MODERN EDUCATION SOCIETY'S
Nowrosjee Wadia College, Pune
(Autonomous)

SYLLABUS OF
M. Sc. BIOTECHNOLOGY (Part-I)

As per National Education Policy 2020, To be implemented from Academic Year 2023-24

Structure and Credit Distribution of PG Biotechnology Degree Program

Vide G.R. No. NEP-2022 /CR No. 09/VISHI-3 / □□□□□□ dated April 20, 2023, the Directive, covering the Credit distribution structure for Four Year UG Honours/ Honours with Research Degree Programme with Multiple Entry and Exit options, was issued. In Continuation of Section 8 of this GR- 'Design of PG Master's Programmes', the Illustrative Table depicting the Credit Distribution for Two Year PG Programme with one Exit Option/ One Year PG Programme is as given below:

Illustrative Credit distribution structure for Two Years/ One Year PG (M.A./M.Sc./M.Com.) and Ph. D. Programme

Year (2 Yr PG)	Level	Sem. (2 Yr)	Major		RM	OJT / FP	RP	Cum. Cr.	Degree
			Mandatory	Electives					
I	6.0	Sem I	12-14 (2*4 +2*2 or 3*4+2)	4	4			20-22	PG Diploma (after 3 Yr Degree)
		Sem II	12-14 (2*4 +2*2 or 3*4+2)	4		4		20-22	
Cum. Cr. For PG Diploma			24-28	8	4	4	-	40-44	
Exit option: PG Diploma (40-44 Credits) after Three Year UG Degree									
II	6.5	Sem III	12-14 (2*4 +2*2 or 3*4+2)	4			4	20-22	PG Degree After 3-Yr UG Or PG Degree after 4-Yr UG
		Sem IV	10-12 (2*4 +2 or 3*4)	4			6	20-22	
Cum. Cr. for 1 Yr PG Degree			22-26	8			10	40-44	
Cum. Cr. for 2 Yr PG Degree			46-54	16	4	4	10	80-88	
2 Years-4 Sem. PG Degree (80-88 credits) after Three Year UG Degree or 1 Year-2 Sem PG Degree (40-44 credits) after Four Year UG Degree									
	8.0		Course Work Min. 12 (3*4)		Training in Teaching / Education/ Pedagogy: 4			16 + Ph. D. Work	Ph.D. in Subject

Abbreviations: Yr.: Year; Sem.: Semester; OJT: On Job Training: Internship/ Apprenticeship; FP: Field projects; RM: Research Methodology; Research Project: RP; Cumulative Credits: Cum. Cr.

(a) With effect from Academic Year 2023-24, Two years Master's Degree Program was be revamped as per the Illustrative Credit Distribution given in the above table.

(b) Credits offered per Semester will be a Minimum of 20 and a Maximum of 22. While minimum credits are mandatory as per National Credit Framework, the Universities can evolve the mechanism for providing Semester/ Level wise credit attainment flexibility within the broad framework.

(c) Under the One-year PG Diploma program, and two-year master's Degree program, the students must complete on-the-job training/internship of 04 credits during summer break, after completion of the second semester of the first year in the respective Major Subject.

(d) The 4 Credits Research Methodology Component is mandatory in the First Year.

(e) Since the Master's Programme is based on DSC Specialization, the PG curricular framework will not include Minor Subject. Electives selected in the PG program may be Relevant to OR Supportive of the Major Subject chosen. The Statutory authorities of the University or Autonomous College can take a decision in this regard.

(f) The students will have to undertake a research project of 4 credits in Semester III and a research project of 6 credits in Semester IV in the second year of the two-year master's degree program. This is also applicable to the students admitted to one one-year PG program after completion of four year UG Program.

(g) Colleges already having permission and recognition for the PG degree programme along with UG degree programme in the same Major shall be automatically allowed to continue PG degree programme in the same Major without undergoing any additional procedures. Similarly, the colleges with approved PG programme and Ph.D. Research Centre in the same Major shall be automatically allowed to continue PG and Ph. D. Degree programme without undergoing any additional procedures.

(h) The exit option at the end of one year of the Master's degree program will commence from AY 2024-25. Students who have joined a two-year Master's degree program may opt for exit at the end of the first year and earn a PG Diploma.

(i) The PG Diploma may be awarded to a student provided they have earned the requisite credits in one year including on-the-job training of 04 credits during summer break, after completion of the second semester of the first year in the respective Major Subject.

(j) The one-year Master's Degree Program will begin with effect from Academic Year 2027-28.

(k) Re-entry to complete the PG degree, after taking the exit option, will be permissible up to 05 years from the date of admission to the PG program.

(l) With regards to the Eligibility criteria and Procedure for admission to the Ph.D. Programme, Duration of the Ph.D. Programme, Eligibility and Allocation of Research Supervisor, Course Work (Credit requirements, number, duration, syllabus, minimum standards for completion), Research Advisory Committee and its Functions, Academic, research, administrative, and infrastructure requirements to be fulfilled by Colleges for getting recognition for offering Ph.D. Programme, Award of Ph. D. Degree etc, the Universities and Autonomous Colleges must comply with UGC (Minimum Standards and Procedure for Award of Ph.D. Degree) Regulations, 2022, dated Nov. 7, 2022.

(m) The University and Autonomous College must adopt this GR within 10 days after its issue .

PREAMBLE OF THE COURSE:

Biotechnology has grown, extensively in last two of decades. This advanced 'interdisciplinary' life science branch encompasses areas viz. molecular biology, genetics, biochemistry, microbiology, immunology, virology, plant and animal tissue culture, chemistry, and engineering. It is a fast emerging "cutting edge" science with distinctive advantages as it finds applications in practically all aspects of life. The subject offers exciting opportunities in various fields from basic research to industry-oriented career. Global and local focus has slowly shifted to using knowledge of life Science for innovative technology development that is being used for betterment of human life. Many fundamental research fields from cell biology to molecular biology, from genetic engineering to stem cell research, from bioinformatics to genomics-proteomics, from environmental biology and to biodiversity, from microbiology to bioprocess engineering, from bioremediation to drug discovery etc. comes under the umbrella of Biotechnology.

The proposed choice-based credit curriculum and grading system will cater to the existing interdisciplinary nature of biotechnology and can also offer many courses to the other branches of life science. The generative power of biological data is effectively harnessed by biotechnology like no other field. Economic and social renaissance is staged on biotechnology especially, since its biomedical and cutting-edge technological applications are tremendously powerful in shaping this century and exciting bio future. Keeping in view the expanse and applications of Biotechnology in every field, there is going to be a perpetual demand for resource personnel with Biotechnology specialization. The postgraduate program is aimed to cater to this ever-increasing demand and to groom the students to excel in their future career. Education and research sectors require such an interdisciplinary trained workforce to develop future generations of science leaders.

Introduction:

Masters in Biotechnology course syllabus is revised as per NEP guidelines 2020 to offer the needs of changing scenarios in biological science. The changing scenario of higher education in India and abroad is

taken into consideration while formulating this syllabus and more oriented towards the current need of modern research and industrial sectors. The present syllabus is as per National Education Policy 2020, which encompasses the fundamental academics at one end and latest technologies in life science at the other. Theory courses will help students develop their knowledge sets on various topics of biotechnology, to which, they are introduced at the undergraduate level. Extensive practical courses are designed to supplement the theory courses with hands on experimentation in wet-lab and on fields. Empowerment of students to face research and industrial outlets is at the center of this syllabus. Students having to select their own courses will develop the depth in specialization and make them ready to face the upcoming scientific advances in the world without any further training. M.Sc. syllabus has been prepared keeping in vision the undergraduate curriculum. At the undergraduate level, students were introduced to many fundamental topics in life sciences such as molecular biology, developmental biology, fermentation technology, biodiversity, bioinformatics, and tissue culture etc. At the post graduate level, they will be also be acquainted with the thrust/new areas of biotechnology like bioinformatics, clinical research, data base management, IPR, Food Technology etc. to give the students the advantage of not only learning these subjects but also give them the edge over others in their employability. A research project/ industrial training

Modules are incorporated to provide a buffer zone for budding biotechnologists eager to enter the life science sector.

Objectives:

To help the students to build interdisciplinary approach

To empower students to excel in various research fields of Life Sciences

To inculcate sense of scientific responsibilities for social and environment awareness.

To acquaint the students with thrust areas of biotechnology

To adapt the internationally acknowledged Choice Based Credit System (CBCS) that offers opportunities to learn core subjects and to explore additional avenues of learning beyond the core subjects for complete development of an individual.

Eligibility for the course M.Sc. Biotechnology.

Any candidate completed B.Sc. in Biotechnology from any recognized university.

Examination pattern

70 Marks for end semester examination and 30 marks for continuous evaluation pattern

35 Marks for External Practical examination and 15 Marks for Internal practical examination

Passing marks

Passing marks will be 40 % in each paper of continuous evaluation and end semester exam separately.

Procedure for continuous evaluation

Written test	20 marks
Assignment	5 Marks
Seminar/ attendance	5 Marks
	30 Marks

Nature of question paper for End semester examination

Que. No.	Type	Max marks
1	2 marks x 7 questions (Any 6)	12
2	4 marks x 4 questions (Any 3)	12
3	5 marks x 4 questions (Any 3)	15
4	5 marks x 4 questions (Any 3) Short notes type	15
5	8 marks x 3 questions (Any 2)	16
	Total	70 marks

Revaluation

There shall be a revaluation of answer scripts of end semester examination (out of 70 marks) of theory papers only, but not of internal or continuous evaluation papers as per Ordnance no. 134 A and B

Grading system

Percentage	Grade	Grade Point
80-100	O: Outstanding	10
70-79	A+: Excellent	9
60-69	A: Very Good	8
55-59	B+: Good	7
50-54	B: Above average	6
45-49	C: Average	5
40-44	P: Pass	4
0-39	F: Fail	0
-	Ab: Absent	0

Course structure semester I (M.Sc. Part -1)

Course Type	Course	Course / Paper Title	Hours / Week	Credit	CIA	ESE	Total
Major Mandatory (4 + 2)	Major Paper 1 (Theory)	**PBTMJ111** Advanced Biological Chemistry	2	4	30	70	100
	Major Paper 2 (Theory)	**PBTMJ112** Genetics and Molecular Biology	2	4	30	70	100
	Major Paper 3 (Practical)	**PBTMJ113** Practicals in Advanced Biological Chemistry	4	2	15	35	50
	Major Paper 4 (Practical)	**PBTMJ114** Practicals in Genetics and Molecular Biology	4	2	15	35	50
Major Electives	Major Paper 5(A) (Theory)	**PBTMJ115(A)** Biostatistics OR	2	4	30	70	100
	Major Paper (B) (Theory)	**PBTMJ115(B)** Food Biotechnology	2	4	30	70	100
	Research Methodology	**PBTRM116** Research methodology	2	4	30	70	100
	OJT / FP	NA	--	--	--	--	--
	RP	NA	--	--	--	--	--
Total Credits				20			

CIA- Continuous Internal assessment
ESE- End Semester Examination

Course structure semester II (M.Sc. Part -1)

Course Type	Course	Course / Paper Title	Hours / Week	Credit	CIA	ESE	Total
Major Mandatory (4 + 2)	Major Paper 6 (Theory)	**PBTMJ121** Recombinant DNA Technology	2	4	30	70	100
	Major Paper 7 (Theory)	**PBTMJ122** Biophysics	2	4	30	70	100
	Major Paper 8 (Practical)	**PBTMJ123** Practicals in Recombinant DNA Technology	4	2	15	35	50
	Major Paper 9 (Practical)	**PBTMJ124** Practicals in Biophysics	4	2	15	35	50
Major Electives	Major Paper 10(A) (Theory)	**PBTMJ125(A)** Intellectual Property Right and Bioethics	2	4	30	70	100
	Major Paper 10(B) (Theory)	OR **PBTMJ125(B)** Pharmaceutical Biotechnology	2	4	30	70	100
	Research Methodology	NA	--	--	--	--	--
	OJT / FP	**PBTOJT126 /PBTFP126** On the Job training /field project*	120	4	30	70	100
	RP	NA	--	--	--	--	--
Total Credits				20			

On the job training/field project* Internship/project/hands-on training in any recognized research institute for 120 hours

CIA- Continuous Internal assessment

ESE- End Semester Examination

Course structure semester III (M.Sc. Part -2)

Course Type	Course	Course / Paper Title	Hours / Week	Credit	CIA	ESE	Total
Major Mandatory (4 + 2)	Major Paper 11 (Theory)	**PBTMJ231** Plant and Animal Biotechnology	2	4	30	70	100
	Major Paper 12 (Theory)	**PBTMJ232** Immunology	2	4	30	70	100
	Major Paper13 (Practical)	**PBTMJ233** Practicals in plant and Animal Biotechnology	4	2	15	35	50
	Major Paper 14 (Practical)	**PBTMJ-234** Practicals in Immunology	4	2	15	35	50
Major Electives	Major Paper 15(A) (Theory)	**PBTMJ235(A)** Genomics and Proteomics	2	4	30	70	100
	Major Paper 15(B) (Theory)	OR **PBTMJ235 (B)** Nano biotechnology	2	4	30	70	100
	Research Methodology	NA	--	--	--	--	--
	OJT / FP	NA	--	--	--	--	--
	RP	**PBTRP236** Research project	120	4	3	70	100
Total Credits				20			

Research project* hands on training/Wet lab work in any recognized research /academic institute for 120 contact hours

CIA- Continuous Internal assessment

ESE- End Semester Examination

Course structure semester IV (M.Sc. Part -2)

Course Type	Course	Course / Paper Title	Hours / Week	Credit	CIA	ESE	Total
Major Mandatory (4 + 2)	Major Paper 16 (Theory)	**PBTMJ241** Bioinformatics	2	4	30	70	100
	Major Paper 17 (Theory)	**PBTMJ242** Bioprocess Engineering	2	4	30	70	100
	Major Paper 18 (Practical)	**PBTMJ243** Practical in Bioinformatics and Bioprocess Engineering	4	2	15	35	50
Major Electives	Major Paper 19(A) (Theory)	**PBTMJ244(A)** Medical and Forensic Biotechnology	2	4	30	70	100
	Major Paper 19(B) (Theory)	OR **PBTMJ244(B)** Virology and Toxicology	2	4	30	70	100
	Research Methodology	NA	--	--	--	--	--
	OJT / FP	NA	--	--	--	--	--
	RP	**PBTRP245** Research project	180	6	45	105	150
Total Credits				20			

Research project*hands on training/Wet lab work in any recognized research /Academic institute for 180 contact hours

CIA- Continuous Internal assessment

ESE- End Semester Examination

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SEMESTER –I Major Paper 1 (Theory)

Year – I	**Paper No- PBTMJ111**	**Credits 4**
Semester - I	**Name of Paper-Advanced Biological Chemistry**	**Hours 60**

Course Outcomes (COs)
On completion of the course, the students will be able to:

- Recognize the structural levels of organization of proteins, 3D structures of proteins, its functions.
- Illustrate the metabolism of carbohydrates through various anabolic and catabolic pathways like glycolysis, Krebs's cycle, Glycogen metabolism, etc.
- Describe structure, functions, and the mechanism of action of enzymes. Learning kinetics of enzyme catalyzed reactions and enzyme inhibitions and regulatory process, Enzyme activity, Enzyme Units, Specific activity.

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit-I	**Protein Chemistry:** • Structure of Proteins: Primary, Secondary, Tertiary, quaternary. Conformation of proteins (Ramachandran plot, secondary structure, domains, motif and fold) • Structure-function relationships in model proteins like ribonuclease A, myoglobin, hemoglobin, chymotrypsin etc.	7
Unit -II	**Protein folding mechanisms, Interaction, Therapeutic protein**: • Protein folding mechanisms and Pathways Factors affecting stability- Molten globule, energy funnel, chaperons. • Protein misfolding and diseases • Protein –protein interaction and protein –DNA interaction • Structure –function relationship • Protein Engineering and its applications • Peptides and Therapeutic Proteins	10

Unit -III	**Enzymes:** • Enzyme – Concept of active site, binding sites, Stereospecificity of enzyme and ES complex formation • Enzyme Activity, Various factors influencing enzyme activity and Enzyme inhibition and its kinetics. • Mechanism of enzyme action and Enzyme regulation Multienzyme complexes	12
Unit -IV	**Enzyme kinetics and Biosensors** • Enzyme kinetics, Rate of reactions, steady state enzyme kinetics, Michaelis-Menten Equation - form and derivation. Significance of Vmax and Km, K/cat. Bisubstrate reactions. Graphical procedures in enzymology. Lineweaver Burk's Plot, Eadiee Hofstee plot, Hanes plot. Biosensors (glucose oxidase, Cholesterol Oxidase),	8
Unit -V	**Metabolomics:** • Glycolytic pathway; Kreb's cycle; Oxidative phosphorylation; Photosynthesis, Gluconeogenesis. • Metabolism of vitamins, Glycogen, Mineral (calcium, iron) Glyoxylatecycle.	8
Unit-VI	**Phytochemistry:** • Introduction to secondary Metabolism, • primary metabolitesas precursors of secondary Metabolite • Pathways for secondary metabolite • Mevalonate pathways • Shikimate Pathway • Isoprene UnitPathways (IPP)	8
Unit -VII	**Study of secondary Metabolite** • Alkaloids • Phenolics • Terpenoids Extraction methods & Qualitative & Quantitative Analysis	7

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SEMESTER –I Major Paper 2 (Theory)

Year – I	**Paper No- PBTMJ112**	**Credits 4**
Semester - I	**Name of Paper- Genetics and Molecular Biology**	**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

- Describe the fundamentals of genetics along with basis of heredity
- Concept of sex determination and sex linked inheritance
- Karyotyping and pedigree analysis of family
- Concept of Gene pool and frequency
- The course has been devised to familiarize students with Molecular Biology which chiefly deals with interactions among various systems of the cell, including those between DNA, RNA and proteins and learning how these are regulated
- To gain an understanding of chemical and molecular processes that occurs in and between cells.
- To acquire insight into the most significant molecular and cell-based methods used today to expandour understanding of biology. Will be able to design and implement experimental procedures using relevant techniques

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Genetic interactions** • Mendels experiment, Mendel's laws, Incomplete dominance,codominance, epistasis, Multiple allelism, , penetrance and expressivity, Pleiotropy, Phenocopies, • Maternal inheritance (mitochondria and chloroplast} • Dosage compensation in mammals and drosophila • Linkage, crossing over, map distance • Tetrad analysis	**8**
Unit -II	**Human Genetics** • Structure and function of human chromosome: Ultrastructure of the human chromosome, • Classification of chromosomes, Sex chromosome, • Inheritance of X-linked gene, examples of X-linked genes • Inheritance of Y-linked gene • Human chromosomal Abnormalities: syndromes • Pedigree analysis in human with example • Diagnostics: Prenatal diagnosis • Karyotype analysis, FISH, Genetic counselling	**7**

Unit -III	**Transposable genetic elements** • Mode of discovery, Characteristics, Types Simple transposons and Complex transposons	**07**
Unit -IV	**Population genetics:** • Populations, Gene pool, Gene frequency; • Hardy-Weinberg Law, concepts • rate of change in gene frequency through natural selection, migration and random genetic drift • Adaptive radiation; Isolating mechanisms; Speciation; Allopatricity and Sympatricity; Convergent evolution; Sexualselection; Co-evolution.	**08**
Unit -V	**Information flow in Biological Systems:** • Nucleic acids - DNA and RNA structure and functions • Physical Properties of ds DNA (UV absorption spectra Denaturation and renaturation) • Kinetics of unwinding of the double helix, Interaction with small ions. • FLP/FRT and CRE/LOX recombination **Genome Structure and Gene family:** ● Chromatin organization and remodeling, chromosome, centromere, telomere. ● Gene families, clusters, Pseudo genes, super-families ● Organelle genomes. C-value paradox and genome size, Cot curves, repetitive and non-repetitive DNA sequences, Cot ½ and Rot ½ values, satellite DNA, DNA melting, and buoyant density.	**7**
Unit - VI	**DNA Topology:** ● DNA supercoiling, a Supercoiled form of DNA, Super helical density, Energetic of supercoiled DNA, Biology of supercoiled DNA (Topological domain of DNA, DNA topoisomerases, Mechanisms of supercoiling in cells, mechanisms of action of topoisomerase I and II, the effect of supercoiling on structure of DNA and role of supercoiling in gene expression and DNA replication) ● Organization of DNA into chromosomes: Packaging of DNA and organization of chromosomes in bacteria and eukaryotic cells; packaging of DNA in eukaryotic nucleosome and chromatin condensation assembly of nucleosomes upon replication. ● Chromatin modification and genome expression.	8

Unit -VII	**Gene Expression in Prokaryotes and Eukaryotes** **Mechanism of Transcription** ● Mechanism of transcription and regulation function of bacterial RNA polymerases. Eukaryotic RNA polymerases- transcription factors, mechanism of transcription, and regulation. ● Mutations, proto-oncogenes, oncogenes and tumor suppressor genes, physical, chemical, and biological mutagens. ● Types of mutations; intra-genic and inter-genic suppression; transpositions- transposable genetic elements in prokaryotes and eukaryotes, role of transposons in the genome. ● Viral and cellular oncogenes; tumor suppressor genes; structure, function, and mechanism of action. ● Activation and suppression of tumor suppressor genes; oncogenes as transcriptional	8
Unit -VIII	**Regulation of Gene expression in prokaryotes and eukaryotes** ● Positive and negative regulation. Lac-, ara-, his- and trp-operonregulation; anti-termination, global regulatory responses; Regulation of gene expression in eukaryotes: Transcriptional, translational, and processing level control mechanisms. **DNA- transposable elements-** ● Types of transposable elements, and its importance in variation and evolution. The possible origin of virus, Oncogenes. ● Transposable elements in bacteria ● Transposable elements of Eukaryotes: Maize, Drosophila andYeast. SINES and LINES, retrotransposons	7

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SEMESTER –I Major Paper 3 (Practical)

Year – I	**Paper No- PBTMJ113**	**Credits 4**
Semester - I	**Name of Paper- Practicals in Advanced Biological Chemistry**	**Hours 60**

Course Outcomes (COs)
On completion of the course, the students will be able to:

- Isolate and precipitate proteins
- Purification of enzymes using various methods
- To gain the knowledge of enzyme kinetics
- Concept of ELISA technique

Sr. No.	COURSE CONTENT / SYLLABUS	No. of Practicals
1	• Extraction, purification, and characterization of protein: • Beta-galactosidase • Extraction and assay of enzyme activity • Isolation, precipitation, and Dialysis • Enzyme Purification by using Column Chromatography- Ion exchange/ Gel filtration • Characterization by Native / SDS PAGE	6
2	**Study of Enzyme Kinetics of beta Galactosidase:** • Effect of substrate concentrations on the rate of enzymatic reaction • Line Weaver Burk double reciprocal plot. • Determination of Km, Vmax, and Kcat.	3
3	Extraction and Qualitative/Quantitative estimation of phytoconstituents Double	1
4	diffusion, Immuno-electrophoresis, Radial immunodiffusion and Rocket Immunoelectrophoresis	2
5	Complement fixation test	1
6	Antibody titer by ELISA method	1
7	Immunoblotting, Dot blot assays	1

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SEMESTER –I Major Paper 4 (Practical)

Year – I	**Paper No- PBTMJ114**	**Credits 4**
Semester - I	**Name of Paper- Practicals in Genetics & Molecular Biology**	**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

- Describe the fundamentals of Genetics, Mendelian laws, and linkage maps
- Study mutagenesis and its genetic effects
- Elaborate karyotype of humans along with disorders
- Restriction mapping
- Amplify Genome
- Gain knowledge on different PCR machines
- Do the extraction of DNA from different sources

Sr. No.	COURSE CONTENT / SYLLABUS	No. of Practicals
1	Problem set on Mendel laws, Non-Mendel laws, Linkage, Three Point test cross	2
2	Preparation of Karyotypes, Determination of Mitotic index.	1
3	Induction of mutation studies in the model system by Chemical /Physical Mutagens	2
4	Study of Sex-Linked Inheritance in Drosophila	1
5	Problem set on Hardy-Weinberg Equilibrium	1
6	Extraction of Genomic DNA from Plant tissue, Animal tissue	2
7	Demonstration of PCR/ Gradient PCR using suitable genes	1
8	Restriction digestion of DNA using suitable RE and resolution on agarose gel	1
9	Analysis of DNA preparations by UV spectrometry and agarose gel electrophoresis	2

10	Quantification of DNA by Spectrophotometric Assay and Melting Temperature (Tm)	2
11	Isolation of RNA and analysis by agarose gel	2
12	Staining of animal cells (Histone by Fast green; DNA by Feulgen; RNA by Methyl green Pyronin).	2

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SEMESTER –I Major Paper 5(A) (Theory)		
Year – I	**Paper No- PBTMJ115(A)** **Name of Paper- Biostatistics**	**Credits 4**
Semester - I		**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

1. Know the statistical analysis of biological data
2. Gain a good understanding of descriptive statistics and graphical tools.
3. Gain a good understanding of measures of correlations
4. know the various data presentation models

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Introduction:** ● Biological variables, and parameters of statistical data display. ● Types of scales: linear, power, log, circular ● Curves and Equations: Linear, saturating, sigmoid, exponential, logistic, power, multinomial, algebraic, differential, partial differential ● Types of variables; Independent and dependent variables; Nominal, Ordinal, ratio, and discrete variable types	7
Unit -II	**Probability distribution definition and applications:** ● Binominal distribution, Poisson distribution, Normal distribution, logic of statistical standard error estimation testing of hypothesis. ● Tests of significance: Null hypothesis, alternative hypothesis, type I error, type II error, level of significance, and power of test.	8
Unit -III	**Types of data:** ● Bivariate data: Definition, scatter diagram, Karl Pearson's coefficient of correlation. Spearman's rank correlation coefficient. Principle of least squares and fitting of polynomials and exponential curves. Linear regression. Partial and multiple correlation (3 variables only). ● Univariate data	7

Unit -IV	**Sampling distribution:** ● Sampling distribution ● difference between parametric and non-parametric statistics ● Chi-square test, t-test, ANOVA, univariate and multivariate analysis, with examples	8
Unit -V	**Presentation of statistical data:** ● tabulation (simple tables, frequency distribution table); ● Charts and diagrams (bar charts, histograms, pie charts,dendrogram). **Types of data presentation:** ● Textual ● Tubular ● Diagrammatic	7
Unit -VI	**The measure of central tendency:** ● Definition ● Mean with problems ● Median with problems ● Mode with problems ● Standard deviation with problems ● Interpretation of Confidence Interval ● Correlation concept and applications, Spearman's rank correlation	8
Unit -VII	**Sampling:** ● Sampling methods; ● Types of sampling; ● Random sampling, ● Probability and non-probability sampling, ● Stratified sampling, etc.	7
Unit -VIII	Data presentation models; ● Covariance models, ● Spatial statistical model, ● Multivariate spatial model, ● Gaussian and non-gaussian random process models	8

References:

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2. Biostatistics: A foundation for analysis 7th Edition, Ferric Darvas
3. Applied statistical designs for the researcher, Neil Ed Taylor, and Francis Group
4. Mount David W. Bioinformatics: Sequence and Genome Analysis. Publisher: Cold Spring Harbor Laboratory Press; Latest Edition
5. Baxevanis Andreas D. Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins, Latest Edition. Publisher: New York, John Wiley & Sons, Inc.
6. Teresa Attwood, Parry-Smith David J. Introduction to Bioinformatics. Publisher: Pearson Education (Singapore) Pte.Ltd., Latest Edition

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MODERN EDUCATION SOCIETY'S

Nowrosjee Wadia College, Pune (Autonomous) NEP

Master of Science in Biotechnology

SEMESTER –I Major Paper 5 (B) (Theory)

Year – I	**Paper No- PBTMJ115(B)** **Name of Paper- Food Biotechnology**	**Credits 4**
Semester - I		**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

- Learn the importance of Food Hygiene maintained in food handling and processing.
- Detailed knowledge about fermentation, fermentation steps, and Organisms used in fermentation.
- To gain the role of nutraceuticals, prebiotics, and probiotics in the improvement of HealthScience

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Microbes in Food Spoilage & Control** • Types of micro-organisms normally associated with food- mold, yeast, and bacteria, Microbial growth pattern, physical and chemical factors, influencing the destruction of micro-organisms. • Micro-organisms in natural food products and their control. Biochemical changes are caused by micro-organisms, deterioration, and spoilage of various types of food products. • Food poisoning and microbial toxins, standards for different foods. Foodborne intoxicants and mycotoxins. **Symbiotics** • Benefits factor affecting symbiotics consumption • Health benefits of symbiotics • Therapeutic effects of symbiotics	8
Unit -II	**Microbial Biotechnology** • Genetically modified microorganisms -Social and ethical issues Genetic engineering Appraisal Committee • Fermentation Technology- Use of microbes in the production of alcohols (Beer, Wine), bread, Yogurt, Organic acids (Acetic acid, Lactic acid, Citric acid), Vitamins • Pigments, Flavors, sweeteners Applications of Biotechnology in food waste management and development of value-added products **Dairy Microbiology** • Microbial flora of milk • Processing and analysis of milk • Milk product with names of organism • Types of milk	10

Unit -III	**Nano-biotechnology** • Use of nanoparticles for delivery of bioactive constituents, Nanoencapsulation, Nano packaging, a n d Nanosensors for detection of pesticides & pathogens • Applications of Nutrigenomics in the food industry • Ethical Concerns, Safety, and Regulatory Issues of biotechnological products
Unit -IV	**Prebiotics and Probiotics -Difference** • Food Sources- Prebiotics [Dietary fiber, Oligosaccharides (Galactooligosaccharides, Fructo-oligosaccharides), Resistant Starch, Sugar alcohols], • Traditional Fermented Foods as sources of ProbioticsStrains of microorganisms used as probiotics • Role in Health and Disease, Mechanism of Action, Levels ofProbiotics required for therapeutic efficacy
Unit -V	**Nutraceuticals** • Concept of Nutraceuticals and functional foods • Major nutraceuticals and their health applications- Bioactive peptides, Curcumin, Conjugated Linoleic acid, Glucosamine, Carnitine, Creatine • Safety and adverse effects associated with the consumption of functional foods and nutraceuticals • Recent trends in food formulation; antioxidant-rich food products; concepts for formulation of foods for drought and disaster afflicted; defense services, sportsmen, space food
Unit -VI	**Role of QC and QA Quality**: • Quality Control, Quality Assurance, Concepts of Quality Control, and quality assurancefunctions in food industries. • **Quality Improvement** Total Quality management: Quality evolution, quality gurus, defining TQM, principals of TQM, stages in implementation, TQM road map. Quality improvement tools, customer focus, cost of quality **Food Packaging** • History • Functions and types of food packaging • Packing machine • Concept of sustainable packaging
Unit -VII	**Food Laws** • Food Laws and Standards: National and International foodlaws, Mandatory and voluntary food laws. **FSSAI** • Indian Food Regulations and Certifications: Food Safety and Standards Act, FSSAI Rules, food adulteration, misbranding, common adulterants in foods, Duties and responsibilities of Food Safety Authorities

Reference books:

1. Anthony Pometto (2005). Food Biotechnology, 2nd Edition. CRC Press
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3. Goldberg, I 1994. Functional Foods: Designer Foods, Pharma foods, Nutraceuticals Chapman & Hall
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5. Aluko, R.E. (2012). Functional Foods and Nutraceuticals. Springer
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MODERN EDUCATION SOCIETY'S
Nowrosjee Wadia College, Pune (Autonomous) NEP

Master of Science in Biotechnology

SEMESTER –I Major Paper (Theory)

Year – I	**Paper No- PBTRM116**	**Credits 4**
Semester - I	**Name of Paper- Research Methodology**	**Hours 60**

Course Outcomes (COs)
On completion of the course, the students will be able to:

- Develop critical thinking and analytical skills: By studying research methodology, students will learn how to critically analyze research studies and methodologies used in various disciplines.
- Acquire practical research skills: Research methodology syllabus equips students with practical research skills necessary for designing, planning, and conducting research studies
- Foster ethical research practices: The research methodology syllabus emphasizes the importance of ethical considerations in research. Students will learn about ethical guidelines and principles governing research involving human subjects, privacy and confidentiality issues, informed consent, and responsible research conduct.

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Basic concept of research methodology** • Definition – History – Evolution of Scientific Inquiry, Scientific Research: • Definition, Characteristics, types, needs of research. • Identification of the problem, assessing the status of the problem, formulating the objectives, preparing design (experimental or otherwise), Actual investigation.	5
Unit -II	**Introduction to Research Methodology** • Meaning and importance of Research – Types of Research – Selection and formulation of Research Problem • Research Design – Need – Features – Inductive, Deductive and Development of models • Developing a Research Plan – Exploration, Description, Diagnosis, Experimentation, Determining Experimental and Sample Designs. • Analysis of Literature Review – Primary and Secondary Sources, Web sources –critical Literature Review	15

	• Hypothesis – Different Types – Significance – Development of Working Hypothesis, Null hypothesis • Research Methods: Scientific method vs. Arbitrary Method, Logical Scientific Methods: Deductive, Inductive, Deductive-Inductive, pattern of Deductive – Inductive logical process – Different types of inductive logical methods.	
Unit -III	**Data Collection and Analysis of data** • Sources of Data – Primary, Secondary and Teritary – Types of Data – Categorical, nominal & Ordinal. • Methods of Collecting Data : Observation, field investigations, Direct studies Reports, Records or Experimental observations • Sampling methods – Data Processing and Analysis strategies- Graphical representation – Descriptive Analysis – Inferential Analysis- Correlation analysis • Least square method - Data Analysis using statistical package – Hypothesis • testing – Generalization and Interpretation – Modeling.	15
Unit -IV	**Scientific Writing** • Structure and components of Scientific Reports – types of Report – Technical Reports and Thesis – Significance – Different steps in the preparation – Layout, structure and Language of typical reports - Illustrations and tables – Bibliography, Referencing and foot notes –Importance of Effective Communication. • Preparing Research papers for journals, Seminars and Conferences – Design of paper using TEMPLATE, Calculations of Impact factor of a journal, citation Index, ISBN & ISSN. • Preparation of Project Proposal - Title, Abstract, Introduction – Rationale, • Objectives, Methodology – Time frame and work plan – Budget and Justification • References • Documentation and scientific writing Results and Conclusions, Preparation of manuscript for Publication of Research paper, Presenting a paper in scientific seminar, Thesis writing. Structure and Components of Research Report, Types of Report: research papers, thesis, Research Project Reports, Pictures and Graphs, citation styles, writing a review of paper, Bibliography	15

Unit -V	**Ethics and Ethical issues** Ethical Issues – Ethical Committees – Commercialization – copyright – Royalties – Intellectual Property Rights and Patent Law – Track Related Aspects of Intellectual Property Rights – Reproduction of published material – Plagiarism – Citation and Acknowledgement – Reproducibility and Accountability.	5
Unit -VI	**The computer: Its role in research** • Introduction, computer, and computer technology • Use of word processing, spreadsheet, and database software. • Plotting of graphs. • Internet and its application: E-mail, WWW, Web browsing, acquiring technical skills, drawing inferences from data, • Software for checking plagiarism: - Urkund, trinity • Criteria of good research • Problems encountered by Researchers in India	5

Reference books:

1. Garg.B.L., Karadia, R., Agarwal,F. and Agarwal, U.K., 2002. An introduction to Research Methodology, RBSA Publishers.
2. Kothari, C.R.(2008). Research Methodology: Methods and Techniques. Second Edition. New Age International Publishers, New Delhi.
3. Sinha, S.C. and Dhiman, A.K., 2002. Research Methodology, Ess Ess Publications. 2 volumes.
4. Gupta S.P. (2008). Statistical Methods. 37th ed. (Rev)Sultan Chand and Sons. New Delhi. 1470 p.
5. Leon & Leon (2202). Internet for everyone, Vikas Publishing House.
6. Wadehra, B.L.2000. Law relating to patents, trade marks, copyright designs and geographical indications. Universal Law Publishing.
7. Research Methodology Dr P M Bulakh,Dr P. S. Patki and Dr A S Chodhary 2010 Published by Expert Trading Corporation Dahisar West, Mumbai 400068
8. Business Research Methods- Donald Cooper & Pamela Schindler, TMGH, 9th editions
9. Business Research Methods- Alan Bryman & Emma Bell, Oxford University Press.

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	MODERN EDUCATION SOCIETY'S **Nowrosjee Wadia College, Pune (Autonomous) NEP**	
Master of Science in Biotechnology		
SEMESTER –II Major Paper 6 (Theory)		
Year – I	**Paper No- PBTMJ121** **Name of Paper- Recombinant DNA Technology**	**Credits 4**
Semester - II		**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

- Learn overall applications of rDNA technology.
- Know the different tools and techniques required
- Acquire the skills of rDNA technology
- Develop the applications of rDNA technology in thefield of medicine, agriculture and industry

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Introduction to r-DNA:** • History and scope of r-DNA technology • Definition of Vectors, Transformation, Transduction, Transfection, Conjugation. Sequencing, PCR, Primer, Probe • Enzymes used in genetic engineering • Restriction patterns • Coupling Tools- Linker and Adaptors	7
Unit -II	**Vectors and its properties** • Plasmids- types of plasmids; • Bacteriophages- lytic, lysogenic; M13 phage. • Cloning vectors- pBR322, pUC18, pGEM3Z; • Artificial chromosomes- BAC, YAC • Shuttle vectors • Plant virus-based vectors; • Cloning vectors for animals, • Viruses as cloning vectors for mammals.	8

Unit -III	**Gene Manipulation Strategies:** • Calcium phosphate precipitation, • Lipofection, • Electroporation, • Microinjection • DEAE-Dextran-Mediated Transfection • Retroviral Infection • Embryonic stem cell transfer • Agrobacterium mediated gene transfer, • Gene gun method • Fusion with bacterial protoplasts • Bacteriophage intermediate transformation	5
Unit -IV	**Gene Bank** • DNA libraries-cDNA library, • Genomic Library- Preparation of cDNA libraries • Genomic DNA libraries Application Gene cloning and gene expression	8
Unit -V	**DNA Sequencing Methods:** • Maxum Gilbert chemical degradation method, • Sanger's dideoxy chain termination method, • Massively Parallel Signature Sequencing (MPSS), • Pyrosequencing, • lon torrent method, • Illumina sequencing, • DNA nanoball sequencing, • Polony Sequencing	7
Unit -VI	**Genomic maps** • Introduction and definition • Genetic Maps: Linkage Maps, Cytogenetic Maps, Physical Maps. • Genetic Markers: Naked-eye Polymorphisms (NEP), protein-Based Markers, DNA Markers • Linkage mapping of DNA Markers: Restriction fragment length polymorphism (RFLP), Random Amplified DNAs (RAPDs) • Physical mapping of genomes: Pulsed-field gel electrophoresis (PFGE), Creation of Contigs.	8

Unit -VII	**Tools used in genetic engineering** • Polymerase chain reaction (PCR) and its principle; primer design, fidelity of thermo-stable enzymes; DNA polymerases. • Types of PCR and their applications-multiplex, nested; reverse transcription PCR, real time PCR, touchdown PCR, hot start PCR • Methods of nucleic acid hybridization-Southern, Northern and Western blotting techniques • Labelling of DNA, RNA and proteins by radioactive isotopes, non-radioactive labelling, and autoradiography. • Site-directed mutagenesis, exon cloning, chromosome walking and jumping, Difference between forward and reverse genetics, microarrays.	9
Unit -VIII	**Application of Recombinant DNA technology:** • Health- Production of vaccine, human insulin Production • Monoclonal Antibodies • Agriculture- Diseases resistance plant, Stress tolerant plant • Plant- Edible vaccine • Animal-genetically modified mice, Cattle, goat, Sheep, pig, fish • Industry- Metabolites and Enzyme Production.	9

References:

1. Old, R. W., Primrose, S. B., &Twyman, R. M. (2001). Principles of Gene Manipulation: an Introduction to Genetic Engineering. Oxford: Blackwell Scientific Publications.
2. Green, M. R., &Sambrook, J. (2012). Molecular Cloning: a Laboratory Manual. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
3. Brown, T. A. (2006). Genomes (3rd ed.). New York: Garland Science Pub.
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5. Technical Literature from Stratagene, Promega, Novagen, New England Biolabetc.
6. Brown, T. A. (2006). Genomes (3rd ed.). New York: Garland Science Pub
7. Brown, T. A (2010) Gene cloning and DNA Analysis: An Introduction, Wiley-Blackwell Publication
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	MODERN EDUCATION SOCIETY'S **Nowrosjee Wadia College, Pune (Autonomous) NEP**	
Master of Science in Biotechnology		
SEMESTER –II Major Paper 7 (Theory)		
Year – I	**Paper No- PBTMJ122** **Name of Paper- Biophysics**	**Credits 4**
Semester - II		**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

- Learn the concept of acid-base and buffers.
- Study various biophysical processes like diffusion, osmosis, viscosity, etc.
- Learn energy rich compounds, bioenergetics and laws of thermodynamics.
- Acquire knowledge on basic biophysical and biochemical aspects
- Learn purification of molecules, analytical tools, electrophoretic separation
- Learn how to interpret protein mobility on PAGE under native and SDS

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Concept of Acid and Base Buffers, Colloids,Viscosity, Thermodynamics:** • Arrhenius theory, Lewis acid and base, Lowry-Bronsted Theory Acid-Base equilibrium in water: Law of Mass Action ionization ofwater, Equilibrium constant and Ionizations constant of water, Concept of pH • Buffers: Concept and definition, Henderson-Hassel Balch equation,Biological buffer systems- Phosphate buffer system, Bicarbonate buffer system • Colloids: Introduction and examples, Classification based on physical state, affinity of phases and molecular size, Properties ofcolloids • Viscosity: concept, Factors affecting viscosity, Measurement of viscosity, Applications of viscometry, Significance of viscosity inbiological systems • Thermodynamics: definition, First and second law of thermodynamics ,Enthalpy, Entropy, Standard free energy change, Exergonic and endergonicreactions, Redox potential and its measurement	8

Unit -II	**Properties of Matter:** ● Adsorption: Introduction, adsorbent, adsorbate, desorption comparison between adsorption and absorption, Types of adsorption Factors affecting adsorption, Characteristics of adsorption, Applications ofadsorption ● Diffusion: definition, Fick's first law of diffusion, diffusion co-efficient and its significance ,types-simple, facilitated, active-primary and secondary diffusion, Rate of diffusion and factors affecting it, Biological importance of diffusion ● Osmosis: definition, osmotic pressure ,mechanism and salient features of osmotic pressure, Definition of osmole, osmolality and Osmolarity, Osmosis and plant cell ,Importance of osmosis in medicine and biology	7
Unit -III	**Microscopy:** ● Principles and Applications of Light, ● Phase Contrast, Fluorescence Microscopy, ● Scanning and Transmission, Electron Microscopy ● Confocal Microscopy, Atomic Force Microscopy, ● Cytophotometry and Flow Cytometry. .	7
Unit -IV	**Chromatography**: ● Introduction, history, concept of distribution coefficient , ● Modes of chromatography, ● Classification of chromatography ● Principle ,theory and applications of-Paper chromatography, ● Thin- layer chromatography, ● Gel filtration chromatography, ● Ion exchange chromatography, ● Affinity chromatography, ● Gas liquid chromatography ● Liquid-liquid chromatography(HPLC)	8
Unit -V	**Electrophoresis:** ● Principle of electrophoresis, ● Migration of an ion in an electric field, ● Factors affecting electrophoretic mobility ● Principle, theory and applications of-Paper electrophoresis, ● Agarose gel electrophoresis, ● Polyacrylamide gel electrophoresis, ● SDS-Polyacrylamidegel, 2Delectrophoresis, ● Isoelectric focusing , ● Capillary electrophoresis, Immuno electrophoresis	7

Unit -VI	**Spectrophotometry:** ● Concept of electromagnetic radiations, ● Electromagnetic spectrum, Laws of absorption- Lambert and Beer Law, Chromophore concept- auxochrome various chromic shifts ● Instrumentation, theory and Applications of UV and Visible Spectroscopy, Fluorescence Spectroscopy, ● Flame spectrophotometry, NMR	8
Unit -VII	**Centrifugation:** ● Principle, types and applications of ultracentrifugation. ● Tracertechniques- radioactive isotopes, ● Half-life of radioactive compounds, ● Autoradiography, Cerenkov radiation, ● liquid scintillation counter	7
Unit -VIII	**Biosensors**: ● Principle, general features, ● Types of biosensors, Electrochemical,conductmetric,,Thermometric, optical etc., ● Applications of biosensors	5

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- Analytical Biochemistry:D. HolmesandH.Peck(Longman)
- Biophysical Chemistry : Upadhye and Upadhye(Himalaya Publ.House) Physica lBiochemistry :K.E.VanHolde(PrenticeHal)
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- https://www.youtube.com/live/vLzl6k5zyBM?si=0dQqZOByjfhUBrWM
- https://youtu.be/MW4PwJxxyt0?si=J64mjooYSb95RiD0
- https://youtu.be/FDzz7M25xdw?si=rKUd7Ee5yy1RuLSO
- https://youtu.be/gU2st5-T1Go?si=kAS7LXTHMrvC2GAe
- https://www.youtube.com/live/_v6GrB95u5Y?si=CJeOOtCu8NLCvMfu

	MODERN EDUCATION SOCIETY'S **Nowrosjee Wadia College, Pune (Autonomous) NEP**	
Master of Science in Biotechnology		
SEMESTER –II Major Paper 8 (Practical)		
Year – I	**Paper No- PBTMJ123** **Name of Paper-Practicals in Recombinant DNA Technology**	**Credits 4**
Semester - II		**Hours 60**

Course Outcomes (COs)
On completion of the course, the students will be able to:

- Isolate the plasmid and genomic DNA.
- Learn restriction Enzyme digestion of plasmid DNA.
- Learn Gene Transfer.
- Learn to run Polymerase Chain Reaction (PCR)
- Prepare competent cells, Vector and Insert Ligation and hybridization

Sr. No.	COURSE CONTENT / SYLLABUS	No of Practical
1.	Plasmid DNA isolation and DNA quantitation	2
2.	Genomic DNA isolation	1
3.	Restriction Enzyme digestion of plasmid DNA	1
4.	Genetic Transfer-Conjugation, gene mapping	2
5.	Polymerase Chain Reaction and analysis by agarose gel electrophoresis	3
6	Preparation of competent cells	1
7.	Transformation of *E. coli* with standard plasmids, Calculation of transformation efficiency.	1
8.	Vector and Insert ligation.	2
9.	Polyacrylamide gel electrophoresis and Western hybridization Southern, Northern, hybridization	3

MODERN EDUCATION SOCIETY'S
Nowrosjee Wadia College, Pune (Autonomous) NEP

Master of Science in Biotechnology

SEMESTER –II Major Paper 9 (Practical)

Year – I	**Paper No- PBTMJ124**	**Credits 4**
Semester - II	**Name of Paper- Practicals in Biophysics**	**Hours 60**

Course Outcomes (COs)
On completion of the course, the students will be able to:

- Able to do calculation for preparation of buffers and solutions.
- Separate biomolecules by chromatography andelectrophoresis

Sr. No.	COURSE CONTENT / SYLLABUS	No. of Practical
1.	Preparation of buffers, molar, normal and ppm solution	2
2.	Amino acid separations by paper chromatography	1
3.	Separation of lipids, Chlorophyll and Tannin by thin layer chromatography	2
4.	Ion Exchange and gel filtration column chromatography	2
5.	SDS –Native PAGE for proteins Separation.	2
6.	Spectrophotometric estimation of protein	2
7.	Demonstration SEM & TEM.	1
8.	Demonstration of FTIR and AAS	1
9.	Demonstration of GC and HPLC	1
10.	Visit to Research Institute/ University and report writing	1

	MODERN EDUCATION SOCIETY'S **Nowrosjee Wadia College, Pune (Autonomous) NEP**	
Master of Science in Biotechnology		
SEMESTER –II Major Paper 10(A) (Theory)		
Year – I	**Paper No- PBTMJ125(A)** **Name of Paper- Intellectual Property Rights and Bioethics**	**Credits 4**
Semester - II		**Hours 60**

Course Outcomes (COs)
On completion of the course, the students will be able to:

- Familiarizing the concept, a business and importance of protection of an Intellectual property for sustained business model
- To gain the knowledge of patent, copyright and trademark, the acts and policies in India and 7abroad
- Practicing a draft patent application preparation
- Conceptualizing ethics in professional practice, biological research and medical
- Research along with various guidelines to be adopted for best practices.

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Introduction to Intellectual Property** ● General introduction to IP and IPR ● History and role of international conventions and treaties- GATT (general Agreement on tariffs and trade), WTO (World trade Organization), WIPO (World Intellectual Property Organization), Trips, Budapest Treaty ● International framework for the protection of IP ● IP as a factor in R & D IP's of relevance to Biotechnology, Agriculture, Bioinformatics and Pharmaceutical Sector	7
Unit -II	**Types of IP Industries:** ● Patents, trademarks, copyright and related rights, Industrial design, traditional knowledge, geographical indications. **Concepts of prior art:** ● Need of prior art for IP types ● Classification search and its implications ● Invention in context of prior art ● Patent databases ● Searching International Databases ● Country-wise patent searches USPTO (The United states patent and trademark office), EPO (The European Patent Office), INDIA	8

Unit -III	**Litigation** • Commercialization of patented innovations; • Licensing outright sale, licensing, royalty; • Patenting by research students and scientists- university/organizational rules in India and abroad, collaborative research - backward and forward IP; benefit/credit sharing among parties/community, • Commercial (financial) and non-commercial incentives	8
Unit -IV	**Patenting Methodology** ● Steps and procedure-Idea incubation Phase, Patentability search (optional step), Patent drafting/ Writing, Filling patent application, Publication of application, Request for examination (RFE), Response to objections, Grant of patent	7
Unit -V	**Bioethics** • Introduction, scope and principle • Ethical conflicts in biological sciences -interference with nature, • Basic concepts of Medical ethics, Animal ethics, Research ethics • Sharing benefits and protecting future generations - Protection of environment and biodiversity, biopiracy.	7
Unit -VI	**Medical ethics:** ● Scope, Perspectives and methodology, ● Principle- Anatomy, Beneficence, Non-maleficence justice, ● Medical ethical issues- Patients right, Equity of resources, confidentiality of the patients, patients' safety, conflict of interest, ethics of privatization, inform consent, dealing with the opposite sex, beginning and end of life, healthcare team effects.	8
Unit -VII	**Animal Ethics-** • Animal rights, ● Animal welfare, ● History of animal use and theories of justice animal laws, Speciesism, ● Animal cognition, ● Wildlife conservation, ● Wild animal suffering, ● The moral status of non-human animals, Human exceptionalism	8

Unit -VIII	**Research Ethics-** ● IRB (Institutional Review Board) and its function ● Ethical issues in clinical research ● Objectives and Principle of research ethics ● Human protectionism ● Contemporary issues Risk and benefits	7

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1. Ganguli, P. (2001). Intellectual property rights: Unleashing the knowledge economy. New Delhi: Tata McGraw-Hill Pub.
2. Complete Reference to Intellectual Property Rights Laws. (2007). Snow White Publication Oct.
3. Kuhse, H. (2010). Bioethics: An anthology. Malden, MA: Blackwell.
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5. World Trade Organisation. http://www.wto.org
6. World Intellectual Property Organisation.
7. https://www.wipo.int/about-ip/en/
8. National Institute of Environmental Health Sciences: What Is Ethics in Research & Why Is It Important? (nih.gov)
9. Animal Ethics and Behavioral Science: An Overdue Discussion | BioScience | Oxford Academic (oup.com)

	MODERN EDUCATION SOCIETY'S **Nowrosjee Wadia College, Pune (Autonomous) NEP**	
Master of Science in Biotechnology		
SEMESTER –II Major Paper 10(B)(Theory)		
Year – I	**Paper No- PBTMJ125(B)** **Name of Paper-Pharmaceutical Biotechnology**	**Credits 4**
Semester - II		**Hours 60**

Course Outcomes (COs)

On completion of the course, the students will be able to:

- Gain insights into the process of drug discovery
- Provide understanding on the mechanisms of various biopharmaceuticals products
- Gain knowledge on the approval process of biopharmaceuticals
- Provide knowledge on the market of biopharmaceutical
- Acquire knowledge on clinical trials of drugs

Sr. No.	COURSE CONTENT / SYLLABUS	Lectures
Unit -I	**Introduction to Pharmaceutical Biotechnology and Drug Discovery** • Biotechnology in the pharmaceutical industry • History of pharmaceutical science • Meaning of drugs, Drugs target: Structure and functions; Physiochemical properties of drugs; drugs from natural sources. • Drug tolerance and intolerance, drug allergy, drug induced side effects with examples.	8
Unit -II	**Production of Biopharmaceuticals** • Introduction and scope of Biopharmaceutical industry • Production of pharmaceuticals by genetically engineered cells (Insulin, Growth hormone, Bloods proteins, Recombinant factor VIII, vitamins, Antibiotics) • Biopharmaceuticals manufacturing: Overview of upstream anddownstream processing • Production of Biopharmaceuticals using synthetic Biology approach (e.g. Artemisinin)	7
Unit -III	**Drug Discovery** • Drug discovery process • Routes of administration of drugs • Role of bioinformatics in drug design • Target identification and validation • Structure-based drug design • Ligand-based drug design • Drug metabolism	8

Unit -IV	**Drug action and Resistance** • Mechanism of action of anti-diabetic, anti-cancer, anti-inflammatoryand antibiotics (any 2 drugs of each) • Mechanism of drug resistance to antibiotics and anticancer drugs withexamples • MDR, XDR, PDR • Assay of drug potency- Bioassays and Immunoassays	7
Unit -V	**Process of Drug development** • Pre-clinical studies Toxicity (Cytotoxicity, Genotoxicity,Reproductive toxicity, Carcinogenicity, Mutagenicity**)** • Animal Models Used in in vivo Research • Microbes and their impact on the pharmaceutical industry • Differences between drug discovery and drug development • Biosensors- working and application of biosensors in pharmaceutical industries	8
Unit -VI	**Introduction on to Biologics and Biosimilar's** • Definition: Small molecules, large molecules/Biologics Categories of Biologics: protein-based hormones, enzymes, monoclonal antibodies, vaccines, blood products, and gene/ cellular therapies. • Similarities and Differences: Small molecules versus generics,Biologics versus Biosimilars. • USFDA Approved Small Molecules and USFDA Approved Generics,USFDA Approved Biologics and USFDA Approved Biosimilars • Therapeutic uses of some of the Biologics/Biosimilars	7
Unit -VII	**Clinical drug development phases** • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending,dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principal studies to establishefficacy) • Phase III studies (Multi ethnicity, multinational, registration studies) • Phase IV studies (Post marketing authorization studies; pits andpractices?) • Safety Monitoring in Clinical Trials (ICH E2) -Adverse event and Serious adverse event reporting in clinical trials; managing and reporting of events.	8

Unit -VIII	**Analysis and reporting in clinical trials (ICH E3 and E9)** • Statistics in clinical trials • Clinical study reports – structure and content • Critical appraisal of clinical study report • Electronic reporting in clinical trials • Regulations Governing Clinical Trials - Clinical Research regulationsin India – CDSCO guidelines, ICMR guidelines •. USFDA regulations to conduct drug studies, Clinical Research regulations in UK – Medicines and Healthcare Products	7

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6. Clinical and Translational Science: Principles of Human Research, 2nd Edition (2016).Edited by David Robertson, Gordon H. Williams.
7. Biopharmaceuticals, Biochemistry and Biotechnology- Gary Walsh, Wiley Pub, 2 nd Edn.2003.
8. New Drugs and Clinical Trials Rules 2019
9. "Organic Chemistry of Drug Design and Drug Action" by Silverman
10. "Drug Metabolism in Drug Design and Development" by Donglu Zhang and Mingshe Zhu