

University of Mumbai



No. AAMS_UGS/ICC/2024-25/185

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 08th September, 2023 relating to the NEP UG & PG Syllabus.

They are hereby informed that the recommendations made by the Board of Studies in Bioanalytical Science at its meeting held on 10th August, 2024 and subsequently passed by the Board of Deans at its meeting held on 23rd October, 2024 vide item No. 6.5 (N) has been accepted by the Hon'ble Vice Chancellor as per the powers confirmed upon him under Section 12(7) of the Maharashtra Public Universities Act, 2016 and that in accordance therewith syllabus for **M.Sc. (Bioanalytical Science) Sem – III & IV** is introduced as per appendix (NEP 2020) with effect from the academic year 2024-25.

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

MUMBAI – 400 032
08th November, 2024


(Dr. Prasad Karande)
REGISTRAR

To,

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

BOD/6.5 (N)/23/10/2024

Copy forwarded with Compliments for information to:-

- 1) The Chairman, Board of Deans,
- 2) The Dean, Faculty of Science & Technology,
- 3) The Chairman, Board of Studies in **Bioanalytical Science**,
- 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, Admissions, Enrolment, Eligibility & Migration Department (AEM).

Copy forwarded for information and necessary action to :-	
1	The Deputy Registrar, (Admissions, Enrolment, Eligibility and Migration Dept)(AEM), dr@eligi.mu.ac.in
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 cap.exam@mu.ac.in
6	The Deputy Registrar, College Affiliations & Development Department (CAD), deputyregistrar.uni@gmail.com
7	The Deputy Registrar, PRO, Fort, (Publication Section), Pro@mu.ac.in
8	The Deputy Registrar, Executive Authorities Section (EA) eau120@fort.mu.ac.in 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), rapc@mu.ac.in
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), concolsection@gmail.com
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, thanesubcampus@mu.ac.in
15	The Assistant Registrar, School of Engg. & Applied Sciences, Kalyan, ar.seask@mu.ac.in
16	The Assistant Registrar, Ratnagiri Sub-centre, Ratnagiri, ratnagirisubcentre@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

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), camu@accounts.mu.ac.in

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 mkarne@economics.mu.ac.in
	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 kishoribhagat@rediffmail.com

	Faculty of Science & Technology Dean 1. Prof. Shivram Garje ssgarje@chem.mu.ac.in 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. Chadrashekhhar 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, dsd@mu.ac.in@gmail.com DSW directr@dsw.mu.ac.in
6	The Director, Department of Information & Communication Technology, director.dict@mu.ac.in

As Per NEP 2020

University of Mumbai



**Title of the P.G. Program
M.Sc. (Bioanalytical Sciences)**

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. No.	Heading	Particulars
1	Title of program O: _____	M.Sc. (Bioanalytical Sciences)
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: <u>SP-125B</u>	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. Prafulchandra Tekale
BOS in Bioanalytical Sciences

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

MSc. (Bioanalytical Sciences) Course Structure Semester III and IV

R: SP-125B

Ye ar	Le vel	Sem (2 Yr)	Major		R M	OJT / FP	R P	Cum . Cr.
			Mandatory*	Electives (Any one) Credits 4				
II	6.5	Sem III	Course 1 Basic Microbiology, Genomics, CE and Toxicology - Credits 4 Course 2 Standardization of ASU Drug- Credits 4 Course 3 Practical - Lab work Credits – 4 Course 4 BA/BE Studies and Method Validation- Credits 2	Course 1 - Bioprocess Technology OR Course 2 – Plant Biotechnology	-	-	4	22
		Sem IV	Course 1 MS Applications, Metabolite studies, Thermal Analysis and Tracer Techniques – Credits 4 Course 2 QC, QA, GMP & GCP - Credits 4 Course 3 Computation Biology & Programming - Credits 4	Course 1 – Nutraceutical and Functional Foods OR Course 2 – Animal Biotechnology	-	-	6	22
Cum. Cr. for PG Diploma			26	8			10	44
Cum Cr for 2 Yr PG degree			54	16	4	4	10	88

Scheme of Examination: (THEORY AND PRACTICALS)

(A) Summative assessments (THEORY):

For 2 credit courses	25 M
• Q.1 Answer any 1 question out of two (Covering Module 1 & 2)	8 M
• Q.2 Answer any 1 question out of two (Covering Module 1 & 2)	7 M
• Q.3 One or 2 marks answers. Questions based on problem solving/ analytical skills/ critical thinking (Covering Module 1 & 2)	10 M
For 4 credit courses	50 M
• Q1. Answer any 2 questions out of 3 (based on Module I)	10 M
• Q2. Answer any 2 questions out of 3 (based on Module II)	10 M
• Q3. Answer any 2 questions out of 3 (based on Module III)	10 M
• Q4. Answer any 2 questions out of 3 (based on Module IV)	10 M
• Q5. Write one Essay type answer out of 3 (based on Module I-IV)	10 M

(B) Formative assessments (informal and formal tests administered during the learning process).

For 2 credit courses	25M
• Group tasks/ Assignments/ Quizzes at the time of completion of each Module	15M
• Spoken/oral examination after completion of each Module	10M
For 4 credit courses	50M
• Open book test/ assignments/ presentation/ quiz/ role play/ MCQ/ problem solving to be designed for each Module	

(C) Summative assessments (Practical):

For 4 credit courses	50M
Minor I	25M
Minor II	15M
OR	
Major	40 M
Journal	5 M
Viva	5 M

(D) Summative assessments (Practical)

For 2 credit	25 M
Major Experiment	18 M
Viva	5 M
Journal	2 M

(E) Formative assessment (Practical) For 2 credits	25 M
---	-------------

Submission of 1 assignment: Poster/presentation based on history / discovery/ Application / problems based on techniques/ experiments performed	15 M
Viva/ Field visit report-	10 M

Semester III

Research Project: 4 credits

It is mandatory for students to review a minimum of 5 research papers from journals under the guidance of mentors (Students can be distributed amongst faculty in more or less equal numbers) and carry out Method Development using any one instrument for any one active molecule/ drug/ phytoconstituent and present in Conference/ symposium/ Research Meet and final presentation 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.

Semester IV

Research Project: 6 credits

Research project / Training with wet lab and/ or *in-silico* experience in fields in /or allied to Bioanalytical Sciences. The project would be graded during the practical examinations on the basis of the submitted project / dissertation report as well as a power-point presentation (50% by internal examiner and 50% by external examiner).

Syllabus

M.Sc. (Bioanalytical Sciences)

(Sem. III & IV)

Course 1. Basic Microbiology, Genomics, CE and Toxicology

Theory

Credits 4

Course Outcomes

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

- understand the basics of microbiology and to recognize its application in pharmaceuticals
- familiarize students with genomics
- introduce students to various concepts and guidelines of toxicology
- familiarize students with Capillary Electrophoresis

Unit	Topic	Credit	Number of Lectures
I	Title: Basic Microbiology and its application in pharmaceuticals 1. Microbes & Their environment, Significance and scope of Microbiology, Biodiversity and types of Microorganisms, Visualization of Microorganisms: Staining, Simple and compound microscopy, Electron Microscopy 2. Growth of Microorganisms, methods to study growth of microorganisms, preservation of microorganisms, maintenance media, etc. 3. Sources of antimicrobial agents: plants and microorganisms, therapeutic Antimicrobial Agents e.g. Erythromycin, Amphotericin B, Cephalosporins and their commercial production, Antimicrobial Drug Resistance and Drug Discovery 4. Control of microbial contamination, sources of contamination of pharmaceutical products 5. Study of microbial load of raw materials used for drug preparation.	4	15
II	Title: Genomics 1. Nucleic Acid chemistry 2. Principles of DNA sequencing 3. DNA & RNA probes 4. Concepts of Gene manipulation (introduction only) 5. Restriction enzymes & their uses 6. Vectors & their uses 7. Producing Transgenic organisms 8. Hybridoma technology 9. cDNA production & applications 10. Gene libraries & applications		15
III	Title: Basic and Regulatory Toxicology 1. Introduction, scope and types of toxicological studies. 2. Toxicants, their route of entry, distribution 3. Metabolism & elimination of toxicants 4. Concept of LD50, ED50 5. Regulatory Toxicology 6. Types of toxicity studies 7. Design considerations. 8. Evaluation of results 9. Extrapolation to man.		15

	10. OECD Guidelines on Toxicological studies 11. CPCSEA guidelines for animal testing centre, ethical issues in animal studies 12. Schedule Y and its interpretation.		
IV	Title: Capillary Electrophoresis 1. Introduction 2. How capillary electrophoresis works 3. Why capillary electrophoresis works 4. CE hardware 5. Use in Bioanalysis		15

Course 2. Standardization of ASU Drug
Theory

Credits 4

Course Outcomes

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

- familiarize students with various steps involved in standardization of ASU drugs
- understand the regulatory aspects of ASU drugs
- introduce students to concepts, requirements for QA & QC of ASU drug
- get informed about the Regulatory Issues wrt OCT, Cosmetics, Food and Nutraceuticals

Unit	Topic	Credit	Number of Lectures
I	Title: Standardization of ASU drugs 1. Need of standardization of Ayurvedic drugs 2. What does standardization involve? 3. Bioanalytical tools for standardization 4. Clinical studies in Standardization 5. Approaches to standardization; 6. Raw materials 7. In-process materials 8. Finished products 9. Developing standardized QC methods 10. Shelf life studies on finished products	4	15
II	Title: QC and QA of ASU drugs 1. Herbal pharmacopoeia and Ayurvedic Formulary of India 2. Approaches to Quality control of ASU formulations 3. Govt initiatives 4. Some Initiatives from manufacturers 5. QC of RM and In-process materials (some examples) 6. QC / OA for finished products (some examples) 7. Applications of Herbal pharmacopoeia and Ayurvedic Formulary of India 8. Recent advances in Quality control of ASU formulations 9. QC / QA for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon, etc.)		15
III	Title: Regulatory Aspects of ASU drugs 1. National initiatives for regulation of ASU drugs 2. Schedule T and Schedule Y of Drugs and Cosmetics Act 3. International initiatives for regulation of ASU drugs with special reference to - WHO guidelines on traditional medicine - Approaches of US and EU to ASU drug regulation 4. Provisions of Drugs and Cosmetics Act applied to ASU (e.g. Schedule T and Y)		15

IV	Title: Regulatory Issues 1. OTC drugs 2. Cosmetics 3. Food supplements 4. Nutraceuticals w.r.t. FSSI regulations		15
-----------	---	--	-----------

**Course 3. Practical – Lab work
Practicals**

Credits 4

1. Plant DNA extraction and separation using agarose Gel. 2. DNA fingerprint (Genomic DNA isolation kit may be used) of two bacterial strains e.g. Resistant and wild strains of <i>E. coli</i>) 3. Gram staining of bacteria and mounting of filamentous and non-filamentous fungi (<i>Staphylococcus aureus</i>, <i>E. coli</i>, <i>Candida albicans</i>, <i>Penicillium sps</i>, <i>Lactobacillus sps</i> etc.) 4. Sterility testing (Microbial load) of drug formulations (According to IP 2013) 5. CCl₄ liver dysfunction in rats and evaluation using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out) 6. LD 50 evaluation using a suitable model (e.g. <i>Daphnia</i> / rice weevil) 7. CE separation of a modern drug from plasma and its formulation (e.g. DFS) 8. CE separation of peptides (e.g. erythropoietin as per E.P.) 9. CE separation of N. Acids 10. PCR (PCR Kit may be used) for Plant DNA and RFLP (RFLP kit may be used) (e.g. <i>Phyllanthus sps.</i>) 11. DNA sequencing using sample from a suitable organism OR Identification of Genetically Modified Organism (GMO identification kit may be used) 12. Blue white screening of mutated organism 13. Serum levels of drug attained by agar cup method 14. Zone of inhibition assay for penicillin (using spiked plasma and formulation) 15. Zone of exhibition assay for Vitamin B12 16. Total viable count of herbal formulations/raw material 17. Screening of pathogens from herbal formulation/raw material (<i>E.coli</i>, <i>S. aureus</i>, <i>Candida albicans</i>) 18. Preparation of herbal formulations and standardization • Any oil based preparation or ayurvedic taila preparation • Any vatti(Ayurvedic) or Guliga(Siddha) • Awahela (semi-solid,jaggery/sugar syrup based formulation) • Any preparation from unani e.g. Saffoof, Jawarish, Majoon. (Students can work on of the above formulation and involve any modern chromatographic techniques, microscopic evaluation, chemical and physical tests for QC of formulation prepared)

Course 4. BA/BE Studies and Method Validation Theory

Credits 2

Course Outcomes

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

- give an introduction to students to the various ethical issues in clinical trials, its powers, dealings and compliances
- train students about the concepts of Bioavailability and Bioequivalence
- well verse students in Analytical method validation techniques

Unit	Topic	Credit	Number of Lectures
I	Title: Bioavailability (BA) & Bioequivalence (BE) studies 1. What is BA? 2. Parameters to evaluate BA of a drug 3. Factors that influence BA of a drug 4. Evaluating BA of a drug 5. Estimating BA parameters of a drug 6. Design of a BA study 7. Conduct of a BA study 8. Data collection and evaluation 9. Reporting a BA study 10. Regulatory requirements of BA 11. What is BE? 12. Parameters to evaluate BE of a drug 13. Factors that influence BE of a drug 14. Evaluating BE of a drug 15. Estimating BE parameters of a drug 16. Design of a BE study 17. Conduct of a BE study 18. Regulatory requirements of BA and BE 19. Data record and evaluation 20. Estimating Pharmacokinetic parameters 21. Assessment of Bioequivalence 22. Regulatory requirements and their compliance in pharmacokinetics	2	15
II	Title: Analytical Method Validation 1. Strategies for Method development 2. What and Why of method validation 3. Regulatory requirements of validation 4. IQ, OQ and PQ of analytical instruments 5. Use of Reference standards 6. Issues of Method transfer 7. Intra and inter lab - Validation 8. Sampling 9. Calibration of glassware and instruments, concepts of Good weighing Practice 10. Use of Reference standards and working standards 11. Format of Certificate of Analysis		15

Elective Course 1. Bioprocess Technology
Theory

Credits 2

Course Outcomes

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

- educate students about the fundamental concepts of bioprocess technology and its related applications.
- prepare them to meet the challenges of new and emerging areas of biotechnology industry.

Unit	Topic	Credit	Number of Lectures
I	Isolation, preservation and maintenance of industrial microorganisms, kinetics of microbial growth and death, product decomposition, effect of environmental conditions. Bioreactors; Media for industrial fermentation, Principles of upstream processing – Media preparation, Inocula development and sterilization	2	15
II	Measurement and control of bioprocess parameters, basic principles of feedback control, proportional, integral and derivative control; Downstream Processing: introduction, removal of microbial cells and solid matter, foam preparation, precipitation, filtration, centrifugation, cell disruptions, liquid-liquid extraction, chromatography, membrane process, drying and crystallization.		15

Practicals

Credits 2

Title	Credit
1. Study The Design, Construction And Control Systems Of A Bioreactor. 2. Estimation Of Glucose By Dinitro Salicylic Acid (Dns) Assay Method 3. Media Optimization By Plackett And Burman 4. Batch Heat Sterilization And Thermal Death Kinetics 5. Batch Growth Kinetics Of Bacteria (Glucose And Diauxic) 6. Production Of Ethanol By Yeast 7. Production Of Wine By Yeast 8. Production Of Amino Acid	2

Elective Course 2. Plant Biotechnology
Theory

Credits 2

Course Outcomes

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

- acquainted with the principles, practices and application of plant tissue culture, plant genomics, genetic transformation and molecular breeding of plants.

Unit	Topic	Credit	Number of Lectures
I	Historical perspective; totipotency; culture and organogenesis; Somatic embryogenesis; establishment of Animal cell cultures – callus culture, cell suspension culture, media culture preparation-	2	15

	nutrients and plant hormones; sterilization techniques; applications of tissue culture - micropropagation; somaclonal variation; androgenesis and its applications in genetics and plant breeding.		
II	Germplasm conservation and cryopreservation; synthetic seed production; protoplast culture and somatic hybridization - protoplast isolation; culture and usage; somatic hybridization - methods and applications; cybrids and somatic cell genetics; plant cell cultures for secondary metabolite production.		15

Practicals

Credits 2

	Title	Credit
1. Organizing Plant tissue culture Laboratory 2. Preparation of Tissue Culture Media 3. Callus Induction 4. Shoot tip culture 5. Embryo / Endosperm Culture 6. Somatic Embryogenesis 7. Hardening and Planting in field 8. Isolation of protoplasts 9. Cell suspension culture 10. Economics of micropropagation project		2

SEMESTER IV

Course 1. MS Applications, Metabolite studies, Thermal Analysis and Tracer Techniques

Theory

Credits 4

Course Outcomes

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

- familiarize students with applications of Quantitative analysis in Bioanalytical Sciences
- familiarize students with applications to Qualitative analysis with example of drug metabolite studies
- make students understand LC/MS/MS with emphasis on profile of drug, proteomics and pesticide residues in food
- introduce students to Tracer techniques in Bioanalytical assays

Unit	Topic	Credit	Number of Lectures
I	Title: MS Basics & Hyphenation 1. MS - Introduction, Components: Inlets, Ion sources, Analyzers, Detectors, Vacuum System, etc, MS/MS, TQ/Ion Trap 2. LC/MS and LC/MS/MS 3. GC/MS and GC/MS/MS 4. Scan events in TQ and other tandem systems and hybrid systems 5. ICP/ MS and its applications in pharmaceuticals and food 6. Recent advances in the field of mass spectrometry	4	15
II	Title: Applications of Qualitative & Quantitative Analysis / LC/MS/MS 1. SM quantitation for e.g. 2. Macromolecule quantitation for e.g. 3. Technique of generating drug metabolites 4. Metabolite Identification 5. Impurity profile in drugs and drug products 6. Proteomics 7. Pesticides, pesticide residues in food		15
III	Title: Analytical Methods & Thermal analysis 1. Method development and applications 2. Sample preparation 3. Headspace GC and GC-MS 4. Principles of Thermal Analysis 5. Instrumentation Requirements 6. Applications of Thermal Analysis 7. Thermal analysis of Bhasma preparations		15
IV	Title: Tracer techniques in Bioanalytical assays 1. Concept of Radioactivity & Half life 2. α , β , γ emitters and their biological applications 3. Using tracers in assays 4. Detectors and counters 5. Concept of autoradiography 6. Radio labeled probes and their uses		15

Course 2. QA & QC, Quality Management, GMP & GCP

Theory**Credits 4****Course Outcomes**

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

- understand the concept of Quality
- Implement Quality Implementation Programs
- give insights to students about Good Manufacturing Practice & Good Clinical Practices

Unit	Topic	Credit	Number of Lectures
I	Title Quality Management – I 1. Introduction to Quality: Definition of Quality, Dimensions of Quality 2. Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), 3. Principles of Six sigma 4. Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. 5. Concept of self-inspection.	4	15
II	Title : Quality Management – II 1. Drug Stability: ICH guidelines for stability testing of drug substances and drug products. 2. ISO 9001:2008, 9001:2015, ISO 14001:2004 3. Pharmaceutical Quality Management - Study of ICH Q8, Quality by Design and Process development report, ICH Q10 4. Operational Excellence and Quality Management Review. NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements 5. Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, OSHAS guidelines, HACCP, risk ranking and filtering according to ICH Q9 guidelines		15
III	Title: Good Manufacturing Practice 1. What is GMP? 2. Requirements of GMP implementation 3. Documentation of GMP practices 4. Regulatory certification of GMP 5. GMP in production of ASU drugs 6. Harmonization of SOP of manufacture 7. Audit for GMP compliances		15
IV	Title: Good Clinical Practice (GCP) 1. GCP guidelines of ICH 2. GCP guidelines of ICMR 3. Ensuring GCP 4. Documentation of GCP practice 5. Audit of GCP compliance		15

Course 3. Computation Biology & Programming

Practicals

Credits 4

Title	Credit
1. Biological Databases with Reference to Expasy and NCBI 2. Queries based on Biological databases 3. Sequence similarity searching using BLAST 4. Pairwise sequence alignment 5. Multiple Sequence and Phylogenetic Analysis 6. Gene Prediction 7. Secondary Structure prediction 8. Molecular docking 9. Bioinformatics tools: Clustal W. omega, BLAST A, Blast O, Fasta, Alignment, Prosite, SCOP, CATH 10. Introduction - History of Python-Getting Started with Python-Programming style and Documentation-Identifiers-Variables-Assignment statements-Expressions- Data Types-Operators-Precedence-Comments-Type Conversions-Common Python Functions-Introduction to Methods and Strings 11. Introduction-Scope-IF Statements-Types of IF Statements-Conditional Expressions-Loops -While Loops-For Loop-Nested Loops-Functions-Definitions-Default Arguments-Calling a Function- Functions with or without returning values-Passings arguments to a function-Call by Value - Call by Reference-Recursion 12. Introduction to Object oriented Programming-Need of class and objects-Defining classes-Constructing Objects-Abstraction and Encapsulation-Overriding Methods - Inheritance and Polymorphism-Modules and Packages-Introduction to String Class-String Functions-Formatting Strings 13. Introduction to Lists-Creation of List-Functions for Lists-Passing List to Functions-Operation on Lists-Searching and Sorting-Multidimensional Lists-Advanced List Processing - Sample programs on Lists-Lotto number and Deck of Cards-Introduction to Tuples-Sets - Creation and Accessing Sets-Dictionary Operations and Methods 14. Introduction - Structure of File - Opening and Writing Data-Accessing Files-File Dialogs-Retrieving data from web-Introduction to Exceptions-Errors and Exceptions-Command line arguments-Need for Exception- Handling Exceptions-Raising Exceptions-Exception Objects-Custom Exception Classes	4

Elective Course 1. Nutraceutical and Functional Foods

Theory

Credits 2

Course Outcomes

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

- describe the various origins of nutraceuticals and functional foods.
- go over the advantages of health and resources for general wellbeing.
- analyze the manner in which ingredients in nutraceuticals are extracted.

Unit	Topic	Credit	Number of Lectures
I	Topic: Functional foods & Nutraceuticals-I 1. Introduction; Nutraceutical Industry: Scope of the industry, Indian and global scenario. Classification of nutraceuticals based on source and chemical nature. 2. Nutraceuticals of plant origin: Plant secondary metabolites- Terpenoids, Phenolics, Alkaloids, phytoestrogens, Pigments, Organo Sulphur compounds. 3. Sources and health benefits of nutraceuticals: Glucans, ascorbic acid, quercetin, kaempferol, rutin, β -carotene, allicin, lycopene, limonene, α -tocopherol, zeaxanthin, caffeine, Olive oil, green tea 4. Minerals - Ca, P, Cu, I, Zn, Se, F, Mg, Mn	2	15
II	Topic: Functional foods and Nutraceuticals-II 1. Nutraceuticals of animal origin: collagen chitin, chitosan, glucosamine, chondroitin sulphate, conjugated linoleic acid, eicosapentenoic acid, docosahexaenoic acid, choline, lecithin. 2. Microbial and algal nutraceuticals: Concept of prebiotics, probiotics and Synbiotics. Prebiotics: Non-digestible carbohydrates- Dietary fibers, functional oligosaccharides, Resistant starch, and gums. Probiotic microorganisms- Features and health benefits. 3. Probiotics in various foods: Dairy-based, fermented, and non- fermented foods. Quality assurance of probiotics and safety Algae as source of omega-3 fatty acids, antioxidants, and minerals. kelp and spirulina		15

Practicals

Credit 2

Title	Credit
1. Extraction and estimation of total sugars from food products (dairy products, fruit juices, bread). 2. Estimation of crude fat contents of foods by Soxhlet's method (Butter, Margarine, edible oil). 3. Estimation of total Nitrogen of foods by Kjeldahl and Micro Kjeldahl methods. 4. To separate the Milk proteins on Native and SDS gels. 5. Assessment of purity and quality using appropriate standard tests for the following ; a. Milk and Paneer b. Butter/ ghee and hydrogenated fat (Vanaspati Ghee)	2

c. Spices and condiments d. Tea and coffee e. Fruit juice f. Pulses 6. Estimation of ascorbic acid from lemon & amla juice by titration method. 7. Estimation of Curcumin/Lycopene. 8. Detection of food additives in packaged food products. 9. Extraction of carotenoids from food samples. 10. Determination of acidity of milk by titrimetric method. 11. Preparation of nutritionally enriched cookies 12. Isolation of Lactobacillus and study of its probiotic characteristics. 13. Production of Yogurt	
---	--

Elective Course 2. Animal Biotechnology

Theory

Credits 2

Course Outcomes

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

- acquainted with the principles, practices and application of animal biotechnology, animal genomics, genetic transformation and molecular breeding animals.

Unit	Topic	Credit	Number of Lectures
I	Title: Animal Cell Culture 1. Brief history of animal cell culture 2. ATC media: serum, serum free and plant based serum alternatives and chemically defined media 3. Application of animal cell culture for virus isolation and in vitro testing of drugs, testing of toxicity of environmental pollutants in cell culture 4. Application of cell culture technology in production of human and animal viral vaccines and pharmaceutical proteins 5. Novel strategies and advancement in mammalian cell line development, large scale production of animal cells, advances in tissue engineering, use of genetic engineering tools for therapy.	2	15
II	Title- Animal Reproductive Biotechnology 1. Structure of sperms reproductive and ovum; 2. Cryopreservation of sperms and ova of biotechnology livestock; artificial insemination; 3. Super ovulation, and embryo recovery and in vitro fertilization; culture of embryos; cryopreservation of embryos; embryo transfer technology; transgenic manipulation of animal embryos; applications of transgenic animal technology; 4. Animal cloning - basic concept, cloning for conservation for conservation endangered species		15

Practicals

Credit 2

	Title	Credit
1. Sterilization Techniques 2. Preparation of Media 3. Preparation of Sera 4. Primary Cell Culture 5. Preparation of established Cell lines 6. Cell Counting and Viability 7. Staining of Animal Cells 8. Preservation of Cells 8. Culture of Virus in Chick Embryo 9. DPPH radical scavenging assay		

References

1. A Textbook of Pharmaceutical Quality Assurance by K. P. R. Chowdary, Pharmamed Press.
2. Analytical Profiles of drug substances and Excipients - Harry G Brittan, Volume 21 - 30, Elsevier,
3. Applied Bioinformatics: An Introduction by Paul M. Selzer, Richard J. Marhöfer, Oliver Koch, and Clemens Wrzodek
4. Basic Tests for Pharmaceutical Substances - WHO (1991)
5. Bioassay Techniques for Drug Development: Atta-ur-Rahman, M. Iqbal Choudhary, and William J. Thomsen
6. Bioavailability and Bioequivalence: An Introduction by Bo Wen and Gordon L. Amidon
7. Biochemical Engineering Fundamentals (2nd edition), JE Baily and DF Ollis, McGraw Hill Book Co. New York. 1986
8. Biochemical Engineering, S Aiba, AE Humphrey and NF Millis, Academic Press. New York 1973
9. Biochemical Reactors, B Atkinson, Pion Ltd., London. 1974
10. Bioinformatics Algorithms: An Active Learning Approach by Phillip Compeau and Pavel Pevzner
11. Bioinformatics for Biologists by Pavel Pevzner and Ron Shamir
12. Bioinformatics: Sequence and Genome Analysis by David W. Mount
13. Biological Sequence Analysis: Probabilistic Models of Proteins and Nucleic Acids by Richard Durbin, Sean Eddy, Anders Krogh, and Graeme Mitchison.
14. Biology of plant metabolomics, Robert Hall, Annual Plant Reviews, 43, Chichester, West Sussex; Ames, Iowa: Wiley-Blackwell, 2011
15. Bioprocess Engineering: Basic Concepts (2nd edition), ML Shuler, and F Kargi, Prentice Hall, Engelwood Cliffs. 2003
16. Bioprocess Technology: Fundamentals and Applications, KTH, Stockholm. 2000
17. Bioreaction Engineering Principles, J Nielson, and J Villadsen, Plenum Press. 1994
18. Brij Mohan Singh*, Ayushi Jain, Anoop Mishra Cosmetic Regulations in India vs. Globally and Challenges in Harmonization International Journal of Pharmaceutical Sciences and Drug Research 2018; 10(3): 150-157
19. Brown, T. A. (2006). Gene Cloning and DNA Analysis: An Introduction. Oxford: Blackwell Publishers.
20. Buchanan, B. B., Gruissem, W., & Jones, R. L. (2015). Biochemistry & Molecular Biology of Plants, Wiley 2002.
21. Chawla, H. S. (2000). Introduction to Plant Biotechnology. Enfield, NH: Science.
22. Chemical Engineering Problems in Biotechnology, M L Shuler, (Ed) AICE. 1989
23. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections: Vera Mihajlovic-Madzarevic.
24. Computational Drug Discovery and Design edited by Jürgen Bajorath
25. Computational Drug Discovery and Design edited by Lengqvist J. and Svensson L.A.
26. Computer-Aided Drug Discovery edited by Zhijian Xu and Huixiao Hong

27. Dale R Baker, Capillary Electrophoresis, John Wiley and Sons
28. Dr. R. D. Lele, Ayurveda & Modern Medicine - 2nd edition revised & enlarged
29. Dr. Sudheendra V. Honwad, A Hand Book of Standardization of Ayurvedic Formulations Paperback – 2012
30. Dr. V. Rajpal, Standardization of Botanicals Vol I, Eastern Publishers
31. Dr.C.R.Karnick, Pharmacopoeial Standards of Herbal Plants Vol I, Sri Satguru, Publisher
32. Dr.C.R.Karnick, Pharmacopoeial Standards Of Herbal Plants Vol II, Sri Satguru, Publisher
33. Drug Design: Principles and Applications edited by Chatterjee S.
34. FDA Regulation of Cosmetics and Personal Care Products, Congressional Research Service (<https://crsreports.congress.gov R42594>)
35. FDA Regulation of Cosmetics and Personal Care Products, Congressional Research Service, Updated March 9, 2022
36. General Methods of Analysis Quality Specifications for Pharmaceutical Substances, Excipients, Dosage Forms.
37. Glick, B. R., & Pasternak, J. J. (2010). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington, D.C.: ASM Press.
38. Good Clinical Practice Standard Operating Procedures for Clinical Researchers: Graeme Scott, Josef Kolman, Paul Meng.
39. Good Manufacturing-Practices for Pharmaceuticals, by Graham Bunn and Joseph 6th Ed. D. Nally (Dec 26, 2006)
40. Gordon, I. (2005). Reproductive Techniques in Farm Animals. Oxford: CAB International.
41. Govt. of India, Min. of Health & Family Welfare, Ayurvedic Formulary of India
42. Govt. of India, Min. of Health & Family Welfare, Ayurvedic Pharmacopoeia of India
43. Guidance Document Food Safety Management Systems
44. Guidance Document Food Safety Management Systems, Food Industry Guide to Implement GMP/GHP Requirements And Risk Assessment By Fssai, India
45. H.E.Schwartz, R.H.Palmieri, Introduction to Capillary Electrophoresis of Proteins and Peptides, Beckman
46. Hamed M.Abdon, Dissolution Bioavailability and Bioequivalence, MACK Publishers
47. How to Practice GMP's - P.P. Sharma
48. ICMR, New Delhi, Medicinal Plants: Quality Standards of Indian medicinal plants
49. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
50. Introduction to Bioinformatics by Arthur M. Lesk
51. Introduction to Functional foods & Nutraceuticals - Rekha Sharma
52. Introduction to Protein-DNA Interactions: Structure, Thermodynamics, and Bioinformatics by Andrew H.-J. Wang
53. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
54. Kelvin Altria and Manus Rogan, Introduction of Quantitative Applications of C.E in Pharmaceutical Analysis, Beckman

55. Learning Python, LutzM, O'Reilly- Shroff, 5th edition, 2013.
56. Let Us Python, Yashwant Kanetkar, BPB publication , 1st edition (2019)
57. Levine, M. M. (2004). New Generation Vaccines. New York: M. Dekker.
58. Lily Y.Young, Microbial Transformation and Degradation of Toxic, Dermot Diamond, John Wiley & Sons
59. Michael Pelczar, E.C.G Chan, Noel R.Krieg, Microbiology, McGraw Hill
60. Modern Practice of Gas Chromatography- Robert L. Grob, Eugene F. Barry
61. Mohd Riyaz Beg, M. Pharm (Pharmacology), Cosmetic-Regulations, Research & Marketing challenges and global compliance: An overview, Institute of Chemical Technology, Mumbai.
62. Molecular Docking: Prediction of Binding by K. A. Connolly
63. Molecular Docking: Principles and Practices by Shaomeng Wang and Abdul Jalees
64. P. K. Chattopadhyay, Herbal Cosmetics & Ayurvedic Medicines (EOU) Paperback, 2015
65. Pharmaceutical Process Validation by Berry and Nash
66. Pharmacokinetics and Metabolism in Drug Design by Dennis A. Smith and Han van de Waterbeemd
67. Pharmacokinetics in Drug Development: Clinical Study Design and Analysis edited by Peter L. Bonate and Danny R. Howard
68. Plant Biotechnology. Umesha, S. (2013).
69. Pörtner, R. (2007). Animal Cell Biotechnology: Methods and Protocols. Totowa, NJ: HumanaPress.
70. Practical Applications of Computational Chemistry to Drug Discovery edited by Nathan Brown
71. Practical Bioinformatics by Michael Agostino and Peter Rice
72. Primrose, S. B., & Twyman, R. M. (2006). Principles of Gene Manipulation and Genomics. Malden, MA: Blackwell Pub.
73. Principles of Fermentation Technology (2nd edition), PF Stanbury, A Whittaker and SJ Hall, Pergamon Press, Oxford. 1995
74. Principles of Good Clinical Practice: McGraw, George, Shearn, Hall and Thomas
75. Principles of Instrumental Analysis- Skoog, Holler, Crouch
76. Process Engineering in Biotechnology, A T Jackson, Prentice Hall, Engelwood Cliffs. 1991
77. Programming in Python3, Mark Summerfield, Pearson Education, 2nd edition (2018)
78. Programming through Python M. T. Savaliya, R.K Maurya, G.M Magar, Staredu Solutions, 1st edition (2018)
79. Python DataScience Handbook, Jake VanderPlas, O'Reilly Media, 1st edition (2016)
80. Q.A. Manual by D.H. Shah
81. Quality Assurance Guide by OPPI
82. Quality Assurance of Pharmaceuticals. A Compendium of Guidelines and Related Material Vol. 1 and Vol. 2, WHO 2007)
83. Randall C.Baselt, Biological Monitoring Methods for Industrial Chemicals Biomedical
84. Razdan, M. K. (2003). Introduction to Plant Tissue Culture. Enfield, NH: Science.
85. Regional Research Lab & IDMA, Indian Herbal Pharmacopoeia Vol II, Regional, Research Lab
86. Regulatory and Pharmacological Basis of Ayurvedic Formulations, Amritpal Singh

87. Ronald M. Atlas, Lawrence C. Parks, Handbook of Microbiological Media, CRC Press
88. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, s2009, ASQ Publications
89. S.F. Bloomfield, R. Baird, R.E. Leak, R. Leech, Microbial Quality Assurance in Pharmaceuticals, Cosmetics and Toiletries, Ellis Horwood
90. Schedule M, Drugs and Cosmetics Act 1940
91. Simon Benita, Microencapsulation Methods and Industrial Applications, Marcel Dekker
92. Slater, A., Scott, N. W., & Fowler, M. R. (2003). Plant Biotechnology: The Genetic Manipulation of Plants. Oxford: Oxford University Press.
93. Slater, A., Scott, N. W., & Fowler, M. R. (2008). Plant Biotechnology: An Introduction to Genetic Engineering. Oxford: Oxford University Press.
94. SOP Guidelines by D.H. Shah
95. Structure-Based Ligand Design edited by Vittorio Limongelli and Wolfgang Jahnke
96. Textbook of Bioavailability and Bioequivalence Studies edited by Pravin Shende and Surendra Ugale
97. The Drugs and Cosmetic Act 1940 by Vijay Malik
98. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition
99. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
100. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
101. The Unani Pharmacopoeia of India 10. Siddha Pharmacopoeia
102. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 200
103. WHO, Specification for the Identity and Purity of some enzymes and certain other substances, W.H.O
104. William Hewitt, Stephen Vincent, Theory and Application of Microbiology Assay, Academic Press

Syllabus MSc. (Bioanalytical Sciences)

Team for Framing of Syllabus

Sr. No	Name	Affiliation	Sign
1.	Dr. Prafulchandra Tekale	GN Khalsa College, Nathalal Parekh Marg Matunga 400019	
2.	Dr. Deepa Verma	Vishnu Waman Thakur Charitable Trust's Bhaskar Waman Thakur College of Science, Yashvant Keshav Patil College of Commerce, Vidhya Dayanand Patil College of Arts (VIVA College)	
3.	Dr Rohan Gavankar	Vishnu Waman Thakur Charitable Trust's Bhaskar Waman Thakur College of Science, Yashvant Keshav Patil College of Commerce, Vidhya Dayanand Patil College of Arts (VIVA College)	
4.	Dr. Naomita Dhume	GN Khalsa College, Nathalal Parekh Marg Matunga 400019	
5.	Dr. Kavita Pandey	GN Khalsa College, Nathalal Parekh Marg Matunga 400019	
6.	Mr. Vinodkumar Didwana	Vishnu Waman Thakur Charitable Trust's Bhaskar Waman Thakur College of Science, Yashvant Keshav Patil College of Commerce, Vidhya Dayanand Patil College of Arts (VIVA College)	

Invited Experts from Academia and Industry

Name	Affiliation (College)/	Contact details / Email
Ms. Madhvi Chawan	Haffkine Bio-Pharmaceutical Corporation Limited	8691955530 madhviqa@gmail.com
Mr. Pushpdeep Mishra	Senior Project Manager, Virtual Labs, IIT Bombay	9096565576 pushpdeepmishra@gmail.com
Mr. Mohammed Mubeen Shaikh	Associate Bioinformatics Engineer, Strand Life Sciences	8355828500 mdmubeensk@gmail.com



**Sign of the BOS
Chairman
Dr. Prafulchandra Tekale
BOS in Bioanalytical Sciences**

**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**