DETAILED SYLLABUS

FOR THE COURSE

MASTER OF TECHNOLOGY (M.TECH.)
IN PHARMACEUTICAL BIOTECHNOLOGY
2017-18

BY

Department of Pharmaceutical Sciences and Technology (DPST)
Institute of Chemical Technology (ICT),
[University under Section-3 of UGC Act 1956]
NBA accredited, Grade 'A' by MHRD, University Par Excellence
Matunga, Mumbai – 400 019

INSTITUTE OF CHEMICAL TECHNOLOGY
Ordinances, Regulations and Syllabi relating to the
Degree of Master of Technology (Pharmaceutical Biotechnology)
M. Tech. (Pharm. Biotech.) – Interdisciplinary course

Admission:

1. Eligibility: The candidate should have passed the degree of Bachelor of Chemical Engineering, B. Pharmacy, B.Tech. in Pharmaceutical Technology/Biotechnology of University of Mumbai OR B. Pharmacy, B.Tech in Pharmaceutical Technology/Biotechnology of any equivalent examination of a post-H.S.C. 4-year degree course of a University recognized by the UGC/AICTE/DBT and of any national/Indian Institute of Technology, with first class (that is, 60% of the marks in aggregate or equivalent grade average). [55% for the backward class candidates only from Maharashtra State]. Admissions will be done strictly on the basis of merit in the valid GATE/GPAT score and performance at the written test conducted at the UICT/ICT.

2. Design of written test would be such that basic knowledge in Pharmaceutical Sciences can be tested in Section-I, while Section-II tests for analytical skills of the candidate.

3. The final merit list would be designed on the basis of 70% weightage to the GATE/GPAT score and 30% weightage to the written test conducted by the Institute.

4. The group of selected candidates, unless selected on a specific project, will be informed of all research activities in the department and available projects for selection of projects / guide. The final allotment of the research guides will be done by the Departmental committee based on the preferences given by the candidates and admissible rules / regulations.

Course Credit System and Structure:

1. The course is conducted on a credit-based 4-semester (2-year) system. There are two semesters in a year: July to December, semester I, and December to May, semester II. Semesters I and II will consist of 15-16 weeks of instructions including a seminar / project, 1-2 weeks of theory examinations and 1-2 weeks of laboratory examinations, wherever applicable.

2. For the first year, the semester I Examination will be held in December / January and semester II Examination will be held in May. The second year will have a research project-based evaluation in each semester carrying equal weightage as that of the first / second semester. The senate-approved schedule of academic activities for the academic year (dates of start and end of classes, dates of final examinations, etc.) will be followed.

3. A certain quantum of work measured in terms of credits is defined for each course. The student acquires credits by passing courses in semesters I and II, whereas the research project-based evaluation in semesters III and IV (second year) will contribute to credits equivalent to that obtained in the first two semesters.

4. Administering of the courses in the first year will mainly consist of Lectures (**L**) and Tutorials (**T**). However, laboratory courses will consist of practical (**P**) hours, wherever applicable.

5. The credit (**C**) for a course will be equal to the number of contact hours (**L+T+P**) per week for that course, that is, for 100 marks it will be 6 and that for 50 marks it will be 3. The research project-based evaluation will be equivalent to 21 credits per semester.
6. For assisting the instructor in conducting tutorials, Teaching Assistants (TA) may be provided. The instructor is expected to inform TA the syllabus covered up to the point of each tutorial and the syllabus to be covered in a particular tutorial. The course instructor is required to provide problem statements and solutions to the TA. The TAs are responsible for administering the problem statements and solutions to the students. The course instructor is also required to be present during the tutorial session.
7. Courses are numbered in an alphanumeric manner as shown in Table 1. Core subject are compulsory. Students have to choose one elective from the list provided herewith and second can be from other department such pharmaceutical, foods and chemical engineering. While choosing the elective subject from department students should check the pre-requisites of that subject.

Attendance:
1. Attendance in all classes (lectures, tutorials, practicals) is compulsory and will be monitored. In general, the Institute expects 100% attendance. 75% attendance is permitted only for health or other emergency situations. A medical certificate from recognised and qualified doctor is necessary for getting sick-leave on health grounds.
(Faculty members are required to submit the attendance sheets to the Department of Pharmaceutical Sciences and Technology office at the end of the semester but before the submission of forms for examination. The office will compile the data and put it on notice board. An early warning will be released to all defaulters by mid-semester examination).
2. A student not having minimum 75 percent attendance for a particular subject may be debarred from appearing in the semester-end examination in that particular subject and given „FF" grade (grades are described below) in that particular subject.
3. The concerned teacher may condone absence from classes due to unavoidable reasons, for a very short period, provided the teacher is satisfied with the explanation.
4. If the period of absence is for short duration (not more than two weeks), application for the leave shall be submitted to the Head of the Department stating fully the reasons for leave, supported by proper documents. The Head of Department may condone such absence based on the application.
5. If the period of absence is more than two weeks, the application for leave shall be submitted stating fully the reasons for leave, supported by proper documents, to the Dean, (A.P.) forwarded through Head of the Department. The Dean may condone such absence based on the application.
6. Additional leave may be granted to attend conference, workshop, seminar, and also for participating in extra-curricular activities, **with prior permission** from the concerned subject-teacher, research supervisor AND the Head of the Department.

Assessment of students' performance in theory courses:
The assessment of students" performance in a theory course will be based on:

(i) Continuous assessment (60% weightage in overall credit of the course)
The continuous assessment will comprise of: quizzes, surprise tests, class tests (open- or closed-book), home assignments, group assignments, presentations, etc. This consists of overall 30%

weightage and another overall 30% will be mid-semester examination. It is expected that the instructor for a particular course should conduct minimum of 3 evaluations (Including one which has to be an **announced mid-semester test** conducted in 8th to 10th week from the start date). In the very first lecture of the course, the instructor should clearly indicate the methodology of continuous assessment that will be followed for a particular course. In case a particular student is absent for a particular internal evaluation, repeat evaluations will not be conducted. For the benefit of and as a process of learning by the students, the corrected evaluations will be made available within two weeks of conducting the assessment.

(ii) Final examination (40% weightage in overall credit of the course)
The final examination is compulsory for all students. Absenteeism in the final examination will be considered as **Failed** in the examination. The final examination will be conducted as per pre-announced time table. The final examination will be one (1) hour duration for three-credit course and one and half (1½) hours duration for six-credit course. This would be given 60% weightage.
In case, a student is absent for the final examination because of extra-ordinary situations, and supports his application with relevant documents, he will be given a grade „I" (grades are described below). Such a student will be eligible for appearing for „Supplementary Examination". The maximum grade obtainable in such supplementary examinations is „**ONE GRADE LESS'** (described below) than that obtained based on the total marks after the supplementary examination. If „EE" is obtained in the supplementary examination, then it remains „EE".

Assessment of students' performance in Laboratory courses:
The assessment of students" performance in a laboratory course will be based on: (i) Continuous assessment: Turn-to-turn supervision of the student's work, their performance in viva-voce examinations, group discussions, and the quality of their work as prescribed through laboratory journals. This would be given 100% weightage.

Assessment of students' performance in Project I / II / III:
In the first semester, students will be given two projects – Projects I and II. In Project I the students will be required to prepare a critical review of a selected topic in Pharmaceutical Biotechnology and allied subjects, and will be supervised by a faculty other than the research supervisor. In Project II, they are supposed to critically assess one research publication. For both these projects, the students need to submit a standard typed report. The students will also be required to make an oral presentation for all these projects. Weightage would be 40% for the presentation and 60% for the report (average of the marks given by internal and external examiners for both presentation and report).
In addition, in the second semester, the students will have to critically analyse literature on their own research area (project III). Project III evaluation will be based on the analysis of existing literature and proposed objectives, methodology, bar chart of activities, and deliverables. Weightage would be 40% for the presentation and 60% for the report (average of the marks given by internal and external examiners for both the presentation and report).

Assessment of students' performance in Second year:

1. Every candidate will give a presentation at the end of the semester III in front of the Research Progress Committee (RPC) formed by the Head of the Department in consultation with the research supervisor, and which will consist of the research supervisor and at least one more faculty member of the Department.

2. The evaluation at the end of semester III will be based on: (i) experimental setup / mathematical model formulation (30%), (ii) analysis of reactants, products / solution strategy (20%), (iii) results and data analysis, including comparison with previous work (50%). The grade for semester III will be awarded by RPC.

3. The cases of plagiarism and data manipulation will be investigated by the concerned committee (RPC) and dealt with sternly. The candidate will be asked to leave the program and the Institute, if proven of charges against him / her.

4. Once the research project approaches completion (tentatively by end of March) as mutually decided by the supervisor and the candidate, the candidate will submit synopsis to RC. An external examiner will be appointed for thesis evaluation, and a copy of the synopsis will be sent to external examiner.

5. The thesis in soft bound form will be sent to examiner for evaluation, tentatively by end of May. The comments received from the external examiner need to be incorporated in the thesis and discussed with the RPC.

6. The viva-voce examination will consist of open research colloquium in the presence of external examiner and RPC members, and questions and answers will be open to all. Only after successful viva-voce examination, the grade for semester IV will be awarded jointly by the external examiner and RPC. Final copy of the thesis will be submitted to the Institute in hard-bound form.

7. The thesis soft copy will be maintained in PDF format with Institutional library and DPST office.

Grading system:

1. As a measure of students‟ performance the following letter grades and corresponding grade points per credit, shall be followed:

Grade	Grade points per credit
AA	10.0
AB	9.0
BB	8.0
BC	7.0
CC	6.5
CD	6.0
DD	5.5
EE	5.0
FF	0
I	0
T	0

Instructor of the course will submit the absolute marks obtained by the candidates (out of 50 or out of 100, as the case may be), in the following heads depending on whether the course is theory or laboratory: (i) Continuous Assessment, (ii) Final Examination, and (iii) Total Marks.

3. Depending on the grace marks (to be decided) by the Results Committee; the absolute marks obtained by the candidates under each subject head will be calculated. These absolute marks will be converted to grades and grade points for each subject for each candidate in the following manner:

a. Candidates who have failed (secured less than 40% of the marks even after considering grace marks) will be given grade „FF‟ for that subject.

b. Based on the absolute marks obtained by the successful (passed) candidates in a particular subject, „CLASS AVERAGE‟ will be calculated for each subject.

c. If „CLASS AVERAGE" is less than 65%, then the „CLASS AVERAGE" is given a grade „CC". AA, AB, BB, and BC grades are given between „CLASS AVERAGE" and „HIGHEST MARKS" based on equal increments. CD, DD, and EE grades are given between „CLASS AVERAGE" and the minimum passing marks based on equal increments (40%).
d. If „CLASS AVERAGE" is greater than 65%, but less than 70%, then the „CLASS AVERAGE" is given a grade „BC". AA, AB, and BB grades are given between „CLASS AVERAGE" and „HIGHEST MARKS" based on equal increments. CC, CD, DD, and EE grades are given between „CLASS AVERAGE" and the minimum passing based on equal increments (40%).
e. If „CLASS AVERAGE" is greater than 70%, then the „CLASS AVERAGE" is given a grade „BB". AA and AB grades are given between „CLASS AVERAGE" and „HIGHEST MARKS" based on equal increments. BC, CC, CD, DD, and EE grades are given between „CLASS AVERAGE" and the minimum passing based on equal increments (40%).
4. 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 subjects for the semester,
„ci" is the number of credits allotted to a particular subject, and
„gi" is the grade points awarded to the student for the subject based on his performance as per the above table.
SGPA will be rounded off to the second place of decimal and recorded as such.
5. 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" = total number of subjects from the first semester onwards up to and including the semester S,
„ci" = number of credits allotted to a particular subject, and
„gi" = grade points awarded to the student for the subject based on his performance as per the above table.
CGPA will be rounded off to the second place of decimal and recorded as such.
6. The CGPA would indicate the cumulative performance of the student from the first semester up to the end of the semester to which it refers.
7. 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 next semester.
8. Candidate will be considered to have passed the course if he / she secures grade „EE" or higher (AA, AB, BB, BC, CC, CD, DD).

Supplementary Examinations:
1. For those candidates who fail (Grade „FF") in one or more subjects, another examination called „Supplementary Examination" (50% weightage) will be held after one month of the declaration of the result for the particular semester.

2. The marks obtained by the candidate during the semester in the Continuous Assessment will be carried forward and added to the marks obtained in the Final Examination.
3. The total marks will be considered for award of grades and grade points. The grades are to be calculated based on the grading scheme discussed in point **No. 3** under the heading „**Grading System**". However, the maximum grade obtainable after such supplementary examination is **'ONE GRADE LESS'** than that obtained after the supplementary examination. If „EE" is obtained in the supplementary examination, then it remains „EE".

Grade the candidate would have got after Supplementary Examination	Grade actually given	Grade Point per Credit
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
FF	FF	0
I	I	0
T	T	0

When a student gets the grade „FF" or „I" in any subject during a semester, the SGPA and CGPA from that semester onwards will be tentatively calculated, taking only „zero point" for each such „FF" or „I" grade. After the „FF" grade(s) has / have been substituted by better grades after the supplementary examination or subsequent semesters, the SGPA and CGPA will be recomputed and recorded to take this change of grade into account.
5. The candidate can continue for the research project in semester III and IV with whatever grade obtained in the previous semesters. However, the candidate must clear all the courses where is has FF and/or I before getting the passing certificate.
6. The records of all candidates will have to be maintained in the Institute for the grade point average calculations.
7. A candidate who remains absent for the regular final examinations and supplementary examinations for **ALL SUBJECTS** will be considered to have dropped out / terminated from the course and will be given a grade „T".

Syllabus: M. Tech. Pharmaceutical Biotechnology

The purpose of the course is to develop trained manpower having specialized knowledge of Pharmaceutical Biotechnology suitable for the industry, academics and research institutes. After getting trained under this program, students are expected to gain and enhance their experience and competences in *Pharmaceutical Biotechnology* with adequate exposure to industrial biotechnology, biotechnology based pharmaceuticals, genetics, molecular biology, Biotech product development, environmental impact, safety and toxicity of biotechnology products, intellectual property rights, animal welfare, risk analysis, consumer perceptions, industry perspectives, and producer perspectives around the world. Further, the graduates will also develop skills in information technology, bio-statistics, scientific writing, oral presentations, team working, problem solving, use of library resources and time management. They will also acquire research ability and experimental skills.

The proposed M.Tech (Pharmaceutical Biotechnology) program will have 4 semesters and the course will be generally in line with the existing structure of M.Tech courses at ICT. Since it has interdisciplinary nature, the design proposed is analogous to the existing DBT supported M.Tech. Bioprocess Technology/M.Tech. Food Biotechnology course. These ongoing courses have been a grand success and highly coveted by students across the country, and hence chosen as the model.

Semester I

	Subject	Credit	Hr/Week			Marks			
			L	T	P	Continuous Assessment	Mid-Semester examination	Final exam	Total
SEMESTER - I									
PBT 2101	Pharmaceutical Biotechnology I	**3**	2	1	0	10	15	25	50
PBT 2102	Advances in Recombinant DNA Technology	**3**	2	1	0	10	15	25	50
PBT 2106	Make-up subject-1 Fundamentals of Microbiology, Molecular Biology and Chemical Engineering	**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
PBT 2114	Project – I (Seminar and Critical Review)	**3**	3	3		--	--	30 (Report) + 20 (Presentation)	50
PBT 2115	Research I	**6**			9	--	--		100
PHP 2505	Laboratory I- Instrumental Methods of Analysis	**3**	--	--	6	25	--	25	50
	Total	**27**	**13**	**8**	**15**	**75**	**75**	**190**	**450**

Semester II

	Subject	Credit	Hr/Week			Marks			
			L	T	P	Continuous Assessment	Mid-Semester examination	Final examination	Total
SEMESTER - II									
PBT 2103	Research Methodology	**3**	2	1	0	10	15	25	50
PBT 2104	Pharmaceutical Biotechnology II	**3**	2	1	0	10	15	25	50
PBT 2105	Advanced Analytical Tools in Biotechnology	**3**	2	1	0	10	15	20	50
	Elective – III	**3**	2	1	0	10	15	25	50
	Elective – IV	**3**	2	1	0	10	15	25	50
PBT 2116	Research II	**9**	--	--	18	--	--		150
PBL 2002	Laboratory –II (Microbiology and Molecular biology)	**3**	--	--	6	25	--	25	50
	Total	**27**	**10**	**5**	**24**	**75**	**75**	**145**	**450**

Duration**: 4 semesters (2 years)**

Semester I and II	By Papers
Semester III and IV	By Research

List of Electives:

1. **PBT 2121 Advanced Biochemistry**
2. **PBT 2122 Advanced Bioinformatics**
3. **PBT 2123 Biostatistics**
4. **PHT 2004 Drug Metabolism**
5. **PBT 2124 Environmental Biotechnology**
6. **PBT 2125 Immunology And Vaccines**
7. **PHT 2002 Intellectual Property Rights and Patent Filing**
8. **PHT 2005 Molecular Biology**
9. **PBT 2126 Protein and Nucleic Acid Formulation Development**
10. **PHT 2302 Pharmacology, Toxicology and Therapeutics**
11. **PBT 2127 Process Biotechnology**
12. **PBT 2128 Tissue Engineering and Biopolymers**
13. **PHT 2107 Targeted Drug Delivery Systems**
14. **BST 2102 Unit Operation in Bioprocesses**
15. **CEE 2003 Environmental Biotechnology**
16. **BSE 2110 Biocatalysis and Green Technology**
17. **FDT 2005 Carbohydrate Chemistry & Technology**
18. **FDT 2072 Nutritional Genomics**

The expected outcomes of the course are that students should acquire and demonstrate:

- A scientific understanding of aspects of biotechnology relevant to the pharmaceutical sector – including fermentation technology and metabolic engineering, recombinant techniques for synthesis of therapeutic proteins, antibodies and vaccines, protein structures, stability and evaluation, molecular biology, cell culture, stem cells and drug discovery and therapy, bioinformatics.
- Practical experience in fermentation based products, molecular biology techniques and analytical techniques for biotech molecule characterization.
- An understanding of how the biological sciences and Pharmaceutical sciences are synergised to produce novel pharmaceutical molecules and pharmaceutical products, including biosimilars, vaccines and immunological products and nucleic acid delivery systems.
- A capacity to undertake research in one or more areas of pharmaceutical biotechnology.

Transferable skills

As part of this program students are expected to gain or enhance their experience and competences in the following skills: IT (Bio-statistics, GeneBank database, NIPL word-processing, use of spreadsheets and databases, use of Web resources), scientific writing, oral presentations, team working, problem solving, use of library resources and time management.

Passing criterion:

Passing criterian will be same as per the rules and regulations for other M. Tech. courses in UICT, University of Mumbai.
40% marks required for passing the individual subject
50% aggregate to pass the course
50% for NEUS and Class work
Thesis – Grading (as per the rules of Unversity of Mumbai)

Subject wise Syllabus

I. Core subjects

1. Pharmaceutical Biotechnology I

1. Biotechnology in the Pharmaceutical Industry (Pre-biotechnology products, impact of biotechnology, post-biotechnology products: biologics and biopharmaceuticals)
2. Genetic manipulation methods
3. Fermentation technology
4. Scale-up process (Inoculum: preparation and development of inoculum for industrial fermentation, optimization of the fermentation process (pH, temperature, and oxygen requirements, Determination of the optimized feeding regimen and biomass quantification
5. Improvement of selected microorganism with increased productivity of the fermented products
6. Fermentation process: Batch and continuous fermentation and fermenters, Fermentation products in Pharmaceutical industry: Antibodies, Therapeutic proteins, Vitamins, Amino acids, Monoclonal Antibodies)

2. Advances in Recombinant DNA Technology

1. Vectors: Cloning vectors: Plasmids, Lambda phages, single stranded DNA vectors (M13, fd, f1); Cosmids, Phasmids and Phagemids, YACs, BACs, PACs; Plant Transformation vectors: Introduction to Ti, Ri plasmids and BIBACs; Expression Vectors for high level protein expression
2. Cloning strategies: Vector preparation and diverse cloning strategies viz. blunt end cloning, directional cloning, TA-cloning of PCR products, linkers and adaptors based cloning methodologies
3. E. coli transformation: Chemical transformation and Electroporation
4. Selection and screening of recombinant transformants: Introduction to marker and reporter genes and selection strategies
5. Labeling and detection of nucleic acid sequences: End-Labeling (3'- and 5'-), Random priming and Nick translation using radioactive non-radioactive labeling techniques
6. Genomic DNA libraries: Procedures for Partial, Representative, Enriched, Large-insert DNA libraries, Half-arm cloning, cDNA libraries: Prominent Adapters/Linkers based directional cloning
7. Gene therapy for genetic diseases

3. Research Methodology

Research

1. Meaning of Research, Purpose of Research, Types of Research (Educational, Clinical, Experimental, Historical, Descriptive, Basic applied and Patent Oriented Research) – Objective of research-
2. Literature survey – Use of Library, Books, & Journals – Medline – Internet, getting patents and reprints of articles as sources for literature survey.
3. Selecting a problem and preparing research proposal for different types of research mentioned above.
4. Methods and tools used in Research

- Qualitative studies, Quantitative Studies
- Simple data organization, Descriptive data analysis
- Limitations and sources of Error
- Inquiries in form of Questionnaire, Opinionnaire or by interview
- Statistical analysis of data including variance, standard deviation, students 't' test and annova, correlation data and its interpretation, computer data analysis,

5. Documentation

- "How" of Documentation
- Techniques of Documentation

- Importance of Documentation
- Uses of computer packages in Documentation

6. The Research Report / Paper writing / thesis writing

- Different parts of the Research paper
  - 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

7. Presentation (Specially for oral)
   - Importance, types, different skills
   - Content of presentation, format of model, Introduction and ending
   - Posture, Genstures, Eye contact, facial expressions stage fright
   - Volume- pitch, speed, pauses & language
   - Visual aids and seating
   - Questionnaire
8. Protection of patents and trade marks, Designs and copyrights
   - The patent system in India – Present status Intellectual property Rights (IPR), Future changes expected in Indian Patents
   - Advantages
   - The Science in Law, Turimetrics (Introduction)
   - What may be patented
   - Who may apply for patent
   - Preparation of patent proposal
   - Registration of patent in foreign countries and vice-versa
9. Sources for procurement of Research Grants
10. Industrial- Institution Interaction
    - Industrial projects – Their feasibility reports
    - Research in Education – Johan V. Best James V. Kahn
    - Presentation skills- Michael Halton- Indian Society for Institute Education
    - A Practical Introduction to copy right – Gavin Mcfarlane
    - Thesis projects in Science and Engineering – Richard M. Davis
    - Scientists in legal system – Ann labor science
    - Thesis and Assignment writing – Jonathan Anderson
    - Writing a technical paper- Donald Menzel
    - Effective Business Report writing – Leland Brown
    - Protection of Industrial property rights- Purushottam Das and Gokul Das
    - Spelling for the million – Edna furmess
    - Preparing for publication – King Edwards Hospital fund for London
    - Information technology – The Hindu speaks
    - Documentation – Genesis & Development 3792
    - Manual for evaluation of Industrial projects – United Nations
    - Manual for the preparation of Industrial feasibility studies

4. Pharmaceutical Biotechnology II

1. Animal Cell Culture: Historical Background, Importance of and progress in Animal Cell Culture, Technology, Biology of Animal Cell; Cellular Interactions, Importance of Serum and Serum Free Media, Culturing and Sub-Culturing of Animal Cells, InVitro Transformation of Animal Cells, Cell Differentiation & Cell Movement, Cloning of Animal Cells, Cell Line Preservation, Cell Line Characterization, Chromosome Spreading and Karyotype Analysis, Mycoplasma: Detection and Control, Monoclonal Antibody Production, Insect Cell Culture: An Overview
2. Plant cell culture: History and evolution, Basics of aseptic culture, In vitro propagation, use of plant growth regulators in tissue culture, plant regeneration, organogenesis, somatic embryogenesis, protoplast isolation and culture, somaclonal variation, in vitro mutagenesis, in vitro selection, secondary metabolite production and cell transformation techniques (including protoplast fusion, direct DNA uptake and plant/ bacterial co-cultivation), use of in vitro techniques for crop improvement.
3. Omics: Proteomics, Genomics and Metabolomics: 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.
4. Physical aspects of the genome. Construction and study of various types of genome maps and large-scale sequencing. The human genome project and the plant genome program. Structural genomics and gene discovery, isolation, localization and characterization. Developing diagnostic tests for plant, animal and human diseases. Identification of biomarkers. Finding genetic markers for plant breeding purposes. Environmental impacts on gene expression. Protein complex structures and amino acids. Protein shapes as affecting its function. Amino acid sequencing. Cellular proteome changes in response to environmental and neighbouring cells conditions. Cataloguing the proteins produced by different cells. Discovering the function of a protein. Determining three-dimensional structure of proteins. Protein crystallography.
5. Integrons and transposons
6. Regulatory aspects of biotechnology based products

5. Advanced Analytical Tools in Biotechnology

1. Diagnostic Methods - Molecular Methods: Isolation and purification of nucleic acid and protein, Electophoresis and visualisation of nucleic acid and protein, Blotting techniques, Sequencing and amplification techniques, PCR and related techniques
2. Genomic and Post-Genomic Analytical Biotechnology: Gene purification and sequencing, Protein sequencing and purification, The goal and applications of genomics and proteomics, Techniques in use for gene and protein analysis, e.g. crystallography, magnetic resonance
3. Immunological Methods: Antibody production and labeling, Immunochemical techniques for in situ analyses (ICC and IHC), Immunochemical techniques for measurement (ELISA, etc), Immunochemical techniques for separation (Immunoprecipitation, etc)
4. Introduction to Bioinformatics: organization of biological data, databases (raw and processed), quering in databases, primer designing, gene finding, motif finding, sequence alignment, protein sequence analysis

6. Fundamentals of Microbiology, Molecular Biology and Chemical Engineering

1. Fundamentals of Microbiology (10 lectures)**:** Microbes – types, size shape and arrangement of bacterial cells, Nutritional requirements – Common ingredients, culture media and types of media, Sterilization – Importance and various methods of sterilization, Cultivation and Preservation of microorganisms – Isolation, pure culture, study of cultural characteristics and methods of preservation, Measurement of microbial growth – Total count and viable count methods, Preparation of microbes for microscopic observation – Compound microscope, stains used, simple staining, differential staining and special staining techniques.

2. Fundamentals of Molecular Biology (10 lectures): The beginnings of Molecular biology, The structure of DNA, Genome organization: Prokaryotes and Eukaryotes., The Versatility of RNA: Types of RNA and their role, DNA replication: Prokaryotic and Eukaryotic, Overview of Transcription in prokaryotes and eukaryotes, From Gene to Protein: Genetic code and Translation, Recombinant DNA technology: An introduction, molecular cloning and some tools for analyzing gene expression
3. Fundamentals of Chemical Engineering (10 lectures): Transport phenomenon, Heat transfer, Mass transfer, Process and equipment design for various operations in processing of pharmaceutical biotechnology based products and discussions on scale-up of operations; Prediction of freezing, heating and drying times

III. Electives

1. Immunology and Vaccines

1. Immunology as a science, module overview, practical application of the module
2. Immunity: basic definitions, types of immunity, organs involved, cells of the immune system, humoral v/s cellular immunity
3. Innate immunity: meaning, cells 'producing' innate immunity, non-cellular innate immunity
4. Adaptive immunity: meaning, cells bringing about specific immunity, production of a specific response
5. Adaptive immunity 2: signaling, steps in the development of a nonself destructive cellular specific immunity, steps in the development of a nonself destructive humoral specific immunity
6. Adaptive immunity 3: cells and antibodies adcc, failure of specific immunity development
7. Antibodies & its diversity: types, development of specific antibodies in the body: vdj recombination
8. Fine balance in immunity: th1 v/s th2 response, why the immune system does not destroy gut flora
9. Mucosal immunology: mediation of immunology on mucosal surfaces, importance
10. Immunological response to disease (example study): components of an immunological response, th1 response type disease, th2 response type disease, alternatively activated macrophages, disease with primary response
11. Immunological pathogenesis: hyper sensitivity, auto immunity
12. Disease of the immune system: immuno therapy, general overview, study of hiv infection & immunity development
13. Cells of the immune system: identification, laboratory culture, primary culture, cell lines
14. Immunological techniques: diagnostic tests, basic/classical/common, elisa/ria call types, western blot
15. Immunological techniques 2: diagnostic tests, elispot, flow cytometry, cell sorting, animal models in immunology

2. Protein Nucleic And Acid Formulation Development

1. Protein engineering
2. Nucleic acids and proteins: physicochemical properties and stabilization
3. Formulation aspects
4. Mechanisms of action
5. Characterization: Raman, Mass Spectrometry, Atomic Force and Scanning Electron Microscopy (AFM and SEM), Confocal microscopy, Flow cytometry, Capillary DSC, MALDI-TOF, circular dichroism
6. Biophysical techniques: pharmacokinetics/pharmacodynamics
7. In vitro studies: cellular trafficking
8. Biosimilars

3. Advanced Biochemistry

1. Proteins: Structures – primary, secondary, tertiary, motifs, structural and functional domains, protein families and macromolecular assemblies.
2. Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands, Ca¬+2 and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage.
3. Purification and characterization of proteins: Electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes and MS, X-ray crystallography, NMR and Homology modeling, amino acid analysis, cleavage of peptides, protein sequencing.
4. Protein biosynthesis: Translation machinery in prokaryotic and eukaryotic systems, comparison of similarities and differences.
5. DNA and nucleic acids: DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms.
6. Carbohydrates: Mono, di and polysaccharides and their nomenclature, stereochemistry, linkages, conjugates of carbohydrates with other molecules - glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles.
7. Lipids: Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as second messengers and cofactors, biological role of lipids

4. Advanced Bioinformatics

1. Motif and cis-Regulatory Module (CRM) Modeling: learning motif models, learning models of cis-regulatory modules, Gibbs sampling, Dirichlet priors, parameter tying, heuristic search, HMM structure search, sequence entropy and mutual information, duration modeling, semi-Markov models
2. Gene Finding: the gene finding task, maximal dependence decomposition, interpolated Markov models, back-off models, pairwise HMMs, Genscan, Twinscan, SLAM
3. RNA-Seq: RNA-Seq technology, transcript quantification with RNA-Seq
4. RNA Analysis: predicting RNA secondary structure, Nussinov/energy-minimization algorithms, stochastic context free grammars, Inside/Inside-Outside/CYK algorithms, searching sequences for a given RNA secondary structure, RSEARCH, RNA gene recognition via comparative sequence analysis, microRNA gene/target prediction
5. Large-Scale and Whole-Genome Sequence Alignment: large-scale alignment, whole-genome alignment, parametric alignment, suffix trees, locality sensitive hashing, k-mer tries, sparse dynamic programming, longest increasing subsequence problem, Markov random fields, MUMmer, LAGAN/MLAGAN, Mauve, Mercator
6. Biological network inference and evolution: Network inference, models of biological network evolution, network alignment
7. Genotype Analysis: haplotype inference, genome-wide association studies (GWAS), quantitative trait loci (QTL) mapping
8. Protein Structure Prediction: secondary structure prediction, threading, branch and bound search, ROSETTA

5. Bio-statistics

1. Application of Statistics, bioinformatics and experimental design to biotech processes: Sampling procedures, populations; types of data, data organization and presentation.
2. Correlation and Regression, linear and quadratic regression Analysis of variance.
3. Correlation coefficient; regression analysis; multivariate analysis; principal component analysis. Probability. Probability distribution.
4. Testing of hypothesis. Experimental design and factorial design.
5. Concepts and use of software. RSM and ANN techniques for optimization of fermentative processes

6. Drug Metabolism

1. Introduction to the different pathways of drug metabolism: Phase I and II reactions, sites of drug metabolism, subcellular localization of drug metabolizing enzymes, cofactors required for catalytic reactions
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.
3. Introduction to other drug metabolism enzyme isoforms/families Glucuronosyltransferases, glutathione transferases, sulfotransferases, N-acetyltransferases, FMO's.
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
5. Introduction to in-silico methods for predicting drug metabolism: Principles behind development of these systems, their potential and their limitations.

7. Environmental biotechnology

1. Application of biotechnology in agriculture e.g. pest control, herbicide resistance
2. GM crops and farm animals, bio-fertilizers
3. Alternative energy resources including biogas, alcohol etc.
4. Treatment of waste from domestic, industrial, agricultural etc. and bioremediation Environmental security and safety; Socio-economic aspects of GM crops

8. Intellectual property Rights and Patent Filing

1. Introduction to IP
2. Copyright, Related Rights, Trademarks, Geographical Indications, Industrial Design
3. Patents
4. WIPO Treaties
5. Unfair Competition
6. Protection of New Varieties of Plants
7. Summary and Discussion on IP Rights

9. Molecular Biology

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.
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.
3. 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.

10. Pharmacology, Toxicology and Therapeutics

1. Evaluation of drug activities,
2. Study models for testing,
3. Toxicity (ICH and OECD guidelines),

4. Importance of transgenic animal models/knock out mice based screening methods, overview of regulatory status-ethical/moral/professional issues in toxicity

11. Process Biotechnology

1. Selection of separation process. Chemical, physical and biochemical aspects of isolation and purification of biomolecules. Product release from a cell
2. Concentration and separation methods: membrane, ion-exchange, precipitation and extraction. Chromatographic methods of purification
3. Chemistry of adsorption, Adsorbents, Equilibria, Yield and purity, Batch adsorption, Kinetic analysis, Discrete stage analysis, Adsorption in fixed beds
4. Design and scale-up of adsorption and chromatography equipment
5. Design of downstream processing equipment. Downstream process economics

12. Tissue Engineering and Biopolymers

1. Principles of materials science and cell biology underlying the design of medical implants, artificial organs, and matrices for tissue engineering
2. Methods for biomaterials surface characterization and analysis of protein adsorption on biomaterials
3. Molecular and cellular interactions with biomaterials are analyzed in terms of unit cell processes, such as matrix synthesis, degradation, and contraction Mechanisms underlying wound healing and tissue remodeling following implantation in various organs
4. Tissue and organ regeneration
5. Design of implants and prostheses based on control of biomaterials-tissue interactions
6. Comparative analysis of intact, biodegradable, and bioreplaceable implants by reference to case studies
7. Criteria for restoration of physiological function for tissues and organs

13. Targeted Drug Delivery Systems

1. Introduction: concept, basis, need, physicochemical and physiological basis, RES
2. Receptor mediated drug targeting
3. Colon targeting approaches
4. Targeting to brain
5. Targeting in cancer and infectious diseases
6. Ligands for targeted drug delivery: monoclonal antibodies

14. Unit Operation in Bioprocesses

1. Downstream Processing in Biotechnology, Selection of unit operation with due consideration of physical, chemical and biochemical aspect of biomolecules, basic review of bioprocess designing.
2. Primary separation and recovery processes: Cell disruption methods for intracellular products, removal of insolubles, biomass (and particulate debris) separation techniques, flocculation and sedimentation, centrifugation and filtration methods.
3. Enrichment operations: Membrane – based separations (micro and ultrafiltration, precipitation methods, extractive separation, aqueous two-phase extraction, supercritical extraction, insitu product removal, integrated bioprocessing.
4. Product resolution / fractionation: Adsorptive chromatographic separations processes, electrophoretic separations, hybrid separation technologies (electrochromatography).
5. Product finishing: precipitation/crystallization, mixing, dialysis, distillation and drying. Ultracentrifugation as a separation technique for fractionation of cells and proteins.
6. Introduction to Process Analytical Technology (PAT) and Quality by Design (QbD). Scale down, monitoring and Validation of bioprocesses

15. Environmental Biotechnology

1. Environmental impact and control; Biosafety

2. Biological treatment: stabilization pond, aerated lagoon, activated sludge process, trickling filter anaerobic treatment
3. Biodegradation of xenobiotic organic chemicals; Biological Detoxification of Hazardous chemicals
4. Environmental Policy & Legislation; Sampling of air and water pollutants; Monitoring techniques and methodology, pH, Dissolved Oxygen (DO); Chemical oxygen demand (COD); Biological Oxygen Demand (BOD); Speculation of metals, monitoring & analysis of CO, NO2, CO2, SO2; Pesticide residue; Phenols and petrochemicals
5. Environmental pollution control- Bioremediation, Bioaugmentation and Biostimulation; Biofilms in treatment of waste water; Biofilm development and biofilm Kinetics; Aerobic Biofilms; Bioreactors for waste water treatments

16. Biocatalysis and Green Technology

1. Catalytic activity of biomolecules – enzymes and ribozymes; Enzyme applications: Hydrolase enzymes – lipases, esterases, proteases etc. with specific examples and mechanism, Lyases – e.g. Aspartase, tyrosine-phenol lyase; Isomerases – e.g. glucose isomerise; Transferases – e.g. aminotransferases, PLP as cofactor; Ligases; Oxidoreductases – dehydrogenases, oxidases, oxygenases, peroxidases.
2. Whole cells as catalysts; Energetically unfavourable reactions at low temperatures and in unfavourable solvents; The Michaelis-Menten model and modes of inhibition; Kinetics of enzyme catalysed reaction; Regulation mechanisms; Mechanisn of enzyme action; Multi-enzyme systems; Selection and screening of biocatalysts for activity, stability and substrate or product selectivity; Extremozymes – protein catalysts for reactions at extremes of temperature, pressure and pH.
3. Principles of green chemistry (e.g. prevention of waste, less hazardous methods, safer chemicals and solvents, energy efficiency, atom economy, use of catalysis, etc.); the design of "greener" effect chemicals, with examples from the development of crop protection agents; the design of "greener" chemical processes, with examples of the use of biocatalysts.

17. Carbohydrate chemistry and technology

1. Different carbohydrates in food products such as starch, cellulose, sugars, pectin, fibre etc. and their significance in diet
2. Their chemistry & changes in them during processing; Chemical & enzymic modification; Interactions with other food constituents and their implications
3. Special application of carbohydrates in gels, emulsions, stabilisation of food systems, simulated and low-fat foods, edible packages etc.

18. Nutritional genomics

1. Gene- environment interaction; gene- diet interaction; principals and practice behind dietary management of genetically transmitted disorders 10
2. Phenylketonuria, galactosemia; G6PD deficiency; lactose intolerance; complex traits; birth disorders; signal transduction; epigenetic mechanism 10
3. Bioactive components of food; nutraceutical; effective gene expression; epigenetic process; signal transduction. Recent developments in the field

IV. Laboratory courses: Microbiology & Molecular Biology Laboratory

1. Study of bacteria, yeasts, moulds, algae, viruses and other microorganisms
2. Morphology, structure, reproduction, isolation, and cultivation
3. Principles of taxonomy and classification, Mutants, Control of microorganisms
4. Laboratory experiments in use of microscopy for identification of microorganisms by morphology and staining technique. Isolation of pure culture
5. Study of growth and optimisation of conditions
6. Preparation of culture media, Sterility test
7. Basic methods in Molecular Biology, including PCR, Blotting techniques, DNA purification, DNA sequencing etc