# University of Mumbai



# No. AAMS\_UGS/ICC/2024-25/137

### **CIRCULAR:**-

Attention of all the Principals of the Affiliated Colleges, Directors of the Recognized Institutions and the Head, University Departments is invited to this office Circular No. AAMS\_UGS/ICC/2023-24/23 dated 08<sup>th</sup> September, 2023 relating to the NEP UG & PG Syllabus.

They are hereby informed that the recommendations made by the Ad-hoc Board of Studies in Biotechnology at its meeting held on 09<sup>th</sup> July, 2024 and subsequently passed by the Board of Deans at its meeting held on 3<sup>rd</sup> September, 2024 <u>vide</u> item No. 6.1(N) have been accepted by the Hon'ble Vice Chancellor as per the power confirmed upon him under section 12 (7) of the Maharashtra Public Universities Act, 2016 and that in accordance therewith syllabus for M.Sc.(Biotechnology) Sem – III & IV is introduced as per appendix (NEP 2020) with effect from the academic year 2024-25.

(The Circular is available on the University's website www.mu.ac.in).

MUMBAI – 400 032 21st September, 2024

(Dr. Prasad Karande)
REGISTRAR

To

All the Principals of the Affiliated Colleges, Directors of the Recognized Institutions and the Head, University Departments.

# BOD 6.1(N) 03/09/2024

Copy forwarded with Compliments for information to:-

- 1) The Chairman, Board of Deans,
- 2) The Dean, Faculty of Science,
- 3) The Chairman, Ad-hoc Board of Studies in Biotechnology
- 4) The Director, Board of Examinations and Evaluation,
- 5) The Director, Department of Students Development,
- 6) The Director, Department of Information & Communication Technology,
- 7) The Director, Centre for Distance and Online Education (CDOE) Vidyanagari,
- 8) The Deputy Registrar, Admission, Enrolment, Eligibility & Migration Department (AEM),

Cop	y forwarded for information and necessary action to :-
1	The Deputy Registrar, (Admissions, Enrolment, Eligibility and Migration Dept)(AEM), <a href="mailto:dr@eligi.mu.ac.in">dr@eligi.mu.ac.in</a>
2	The Deputy Registrar, Result unit, Vidyanagari drresults@exam.mu.ac.in
3	The Deputy Registrar, Marks and Certificate Unit,. Vidyanagari dr.verification@mu.ac.in
4	The Deputy Registrar, Appointment Unit, Vidyanagari dr.appointment@exam.mu.ac.in
5	The Deputy Registrar, CAP Unit, Vidyanagari <a href="mailto:cap.exam@mu.ac.in">cap.exam@mu.ac.in</a>
6	The Deputy Registrar, College Affiliations & Development Department (CAD), <a href="mailto:deputyregistrar.uni@gmail.com">deputyregistrar.uni@gmail.com</a>
7	The Deputy Registrar, PRO, Fort, (Publication Section), <a href="mailto:Pro@mu.ac.in">Pro@mu.ac.in</a>
8	The Deputy Registrar, Executive Authorities Section (EA) <a href="mailto:eau120@fort.mu.ac.in">eau120@fort.mu.ac.in</a>
	He is requested to treat this as action taken report on the concerned resolution adopted by the Academic Council referred to the above circular.
9	The Deputy Registrar, Research Administration & Promotion Cell (RAPC), <a href="mailto:rape@mu.ac.in">rape@mu.ac.in</a>
10	The Deputy Registrar, Academic Appointments & Quality Assurance (AAQA) dy.registrar.tau.fort.mu.ac.in ar.tau@fort.mu.ac.in
11	The Deputy Registrar, College Teachers Approval Unit (CTA), <a href="mailto:concolsection@gmail.com">concolsection@gmail.com</a>
12	The Deputy Registrars, Finance & Accounts Section, fort draccounts@fort.mu.ac.in
13	The Deputy Registrar, Election Section, Fort drelection@election.mu.ac.in
14	The Assistant Registrar, Administrative Sub-Campus Thane, <a href="mailto:thanesubcampus@mu.ac.in">thanesubcampus@mu.ac.in</a>
15	The Assistant Registrar, School of Engg. & Applied Sciences, Kalyan, ar.seask@mu.ac.in
16	The Assistant Registrar, Ratnagiri Sub-centre, Ratnagiri, ratnagirisubcentar@gmail.com
17	The Director, Centre for Distance and Online Education (CDOE), Vidyanagari, director@idol.mu.ac.in
18	Director, Innovation, Incubation and Linkages, Dr. Sachin Laddha pinkumanno@gmail.com
19	Director, Department of Lifelong Learning and Extension (DLLE),  dlleuniversityofmumbai@gmail.com

Сор	Copy for information :-			
1	P.A to Hon'ble Vice-Chancellor, vice-chancellor@mu.ac.in			
2	P.A to Pro-Vice-Chancellor pvc@fort.mu.ac.in			
3	P.A to Registrar, registrar@fort.mu.ac.in			
4	P.A to all Deans of all Faculties			
5	P.A to Finance & Account Officers, (F & A.O), <a href="mailto:camu@accounts.mu.ac.in">camu@accounts.mu.ac.in</a>			

# To,

1	The Chairman, Board of Deans
	pvc@fort.mu.ac.in

# 2 Faculty of Humanities,

### Dean

1. Prof.Anil Singh
Dranilsingh129@gmail.com

# **Associate Dean**

- 2. Dr.Suchitra Naik Naiksuchitra27@gmail.com
- 3.Prof.Manisha Karne <a href="mkarne@economics.mu.ac.in">mkarne@economics.mu.ac.in</a>

# Faculty of Commerce & Management,

# Dean

1. Dr.Kavita Laghate kavitalaghate@jbims.mu.ac.in

# **Associate Dean**

- 2. Dr.Ravikant Balkrishna Sangurde Ravikant.s.@somaiya.edu
- 3. Prin.Kishori Bhagat <u>kishoribhagat@rediffmail.com</u>

	Faculty of Science & Technology
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	Associate Dean
	2. Dr. Madhav R. Rajwade  Madhavr64@gmail.com
	3. Prin. Deven Shah sir.deven@gmail.com
	Faculty of Inter-Disciplinary Studies,
	Dean
	1.Dr. Anil K. Singh
	aksingh@trcl.org.in
	Associate Dean
	2.Prin.Chadrashekhar Ashok Chakradeo
	cachakradeo@gmail.com
3	Chairman, Board of Studies,
4	The Director, Board of Examinations and Evaluation,
	dboee@exam.mu.ac.in
5	The Director, Board of Students Development,
J	dsd@mu.ac.in  DSW director@dsw.mu.ac.in
6	The Director, Department of Information & Communication Technology,
	director.dict@mu.ac.in

BOD - 3/9/2024 12 (7) of M.P.U.A. 2016 Item No. - 6.1 (N)

# As Per NEP 2020

# University of Mumbai



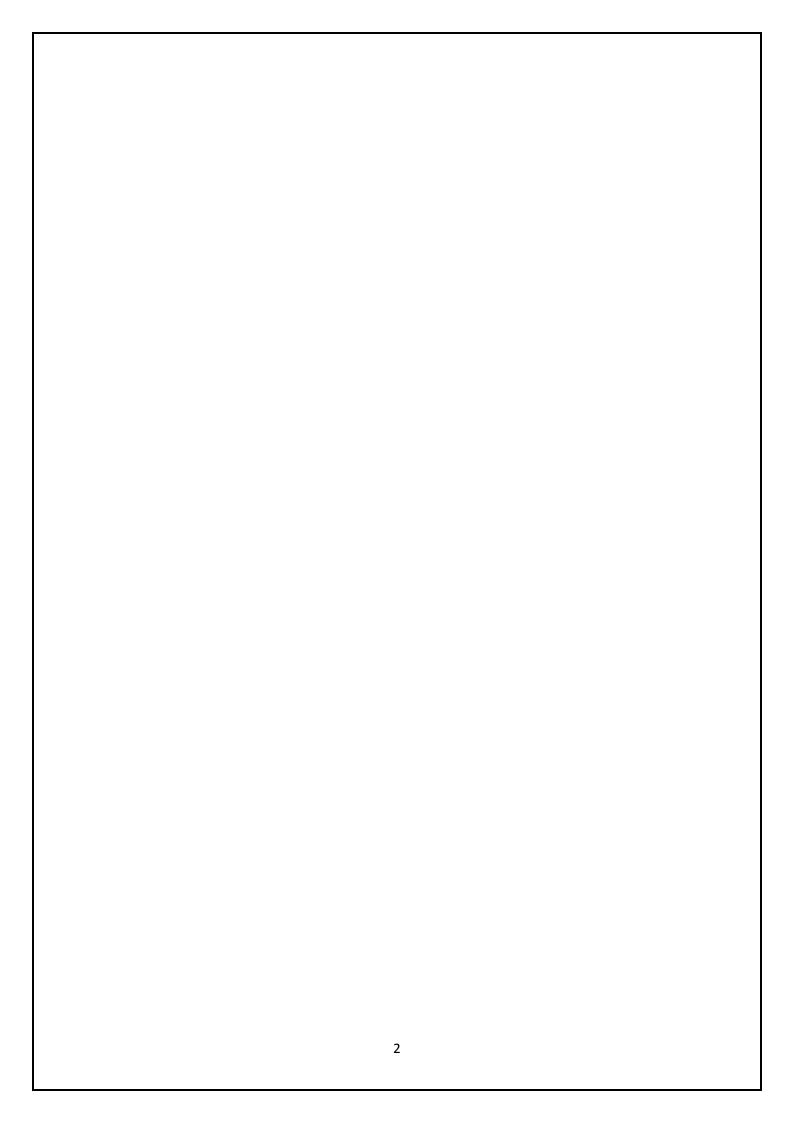
Title of the P.G. Program M.Sc. (Biotechnology)

Syllabus for Semester – Sem.- III & IV

Ref: GR dated 16th May, 2023 for Credit

Structure of PG

(With effect from the academic year 2024-25)





# (As per NEP 2020)

Sr.	Heading	Particulars
No.		
1	Title of program	M.Sc. (Biotechnology)
	O:	
2	Scheme of Examination R:	NEP 50% Internal 50% External, Semester End Examination Individual Passing in Internal and External Examination
3	Standards of Passing R:	40%
4	Credit Structure R: SP-60B	Attached herewith
5	Semesters	Sem. III & IV
6	Program Academic Level	6.5
7	Pattern	Semester
8	Status	New
9	To be implemented from Academic Year	2024-25

Sign of the BOS Chairman Dr. Varsha Kelkar-Mane Ad-hoc BoS (Biotechnology) Sign of the Offg. Associate Dean Dr. Madhav R. Rajwade Faculty of Science & Technology Sign of the Offg. Dean Prof. Shivram S. Garje Faculty of Science & Technology

# 1) Scheme of Examination: (THEORY AND PRACTICALS):

# a) Summative assessments (THEORY):

For 2 credit courses	:	25 M (1 hr)			
Q.1 Answer any 1 question out of two (CQ.2 Answer any 1 question out of two (QQ.3 One or 2 marks answers. Questions	Covering Module 1 & 2 s based on problem so	2) 7 M olving/			
analytical skills/ critical thinking (Co	vering Module 1 & 2)	10 M			
For 4 credit courses		50 M (2 hr)			
Q1. Answer any 2 questions out of 3	(based on Module I	,			
Q2. Answer any 2 questions out of 3	(based on Module I	•			
Q3. Answer any 2 questions out of 3	(based on Module I	•			
Q4. Answer any 2 questions out of 3	(based on Module I	,			
Q5. Write one Essay type answer out of	3 (based on Module	I-IV) 10 M			
b) Formative assessments (informal	and formal tests admi	nistered during			
the learning process).  For 2 credit courses		25M			
<ul> <li>Group tasks/ Assignments/ Quizz</li> </ul>	es at the time of com				
Module	es at the time of com	15M			
	malation of each Mod				
<ul> <li>Spoken/oral examination after completion of each Module</li> <li>For 4 credit courses</li> </ul>					
At least 2 of the following for 25M each	to he designed	50M			
Open book test/assignments/presentation		/problem solvina			
5, 5 55 55 55 55		3			
c) Summative assessments (PRACTIC	ALS):				
Summative assessments For 2	credits	25 M			
Format will be shared prior to examination	ons				
Formative assessment For 2	credits	25 M			
Submission of 1 assignment: Poster/pre	sentation based on				
history/discovery/Application /problems	based on techniques/	•			
performed		15 M			
Viva/Field visit report-		10 M			
Summative Assessments For 4		50M			
Format will be shared prior to examination	ons				
Formative assessment For 4	credits	50M			
Submission of at least 2 of the following					
assignments/ Poster/presentation based based on techniques/spots/identification					

### Sem III

# **Research Project 4 credits**

It is mandatory for students to review minimum 5 recent research papers from indexed journals / Journals with ISSN numbers under the guidance of mentors / in house faculty and write a review article/report/work plan that would be presented during the practical examinations for 100M (50% by internal examiner and 50% by external examiner) Plagiarism check certificate to be appended in the report submitted.

### Sem IV

# **Research Project- 6 credits**

Research project /Training under the guidance of industry/ R&D mentors / in house faculty with wet lab and/or *in-silico* experience in fields in /or allied to Biotechnology. The project would be graded during the practical examinations based on the submitted project / dissertation report as well as a power-point presentation. (50% by internal examiner and 50% by external examiner).

Sign of HOD

Professor Varsha Kelkar Mane University Dept of Biotechnology

Sign of Dean,

Professor Shivram Garje Name of the Faculty: Science

# R: SP-60B

	Le	Sem	Major		R	OJT / FP	R P	Cu
	vel	(2 Yr)	Mandatory*	Electives Any one	M	/ ГР	F	m. Cr.
				Credits 4				
			Course 1 Nanobiotechnology Credits 4  Course 2 Environmental	Food Biotechnology and Nutraceuticals  Credits 4 (2 credits theory + 2 credits practicals)	-	-	4	22
II	6.5	Sem III	Course 3 Practical – lab work Credits 4	OR Elective Course 2 Clinical Biochemistry Credits 4 (2 credits theory + 2 credits practical)				
			Course 4 Bioanalytical and Biophysical techniques Credits 2	OR Elective Course 3 Advanced Epidemiology and Applied Microbiology Credits 4 (2 credits theory + 2 credits practicals)				
				OR Elective course 4 Any of MOOCs Credits 4				
		Sem IV	Course 1 Omics and Systems Biology Credits 4  Course 2 Drug Discovery and Clinical Studies	Elective Course 1 Biologics and regulatory affairs Credits 4 OR Elective Course 2 NGS and	-	-	6	22
			Credits 4 (2 credits theory + 2 credits practicals)  Course 3	Bioinformatics Credits 4 (2 credits Theory + 2 credits)				
			Molecular Enzymology Credits 4 (2 credits theory + 2 credits practicals)	OR Elective course 3 Any of MOOCs Credits 4				
	n. Cr. oma	for PG	26	8			10	44
Cum Cr for 2 Yr		r 2 Yr	54	16	4	4	10	88

PG dearee			

# Semester - III

# Syllabus M.Sc. (Biotechnology) (Sem. III & IV)

# Semester -III

# Course 1 -- Nanobiotechnology

Credits 4

Course Outcomes: On successful completion of the course the learner would be

CO1: acquainted with the perspective of Nanotechnology at national and international levels.

CO2: well versed with approaches used for nanoparticle synthesis.

CO3: able to introduce examples of nanoparticles present in nature.

CO 4: able to understand the role of various characterization techniques used in nanotechnology

Modules	Topics	Credits	No of lectures
Module I: Introduction to Nanotechnology	Introduction to Nanotechnology (1 lecture), Nano-Geosystem for Abiotic Nanoparticles Formation Nanoscience and their applications (3 lectures), Nano-Biosystem Consisting of Biotic Nanoparticles (3 lectures), Examples of Nanotechnology in Ayurveda (3 lectures), Nanotechnology research development and innovation in India, Nanotechnology and Regulation (3 lectures), Global and Indian Perspective, Global trends in Nanotechnology (2 lectures)	4	15
Module II: Synthesis of Nanomaterials	Nanometre scale materials: Nanometre-Scale Metals, Metal Oxides, Nano polymers, Quantum Dots, Nanocarbons /Carbon nanostructures, (4 lectures)Synthesis of nanometre-scale materials: Top-down and bottom-up approach, Physical methods of synthesis -Mechanical methods-ball milling, Melt Mixing, Physical method deposition, Laser Vaporization (Ablation) method (4 lectures),Chemical methods of synthesis – introduction and advantages, introduction to Colloids and synthesis of Colloids, sol-gel method, hydrothermal synthesis (4 lectures), Biological methods of synthesis- synthesis using microorganisms, synthesis using plants, synthesis using DNA (3 lectures)		15

Module III: Nanotechnology in nature	Self-Assembly of nanoparticles: Mechanism of Self Assembly, Examples of Self Assembly -Self-Assembly of Nanoparticles Using Organic Molecules, Self-Assembly in Biological Systems, Self-Assembly in Inorganic Materials. (5 lectures) Examples of Nanostructures in Nature Superhydrophobic surfaces of plants, Biomineralization of silica by diatoms, Silicification by sponges, Magnetic particles in animals and microorganisms, Serpent Sea star, beak of squid, beard of Mussels (5 Lectures)  Biological nanostructures and Nanorobotics: ATP synthase, the kinesin, myosin, dynein, flagella modulated motion. (5 lectures)	15
Module IV: Properties and Characterizatio n of nanoparticles	Characterization of Nanoparticles: Microscopy-SEM, TEM, Scanning Tunnelling Microscopy, Atomic Force Microscopy (3 lectures) UV-Vis Spectroscopy, Dynamic Light Scattering, X-Ray Diffraction, FTIR, X Ray Photoelectron Spectroscopy (5 lectures) Plasmonic material, Localised Surface Plasmon Resonance, Nano magnetism, types of magnetic materials (3 lectures) Nanotoxicology: Toxicity of Nanomaterials, Factors Responsible for the Nanomaterial Toxicity, Routes of Exposure to Engineered nanoparticles, Mechanisms of Nanoparticle toxicity, toxicology of nanocarriers (4 lectures)	15

- 1. History of Nanotechnology from Prehistoric to Modern times, Madhuri Sharan, Wiley (2019)
- 2. Nanotechnology development in India: An overview, Amit Kumar, Research & Information system for developing countries (RIS), Dec2014.
- 3. A Laboratory Course in Nanoscience and Nanotechnology by Poinern, Gérrard Eddy Jai, CRC press.
- 4. Nanostructures, nanomaterials synthesis, properties applications by Guozhong Cao, Imperial College press.
- 5. Nanotechnology-Principles and Practices, Sulabha K. Kulkarni (auth.) -Springer International Publishing (2015).
- 6. Nanobiotechnology II\_ More Concepts and Applications-Chad A. Mirkin, Christof M. Niemeyer Wiley VCH (2007)
- 7. Bio directed synthesis and assembly of nanomaterials., Crookes-Goodson, W. J., Slocik, J. M., & Naik, R. R. Chemical Society Reviews, 37(11)(2008)..

- 8. Nanorobotics: a field inspired by nature, Chapter 7. In: Bar-Cohen, Y. (ed.) Biomimetics: BiologicallyInspiredTechnologiesUmmat, A., Dubey, A., Mavroidis, C.: Bio. CRC, Boca Raton (2006)
- 9. Nanomedicine in drug delivery-Arun Kumar CRC Press \_ Taylor & Francis (2013) 10. The Nanoscope: Encyclopedia of Nanoscience and Nanotechnology, Diwan, P., & Bharadwaj, A. (Eds.). (2005). Pentagon Press. Volume 3
- 11.NanoBioTechnology\_BioInspired Devices and Materials of the Future, Oded Shoseyov, Ilan Levy(2008, Humana Press)
- 12. "The Promising Future in Medicine: Nanorobots." Apoorva Manjunath, and Vijay Kishore, Biomedical Science and Engineering, vol. 2, no. 2 (2014).
- 13. Textbook of Nanoscience and Nanotechnology by B.S. Murty, P. Shankar, Baldev Raj, B B Rath, James Murday.
- 14. Toxicology of Nanomaterials-Yuliang Zhao, Zhiyong Zhang, and Weiyue Feng-Wiley-VCH (2016)
- 15. Nanorobotics in Nanomedicine from Visakh P. M. Nanomaterials and Nanotechnology in Medicine-Wiley (2022)
- 16. Introduction to Bionanotechnology-Young-Chul Lee, Ju-Young Moon Springer (2020)

# **Course 2 – Environmental Biotechnology**

**Credits 4** 

**Course Outcomes:** On successful completion of the course the learner would be able to: CO1: Understand various types of pollution, their monitoring, latest mitigation strategies and

management of the same.

CO2: Understand various Health hazards of pollution and waste, solid waste management, biodiversity concepts and data management, ecology and environmental monitoring.

CO3: Understand various concepts of environmental biotechnology, latest developments in the area and use of microbiological, molecular and analytical methods in environmental biotechnology.

Modules	Topics	Credits	No of lectures
Module I: Microbial Diversity & Ecology	Introducing biodiversity informatics, Global patterns of distribution of Microbial biodiversity, biomes, Composition and distribution of biodiversity in India (5 lectures) Taxonomic Database Working Group (TDWG) standards, compatibility and interoperability, taxonomically intelligent systems (5 lectures) Global biodiversity information system-Overview of the UNEP/GEF biodiversity data management project (BDM) (5 lectures)		15
Module II: Environmental Degradation	Impact of anthropogenic activities, of environment: Soil/Land, Water, Air, Forest, Oceans and the coasts. Plastic and Microplastic pollution (5 lectures), Ozone Layer Depletion, Atmospheric Brown Cloud, Impact on Flora and Fauna, Impact on Crop Yield (5 lectures). Causes of soil salinity; Chemical and metallic pollution of agricultural soil; Bioleaching of metals, bioaugmentation & biomagnification for soil remediation. (5 lectures)	4	15
Module III: Environmental Monitoring	Environmental monitoring: Definition and process; Sampling – land (site), water & air; Biological indicators (Marine microbes, algae and crustaceans); GIS for environment monitoring and assessment (4 lectures) Physico-chemical characteristics of water; IOT for water quality monitoring – General working, Application (3 Lectures) Ecological balance and ecological footprint, concept of carbon credit, carbon footprint (2 lectures) Biosensors and biochips – mechanism, principle and working, (3 lectures) Environment Impact Assessment: EIA complete process, Importance of EIA (3 lectures)		15
Module IV: Methods to Control Pollution	Methods to control pollution: Biochar, Ecoenzymes, Garbage enzyme for environment remediation, Methods in determining biodegradability; Use of microbes (Bacteria and Fungi) (3 lectures) Catalytic Systems, Bioremediation, Biotransformation and Biodegradation. (5 lectures) Methods in		15

- 1. Chandrappa, R., & Kulshrestha, U. C. (2015). Sustainable air pollution management: theory and practice. Springer.
- 2. Karl B. Schnelle & Charles A. Brown, (2002) Air pollution control technology Handbook. CRC Press
- 3. Singh, R. L. (Ed.). (2017). Principles and applications of environmental biotechnology for a sustainable future. Springer Singapore.
- 4. Enger, E. D., Smith, B. F., & Bockarie, A. T. (2000). Environmental science: A study of interrelationships (p. 434). Boston, MA: McGraw-Hill.
- 5. Rittmann, B. E., & McCarty, P. L. (2012). Environmental biotechnology: principles and applications. Tata McGraw-Hill Education.
- 6. Wainwright, M. (2012). An introduction to environmental biotechnology. Springer Science & Business Media.
- 7. Bolan, N. S., Park, J. H., Robinson, B., Naidu, R., & Huh, K. Y. (2011). Phytostabilization: a green approach to contaminant containment. In Advances in agronomy (Vol. 112, pp. 145-204). Academic Press.
- 8. Pradhan, A. K., & Pradhan, N. (2015). Microbial biosurfactant for hydrocarbons and heavy metals bioremediation. In Environmental Microbial Biotechnology (pp. 91-104). Springer.
- 9. Rittmann, B. E., & McCarty, P. L. (2012). Environmental biotechnology: principles and applications. Tata McGraw-Hill Education.
- 10. Foin, T. C. (1976). Ecological systems and the environment. Houghton Mifflin.
- 11. Wise, D. L. (1988). Biotreatment systems: Volume II, Springer.
- 12. Sheng, Y., Qu, Y., Ding, C., Sun, Q., & Mortimer, R. J. (2013). A combined application of different engineering and biological techniques to remediate a heavily polluted river. Ecological engineering, 57, 1-7.
- 13. Maier, R. M., Pepper, I. L., & Gerba, C. P. (2009). Environmental microbiology (Vol. 397). Academic press.
- 14. Olguni, E.J. et al. (2000) Environmental Biotechnology and Cleaner Bioprocess, Taylor & Francis.
- 15. Gareth M. Evams et al., (2003) Environmental Biotechnology: Theory & Applications, Wiley.
- 16. Milton fingerman et al. (1999) Recent Advances in Marine Biotechnology Volume 3, AbeBooks Inc.
- 17. Upadhyay, L. S., & Verma, N. (2015). Role of Biosensors in Environmental Monitoring. In Environmental Microbial Biotechnology (pp. 77-90). Springer.
- 18. Geetha, S., & Gouthami, S. (2016). Internet of things enabled a real time water quality monitoring system. Smart Water, 2(1), 1.
- 19. Gibas, C., Jambeck, P., & Fenton, J. M. (2001). Developing bioinformatics computer skills. " O'Reilly Media, Inc.".
- 20. Attwood, T.K. & Parry-Smith D.J. (2003). Introduction to Bioinformatics. Pearson Education.
- 21. Rastogi, S. C., Rastogi, S. C., Mendriratta, N., & Rastogi, P. (2006). Bioinformatics:

Concepts, Skills & Applications. CBS Publishers & Distributors Pvt. Limited.

- 22. Sensen, C. W. (2005). Handbook of genome research: genomics, proteomics, metabolomics, bioinformatics, ethics and legal issues; Vol. 1 und 2. Wiley-VCH Verlag GmbH & Co. KGaA.
- 23. Ecology and Environment: P.D. Sharma, 1994.
- 24. Concept of Ecology: E.J. Kormondy, 1996, Concept of modern Biology Series, Prentice Hall
- 25. A textbook of environmental pollution and control. S S. Dara

# Course 3 – Practical–Lab Work-I (Nanobiotechnology and Environmental Biotechnology) Credits 4

Course Outcomes: On successful completion of the course the learner would be able to

CO1: Synthesize, characterize & perform antimicrobial activity of synthesized nanoparticles.

CO2: Profile soil, based on Physico-chemical parameters

CO3: Screen industrially important microorganism

Topics:	Credits	No. of
1. Biosynthesis and characterization of silver nanoparticles by using		Hours
plant/leaf extracts/green tea.	4	120
2. Synthesis and characterization of zinc sulphide nanoparticles by a		
reverse micelle method		
3. Synthesis and characterization of Fluorescent Carbon		
Nanoparticles from Candle Soot and their separation of using the		
Thin-Layer Chromatographic Method		
4. Synthesis of alginate beads and investigation of citric acid release		
from a nanoshell coating of polymer		
5. Antimicrobial activity testing of Nanoparticles/nanocomposites		
6. To study the soil profiles for their height, colour, texture, electrical		
conductivity, temp, pH, salinity, Bulk density, Specific gravity, water		
holding capacity of soil.		
7. Screening of rhizosphere microflora for agriculture applications.		
8. Detection and isolation of industrially important microorganisms -		
enzyme producers (for eg. lipase etc.)		
9. Microbial degradation of textile dyes/pesticides/hydrocarbons and oils		
10. Growth curve of metal tolerant organisms isolated from soil/ water		
11.ETP: Primary, chemical and biological treatment. (Visit and report		
writing)		
12. Identification and enlist the abiotic and biotic components of a forest		
ecosystem. (Visit and report writing		
· · · · · · · · · · · · · · · · · · ·		
13. Enlist the biotic components of a Pond ecosystem. (Visit and report		
writing)		
14. Measurement of sounds by DB metre in silent, industrial, residential and		
commercial zones.		
15. Detection of heavy metals concentration in soil/ water by AAS		
(Demonstration)		

- 1. A Laboratory Course in Nanoscience and Nanotechnology by Poinern, Gérrard EddyJai Pg 97-105,Pg 106-111,Pg 116-121,Pg 155-172.
- 2. Njuguna, J., Vanli, O. A., & Liang, R. (2015). A review of spectral methods for dispersion characterization of carbon nanotubes in aqueous suspensions. Journal of Spectroscopy, 2015.
- 3. Singh, J. P., Nandi, T., Ghosh, S. K., Srivastava, J., Tripathi, S. K., & Prasad, N. E. (2018). Carbon nanoparticle synthesis, separation, characterization, and tribological property evaluation. Separation Science and Technology, 53(14), 2314-2326.
- 4. Qais, F. A., Shafiq, A., Khan, H. M., Husain, F. M., Khan, R. A., Alenazi, B., & Ahmad, I.(2019). Antibacterial effect of silver nanoparticles synthesized using

- Murraya koenigii (L.) against multidrug-resistant pathogens. Bioinorganic Chemistry and Applications, 2019.
- 5. Aritonang, H. F., Koleangan, H., & Wuntu, A. D. (2019). Synthesis of silver nanoparticles using aqueous extract of medicinal plants' (Impatiens balsamina and Lantana camara) fresh leaves and analysis of antimicrobial activity. International journal of microbiology, 2019.
- 6. Ponarulselvam, S., Panneerselvam, C., Murugan, K., Aarthi, N., Kalimuthu, K., & Thangamani,S. (2012). Synthesis of silver nanoparticles using leaves of Catharanthus roseus Linn. G. Don and their antiplasmodial activities. Asian Pacific journal of tropical biomedicine, 2(7), 574.
- 7. Nakhjavani, M., Nikkhah, V., Sarafraz, M. M., Shoja, S., & Sarafraz, M. (2017). Green synthesis of silver nanoparticles using green tea leaves: experimental study on themorphological, rheological and antibacterial behaviour. Heat and Mass Transfer, 53(10), 3201-3209.
- 8. Rolim, W. R., Pelegrino, M. T., de Araújo Lima, B., Ferraz, L. S., Costa, F. N., Bernardes, J.S.. & Seabra, A. B. (2019). Green tea extract mediated biogenic synthesis of silver nanoparticles: characterization, cytotoxicity evaluation and antibacterial activity. Applied Surface Science, 463, 66-74.
- 9. Shahzadi, S., Zafar, N., & Sharif, R. (2018). Antibacterial activity of metallic nanoparticles. Bacterial pathogenesis and antibacterial control. IntechOpen, London, 51-71.
- 10. <a href="https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/1471-2458-12-594">https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/1471-2458-12-594</a>
- 11. https://www.mdpi.com/1660-4601/14/7/815/htm
- 12. https://link.springer.com/article/10.1134/S0020168511140184
- 13. https://www.ijraset.com/fileserve.php?FID=17992
- 14. <a href="https://www.researchgate.net/publication/241028913">https://www.researchgate.net/publication/241028913</a> Microorganisms in Soil Water and Air
- 15. http://www.fao.org/3/ag359e/ag359e.pdf
- 16. <a href="http://www.fao.org/fileadmin/templates/nr/images/resources/pdf\_documents/manual-soil\_20bioassessment.pdf">http://www.fao.org/fileadmin/templates/nr/images/resources/pdf\_documents/manual-soil\_20bioassessment.pdf</a>

# **Course 4 - Bioanalytical and Biophysical techniques**

Credits 2

**Course Outcomes:** On successful completion of the course the learner would demonstrate and explain the understanding of the

CO 1: Principles of different Bioanalytical techniques, related sample preparation methods, possible data outcomes and their interpretation.

CO 2: Applications of Analytical techniques in the different study designs for investigations, estimations and analysis of technical parameters.

Modules	Topics	Credits	No of Lectur es
Module I: Microscopy and Fluorescence techniques	Microscopy and sample preparation techniques: Bio AFM, ESEM, STEM, Confocal microscopy and Electron microscopy (TEM/SEM) and their respective sample preparation. Cell imaging Techniques- <i>In vitro</i> and <i>In vivo</i> ; Immuno-electron microscopy. (Applications in experimental analysis for each). – (7 lectures)  Fluorescent conjugates and techniques: a) Principle of fluorescence, Quantum Yield Use of Fluorescent films, fluorochromes and fluorophores/dyes used in bioanalytical techniques. b) Uses and applications of labelling/ Coupling/conjugating antibodies with fluorophores/enzymes – (e.g. fluorescein and FITC/ rhodamine/ Texas-red/BODIPY (Boron-dipyrromethene) etc. and Alkaline phosphatase, Horseradish peroxidase, biotin/avidin). (8 lectures)	2	15
Module II: Flow Cytometry and Cytotoxicity for Cellular Analysis	<ul> <li>a) Types: Acoustic Focusing Cytometers, Cell Sorters (FACS), Imaging Cytometry and Mass Cytometers. (4 lectures)</li> <li>b) Reagents: Small Organic Molecules (Alexa Fluor), Phycobiliproteins, Metal Conjugates, Nucleic Acid Dyes, Quantum Dots etc. (4 lectures)</li> <li>c) Applications in Immunophenotyping, apoptosis analysis, Cell Cycle Analysis, RNA Flow Cytometry etc. (3 lectures)</li> <li>d) Cytotoxicity: Functional Assays – Lymphoproliferation, Cell Cytotoxicity (MTT assay), mixed lymphocyte reaction, Apoptosis (Annexin V Assay), Cytokine expression etc. (4 lectures)</li> </ul>		15

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- 12. Van Engeland, M., Nieland, L. J. W., Ramaekers, F. C. S., Schutte, B., & Reutelingsperger, C. P. M. (1998). Annexin V-affinity assay: A review on an apoptosis detection system based on phosphatidylserine exposure. *Cytometry*, 31(1), 1–9. https://doi.org/10.1002/(SICI)1097-0320(19980101)31:1<1::AID-CYTO1>3.0.CO;2-R

# Elective Course 1: Food Biotechnology and Nutraceuticals (Theory) Credits 2

**Course Outcomes:** On successful completion of the course the learner would demonstrate and explain the understanding of the following:

CO1: the basic principles and need of food fortification, GMOs and Nutraceuticals

CO2 : approaches to meet nutritional needs CO3: the strategies for food fortification

Modules	Topics	Credi ts	No. of Lecture s
Module I: Food Biotechn ology and nutrition	Strategies for augmenting food production- Green, White, Brown and Blue revolution (3 lectures)  Biofortification: Definition and its significance.  Methods for biofortification of plant based foods- agronomic biofortification, plant breeding, genetic engineering/ transgenic approach. (3 lecture)  Advanced food preservation techniques- electrothermal, freezing and pulse electric field methods, Ultrasound technology and ozone treatment, nanotechnology in food preservation, smart packaging (5 lectures)  Nutrigenomics: Food nutrition & gene regulation, Impact of dietary glucose, fat, vitamins in gene expression (4 lectures)	1	15
Module II : Nutrace uticals	Nutraceuticals: Definition, characteristic features, and classification based on source and chemical nature. (3 lectures) Nutraceuticals-Sources (plant based, animal based, algae based. (1 lecture) Functional foods: Characteristic features and classification. (2 lectures), Prebiotics, Probiotics and Synbiotics (3 lectures) Applications of nutraceuticals and functional foods: in human health and nutrition. (3 lectures) (eg. diabetes, Obesity, Sports) Nutraceutical and functional food regulations in India. (1 lecture), Toxic Contamination of Nutraceuticals and Functional Food Ingredients- pesticides/ heavy metals/ mycotoxins and other Contaminants (2 lectures)	1	15

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- 4. Dietetics- B. Srilakshmi, (2007), New Age International Publishers, 7th Edition.
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- 6. Functional Food Ingredients and Nutraceuticals processing technologies -John Shi,,Taylor and francis
- 7. Phytochemical of Nutraceutical Importance- Dhan Prakash and Girish Sharma,.

- 8. Handbook of Nutraceuticals and Functional Foods, Edited By Robert E.C. Wildman, Robert Wildman, Taylor
- 9. Handbook of Probiotics and Prebiotics, Second Edition, Editor(s): Yuan Kun Lee Seppo Salminen
- 10. Print ISBN: 9780470135440 Online ISBN:9780470432624 DOI:10.1002/9780470432624
- 11. C. Wallace, Edition 2nd Edition, CRC Press, DOI https://doi.org/10.1201/9781420006186 eBook ISBN 9780429195563 https://www.researchgate.net/publication/322658329\_Nutraceuticals\_and\_Fu nctional\_Foods
- 12. Nutraceuticals and Functional Foods in Human Health and Disease Prevention (PDFDrive). pdf Edited by Debasis Bagchi Harry G. Preuss Anand Swaroop CRC Press ISBN: 13: 978-1-4822-3722-1
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- 21. National nutrition policy
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- 25. Chapter Indian History Of Indian Agriculture- IGNTU <a href="https://www.igntu.ac.in/eContent/IGNTU-eContent-375577792959-BA-AIHC-6-DrJanardhanaB-ScienceandTechnologyinAncientIndia-4.pdf">https://www.igntu.ac.in/eContent/IGNTU-eContent-375577792959-BA-AIHC-6-DrJanardhanaB-ScienceandTechnologyinAncientIndia-4.pdf</a>
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# Elective Course 1: Food Biotechnology and Nutraceuticals (Practicals)

Credits 2

Course outcomes: On successful completion of the course the learner would be able to

CO1: Apply the understanding of different techniques learnt, for qualitative and quantitative analysis of food to analyse different food products.

CO2: comprehend different food standards for various categories of foods.

CO3: Understand and learn about the use of food preservatives in fruit and vegetable preservation.

# **Practicals based on Food Biotechnology and Nutraceuticals**

- 1. Estimation of vitamin A from fruits/ vegetable
- 2. Extraction and Estimation of antioxidant properties of phytochemicals by DPPH and anthocyanins extraction
- 3. Qualitative test for tannins, phenols, isoflavones, alkaloids.
- 4. Estimation of gluten from food sample.
- 5. Estimation of minerals in food samples iron, phosphorus, Zinc and calcium (In fortified and non-fortified foods)
- 6. Extraction & estimation of alkaloids (caffeine/ Catechin)
- 7. Molecular techniques in the detection of food pathogens and GM foods (Demo)
- 8. Estimation of Specific food Preservative / ingredients such as glycerine, vinegar, Benzoic acid from food products
- 9. Assignment on health benefits of nutraceutical ingredients
- 10. Visit to any food processing Industry

- 1. Jay M.J (2015) -Modern Food Microbiology, Fourth Edition, CBS Publishers and Distributors, New Delhi (for food preservation techniques)
- 2. Joy P. P., Surya S. and Aswathy C. prsvkm\_laboratory\_manual\_of\_biochemistry, Kerala Agricultural University, Pineapple Research station 2015

# **Elective Course 2: Clinical Biochemistry: (Theory)**

Credits 2

**Course Outcomes:** On successful completion of the course the learner would be able to

CO1: integrate the knowledge gained in clinical biochemistry viz hematopoietic system with day-to-day examples

CO2: Understand the role of nutrients and electrolytes in physiological functioning

Modules	Topics	Credits	No of lectures
Module I: Haem Disorder s and Protein calorie Malnutrit ion	Haemoglobin structure and function, Met-Hb, embryonic-Hb structure and function, heme metabolism associated diseases, Hemoglobinopathies, haemoglobin bart's, haemoglobin Lepore, sickle cell anaemia, Haemolytic anaemia thalassemia, Heinz bodies, hereditary Spherocytosis, hereditary Elliptocytosis, extracorpurscular defects.  Malnutrition Kwashiorkor, marasmus Keratomalacia, measurement of fuel values of foods, measurement and calculation of BMR, Calorimetry.		15
Module II: Electroly tes and biochem ical diagnosi s	Electrolytes, reabsorption of electrolytes, acid- base balance, regulation of electrolyte content of body fluids and maintenance of pH, regulation of sodium and water balance, renin- angiotensin system, clinical investigation of sodium, potassium, chloride. Biochemical diagnosis of diseases by enzymatic assays; Clinical tissue analysis, biopsy, liquid biopsy, circulating RNA and DNA as molecular diagnosis of different diseases.	2	15

- 1. Harpers Illustrated Biochemistry 30th Edition, McGraw-Hill Education
- 2. Clinical Biochemistry and Metabolic Medicine Eighth Edition by Martin Andrew Crook, CRC Press
- 3. Textbook of Biochemistry for Medical Students, 7th edition, by D M Vasudevan, ,Sreekumari SKannan Vaidyanathan
- 4. Jaypee. Clinical chemistry: Techniques, Principles, Correlations, 6th Edition, by Bishop, Fody and Schoeff
- 5. Biochemistry-Lippincott Williams & Wilkins

# **Elective Course 2: Clinical Biochemistry: (Practicals:)**

Credits 2

**Course Outcomes:** On successful completion of the course the learner would be able to

CO1: Identify and understand Hemoglobinopathies

CO2: understand the role of enzymes in clinical diagnosis

- 1. Observe permanent slides for Hemoglobinopathies
- 2. Determine haemoglobin concentration using Sahil's method
- 3. Determine Protein content in commercial protein powders/health drinks by biurets method
- 4. Calculating BMI- demonstration
- 5. Determination of serum SOD, Catalase, Glutathione peroxidase activity.

- 1. Practical Clinical Biochemistry Harold Varley
- 2. https://sites.google.com/ignou.ac.in/bscbch-biochemistry/self-learning-material/bbcel-142-nutritional-biochemistry-practical

# Elective Course 3: Advanced Epidemiology and Applied Microbiology (Theory) Credits 2

**Course Outcomes:** On successful completion of the course the learner would be able to CO1: Understand key epidemiological principles for preventing, controlling and managing pandemic and emerging infectious diseases.

CO2: Gain comprehensive knowledge of viral and emerging infections, including latest developments in diagnostics and therapeutics.

CO3: Acquire understanding of antimicrobial resistance mechanisms and assessment methods for managing drug resistance in populations.

Modules	Topics	Credits	No of Lectures
Module I: Advanced Epidemiology	History and Overview of basic epidemiology (2 lectures) Descriptive epidemiology, Analytical epidemiology, Experimental epidemiology (2 lectures) Types of Epidemiological studies (5 lectures) Observational studies - Descriptive studies, Ecological studies, Ecological fallacy, Cross-sectional studies, Case-control studies, Cohort studies. Experimental epidemiology - Randomised controlled trials, Field trials, Community trials, Potential errors in epidemiological studies - Random error, Sample size, Systematic error, Selection bias, Measurement bias, Application of basic biostatistics in epidemiology (3 lectures) Case reporting – meaning, significance (1 lecture) Organisations in disease control & Research – National/ International any two of each (2 lectures)	2	15
Module II: Applied Microbiology	Viral infections and Emerging pathogens: Detailed Study of following infections including Etiological agent its structure and genome organisation, Transmission, Pathogenesis, Clinical Manifestations, Lab diagnosis, Prophylaxis, strategies for prevention & treatment, Viral infections: (3 lectures) Viral Hepatitis and Chikungunya, Emerging pathogens: (5 lectures) New Variants of Vibrio cholerae O1 El Tor, Nipah virus, SARS-CoV, Antibacterial susceptibility testing (2 lectures) Conventional and advanced methods of drug susceptibility testing Antiviral susceptibility testing (3 lectures)		15

assay (PRA), dye uptake assay (DU), neuraminidase inhibition, PBMC cocultivation
Genotypic testing methods - DNA sequencing, PCR amplification, restriction enzyme digestion,
microarrays, Detection of drug resistance in - (2
lectures) Staphylococci, Enterococci, Gram negative bacteria ESBLs

### **Elective Course 3:**

# Advanced Epidemiology and Applied Microbiology (practical): Credits 2

Course Outcomes: On successful completion of the course the learner would be able to

CO1: Apply various analytical skills in diagnostics of viral and pathogenic infections.

CO2: Utilise statistical approaches in epidemiological studies.

CO3: Determine antimicrobial susceptibility and antimicrobial resistance.

- 1. Serodiagnosis of HBsAg infection: Rapid latex agglutination detection of HBsAg (Kit based).
- 2. Diagnosis for Swine flu-H1N1: Hemagglutination inhibition assay.
- 3. Rapid identification for Chikungunya virus (IgM &IgG) kit method.
- Identification of Vibrio cholerae 0139: Cholera red test, String test, Oxidase test, & Isolation on TCBS medium.
- 5. Serological diagnosis for V.c.0139 using specific monotypic antisera.
- 6. Determination of MIC by E test.
- 7. Antimicrobial Synergy testing by Checkerboard Assay.
- 8. Biostatistics problems on epidemiology.
- 9. Epidemiological case reporting.

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- 3. Mim's Medical Microbiology, 5 th edition, Richard V. Goering, Hazel M. Docrell, Mark Zuckerman, Ivan M. Roitt, Peter L. Chiodini, ELSEVIER.
- 4. Microbiology An Introduction 10th Edition Gerard J. Tortora, Berdell R. Funke, Christine L.Case. Library of Congress Cataloging-in-Publication Data.
- 5. Fenner and White's medical virology. Academic Press, fifth edition 2016 Burrell, Christopher J., Colin R. Howard, and Frederick A. Murphy, Elsevier.
- 6. Ananthanarayan and Paniker's Textbook of Microbiology, Tenth edition, 2017 by Reba Kanungo, 10th ed Universities Press.
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- 9. Bailey and Scott's Diagnostic Microbiology 14th edition, 2015 Elsevier Health Sciences.
- 10. Vibrio cholerae O139 Bengal. Albert, M J. (1994), *Journal of clinical microbiology* vol. 32(10), pp 2345-9. doi:10.1128/jcm.32.10.2345-2349.1994 <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC264063/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC264063/</a>
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- 17. Antibiotics in laboratory medicine. 5th Edition Lorian, V. (Ed.) 2005. Lippincott Williams & Wilkins.

# Semester - IV

# **Semester IV**

# **Course 1: Omics and Systems Biology**

**Credits 4** 

**Course Outcomes:** On successful completion of the course the learner would be able to **CO1**: Understand the fundamental concepts and applications of genomics, transcriptomics, and proteomics, including genome mapping, RNA sequencing, and protein identification techniques.

**CO2**: Learner will gain knowledge in the tools and methodologies of metabolomics and lipidomics, as well as an introduction to systems biology, data mining, and the use of big data in biological research.

Modules	Topics	Credits	No of
	Companies (Electures)		lectures
	Genomics:(5 lectures)		15
Module I:	Genome and Genomics, Genome Mapping, Physical		
	and Genetic maps, Genome sequencing, Genome		
Genomics,	annotation, Functional genomics and Applications of		
Transcriptom	genomics. Transcriptomics: (5 lectures)		
ics and Proteomics	RNA sequencing, Microarrays, Regulatory RNAs-		
Proteomics	small and large, Applications of transcriptomics.		
	Proteomics: (5 lectures) Basic concepts, Tools of		
	Proteomics- SDS PAGE, 2-D PAGE, Liquid		
	chromatography, Protein identification by peptide		
Madulalli	mass fingerprinting, Applications of Proteomics.		15
Module II: Metabolomic	Metabolomics: (8 lectures)		15
	Fundamental concepts, Tools of metabolomics-		
s, Lipidomics	Capillary electrophoresis, Gas chromatography,		
	Mass Spectrometry Electrochemical detectors, Case	4	
	studies related to metabolomics, Applications of	4	
	Metabolomics. Lipidomics: (7 lectures)		
	Basic concepts, Tools of lipidomics- Mass spectroscopy, TLC, HPLC, GC Capillary		
Module III:	electrophoresis, MALDI, Applications of Lipidomics.  Understanding of Biological Systems: Systems		15
Introduction			15
	Structure, Systems Dynamics, Systems Design and		
to Systems	Control, Systems Project (5 lectures)		
Biology	Models and Modelling Systems in Systems Biology:		
	Definition of a Model, Key Properties, Basics of		
	Computational Models, Networks, Data Integration, Standards, and Model Organism (5 lectures)		
	Standards, and Model Organism (Stectures)  Standards and Formats for Systems Biology:		
	Computational Databases and Software Tools (2		
	lectures), Biological Networks: Metabolic Networks,		
	,, ,		
	Gene Regulatory Networks, PPI Networks (3 lectures)		
Module IV:	An overview of data mining (4 lectures)		15
Data Mining	Data mining process models		10
and Big Data	Data collection Data preprocessing		
and Dig Data	Introduction to Knowledge Discovery in		

1	
	Databases (KDD): (4 lectures)
	The KDD Process, Taxonomy of Data Science
	Methods Big Data (1 lectures)
	Drug discovery and development process. (2
	lectures)
	Big Data in Biology (1 lecture)
	Big Data Resource- Public Resources, Proprietary
	Databases (3 lectures)

- 1. Hiroaki Kitano, Foundations of Systems Biology, MIT Press (2001)
- 2. Klipp, Edda, Kowald, Axel, Liebermeister, Wolfram, Wierling, Chr, Systems biology, a textbook (2016, Wiley-VCH)
- 3. Jon Holy, Ed Perkins (auth.), Stephen Krawetz (eds.) Bioinformatics for Systems Biology-Humana Press (2009)
- 4. Mikaël Lucas, Plant Systems Biology\_Methods and Protocols (Methods in Molecular Biology, 2395)-Humana (2021)
- 5. Walhout, Marian (Auth.) Handbook of Systems Biology-Academic Press (2012)
- 6. Zengyou He, Woodhead Publishing Series in Biomedicine: Number 76 Data Mining for Bioinformatics Applications, ISBN: 978-0-08-100107-3 (online)
- 7. Maimon, O., Rokach, L., Shmueli, E. (2023). Data Science and Knowledge Discovery Using Machine Learning Methods. In: Rokach, L., Maimon, O., Shmueli, E. (eds) Machine Learning for Data Science Handbook. Springer, Cham. https://doi.org/10.1007/978-3-031-24628-9\_1
- 8. Bhattarai, S., Kumar, R., Nag, S., Namasivayam, V. (2022). Big Data in Drug Discovery. In: Singh, S. (eds) Machine Learning and Systems Biology in Genomics and Health. Springer, Singapore. <a href="https://doi.org/10.1007/978-981-16-5993-5">https://doi.org/10.1007/978-981-16-5993-5</a> 2
- 9. Transcriptomics: Expression pattern analysis Virendra Gomase, Somnath Tagore.
- 10. Lipidomics Technologies and Applications- Kim Ekroos.
- 11. Metabolomics Methods and protocols Wolfram Weckwerth.
- 12. Mass Spectrometry for Biotechnology Gary Soiuzdak.
- 13. Proteomics for biological discovery Timothy Veenstra and John Yates.
- 14. Introduction to proteomics Tools for biology Daniel C Liebler.

# **Course 2: Drug Discovery and Clinical Studies (Theory)**

Credits 2

**Course Outcomes:** On successful completion of the course the learner would be able to CO1: Demonstrate an integrated understanding of drug development processes, drug discovery informatics, and the use of software tools in drug discovery.

CO2: Navigate the ethical and regulatory process of drug development, ensuring that new drugs are developed responsibly and in compliance with relevant guidelines and standards.

Modules	Topics	Credit s	No.of lectures
Module I: Clinical Research Informatics in Drug Discovery	Chemical Genomics- Identification of New Drug Targets Chemical Proteomics-Characterization of the Drug Target Chemical Genetics- Validation of the Drug Target; Combinatorial Chemistry. High-Throughput Screening; Fragment-Based Drug Development) Drug Discovery Informatics (4 Lectures) Information Resources- Role of different databases in CADD- Literature databases (MEDLINE); Chemical databases (DrugBank); Biological databases (Biochemical Genetic and Genomic (BiGG); Structure Databases (Protein Data Bank); Software Tools Used in Drug Discovery (4 Lecture) Chemical Drawing Tools (Chemical Sketch); Target Prediction Tools (Swiss Target Prediction ); ADME Toxicity Prediction Tools (SwissADME); Docking Tools (Auto Dock)	2	15
Module II: Clinical Trial Design And Indian Regulations	Clinical Trial Design: (2 lectures): Basic framework of clinical trial  Types of clinical trials (6 Lectures): Randomised clinical trials and different phases; Adaptive randomization methods; Seamless design; Internal pilot design; Design selection factors  The national regulatory body (4 Lectures)  Regulations and The Roles and Responsibilities of Stakeholders in the Sharing of Clinical Trial Data (3 Lectures): Participants in clinical trials, Investigators, Research institutions and universities, Journals and Professional societies		15

- 1. Schmidt, M.F. (2022). Introduction. In: Chemical Biology. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-64412-6
- 2. Reang, J. et al. (2023). Informatics: Tools and Databases in Drug Discovery.

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- Committee on Strategies for Responsible Sharing of Clinical Trial Data; Board on Health Sciences Policy; Institute of Medicine. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk. Washington (DC): National Academies Press (US); 2015 Apr 20. PMID: 25590113.
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DOI: http://dx.doi.org/10.18203/2349-3259.ijct20204486

**Course Outcome:** On successful completion of the course the learner would be able to

CO1: Demonstrate the skill of online tool utilization for the analysis of drug molecule properties.

Sr. No	Experiment
1	A finding of a drug-gene interaction or potentially druggable category using The Drug Gene Interaction Database (DGIdb)
2	Predicting ligands and recognition of binding patterns common to a set of protein structures using ProBiS.
3	Draw or edit the molecule of interest, and generate SMILES or InChI descriptors.
4	Predict ADME parameters, pharmacokinetic properties, druglike nature and medicinal chemistry friendliness of small molecules to support drug discovery.
5	Prediction of toxicity of chemicals using ProTox 3.0 web server.
6	Computational protein-ligand docking using AutoDock (DEMO)
7	Case study on clinical trials

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- 9. https://www.sciencedirect.com/science/article/pii/S0002916523017008
- 10. http://probis.cmm.ki.si/
- 11. http://probis.cmm.ki.si/download/ProBiS-2012-Users-Guide.pdf

# Course 3: Molecular Enzymology (Theory)

**Credits 2** 

**Course Outcomes:** On successful completion of the course the learner would be able to understand the

CO1: Role of enzymes as diagnostic tools and its industrial applications.

CO2: Methods of enzyme engineering to enhance their activity and half life.

CO3: Outcome of enzyme deficiencies, significance of enzymes as a diagnostic tool in therapy and as biosensors.

Modules	Topics	Credits	No of lectures
Module I: Enzyme engineering and applications of engineered enzymes	Introduction to enzyme engineering and engineering tools for enzymes - brief history; molecular modifications of enzymes - irrational designs (directed evolution & random mutagenesis, molecular breeding of DNA - homologous DNA shuffling, circular permutation, random insertion/deletion mutations), rational design and computational design (precise design); de novo enzyme design and semi - rational design (focus on few mutation sites) (7 lectures)  Applications of engineered enzymes - medicine; food and drink industry; detergent industry; feed industry; pharmaceutical industry; textile industry. (8 lectures)		15
Module II:	Inherited metabolic diseases and enzyme		15
Enzyme	deficiency- Alkaptonuria, Maple Syrup Urine		
deficiencies,	disease, Galactosemia, Pompe disease, Gaucher	2	
diagnostic	disease, Fabry		
enzymes and	disease. HGPRT deficiency (5 lectures)		
therapeutics	Enzymes and Isoenzymes in diagnosis of		
	diseases- liver diseases, cardiac diseases, GI tract diseases, muscle and bone diseases, malignancies (3 lectures)  Enzymatic Biosensors As Diagnostic Tools-Biosensors- basic instrumentation, Biosensors for detection of- Glucose in Blood, Urea in Blood and Urine (2 lectures)  Enzymes of therapeutic value- Asparaginase, DNase, Glucocerebrosidase, α-Galactosidase, urate oxidase and laronidase, Superoxide dismutase, Application of enzymes as Debriding agents, Digestive aids and Thrombolytic agents (5 lectures)		

# References (Theory):

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- Current developments in Biotechnology and Bioengineering. Sudhir Singh, Ashok Pandey, Sudesh Kumar. Synthetic Biology, Cell Engineering and Bioprocessing
- 3. Trevor Palmer Understanding Enzymes-E. Horwood (1991)
- 4. Biomass, Biofuels, Biochemicals: Advances in Enzyme Technology, First edition (2019), Ram Sarup Singh, Reeta Rani Singhania, Ashok Pandey and Christian Larroche, Elsevier
- 5. Atlas of Inherited Metabolic Diseases, Third edition, (2011), William L Nyhan, Bruce A Barshop and Aida I Al-Aqeel, CRC Press Taylor & Francis Group
- 6. Textbook of Medical Biochemistry, fourth updated edition (2020), Dinesh Puri, Elsevier
- Textbook of Medical Biochemistry, eighth edition (2012), MN
   Chatterjea, Rana Shinde, Jaypee Brothers Medical Publishers Pvt. Limited
- 8. Pharmaceutical Biotechnology Concepts and Applications (2007), Gary Walsh, John Wiley & Sons Ltd
- Industrial Enzyme Applications (2019) Vogel, Andreas. May Oliver, WILEY-VCH
- 10. Directory of therapeutic enzymes (2006), Barry M. McGrath and Gary Walsh, CRC Press Taylor & Francis Group
- 11. Enzyme Engineering <a href="https://amazingbiotech.blogspot.com/2013/11/enzyme-engineering.html">https://amazingbiotech.blogspot.com/2013/11/enzyme-engineering.html</a>
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- 14. What Is Enzyme Engineering? Application of Enzyme Engineering <a href="https://infinitabiotech.com/blog/application-of-enzyme-engineering/">https://infinitabiotech.com/blog/application-of-enzyme-engineering/</a>
- 15. Industrial Enzymes(chapter 13, Industrial Bio refineries and White Biotechnology) Elsevier article link: <a href="https://www.researchgate.net/publication/311997374">https://www.researchgate.net/publication/311997374</a>
- 16. Inborn errors of Metabolism (chapter 3- Advances in Biochemistry & application in medicines) link: <a href="mailto:inborn-errors-of-metabolism.pdf">inborn-errors-of-metabolism.pdf</a> (openaccessebooks.com)
- 17. (PDF) Enzymes as Diagnostic Tools (researchgate.net)

# Course 3: Molecular Enzymology and Enzyme Technology - Practical Credits 2

Course Outcomes: On successful completion of the course the learner would be able to

CO1: Study the effects of inhibitors on microbial enzymes

CO2: Learn techniques of enzyme purification and its importance

CO3: Design enzyme assays to measure enzyme activity under different conditions

# **Topics:**

- 1. Microbial Enzyme production:
  - a. Partial purification using ammonium sulphate precipitation.
  - b. Dialysis of the salt-precipitated protein.
  - c. Assessing the enzyme activity and the protein content.
- 2. Effect of inhibitors/ chemicals on enzyme activity.
- 3. Extraction of enzymes from plant sources.
- 4. To determine Specific activity of α Amylase.

### **REFERENCES:**

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- 2. Satyanarayan and Chakrapani, Biochemistry. New Delhi, Elsevier Health Sciences APAC, 2013.
- 3. Berg JM, Tymoczko JL, Stryer L (2002): Biochemistry, 5th ed., Freeman WH and Co., New York.
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- 7. Understanding enzymes (3rd edition). Edited by Trevor Palmer, Ellis Horwood, Chichester, 1991.
- 8. Protein purification principles, High Resolution Methods, and Applications, 3rd Edition, Jan-Christer Janson, John Wiley & Sons, Inc., Hoboken, New Jersey.
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- 12. https://www.labome.com/method/Protein-Purification.html
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- 17. Fundamentals of Enzyme Engineering, Young Je Yoo, Yan Feng, Yong-Hwan Kim Camila Flor J. Yagonia, : Springer Netherlands 2017.

# Elective Course 1 Biologics and Regulatory Affairs (Theory) Credits 4

Course Outcomes: On successful completion of the course the learner would be

CO1: Familiar with the basic concepts and significance of Biologics/Biosimilar in addition to having knowledge about its therapeutic applications.

CO2: Knowledgeable in the steps involved in the production of Biologics/Biosimilars

CO3: Aware of the protocols/techniques required for characterization of the Biosimilar relative to the Reference Biologic

CO4: Acquainted with the regulatory aspects of approval of Biosimilars.

	d with the regulatory aspects of approval of Biosimilars		
Modules	Topics	Credit s	No of Lecture s
Module I: Introduction to Biologics and Biosimilars	Definition and Introduction of: Drugs, Small molecules, Generics, Large molecules/Biologics; Introduction to Biologics (reference drug) and Biosimilars. Synonyms of Biosimilars. Need for Biosimilars (2 Lectures) Similarities and Differences: Small molecules and generics, Biologics and Biosimilars. small molecules (Generics) and Large molecules (biosimilars). (2 lectures) Categories of Biologics: (2 examples each with description, production, applications) protein-based hormones, enzymes, monoclonal antibodies, vaccines, blood products, and gene & cellular therapy products (6 lectures) USFDA Approved- Small Molecules, Generics, Biologics and Biosimilars (two examples of each) (2 lectures) The three tenets of Biosimilarity Small versus large molecule regulation in the US (2 lectures) Acceptable quality differences between approved Biosimilar and innovator product (reference drug) (1 lecture)	4	15
Module II: Biosimilars Drug Substance Development and Manufacturin g: Effective CMC Strategy	Introduction to the Chemistry, Manufacturing and Controls (CMC) strategy and understanding of the Reference Drug (1 lecture) Choice of Expression Systems and Clonal Selection (1 lecture) Development of upstream and downstream processes and scale up to manufacturing. (2 lectures) Effect of Raw Materials on Product Quality (1 lecture) Effect of Manufacturing Conditions on Product Quality and Control Strategy for Biosimilars (1 lecture) Implementing a Successful CMC and Analytical Strategy for the Development of Biosimilars (3		15

	lectures) Example: Production of Monoclonal antibody, downstream processing of Mab (4 lectures) Introduction to the concept of Biobetters vs Biosimilars (2 lectures)	
Module III: Character ization of Biologics and Biosimilars	(Protein product characterization, Reference product characterization, Biosimilar product characterization) Appearance, particulates, pH, osmolality, particle size-To check homogeneity and general properties. (1 Lecture)  Molecular Weight, Protein Sequence/ amino acid composition- To check identity of biologic.(2 Lectures)  Post translational Modifications: Glycosylation, Sialylation, Phosphorylation, Acetylation, and Myristoylation- To check active/ inactive form of biologic.(1 Lecture)  Size and Purity on HPLC / MALDI - To check homogeneity & absence of impurities.(2 Lectures) Isoform pattern -To check conservation of secondary structure. (1 Lecture)  Gel electrophoresis:IEF, SDS PAGE and Native PAGE, Western blot -To check purity/ nativity.(2 Lectures)  Fluorescence spectrum -To check presence of impurities such as quenchers.(1 Lecture)  FTIR spectrum and NMR spectrum-To check presence of prosthetic group & conservation of tertiary structure. Bioassays. (3 Lectures)  Example of characterization using Monoclonal Antibody as an example.(2 Lectures)	15
Module IV: Quality assurance & regulatory affairs of Biologics and Biosimilars	Introduction to Regulatory Affairs and approvals of Biosimilars. (1 Lecture) Products approved under the FD&C (505) (b) (2) pathway/Act .(3 Lectures) PHS/BCPI Act 2009: Innovator Biologics Approval, Biosimilar Pathway, Totality of Evidence, Information required to demonstrate biosimilarity, Interchangeability, Product Switching, Product Naming. (6 Lectures) Global regulatory framework in India (1 Lecture) Europe (1 Lecture) UK (1 Lecture) Brazil (1 Lecture) China (1 Lecture)	15

- 1. Biosimilars, Regulatory, Clinical and Biopharmaceutical Development, Editors: Hiten J. Gutka •Harry Yang Shefali Kakar, AAPS Advances in the Pharmaceutical Sciences Series Volume 34, Pg 173-182.
- 2. Biosimilars of Monoclonal Antibodies, A Practical Guide to Manufacturing Preclinical, and Clinical Development Edited by Cheng Liu, Ph.D., K. John Morrow, Jr., Ph.D.Copyright c 2017 by John Wiley & Sons, Inc. All rights reserved Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
- 3. Introduction to Biologic and Biosimilar Product Development and Analysis Karen M. Nagel AAPS Introductions in the Pharmaceutical Sciences Editor-in-Chief:Robin M. Zavod Midwestern University, Downers Grove, IL, USA
- 4. Biosimilars: Key regulatory considerations and similarity assessment tools: Carol F. Kirchhoff, Xiao-Zhuo Michelle Wang, Hugh D. Conlon, Scott Anderson, Anne M. Ryan, and Arindam Bose.
- 5. https://ibkp.dbtindia.gov.in/DBT\_Content\_Test/CMS/Guidelines/20181115140 059519\_Guidelines-on-Similar-Biologics-2016.pdf.
- 6. Regulatory Requirements of 'Similar Biologics' for Marketing Authorization in India. Review Article. Sharmila et al., International Journal of Drug Regulatory Affairs; 2017, 5(1), 20-24.
- 7. Introduction to Biosimilars and Regulatory Requirements. Fact Sheet 3. International Federation of Pharmaceutical Manufacturers & Association (Geneva) & International Alliance of Patients Organization (UK)
- 8. Regulatory guidelines for approval of Biosimilars in India, Europe, Brazil and China: A comprehensive overview
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# Elective Course 2: NGS and Bioinformatics (Theory) Credits 2

**Course Outcomes:** On successful completion of the course the learner would be able to CO1: Perform NGS library preparation techniques for DNA and RNA sequencing. CO2: Interpret sequencing data to identify genetic variants, gene expression patterns, and

genomic features.

Modules	Topics	Credit	No of lectures
Module I: Human Genomics and Next Generation Sequencing (NGS)	Sequencing Technologies (3 lectures), Library Preparation for NGS (2 lectures), NGS Applications	2	15
Module II NGS Alignment & Quantificatio n	Essential NGS File Formats (FASTQ, SAM/BAM, VCF) (3 lectures) Quality Control (FastQC) (1 lecture), DNA-Seq Read Alignment Algorithms (BWA, Bowtie2), (2 lectures) RNA-Seq Read Alignment with Splice Junction Detection (HISAT2, STAR), (3 lectures) Read Quantification (RPKM, FPKM, TPM (3 lectures) Normalisation Techniques for Differential Expression Analysis (DESeq2, EdgeR) (3 lectures)		15

- 1. Human molecular genetics, 5th ed., Tom Strachan & Andrew Read, CRC press.
- 2. Next-Generation Sequencing Data Analysis, 2nd ed., Xinkun Wang, CRC press.
- 3. Next Generation Sequencing and Data Analysis, 1st ed., Melanie Kappelmann-Fenzl, Springer International publishing
- 4. Bioinformatics: A Practical Guide to Next Generation Sequencing Data Analysis, 1st ed., Hamid D. Ismail, CRC press

# **Elective Course 2 : NGS and Bioinformatics (Practicals)**

**Credits 2** 

Course outcomes: On successful completion of the course the learner would be able to

CO1: Demonstrate proficiency in using R for data manipulation and analysis.

CO2: Create and execute shell scripts to automate system administration tasks.

# **Practicals based on NGS and Bioinformatics**

- 1. Navigating the Linux Command Line
- 2. Managing Files and Text in Linux
- 3. Getting Started with R Programming
- 4. Data Handling and Cleaning in R
- 5. Integrating Linux and R for Automated Data Analysis
- 6. Setting Up Environment with Miniforge
- 7. RNA-Seq Data Preprocessing
- 8. Alignment with Splice-Aware Aligners
- 9. Read Counting and Quantification
- 10. Differential Expression Analysis
- 11. Submission of Assignments Data analysis using suitable databases.
- 12. Data plots using R or any other programming language.

Sign of the BOS Chairman Dr. Varsha Kelkar-Mane Ad-hoc BoS (Biotechnology)

Sign of the Offg. Associate Dean Dr. Madhav R. Rajwade Faculty of Science & Technology Sign of the Offg. Dean Prof. Shivram S. Garje Faculty of Science & Technology