ANDHRA UNIVERSITY

MASTER OF PHARMACY

(2020)

Regulations and Syllabus

Four semester pattern

With effect from 2020-21

M.PHARM (2020) REGULATIONS AND SYLLABUS

INDEX:

1. Admission, instruction and attendance

The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

1.1. The candidate must have passed the B.Pharm. Degree examination of this University or B.Pharm. Degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2. Every student, selected for admission to PG Pharmacy program in any PCI approved institution should have obtained registration with the State Pharmacy Council or should obtain the same within one month from the date of his/her admission, failing which the admission of the candidate shall be cancelled.

1.3. The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus.

1.4. The subjects of specializations for Master of Pharmacy Course shall be as follows:

1. Pharmaceutical Analysis
2. Pharmaceutical Chemistry
3. Pharmaceutics
4. Pharmaceutical Biotechnology
5. Pharmacology
6. Pharmacognosy
7. Pharmaceutical Regulatory Affairs
8. Pharmaceutical Quality Assurance
9. Industrial Pharmacy
10. Pharmacy Practice

1.5. Instruction and examination in each academic year is spread over two semesters with a minimum of 96 working days in each semester (192 in any given academic year). The odd semesters shall be conducted from the month of July to November and the even semesters shall be conducted from the month of December to April.

1.6. Each period of instruction is of 45 minutes duration. Eight periods of instruction are provided on each day and there are six working days in a week (Monday to Saturday).

1.7. Attendance Requirements: A regular course of study during an academic semester means a minimum of average attendance of 80% of all the courses of the semester computed by totaling the number of periods of lectures and practicals, as the case may be, held in every course. In special cases where sufficient causes were shown, the Vice-

Chancellor may on the recommendation of the Principal concerned condone the deficiency in the average attendance to an extent of 9% for reasons such as ill health, if the application for condonation is submitted at the time of actual illness and is supported by certificate of; authorized Medical officer approved by the Principal. However, in the case of students, who participate in activities like N.S.S., N.C.C., Inter-Collegiate tournaments conducted by Andhra University, Inter-University tournaments conducted by Inter-university Board and any such other activities involving the representation of the College/University with the prior approval of the principal, the candidate may be deemed to have attended the college during the period solely for the purpose of the examination.

1.7. A candidate who cannot satisfy the attendance requirements in clause 1.5 because of late admission under special circumstances reasonable and acceptable to the University on the basis of document, shall fulfill the following conditions; Average attendance: A candidate shall have attended at least a total of 90% of the periods-lectures/practicals as the case may be held from the date of admission and also shall attend at least 50% of the total working days during that academic semester (Late admission means, admissions made after 45 days from date of commencement of the academic semester for the course).

1.8. If any candidate fails to satisfy the regulation under 1.5 or 1.6 she/he shall not be allowed for the University Examinations at the end of the semester, and he/she shall not be allowed for promotion to the next higher class of study. He/she shall be required to repeat the regular course of study of that academic semester along with the next regular batch.

1.9. A regular record of attendance in theory, practical, seminar, assignment, journal club, discussion with the supervisor, research work presentation and dissertation shall be maintained by the department/teaching staff of respective courses.

2. Examinations – Internal assessment and Semester-end

2.1. Assessment for the award of degree shall consists of (a) internal assessment for 30 marks in each of the theory and practical courses separately. (b) Semester-end examination as detailed in the scheme of examination for 70 marks in each of the theory and practical separately.

2.2. Regulations concerning internal assessment: Internal assessment consist of continuous mode (10 marks for theory and 15 marks for practical) and sessional examinations (20 marks for theory and 15 marks for practical)

2.2.1. Scheme for awarding continuous mode marks for theory and practical

Theory-Criteria	**Marks**
Attendance	5
Student-Teacher Interaction	5
Theory sessional examination	20
Total theory internal assessment	**30**
Practical-Criteria	
Attendance	5
Record + Viva-voce	10
Practical sessional examination	15
Total practical internal assessment	**30**

2.2.1.1. Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory/Practical
95 -100	5
90-94	4
85-89	3
80-84	2
Less than 80	0

2.2.1.2. Guidelines for allotment of marks for Student-Teacher interaction

The teacher shall create some interactive sessions for theory topics and every student shall interact on the given topic relating to its application in pharmacy. The teacher should assess the student capacity for understanding of the concept taught. It shall not be like seminars.

2.2.1.3. Guidelines for allotment of marks Record + Viva-voce

The teacher should conduct viva-voce at the end of each practical and evaluate the record on continuous mode and shall award these marks.

2.2.4. Guidelines for sessional examinations

Two sessional examinations shall be conducted for each theory/practical course. The average marks of the two shall be computed.

The teacher who teaches the subject shall ordinarily to be the internal examiner.

There shall be no provision for the improvement of the sessional marks.

There is no minimum mark prescribed for sessional examination for pass in the end semester examination.

If any student is absent for a single or both sessional examinations, the candidate will be awarded "ZERO" in the respective examination.

The theory average sessional mark shall be finally computed for 20 marks and average practical sessional mark shall be finally computed for 15 marks.

2.3. Regulations concerning M.Pharm I and II semester evaluation pattern:

2.3.1. There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be single valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done by examiner. The duration of the practical examination is of 6 hours as prescribed.

2.3.2. However the student may apply for revaluation of any subject in theory papers after declaring the results as per University examination guide lines.

2.3.3. Seminar

A seminar at the end of first and second semesters is separately conducted keeping in view of the enrichment of required communication, presentation and explanatory skills. A minimum of four seminars shall be given during the semester before the Program Committee and other students and documented separately for record in a Semester Seminar Register.

2.3.4. Comprehensive viva

At the end of II Semester comprehensive viva will be conducted for all the subjects

covering the theory subjects of I & II semesters by the external examiner and eligible internal examiners (at least two from the college) who taught these subjects. The candidate should obtain minimum of 50% marks for passing the examination.

2.3.4. Journal Club

In case of Journal Club, based on the research proposal, each student shall collect a minimum of 5 research papers (published in a reputed journal with impact factor of Thomson & Reuters of not less than 1.0) and should discuss in a Programme Committee (consisting of Head of the Department, Research Supervisor and other Senior faculty members) and documented separately for record in a Journal Club Register.

2.3.5. A student shall be eligible to carry forward all the courses of I, II semesters. However, he/she shall not be eligible to attend the courses of IV semester until the candidate clears III semester Midterm Project Review.

2.4. Regulations concerning M. Pharm. III and IV Semester evaluation pattern:

2.4.1. Evaluation of the seminar on the objectives and work plan of the proposed project is to be completed within one month from the commencement of the project date with three examiners from the same college consisting of research guide, another teacher in the concerned specialization and third teacher from different specialization. These teachers must fulfill the eligibility criteria laid down in Section 3.

2.4.2. Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected topic will be done by the research guide and external examiner. The seminar on the selected topic shall not be the one connected with the topic of the thesis work but should be related to concerned specialization.

2.4.3. A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

2.4.4. The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

2.4.5. A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

2.5. Guidelines for writing the thesis

The thesis should have the following pages in order:

1. Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.
2. The inner title page containing the same details on white background.
3. Certificate from the Head of the institution
4. Certificate from the Research Director
5. Certificate from the ethical committees for approval of study, if any

6. Declaration by the student
7. Acknowledgements
8. Index highlighting chapter titles and sections titles
9. Index for tables, figures and plates, if any
10. Abbreviations and symbols
11. Materials used in the investigation with their procurement details like name of the company, batch number etc.
12. Equipment used in the study with the model number and other details
13. The thesis should contain the following chapters:
    a) Aim and objectives of the investigation
    b) Introduction and literature survey
    c) Description: Methods and Materials, etc.
    d) Experimental work
    e) Results and discussion
    f) Summary and conclusions
    g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

2.5.1. The thesis should be typed in times new roman in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

2.5.2. The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

2.5.3. No code names or numbers are allowed to be written in the thesis for the materials used in the project.

2.5.4. The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

2.5.5 Project Work/IV Semester Assessment – Division of Marks:

Course 402 -Thesis Evaluation (Max. Marks – 150)

Criteria of Evaluation	**Marks**
Seminar/Presentation of work	20
Objective(s) of the work done	20
Methodology adopted	40
Results and Discussion	40
Conclusions and Outcomes	30
Total	**150**

The division of marks shall be clearly indicated for every candidate in the marks statement being sent to the University.

2.6. End Semester examinations

The End Semester examination for each theory, practical and other courses through

semesters I to IV shall be conducted by the University except for the subject with asterisk symbol (*) in the tables of the each specialization courses (Non University Examinations) for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the University. In case of theory examinations, the question paper of the corresponding subject shall be mailed (Official mail id) to the Controller of Examinations and Chairman, BOS with signature of the Head of the Institute in PDF format within twenty four hours after completion of the examination.

3. Eligibility criteria for appointment as examiner for M.Pharm examination

3.1. In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

3.2. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

3.2.1. The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

3.2.2. The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

3.2.3. The recognized M.Pharm guides are not eligible to guide more than **6** students in one academic year including joint guidance.

4. Regulations for pursuing M.Pharm III and IV Semester project

4.1. Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

4.2. All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

5. Declaration of results and classification:

5.1. A candidate shall be declared to have passed the examination held at the end of each semester if obtains i) not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce at the end of each semester end examination and ii) an aggregate of 50% of all examinations of that semester including sessoinals. There are no minimum marks prescribed for sessional examination.

5.2. A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

5.3. A candidate who fails to secure 50% of marks on the aggregate but secures 50% or

more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to satisfy the requirement of 50% aggregate.

5.4. Declaration of class

The classes shall be awarded on the basis of CGPA as follows

First Class with Distinction = CGPA of 7.50 and above

First Class = CGPA of 6.00 to 7.49

Second Class = CGPA of 5.00 to 5.99

6. Grading system:

6.1. Appropriate letter grades are awarded in each theory and practical subject to only such candidates who have passed in the university examinations. Internal assessment marks and university examination marks put together will be taken into account for the letter grading system in each subject separately.

6.2. A candidate registered for the university examination but fails to appear or fails to score the minimum required 40% marks in the university examination will get a grade 'F', indicating failure or grade of incompletion.

6.3. A subject successfully completed cannot be repeated. Final evaluation of each subject (theory and practical separately) will be carried out on a 10- point grading system corresponding to the marks obtained in that subject. Each subject letter grade is converted into a specific grade value associated with the letter grade as given below (Table).

6.4. Grading of performances

Based on the performance, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given below.

10-Point grading system

Percentage of marks	Grade	Grade points
90.00 - 100	O	10.0
80.00 - 89.99	A	9.0
70.00 – 79.99	B	8.0
60.00 – 69.99	C	7.0
50.00 – 59.99	D	6.0
40.00 – 49.99	E	5.0
< 40.00	F (Fail)	0.0
The grade W represents failure due to insufficient attendance in the semester or year	W	0.0
Incomplete (subsequently to be changed into pass or E or O or F grade in the same semester)	I	0.0

6.5 The Semester grade point average (SGPA):

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the

grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4G4}{C1+C2+C3+C4}$$

The SGPA is calculated to two decimal points. It should be noted that, the SGPA for any semester shall take into consideration the F and AB grade awarded in that semester. For example if a learner has F or AB grade in course 4, the SGPA shall then be computed as:

$$\textbf{SGPA} = \frac{C1G1+C2G2+C3G3+C4*ZERO}{C1+C2+C3+C4}$$

The credits allotted to each course are given in the respective specialization **Tables 1-10**.

6.6. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all IV semesters and their courses. The CGPA shall reflect the failed status in case of F grade(s), till the course(s) is/are passed. When the course(s) is/ are passed by obtaining a pass grade on subsequent examination(s) the CGPA shall only reflect the new grade and not the fail grades earned earlier. The CGPA is calculated as:

$$\textbf{CGPA} = \frac{C1S1+C2S2+C3S3+C4S4}{C1+C2+C3+C4}$$

Where C_1,C_2,C_3, C4…is the total number of credits for semester I, II, III and IV and S1, S2, S3 and S4 are the SGPA of semester I, II, III and IV.

7. Guidelines for paper setting and model papers.

7.1. Guidelines for theory paper setting for semester end examinations

7.1.1. The semester end question paper in each theory course is to be set for a total of 70 marks by an external paper setter as per the general model given below.

7.1.2. Question paper consists of 5 questions each carrying 5 marks out of which 4 questions are to be answered by the candidate and 7 questions each carrying 10 marks out of which 5 questions are to be answered by the candidate for a total of 70 marks. Each main question may contain subsections like a, b, c etc.

7.1.3. The questions given should be spread over the entire syllabus in an even manner covering all the units as per the pattern of the question paper given below.

7.1.4. Model question paper for theory course:

Course No.

Specialization Name:

Title of the course:

Time: 3 Hours **Max. Marks: 70**

Part A (Question Numbers 1-5)

Answer any **four** questions out of five questions 4X5=20

One question has to be set from each unit.

Part B

Answer any **five** questions out of **seven** questions (Question Numbers 6-12) 5X10=50

Five questions are to be set from five units and the remaining two should cover at least four out of five units. The main questions may contain sub question like 6(a), 6(b) etc.

7.2. Guidelines for practical paper setting for semester end examination

7.2.1. The question paper in each semester end practical examination is to be set jointly by two examiners and evaluated, one external and one internal as per the general model provided below.

7.2.2. Model question paper for practical course:

Course No.

Title of the course

Time: 6 hrs.

1. Synopsis	10 marks
2. Major experiment	30 marks
3. Minor experiment	20 marks
4. Viva voce	10 marks
Total:	**70 marks**

7.3. Guidelines for theory/practical sessional examination paper setting:

Question paper pattern for theory Sessional examinations

Max. Marks: 30

Time: 2 Hours

Part A

Answer any **two** questions out of three questions 2X5=10

Part B

Answer any **two** questions out of three questions 2X10=20

Each of the sessional examination question paper should cover at least half the units of the syllabus.

Question paper pattern for practical sessional examinations

Max. Marks: 30

Time: 4 hours

1. Synopsis	5 Marks
2. Experiment	20 Marks
3. Viva	5 Marks
Total:	**30 Marks**

Table 4: Pharmaceutical Biotechnology (MPB)

Code	Course	Credits	Hours/ week	Internal Assessment			Semester End Exam	Total
				Continuous mode	Sessional Exam	Total		
I Semester								
MPB 101T	Modern Pharmaceutical Analytical Techniques	4	4	10	20	30	70	100
MPB 102T	Microbial Genetics and Cellular Biology	4	4	10	20	30	70	100
MPB 103T	Bioprocess Engineering and Technology	4	4	10	20	30	70	100
MPB 104T	Advanced Pharmaceutical Biotechnology	4	4	10	20	30	70	100
MPB 105P	Pharmaceutical Biotechnology Practical - I	2	6	15	15	30	70	100
MPB 106P	Pharmaceutical Biotechnology Practical - II	2	6	15	15	30	70	100
MPB 107	Seminar*	2	4	50	---	---	---	50
	Total	**22**	**32**	---	---	---	---	**650**
II Semester								
MPB 201T	Proteins and Protein Formulation	4	4	10	20	30	70	100
MPB 202T	Immunotechnology	4	4	10	20	30	70	100
MPB 203T	Bioinformatics and Computational Biotechnology	4	4	10	20	30	70	100
MPB 204T	Biological Evaluation of Drug Therapy	4	4	10	20	30	70	100
MPB 205P	Pharmaceutical Biotechnology Practical III	2	6	15	15	30	70	100
MPB 206	Comprehensive Viva	2	---	---	---	---	---	50
MPB 207	Seminar*	2	2	50	---	---	---	50
	Total	**22**	**26**	---	---	---	---	**600**

Table 4: Pharmaceutical Biotechnology (MPB) continued

III Semester								
MRM 301T	Research Methodology and Biostatistics*	2	4	10	20	30	70	100
MPB 302	Journal Club*	2	2	50	---	---	---	50
MPB 303	Discussion /Presentation (Dissertation Title & Project Proposal)*	2	---	50	---	---	---	50
MPB 304	Seminar on selected topic	4	4	---	---	---	100	100
MPB 305	Research Work Progress (Mid Term Report)	10	20	---			200	100
	Total:	**20**	**30**	**---**	**---**	**---**	---	**400**
IV Semester								
MPB 401	Journal Club*	2	2	50	**---**	**---**	---	50
MPB 402	Thesis evaluation	12	20	---	**---**	**---**	150	150
MPB 403	Thesis viva	4	---	---	**---**	**---**	50	50
	Total:	**20**	**22**	**---**	**---**	**---**	---	**250**

* Non-University Examination

M.Pharm – Pharmaceutical Biotechnology

PROGRAM EDUCATIONAL OBJECTIVES

1. To provide an in depth and advanced pharmaceutical education leading to M. Pharm. Pharm Biotech specialization
2. To combine pharmacy knowledge and skills with molecular biotechnology field.
3. To nurture pharmacists to contribute effectively in the health care system with respect to genetic disorders
4. To provide hands on training to impart research aptitude in Molecular and Industrial biotechnology
5. To inculcate leadership and entrepreneurship capabilities in future pharmacists in the area of biopharmaceuticals manufacturing.

PROGRAM OUTCOMES

PO1: Demonstrate ability to acquire, manage and use current information for problem solving in the area of biotechnology.

PO2: Describe the synthesis, formulation, analysis, pharmacological, therapeutical, toxicological, and regulatory aspects of biopharmaceuticals and biologics.

PO3: Assess the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of pharmaceuticals

PO4: Develop problem-based learning approach and analytical thinking in his/her academic and professional life

PO5: Apply critical thinking skills and documentation related to research investigation

PO6: Ability to plan and implement professional activities

PO7: Show leadership in the diverse areas of the profession

PO8: Inculcating the skills of scientific communication and research articles writing

PO9: Participation in the interdisciplinary research with other health care communities and providing innovative solutions

PO10: Participate in healthcare initiatives to create awareness about usage of eco-friendly products in society about the effective and safe use of medicines

PROGRAM SPECIFIC OUTCOMES(PSOs)

PSO1: Student able to expertise in molecular biology techniques.

PSO2: Able to apply the biotechnology practical knowledge in the formulation development of biopharmaceuticals.

PSO3: Able to do profuse jobs in the biotechnology industries and to write effective project reports in view of changing technologies

PSO4: Able to work along with health professionals in identification and analysing the diseases related genetic disorders.

M. PHARM – PHARMACEUTICAL BIOTECHNOLOGY

COURSE: MOLECULAR GENETICS AND CELLULAR MICROBIOLOGY - MPB (102T)

COURSE EDUCATIONAL OBJECTIVES(CEO's): The student shall able to:

1. Understand the fundamentals of microbiology which are applied in biotechnology.
2. Know the concepts of molecular genetics, cell biology and embryology applicable to industrial microbiology and in the manufacture of biopharmaceuticals.
3. Develop the concepts of microbial pathogenesis and cell culture techniques in in drug development.

LEARNING OUTCOMES(LO's): The student able to learn after completion of

UNIT 1:

1. The structure, morphology, cultural conditions required for the growth and isolation of various types of microorganisms including viruses.
2. The industrial importance and applications of various microorganisms.

UNIT 2:

1. Structure of nucleic acids and their composition in living cells.
2. Various steps involved in central dogma of the molecular biology and the concept of gene regulation.

UNIT 3:

1. Cell function, cell to cell communication, cell cycle and its regulation.
2. Concepts of fertilization, events in fertilization process and applications of germ cells and stem cells.

UNIT 4:

1. Principles involved in growth and maintenance of microbial cell cultures and animal cell cultures.
2. In vitro cell culture techniques and their application in molecular biology research and drug development.

UNIT 5:

1. Identification and microscopic characterization of pathogenic microorganisms, mechanism of pathogenicity.
2. Various types of common microbial diseases and viral infections and their etiology, pathology and treatment.

COURSE OUTCOMES(CO's): After completion of the course the student gets knowledge in

1. Growth, cultural and physiological conditions required for various types of microorganisms and their industrial importance'
2. The basic concepts in central dogma of the molecular biology and their applications in industrial microbiology
3. The concepts of embryonic development of a eukaryotic cell, cell structure, cell cycle and its regulation and its role in mutational condition.
4. The nutritional requirements of a microbial and animal cell and virulence factors and types of microbial diseases

COURSE: BIOPROCESS ENGINEERING &TECHNOLOGY - MPB (103T)

COURSE EDUCATIONAL OBJECTIVES(CEO's): The student shall able to:

1. Understand the concepts in fermentation process, types of equipment used,functions, process automation and control of bioprocess parameters.
2. Know the theory of mass transfer in a biological process and its control against outside environment and other parameters.
3. Understand the scale-up concept, upstream and downstream process in fermentation, utilization of immobilized culture systems.
4. Know the bioprocessing of industrially important microbial metabolites and their biosynthetic pathways.

LEARNING OUTCOMES(LO's): The student able to learn after completion of

UNIT 1:

1. Design and working of bioreactor, its ancillary parts & their design and measurement of various bioprocess parameters like pH, temperature, dissolved O_2 and CO_2.

2. Types of bioreactors, their application and computer controlled bioreactor systems.

UNIT 2:

1. Oxygen transfer rate theory in a biological system, determination of K_L.a value and factors affecting it
2. Air sterilization methods, air sampling and rheological properties of a fermentation system in bioprocessing.

UNIT 3:

1. Sterilization methods (HTST) used for fermentation medium, liquids and other material.
2. Immobilized culture systems types, cultivation and their application.

UNIT 4:

1. Theory, equipment involved and working in various unit operations of downstream process in purification of the metabolites
2. Maintenance of industrially important microbial cultures and their improvement in the yield of bioactive metabolites.

UNIT 5:

1. Microbiological production of industrially important selected organic acids, organic solvents, amino acids, antibiotics and vitamins.
2. Biosynthetic pathways of secondary metabolites and biotransformations

COURSE OUTCOMES(CO's): After completion of the course the student can get knowledge in

1. Design, operation, ancillary parts required, types and computer controlled automation of bioreactors/fermenters and their industrial applications
2. Oxygen transfer rate, measurement, factors affecting and rheological properties in a fermentation process.
3. Types of sterilization process used, types of culture systems used and approaches for immobilization in bioprocess manufacturing of a metabolite.
4. Microbial production of various types of industrially and therapeutically useful metabolites

COURSE: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY - MPB (104T)

COURSE EDUCATIONAL OBJECTIVES(CEO's): The student shall able to

1. Understand the advanced topics in enzyme technology and production of various enzymes.
2. Know the principles of genetic engineering and its application in manufacturing of biopharmaceuticals.
3. Get knowledge in therapeutic peptide formulations and their delivery.
4. Know the concepts of advanced topics in biotechnology like transgenic animals, human genome project, cell signalling and microbial biotransformation.

LEARNING OUTCOMES(LO's): The student able to learn after completion of

UNIT 1:

1. General properties, dynamics and classification of enzymes.
2. Microbiological production of various enzymes, properties and various applications.

UNIT 2:

1. Various steps involved in rDNA technology, principle in PCR, concept of protein engineering.
2. Application of rDNA technology in the manufacturing of selected biopharmaceuticals (proteins)

UNIT 3:

1. Targeted and controlled release of protein drug delivery systems through various routes of administration.
2. Use of transgenic animals in protein production and gene therapy.
3. Human chromosome structure, types, abnormalities and syndromes.

UNIT 4:

1. Cell signalling pathways, concepts of spatial and temporal aspects of cell signalling.
2. Cell signalling related to cell processes , cell cycle and proliferation.
3. Various oncogenes and their proteins.

UNIT 5:

1. Concept of biotransformation in the synthesis of chiral drugs and steroids.
2. Microbial degradation mechanisms and application in environmental monitoring.
3. Elements of a biosensor, types of biosensors and their applications

COURSE OUTCOMES(CO's): After completion of the course the student can get knowledge in

1. Enzyme preparation, purification from microbiological source and various types of applications.
2. r DNA technology detailed process and its application in the manufacture of various types of biopharmaceuticals.
3. Peptide drug delivery systems for targeted and controlled delivery of proteins.
4. Evolution of human genome project and application of transgenic animals in drug research.
5. Microbial degradation mecahnisms, biosensors and their application and concepts of cell signalling process.

COURSE:- PROTEINS AND PROTEIN FORMULATIONS- MPB (201T)

COURSE EDUCATIONAL OUTCOMES (CEO's):- The student shall be able to

1. Understand the basic structure of proteins, modifications of protein structure with r DNA of and chemical treatment to get a desirable function for better use in industry, medicines and agriculture.
2. Get knowledge on various methods to modify pesticides structure , to improve the pharmacokinetic properties.
3. Know the protein identification and characterization
4. Understand various methods of protein purification.
5. Know protein formulations.

LEARNING OUTCOMES(LO's):- the students shall be able to plan / get / know

UNIT 1:-

1. Structure of proteins isolation and purification of proteins , stability and activity of protein after protein basic structure modification.
2. Different methods of protein engineering and direct evolution.

UNIT 2 :-

1. Methods which modify peptide structure in drug development.
2. Rational drug design such as CADD techniques.

UNIT 3:-

1. Identification and characterization of protein
2. Various methods of purification.

UNIT 4:-

1. Different strategies used in formation of DNA and proteins, analytical and biophysical parameters of proteins and DNA in pre formulation.
2. Characterization techniques and forced degradation of proteins.

UNIT 5:-

1. Various methods of protein sequencing.
2. Characterization Edman degradation , chemotrophic peptide mapping.

COURSE OUTCOMES(CO's) :- After completion of the course the students can get knowledge in

1. Basic structure of protein modification of protein structure to get desired function.
2. Different methods of protein purification.
3. Peptide modification methods coma CADD
4. Protein identification and characterization
5. Protein based formulations.

COURSE:- IMMUNOTECHNOLOGY –MPB (202T)

COURSE EDUCATIONAL OUTCOMES (CEO'S):- The student shall be able to

1. Understand the basics of immunology and the immune system.
2. Know the role of cytokines in immune regulation and tolerance.
3. Not types and methods of vaccine production; stem cell technology use in immunology
4. Get knowledge on production , purification and applications of microbial antibiotics in Pharma industry
5. Understand the diseases are the conditions caused by a dysfunction of the immune system and autoimmune diseases.

LEARNING OUTCOMES(LO'S):- The students shall be able to plan / get / know

UNIT 1:-

1. Basic idea of immunology and immune system such as types of immune responses , anatomy of immune response
2. Lymphocytes thymus derived lymphocytes, MHC complex , APC mechanism of phagocytosis.

UNIT 2 :-

1. Immune regulation by cytokines is important to promote responses to infection.
2. Types of hypersensitivity reactions.

UNIT 3:-

1. Types of vaccines and various methods of vaccine production.
2. Stem cell technology application to immunology.

UNIT 4:-

1. Different hybridoma techniques- fusion methods of myeloma cell beta lymphocytes, selection and screening techniques.
2. Production and purification of monoclonal antibodies and their applications unit industry.

UNIT 5:-

1. Immune intervention of diseases.
2. The concepts of immunodiagnostics..

COURSE OUTCOMES(CO'S) :- After completion of the course the students can get knowledge in

1. The basics of immunology and immune system.
2. Immuno regulation and hypersensitivity reactions so that it can access health problems with immunological background.
3. Development of vaccines, production and purification of monoclonal antibodies and their application in Pharma industry.
4. Understand the concept of immunodiagnostics.

COURSE:- BIOINFORMATICS AND AND COMPUTATIONAL BIOTECHNOLOGY - MPB (203T)

COURSE EDUCATIONAL OUTCOMES (CEO's):- The student shall be able to:-

1. Know the basic concepts of bioinformatics, data mining of protein and nucleic acid databases.
2. Get knowledge on sequence alignment for sequence analysis.
3. Understand the protein structure prediction concepts for drug designing.
4. Know how to construct phylogenetic tree and genome annotation technique.
5. Understand target , lead , timeline for drug designing.

LEARNING OUTCOMES(LO's):- The students shall be able to plan / get / know

UNIT 1:- .

1. The basic concepts of bioinformatics, data mining of protein, nucleic acid databases and application of data mining.
2. Collection and storing the sequence.

UNIT 2 :-

1. Various sequence analysis tools.
2. Differentiate sequence alignment techniques such as FAST3 , CLUSTAL W and CLUSTAL X

UNIT 3:-

1. Protein structure prediction suggest protein folding, model generation , significance analysis , scoring techniques, sequence sequence scoring.
2. Docking methods.

UNIT 4:-

1. Genomic analysis , evolution of genomes, protein expression and its regulation in higher organisms.
2. Phylogenetic analysis.

UNIT 5:-

1. Target , lead , timeline, for drug development, drug discovery, target modulators.
2. In silico gene expression, microarray, active site analysis and prediction of drug quality.

COURSE OUTCOMES(CO's) :- After completion of the course the students can get knowledge in

1. Basic concepts for bioinformatics, data mining and data analysis.
2. Protein expression and its regulation in higher organisms.
3. Genomic analysis and bioinformatics approach to analyze protein diversity and drug designing.
4. Cell communication, cell cycle and molecular basis of cancer.

COURSE :- BIOLOGICAL EVALUATION OF DRUG THERAPY – MPB (204T)

COURSE EDUCATIONAL OUTCOMES (CEO'S):- The student shall be able to

1. Learn the general principles and limitations of of biological standardization , preclinical drug evaluation of its biological activity , potency and toxicity.

2. Understand the concepts of pyrogens.
3. Know the biological medicines in development of various disease.
4. Understand the regulatory aspects of drugs , biological and medical devices.
5. Learn the Biological evaluation of drugs in vitro and in Vivo.

LEARNING OUTCOMES(LO'S):- The students shall be able to plan / get / know

UNIT 1 :-

1. Basic principles and limitation of standardization of biologicals.
2. Preclinical drug evaluation of its biological activity , potency and toxicity.

UNIT 2 :-

1. Source , chemistry and properties of bacterial pyrogens , endotoxins , microbial assay of antibiotics , vitamins and drugs.
2. The biological evaluation of drugs in vitro and in Vivo models and cell line study studies.

UNIT 3 :-

1. Biological medicines in development for various diseases by therapeutic category.
2. Biological medicines and development for various diseases by product category.

UNIT 4 :-

1. Regulatory aspects of drugs, biological and medical devices.
2. New drug applications for global Pharmaceutical product approvals.

UNIT 5 :-

1. bioavailability studies of biopharmaceuticals.
2. Pharmacokinetic models, application of pharmacokinetics in new drug development of biopharmaceuticals and designing of dosage forms and ndps of biopharmaceuticals.

COURSE OUTCOMES(CO'S) :- after completion of the course the students can get knowledge in

1. The general concept of standardization of biologicals , preclinical drug evaluation.
2. Concept of pyrogens so that when the biological evaluation of drugs in in vitro and in Vivo.
3. Understand the biological medicines in development of various diseases.
4. Regulation for governing the approval of biological products.

COURSE:- PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL –II (MPB – 205P)

COURSE EDUCATIONAL OUTCOMES (CEO's):- The student shall be able to

1. Learn the isolation and analysis of of biological macromolecules such as proteins and DNA.
2. know how to apply experimental and analytical skills in use of modern biotechnology cal tools and cell culturing.
3. Learn the skill of using microorganisms to analyse antibiotics , vitamins, Pharmaceutical preparations.
4. Analyze and comprehend the immuno diagnostic and pharmacokinetics of biological preparations

LEARNING OUTCOMES(LO's):- The students shall be able to plan / get / know

1. Isolation, identification and characterization of protein.
2. r DNA technology.
3. Protein formulations.
4. Database searching, sequence analysis methods, protein structure prediction.
5. Gene annotation methods, phylogenetic analysis.
6. Preparation of DNA for PCR.
7. PCR, RT- PCR working and programming.
8. Primer design using software, gene DNA amplification by random or specific primers.
9. Western blotting.

COURSE OUTCOMES(CO's) :- after completion of the course the students can get knowledge in

1. Isolation and analysis of biological macromolecules.
2. Applying experimental and analytical skills in use of modern biotechnological tools and cell culturing.
3. Usage of microorganisms to analyze antibiotics, vitamins, Pharmaceutical preparations.
4. Analyse and comprehend the immunodiagnostic and pharmacokinetics of biological preparations.

PHARMACEUTICAL BIOTECHNOLOGY (MPB)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

(Note: Common paper for MPA, MPC, MPH, MPB, MPL, MPG, MQA, & MIP, specializations)

Unit 1:

a. UV-visible spectroscopy: Introduction, theory, laws and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect and applications of UV-visible spectroscopy.

b. IR spectroscopy: Theory, modes of molecular vibrations, sample handling, instrumentation of dispersive and Fourier-Transform IR Spectrometer, factors affecting vibrational frequencies and applications of IR spectroscopy, data interpretation.

c. Spectroflourimetry: Theory of fluorescence, factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), quenchers, instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, instrumentation, interferences and applications. **12 Hours**

Unit 2:

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. **10 Hours**

Unit 3:

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy. 1**0 Hours**

Unit 4:

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

a) Thin Layer chromatography **b)** High Performance Thin Layer Chromatography **c)** Ion exchange chromatography **d)** Column chromatography **e)** Gas chromatography **f)** High Performance Liquid chromatography **g)** Ultra High Performance Liquid chromatography **h)** Affinity chromatography **i)** Gel Chromatography. **14 Hours**

Unit 5:

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

c. Thermal Techniques: Principle, instrumentation, advantage and disadvantages, Pharmaceutical applications of DSC, DTA & TGA.

d. Microscopic techniques: Principles and applications of Scanning Electron Microscopy

and Transmission Electron Microscopy analysis. **14 Hours**

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein. 6th ed. John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler & Timothy A Nieman. 5th ed. Eastern Press, Bangalore, 1998.
3. Instrumental Methods of Analysis – Willards. 7th ed. CBS Publishers, New Delhi.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake. Vol 2. 4th ed. CBS Publishers, New Delhi
5. Organic Spectroscopy - William Kemp. 3rd ed. ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation – P.D. Sethi. 3rd ed. CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B – J.W. Munson. Vol 11. Marcel-Dekker Series.
8. Spectroscopy of Organic Compounds - P.S. Kalsi. 2nd ed. Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis - K.A. Connors. 3rd ed. John Wiley & Sons.

MICROBIAL GENETICS AND CELLULAR BIOLOGY (MPB 102T)

Unit 1:

Microbiology: Introduction – Prokaryotes and eukaryotes. Bacteria, fungi, actionomycetes and virus - structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms - examples and applications. **12 Hours**

Unit 2:

Molecular biology: Structure of nucleus and chromosome, nucleic acids and composition, structure and types of DNA and RNA. Central dogma of molecular biology: Replication, transcription and translation.

Gene regulation, Gene copy number, transcriptional control and translational control.

RNA processing, modification and maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids- types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny. **12 Hours**

Unit 3:

Cell structure and function: Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobics, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – the life and death of cells in tissues.

Cell cycle and cytoskeleton: Cell division and its regulation, G-Protein cCoupled receptors, kinases, nuclear receptors, cytoskeleton & cell movements, intermediate filaments.

Apoptosis and oncogenes

Programmed cell death, tumor cells, carcinogens & repair.

Differentiation and developmental biology: Fertilization, events of fertilization, in vitro fertilization, embryonic germ cells, stem cells and their application. **12 Hours**

Unit 4:

Principles of microbial nutrition: Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. Growth of animal cells in culture. General

procedure for cell culture, nutrient composition, primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In vitro screening techniques-cytotoxicity, anti-tumor, anti-viral assays. **12 Hours**

Unit 5:

Microbial pathology: Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.

12 Hours

REFERENCES

1. Pharmaceutical Microbiology - W.B. Hugo & A.D. Russel. Blackwell Scientific Publications, Oxford London.
2. Industrial Microbiology - Prescott & Dunn. CBS Publishers, New Delhi.
3. Microbiology – Pelczar & Chan Kreig. Tata McGraw Hill.
4. Molecular Biology - David Freifelder. 2nd ed. Narosa Publishing House.
5. Culture of Animal Cells – A Manual of Basic Techniques - R. Ian Freshney. 6th ed. John Wiley & Sons.
6. Molecular Cell Biology - David Baltimore. W.H. Freeman & Co Publishers.
7. Cell biology - Julio E Cells. Vol 1-3.
8. Bergeys Manual of Systematic Bacteriology, Williams and Wilkins - A Waverly Company.

BIOPROCESS ENGINEERING AND TECHNOLOGY (MPB 103T)

Unit 1:

Introduction to fermentation technology: Basic principles of fermentation. Study of the design and operation of bioreactor. Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam.

Types of bioreactor: CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application. Computer control of fermentation process. System configuration and application **12 Hours**

Unit 2:

Mass transfer: Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

Rheology: Rheological properties of fermentation system and their importance in bioprocessing. **12 Hours**

Unit 3:

Scale up of fermentation process: Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization.

Cultivation and immobilized culture system: Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems.

Introduction to immobilization: Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in

the industry. Reactors for immobilized systems and perspective of enzyme engineering.

12 Hours

Unit 4:

Scale down of fermentation process: Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery.

Isolation and screening: Primary and secondary, maintenance of stock culture, strain improvement for increased yield. **12 Hours**

Unit 5:

Bioprocessing of the industrially important microbial metabolites

a) Organic solvents – alcohol and glycerol
b) Organic acids - citric acids, lactic acids,
c) Amino acids - glutamic acids, lysine, cyclic AMP and GMP
d) Antibiotics - penicillin, streptomycin, griseofulvin,
e) Vitamins - B_{12}, riboflavin and vitamin C

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids.

Regulations governing the manufacturing of biological products. **12 Hours**

REFERENCES

1. Principles of Fermentation technology - Peter Stanbury, Allan Whitaker & Stephen Hall. Elsevier.
2. Industrial Microbiology - L.E. Casida. John Wiley & Sons.
3. Current protocols in Molecular Biology - F.M. Asubel. Vol 1 & 2. John Wiley Publishers.
4. Bioreactor Design and Product Yield - Biotol Board. Butterworth and Helhemann Publishers.
5. Industrial Microbiology - H. Patel. Macmillan India Limited.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (MPB 104T)

Unit 1:

Enzyme technology: Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.

12 Hours

Unit 2:

Genetic engineering: Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E. coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNA sequences. Gene library and cDNA

Applications of the above technique in the production of regulatory proteins - interferon, interleukins, blood products - erythropoietin, vaccines - hepatitis-B, hormones – insulin.

12 Hours

Unit 3:

Therapeutic peptides: Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

Transgenic animals: Production of useful proteins in transgenic animals and gene therapy.

Human genome: The human genome project - a brief study. Human chromosome – structure and classification, chromosomal abnormalities – syndromes. **12 Hours**

Unit 4:

Signal transduction: Introduction, cell signalling pathways, ion channels, sensors and effectors, ON and OFF mechanisms, spatial and temporal aspects of signalling, cellular process, development, cell cycle and proliferation, neuronal signalling, cell stress, inflammatory responses and cell death, signalling defects and diseases.

Oncogenes: Introduction, definition, various oncogenes and their proteins. **12 Hours**

Unit 5:

Microbial biotransformation:

Biotransformation for the synthesis of chiral drugs and steroids.

Microbial biodegradation: Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein. Applications of microbes in environmental monitoring.

Biosensors: Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors. **12 Hours**

REFERENCES

1. Biotechnology - The biological principles – M.D. Trevan, S. Boffey, K.H. Goulding & P.F. Stanbury.
2. Immobilization of Cells and Enzymes – Hosevear Kennadycabral & Bicker Staff
3. Principles of Gene Manipulating - R.W. Old & S.B. Primrose.
4. Molecular Cell Biology - Harvey Lodish, David Baltimore, Arnold Berk, S. Lawence Zipursky, Paul Matsudaira & James Darnell.
5. Modern Biotechnology - S.B. Primrose.
6. Gene Transfer and Expression Protocols - Methods in Molecular Biology - E.T. Murray. Vol 7.
7. Current Protocols in Molecular Biology - F.M. Asubel. Vo1 1 & 2. John Wiley Publishers.
8. Current Protocols in Cellular Biology, Vo1 1 & 2. John Wiley Publishers.
9. Principles of Human Genetics - Curt Stern. Published by W.H. Freeman.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I (MPB 105P)

1. Experiments based on HPLC
2. Isolation and purification of microorganism from the soil
3. Microbial contamination of water and biochemical parameters.
4. Determination of minimum inhibitory concentration by gradient plate technique and serial dilution method.
5. UV- survival curve and Dark repair
6. Sterility test for pharmaceutical preparations
7. Sub culturing of cells and cytotoxicity assays.
8. Construction of growth curve and determination of specific growth rate and doubling time
9. Fermentation process of alcohol and wine production

10. Fermentation of vitamins and antibiotics

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - II (MPB 106P)

1. Whole cell immobilization engineering
2. Thermal death kinetics of bacteria
3. Replica plating
4. Bio-autography.
5. Isolation and estimation of DNA
6. Isolation and estimation of RNA
7. Isolation of plasmids
8. Agarose gel electrophoresis.
9. Transformation techniques
10. SDS – polyacrylamide gel electrophoresis for proteins
11. Polymerase chain reaction technique.

Second Semester

PROTEINS AND PROTEIN FORMULATIONS (MPB 201T)

Unit 1:

Protein engineering: Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution. **12 Hours**

Unit 2:

Peptidomimetics: Introduction, classification; Conformationally restricted peptides, design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics. **12 Hours**

Unit 3:

Proteomics: Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, isotope labelling, N- and C-terminal tags.

2-Dimensional gel electrophoresis. Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments **12 Hours**

Unit 4:

Protein formulation: Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre - formulation, liposomes, neon-spears, neon-particulate system, PEGylation, biological activity, biophysical characterization techniques, forced degradation studies of protein. **12 Hours**

Unit 5:

Methods of protein sequencing:

Various methods of protein sequencing, characterisation, Edman degradation, tryptic and/or chymotryptic peptide mapping. **12 Hours**

REFERENCES

1. Molecular Cell Biology - H. Lodhishet Al. W. H. Freeman and Company
2. Protein Purification – Hand Book – Amersham. Pharmacia Biotech
3. Fundamentals of Protein Structure and Function - Engelbert Buxbaum. Springer Science
4. Protein Engineering and Design - Sheldon J Park & Jennifer R Cochran. CRC Press.

5. Protein Purification, Principle and Practice - Robert K Skopes. Springer Link.
6. Proteins-Structure and Function - David Whitford. John Wiley & Sons.
7. Protein Formulation and Delivery - James Swarbrick. Informa Healthcare USA, Inc.
8. Formulation, Characterization, and Stability of Protein Drugs - Rodney Pearlman & Y. John Wan., Kluwer Academic Publishers.

IMMUNOTECHNOLOGY (MPB 202T)

Unit 1:

Fundamental aspects of immunology: Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure. Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity. Humoral immunity. Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies. Cell mediated Immunity. Thymus derived lymphocytes (T cells) – their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis **12 Hours**

Unit 2:

Immune regulation and tolerance: Complement activation and types and their biological functions, cytokines and their role in immune response.

Hypersensitivity: Hypersensitivity Types I-IV, Hypersensitivity reactions and treatment. Autoimmune diseases **12 Hours**

Unit 3:

Vaccine technology: Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics. Stem cell technology applications to immunology. **12 Hours**

Unit 4:

Hybridoma technology: Hybridoma techniques – fusion methods for myeloma cells and B-lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in pharmaceutical industry. **12 Hours**

Unit 5:

Immunological disorder: Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders.

Immunodiagnosis: Antigen antibody interaction – Precipitation reaction, agglutination reactions, principles and applications of ELISA, radio immuno assay, Western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction. **12 Hours**

REFERENCES

1. Immunology – an Introduction - J. Kubey.
2. Immunodiagonstics - S.C. Rastogi. New Age International.
3. Immunology and Immunotechnology - Ashim Chakravarthy. Oxford University Press.
4. Molecular Immunology - E. Benjamini.

BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY (MPB 203T)

Unit 1:

Introduction to bioinformatics: Definition and history of bioinformatics, internet and bioinformatics, introduction to data mining. Applications of data mining to bioinformatics,

biological database. Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and applications of bioinformatics. **12 Hours**

Unit 2:

Sequence analysis: Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTAL W and CLUSTAL X for the multiple sequence alignment. Tools used for sequence analysis. **12 Hours**

Unit 3:

Protein informatics: Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment-methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing.

Protein structure prediction: Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence- sequence scoring.

Docking: Docking problems, methods for protein- ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results. **12 Hours**

Unit 4:

Diversity of genomes: Prokaryotic and eukaryotic gene families. Genome analysis: Introduction, gene prediction methods, gene mapping and applications - genetic and physical mapping, integrated map, sequence assembly and gene expression. Completed genomes: Bacterium, nematode, plant and human

Evolution of genomes, lateral or horizontal transfer among genomes, transcriptome and proteome-general account

Phylogenetic analysis. Evolutionary change in nucleotide sequences, rates and patterns of nucleotide substitution, models for nucleotide substitution, construction of phylogenetic tree, genome annotation technique. **12 Hours**

Unit 5:

Target searching and drug designing: Target and lead, timeline for drug development, target discovery, target modulators, in silico gene expression, microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality. **12 Hours**

REFERENCES

1. Bioinformatics Sequence and Genome Analysis - David W Mount. CBS Publishers, New Delhi.
2. Bioinformatics - Concepts Skill and Applications - S.C. Rastogi, Namata Mendiaratta & Parag Rastogi. CBS Publishers, New Delhi.
3. Protein Structure and Molecular Properties - T.E. Creighton. W.H. Freeman and Company.

4. Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins - Andreas D Baxevanis & B.F. Francis Ouellette. John Wiley & Sons.
5. Introduction to Bioinformatics - Arthur M Lesk. Oxford University Press.
6. Bioinformatics: A Practical Approach - Shui Qing Ye. Chapman & Hall/CRC.
7. Bioinformatics for DNA Sequence Analysis - David Posada. Humana Press.
8. Introduction to Bioinformatics - A.M. Lesk. Oxford University Press.
9. Bioinformatics - S.I. Letovsky. Kluwer Academic Publishers.
10. Bioinformatics - P. Baldi & S. Brunak. The MIT Press.

BIOLOGICAL EVALUATION OF DRUG THERAPY (MPB 204T)

Unit 1:

Biological standardization: General principles, scope and limitation of bio-assay, bioassay of some official drugs.

Preclinical drug evaluation: Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED_{50} and LD_{50} determination, special toxicity test like teratogenecity and mutagenecity.

Guidelines for toxicity studies: Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials. **12 Hours**

Unit 2:

Pyrogens: Sources, chemistry and properties of bacterial pyrogens and endotoxins, official pyrogen tests. Microbiological assay. Assay of antibiotics and vitamins. Biological evaluation of drugs. Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / in vitro models / cell line study). **12 Hours**

Unit 3:

Biologic medicines in development for various diseases - by therapeutic category: genetic disorders, eye related disorders, digestive disorders, diabetes related conditions, cardiovascular disease, cancer related conditions, blood disorders, autoimmune disorders, infectious diseases, neurologic disorders, skin diseases, organ transplantation.

Biologic medicines in development for various diseases by product category: Antisense, vaccines, recombinant hormones/proteins, monoclonal antibodies (MAB), interferons, growth factors, gene therapy, RNA interference. **12 Hours**

Unit 4:

Regulatory aspects of drugs, biologics and medical devices: An introduction to the regulations and documents necessary for approval of a medical product. Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals **12 Hours**

Unit 5:

Bioavailability: Objectives and consideration in bio-availability studies of biopharmaceuticals, concept of equivalents, measurements of bio-availability. Determination of the rate of absorption, bioequivalence and its importance, regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of biopharmaceuticals.

Pharmacokinetics: Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals. **12 Hours**

REFERENCES

1. Standardization and Control of Biologicals Produced by Recombinant DNA Technology - F.T. Perkins & W. Hennessen. International Association of Biological Standardization.
2. Biological Standardization - J.H. Burn. Oxford University Press.
3. Drug Discovery and Evaluation in Pharmacology assay - Vogel
4. Design and Analysis of Animal Studies in Pharmaceutical Development - Chow, Shein & Ching.
5. Animal and Clinical Pharmacologic Techniques in Drug Evaluation - Nodine & Siegler.
6. Screening Methods in Pharmacology - R.A. Turner, Vol 1 & 2.

PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - III (MPB 205P)

1. Protein identification
2. Protein characterization
3. Recombinant DNA technology
4. Protein formulations
5. Database searching
6. Sequence analysis methods
7. Protein structure prediction
8. Gene annotation methods
9. Phylogenetic analysis
10. Preparation of DNA for PCR applications – Isolation, purity and quantification
11. Introduction to PCR – working of PCR, programming
12. Introduction to RT-PCR – working, programming
13. Primer design using software
14. Gene DNA amplification by random / specific primers
15. Western Blotting

Third Semester

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

(Note: Common Paper for all specializations)

Unit 1:

General research methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. **12 Hours**

Unit 2:

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (Wilcoxan rank tests, analysis of variance, correlation, Chi-square test), null hypothesis, P values, degree of freedom, interpretation of P values. **12 Hours**

Unit 3:

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-malfeasance, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality. **12 Hours**

Unit 4:

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals. **12 Hours**

Unit 5:

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care. **12 Hours**

REFERENCES

1. Pharmaceutical Statistics: Practical and Clinical Applications - Stanford Bolton & Charles Bon. 5th ed. CRC Press.
2. Biostatistics: A Foundation for Analysis in the Health Sciences - Wayne W Daniel. 10th ed. John Wiley & Sons.
3. Introduction to Research in the Health Sciences - Stephen Polgar & Shane Thomas. 7th ed. Elsevier.
4. www.cpcsea.nic.in
5. www.wma.net