Regulations and Syllabi for 2 years – 4 semesters Master of Technology (M. Tech.) Degree in Pharmaceutical Technology of Chemical Technology, University of Calcutta

1. A candidate who has passed the B. Tech. in Chemical Technology with specialization in Pharmaceutical and Fine Chemical Technology or an equivalent examination recognized by the Calcutta University shall be eligible for admission to the Master of Technology (M. Tech.) course in Pharmaceutical Technology.
2. The duration of the M. Tech. course shall be of two academic years and the examination shall be held in four semesters (two semesters in each academic year).
3. A candidate shall be eligible to sit for the examination provided he/she pursues a regular course of studies in the Department of Chemical Technology and attends at least 65% of the working days in both theoretical and practical classes in each semester**.**
4. M. Tech. First Semester examination shall ordinarily commence at the end of six months. M. Tech. Second Semester examination shall ordinarily commence after six months of the M. Tech. First Semester examination. M. Tech. Third Semester examination shall ordinarily commence after six months of the M. Tech. Second Semester examination. M. Tech. Fourth Semester examination shall ordinarily commence after six months of the M. Tech. Third Semester examination.
5. A candidate for the M. Tech. in different semesters examination shall be examined in the subjects mentioned hereunder.
6. The credit based examination system will be followed for all Semester examinations. The Semester wise credit points are as follows:

Semester	I	II	III	IV	TOTAL
Credits	20	20	20	20	80

All theoretical and laboratory/practical papers will have a total 100 marks. Generally the credit points of theoretical and practical papers are 4 each. However different credit point may be assigned to some subjects involving project work and design etc., the detailed structure with credit points is given in Schedule-I. The total marks for the Four Semester M. Tech. Examination in Pharmaceutical Technology shall be 2000.

7. Each theoretical paper carrying 100 marks (4 Credits) shall be of minimum of 60 hours duration spread over the each semester session.
8. The duration of semester examination for each theory question paper is three hours.
9. Research Project (Thesis) shall be assigned to a candidate at the beginning of Third Semester. He/she shall work on the assigned problem in a departmental laboratory under the guidance of a teacher of the department. However, a candidate may also be allowed to work on the assigned problem under the joint guidance of a teacher of the department and a person from a Research Institute/Industrial Organisation of repute if approved by the Board of Post-Graduate Studies. He/she shall prepare and submit three type- written and bound copies of the thesis on his/her project work to the Head of the Department of Chemical Technology at least one month before the commencement of M. Tech. Fourth Semester Examination to make him/her eligible to sit for the examination.
10. The total marks obtained in each subject whether theory or practical will be converted into grade points. The Semester grade sheets and transcripts of the first three semesters will have only credits, grades, grade points and SGPA. The final grade sheets will have only credits, grades, grade points, SGPA as well as CGPA and the total marks obtained out of 2000. The performance grading will be considered as follows:

Grades	Marks %	Grade points
Ex	90 and above	10
A	80-89	9
B	70-79	8
C	60-69	7
D	50-59	6
F (Fail)	49 and below	NIL

11. Eligibility of success/failure in a Semester Examination:
    a) The student has to secure at least 50% or above marks (e.g. Grade-D) in each theoretical, practical papers and viva-voce individually in order to pass the examination.

b) If a student fails in more than two subjects having total credits more than 8, he/she will have to repeat the whole Semester and will not be allowed to continue his studies to the next Semester classes. The student will eventually face a year loss.

c) If a student fails in less than two subjects amounting 8 credits or less in a Semester but earns rest of the credits, he/she will be allowed to continue to the next Semester, ***provided that total of such backlog credits within the entire course period of four semesters is 16 or less***. [Example: In the *first and second* Semesters, one has to earn at least 20 - 8= 12 credits; this may vary in other Semesters]

d) Supplementary examinations of all papers of present Semester will be arranged soon after the publication of results of regular examinations of the present Semester. If the candidate fails to clear the supplementary paper(s), he / she will get another chance to clear the same in the corresponding semester in the next academic session.

e) Removal from a course: If a student fails to pass the same Semester examination two times, she/he will have to leave the course. To acquire 80 credits in 4 Semesters, a student will have to utilize all the allowed chances within four years (i.e. 8 consecutive Semesters).

f) Eligibility for a Degree: The total credits for M. Tech. courses are 80 for a 4 semester course. Thus a student who successfully could earn 80 credits in 4-Semester (i.e. 2-year) course would be eligible for a M. Tech. Degree in Pharmaceutical Technology.

12. Eligibility to appear for additional Semester Examination

a) A student who does not appear in some or all the examinations in a Semester for representing the University in sports, cultural activities, NSS or any other reason considered valid under exceptional circumstances and to the satisfaction of the Head of the Department and subsequently Head of the Institute is eligible to appear for additional examination within three months and may continue in the next Semester courses.

b) If a candidate discontinues his/her studies after any individual semester examination he/she will be allowed to appear at the next M. Tech. semester examination in the following two years from the date of M. Tech. semester examination, the candidate appeared last after getting prior approval from PG Board of Studies.

13. Calculation of SGPA and CGPA and award of Degree:

a) Each Semester Grade point average is calculated by dividing the sum of products of Grade point and course credit by sum of all course credit in the Semester.

$$SGPA = \Sigma CG/\Sigma C$$

Where, G is grade and C is credit for a paper/subject.

Similarly CGPA can be calculated using the same formula considering all subjects and credit for all Semesters taken together.

Though grade in a particular subject will be obtained by conversion of absolute marks obtained in that subject, the Grade Sheet will however have no mention of marks and it would show only grades and SGPA.

b) All successful candidates will be issued consolidated Grade Sheets (having CGPA) together with 4th Semester Grade Sheet (having SGPA) along with the consolidated marks in 4 semesters. They will be awarded the Degree Certificate in the following format .

UNIVERSITY OF CALCUTTA

SEAL

The Degree of Masters of ------- Engineering/Technology has been awarded to Sri/Smt ---- after successful completion of the course whose final Semester Examination was held on --- . He/She has been placed in the --- Class.

Senate House Vice Chancellor

Course Structure and Syllabus for 2-year 4-semester M. Tech. Course in Pharmaceutical Technology

Schedule - I

1st Semester:

Paper No	Sub Code	Subject	Periods			Cr	Marks		
			L	T	P		IA	UE	TM
Theory									
I	**CHT101**	Process Modeling and Simulation	4	1	-	4	-	100	100
II	**PHT102**	Advanced Pharmaceuticals Analysis	4	-	-	4	-	100	100
III	**PHT103**	Medicinal Chemistry	4	-	-	4	-	100	100
Practical									
IV	**CHT104**	Computer Application in Chemical Industries	-	-	4	4		100	100
V	**PHT105**	Pharmaceutical Analysis and Quality Assurance	-	-	4	4		100	100
		Total	12	1	8	20		500	500

2nd Semester:

Paper No	Sub Code	Subject	Periods			Cr	Marks		
			L	T	P		IA	UE	TM
Theory									
VI	**CHT201**	Optimization	4	1	-	4	-	100	100
VII	**PHT202**	Pharmaceutical Biotechnology	4	-	-	4	-	100	100
VIII	**PHT203**	Pharmaceuticals and Cosmetics Process Technology	4	-	-	4	-	100	100
IX	**PHT204**	Industrial Management and Regulatory Affairs	4	-	-	4	-	100	100
Practical									
X	**PHT205**	Pharmaceutical Technology Laboratory	-	-	4	4	-	100	100
		Total	16	1	4	20	-	500	500

3rd Semester:

Paper No	Sub Code	Subject	Periods			Cr	Marks		
			L	T	P		IA	UE	TM
XI	**PHT301**	a. Project Feasibility – Report	-	3	8	8	-	200	200
		b. Project Feasibility – Viva Voce	-	-	-	4	-	100	100
XII	**PHT302**	Seminar	-	3	-	4	-	100	100
XIII	**PHT303**	General Viva Voce	-	-	-	4	-	100	100
		Total	-	6	8	20	-	500	500

4th Semester:

Paper No	Sub Code	Subject	Periods			Cr	Marks		
			L	T	P		IA	UE	TM
XIV	**PHT401**	a. Research Project – Thesis	-	5	10	15	-	400	400
		b. Research Project – Viva Voce	-	-	-	5	-	100	100
		Total	-	5	10	20	-	500	500

Total Credit Point: 20 + 20 + 20 + 20 = 80; **Grand Total:** 2000

IA: Internal Assessment; UE: University Examination; TM: Total Marks

NB. Both Research Project assignment and the Project Feasibility assignment will be allotted at the beginning of 3rd Semester. The Research Project assignment to be evaluated at the end of the 4th Semester while Project Feasibility assignment to be evaluated at the end of 3rd Semester.

SYLLABI OF 2 YEARS (FOUR SEMESTER) M.TECH. COURSE IN PHARMACEUTICAL TECHNOLOGY

First Semester

Paper I

Course CHT 101 **100 Marks/ 4 credits**

Process Modelling and Simulation

Module 1: Mathematical Modeling Fundamentals: Art of modeling, laws, assumptions, degrees of freedom, consistent modeling, synthesis, analysis and optimization. General purpose modeling, specific purpose modeling, scientific modeling, engineering modeling.

Module 2: Models of equipment, unit operation/unit process; material & energy balance, property relations, Constraints, steady state and unsteady state models. Specific Equipment Design models: Batch reactor, continuous tank reactor, Continuous tubular, catalytic reactor, heat exchanger, Distillation column.

Module 3: Plant modeling, stream variable and stream properties, tear stream and tear variable, modular approaches: sequential, simultaneous and equation solving approaches. Sequencing and ordering of solving equations.

Plant modeling: A plant with/without a recycle stream, plant with controlling elements.

Module 4: Solution algorithm and flow chart development for various mathematical models.

Computer simulation**:** Programming languages, sequences and algorithm development.

Specific simulators**:** Binary distillation column, Heat exchanger, reactor, flasher.

Plant flowsheeting: Three CSTR in series, Propylene dimerization plant, sulfuric acid plant, etc.

Paper II

Course PHT 102 **100 marks/ 4 credits**

Advanced Pharmaceuticals Analysis

Module 1: Chromatography (HPLC, GLC, TLC, HPTLC, UPLC, Column chromatography) for analysis of pharmaceuticals. Principles and applications of ion chromatography, affinity chromatography, chromatography of chiral compounds, size exclusion chromatography, supercritical fluid chromatography. Hyphenated techniques in drug analysis.

Pharmacognostic analysis. Stability testing for phytopharmaceuticals, regulatory requirements, finger printing, biomarkers, chemical interactions and complexity.

Module 2: Spectroscopy (UV-Vis-NIR, FTIR, NMR, FT-Raman) for drug analysis and organic compound identification. Thermal analysis in pharmaceuticals DSC, DTA, TGA. Light scattering techniques and particle analysis. Electrophoresis and Zeta potential studies.

Electrochemistry (Voltammetry, Amperometry, Potentiometry and Polarography) in the analysis of drugs and pharmaceuticals.

Module 3: Biological standardization. Toxicity studies of drugs. Principles of Immunoanalytical techniques, DNA Hybridization, enzyme assays, protein analysis, ELISA, Principles of PCR, DNA finger printing. Analysis of Industrial wastes.

Paper III

Course PHT 103 **100 marks/4 credits**

Medicinal Chemistry

Module 1: Enzyme kinetics, catalysis and drug action. Drug metabolism in Phase I and Phase II transformations. Concept of hard and soft drugs. ADME and toxicity profiles.

Module 2: Synthesis approaches in drugs and pharmaceuticals, retro synthetic analysis; stereoselective and chemoselective synthesis of new generation chemotherapeutic agents. Chemically targeted drugs. Steroidal drugs. Macromolecular drugs – peptides, lipoproteins. Self assembly formations in biology.

Module 3: Molecular modeling and dynamics, Monte Carlo simulations. Informatics techniques- bioinformatics and chemoinformatics.

Enzymes in chiral synthesis, Kinetic resolution. Asymmetric synthesis protocols in amino acids and beta lactams.

Paper IV

Lab – I

Course CHT 104 **100 marks/4 credits**

Computer Application in Chemical Industries

Writing computer program to solve complex design and modeling problems like heat exchangers, flashers, reactors, distillation columns, plant simulation problems etc.

Paper V

Lab – II

Course PHT 105 **100 marks/4 credits**

Pharmaceutical Analysis and Quality Assurance

Quantitative analysis of APIs and finished products including Multi component analysis, using UV-Vis-NIR, FTIR, HPLC, HPTLC.

Molecular Purity analysis using NMR, HPLC, HPTLC. Gas chromatography, residual solvent analysis.

Enzyme based assays, enzyme inhibition kinetics, biochemical analysis using instrumental techniques like ELISA.

Analysis of environmental contaminants, PPCPs, colorants, BOD, COD studies. Microbial assays for antibiotics and vitamins, sterility testing.

Second Semester

Paper VI

Course CHT 201 **100 marks/4 credits**

Optimization

Module 1: Introductory concepts : Objective function, single valued function, multivalued function, non-linear function, linear function, stationary point, relative and absolute extreme, convex, concave and unimodal functions, gradient reduction method, jacobian and hessian matrix.

Module 2: Optimization of univariate system using analytical method. Search techniques, quadratic interpolation, cubic interpolation. Optimization of multivariate unconstrained system using.
Module 3: Search techniques. First order methods and second order methods. Optimization of multivariate constrained systems using Lagrange multipliers, penalty function, linear programming and non-linear programming.
Module 4: Computer programming of optimization of specific problems related with chemical industry.

Paper VII

Course PHT 202 **100 marks/4 credits**

Pharmaceutical Biotechnology

Module 1: Operon concept: lac, trp, ara, his, and gal operons; Constitutive and Inducible; Operators; Regulatory elements.
Plasmids; Bacteriophages; Restriction Enzymes; DNA ligase, T4 DNA polymerase, Cohesive and blunt end ligation.
Membrane Structure: lipid bilayer, membrane proteins
Membrane Transport of Small Molecules and principles of membrane transport, carrier proteins and active membrane transport.
Cell wall Structure: Synthesis steps and action of Antibiotics on Cell wall.
General principles of cell communication, signaling through G protein linked cell surface receptors, signaling through enzyme linked cell surface receptors, signaling pathways.
Mutations: Oncogenes and Tumor suppressor genes, Nonsense, missense, point and Frameshift mutations; Viral and cellular oncogenes; Tumor suppressor genes from humans; Structure, function and mechanism of action of p53 tumor suppressor proteins; Mutations and their chemical basis; Mutagens and their use in Biotech.
Virus: Types, life cycle, Nucleic acid and protein synthesis, release, Chemotherapy, Enumeration, AIDs and its therapy.
Module 2: The Cell Cycle and Programmed Cell Death, an overview of the cell cycle, components of the cell cycle control system, intracellular control of cell cycle events, apoptosis, extra cellular control of cell division and cell growth
Vectors: Lambda vectors; Insertion and Replacement, Cosmids; Artificial chromosome vectors, Animal Virus derived vectors, SV 40; vaccinia/bacculo & retroviral vectors; Expression vectors; Yeast vectors, Shuttle vectors,
Insertion of Foreign DNA into Host Cells; Transformation; Principles for maximizing gene expression and product formation, Fermentation and Scale-up of rDNA products, Production of Industrial enzymes etc.
Module 3: Principles and applications of Biosensors, examples like glucose monitoring, DNA biosensors, microbial biosensors. Principles and application of product bioseparation.
Antibody synthesis – design, validation and application.

Paper VIII

Course PHT 203 **100 marks/4 credits**

Pharmaceuticals and Cosmetics Process Technology

Module 1: Unit operations involved in manufacturing of dosage forms. Solubility and drug solubilization techniques. Particle size and shape factors significance in dosage forms.
Preformulation studies.
Sterile products and admixtures: Formulation development.
NDDS – sustained release systems, transdermal formulations, nanomedicines, microparticles and microcapsules.
Stability studies, GMP/GLP practices.

Module 2: Cosmetics formulation and requirements-fundamentals of cosmetic product development, regulatory requirements etc. Cosmetic formulations, classification and examples of different preparation types like sunscreen agents, anti-ageing products, baby care products, herbal cosmetics etc. Manufacture of cosmetics and stability study. Concepts of cosmetic safety and performance.
Package protocols for different dosage forms, packaging materials for pharmaceuticals, labeling, screening of package, bar-coding.

Paper IX

Course PHT 204 **100 marks/4 credits**

Industrial Management and Regulatory Affairs

Module 1: National Drug Regulatory requirements, National Drug Policy, Drugs and Cosmetics Act, NPPA. USFDA, FDA guidelines on IND, NDA and ANDA approvals. Bio-equivalence, Biowaiver. Types of ANDA filing, exclusivities.

Module 2: ICH Guidelines, WHO guidelines, ISOs- Production design, certification. FDA guidance for industries and comparative implications.
Indian Patent Act, drugs and pharmaceuticals. Indigenous products patenting, biodiversity regulations. Intellectual property agreements, TRIPS, WTO treaties, Budapest Convention.

Module 3: OECD guidelines, LD50, acute, subacute and chronic toxicity studies; toxicity and carcinogenicity testing protocols, current requirements.
Ethics in animal experimentations. Human experimentation-Nuremberg code and Helsinki declaration. Cartagena Protocol on Biosafety Considerations. Environmental Issues, Biosafety, biodiversity regulations.

Paper X
Lab – III

Course PHT 205 **100 marks/4 credits**

Pharmaceutical Technology Laboratory

Synthesis and analysis of polymeric and metal nanoparticles.
Operation principles in pharmaceuticals drying, including spray drying, tray dryers etc. Size reduction techniques, ball milling, sieving analysis, granulation, drug dissolution.
Stability experiments of pharmaceutical formulations.
Synthesis (3 or more steps) and isolation of pharmaceutically important compounds. Synthesis of permitted dyes, intermediates, quality analysis.

Third Semester

Paper XI

Course PHT 301 **(200+100) Marks/(8+4) credits**

a) **Project Feasibility**

Each student shall be required to submit two bound type written copies of a project report on a proposed chemical plant manufacturing product/products related to one's course/subject to be worked out under the supervision of a faculty member. The report shall include mass and energy balances, type and capacity of equipment selected and recommended, plant layout, feasibility analysis highlighting market survey, pattern of assistance available from the central and state government agencies, bank and financial institutions. Assistance for technology, raw materials, finance.

Legal obligation.

b) The student is to appear in a **Viva-Voce** examination.

Paper XII

Course PHT 302 **100 Marks/4 credits**

Seminar

Each student will be required to prepare and submit an assay or review paper on selected technological topic related to subject under the supervision of a faculty member. He/She shall give a talk based on his/her paper before the Seminar. The attendance in the seminar is compulsory for all the students.

Paper XIII

Course PHT 303 **100 Marks/4 credits**

General Viva Voce

Fourth Semester

Paper XIV

Course PHT 401 **(400+100) Marks/ (15+5) credits**

Research Project

(a) Each student shall be required to carry out under the supervision of a faculty member original investigation on an industrial problem related to subject. He/She shall submit three type-written bound copies of thesis embodying the results of his/her investigations

(b) The student shall defend his/her thesis in a **viva-voce** examination.