ADMISSION & EXAMINATION
BYE-LAWS
FOR

MASTER OF PHARMACY
IN
BIOTECHNOLOGY

Program Code: MPB

SCHOOL OF PHARMACEUTICAL EDUCATION AND RESEARCH
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BOS MEETING DETAILS

- **Approval date of the BOS/School Board meeting for the present syllabus:**

Name of the program	Department	Board of School (BOS) Approval Date
M. Pharm	Biotechnology	21.04.2017

- **Approval date of the Academic Council meeting for the present syllabus**

Name of the program	Program Code	Dates of Revision
M. Pharm	MPB	31.05.2017

VISION AND MISSION STATEMENTS

Vision Statement: To create an atmosphere for quality education and research enabling students to excel in drug and drug delivery systems

Mission Statements:

MS 1: To support infrastructure for research through grants and industry academia interaction

MS 2: To provide an environment for the conduct of academic activities required to transform student's calibre.

MS 3: To create a learning environment where the faculty and students can discover, examine, embrace and comprehend technological changes for self-reliance.

MS 4: To strengthen education policies and programs for creating ideals representative of a democratic society.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

After completion of the M. Pharm (Pharmaceutics), the post graduates will be able to:

PEO1: Apply knowledge in solving industry-relevant programs.

PEO2: Carry out quality research in different facets of the program including higher education.

PEO3: Foster abilities to design and fabricate new products or techniques, benefiting the society at large.

PEO4: Combine practical pharmaceutical knowledge and abilities with research ability for a better output.

PEO5: Inculcate entrepreneurial skills in aspiring pharmacy professionals

PEO6: Develop leadership skills to be applied in R&D, production and other facets of the profession

Mapping Program Educational Objectives (PEOs) with Mission Statements (MS)

	MS-1	MS-2	MS-3	MS-4
PEO-1	3	2	3	3
PEO-2	3	3	3	2
PEO-3	3	3	3	3
PEO-4	2	2	3	3
PEO-5	3	3	3	2
PEO-6	3	3	2	3

Level of Mapping: '3' is for 'high-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

PROGRAMME SPECIFIC OUTCOME (PSO)

After completion of the M. Pharm (Pharmaceutics), the post graduates will be able to:

PSO1: Analyse different departments of the pharmaceutical industry like manufacturing, R&D, quality assurance, intellectual property rights and regulatory affairs

PSO2: Design and develop interfaces for entrepreneurship particularly in field of formulation research and development, pharmaceutical production, pharmaceutical consulting services, medicine sales, and distribution.

PSO3: Comprehend knowledge as drug analyst, research scientist, drug inspector and qualified teachers in the public and private organizations.

PROGRAM OUTCOMES (POs)

After going through the two years Master Program in Pharmaceutics, graduates will exhibit the ability to:

PO1: Applied Pharmacy Knowledge: Use knowledge of the fundamental elements in sync with updated technologies, tailored biopharmaceutical application and regulatory requirements pertaining to the development of innovative drug delivery systems.

PO2: Research and development: Utilize skills to create novel medicine delivery strategies for the available range of active therapeutic substances. Good understanding of the computer-based tools required for the product development research.

PO3: Problem analysis: Cultivate the problem solving skills that are generally encountered during pharmaceutical product development, including scale-ups and meeting the expectations of regulation by applying the concept of critical thinking and in-depth analysis.

PO4: Modern tool usage: Use latest product optimization tools along with statistical analysis during the novel product development, like computer aided drug design techniques and *in silico* studies.

PO5: Communication: Prepare quality documents, reports and effective presentation. Hone communication skills and the ability to successfully carry out obligations related to the development of knowledge in accordance with the demands of the academia and industry.

PO6: Professional identity: Create a profession that is dedicated to providing quality services that exceed the stakeholder's expectations like customers, industries, academia, regulatory bodies and to give direction and contribute to the improvement of services and technologies.

PO7: Leadership skills: Organize and execute the objectives related to research and development within a set timeline. Nurturing the skills from the beginning to manage and utilize the available resources judiciously.

PO8: Planning abilities: Implement the knowledge and **s**kills for proper planning and running different steps which are involved in the time bound deliverables like R&D, production, regulatory submissions and product life cycle management.

PO9: Pharmaceutical ethics: Show a high level of morality, honesty and integrity. Implement ethical principles when drawing conclusions and accept responsibility for the repercussions is any.

PO10: Environmental sustainability: Use expertise and skills to solve the issues of environmental pollution, harmful industrial waste, along with wastage and also improve manufacturing processes while maintaining the sustainability practices.

PO11: Life-long learning: Readily engage in independent and ongoing learning processes in response to evolving needs and scientific advances. Using input from other professionals and identifying learning needs for life-long learning improvement. Recognize the importance of conferences, seminars, and workshops in the advancement of knowledge.

Mapping of Program Outcomes (POs) and Program Specific Outcomes (PSOs) with Program Educational Objectives (PEOs)

	PEO-1	**PEO-2**	**PEO-3**	**PEO-4**	**PEO-5**	**PEO-6**
PO-1	3	3	3	2	3	3
PO-2	2	2	3	3	2	3
PO-3	2	3	3	3	2	1
PO-4	3	3	3	2	1	2
PO-5	2	3	3	3	3	3
PO-6	2	3	3	2	3	3
PO-7	2	2	2	3	2	1
PO-8	2	2	3	3	3	3
PO-9	2	2	3	3	3	3
PO-10	3	2	3	3	2	1
PO-11	3	3	3	3	3	3
PSO-1	3	3	3	2	2	3
PSO-2	3	3	3	2	2	3
PSO-3	3	3	3	2	2	3

Level of Mapping: '3' is for 'high-level' mapping, 2 for 'Medium-level' mapping, 1 for 'Low-level' mapping.

CONSOLIDATED SEMESTER WISE PROGRAMME DETAILS

Tables-I: Schemes for internal assessments and end semester examinations semester wise

Semester 1

Course code	**Name of the course**	**Internal Assessment**				**End Semester Exams**		**Total Marks**	**Credit points**
		Continuous mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPB101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100	4
MPB102T	Microbial And Cellular Biology	10	15	1 Hr	25	75	3 Hrs	100	4
MPB103T	Bioprocess Engineering and Technology	10	15	1 Hr	25	75	3 Hrs	100	4
MPB104T	Advanced Pharmaceutical Biotechnology	10	15	1 Hr	25	75	3 Hrs	100	4
MPB105P	Pharmaceutical Biotechnology Practical I	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment	-	-	-	-			100	4
	Total							**650**	**26**

Semester II

Course code	Name of the course	**Internal Assessment**				**End Semester Exams**		**Total Marks**	**Credit points**
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MPB201T	Proteins and Protein Formulation	10	15	1 Hr	25	75	3 Hrs	100	4
MPB202T	Immunotechnology	10	15	1 Hr	25	75	3 Hrs	100	4
MPB203T	Bioinformatics and Computer Technology	10	15	1 Hr	25	75	3 Hrs	100	4
MPB204T	Biological Evaluation of Drug Therapy	10	15	1 Hr	25	75	3 Hrs	100	4
MPB205P	Pharmaceutical Biotechnology Practical II	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment							100	4
	Total							**650**	**26**

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100	4
-	Journal club	-	-	-	25		3 Hrs	25	1
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50		3 Hrs	50	2
-	Research Work	-	-	-	-	350	1 Hrs	350	14
Total								525	21

* Non-University Exam

Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks	Credit points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
-	Journal club	-	-	-	25	-	-	25	1
-	Discussion / Presentation (Proposal Presentation	-	-	-	75	-	-	75	16
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400	3
Total								**500**	**20**

RULES AND REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M. Pharm) Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2016-17. The regulations framed are subject to modifications from time to time by the authorities of the university.

2. Minimum qualification for admission

A Pass in the following examinations

a) B. Pharm Degree examination of an Indian university established by law in India from an institution approved by Pharmacy Council of India and has scored not less than 55 % of the maximum marks (aggregate of 4 years of B. Pharm.)

b) Every student, selected for admission to post graduate 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.

Note: It is mandatory to submit a migration certificate obtained from the respective university where the candidate had passed his/her qualifying degree (B. Pharm.)

3. Duration of the program

The program of study for M. Pharm. shall extend over a period of four semesters (two academic years). The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semester shall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from the month of December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

8 Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course and is obtained by using a multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

9. Minimum credit requirements:

The minimum credit points required for the award of M. Pharm. degree is 95. However, based on the credit points earned by the students under the head of co-curricular activities, a student shall earn a maximum of 100 credit points. These credits are divided into Theory courses, Practical, Seminars, Assignments, Research work, Discussions with the supervisor, Journal club and Co-Curricular activities over the duration of four semesters. The credits 3 are distributed semester-wise as shown in Table 14. Courses generally progress in sequence, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

10. Academic work

A regular record of attendance both 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.

11. Course of study

The course of study for M. Pharm shall include Semester Wise Theory & Practical as given in Table– II-III. The number of hours to be devoted to each theory, and practical course in any semester shall not be less than that shown in Table –II-III

Table II-: Course of study for Semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
MPB101T	Modern Pharmaceutical Analytical Techniques	4	-----	4
MPB102T	Microbial And Cellular Biology	4	-----	4
MPB103T	Bioprocess Engineering and Technology	4	----	4
MPB104T	Advanced Pharmaceutical Biotechnology	4	----	4
MPB105P	Pharmaceutical Biotechnology Practical I	12	----	6
-	Seminar/Assignment	7	----	4
Total		**35**		**26**

Table III-: Course of study for Semester II

Course code	Name of the course	No. of hours	Tutorial	Credit points
MPB201T	Proteins and Protein Formulation	4	-	4
MPB202T	Immunotechnology	4		4
MPB203T	Bioinformatics and Computer Technology	4	-	4
MPB204T	Biological Evaluation of Drug Therapy	4	-	4
MPB205P	Pharmaceutical Biotechnology Practical II	12	-	6
-	Seminar/Assignment	7	-	4
Total		**35**		**26**

Table-IV: Semester wise credits distribution

Semester	Credit Points
I	**26**
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total credit points	Minimum=95 Maximum=10*

* Credit Points for Co-curricular Activities

12. Program Committee

1. The M. Pharm. programme shall have a Programme Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Programme Committee shall be as follows: A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M. Pharm specialization and four student representatives (two from each academic year), nominated by the Head of the institution.

3. Duties of the Programme Committee:

   i. Periodically reviewing the progress of the classes.

   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.

   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

   iv. Communicating its recommendation to the Head of the institution on academic matters.

   v. The Programme Committee shall meet at least twice in a semester preferably at the end of each sessional exam and before the end semester exam.

13. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table IV- VII

End Semester examinations

The End Semester Examinations for each theory and practical course through semesters I to IV shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table IV: Scheme for awarding internal assessment: Continuous mode

Theory	
Criteria	**Maximum Marks**
Attendance (Refer Table – V)	8
Student – Teacher interaction	2
Total	10
Practical	
Attendance (Refer Table – V)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	20

Table V: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	8	10
90 – 94	6	7.5
85 – 89	4	5
80 – 84	2	2.5
Less than 80	0	0

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Pharm.programme if he/she secures at least 50% marks in that particular courseincluding internal assessment.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

Reexamination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table VI. The exact dates of examinations shall be notified from time to time.

Table VI: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and IIsemesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

Letter grades and grade points allocations:

Based on the performances, 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 in Table – VII.

Table VII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

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 obtainedin 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:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4}{C_1 + C_2 + C_3 + C_4}$$

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 ABS grade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO}{C_1 + C_2 + C_3 + C_4}$$

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 statusin case of F grade(s), till the course(s) is/are passed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA

shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4}{C_1 + C_2 + C_3 + C_4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

Declaration of class

The class 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

Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Evaluation of Dissertation Book:

Objective(s) of the work done 50 Marks

Methodology adopted	150 Marks
Results and Discussions	250 Marks
Conclusions and Outcomes	50 Marks
Total	500 Marks

Evaluation of Presentation:

Presentation of work	100 Marks
Communication skills	50 Marks
Question and answer skills	100 Marks
Total	250 Marks

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Pharm program shall not be eligible for award of ranks. Moreover, thecandidates should have completed the M. Pharm program in minimum prescribed number of years, (two years) for the award of Ranks.

Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get freshRegistration.

Revaluation I Re-totaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for retotaling by paying prescribed fee.

Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

SYLLABUS

M.PHARM. SEMESTER I	
Course Code MPB 101T	**Title of the course: Modern Pharmaceutical Analytical Techniques**
Course Code MPB102T	**Title of the course: Microbial And Cellular Biology**
Course Code MPB103T	**Title of the course: Bioprocess Engineering and Technology**
Course Code MPB104T	**Title of the course: Advanced Pharmaceutical Biotechnology**
Course Code MPB105P	**Title of the course: Pharmaceutical Biotechnology Practical I**

Name of the Academic Program: M. Pharm (Pharmaceutical Biotechnology)

Course Code:(MPB 102T)

Title of the Course: MICROBIAL AND CELLULAR BIOLOGY

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply Importance of Microorganisms in Industry **(Cognitive level: Apply)**

CO2: Apply basics of molecular biology **(Cognitive level: Apply)**

CO3: Explain Structure and function of cell and cell communication **(Cognitive level: Apply)**

CO4: Apply mammalian cell culture technique **(Cognitive level: Apply)**

CO5: Describe microbial pathogen and cure for microbial infections **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	2	2	3	1		3		3	2	2	2
CO2	3	3	2	3					2	2	3	3		2
CO3	3	2	2	3	3	2	2		2	2	3	2		2
CO4	3	3	3	2		1			2	2	3	3	2	2
CO5	3	3	3	3	1		3	2	2	2	3	3		2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **THEORY** **60Hrs**

1. Microbiology **12 Hrs**

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

2 Molecular Biology: **12 Hrs**

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.

3 Cell structure and function **12 Hrs**

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. Celljunctions/adhesion and extra cellular matrix, germ cells and fertilization, histology – thelife and death of cells in tissues. Cell Cycle and Cytoskeleton Cell Division and its Regulation, G-Protein Coupled 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 its Application.

4 Principles of microbial nutrition **12 Hrs**

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.

5 Microbial Pathology **12 Hrs**

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.

References:

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.

3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I, II,III by Julio E. Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm (Pharmaceutical Biotechnology)

Course Code: MPB 103T

Title of the Course: BIOPROCESS ENGINEERING AND TECHNOLOGY

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply and design of fermentation technology **(Cognitive level: Apply)**

CO2: Apply Scale up and scale down processing of bioprocess **(Cognitive level: Apply)**

CO3: Apply and analyse bioprocessing of microbial metabolites in pharmaceutical industry **(Cognitive level: Apply)**

CO4: Apply & understand Regulation governing the manufacturing of biological products **(Cognitive level: Apply)**

CO5: Apply & understand fermentation process kinetics **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	3		2	2		3		3	2		2
CO2	3	2	2	3			2		2	2	3	3		3
CO3	3	2	3	3		2			2	2	3	2		2
CO4	3	3	3	2	2	3	3	3	2	2	2	3		2
CO5	3	3	2	3				3	2	2	3	3		3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed syllabus **THEORY** **60 Hrs**

1. Introduction to fermentation technology: **12 Hrs**

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

2 Mass transfer: 12 Hrs

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.

3 Scale up of fermentation process 12 Hrs

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.

4 Scale down of fermentation process 12 Hrs

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 stockculture, strain improvement for increased yield.

5 Bioprocessing of the industrially important microbial metabolites 12 Hrs

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 - B12, Riboflavin and Vitamin C

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids Regulation governing the manufacturing of biological products.

Book suggested for reading

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.

4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.
5. H. Patel, Industrial microbiology, Macmillan India Limited.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm (Pharmaceutical Biotechnology)

Course Code: MPB 104T

Title of the Course: ADVANCED PHARMACEUTICAL BIOTECHNOLOGY

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply latest technology development in biotechnology technique, tools and their uses in drug and vaccine development. **(Cognitive level: Apply)**

CO2: Apply and analyses Identify appropriate sources of enzymes for bio-catalysis purpose **(Cognitive level: Apply)**

CO3: Create genetic engineering techniques in gene manipulation, r DNA technology and gene amplification **(Cognitive level: Apply)**

CO4: Apply & analyses pharmacogenomics **(Cognitive level: Apply)**

CO5: Apply regulatory approval process and key regulatory agencies for new drugs, biologics, devices, and drug-device combinations **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	3	2		2	2	3		3	2		2
CO2	3	3	2	3				2	2	2	3	3	2	3
CO3	3	3	3	3		2	3	2	2	2	3	3		2
CO4	3	2	2	3		2	2	3	2	3	3	3	3	2
CO5	3	3	2	3		2	3	3	2	2	3	3		3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **THEORY** **60Hrs**

1. Enzyme Technology **12 Hrs**

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.

2 Genetic Engineering 12 Hrs

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

3 Therapeutic peptides 12 Hrs

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

4 Signal transduction 12 Hrs

Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

Oncogenes

Introduction, definition, various oncogenes and their proteins.

5 Microbial Biotransformation 12 Hrs

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.

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Book suggested for reading:

1. Biotechnology-The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: Hosevear Kennady Cabral & Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B. Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S Lawence Zipursky, Paul Matsudaira, James Darnell.
5. Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Edit E.T. Murray
6. Current protocols in Molecular Biology, Vo1.I & II: F.M. Asubel, John Wiley Publishers
7. Current protocols in cellular biology, Vo1.1 & II John Wiley publishers.
8. Principles of human genetics; by Curt Stern, Published by W.H. Freeman.

Teaching-Learning Strategies in Brief

The teaching learning strategies, followed are board and chalk teaching, Learning through discussion among the peer group, classroom interaction, discussion of research papers of Journals related to topics, power point presentation, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam. The average marks of two best sessional exams are computed out of 15 marks. Continuous mode evaluation is of 10 marks comprising of attendance- 8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 marks; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks) and Student-Teacher interaction: 2 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks).

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Name of the Academic Program: M. Pharm (Pharmaceutical Biotechnology)

Course Code: MPB 105T

Title of the Course: PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL - I

L-T-P: 0-0-12 **Credits: 6**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply Microorganisms in Industry **(Cognitive level: Apply)**

CO2: Apply molecular biology technique **(Cognitive level: Apply)**

CO3: Apply the Application of protein analysis **(Cognitive level: Apply)**

CO4: Describe & apply different analytical technique **(Cognitive level: Understand)**

CO5: Explain & apply fermentation process **(Cognitive level: Understand)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	2	3	3	2	3	3		3	2	2	2
CO2	3	3	3	3			1	2	2	2	3	3	3	2
CO3	3	2	3	3	2	2		1	2	2	3	2	1	2
CO4	3	3	3	2			2		2	3	3	3	2	3
CO5	3	3	3	3	2	1		2	3	2	3	3	1	2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **12 Hrs/Week**

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Isolation and Purification of microorganism from the soil
8. Microbial contamination of Water and biochemical parameters.
9. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method.
10. UV- survival curve and Dark repair
11. Sterility test for pharmaceutical preparations
12. Sub culturing of cells and cytotoxicity assays.
13. Construction of growth curve and determination of specific growth rate and doubling time
14. Fermentation process of alcohol and wine production
15. Fermentation of vitamins and antibiotics
16. Whole cell immobilization engineering
17. Thermal death kinetics of bacteria
18. Replica plating
19. Bio-autography.
20. Isolation and estimation of DNA
21. Isolation and estimation of RNA
22. Isolation of plasmids
23. Agarose gel electrophoresis.
24. Transformation techniques
25. SDS – polyacrylamide gel electrophoresis for proteins
26. Polymerase chain reaction technique.

Book suggested for reading

Commented [M1]: ????

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.

6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I, II,III by Julio E. Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.
9. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
10. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are chalk-board teaching, learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (50 marks) and End semester examination (100 marks). Internal assessment consists of continuous mode (20 marks) and sessional examinations (30 marks). Continuous mode evaluation is of 10 marks comprising of Attendance- 10 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2.5 mark; 85-89:5 mark; 90-94: 7.5 marks and 95-100: 10 marks) and based on practical records, regular viva voce, etc. -10 marks. There are two Sessional exams (each conducted for 40 marks and computed for 30 marks) and one improvement exam (40 marks and computed for 30 marks). The average marks of two best sessional exams are computed out of 30 marks.

Total Marks are 150 for the subject (Internal Assessment: 50 marks and End Semester Examination: 100 Marks)

M.PHARM. SEMESTER II	
Course Code MPB 201T	**Title of the course: Proteins and Protein Formulation**
Course Code: MPB 202T	**Title of the course: Immunotechnology**
Course Code: MPB 203T	**Title of the course: Bioinformatics and Computer Technology**
Course Code: MPB 204T	**Title of the course: Biological Evaluation of Drug Therapy**
Course Code: MPB 205P	**Title of the course: Pharmaceutical Biotechnology Practical II**
-	**Seminar/Assignment**

Name of the Academic Program: M. Pharm-II Semester (Pharmaceutical Biotechnology)

Course Code: MPB 201T

Title of the Course: PROTEINS AND PROTEIN FORMULATIONS

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply various methods of purification of proteins **(Cognitive level: Apply)**

CO2: Apply and analyse peptides in drug development **(Cognitive level: Apply)**

CO3: Apply and develop protein identification and characterization **(Cognitive level: Apply)**

CO4: Apply and develop protein & peptide-based formulations **(Cognitive level: Apply)**

CO5: Apply and analyse sequencing of proteins and its structure **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	3	2		2	2	3		3	2		2
CO2	3	3	2	3				2	2	2	3	3	2	3
CO3	3	2	3	2		2	2	2	2	2	3	3	3	2
CO4	3	2	2	3		3	3	3	2	3	3	3	3	3
CO5	3	3	3	3	2	2	3	3	2	2	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed syllabus **THEORY** **60 Hrs**

1 Protein engineering **12 Hrs**

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.

2 Peptidomimetics **12 Hrs**

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.

3 Proteomics **12 Hrs**

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

Two-Dimensional gel electrophoresis

Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments

4 Protein formulation **12 Hrs**

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.

5 Methods of protein sequencing **12 Hrs**

Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping.

Book Suggested for Reading

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification – Hand Book, Amersham pharmacia biotech
3. Engelbert Buxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins-Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA, Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are chalk-board teaching, learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). Continuous mode evaluation is of 10 marks comprising of Attendance -8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 mark; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks), Academic activities

Student teacher interaction-2 marks. There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam (30 marks and computed for 15 marks). The average marks of two best sessional exams are computed out of 15 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks)

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Name of the Academic Program: M. Pharm-II Semester (Pharmaceutical Biotechnology)

Course Code: MPB 202T

Title of the Course: IMMUNOTECHNOLOGY

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply techniques like immunodiagnostic procedure **(Cognitive level: Apply)**

CO2: Analyse Characterization of lymphocytes, purification of antigens and antibody. **(Cognitive level: Analyse)**

CO3: Apply & analyse Access health problems with immunological background **(Cognitive level: Apply)**

CO4: Analyse & evaluate immune intervention of diseases **(Cognitive level: Analyse)**

CO5: Develop, crate and evaluate biological products **(Cognitive level: Evaluation)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	3	2		2	2	3		3	2		2
CO2	3	3	2	3				2	2	2	3	3	2	3
CO3	3	2	3	2		3	2	3	3	2	2	3	3	2
CO4	3	2		3		3	3	3	2	3	3	2	3	3
CO5	3	3	3	3	2	2	3	2	3	2	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **Theory** **60 Hrs**

1. Fundamental aspects of immunology 12 Hrs

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

B – 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

2 Immune Regulation and Tolerance 12 Hrs
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

3 Vaccine technology 12 Hrs
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
Stem cell technology and applications to immunology

4 Hybridoma Technology 12 Hrs
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.

5 Immunological Disorder 12 Hrs
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.

Book Suggested for Reading

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

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are chalk-board teaching, learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

Theory

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). Continuous mode evaluation is of 10 marks comprising of Attendance -8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 mark; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks), Academic activities

Student teacher interaction-2 marks. There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam (30 marks and computed for 15 marks). The average marks of two best sessional exams are computed out of 15 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks)

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Name of the Academic Program: M. Pharm-II Semester (Pharmaceutical Biotechnology)

Course Code: MPB 203T

Title of the Course: BIOINFORMATICS AND COMPUTATIONALBIOTECHNOLOGY

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply and Use of computers in developing a new drug **(Cognitive level: Apply)**

CO2: Analyse biological concepts for bioinformatics **(Cognitive level: Apply)**

CO3: Apply Searching the biological databases **(Cognitive level: Apply)**

CO4: Apply & develop drug design **(Cognitive level: Apply)**

CO5: Apply and analyse Target searching to solve biological problem **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	3	2		2	2	3		3	2		2
CO2	3	3	3	3				3	2	2	3	3	2	3
CO3	3	2	2	2	3	3	2	2	3	2	2	3	3	2
CO4	3	2	2			2	2	3	3	3	3	2	3	3
CO5	3	3	3	3	2	2	3	2	2	2	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **THEORY** **60 Hrs**

1. Introduction to Bioinformatics 12 Hrs

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.

2 Sequence analysis 12 Hrs

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.

3 Protein informatics 12 Hrs

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.

4 Diversity of Genomes 12 Hrs

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.

5 Target searching and Drug Designing 12 Hrs

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

Book Suggested for Reading

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics- Concepts Skill and Applications, CBS Publishers and Distributors
3. T. E. Creighton, Protein Structure and Molecular Properties, W. H. Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

Teaching-Learning Strategies in brief

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Assessment methods and weightages in brief

Theory

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). Continuous mode evaluation is of 10 marks comprising of Attendance -8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 mark; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks), Academic activities

Student teacher interaction-2 marks. There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam (30 marks and computed for 15 marks). The average marks of two best sessional exams are computed out of 15 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks)

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Name of the Academic Program: M. Pharm-II Semester (Pharmaceutical Biotechnology)

Course Code: MPB 204T

Title of the Course: BIOLOGICAL EVALUATION OF DRUG THERAPY

L-T-P: 4-0-0 **Credits: 4**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply general concept of standardization of biological. **(Cognitive level: Apply)**

CO2: Analyse importance of transgenic animals and knockout animals. **(Cognitive level: Apply)**

CO3: Apply & Analyse the biological medicines in development of various diseases. **(Cognitive level: Apply)**

CO4: Apply & Develop the biological products including vaccines. **(Cognitive level: Apply)**

CO5: Apply the biological evaluation of drugs *in vitro* and *in vivo* **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	3	2		2	2	3		3	2		2
CO2	3	2	2	2				3	2	2	3	3	2	3
CO3	3	2	2	2	3	2	2	2	2	2	2	3	3	2
CO4	3	3	3			2	2	3	3	3	3	2	3	3
CO5	3	3	3	3	2	2	2	2	2	2	3	3	3	3

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **THEORY** **60 Hrs**

1. Biological Standardization 12 Hrs

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, ED50 and LD50

determination, special toxicity test like teratogenecity and mutagenecity.

Guidelines for toxicity studies

Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.

2 Pyrogens 12 Hrs

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).

3 Biologic Medicines in Development for various diseases - By Therapeutic Category 12 Hrs

- 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
- Organe 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

4 Regulatory aspects: Drugs, biologics and medical devices An introduction to the regulations and documents necessary for approval of a medical product. 12 Hrs

Regulatory consideration

Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and

medical devices.
New Drug Applications for Global Pharmaceutical Product Approvals

5 Bioavailability 12 Hrs

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

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.

Book Suggested for Reading

1. Perkins F.T., Hennessen W. Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in Pharmaceutical development.
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
6. Screening methods in pharmacology (vol I & II), R.A. Turner.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are chalk-board teaching, learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

Theory

There are two components of assessment: Internal assessment (25 marks) and End semester examination (75 marks). Internal assessment consists of continuous mode (10 marks) and sessional examinations (15 marks). Continuous mode evaluation is of 10 marks comprising of Attendance -8 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2 mark; 85-89: 4 marks; 90-94: 6 marks and 95-100: 8 marks), Academic activities

Student teacher interaction-2 marks. There are two Sessional exams (each conducted for 30 marks and computed for 15 marks) and one improvement exam (30 marks and computed for 15 marks). The average marks of two best sessional exams are computed out of 15 marks.

Total Marks are 100 for the subject (Internal Assessment: 25 marks and End Semester Examination: 75 Marks)

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Name of the Academic Program: M. Pharm-II Semester (Pharmaceutical Biotechnology)

Course Code: MPB 205T

Title of the Course: PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL-II

L-T-P: 0-0-12 **Credits: 6**

(L=Lecture hours, T=Tutorial hours, P=Practical hours)

COURSE OUTCOMES (COs)

After completing this Course, the students should be able to:

CO1: Apply the isolation of microbial screening **(Cognitive level: Apply)**

CO2: Apply molecular biology of microbial cells **(Cognitive level: Apply)**

CO3: Apply the Application of drug design & bioinformatic **(Cognitive level: Apply)**

CO4: Describe & apply PCR technique **(Cognitive level: Understand)**

CO5: Apply different industrial bioprocess **(Cognitive level: Apply)**

Mapping of Course Outcomes (COs) with Program Outcomes (POs) and Program Specific Outcomes (PSOs)

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PSO1	PSO2	PSO3
CO1	3	3	3	2	3	2	1	3	3		3	2	3	2
CO2	3	3	3	3	1	3	2		2	2	3	3	2	3
CO3	3	3	2	3		2		1	3	2	3	3		2
CO4	2	3	3	2	2		3		2	3	2	3	1	3
CO5	3	3	3	3	1		1	2	3	2	3	3		2

Each Course Outcome (CO) may be mapped with one or more Program Outcomes (POs). Write '3' in the box for 'High-level'mapping, 2 for 'Medium-level'mapping, 1 for 'Low'-level'mapping.

Detailed Syllabus **12 Hrs/ Week**

1. Protein identification
2. Protein characterization
3. Protein biochemistry
4. Recombinant DNA Technology
5. Protein expression
6. Protein formulations

7. Database searching
8. Sequence analysis methods
9. Protein structure prediction
10. Gene annotation methods
11. Phylogenetic analysis
12. Protein, DNA binding studies
13. Preparation of DNA for PCR applications – Isolation, Purity and Quantification
14. Introduction to PCR – working of PCR, Programming.
15. Introduction to RT-PCR – working, programming.
16. Primer design using softwares.
17. Gene DNA amplification by random / specific primers.
18. Southern Hybridization
19. Western Blotting
20. Gene transformation

References:

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells – A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore,Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol-I, II,III by Julio E. Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.
9. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
10. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.

Teaching-Learning Strategies in brief

The teaching learning strategies, followed are chalk-board teaching, learning through discussion among the peer group, classroom interaction, quiz, presentations, Q & A session and reflective learning.

Assessment methods and weightages in brief

Practical

There are two components of assessment: Internal assessment (50 marks) and End semester examination (100 marks). Internal assessment consists of continuous mode (20 marks) and sessional examinations (30 marks). Continuous mode evaluation is of 10 marks comprising of Attendance- 10 marks (calculated as: Percentage of Attendance: Allotment of marks- Less than 80: 0 marks; 80-84: 2.5 mark; 85-89:5 mark; 90-94: 7.5 marks and 95-100: 10 marks) and based on practical records, regular viva voce, etc. -10 marks. There are two Sessional exams (each conducted for 40 marks and computed for 30 marks) and one improvement exam (40 marks and computed for 30 marks). The average marks of two best sessional exams are computed out of 30 marks.

Total Marks are 150 for the subject (Internal Assessment: 50 marks and End Semester Examination: 100 Marks)

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