| 8 | Polymeric Drugs and drug Delivery Systems Raphael M. Ottenbrite and Sung Wan Kim, eds. Technomic, 2001. |  |
| 9 | Controlled Drug Delivery – Foudamentals& applications by J. R. Robinson-2nd edition – Marcel Dekker, 1987 |  |
| 10 |  Dermatological Formulations: Percutaneous absorption by Brian W. Barry |  |
| 11 | Electricity Assisted Transdermal and Topical Drug Delivery by Ajay K. Banga, Tayior and Francis; (September 1998) |  |
| 12 | Mechanisms of Transdermal Drug Delivery Volume: 83 Edited By: Russell O. Potts; Richard H. Guy. 1997. |  |
| 13 | Transdermal Controlled Systemic medications by Y. W. Chien, Marcel Dekker, 1987 |  |
| 14 | Biopharmaceutics of Ocular Drug Delivery by Peter Edman CRC Press: (November 18, 1992) |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Detail preformulation considerations for the above drug delivery systems |  |
| 2 | Detail knowledge about technological advances of drug delivery systems |  |
| 3 | Detail understanding of characterization and evaluation techniques of above drug delivery systems |  |

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|  | **Course Code: PHT 2206** | **Course Title: Advanced Pharmaceutical Chemistry** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: II** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Organic Chemistry, Pharmaceutical chemsitry courses of ICT or equivalent |  |
| **List of Courses where this course will be prerequisite** |
|  | ~~-~~ |  |
| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
| Students will be exposed to recent advances in organic chemistry and its applications in pharmaceutical industry. |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| 1 | Solid phase synthesis: Concept, resins, linkers, characterizations, examples.  | 3+2 |
| 2 | Peptide synthesis: Protected amino acids, coupling agents, strategies in synthesis with examples of peptide drugs and hormones. Solid phase synthesis and peptide synthesizers.  | 3+1 |
| 3 | Oligonucleoside Synthesis: Methodologies, solid phase oligonucleosides synthesis.  | 2+1 |
| 4 | Combinatorial synthesis: liquid phase and solid phase, deconvolution techniques, design of libraries, these to be discussed with illustrative examples of combinatorial libraries. | 1+1 |
| 5 | Organic nanomaterials (Single molecular and molecular assemblies): Design, synthetic strategies, characterisation and properties. E.g. dendrimers, polymeric nanomaterials, carrier-systems for drug targeting. | 4+2 |
| 6 | Fluorescent and imaging materials: Design and synthesis, properties and applications. | 2+1 |
| 7 | Photochemical Reactions: Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. | 3+1 |
| 8 | Organic Name Reactions (Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Mitsunobu reaction, Sharpless asymmetric epoxidation and dihydroxylation, Metathesis)  | 4+2 |
| 9 | Synthetic Reagents & Applications:Aluminiumisopropoxide, *N*-bromosuccinamide, diazomethane, dicyclohexylcarbodimide, Wilkinson reagent, Wittig reagent. osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, triphenylphosphine, benzotriazol-1-yloxy) tris (dimethylamino) phosphoniumhexafluoro-phosphate (BOP) | 8+4 |
| **List of Text Books/ Reference Books** |
| 1 | Advanced Organic Chemistry, 4th Ed., Parts A and B, Carey F. A and Sundberg, R. J. |  |
| 2 | Chirotechnology, industrial synthesis of optically active compounds, Sheldon R.A. |  |
| 3 | Textbook of Drug Design and Discovery, Krogsgaard-Larsen P, Liljefors, T, Madsen U |  |
| 4 | Advanced Organic Chemistry, March J. |  |
| 5 | Combinatorial Chemistry: Synthesis and Applications, Wilson S. R. and Czamik A |  |
| 6 | Organic Synthesis, The disconnection Approach, Warren S |  |
| 7 | Synthon Approach, Iyer R.P et.al. |  |
| 8 | Organic Chemsitry, J. Clayden |  |
| 9 | The Logic of Chemical Synthesis, E.J. Corey |  |
| 10 | Classics in Total Synthesis, K.C. Nicolou and E.J. Sorensen |  |
|  |  |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Concept of peptide chemistry |  |
| 2 | Concept of combinatorial chemistry |  |
| 3 | Understanding of organic nanomaterials and fluorescent and imaging materials |  |
| 4 | Concept of Photochemical reactions |  |
| 5 | Application of selected name reactions |  |

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|  | **Course Code: PHT 2022** | **Course Title: Active Pharmaceutical Ingredients Technology** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: II** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Process technology of Drug and intermediates |  |
| **List of Courses where this course will be prerequisite** |
|  |  |  |
| **Description of relevance of this course in the M. Tech. Program** |
| Study of Chemical technology of selected APIs including Chiral APIs. Importance of GMP, QA, RA and safety in API industry |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Current status of pharmaceutical industry: Status of bulk drugs, natural products and formulations in India vis-a-vis industrialized nations. Import and Export of APIs | 2+1 |
| **2** | Scale-up Techniques: for process research and development, optimization, maximization of productivity, in-process control techniques. | 2+1 |
| **3** | Chemical technology of selected APIs : Case studies with emphasis on rationale for selection of routes, raw materials, process control methods, pollution control procedures, polymorphs, safety etc.  | 7+3 |
| **4** | Chemical technology of Chiral APIs: Case studies with emphasis on rationale for selection of routes, raw materials, process control methods, pollution control procedures, polymorphs, safety etc.  | 7+3 |
| **5** | Impurity consideration: Introduction, Steps to optimizing reactions, minimizing impurity formation by indentifying impurities first, method development for separation, synthesis and isolation of impurities and their characterization | 4+3 |
| **6** | Overview of plant layout, plant design, utilities and process flow sheets | 2+1 |
| **7** |  Raw material consumption and Costing | 2+1 |
| **8** | Overview of GMP and Safety in API industry | 2+1 |
| **9** | Overview of Quality Assurance and Regulatory Affairs | 2+1 |
| **List of Text Books/ Reference Books** |
| 1 | Process Chemistry in Pharmaceutical Industry by Kumar Gadamasetti, Vol I & II |  |
| 2 | Advanced Organic Chemistry by Jerry March |  |
| 3 | Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up by Peter J. Harrington , Wiley |  |
| 4 | Practical Process Research and Development by Neal G. Anderson, Academic Press |  |
| 5 | Strategies for Organic Drug Synthesis and Design by Daniel Lednicer |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Grasp the manufacturing of various APIs |  |
| 2 | Understand the process flow diagram and various process parameters |  |
| 3 | Identify and solve engineering problems during production |  |
| 4 | Appreciate the importance of GMP,QA and RA departments in API industry |  |

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|  | **Course Code: PHP 2509** | **Course Title: Pharmaceutical Technology Laboratory** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: II** | **Total contact hours: 90**  | **0** | **0** | **6**  |
| **List of Prerequisite Courses** |
|  | Technology of solid dosage forms, Technology of sterile products, Sterile dosage form laboratory, Pharmaceutical Chemistry Laboratory of B. Tech syllabus of ICT or equivalent |  |
| **List of Courses where this course will be prerequisite** |
|  |  |  |
| **Description of relevance of this course in the M. Tech. Program** |
| To train the students with respect to practical aspects of advance formulation development technology |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Solubilization of drugs by two novel techniques | 6 |
| **2** | Scale up and evaluation of CR tablet manufacturing | 9 |
| **3** | Multiparticulate formulations | 6 |
| **4** | Lyophilization / spray drying | 3 |
| **5** | Mucosal gels, films, tablets | 6 |
| **6** | Transdermal gels and films | 6 |
| **7** | Ophthalmic gels | 3 |
| **8** | In situ parenteral implants | 3 |
| **9** | DPI / MDI | 3 |
| **10** | Separation and characterization of impurities by chromatographic techniques  | 6 |
| **11** | i Examples of Tosylation, Transfer Hydrogenation, Wittig, Claisen Schmidt, cycloaddition, sulfonation, dehydration (any three) | 9 |
| **12** | Synthesis of two complex molecules/ drug intermediates which may include 3 or more steps to isolate, purify (chemical methods and through chromatography) and characterize the product from each step | 18 |
| **13** | Unit processes (hydrogenation, oxidation etc.) and unit operations in process chemistry  | 12 |
| **List of Text Books/ Reference Books** |
| 1 | Vogel's Text book of Practical Organic Chemistry, 5th Edition |  |
| 2 | Green methods of Preparation published by DST |  |
| 3 | Collective volume of organic synthesis |  |
| 4 | Recent literature references (full paper) on specific topics |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Perform novel techniques for the solubilisation of drugs |  |
| 2 | Perform scale-up of CR tablets |  |
| 3 | Perform Multiparticulate formulations |  |
| 4 | Prepare Mucosal, transdermal, ophthalmic formulations  |  |
| 5 | Prepare In situ parenteral implants, DPI/MDI  |  |
| 6 | Perform process development of APIs |  |
| 7 | Understand Green chemistry, hazards, effluents and statistical methods of optimizations |  |
| 8 | Identify process variables and implication in scale up |  |

**ELECTIVES**

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| --- | --- | --- | --- |
|  | **Course Code: PHT 2101** | **Course Title: Research Methodology** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: I** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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|  |  |  |
| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
|  |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) – Objective of research- |  |
| **2** | Literature survey – Use of Library, Books, & Journals – Medline – Internet, getting patents and reprints of articles as sources for literature survey. |  |
| **3** | Selecting a problem and preparing research proposal for different types of research mentioned above. |  |
| **4** | Methods and tools used in Research* + Qualitative studies, Quantitative Studies
	+ Simple data organization, Descriptive data analysis
	+ Limitations and sources of Error
	+ Inquiries in form of Questionnaire, Opinionnaire or by interview
	+ Statistical analysis of data including variance, standard deviation, students ‘t’ test and annova, correlation data and its interpretation, computer data analysis,
 |  |
| **5** | Documentation* + “How” of Documentation
	+ Techniques of Documentation
	+ Importance of Documentation
	+ Uses of computer packages in Documentation
 |  |
| **6** | The Research Report / Paper writing / thesis writing* + Different parts of the Research paper
1. Title – Title of project with author’s name
2. Abstract – Statement of the problem Background list in brief and purpose and scope
3. Key-words-
4. Methodology-Subject, Apparatus / Instrumentation, (if necessary) and procedure
 |  |
| **7** | Results – tables, Graphs, Figures, and statistical presentation |  |
| **8** | Discussion – Support or non- support of hypothesis – practical & theoretical implications, conclusions |  |
| **9** | Acknowledgements |  |
| **10** | References |  |
| **11** | Errata |  |
| **12** | Importance of spell check for Entire project |  |
| **13** | Use of footnotes |  |
| **14** | Presentation (Specially for oral)* + Importance, types, different skills
	+ Content of presentation, format of model, Introduction and ending
	+ Posture, Genstures, Eye contact, facial expressions stage fright
	+ Volume- pitch, speed, pauses & language
	+ Visual aids and seating
	+ Questionnaire
 |  |
| **15** | Protection of patents and trade marks, Designs and copyrights* + The patent system in India – Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents
	+ Advantages
	+ The Science in Law, Turimetrics (Introduction)
	+ What may be patented
	+ Who may apply for patent
	+ Preparation of patent proposal
	+ Registration of patent in foreign countries and vice-versa
 |  |
| **16** | Sources for procurement of Research Grants |  |
| **17** | Industrial- Institution Interaction - Industrial projects – Their feasibility reports |  |
|  |  |  |
| **List of Text Books/ Reference Books** |
| 1 | Research in Education – Johan V. Best James V. Kahn |  |
| 2 | Presentation skills- Michael Halton- Indian Society for Institute Education |  |
| 3 | A Practical Introduction to copy right – Gavin Mcfarlane |  |
| 4 | Thesis projects in Science and Engineering – Richard M. Davis |  |
| 5 | Scientists in legal system – Ann labor science |  |
| 6 | Thesis and Assignment writing – Jonathan Anderson |  |
| 7 | Writing a technical paper- Donald Menzel |  |
| 8 | Effective Business Report writing – Leland Brown |  |
| 9 | Protection of Industrial property rights- Purushottam Das and Gokul Das |  |
| 10 | Spelling for the million – Edna furmess |  |
| 11 | Preparing for publication – King Edwards Hospital fund for London |  |
| 12 | Information technology – The Hindu speaks |  |
| 13 | Documentation – Genesis & Development 3792 |  |
| 14 | Manual for evaluation of Industrial projects – United Nations |  |
| 15 | Manual for the preparation of Industrial feasibility studies |  |
| **Course Outcomes (students will be able to…..)** |
| 1 |  |  |
| 2 |  |  |

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| --- | --- | --- | --- |
|  | **Course Code: PHT 2001** | **Course Title: Biopharmaceutics and Pharmacokinetics** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Biopharmaceutics and Pharmacokinetics (B. Pharm) or equivalent |  |
|  |  |  |
| **List of Courses where this course will be prerequisite** |
|  |  |  |
|  |  |  |
| **Description of relevance of this course in the M. Pharm Program** |
| To train students with reference to Biopharmaceutics and Pharmacokinetics |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
|  |  | L | T |
|  | **Biopharmaceutics** |  |  |
| **1** | **Introduction: Recap of ADME, bioavailability, bioequivalence and factors affecting the same**  | 1 | 1 |
| **2** | **Molecular basis of drug Absorption & transport** * The Molecular structure and nature of the cell membranes & nuclear membranes
* Transcellular absorption
1. Nature of passive transcellular

absorption1. Carriers for the active transport

of drugs (With special emphasis on p-glycoprotein & design of pgp inhibitors)1. Methods of studying the carrier mediated transport
* Paracellular absorption
1. The molecular organization of the paracellular space
2. The regulation of paracellular permeability
3. Methods of studying the paracellular absorption
* Penetration enhancers & study of their molecular mechanisms of action
* Drug delivery to cell organelles
1. Extracellular barriers
2. Intracellular barriers

Study of cell penetrating peptides and fusogenic peptides and their applications in drug delivery | 9 | 4 |
| **3** | **Drug Membrane interactions** * Possible effects of drugs on the membranes & effect of membrane on drugs
* Role of drug membrane interaction in pharmacokinetics & pharmacodynamics of drugs
* Development of predictive models for drug membrane interactions (in vitro & computational)
* Study of the drug membrane interactions
 | 3 | 1 |
| **4** | **Pharmacogenomics** * Genetic basis of variation of pharmacokinetics
* Methods for pharmacogenomic profiling & study
 | 2 | 1 |
|  | **Pharmacokinetic** |  |  |
| **1** | Introduction to ADME and basic pharmacokinetic parameters like Volume of distribution, Elimination half life, Elimination rate constant, Clearance, Area undercurve, Bioavailability, calculation of parameters from plasma and urine data | 2 | 2 |
| **2** | Role of Pharmacokinetics in drug discovery; drug development and processdevelopment; |  |  |
| **3** | Mathematical approach to pharmacokinetic modeling; one-compartment open modelsand data analysis; multiple-dose pharmacokinetics; two-compartment open models;physiological pharmacokinetic models; nonlinear pharmacokinetics; metabolitepharmacokinetics; pharmacokinetic-pharmacodynamic modeling, Case studies andproblem solving w.r.t. above including design of controlled release dosage forms andother novel drug delivery systems based on pharmacodynamic and pharmacokineticrationale.  | 9 | 4 |
| **4** | In-vitro-In-vivo correlation | 2 | 1 |
| **5** | Individualization of dosage regimen, conversion from IV dosing to oral dosing, determination of dose, frequency of administration and route of administration, therapeutic drug monitoring, dosing of drug in infants and elders, variability in clinical response and pharmacokinetics w.r.t. renal and hepatic diseases. **2L**  | 2 | 1 |
| **List of Text Books/ Reference Books** |
| 1 | Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi |  |
| 2 | Biopharmaceutics and Pharmacokinetics; By Robert F Notari |  |
| 3 | Applied biopharmaceutics and pharmacokinetics, Leon Shargel and AndrewB.C.YU 4th edition,Prentice-Hall Inernationaledition.USA |  |
| 4 | Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar andSunil B.Jaiswal,VallabhPrakashanPitampura, Delhi |  |
| 5 | Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott byADIS Health Science Press. |  |
| 6 | Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th editionRevised and expanded by Rebort F Notari Marcel Dekker Inn, New York andBasel, 1987. |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Understand the basic concepts in biopharmaceutics and pharmacokinetics andtheir significance |  |
| 2 | Use of plasma drug concentration-time data to calculate the pharmacokineticparameters to describe the kinetics of drug absorption, distribution,metabolism, excretion, elimination |  |
| 3 | To understand the concepts of bioavailability and bioequivalence of drugproducts and their significance |  |
| 4 | Understand various pharmacokinetic parameters, their significance &applications. |  |
| 5 | In-vitro-In-vivo correlation |  |

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|  | **Course Code: PHT 2002** | **Course Title: Intellectual property Rights and Patent Filing** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | B. Pharm (Pharmaceutics) of ICT or equivalent |  |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech Program** |
| To train the students on IPR |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
|  |  | **L (30)** | **T (15)** |
| **1** | Introduction to IP | 2 | 0 |
| **2** | Copyright, Related Rights, Trademarks, Geographical Indications, Industrial Design | 5 | 3 |
| **3** | Patents | 15 | 8 |
| **4** | WIPO Treaties | 2 | 1 |
| **5** | Unfair Competition | 2 | 1 |
| **6** | Protection of New Varieties of Plants | 2 | 1 |
| **7** | Summary and Discussion on IP Rights | 2 | 1 |
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| **List of Text Books/ Reference Books** |
| 1 | Intellectual Property Rights – Basic concepts by M.M.S Karki |  |
| 2 | Law Relating to Intellectual Property Rights (Fourth Edition, 2015) – by Dr. M.K.Bhandari |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Understand the Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals |  |
| 2 | Understand copyright, trademarks and industrial design |  |
| 3 | Understand basics of patent, filing process etc. |  |
| 4 | Understand IR rights |  |

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|  | **Course Code: PHT 2003** | **Course Title: Advanced Biochemistry** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Proteins: Structures – primary, secondary, tertiary, motifs, structural and functional domains, protein families and macromolecular assemblies. | 4+2 |
| **2** | Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands, Ca­+2 and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage | 4+2 |
| **3** | Purification and characterization of proteins: Electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes and MS, X-ray crystallography, NMR and Homology modeling, amino acid analysis, cleavage of peptides, protein sequencing. | 4+2 |
| **4** | Protein biosynthesis:Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences. | 4+2 |
| **5** | DNA and nucleic acids:DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms. | 6+3 |
| **6** | Carbohydrates: Mono, di and polysaccharides and their nomenclature, stereochemistry, linkages, conjugates of carbohydrates with other molecules - glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles. | 4+2 |
| **7** | Lipids: Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids | 4+2 |
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| **List of Text Books/ Reference Books** |
| 1 | Lehninger Principles of Biochemistry, Lehninger and Nelson D. L.; Biochemistry, Stryer L.; Molecular Cell Biology, Lodish H. and Darneu J. |  |
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| **Course Outcomes (students will be able to…..)** |
| 1 | Understand protein structures and motifs |  |
| 2 | Biochemistry of proteins, lipids and carbohydrates |  |
| 3 | Purification of proteins including latest developments |  |
| 4 | Understand basics of nucleic acids |  |

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|  | **Course Code: PHT 2004** | **Course Title: Drug Metabolism** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Introduction to the different pathways of drug metabolism: Phase I and II reactions, sites of drug metabolism, subcellular localization of drug metabolizing enzymes, cofactors required for catalytic reactions | 7 |
| **2** | Cytochrome P450 oxidative system: Catalytic cycle of P450 reactions, mechanism of P450 hydroxylation reactions, introduction to CYP450 superfamily of enzymes and their classification, human CYP450s involved in drug metabolism and their typical substrates, inhibitors and inducers. | 7 |
| **3** | Introduction to other drug metabolism enzyme isoforms/families Glucuronosyltransferases, glutathionetransferases, sulfotransferases, N-acetyltransferases, FMO’s. | 10 |
| **4** | Methods for studying drug metabolism: Isolated enzymes, recombinant enzymes, subcellular fractions, hepatocytes, perfused liver, in-vivo drug metabolism studies – introduction to these methods, their utility, advantages and limitations | 4 |
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| **List of Text Books/ Reference Books** |
| 1 | Foye’s Principles of Medicinal Chemistry, William D.A and Lemke T.L., 5th Edition; Handbook of Drug Metabolism, Woolf T.F.; |  |
| 2 | Drug Metabolising Enzymes, Lee J.S., Obach S.R., Fisher M.B.; Cassaret |  |
| 3 | Doull’sToxicilogy, The Basic Science of Poisons, Klaasen C. D., Amdur M.O., and Adull J.; |  |
| 4 | Fundamentals of Drug Metabolism and Disposition, La Du B.N., Mandel H.L., & Way L.E. |  |
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| **Course Outcomes (students will be able to…..)** |
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|  | **Course Code: PHT 2005** | **Course Title: Molecular Biology** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Introduction to recombinant DNA technology: Introduction to DNA and its functions, Replication of DNA and its transcription and translation, restriction enzymes and their properties, vectors for use in rDNA technology, creation and introduction of rDNA molecules, cloning and expression of rDNA molecules, cloning and expression systems, their advantages and limitations, application of rDNA technology in production of pharmaceutical and in drug discovery and development. | 14 |
| **2** | High throughput screening: Introduction to the principles of screening and the philosophy of HTS, considerations in HTS method development, validation of HTS methodology, some examples of typical HTS assays and the principles involved therein. | 4 |
| **3** | Genomics/Proteomics: Introduction to the definitions of various ‘omics’, introduction to the general field of genomics and proteomics, introduction to some methods used in analyzing gene expression at the mRNA and protein level, basic principles of DNA/Protein microarrays and their applications. | 6 |
| **4** | Human Genome Initiative: Introduction to the genome, genome complexity and genome organization, basic approaches towards sequencing of genomes, the approach for sequencing the human genome, sources for obtaining human genome sequence information, data mining of the human genome sequence for information and other potential applications, introduction to bioinformatics. | 6 |
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| **List of Text Books/ Reference Books** |
| 1 | Molecular Biotechnology, Principles and Applications of recombinant DNA, Glick B. R. & Pasternak J.J.; Principles of Genome Analysis & Genomics, Primrose S.B. &Twyman R.M.; Gene Biotechnology , Jogdand S.N.; Biotechnology-Theory & Techniques, Gen Engg, Mutagenesis, Separation Technology, Chirirjian J G; Pharmaceutical Biotechnology – A introduction for Pharmacists & Pharmaceutical Scientists, Crommelin D.A. &Sindelar R. D. |  |
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| **Course Outcomes (students will be able to…..)** |
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|  | **Course Code: PHT 2007** | **Course Title: Packaging Technology** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | B. Pharm courses (Pharmaceutics) and B. Tech courses (Pharmaceutical Formulation Technology) of ICT or equivalent |  |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
| To train the students on packaging and labeling of pharmaceutical products |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
|  |  | **L (30)** | **T (15)** |
| **1** | Its status and scope in Pharmaceutical Industry | 1 | 0 |
| **2** | Classification of packaging material into primary and secondary packaging, functions of packaging. | 2 | 1 |
| **3** | Primary Packaging Material:* 1. Glass containers (ampoules, vails and bottles) metals (tins for consmetic powders, tubes for skin and ophthalmic ointments, Aluminium containers and foils) 9 Fibers board and paperboard for bulk packaging in containers and drums).
	2. Containers and laminations of the metal containers Films and Foils- including AL, PVC, used ins trip packaging and blister packaging of tablets, cellulosics and cellophone.
	3. Plastic- polymers and copolymers, electrosetting and thermoforming (Medium and high density polystyrene PET)
	4. Equipment in primary packaging including strip packing, blister packing powder filling ,liq filling, aerosol filling, snap on closures.
	5. Design and specification for he containers including bottles, thread, their dimensions and others.
 | 5 | 2 |
| **4** | 1. Secondary Packaging Materials: Folding cartons and set of boxes, Materials of construction, design and specifications-corrugated fiberboard, Packaging inserts- specifications and test methods and quality control.
2. Cushioning – Cushioning materials, applications for impact, vibrations, temperature and humidity closures, applicatures fasteners and adhesives- cap threads, cap liners, aluminium bands, shrink brands, stoppers and plugs, tapes, adhesives.
3. Shrink Warp Process
 | 6 | 3 |
| **5** | Specifications, quality control tests and methods and evaluation of packaging of materials. | 10 | 4 |
| 6 | Labels and labeling1. Direct printing heat transfer, ordinary labels, adhesives
2. Standards and Quality Control test including dimensions printing and lists such as folding test, gluing, ageing, block vibration and shock for the boxes
3. Toxicity and safety of printing inks
 | 2 | 2 |
| **7** | Sterilization of containers:Different methods of sterilization for containers (primary) including autoclaving, dry heat, gas sterilization, ionizing and non-ionizing radiations | 1 | 1 |
| **8** | Stability of packaging materials | 2 | 1 |
| **9** | Law and regulation governing packaging | 1 | 1 |
| **List of Text Books/ Reference Books** |
| 1 | Pharmaceutical Packaging Technology – CRS press, Taylor and Francis group |  |
| 2 | Pharmaceutical Packaging Handbook by Edward J. Bauer, CRS press, Taylor and Francis group |  |
| **Course Outcomes (students will be able to…..)** |
| 1 | Understand different types of packaging |  |
| 2 | Understand primary and secondary packaging materials used |  |
| 3 | Understand quality control tests, methods and evaluation of packaging of materials |  |
| 4 | Understand labeling |  |
| 5 | Understand different types of sterilization methods |  |

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|  | **Course Code: PHT 2012** | **Course Title: Medicinal Natural Products** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | General biosynthetic pathways in the formation of secondary metabolitesMethods of investigation in biogenetic studies.Biosynthesis of phenyl propanoidsIsolation, identification, classification, structure determination and important pharmacological activities of flavonoids. Detailed study of rutin including extraction and isolation.Tumour inhibitors from plants.Pesticides of natural origin.Poisonous plants.Plant allergens. |  |
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| **List of Text Books/ Reference Books** |
| 1 | Medicinal Natural Products- A Biosynthetic Approach. Dewick P.M. 2nd edition/2002 John Wiley & Sons Ltd. |  |
| 2 | Pharmacognosy &Phytochemistry Medicinal Plants. Bruneton J. 2nd edition/1999 Lavoisier Publishing Inc. |  |
| 3 | Phytochemical Methods- A Guide to modern techniques of Plant analysis. Harborne J.B. 3rd edition/1998 Springer |  |
| 4 | Natural Products- A Laboratory Guide Ikan R.2nd edition/1994 Academic Press |  |
| 5 | Pharmacognosy. Tyler V.E. 8th edition/1981 Lea &Febiger |  |
| 6 | Textbook of Pharmacognosy. Trease& Evans, 15th edition/2002 Harcourt Publishers |  |
| 7 | Textbook of Pharmacognosy. Wallis 5th edition/1967 J. & A. Churchill Ltd. |  |
| 8 | Plant Drug Analysis- A Thin Layer Chromatography Atlas Wagner H. 1984 Springer-Verlag |  |
| 9 | Wealth of India (11 volumes) Publications and Information Directorate, CSIR 1992 |  |
| 10 | Atlas of Microscopy of Medicinal Plants, Culinary Herbs and Spices Jackson B.P. CBS Publishers  |  |
| 11 | The Merck Index Merck Research Laboratories 13th edition, 2001 Merck & Co., Inc |  |
| **Course Outcomes (students will be able to…..)** |
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|  | **Course Code: PHT 2014** | **Course Title: Chiral Synthesis** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Introduction, concept and importance of chiralityResolution of racemic mixturesStereoselective and stereospecific synthesisClassification of types of reactions involved in chiral synthesis for compounds with one and two chiral centersExamples of reactions of the above types; useful in drug synthesis to be covered.Analytical methods in chiral synthesis. |  |
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| **List of Text Books/ Reference Books** |
| 1 | Chirality in Industry Vol –I, II and III , R. A. Sheldon,  |  |
| 2 | Chiral catalysis, Noyori, Asymmetric Catalysis vol I, II & III , Noyori. |  |
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| **Course Outcomes (students will be able to…..)** |
| 1 | Importance of chirality and overview |  |
| 2 | Non biological resolutions- resolution of racemates by distereoisomeric salt formation |  |
| 3 | Asymmetric synthesis by chemical methods |  |
| 4 | Overview of immobilization techniques and membrane reactors |  |
| 5 | Understanding regulatory aspects of chiral drugs |  |

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|  | **Course Code: PHT 2016** | **Course Title: Quality Assurance and Validation** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | B. Pharm courses (Pharmaceutics) of ICT or equivalent |  |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
| To train the students on GLP, GMP and validation of pharmaceuticals |
| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
|  |  | **L (30)** | **T (15)** |
| **1** | CGMP – Status and regulations,  | 2 | 1 |
| **2** | GLP | 1 | 0 |
| **3** | Validation: Process validation for sterile and non-sterile formulations | 9 | 4 |
| **4** | Validation of Pharmaceutical water systems, validation of utilities, validation of environmental control systems | 5 | 3 |
| **5** | Systems validation and quality audits | 5 | 3 |
| **6** | Documentation | 8 | 4 |
| **List of Text Books/ Reference Books** |
| 1 | Beotra’s Law of Drugs Medicins and Cosmetics K. K. Singh, L. R. Bugga for the Law Book Co. Pvt. Ltd. Allahabad |  |
| 2 | Modern Pharmaceutics, G. S. Banker, New York, Marcel Dekker 1990 |  |
| 3 | Fundamentals of Pharmacy, Blome H. E., Philadelphia, Fea and Febiger, 1985 |  |
| 4 | Pharmaceutical Production Facilities: Design and Applications, G. C. Cole, New York Ellis Horwood 1990 |  |
| 5 | Microbial Quality Assurance in Pharmaceuticals Cosmetics and Toiletries, S. F. Bloomfield, Chichester, Ellis, Horwood, 1998. |  |
| 6 | Encyclopedia of Pharmaceutical Technology, J. Swarbrick, New York, Marcel Dekker, 1993 |  |
| 7 | Remington’s Pharmaceutical Sciences, A. R. Gennaro Mac Pub. Co. Easton, Pennsylvania 1990 |  |
| 8 | Indian Pahrmacopoiea, British Pahrmcopoiea, United States Pharmcopoiea. |  |
| 9 | Good Laboratory Practice Regulations A. F. Hirsch, New York, Marcel Dekker, 1989 |  |
| 10 | Good Laboratory Practice Regulations Weinberg New York, Marcel Dekker, 1995. |  |
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| **Course Outcomes (students will be able to…..)** |
| 1 | Understand basics of quality assurance |  |
| 2 | Understand validation and documentation |  |

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|  | **Course Code: 2023** | **Course Title:** Technological of Fine and Speciality Chemicals  | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Catalysis and catalytic processes |  |
| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Tech. Program** |
| Study of Chemical technology of selected Fine chemicals and Speciality chemicals |
| **Sr. No** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | **Introduction**. Characteristic features of fine and speciality chemicals manufacture.Types of Catalysts in Fine Chemicals Synthesis**.** Role of Heterogeneous Catalyst in Improving Selectivity**.** Aspects of Process Development of Fine Chemicals**.** Relevant Separation Methods**.** Different Types of Manufacturing Facilities of Fine Chemicals | 4+3 |
| **2** | **Chemistry of Fine and Speciality Chemicals Synthesis**. What are fine and speciality chemicals? Historical development of organic synthesis. Fine and speciality chemicals vs. bulk chemicals manufacture. Process selection: process profile analysis. Factors influencing process choice: cleaner and safer technologies. E factors and atom utilization. The role of catalysis in waste minimization. Fine chemicals and speciality chemicals and catalysis: examples. | 6+2 |
| **3** | **Types of Catalysts in Fine Chemicals and speciality Synthesis**. Introduction. Mechanism of catalysis. Heterogeneous catalysts - types and preparation. Catalyst performance: activity, selectivity, and stability. Catalyst selection. Catalyst characterization. Homogeneous catalysis. Phase-transfer catalysis. Biocatalysis. | 6+2 |
| **4** | **Role of Heterogeneous Catalyst in Improving Selectivity.**Heterogenization of homogeneous catalysis. Additional liquid phase. Rate and selectivity improvement via manipulation of 'microenvironment'. Rate and selectivity improvement via manipulation of 'macroenvironment'. Unconventional techniques. Continuous processes. | 4+3 |
| **5** | **Aspects of Process Development of Fine and speciality Chemicals**. Introduction. Steps in process development. Scale-up procedures. Chemical reactor scale-up, design, and operation. Acronyms and symbols. | 5+2 |
| **6** | **Brief overview of Relevant Separation Methods**. Distillation. Extraction. Crystallization. Adsorption. Membrane separations.**Brief overview of Different Types of Manufacturing Facilities of Fine and speciality Chemicals**. Types of production plants. Typical equipment in a multi-product plant. Production costs. Design and scheduling of batch plants. Principles of good manufacturing practice. | 5+3 |
| **List of Text Books/ Reference Books** |
| 1 | Fine Chemicals Manufacture: Technology and Engineering, A. Cybulski M.M. Sharma R.A. Sheldon J.A. Moulijn |  |
| 2 | Sustainable Value Creation in the Fine and Specialty Chemicals Industry – R Rajagopal |  |
| 3 | Specialty Chemicals Innovations in industrial synthesis and applications - B Perason |  |
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| **Course Outcomes (students will be able to…..)** |
| 1 | Grasp the manufacturing of various Fine chemicals and speciality chemicals |  |
| 2 | understand the process flow diagram and various process parameters |  |
| 3 |  Identify and solve engineering problems during production |  |

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|  | **Course Code: PHT 2305** | **Course Title: Clinical Research Management** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester: II** | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
|  | Anatomy, Physiology and Pathology-I, II, Pharmacology I to IV and Clinical Pharmacy and drug interactions of ICT B Pharm syllabus or any equivalent course. |  |
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| **List of Courses where this course will be prerequisite** |
|  | Clinical trials, regulatory affairs |  |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **L(30)** | **T(15)** |
| **1** | Brief Introduction to Clinical Research1. What is Clinical Research? Why Clinical Research?
2. Sectors of Clinical Research
3. Types of clinical trials
4. Regulatory guidelines
5. Ethics
6. Management of Clinical research
 | 1 | 0 |
| **2** | Scientific & Technical aspects of Clinical Research1. Development of Investigational product/drug for human administration—Phase I, II, III and IV trials
2. Technical requirements
 | 2 | 1 |
| **3** | Regulatory Requirements of Clinical Research1. Regulatory guidelines--- Schedule Y, US FDA, EU guidelines to be discussed in detail
2. Brief outline of ICH-GCP
 | 4 | 2 |
| **4** | ETHICS in Clinical Research1. Ethics to be followed during the conduct of different phases of Clinical Trials
2. Importance of Ethical conduct of clinical Trials
3. Ethics Committee --- role, responsibilities and function
4. Regulatory expectations from ethics committee
 | 5 | 2 |
| **5** | Procedural and Practical Clinical Research1. SOPs to be discussed in detail
2. Practical implementation of SOPs
 | 4 | 2 |
| **6** | Management of Clinical Research1. Sponsor & Investigator – CRO/ NGO
2. Patients / Volunteers recruitment
3. Medical and technical teams
4. Pharmacy and responsibilities of pharmacists
5. Vendors
6. Medical management
7. Logistics
 | 7 | 4 |
| **7** | Quality control and Quality Assurance in Clinical Trials1. Monitoring of clinical trials
 | 2 | 1 |
| **8** | Data Management and Statistics | 3 | 2 |
| **9** | Pharmacovigillance1. Adverse event reporting
 | 2 | 1 |
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| **List of Text Books/ Reference Books** |
| 1 | Clinical Pharmacy and therapeutics by Roger Walker. |  |
| 2 | Clinical pharmacy practice by MilapNahata. |  |
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| **Course Outcomes (students will be able to…..)** |
| 1 | Understand theoretically the current scenario of Clinical Research |  |
| 2 | Understand the scope of clinical research including clinical trials, regulatory requirements, ethics, management, quality control and quality assurance of Clinical research. |  |
| 3 | Develop skills in different fields and aspects of clinical research |  |
| 4 | Additional qualification as a prerequisite to be employed in the clinical research Industry worth $64 billion |  |

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|  | **Course Code: PHT 2011** | **Course Title: Advances in Receptor Pharmacology** | **Credits = 3**  |
| **L** | **T** | **P** |
| **Semester:**  | **Total contact hours: 45** | **2** | **1** | **0** |
| **List of Prerequisite Courses** |
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| **List of Courses where this course will be prerequisite** |
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| **Description of relevance of this course in the M. Pharm / M. Tech. Program** |
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| **Sr. No.** | **Course Contents (Topics and subtopics)** | **Reqd. hours** |
| **1** | Receptor classificationIon Channels: Transmitter gated channels / ligand gated channels. Eg. Nicotinic receptors, GABAa or glutamate receptorsG-protein coupled receptor – G-proteins function, β- adrenergic receptors, muscarinic receptors.Cytosolic receptors / Transcriptional regulators e.g. steroid receptors, hormone receptorsSecond messenger systems |  |
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| **List of Text Books/ Reference Books** |
| 1 | Pharmacology 3rd edition –H. P. Rang and M. M. Dale |  |
| 2 | Textbook of receptor Pharmacology by John C. Foreman, TorbenJohasen |  |
| 3 | Drug receptors and their effectors edited by Niel J. M. Birdsall |  |
| 4 | Drug receptors by H. P. Raug |  |
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| **Course Outcomes (students will be able to…..)** |
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