INSTITUTE OF CHEMICAL TECHNOLOGY

Ordinances, Regulations and Syllabi relating to the Degree of Master of Technology (Pharmaceutical Chemistry and 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 3rd semester of the Programme). 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 Programme committee periodically proposed the Programme outcomes having consistency with the Graduate Attributes (GO) available with National Board of Accreditation (NBA). The committee critically analysed information obtained from graduated students, employers and immediately passed out students. The Programme outcomes are as follows:

Sr. No.	Programme Outcomes (POs)
	Students will develop…
1	An ability to independently tackle Research or Investigation and Development Work to Solve Practical Problems
2	An ability to independently and confidently Write and Present a substantial Technical Report or Document
3	An ability to demonstrate a Degree of Mastery in the domain of Pharmaceutical Technology as demonstrated through superior performance
4	An ability to use and evaluate Modern Techniques and Tools applied routinely in Bulk Drug Synthesis, Formulation Development, Process Parameters, Analysis and Packaging of Drug Substances and Finished Pharmaceu-tical Products
5	An ability to design solutions for Complex Pharmaceutical Technology Problems and Design System Components or Processes that meet the Specified Needs with appropriate considerations related to Public Health and Safety, along with Regulatory, Societal, and Environmental considera-tions

Credit system is a systematic way of describing an educational Programmeme 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 Programmeme. 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 Programmeme 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
(4) 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:

a) 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.
b) 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

c) 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 Programmeme. (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:

$$SGPA = \frac{\left(\sum_{i=1}^{n} c_i g_i\right)}{\left(\sum_{i=1}^{n} c_i\right)}$$

Where
'n' is the number of courses for the semester,
'c_i' is the number of credits allotted to a particular course, and
'g_i' 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:

$$CGPA = \frac{\left(\sum_{i=1}^{m} c_i g_i\right)}{\left(\sum_{i=1}^{m} c_i\right)}$$

Where
'm' is the total number of courses from the first semester onwards up to and including the semester S,
'c_i' is the number of credits allotted to a particular course, and
'g_i' 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 Pharmaceutical Chemistry	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									
PHP2513 - Industrial Training of duration of minimum of 15 weeks to maximum of six months as per approval of research supervisor and Head of the Department with total assigned credit as 30 and marks as 450									
SEMESTER IV									
PHP2514- Research Project, Thesis and Open defense with total assigned credit as 30 and marks as 450									

List of Electives*

1. **PHT2101** - Research Methodology
2. **PHT2001** - Biopharmaceuticcs and Pharmacokinetics
3. **PHT2002** - Intellectual property Rights and Patent Filing
4. **PHT2003** - Advanced Biochemistry
5. **PHT2004** - Drug Metabolism
6. **PHT2005** - Molecular Biology
7. **PHT2007** - Packaging Technology
8. **PHT2012** - Medicinal Natural Products
9. **PHT2014** - Chiral Synthesis
10. **PHT2016** - Quality Assurance and Validation
11. **PHT2023** - Technological of Fine and Speciality Chemicals
12. **PHT2305** - Clinical Research Management
13. **PHT2011** - Advances in Receptor Pharmacology

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

SEMESTER I

Course Code: PYT2106	Course Title: Physical Methods of Analysis	Credits = 3		
		L	T	P
Semester: I	Total Contact Hours: 45	2	1	0

List of Prerequisite Courses

Organic Chemistry, Physical Chemistry, Pharmaceutical Analysis, Analytical Chemistry, Pharmaceutical Chemistry

List of Courses where this course will be prerequisite

Active Pharmaceutical Ingredients Technology (PHT2022), Advanced Pharmaceutical Technology (PHT2021), Research Project (PHP2512)

Description of relevance of this course in the M. Pharm /M. Tech. Programme

The course systematically develops a thorough understanding of serveral routinely used and specialized instrumental methods of analysis with particular emphasis advanced applications in pharmaceutical, material, environmental and forensic sciences. The analytical sciences play a crtitical role in specialized and regulatory fields such as current Good Manufacturing Practices (cGMP), particularly the quality control and quality assurance of drugs and drug products. The students gain an in-depth view of the capabilities, limitations and applicability domains of modern analytical tools and techniques and are able to chose an appropriate instrumental method of for the analytical problem at hand.

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. hours
1	**Fourier-Transform Infrared (FTIR) Spectroscopy:** Molecular vibrations, Frequency shifts associated with structural changes, Basic theory of FTIR, Inteferogram, Digitization of interferogram, Data points collection, Instrumen-tation and advantages of FTIR, Qualitative and quantitative analysis using FTIR	6
2	**Ultraviolet/Vis (UV/Vis) Spectroscopy:** Electronic transitions, Spectrum, Shift of bands with solvents, Isolated double bonds, Conjugated dienes, Carbonyl compounds, Aromatic and heteroaromatic compounds, Applications of UV/Vis spectroscopy in pollution control and chemical industry	6
3	**Nuclear Magnetic Resonance (NMR) Spectroscopy:** Basic principle of NMR phenomenon, Relaxation processes, Spin-spin interaction, Chemical shifts, Interpretation of ^{1}H NMR spectra, Correlation spectroscopy, Hydrogen bonded to carbon and other nuclei, Instrumentation - Continuous and pulsed NMR, Introduction to ^{13}C NMR	8
4	**X-ray Diffraction (XRD)**: Crystal geometry and structural determination, Bragg's law, Powder method, X-ray spectrometers – Wide- and small-angle diffractrometers, Chemical analysis by XRD	4
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), Fiber-optic dynamic light scattering (FDLS)	4
6	**Chromatography:** Basic theory of Separation, Efficiency, Resolution, Liquid chromatogra-phy, High-performance liquid chromatography (HPLC), Gas chro-matography - columns and detectors, Qualitative and quantitative analysis by chromatographic methods	9
7	**Mass Spectrometry:** Basic principle, Ionization techniques - Electron impact (EI), Electrospray (ESI), Chemical (CI), Fast-atom bombardment (FAB), Matrix-assisted laser desorption (MALDI), Atmospheric pressure chemical ionization (APCI), Atmospheric pressure photoionization (APPI), Fragmentation processes in organic compounds, Interpretation of mass spectra, molecular weight and molecular formula determination, Instrumentation – Different types of mass analyzers, quadrupole and time-of-flight, Applications of mass spectrometry in pharmaceutical, environmental and frorensic sciences.	8

List of Textbooks/ Reference Books

1	Fundamentals of Analytical Chemistry; 9th ed.; Skoog, D. A., West, D. M., Holler, F. J., Crouch, S. R., Eds.; Cengage Learning, Boston, USA (2014).
2	William Kemp, Organic Spectroscopy; 3rd ed.; Macmillan Education, UK (1991).
3	Introduction to Spectroscopy; Pavia, D. L., Lampman, G. M., Kriz, G. S., Vyvyan, J. R., Eds.; Cengage Learning, Stamford, USA (2015)
4	Vogel's Textbook of Quantitative Chemical Analysis; 6th ed.; Mendham, J., Denney, R. C., Barnes, J. D., Thomas, M., Sivasankar, B., Eds.; Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi, India (2000)
5	Pharmaceutical Analysis; Lee, D. C., Webb, M., Eds.; Blackwell Publishing Ltd., Oxford, UK (2003)
6	Practical Pharmaceutical Chemistry; 4th ed. - Part 2; Beckett, A. H., Stenlake, J. B., Eds.; The Athlone Press, London, UK (1988).
7	Analytical Chemistry; 6 th ed.; Christian, G. D., Ed.; Wiley India (P.) Ltd., New Delhi, India (2008)
8	Vogel's Textbook of Quantitative Chemical Analysis; 5th ed.; Jeffery, G. H., Basset, J., Mendham, J., Denney, R. C., Eds.; Dorling Kindersley (India) Pvt. Ltd. (Pearson Education Ltd.), New Delhi, India (2000).
Course Outcomes (Students will be able to..)	
1.	Suggest a suitable method of analysis for a given sample
2.	Able to interpret the data generated from various instrumental method of analysis
3.	Appreciate the importance of sample preparation methodology for high-quality analytical data
4.	Apply the knowledge to specialized applications such as structural elucidaton of new molecules
5.	Understand and fine-tune various chromatographic parameters affecting chromatographic separations
6.	Intepret the parameters related to particle size analysis such as particule size distribution, polydispersity index, etc.
7.	Understand the advanced applications of mass spectrometry such as proteomics, drug discovery, materials and forensic sciences

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

	Organic Chemistry, Physical Methods of Analysis , Pharmaceutical Chemistry, Catalysis, Chemical Reaction Engineering, Energy and Material Balance, 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 Conduction, Radiation. Basic course in Fluid Flow and Heat Transfer, Thermodynamics of Phase Equilibria

List of Courses where this course will be prerequisite

	Active Pharmaceutical Ingredients Technology (PHT2022), Research Project (PHP2512)

Description of relevance of this course in the M. Tech. Programme

The emphasis is on manufacturing of quality products, especially APIs, 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 outcome. The student is expected to handle and manage process parameters and unit operations for assurance of quality. Another task is development of new process chemistry and development, keeping in mind safety and environmental considerations. Generation of data for scale-up. The course content is designed, with combination of diverse relevant topics to make it apt for the M. Tech. Programme.

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. hours
1	Principles of Chemical Process Development	4
2	Background information, Literature search methodologies	4
3	Selection of route for synthesis/manufacture, Green processes	4
4	Process safety, MSDS, Safety laboratory data	4
5	Scale-up methods, Introduction to scale-up methods, Principles of similarities, Pilot plant and models	4
6	Flow Chemistry: Concepts, Fundamentals of flow chemistry	4
7	Analytical methods - HPLC, GC, NMR, UV/Vis spectroscopy, Mass spectrometry and their application in process development field	4
8	Effluent treatment methodologies	4
9	Economic evaluation of project	4
10	Commercial processes of fine chemicals and APIs – Five case studies	9

List of Textbooks/ Reference Books

1	Levenspiel, O. Chemical Reaction Engineering; 3rd ed.; John Wiley & Sons, New York (1999)
2	Smith, J. M. Chemical Engineering Kinetics; 3rd ed.; McGraw Hill, New York (1981)
3	Prentice Hall International Series in the Physical and Chemical Engineering Sciences. Elements of Chemical Reaction Engineering; Fogler, H. S., Ed.; 4th ed.; Prentice Hall, New Jersey (2008)
4	Heterogeneous Reactions: Analysis, Examples, and Reactor Design; Doraiswamy, L. K.; Sharma, M. M., Eds.; Vol. II; John Wiley & Sons, New York (1984).
5	Chemical Reactor Analysis and Design; Froment, G. F.; Bischoff, K. B., Eds.; 2nd ed.; John Wiley & Sons, Singapore (1990).
6	Momentum, Heat and Mass Transfer; Bennet, C. O.; Myers, J. O., Eds.; McGraw Hill, New York (1995).
7	Transport Phenomena; Bird, R. B.; Stewart, W. E.; Lightfoot, E. N., Eds.; John Wiley & Sons, New York (2007)
8	Geankoplis, C. J., Hersel, A. A., Lepek, D. H. Prentice Hall International Series in the Physical and Chemical Engineering Sciences. Transport Processes and Separation Process Principles; 5th ed.; Prentice Hall, New

	Jersey (2018)
9	King, C. J. Separation Processess; Tata McGraw Hill, New Delhi (1982)
10	Seader, J. D.; Henley, E. J.; Roper, D. K. Separation Process Principles; 3rd ed.; John Wiley & Sons, USA (2010).
11	Jordon, D. J. Chemical Process Development. Parts 1 and 2; R. E. Krieger Publications (1988).
12	Johnstone, R. E., Thring, M. W. Chemical Engineering Series. Pilot Plants, Models and Scale-up Methods in Chemical Engineering; McGraw Hill Inc., New York (1957)
13	Flow Chemistry: Recent review articles and papers dealing with APIs and simple and multi-step synthesis in flow format
Course Outcomes (Students will be able to…)	
1.	Explain the basis of heat transfer coefficient based on analogies of momentum and heat transfer.
2.	Understand and appreciate safety aspects of chemical processes on laboratory and industrial scale
3.	Understand and analyse flow pattern influencing mass and heat transfer resulting in variation in chemical recation outcome.
4.	Understand the fundamental and applications of flow chemistry
5.	Generate data at the lab-scale required for scale-up.
6.	Understand and appreciate the effluent treatment technologies

Course Code: PHT2019	Course Title: Industrial Pharmacy	Credits = 3		
		L	T	P
Semester: I	Total Contact Hours: 45	2	1	0

List of Prerequisite Courses

Technology of Liquids and Topicals, Validation and Regulatory Requirements of B. Tech. Syllabus of ICT or Equivalent

List of Courses where this course will be prerequisite

Drug Delivery Technology (PHT2020), Packaging Technology (PHT2007, Elective), Quality Assurance and Validation (PHT2016, Elective)

Description of relevance of this course in the M. Tech. Programme

This course is designed to impart fundamental knowledge on pharmaceutical product 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	9
2	**Unit Operations for Pharmaceutical Development:** Equipment design and operation, mixing, milling, drying, filtration and related operations	6
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.	9
4	**Scale-up Considerations:** Large-scale manufacturing of monophasic and biphasic liquids, semisolids and solids	12
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.	9

List of Textbooks/Reference Books

1	Udupa, N., Bhat, K. A Concise Textbook of Drug Regulatory Affairs; 1st ed.; Manipal University Press, Manipal, India (2015).
2	Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy; 4th ed.; Khar, R. K., Vyas, S. P., Ahmad, F. J., Jain, G. K., Eds; CBS Publishers and Distributors, Pvt. Ltd., New Delhi, India (2016)
2	The Pharmaceutical Regulatory Process; 2nd ed.; Berry, I. R., Martin R. P., Eds.; CRC Press, United States (2019)
3	FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics; 3rd ed.; Pisano, D. J., Mantus, D. S., Eds.; CRC Press, United States (2014)
4	Singer, D. C.; Van Staden, J. F.; Stefan, R.-I.; Laboratory Auditing for Quality and Regulatory Compliance. Drugs and The Pharmaceutical Sciencs, Vol. 150; 1st ed.; CRC Press, United States (2005)
5	CFR - Code of Federal Regulations Title 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
6	21CFR Part 211. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211
7	Common Technical Document (CTD). https://www.ich.org/page/ctd
8	eCTD: https://ich.org/page/ich-electronic-common-technical-document-ectd-v40
9	Dosage Form Design Parameters. Advances in Pharamaceutical Product Development and Research Series, Vol. II; Tekade, R. K., Ed.; Academic Press, London, UK (2018)

Course Outcomes (students will be able to…)

1.	Understand and appreciate Pharmaceutical Product Development

2.	Gain an in-depth knowledge on the unit operations in Pharmaceutical Product Development
3.	Understand the process of technology transfer from lab-scale to commercial batch
3	Realixe the importance and contents of the Laws, Acts and the Processes therein that regulate the Pharmaceutical Industry in India and Worldwide
4	Understand the approval process and regulatory requirements for drug products

	Course Code: PHP2505	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

	Pharmaceutical Technology Laboratory (PHP2509); Research Project (PHP2512)

Description of relevance of this course in the M. Tech. Programme

Analysis by instrumental methods is at the core of industrial synthesis, formulation development, monitoring of processes, quality control of raw materials and finished products, in-process quality control and several related processes

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. hours
1.	UV/Visible Spectroscopy: i. Calibration of UV/Vis spectrophotometer ii. Study the effect of solvent on λ_{max} of drug substances iii. Find Beer's law limit of drugs in a suitable solvent iv. Standard calibration curve by UV spectroscopy at a) λ_{max} b) λ_{max} + 10 nm c) λ_{max} – 10 nm v. Determination of pKa vi. Multicomponent analysis vii. Absorbance corrected for interference method viii. Simultaneous equation method ix. Absorbance ratio method x. Area-under-the-curve method xi. First-derivative spectrophotometric method	24
2.	Analysis of drugs from formulations focusing on separation of drug from the formulation excipients	12
3.	IR Spectroscopy: i. Calibration of IR spectrophotometer ii. Sample preparation (solid/liquids) and interpretation of IR bands for important functional groups	12
4.	Differential Scanning Calorimetry (DSC) analysis of drugs in crystalline and amorphous forms	12
5.	Chromatography: i. Calibration of HPLC, determination of response factor by HPLC ii. Gas Chromatograph (GC) handling and analyses of API intermediates iii. TLC mobile phase selection for various mixtures and reaction monitoring iv. Preparative TLC analysis v. pH stability evaluation of a drug by TLC vi. Separation of components by column chromatography	18
6.	Structural Interpretation by Spectroscopic Methods: i. Interpretations of mass, ^{1}H, ^{13}C NMR spectra ii. Structural Elucidation Workshop: Interpretation of ^{1}H-, ^{13}C-NMR, IR and mass spectra of simple compounds	12

List of Textbooks/ Reference Books

1.	Perkampus, H.- H.; UV/VIS Spectroscopy and its Applications; Springer-Verlag, Berlin (1992)
2.	Görög, S.; Ulraviolet-Visible Spectrophotometry in Pharmaceutical Analysis; CRC Press, United States (1995)
3.	Silverstein, R. M.; Webster, F. X.; Kiemle, D. J. Spectrometric Identification of Organic Compounds; 7th ed.;

	John Wiley & Sons, New York (2005)
4.	Willard, H. H., Merritt, L. L., Dean, J. A., Settle, F. A., Jr.; Instrumental Methods of Analysis; 7th ed.; Wadsworth Publishing Company, United States (1988).
5.	Dyer, J. R. Applications of Absorption Spectroscopy of Organic Compounds; Prentice Hall India Learning Private Limited, New Delhi (1978).
6.	C.N.R. Rao - Chemical Applications of Infrared spectroscopy. (Academic Press, N.Y.).
7.	Jackman, L. M., Sternhell, S.; International Series in Organic Chemistry: Application of Nuclear Magnetic Resonance Spectroscopy in Organic Chemistry; 2nd ed.; Barton, D. H. R., Doering, W., Eds.; Pergamon Press, London (1969).
8.	F.W. McLafferty and F. Turecek- Interpretation of Mass Spectra.
9.	R.J. Hamilton and P. A. Sewell- Introduction to High Performance Liquid Chromatography. (Chapman and Hall, London).
10.	J.W. Munson- Pharmaceutical Analysis: Modern methods -Part A and Part B (Marcel Dekker, Inc., New York)
11.	Introduction to Spectroscopy; 5th ed.; Pavia, D. L., Lampman, G. M., Kriz, G. S., Vyvyan, J. R., Eds.; Cengage Learning, Stamford, USA (2015).
12.	Analytical Chemistry: A Modern Approach to Analytical Science; 2nd ed.; Kellner, R., Mermet, J.- M., Otto, M., Valcárcel, M., Widmer, H. M., Eds.; Wiley-VCH, London (2004).
13.	Ewing's Analytical Instrumentation Handbook, 4th ed.; Grinberg, N., Rodrigues, S., Eds.; CRC Press, London (2019).
14.	Sethi, P. D.; Quantitative Analysis of Drugs in Pharmaceutical Formulations; 3rd ed.; CBS Publishers and Distributors Pvt. Ltd., New Delhi, India (2008).
15.	Indian Pharmacopoeia 2018, Vol. I-IV; 8th ed.; The Indian Pharmacopoeia Commission, Gaziabad, India (2018)
16.	USP 2019 – United States Pharmacopoeia 42 – National Formulary 37 (USP 42 – NF 37), Vol. 1-5; The United States Pharmacopeial Convention, USA (2019).
17.	BP 2020 – British Pharmacopoeia 2020, Vol. 1-5; British Pharmacopoeia Convention, UK (2019).
18.	Practical Pharmaceutical Chemistry; 4th ed. – Parts 1 and 2; Beckett, A. H., Stenlake, J. B., Eds.; The Athlone Press, London, UK (1988)
19.	F. D. Snell and C. T. Snell- Colorimetric Methods of analysis (Van Nostrand Reinhold Company, N.Y.).
20.	***Journals:*** Biomedical Chromatography; Journal of Medicinal Chemistry; Analytical Chemistry; Journal of Analytical Chemistry; Analytical Methods; Trends in Analytical Chemistry; Analytical and Bioanalytical Chemistry
Course Outcomes (students will be able to…..)	
1.	Analyze drug intermediates, drug substances and drug products
2.	Perform calibration of major analytical instruments
3.	Develop chromatographic methods (HPLC, GC, TLC)
4.	Analyze (quantification and separation) the components of mixtures
5.	Interpret the outcomes of the analytical techniques (analytical results) logically to deduce the structure of small-organic compounds and/or conclude about the purity and overall quality

SEMESTER II

	Course Code: PHT2020	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					
	Research Project (PHP2512)				
Description of relevance of this course in the M. Tech. Programme					
Students acquire critical knowledge on the know-how of various scientific and technological aspects of a variety of Drug Delivery Systems (DDS)					
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		10		
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 Considerations		9		
3.	**Mucosal Drug Delivery Systems:** Bioadhesion and bioadhesive polymers, Formulation considerations for mucosal administration		8		
4.	**Pulmonary Drug Delivery Systems:** Design of pressurized aerosols, Inhalers (dry powder and metered-dose), Devices for administration and evaluation		5		
5.	**Transdermal Drug Delivery Systems:** Percutaneous absorption and penetration enhancers, Development of transdermal gels, patches with reference to Manufacturing equipment, Components and evaluation, Iontophoretic and sonophoretic DDS		8		
6.	**Miscellaneous:** *Injectables:* Preformulation factors and essential requirements, Vehicles, Additives, Formulations of injections, Sterile powders, Large-volume parenterals, and Lyophilization. *Ophthalmic DDS:* Design of controlled-release ophthalmic DDS including gels, inserts, novel DDS and evaluation		5		
List of Textbooks/Reference Books					
1.	Handbook of Pharmaceutical Controlled Release Technology; 1st ed.; Wise, D. L., Ed.; CRC Press, London (2000).				
2.	Drugs and the Pharmaceutical Sciences Series; Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development; Vol. 98; Mathiowitz, E., Chickering III, D. E., ; Lehr, C.-M., Eds.; CRC Press, United States (1999).				
3.	Drugs and the Pharmaceutical Sciences Series; Nasal Systemic Drug Delvery Series; Vol. 39; 1st ed.; Chien, Y. W., Su, K. S. E., Chang, S.-F., Eds.; Informa Healthcare, United States (1989).				
4.	Drugs and the Pharmaceutical Sciences Series; Transdermal Drug Delivery; Vol. 123; 2nd ed.; Guy, R. H., Hadgraft, J., Eds.; CRC Press, United States (2003).				
5.	Drugs and the Pharmaceutical Sciences Series; Ophthalmic Drug Delivery Systems; Vol. 30; 2nd ed.; Mitra, A., Ed.; CRC Press, United States (2003).				
6.	Drugs and the Pharmaceutical Sciences Series; Novel Drug Delivery Systems; Vol. 50; 2nd ed.; Chien, Y. W., Ed.; CRC Press, United States (1991)				
7.	Controlled Release Veterinary Drug Delivery: Biological and Pharmaceutical Considerations; Rathbone, M. J., Gurny, R., Eds.; Elsevier Science, Amsterdam, The Netherlands (2000).				
8.	Polymeric Drugs & Drug Delivery Systems; Ottenbrite, R. M., Kim, S. W., Eds.; CRC Press, United States (2001).				
9.	Drugs and the Pharmaceutical Sciences Series; Controlled Drug Delivery – Fundamentals and Applications; Vol.				

	29; 2nd ed.; Robinson, J., Lee,V. H. L., Eds.; CRC Press, United States (1987).
10.	Barry, B. W.; Drugs and the Pharmaceutical Sciences Series; Dermatological Formulations: Percutaneous Absorption; Vol. 18; CRC Press, United States (1983).
11.	Banga, A. K.; Electricity Assisted Transdermal and Topical Drug Delivery; Taylor & Francis, London (1998).
12.	Drugs and the Pharmaceutical Sciences Series; Mechanisms of Transdermal Drug Delivery; Vol. 83; Potts, R. O.; Guy, R. H. Marcel Dekker, Inc., New York (1997).
13.	Drugs and the Pharmaceutical Sciences Series; Transdermal Controlled Systemic Medications; Vol. 31; Chien, Y. W., Ed.; Taylor & Francis, New York (1987).
14.	Handbooks in Pharmacology and Toxicology Series; Biopharmaceutics of Ocular Drug Delivery; Vol. 6; 1st ed.; Edman, P., Ed.; CRC Press, New York (1992)

Course Outcomes (Students will be able to…)	
1.	Understand and appreciate the basics of oral and nano drug delivery systems
2.	Gain an in-depth understanding of specialized drug delivery systems such as mucocal and pulmonary.
3.	Follow the underlying principles of transdermal drug delivery systems and their industrial-scale manufacturing
4.	Gain an overview of the parenteral and ophthalmic drug delivery systems including their manufacturing aspects
5.	Detail understanding of characterization and evaluation techniques for the above drug delivery systems

	Course Code: PHT2206	**Course Title: Advanced Pharmaceutical Chemistry**	**Credits = 3**		
			L	**T**	**P**
	Semester: II	**Total Contact Hours: 45**	**2**	**1**	**0**

List of Prerequisite Courses

Advanced Organic Chemistry, Pharmaceutical Chemistry courses of ICT or Equivalent

List of Courses where this course will be prerequisite

Research Project (PHP2512)

Description of relevance of this course in the M. Pharm / M. Tech. Programme

Students will be gain an in-depth understanding of the recent advances in organic chemistry and their applications in pharmaceutical industry

Sr. No.	**Course Contents (Topics and Subtopics)**	**Reqd. hours**
1.	**Solid-phase Synthesis:** Concepts, Resins, Linkers, Characterization, Case studies	5
2.	**Peptide Synthesis:** Protected amino acids, Coupling agents, Strategies in synthesis with examples of peptide drugs and hormones, Solid-phase synthesis of peptides and peptide synthesizers	4
3.	**Oligonucleoside Synthesis:** Methodologies, Solid-phase oligonucleosides synthesis	3
4.	**Combinatorial Synthesis:** Liquid-phase and solid-phase, Deconvolution techniques, Design of libraries, Case studies	2
5.	**Organic Nanomaterials (Single Molecular and Molecular Assemblies):** Design, Synthetic strategies, Characterisation and properties of Dendrimers, Polymeric Nanomaterials, Carrier-systems for drug targeting	6
6.	**Fluorescent and Imaging Materials:** Design, Synthesis, Properties and Applications	3
7.	**Photochemical Reactions:** Basic principles of photochemical reactions, Photo-oxidation, Photo-addition and Photo-fragmentation	4
8.	**Organic Name Reactions:** Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Mitsunobu reaction, Sharpless asymmetric epoxidation and dihydroxylation, Metathesis	6
9.	**Synthetic Reagents and Applications:** Aluminium isopropoxide, *N*-Bromosuccinamide (NBS), Diazomethane, Dicyclohexyl carbodimide (DCC), Wilkinson reagent, Wittig reagent. Osmium tetroxide, Titanium chloride, Piazopropane, Diethyl azodicarboxylate (DEAD), Triphenyl-	12

	phosphine, (Benzotriazol-1-yloxy) tris(dimethylamino)phosphonium hexafluorophosphate (BOP)	
List of Textbooks/Reference Books		
1.	Carey F. A., Sundberg, R. J. Advanced Organic Chemistry: Part A: Structure and Mechanisms; 5th ed.; Springer, UK (2005)	
2.	Carey F. A., Sundberg, R. J.; Advanced Organic Chemistry: Part B: Reaction and Synthesis; 5th ed.; Springer, UK (2007)	
3.	Sheldon R.A.; Chirotechnology: Industrial Synthesis of Optically Active Compounds; 1st ed.; CRC Press, London (1993).	
3.	Textbook of Drug Design and Discovery; 5th ed.; Stromgaard, K., Krogsgaard-Larsen, P., Madsen, U., Eds.; CRC Press, London (2016).	
4.	Smith, M. B.; March's Advanced Organic Chemistry: Reactions, Mechanisms and Structure; 7th ed.; Wiley, India (2015).	
5.	Combinatorial Chemistry: Synthesis and Applications, Wilson S. R., Czarnik, A. W., Eds.; Wiley, London (1997).	
6.	Warren S., Wyatt, P.; Organic Synthesis: The Disconnection Approach; Wiley, New York (2008).	
7.	Iyer, R. P.; Synthesis of Drugs: A Synthon Approach; Sevak Publications, India (1985).	
8.	Clayden, J., Greeves, N., Warren, S.; Organic Chemsitry; 2nd ed.; Oxford University Press, London (2012).	
9.	Corey, E. J., Cheng, X.-M.; The Logic of Chemical Synthesis; 1st ed.; Wiley India Pvt. Ltd., New Delhi (1995).	
10.	Nicolou, K. C., Sorensen, E. J.; Classics in Total Synthesis; 1st ed.; Wiley-VCH, London (1996).	
Course Outcomes (students will be able to…)		
1.	Understand and apply concepts of peptide and oligonucleotide synthesis with particular emphasis on solid-phase synthesis	
2.	Understand the design and synthesis of combinatorial libraries	
3.	Understand and appreciate various facets of organic nanomaterials, fluorescent and imaging materials	
4.	Understand and apply the synthetic utility of photochemical reactions	
5.	Appreciate the synthetic usefulness of various name reactions in Organic and Medicinal Chemistry	

	Course Code: PHT2022	**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 (PHT1046), Advanced Pharmaceutical Technology (PHT2021)				
List of Courses where this course will be prerequisite					
	Research Project (PHP2512)				
Description of relevance of this course in the M. Tech. Programme					
The course is designed to impart and in-depth understading of API manufacturing industry with particular emphasis on the study of chemical technology of selected APIs including chiral APIs, importance of current good manufacturing practices (cGMP), Regulatory Affairs Quality Assurance (RAQA), green processes and safety					
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		3		
2.	**Scale-up Techniques:** Process research and development, Optimization, Maximization of productivity, In-process control techniques		3		

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.	10
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.	10
5.	**Impurity Considerations:** Introduction, Steps to optimizing reactions, Minimizing impurity formation by indentifying impurities first, Method development for separation, Synthesis and Isolation of impurities and their characterization	7
6.	Overview of plant layout, plant design, utilities and process flow sheets	3
7.	Raw material consumption and Costing	3
8.	Overview of GMP and Safety in API industry	3
9.	Overview of Quality Assurance and Regulatory Affairs	3

List of Textbooks/Reference Books

1.	Process Chemistry in Pharmaceutical Industry; 1st ed.; Gadamasetti, K., Ed.; CRC Press, London (1999).
2.	Smith, M. B.; March's Advanced Organic Chemistry: Reactions, Mechanisms and Structure; 7th ed.; Wiley, India (2015).
3.	Harrington, P. J.; Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up; Wiley, London (2011).
4.	Anderson, N. G.; Practical Process Research & Development: A Guide for Organic Chemists; 2nd ed.; Academic Press, London (2012).
5.	Lednicer, D.; Strategies for Organic Drug Synthesis and Design; 2nd ed.; John Wiley & Sons, Inc., New York (2008).

Course Outcomes (students will be able to…..)

1.	Grasp the underlying technologies in the manufacturing of various APIs including chiral APIs
2.	Understand the process flow-diagram and various process parameters
3.	Identify and solve engineering problems during production (trouble-shooting)
4.	Understand and appreciate the significance of impurities in pharmaceutical product development
5.	Appreciate the importance of cGMP, RAQA departments in API industry

	Course Code: PHP2509	**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 (PHT1012), Technology of Sterile Products (PHT1014), Sterile Products Laboratory (PHP1014), Pharmaceutical Chemistry Laboratory (PHP1042) of B. Tech syllabus of ICT or Equivalent

List of Courses where this course will be prerequisite

Research Project (PHP2512)

Description of relevance of this course in the M. Tech. Programme

To train the students with respect to practical aspects of advanced formulation development technology

Sr. No.	**Course Contents (Topics and Subtopics)**	**Reqd. hours**
1.	Solubilization of drugs by at least two novel techniques	6
2.	Scale-up and evaluation of controlled-release 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.	Examples of Tosylation, Transfer hydrogenation, Wittig reaction, Claisen-Schmidt condensation, Cycloaddition, Sulfonation, Dehydration (Any three)	9
12.	Synthesis of two complex molecules/drug intermediates which may include three 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 Textbooks/ Reference Books		
1.	Furniss, B. S., Hannaford, A. J., Smith, P. W. G., Tatchell, A. R.; Vogel's Textbook of Practical Organic Chemistry; 5th ed.; John Wiley & Sons, New York (1991).	
2.	Green Chemistry in Industry: Green Chemical Processing.; Benvenuto, M. A., Plaumann, H., Eds.; de Gruyter, Berlin, GmbH (2018).	
3.	Organic Syntheses Collective Volumes 1-11; Organic Syntheses Annual Volumes 1-96	
4.	Recent articles relevant Journals realated to a particular topic	
Course Outcomes (students will be able to…)		
1.	Apply novel techniques for the solubilisation of small-molecule drugs/New Chemical Entities (NCEs).	
2.	Perform scale-up of controlled-release tablets.	
3.	Develop multiparticulate formulations.	
4.	Prepare mucosal, transdermal and ophthalmic formulations.	
5.	Prepare in situ parenteral implants, DPI/MDI.	
6.	Perform process development of APIs.	
7.	Understand Green Chemistry Principles, hazards, effluents and statistical methods of optimization.	
8.	Identify process variables and implication in scale-up.	

Electives

	Course Code: PHT2101	Course Title: Research Methodology	Credits = 3		
			L	T	P
	Semester: I	Total Contact Hours: 45	2	1	0

List of Prerequisite Courses

Previous (during undergraduate) exposure to research project(s) is desirable but not necessary

List of Courses where this course will be prerequisite

Research Project (PHP2512)

Description of relevance of this course in the M. Pharm. and M. Tech. Programmes

The formal exposure to various elements of research methods such as problem formulation, literature search, planning of various activities, documentation, budgeting, purchase, report/thesis compilation, manuscript writing, patent drafting, is critical for polishing the naïve research attitude and aptitude in the PG students of the programme. The course is designed to formally introduce various concepts of research methodology in stepwise manner to the students.

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. hours
1.	**Basics:** Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) – Objective of research-	7
2.	**Literature Survey** – Use of Library, Books, & Journals – Medline – Internet, getting patents and reprints of articles as sources for literature survey.	4
3.	Selecting a problem and preparing research proposal for different types of research mentioned above.	4
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 Analysis of variance (ANOVA), Correlation data and its interpretation, Computer data analysis	7
5.	**Documentation:** 'How' of documentation; Techniques of documentation; Importance of documentation; Uses of computer packages in documentation	6

6.	**Research Report/Paper/Thesis Writing**
	• Different parts of the Research paper
	  • Title – Title of project with author's name
	  • Abstract – Statement of the problem Background list in brief and purpose and scope
	  • Key-words-
	  • Methodology-Subject, Apparatus/Instrumentation, (if necessary) and procedure
	  • Results – Tables, Graphs, Figures, and Statistical Presentation
	  • Discussion – Support or non-support of hypothesis – practical & theoretical implications, conclusions
	  • Acknowledgements
	  • References
	  • Errata
	  • Importance of spell check for Entire project
	  • Use of footnotes
		5

7.	**Presentation (Oral/Poster):** 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	3
8.	**Introduction to Intellectual Property (IP) Aspects of Research (Patents and Trademarks,**	

	Designs and Copyrights): The Patent System in India – Present status of Intellectual Property Rights (IPR), Future changes expected in Indian Patents System; Advantages; The Science in Law, Turimetrics (Introduction); What may be patented; Who may apply for patent; Preparation of patent document; Registration of patent in foreign countries and vice-versa	6
10	**Sources for procurement of Research Grants**	1
11	**Industry - Institution Interaction** Industrial projects and their feasibility reports	2

	List of Textbooks/ Reference Books
1.	Best, J. W., Kahn, J. V., Jha, A. K.; Research in Education; 10th ed.; Pearson, New Delhi, India (2005).
2.	Mcfarlane, G.; Business Law Series: A Practical Introduction to Copyright; McGraw-Hill, UK (1982)
3.	**Davis, R. M.; Thesis Projects in Science and Engineering**: A Complete Guide from Problem Selection to Final Presentation; St. Martin's Press, (1980).
4.	Anderson, J., Durston, B. H., Poole, M. E.; Thesis and Assignment Writing; John Wiley, United States (1970).
5.	Menzel, D.; Writing a Technical Paper; McGraw-Hill, United States (1961).
6.	Brown, L.; Effective Business Report Writing ; Prentice-Hall, United States (1973).
7.	WIPO Intellectual Property Handbook; WIPO Publication (2004).
8.	Carter, M.; Designing Science Presentations: A Visual Guide to Figures, Papers, Slides, Posters, and More; Academic Press, London (2013).
9.	Ranganathan, S. R.; Documentation : Genesis and Development; Ess Ess Publications, India (2006).
10.	Manual for Evaluation of Industrial Projects – United Nations Industrial Development Organization (UNIDO) Publication (1986). (https://open.unido.org/api/documents/4788156/download/MANUAL%20FOR%20EVA)
11.	Behrens, W.; Hawranek, P. M.; Manual for the Preparation of Industrial Feasibility Studies; United Nations Industrial Development Organization (UNIDO) Publication (1991) (https://owaisshafique.files.wordpress.com/2011/04/manual_for_the_preparation_of_industrial_feasibility_studies.pdf)

Course Outcomes (Students will be able to…)	
1.	Understand the basic concepts of research and the components therein, formally
2.	Understand and appreciate the signifance of statistics in Pharmaceutical, Materials and Life Sciences research
3.	Know the importance and appreciate the critical role played by literature survey in research
4.	Gain an in-depth knowledge on the documentation in research
5.	Appreciate the importance of various parts of a research report/paper/thesis in presentation of research results
6.	Understand what it takes to deliver a good oral/poster presentation
7.	Know the significance of various types of IPRs in research
8.	Appreciate the significance of industry-institute interaction in exploring the translational side of a research project

	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	
	Pharmaceutics, Pharmacology, Biopharmaceutics and Pharmacokinetics (B. Pharm.) or Equivalent
List of Courses where this course will be prerequisite	
	Pharmaceutical Product Development, Mathematical Modeling of Pharmacokinetic Processes, Research Project (PHP2512)

Description of relevance of this course in the M. Pharm Programme

Given the importance of Biopharmaceutics and Pharmacokinetics (BP/PK) in Pharmaceutical Product Development and Drug Action, the course necessarily provides an in-depth understanding of various concepts, processes and their molecular mechanism in drug action, which is critical for dosage form design, optimization of pharmaceutical formulations, adverse effects/toxicities of drugs, drug-drug interactions, etc. The conceptual understanding of various principles covered in this course can potentially open-up doors to highly specialized fields such as mathematical modeling of pharmacokinetic processes.

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. hours
	Biopharmaceutics	
1.	**Introduction:** Recap of ADME, bioavailability, bioequivalence and factors affecting the same	2
2.	**Molecular Basis of Drug Absorption and Transport** • Molecular structure and nature of the cell and nuclear membranes • Transcellular absorption 1. Nature of passive transcellular absorption 2. Carriers for the active transport of drugs (With special emphasis on p-glycoprotein (P-gp) and design of P-gp inhibitors) 3. Methods of studying the carrier mediated transport • Paracellular absorption 1. Molecular organization of the paracellular space 2. 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	12
3.	**Drug-Membrane Interactions** • Possible effects of drugs on the membranes and 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 and computational) • Study of the drug membrane interactions	4
4.	**Pharmacogenomics** • Genetic basis of variation of pharmacokinetics • Methods for pharmacogenomic profiling and study	3
	Pharmacokinetics (PK)	
1.	**Study of Basic Pharmacokinetic Parameters:** Volume of distribution (V_d), Elimination half – life ($t_{1/2}$), Elimination rate-constant, Clearance (C_L), Area-under-curve (AUC), Bioavailability (%F), Calculation of PK parameters from plasma and urine data	4
2.	Role of PK in drug discovery and drug development	3
3.	**Mathematical Approach to PK Modeling:** Two-compartment open models; Physiological pharmacokinetic models; Nonlinear pharmacokinetics; Metabolite pharmacokinetics;	12

	pharmacokinetic-pharmacodynamic modeling, Case studies and problem with respect to above including design of controlled release dosage forms and other novel drug delivery systems based on pharmacodynamic and pharmacokinetic rationale.	
4.	In-Vitro-In-Vivo Correlation (IVIVC)	4
5.	Individualization of dosage regimen, Conversion from IV dosing to oral dosing, Determination of dose, Frequency and route of administration, Therapeutic Drug Monitoring (TDM), Dosing of drug in infants and elders, Variability in clinical response and pharmacokinetics with respect to renal and hepatic diseases	3
List of Textbooks/ Reference Books		
1.	Rowland And Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications; 5th ed.; Derendorf, H., Schmidt, S., Eds.; Wolter Kluwer, New York (2019).	
2.	Rowland, M, Tozer, T. N. Clinical Pharmacokinetics: Concepts and Applications; 4th ed.; Wolter Kluwer, New York (2011).	
3.	Applied Biopharmaceutics and Pharmacokinetics; 7th ed.; Shargel, L., Yu, A. B. C., Eds.; McGraw Hill Education, New York (2016).	
4.	Gibaldi, M.; Biopharmaceutics and Clinical Pharmacokinetics; 4th ed.; Pharma Book Syndicate, New Delhi (2005).	
5.	Handbook of Clinical Pharmacokinetics; Gibaldi, M., Prescott, L., Eds.; ADIS Health Science Press, New York (1983).	
6.	Notari, R. E. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction; 4th ed.; Marcel Dekker Inc., New York (1987).	
Course Outcomes (students will be able to…)		
1.	Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance to overall drug action	
2.	Use of plasma drug concentration-time data to calculate various pharmacokinetic parameters to describe the kinetics of drug absorption, distribution,metabolism, excretion/elimination	
3.	Understand the concepts of bioavailability and bioequivalence of drug products and their significance to drug efficacy	
4.	Understand various pharmacokinetic parameters and their significance in dosage form design and formulation optimization	
5.	Gain and overview of In-vitro/In-vivo correlation (IVIVC)	

	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					
	Courses of B. Pharm./B. Tech. from any reputed University				
List of Courses where this course will be prerequisite					
	Research Project (PHP2512)				
Description of relevance of this course in the M. Pharm / M. Tech Programme					
To make students familiar with the critical elements of Intellecylar Property Rights (IPRs), types of IPRs, Impotance of maintaining IPR for intellectual and economic development, Laws regulating IPRs in India, Processes involved in filing/registering IPR, in India and globally. The thorough understanding of these aspects are critical for students' survival in knowledge economy to deal with technical competitiveness, business intelligence, ultimately helping business processes to thrive and progress					

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. Hours
1.	Introduction to IP	2
2.	Copyright, Related Rights, Trademarks, Geographical Indications, Industrial Design	8
3.	Patents	23
4.	WIPO Treaties	3
5.	Unfair Competition	3
6.	Protection of New Varieties of Plants	3
7.	Summary and Discussion on IP Rights	3
List of Textbooks/ Reference Books		
1.	Karki, M. M. S.; Intellectual Property Rights: Basic Concepts (2009)	
2.	The Patents Act, 1970 (http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf)	
3.	Ahuja, V. K.; Law Relating to Intellectual Property Rights; 3rd ed.; Lexis Nexis, London (2017)	
4.	WIPO Academy - [PDP] Professional Development Program. https://welc.wipo.int/acc/index.jsf?page=pdpCatalog.xhtml&lang=en (Accessed on January 8, 2020)	
Course Outcomes (students will be able to…..)		
1.	Understand the IPR Legislations and their implications in the development and marketing of pharmaceuticals	
2.	Understand Copyrights, Trademarks, Industrial Designs and Geographical Indications (GIs)	
3.	Understand basics of Patent Filing Process	
4.	Understand IPR rights and their usefulness	

	Course Code: PHT2003	Course Title: Advanced Biochemistry	Credits = 3		
			L	T	P
	Semester:	Total Contact Hours: 45	2	1	0

List of Prerequisite Courses

	Biochemistry, Organic Chemistry, Pharmaceutical Chemistry, Medicinal Chemistry

List of Courses where this course will be prerequisite

	Biopharmaceutics and Pharmacokinetics, Research Project (PHP2512)

Description of relevance of this course in the M. Pharm / M. Tech. Programme

This course is important for understanding the basics of many subjects, particularly the ones related to Biological, Life, and Pharmaceutical Sciences, which deal with biomacromolecules and their structure-function aspects. The in-depth understanding of this subject is critical for many other courses such as Molecular Biology, Pharmaceutical Biotechnology and related subjects.

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.	6
2.	**Mechanisms for Regulating Protein Function:** Protein-protein interactions, interaction with ligands, Ca^{+2} and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage	6
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.	6
4.	**Protein Biosynthesis:** Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences.	6
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.	9
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	6
7.	**Lipids:** Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids	6

List of Textbooks/ Reference Books

1.	Ferrier, D. R.; Lippincott's Illustrated Reviews Biochemistry; 7th ed.; Wolter Kluwer, London (2017).
2.	Nelson, D. A., Cox, M. M. Lehninger Principles of Biochemistry: International Edition; 7th ed.; WH Freeman, London (2017).
2.	Textbook of Biochemistry with Clinical Correlations; 7th ed.; Thomas, D., Ed.; John Wiley & Sons, London (2010).
3.	Vasudevan, D. M., Sreekumari, S.; Vaidyanathan, K.; Textbook of Biochemistry for Medical Students; 9th ed.; Jaypee Brothers Medical Publishers, New Delhi (2019).
4.	Harper's Illustrated Biochemistry; 31st ed.; Rodwell, V. W., Bender, D. A., Kennelly, P. J., Weil, P. A., Eds.; McGraw Hill Education, London (2018).

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

	Course Code: PHT2004	Course Title: Drug Metabolism	Credits = 3		
			L	T	P
	Semester:	Total Contact Hours: 45	2	1	0

List of Prerequisite Courses

	Medicinal Chemistry, Pharmacology

List of Courses where this course will be prerequisite

	Research Project (PHP2512)

Description of relevance of this course in the M. Pharm / M. Tech. Programme

The course prepares the students to understand and appreciate the impotance of drug metabolism in drug action. The basic understanding of the metabolic liabilities in small-molecule drugs are extremely important for designing aspects at the beginning of drug discovery and development.

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. hours
1.	**Introduction to the Pathways of Drug Metabolism:** Phase I and II reactions, sites of drug metabolism, subcellular localization of drug metabolizing enzymes, cofactors required for catalytic reactions	10
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.	10
3.	**Introduction to Other Drug Metabolising Enzyme Isoforms/Families:** Glucuronyl transferases, 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
5.	Toxicological Aspects of Drug Metabolism	5
6.	Case Studies: Drug Metabolism in Drug Design	6

List of Textbooks/ 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.

Course Outcomes (students will be able to…..)

1.	Understand and appreciate drug metabolic systems and biotransformation of small-molecule drugs and NCEs
2.	Understand and appreciate the relevance of drug metabolism in drug action and toxicity
3.	Gain an overview of the methods to study drug metabolism in vitro
4.	Gain an in-depth understanding and learn from the Case Studies various aspects of drug design related to drug metabolism

	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					
	Biochemistry, Pharmaceutical Biotechnology or equivalent				
List of Courses where this course will be prerequisite					
	Research Project (PHP2512)				
Description of relevance of this course in the M. Pharm / M. Tech. Programme					

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.	6
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.	8
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.	8
5.	Introduction to Data Mining Methods and Databases in Molecular Biology	5
5.	Case Studies in Molecular Biology	4

List of Textbooks/ Reference Books	
1.	Molecular Biotechnology, Principles and Applications of recombinant DNA, Glick B. R. & Pasternak J. J.;
2.	Principles of Genome Analysis & Genomics, Primrose S. B. & Twyman R. M.;
3.	Gene Biotechnology , Jogdand S.N.;
4.	Biotechnology-Theory & Techniques, Gen Engg, Mutagenesis, Separation Technology, Chirirjian J. G;
5.	Pharmaceutical Biotechnology – A introduction for Pharmacists & Pharmaceutical Scientists, Crommelin D. A. & Sindelar R. D.

Course Outcomes (students will be able to…)	
1.	Understand basic of recombinant DNA technology and its importance in biopharmaceuticals manufacturing
2.	Gain an in-depth overview of HTS methodologies and their applications in drug discovery and other allied fields
3.	Assess the impact of human genome project on biological and life sciences
4.	Gain an in-depth overview of importance of data mining and vaious databases in bioinformatics analysis
5.	Learn from the Case Studies of various applications of Molecular Biology in various industries

	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
	List of Courses where this course will be prerequisite
	Research Project (PHP2512)
	Description of relevance of this course in the M. Pharm / M. Tech. Programme
	To train the students on packaging and labeling of pharmaceutical products as well as the regulatory aspects of packaging and labeling of pharmaceutical products

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. Hours
1.	Its status and scope in Pharmaceutical Industry	1
2.	Classification of packaging material into primary and secondary packaging, functions of packaging	3
3.	**Primary Packaging Material:** a. 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). b. 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. c. Plastic- polymers and copolymers, electrosetting and thermoforming (Medium and high density polystyrene PET) d. Equipment in primary packaging including strip packing, blister packing powder filling ,liq filling, aerosol filling, snap on closures. e. Design and specification for he containers including bottles, thread, their dimensions and others.	7
4.	a. **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. b. **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. c. Shrink Warp Process	9
5.	Specifications, quality control tests and methods and evaluation of packaging of materials.	14
6.	**Labels and Labeling:** a. Direct printing heat transfer, ordinary labels, adhesives b. Standards and Quality Control test including dimensions printing and lists such as folding test, gluing, ageing, block vibration and shock for the boxes c. Toxicity and safety of printing inks	4
7.	**Sterilization of Containers:** Different methods of sterilization for containers (primary) including autoclaving, dry heat, gas sterilization, ionizing and non-ionizing radiations	2
8.	Stability of Packaging Materials	3
9.	Law and regulation governing Packaging	2

	List of Textbooks/ 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

	Course Code: PHT2012	Course Title: Medicinal Natural Products	Credits = 3		
			L	T	P
	Semester:	Total contact Hours: 45	2	1	0

List of Prerequisite Courses	
	Pharmacognosy, Medicinal Chemistry, Biochemistry, Pharmacology
List of Courses where this course will be prerequisite	
	Research Project (PHP2512)

Description of relevance of this course in the M. Pharm / M. Tech. Programme

The course provides necessary understanding of various biosynthetic pathways of natural products of plant origin and their utility as therapeutic agents (e.g., anticancer, antimalarials, antibiotics, antidepressants, antihypertensive, antioxidants, etc.)

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. Hours
1.	General biosynthetic pathways involved in the biosynthesis of secondary metabolites	6
2.	Methods of investigation in biogenetic studies	4
3.	Biosynthesis of phenyl propanoids Isolation, identification, classification, structure determination and important pharmacological activities of flavonoids. Detailed study of rutin including extraction and isolation	12
4.	Tumour inhibitors from plants	4
5.	Pesticides of natural origin	3
6.	Poisonous plants	3
7.	Plant allergens	3

List of Textbooks/ 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…)	
1.	Learn from Case Studies and Examples the importance of secondary metabolites as therapeutic agents
2.	Understand and appreciate various biosynthetic pathways leading to production of secondary metabolites
3.	Understand the developmental aspects of plant products and their semisynthetic analogs
4.	Gain an overview of poisonous and allergenic plants

	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					
	Organic Chemistry, Pharmaceutical Chemistry, Medicinal Chemistry of B. Pharm. Or equivalent				
List of Courses where this course will be prerequisite					
	Research Project (PHP2512)				
Description of relevance of this course in the M. Pharm / M. Tech. Programme					

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. Hours
1.	Introduction, Concepts and importance of chirality in Pharmaceutical and Biological Sciences	5
2.	Resolution of Racemic Mixtures and Case Studies	10
3.	Stereoselective and Stereospecific Synthetic Methodology: Basic concepts, Important Reactions and Applications	8
4.	Classification of Types of Reactions involved in Chiral Synthesis for compounds with one- and two chiral centers	8
5.	Case Studies in Chiral Synthesis from Journal Reports	10
6.	Analytical Methods in Chiral Synthesis	4
List of Textbooks/ 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.	
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	

	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

List of Courses where this course will be prerequisite

Research Project (PHP2512)

Description of relevance of this course in the M. Pharm / M. Tech. Programme

To train the students on GLP, GMP and validation of pharmaceuticals

Sr. No.	Course Contents (Topics and Subtopics)	Reqd. Hours
1.	cGMP – Status and Regulations	3
2.	GLP	1
3.	Validation: Process validation for sterile and non-sterile formulations	13
4.	Validation of Pharmaceutical water systems, validation of utilities, validation of environmental control systems	8
5.	Systems validation and quality audits	8
6.	Documentation	12

List of Textbooks/ 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)

Course Outcomes (students will be able to…)

1. Understand basics of quality assurance with particular emphasis on industry practices
2. Understand validation and documentation with particular emphasis on industry practices

	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					
	Advanced Pharmaceutical Technology; Research Project (PHP2512)				
Description of relevance of this course in the M. Tech. Programme					
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	7
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.	8
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.	8
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.	7
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.	7
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.	8

List of Textbooks/ 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
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

	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.

List of Courses where this course will be prerequisite

Clinical Trials, Regulatory Affairs

Description of relevance of this course in the M. Pharm / M. Tech. Programme

The course is designed to aquaint the student to the world of Clinical Research and Clinical Trials. It covers the regulatory aspects of Clinical trials along with the management aspects. The importance of Quality Control and Quality Assurance, Ethics, Data integrity, in addition to the data management is crucial for the successful conduct of the Clinical Trials.

Sr. No	Course Contents (Topics and Subtopics)	Reqd. Hours
1.	**Brief Introduction to Clinical Research** I. What is Clinical Research? Why Clinical Research? II. Sectors of Clinical Research III. Types of clinical trials IV. Regulatory guidelines V. Ethics VI. Management of Clinical research	1
2.	**Scientific & Technical aspects of Clinical Research** I. Development of Investigational product/drug for human administration—Phase I, II, III and IV trials II. Technical requirements	3
3.	**Regulatory Requirements of Clinical Research** I. Regulatory guidelines--- Schedule Y, US FDA, EU guidelines to be discussed in detail II. Brief outline of ICH-GCP	6
4.	**ETHICS in Clinical Research** I. Ethics to be followed during the conduct of different phases of Clinical Trials II. Importance of Ethical conduct of clinical Trials III. Ethics Committee --- role, responsibilities and function IV. Regulatory expectations from ethics committee	7
5.	**Procedural and Practical Clinical Research** I. SOPs to be discussed in detail II. Practical implementation of SOPs	6
6.	**Management of Clinical Research** I. Sponsor & Investigator – CRO/ NGO II. Patients / Volunteers recruitment III. Medical and technical teams IV. Pharmacy and responsibilities of pharmacists V. Vendors VI. Medical management VII. Logistics	11
7.	**Quality control and Quality Assurance in Clinical Trials** I. Monitoring of clinical trials	3
8.	Data Management and Statistics	5
9.	**Pharmacovigillance** I. Adverse event reporting	3

List of Textbooks/ Reference Books

1. Clinical Pharmacy and therapeutics by Roger Walker.
2. Clinical pharmacy practice by MilapNahata.

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

	Course Code: PHT2011	**Course Title: Advances in Receptor Pharmacology**	**Credits = 3**		
			L	**T**	**P**
	Semester:	**Total Contact Hours: 45**	**2**	**1**	**0**

List of Prerequisite Courses

Pharmacology, Medicinal Chemistry of ICT or equivalent

List of Courses where this course will be prerequisite

Research Project (PHP2512)

Description of relevance of this course in the M. Pharm / M. Tech. Programme

Sr. No.	**Course Contents (Topics and Subtopics)**	**Reqd. Hours**
1.	Receptors: Classification and Overview of each class with representative examples	5
2.	Ion Channels: Transmitter-gated channels/ligand gated channels. Eg. Nicotinic receptors, $GABA_A$ or glutamate receptors	10
3.	G-protein Coupled Receptor – G-proteins function, β- adrenergic receptors, muscarinic receptors	10
4.	Cytosolic receptors / Transcriptional regulators e.g. steroid receptors, hormone receptors	10
5.	Second Messenger Systems: Molecular mechanisms of downstream signaling mechanisms by these messenger systems	5
6.	Case Studies in Receptor Pharmacology	5

List of Textbooks/ Reference Books

1	Drug Discovery Series/4. G-Protein Coupled Receptors in Drug Discovery; Lundstrom, K. H., Chiu, M. L., Eds; Taylor & Francis, Boca Raton, Florida (2006).
	Drug Receptors – Advances in Research and Application; Acton, Q. A., Ed.; ScholarlyEditions, Atlanta, USA (2012).
2	Textbook of Receptor Pharmacology; John C. Foreman, Torben Johasen (2017).
3	Biological Council: The Co-ordinating Committee for Symposia on Drug Action. Drug Receptors and Their Effectors; 1st ed.; Birdsall, N. J. M., Ed.; Macmillan Publishers Ltd., London (1981).
4	Drugs and the Pharmaceutical Sciences. Receptor-Based Drug Design; Vol. 89; Leff, P.; Marcel Dekker, Inc., New York (1998).

Course Outcomes (students will be able to…)

1.	Understand and appreciate the molecular mechanisms of receptor activation
2.	Gain and in-depth understanding of ion-channels, GPCRs and other receptors as drug targets
3.	Understand the principles behind drug design for ligands for various receptor types
4.	Related the Principles and Practice of Drug Design from Case Studies in Receptor Pharmacology