

University of Mumbai



No. UG/ 03 of 2020-21

CIRCULAR:-

Attention of the Principals of the Affiliated Colleges, the Head of the University Departments and Directors of the recognized Institutions in Science & Technology Faculty is invited to the syllabus uploaded Academic Authority Unit which was accepted by the Academic Council at its meeting held on 27th February, 2013 vide item No.4.67 relating to the revised syllabus as per the (CBSGS) for the M.Sc.(Part-II) (Sem. III & IV) in Bio-Technology.

They are hereby informed that the recommendations made by the Ad-hoc Board of Studies in Bio-Technology at its meeting held on 6th May, 2020 and subsequently made by the Board of Deans at its meeting held on 20th July, 2020 have been accepted by the Academic Council at its meeting held on 23rd July, 2020 vide item No.4.104 and that in accordance therewith, the revised syllabus as per the (CBCS) of M.Sc. (Part II) (Sem. III & IV) in Bio-Technology has been brought into force with effect from the academic year 2020-21, accordingly. (The same is available on the University's website www.mu.ac.in).

MUMBAI - 400 032
14th September, 2020


(Dr. Vinod Patil)
I/c REGISTRAR

To

The Principals of the affiliated Colleges, the Head of the University Departments and Directors of the recognized Institutions in Science & Technology Faculty. (Circular No. UG/334 of 2017-18 dated 9th January, 2018.)

A.C/4.104/23/07/2020

No. UG/ 03 -A of 2020-21

MUMBAI-400 032

14th September, 2020

Copy forwarded with Compliments for information to:-

- 1) The I/c Dean, Faculty of Science & Technology,
- 2) The Chairman, Board of Studies in Bio-Technology,
- 3) The Director, Board of Examinations and Evaluation,
- 4) The Director, Board of Students Development,
- 5) The Co-ordinator, University Computerization Centre,


(Dr. Vinod Patil)
I/c REGISTRAR

UNIVERSITY OF MUMBAI



Program : M.Sc. Biotechnology

Course : M.Sc. Biotechnology

Syllabus for Semester: III & IV

(Choice Based and Credit System with effect from the
Academic year 2020-21)

AC _____

Item No. _____

UNIVERSITY OF MUMBAI**Syllabus for Approval**

Sr. No.	Heading	Particulars
1	Title of the Course	M.Sc. (Biotechnology)
2	Eligibility for Admission	B.Sc. (Biotechnology)
3	Passing Marks	40%
4	Ordinances / Regulations (if any)	--
5	No. of Years / Semesters	2 years/ Four semesters
6	Level	P.G. / U.G. / Diploma / Certificate (Strike out which is not applicable)
7	Pattern	Yearly / Semester (Strike out which is not applicable)
8	Status	New / Revised (Strike out which is not applicable)
9	To be implemented from	From Academic Year 2020-2021

Date:

Signature :

Name: **Dr. Anuradha Majumdar** (Dean, Science and Technology)**Dr. Archana Rath** (Chairperson, Ad Hoc BOS in Biotechnology)

PREAMBLE

In recent years, there has been a paradigm shift in education in terms of course content and learning outcomes. In keeping with it, the Faculty of Science & Technology, University of Mumbai, has taken a progressive step to align various programs under its purview with the current Higher Education Policy of the Government of India. The present M.Sc. Biotechnology Second Year (Semester III and IV) syllabus has been designed with the idea of incorporating outcome-based-learning for fruitful engagement of learners. The syllabus has undergone several curriculum revision exercise based on the remodeled M.Sc. Biotechnology Curriculum, May 2017, Department of Biotechnology, Ministry of Science and Technology, Government of India. The revised syllabus is an outcome of several rounds of deliberations, discussions, feedback and multiple brainstorming sessions involving various contributors & stakeholders- academicians, researchers, industry experts and students. Course Objectives and Course Outcomes have been clearly defined for each paper in the syllabus to guide teachers in order to make learning process more effective. A lot of focus has been given in the syllabus to cover latest developments in the area of biotechnology and to equip students with necessary knowledge and skills. Relevant papers to make students industry ready have also been included. Attempts have been made to draft a robust, well defined syllabus keeping in view the best learning outcome which shall enable students to pursue high quality research or increase employability of the students. Online course component has been introduced in the curriculum in keeping with the digital initiatives of MHRD to provide good quality self-learning content through MOOCs under SWAYAM and allied platforms.

It is hoped that the revised syllabus shall serve its objective of promoting outcome-based learning to meet the changing needs of the biotechnology sector.

Dr. Anuradha Majumdar	(Dean, Science and Technology)
Prof. Shivram Garje	(Associate Dean, Science)
Dr. Archana Rath	(Chairperson, Ad Hoc BOS in Biotechnology)
Dr. Deepali Karkhanis	(Member)
Dr. Sneha Panvalkar	(Member)
Dr. Seema Kokitkar	(Member)
Dr. Tara Menon	(Member)
Dr. Jayaprada R. Chunduri	(Member)
Dr. Bhupendra Pushkar	(Member)
Dr. Rajesh C. Patil	(Member)

MSc Biotechnology Course Structure
Semester III

Course code	Title	Theory /Practical	Marks	Credits	Nos of Lectures /week
PSBT 301	Applied virology and microbiology	Theory	100	4	1
PSBT 302	Environmental Biotechnology	Theory	100	4	1
PSBT 303	Biologics and Regulatory Affairs	Theory	100	4	1
PSBT 304	Molecular Enzymology and Enzyme Technology	Theory	100	4	1
PSBTP301	Practical I	Practical	50	2	4
PSBTP302	Practical II	Practical	50	2	4
PSBTP303	Practical III	Practical	50	2	4
PSBTP304	Practical IV	Practical	50	2	4
	TOTAL		600	24	

MSc Biotechnology Course Structure

Semester IV

Course code	Title	Theory /Practical	Marks	Credits	No. of Lectures/ week
PSBT 401	Nanobiotechnology	Theory	100	4	1
PSBT 402	OMICS & Systems Biology	Theory	100	4	1
PSBT 403	Drug Discovery & Clinical Study	Theory	100	4	1
PSBT 404	Scientific Writing & Food Biotechnology	Theory	100	4	1
PSBTP401	Practical I	Practical	50	2	4
PSBTP402	Practical II	Practical	50	2	4
PSBTP403 & PSBTP404	Practical III & IV	Practical	100	4	8
	TOTAL		600	24	

Teaching pattern:

One (01) Credit would be of thirty-forty (30-40) learning hours; of this, more than fifty per cent of the time will be spent on classroom instructions including practical as prescribed by the University. Rest of the time would be invested for assignments, projects, journal writing, case studies, library work, industrial visits, attending seminars/workshops, preparations for examinations etc. would be considered as notional hours. The present syllabus considers (60L as classroom teaching and 15 lectures as Notional hours/ paper). Each lecture duration would be for 60 min. The names of the reference books provided in the syllabus are for guidance purpose only. Students and faculty are encouraged to explore additional reference books, online lectures, videos, science journals for latest/ additional information.

Scheme of Examinations:

- (a) Internal assessment of 40 marks per course per semester should be conducted.
- (b) External assessment of 60 marks per course per semester at the end of every semester
- (c) Practical examination of 200 marks should be conducted at the end of every semester.

A. Semester III- Theory -Internal assessment (40%) -40 marks

Sr No	Evaluation type	Marks
1.	Assignments that can include article writing, report writing, preparation of a review, on any topic selected from each paper OR PowerPoint presentation on a topic from the syllabus or related to the syllabus <i>Note: The student can submit only 2 assignments and give 2 PowerPoint presentations per semester. Respective college/department can decide the allocation.</i>	30
2.	a. Active participation in routine class instructional deliveries	05
	b Overall conduct as a responsible student, w.r.t manners, skill in articulation, leadership qualities demonstrated through organizing co-curricular activities, etc.	05
	Total Marks	40

Semester IV- Theory -Internal assessment (40%) -40 marks

Sr. No	Evaluation type	Marks
1.	For PAPER 1 & 2 Assignments that can include article writing, report writing, preparation of a review, on any topic selected from each paper OR PowerPoint presentation on a topic from the syllabus or related to the syllabus <i>Note: The student can submit only 1 assignment and give 1 PowerPoint presentations per semester. Respective college/department can decide the allocation</i> FOR PAPER 3: The students have to present a clinical case/trial study report.	30
2.	a. Active participation in routine class instructional deliveries	05
	b Overall conduct as a responsible student, w.r.t manners, skill in articulation, leadership qualities demonstrated through organizing co-curricular activities, etc.	05
	Total Marks	40

Sr. No	Evaluation type	Marks
3.	FOR PAPER 4: The internal assessment will comprise of the following: a. Online course: The student is expected to complete at least one online course relevant for the subject from any of the appropriate reputed online platforms. A proof of successful completion of the online course must be provided for the award of marks.	20
	b. Research Proposal: The student is expected to submit a research proposal relevant to the subject.	20
	Total Marks	40

B. Theory -External examination -60%**Semester End Theory Assessment- 60 marks**

- The duration of this exam will be of 2.5 hours (150 minutes)
- The theory question paper will have 5 questions each of 12 marks.
- For each unit, there will be one question and the fifth will be based on all the four units.
- The fifth question will have 6 sub-questions out of which the student has to attempt any 3.
- All questions shall be compulsory with internal choice within the questions such that each question will be set of 24 marks with options.

Practical Examination Evaluation scheme (50 marks per paper)

1.	Practical Question 1	25
2.	Practical Question 2	15
3.	Journal	5
4.	Viva Voce	5
OR		
1.	Practical Question	40
2.	Journal	5
3.	Viva Voce	5
	Semester IV- Project Dissertation	100 Marks
	For semester IV it is mandatory for students to undergo Hands-on Project training in an established research laboratory or college laboratory for 4-6 months; This should involve one or more relevant instrumentation technique. Thesis on the same to be evaluated by the guide alternatively by an internal examiner for 50M based on the student's performance, written matter and experimentation. A certificate must be appended with the thesis. The external examiner will assess for 50M as a Presentation during practical exams. Marks allotted by Internal examiner would be scaled down if required as per university guidelines.	

A certified copy of the journal is essential to appear for the practical examination.

Note:

- In case of any changes in the above-mentioned evaluation scheme, the chairperson of examinations would provide the necessary details and the format.
- The practical examinations at a center would be evaluated by one external examiner assigned by the University and one internal examiner assigned by the college/department.

M.Sc. BIOTECHNOLOGY

SEMESTER- III

PSBT301- Applied Virology & Microbiology				
Course Objectives	Students will be exposed to pandemic diseases, significance of epidemiology in studying various diseases and societal & economic issues related to such diseases. Students will also learn details about emerging viral, bacterial, parasitic pathogens. Students will learn advanced, automated methods for determining antimicrobial susceptibility, drug resistance and various aspects of biofilms.			
Course Outcomes	Students will understand epidemiological principles in prevention, control and management of pandemic disease. They will acquire understanding of antimicrobial resistance for management of drug resistance in population. Students will understand the different aspects of biofilm and their management. They will also get insights into latest development of diagnostics & therapeutics for such diseases.			
Course Code	Unit	Unit Details	Credits	Lectures
PSBT302	I Pandemic diseases, pathogenesis, diagnosis and treatment	Introduction to Pandemic diseases and causative agent like H1N1, MERS, SARS, Swine flu, COVID-19, Nipah virus, Ebola virus. Structure of these virus-coat and envelope protein, genome composition Pathogenesis (Mechanism of infection) and Acute Clinical manifestations (Signs and symptoms) of H1N1, MERS, SARS, Swine flu, COVID-19, Nipah virus, Ebola virus Diagnosis, and Treatment for H1N1, MERS, SARS, Swine flu, COVID-19, Nipah virus, Ebola virus Economic and Social loss due to t Viruses	1	15
	II Epidemiology of infectious diseases	Concept of Host, Reservoir, Source of infection, Carrier, Epidemic, Endemic, Pandemic, Outbreak History, Definition scope, importance of epidemiology Epidemiology, Health & Public Health Epidemiological principles in prevention & control of disease Measures of disease frequency – Concept of incidence, prevalence, Incidence rate, cumulative incidence, case fatality Epidemiological studies Organizations in disease control & Research – WHO, CDC, UNICEF, NACO, ICMR, NARI, NIV & NGOs	1	15

	III Medical Microbiology	Emerging Pathogens / Infections : Diseases caused by Bacteria / parasites/ viruses Name of causative agent, Name of disease caused, History, Antigenic structure, virulence factors, source of infection, Transmission, Pathogenesis, Clinical manifestations, Laboratory diagnosis, Treatment, Prophylaxis, vaccines , Current research and developments Bacteria as emerging pathogens / Diseases caused by bacteria : MOTT, Legionella, Conditions caused by <i>Helicobacter pylori</i> Viruses as emerging pathogens / Diseases caused by viruses : HIV (AIDS), Chikungunya, Dengue, Parasites as emerging pathogens / Diseases caused by parasites : Malaria , <i>Entamoeba histolytica</i> (Amoebic dysentery)	1	15
	IV Biofilms & Antimicrobial Activity	Structure of Biofilm – Extracellular polymeric substances, Biofilm architecture. Stages in formation of Biofilm. Microbial interactions in Biofilms (Quorum sensing) Need for formation of Biofilms by microorganisms Microorganisms commonly associated with biofilms on indwelling medical devices Response of biofilms to host defense mechanisms & antimicrobial agents Recent advances in biofilm management. Conventional methods of drug susceptibility testing (Kirby-Bauer disc diffusion, Stoke's method, E test) Advanced methods- Macro & Micro broth dilution methods, Time kill curves, serum killing curves, checker-board assays. Detection of drug resistance in Staphylococci, Streptococci, Enterococci. Automated methods of sensitivity testing. Concept of CLSI standards	1	15

PSBTP-301 Practicals

1. Viral Titering – Plaque Assay, Tissue Culture Infectious Dose (TCID), Chicken Embryo Infectious Dose (CEID)
2. Immunoassays: For detection of the virus antigens by ELISA / RIA
3. Detection techniques for COVID like RT- PCR and various RAPID tests
4. Diagnosis of dengue (kit method)
5. Diagnosis of Chikungunya (kit method)
6. Antibiotics susceptibility testing by broth Macro dilution method & Micro broth dilution method
7. Study of microbial biofilm formation on various surfaces & Biofilm visualization by staining
8. Demonstration of minimum biofilm inhibition concentration of antibiotics/disinfectants.

References

1	Microbiology An introduction 10 th edition Gerald Tortora, Burdell Funke, Christine Case, pearson Education Inc. Publication 2010
2	Basic Epidemiology R. Bonita, Beaglehole, T. Kjellstrom, 2 nd Edition, 2006, WHO
3	Principles of Epidemiology in Public Health Practice, Third edition, US Department of Health & Human Services, CDC, 2012
4	Martin Rusnák, Viera Rusnáková, Georges Kamto, RELATIONS BETWEEN EPIDEMIOLOGY AND PUBLIC HEALTH, 2018 https://www.researchgate.net/publication/323964710
5	Evaluation and use of Epidemiological evidence for environmental health risk assessment guideline document World Health Organization 2000 eur/00/5020369
6	Ananthanarayan and Paniker's Textbook of Microbiology, by Reba Kanungo, 10th Universities Press; Tenth edition, 2017
7	Koneman's Colour Atlas & Textbook of Diagnostic microbiology, 7 th edition, 2017, Lippincott, Williams & Wilkins.
8	Mackie & McCartney Medical Microbiology, J. G. Collee, J. P. Duguid, A. G. Fraser, B. P. Marmion, Thirteenth edition, Churchill Livingstone
9	Bailey and Scotts Diagnostic Microbiology Forbes, Sahem et al 12 th ed, Moshby

PSBT302-Environmental Biotechnology				
Course Objectives:		This course aims to introduce learners to latest concepts in environmental biotechnology, various types of pollutions, monitoring, latest mitigation strategies and management of the same. Health hazards of pollution and waste, solid waste management, biodiversity concepts and data management and environmental monitoring.		
Course Outcomes:		At the end of the course, students will be able to understand various concepts of environmental biotechnology, latest development in the area and use of microbiological, molecular and analytical methods in environmental biotechnology.		
Course Code	Unit	Unit Details	Credits	Lectures
PSBT 302	I Air	Air pollution & air Quality Monitoring, Sampling, Source Apportionment. Air Pollution Management in Urban Settlement & Rural Areas, Integrated Air Pollution Management, Green Belt. Biofilters/ Bioscrubber. Catalytic Systems. Green Technology. Ozone Layer Depletion Atmospheric Brown Cloud Impact on Flora and Fauna Impact on Crop Yield, concept of carbon credit, footprint.	1	15
	II Soil	Causes of soil salinity; Chemical and metallic pollution of agricultural soil; Mining and soil pollution; Soil pollution and air quality; Bioleaching of metals, bioaugmentation & biomagnification for soil remediation. Phytostabilization - Contaminant removal, Soil cover, Rhizosphere modification, Geotextile capping solid waste; Industrial solid waste; Domestic solid waste; Agricultural solid waste; Municipal solid waste; Major sources of solid wastes; Effects of solid waste generation on quality of air, water and public health; solid waste management, Disposal of organic and medical waste; Recovery and recycling of metallic waste; Disposal of plastic waste and hazardous wastes.	1	15
	III Water	Biofilms in treatment of waste water; Biofilm development and biofilm Kinetics; Aerobic Biofilms. Marine pollution-major pollutants (heavy metal, pesticide, oil, thermal, radioactive, plastics, litter and microbial, microplastics); Biological indicators (Marine microbes, algae and crustaceans) and accumulators: Biotechnological application of hazardous waste management of water; Use of microbial systems, Phytoremediation strategies in constructed wetlands, Designing constructed wetlands, Substrate, Hydraulic loading rate, Hydraulic retention time, The selection of plant species, Surface area of	1	15

		wetland, Mechanisms to remove pollutants from constructed wetlands		
	IV Biodiversity & Environment Monitoring	Introducing biodiversity informatics, Global patterns of distribution of biodiversity, biomes, Composition and distribution of biodiversity in India, Taxonomic Database Working Group (TDWG) standards, compatibility and interoperability, taxonomically intelligent systems, Global biodiversity information system-Overview of the UNEP/GEF biodiversity data management project (BDM), Biosensors in Environmental Monitoring – Working & its application for monitoring environment pollutants, Application of protein biomarkers ; Biosensors and biochips. IOT for water quality monitoring – General working, Application, water Parameters	1	15

PSBTP 302-PRACTICALS

1. Soil and water quality assessment (temp, pH, salinity, water holding capacity of soil etc.)
2. Study of metal tolerance of microorganisms isolated from soil/water
3. Soil ecosystem analysis/ analysis of microorganisms of soil
4. Analysis of compost
5. Detection of heavy metals concentration in soil/ water
6. Study and comparison of different air samplers
7. Growth curve of metal tolerant organism isolated from soil/ water.

REFERENCES

1. Chandrappa, R., & Kulshrestha, U. C. (2015). <i>Sustainable air pollution management: theory and practice</i> . Springer.
2. Karl B. Schnelle & Charles A. Brown, (2002) Air pollution control technology Handbook. CRC Press
3. Singh, R. L. (Ed.). (2017). <i>Principles and applications of environmental biotechnology for a sustainable future</i> . Springer Singapore.
4. Enger, E. D., Smith, B. F., & Bockarie, A. T. (2000). <i>Environmental science: A study of interrelationships</i> (p. 434). Boston, MA: McGraw-Hill.
5. Rittmann, B. E., & McCarty, P. L. (2012). <i>Environmental biotechnology: principles and applications</i> . Tata McGraw-Hill Education.
6. Wainwright, M. (2012). <i>An introduction to environmental biotechnology</i> . 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 <i>Advances in agronomy</i> (Vol. 112, pp. 145-204). Academic Press.
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heavy metals bioremediation. In <i>Environmental Microbial Biotechnology</i> (pp. 91-104). Springer.
9. Rittmann, B. E., & McCarty, P. L. (2012). <i>Environmental biotechnology: principles and applications</i> . Tata McGraw-Hill Education.
10. Foin, T. C. (1976). <i>Ecological systems and the environment</i> . Houghton Mifflin.
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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. <i>Ecological engineering</i> , 57, 1-7.
13. Maier, R. M., Pepper, I. L., & Gerba, C. P. (2009). <i>Environmental microbiology</i> (Vol. 397). Academic press.
14. Olguni, E.J. et al. (2000) <i>Environmental Biotechnology and Cleaner Bioprocess</i> , Taylor & Francis.
15. Gareth M. Evams et al., (2003) <i>Environmental Biotechnology: Theory & Applications</i> , Wiley.
16. Milton fingerman et al. (1999) <i>Recent Advances in Marine Biotechnology Volume 3</i> , AbeBooks Inc.
17. Upadhyay, L. S., & Verma, N. (2015). Role of Biosensors in Environmental Monitoring. In <i>Environmental Microbial Biotechnology</i> (pp. 77-90). Springer.
18. Geetha, S., & Gouthami, S. (2016). Internet of things enabled real time water quality monitoring system. <i>Smart Water</i> , 2(1), 1.
19. Gibas, C., Jambeck, P., & Fenton, J. M. (2001). <i>Developing bioinformatics computer skills</i> . " O'Reilly Media, Inc."
20. Attwood, T.K. & Parry-Smith D.J. (2003). <i>Introduction to Bioinformatics</i> . Pearson Education.
21. Rastogi, S. C., Rastogi, S. C., Mendiratta, N., & Rastogi, P. (2006). <i>Bioinformatics: Concepts, Skills & Applications</i> . CBS Publishers & Distributors Pvt. Limited.
22. Sensen, C. W. (2005). <i>Handbook of genome research: genomics, proteomics, metabolomics, bioinformatics, ethics and legal issues; Vol. 1 und 2</i> . Wiley-VCH Verlag GmbH & Co. KGaA.

PSBT303- Biologics & Regulatory Affairs				
Course Objectives:		To introduce learner to the basic concept of Biologics and Biosimilars, and its therapeutic uses To expose learner to the methodologies/steps involved in the production of Biologics/Biosimilars To educate learner with the nuances of characterization of Biosimilars with emphasis on Reference Biologic To familiarize learner with the regulatory aspects of approval of a Biologic/Biosimilar		
Course Outcomes:		At the end of the course, the learner will be: Familiar with the basic concepts and significance of Biologics/Biosimilar in addition to having knowledge about its therapeutic applications Knowledgeable in the steps involved in the production of Biologics/Biosimilars Aware of the protocols/techniques required for characterization of the Biosimilar relative to the Reference Biologic Acquainted with the regulatory aspects of approval of a Biosimilars.		
Cour se Code	Unit	Paper 3: Biologics & Regulatory Affairs	Credits	Lectures
PSBT 303	Unit 1 Introducti on to Biologics and Biosimilar s	Definition: Drugs, Small molecules, Large molecules/Biologics Categories of Biologics: protein-based hormones, enzymes, monoclonal antibodies, vaccines, blood products, and gene/ cellular therapies. Similarities and Differences: Small molecules versus generics, Biologics versus Biosimilars. USFDA Approved Small Molecules and USFDA Approved Generics USFDA Approved Biologics and USFDA Approved Biosimilars Indian Regulatory Scenario in relation to Small Molecules and Biologics Therapeutic uses of some of the Biologics/Biosimilars Acceptable quality differences between approved Biosimilar and innovator's product	1	15

	Unit 2 Production of Biologics and Biosimilars	Reference Biologic and its significance, Choice of expression system/s and stability of cell lines Development of upstream and downstream processes and scale up to manufacturing Major factors contributing to the maintenance of product quality: raw materials and manufacturing conditions, virus filtration, mycoplasma removal, ultrafiltration Example: Production of Monoclonal antibody, downstream processing of Mab Introduction to the concept of Biobetters vs Biosimilars	1	15
	Unit 3 Characterization of Biologics and Biosimilars	Appearance, particulates, pH, osmolality, particle size Molecular Weight, Protein Sequence and/or amino acid composition Glycosylation, Sialylation, Phosphorylation, Acetylation, and Myristoylation, if any Sulfhydryl groups(s) and di-sulphide bridges. Size and Purity on HPLC/ MALDI Isoform pattern. Gel electrophoresis (IEF, SDS PAGE and Native PAGE), Western blot Fluorescence spectrum FTIR spectrum and NMR spectrum Bioassays, characterization using Monoclonal Antibody as an example	1	15
	Unit 4 Quality assurance & regulatory affairs of Biologics and Biosimilars	Introduction to Regulatory Affairs and approvals of Biosimilars, Products approved under the FD&C .PHS/BCPI Act 2009: Innovator Biologics Approval, Biosimilar Pathway, Totality of Evidence, Information required to demonstrate biosimilarity, Interchangeability, Product Switching, Product Naming Global regulatory framework	1	15

PSBT303- Practicals:

- 1) Electrophoresis {PAGE (native, SDS, reducing, non- reducing)} to characterize the protein with regard to its molecular weight, structure/subunits/SS bonds etc., or for detection of impurities in the product
- 2) Concentration of protein with Folin Lowry
- 3) Western blot/dot blot for purity of product demonstration/ dummy sandwich preparation of semi-dry or wet western blot sandwich.
- 4) HPLC /FTIR/NMR spectrum based theory questions may be asked for interpretation
- 5) Visit to a facility manufacturing Biosimilar

1. **Biosimilars:** Regulatory, Clinical and Biopharmaceutical Development, Editors: Hiten J. Gutka • Harry Yang • Shefali Kakar, AAPS Advances in the Pharmaceutical, Sciences Series, Volume 34.
2. <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>.
3. <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity>.
4. <http://nib.gov.in/NIB-DBT2016.pdf>.
5. 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.
6. 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.
7. 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.
8. Introduction to Biosimilars and Regulatory Requirements. Fact Sheet 3. International Federation of Pharmaceutical Manufacturers & Association (Geneva) & International Alliance of Patients Organization (UK).

PSBT304- Molecular Enzymology and Enzyme Technology

Course Objectives	To get familiarity with the basic concepts of enzymes like enzyme kinetics, catalytic power of enzymes, active site and transition state, regulatory and allosteric enzymes, on protein enzymes.
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	Techniques of enzyme purification and its importance. Need for enzyme engineering and its benefits and applications. Role of enzymes as a diagnostic tool and for industrial applications. Use of enzymes as Biosensors.
Course Outcomes	Enzyme deficiencies and use of enzymes as therapeutics. At the end of the course the student will be aware of the enzyme kinetics, the catalytic power of an enzyme, changes in the active site, and the importance of the transition state. The importance of obtaining enzymes in their pure form and the ways it can be achieved. The need for and methods for enzyme engineering to enhance its activity or half life. The significance of enzymes as diagnostic tools, in therapy, industrial application and as biosensors; and the outcome of enzyme deficiencies.

Course code	Unit	Molecular Enzymology and Enzyme Technology	Credits	Lectures
PSBT304	I Basic concepts -	Brief history and introduction; chemical nature and properties of enzymes; how enzymes work -mechanism of action; catalytic power and specificity of enzymes; types of catalysis; active site ; transition state and evidence for enzyme transition state complementarity; enzyme kinetics – factors affecting enzyme activity ; enzyme inhibition; enzyme specificity; regulatory enzymes , regulation of enzyme activity; allosteric enzymes and their kinetic properties; units of enzymes; non protein enzymes; coenzymes and cofactors; isoenzymes; enzyme pattern in diseases.	4	15
	II Techniques of Enzyme purification and studies/enzyme engineering	Based on molecular size (Dialysis/ ultrafiltration, density gradient centrifugation, size exclusion chromatography); based on solubility of proteins (Isoelectric precipitation, salting out); based on electric charge (Ion exchange chromatography, Electrophoresis-capillary electrophoresis, 2D electrophoresis); based on adsorption properties (Adsorption and Affinity chromatography). Other techniques: Immobilized metal ion affinity chromatography, Hydrophobic interaction chromatography, Reversed phase chromatography and		15

		Chromatofocusing. Enzyme engineering – Introduction, Objectives, Principles, Examples and Steps involved in enzymes engineering. Random mutagenesis and molecular breeding of DNA. Recent advances in Rational approaches for Enzyme engineering. Applications of enzyme engineering.		
	III Industrial & medical application of enzymes	Textile Industry, Detergent Industry , Pulp and Paper Industry , Animal Feed Industry: Enzyme Technology for Detoxification of Mycotoxins in Animal Feed , Phytases for Feed Applications and Leather Industry. Enzyme Applications for Human and Animal Nutrition. Biosensors – Introduction, instrumentation, Types and examples. Enzymes based sensors as diagnostic tools- Biosensors for Blood Glucose, Biosensors for Urea in Blood and Urine, Biosensors for Uric Acid, Biosensors for Arginine, Biosensors for Asparagine, Biosensors for Creatinine, Biosensors for Cholesterol, Allosteric enzyme-based biosensors.		15
	IV Enzyme deficiencies/diagnostic enzymes/ therapeutics	Disorders of amino acid metabolism- Phenylketonuria, Alkaptonuria, Homocystinuria. Disorders of carbohydrate metabolism – Galactosemia, Hereditary fructose intolerance, Hereditary lactose intolerance. Disorder of lipid metabolism - Gaucher disease, Fabry disease. Disorders of purine and pyrimidine metabolism- HGPRT deficiency, Adenosine deaminase deficiency, Orotic aciduria. Enzymes in diagnosis of diseases- Liver disorders, Cancer, Cardiac disorders. Role of Other enzymes- Lysozyme, Butyrylcholinesterase and Lipases. Therapeutic uses of enzymes - enzymes in replacement therapy,		15

		enzymes in cancer treatment, enzymes for fibrinolysis, enzymes used for various treatments and enzyme gene therapy.		
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PSBTP 304-PRACTICALS

- Microbial Enzyme production:
 - Partial purification using ammonium sulphate precipitation.
 - Dialysis of the salt-precipitated protein.
 - Assessing the enzyme activity and the protein content.
- Effect of inhibitors/ chemicals on enzyme activity.
- Extraction of enzymes from plant sources.
- Measurement of Enzymatic Activity by Using a Colorimetric Assay.
- Purification of Acid Phosphatase from Wheat Germ.
- Enzyme Immunoassays.
 - Methods for Enzyme Immunoassays.
 - Non-competitive Solid-phase Enzyme Immunoassay.
 - Competitive, Solid-phase Enzyme Immunoassay.
- Determining of Alkaline Phosphatase (ALP) Concentration in Blood Plasma.
- Measuring Lactase Enzymatic Activity.
- Screening of new microbial strains for production of enzymes and perform its activity staining (zymogram).
- To determine Specific activity of α Amylase from different sources.

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- Lehninger Principles of Biochemistry (4th Ed. Nelson, D., and Cox, M.; W.H. Freeman and Company, New York, 2005.
- Satyanarayan and Chakrapani, Biochemistry. New Delhi, Elsevier Health Sciences APAC, 2013.
- Berg JM, Tymoczko JL, Stryer L (2002): Biochemistry, 5th ed., Freeman WH and Co., New York.
- https://shodhganga.inflibnet.ac.in/bitstream/10603/100595/7/07_chapter%201.pdf General Introduction to enzymes.
- <https://iopscience.iop.org/book/978-0-7503-1302-5/chapter/bk978-0-7503-1302-5ch1> Introduction to enzymes and their applications.
- Biochemistry by Lehninger, 2nd Ed, Kalyani publication 2008.
- Understanding enzymes (3rd edition). Edited by Trevor Palmer, Ellis Horwood, Chichester, 1991.
- Protein purification principles, High Resolution Methods, and Applications, 3rd Edition, Jan-Christer Janson, John Wiley & Sons, Inc., Hoboken, New Jersey.
- <https://www.biotecharticles.com/Applications-Article/Methods-of-Purification-of-Enzymes-583.html>
- https://www.creative-enzymes.com/service/enzyme-purification_307.html Enzyme Purification
- http://web.sungshin.ac.kr/~spark/class/enzchem/EnzChem_ch02.pdf Chapter 2 - purification of enzymes
- <https://www.labome.com/method/Protein-Purification.html>
- <http://www1.lsbu.ac.uk/water/enztech/index.html> Chapter 6 Enzyme preparation and use

14. <https://docplayer.net/20937505-Protein-purification-nison-sattayasai-khon-kaen-university-thailand-1-introduction-2-extraction-of-protein.html>
15. http://www.processdevelopmentforum.com/ppts/posters/Protein_purification_methods-_overview,_29155460.pdf
16. https://www.researchgate.net/publication/281102215_How_to_purify_proteins
17. Fundamentals of Enzyme Engineering, Young Je Yoo, Yan Feng, Yong-Hwan Kim, Camila Flor J. Yagonia, : Springer Netherlands 2017.

M.Sc. BIOTECHNOLOGY

SEMESTER- IV

PSBT401- Nanobiotechnology				
Course Objectives	The course aims at providing a general and broad introduction to multi-disciplinary field of nanotechnology. It will familiarize students with the synthesis and applications of nanomaterials in the field of medicine. The course will also give an insight into complete systems where nanotechnology can be used to improve our everyday life.			
Course Outcomes	Students should be able to understand the basic science behind the properties of nanomaterials and the principles behind advanced experimental techniques for studying nanomaterials. Also understand the different aspects and applications of nanomaterials.			
Course Code	UNIT	Unit Details	Credits	Lectures
PSBT401	I Introduction to nanotechnology and nanomaterials	Introduction: Nanotechnology, Nature's biological pathway, Examples of nanomaterials and nanostructures found in nature. Nanometer-scale materials: Nanometer-Scale Metals Nano Metal Oxides, Nanopolymers, Quantum Dots, Carbon nanostructures. Nanorobotics devices of nature ATP synthase, the kinesin, myosin, dynein, flagella modulated motion.	1	15
	II Synthesis of Nanomaterials	Synthesis of nanometer-scale materials- Top down and Bottom up approaches. Self-Assembly of nanoparticles and its mechanism. Bio-directed synthesis and assembly of nanomaterials Synthesis and Assembly of Nanoparticles and Nanostructures Using Bio-Derived Templates	1	15
	III Nanotechnology in drug delivery	Biological Barriers to Nanocarrier-Mediated Delivery of Therapeutic and Imaging Agents, Nano-Sized Carriers for Drug Delivery, nano enabled drug delivery system, nanorobotics in medicine, Nanomedicine: biopharmaceutics, implantable materials, implantable chemicals, surgical aids	1	15
	IV	Applications of Nanomaterials.	1	15

	Applications of nanotechnology and Nanotoxicology	Nanotoxicology: Unique Properties, Toxicity of Nanomaterials, Factors Responsible for the Nanomaterial Toxicity, Routes of Exposure, Mechanisms of Nanoparticle Toxicity, In Vitro Testing Methods for Nanomaterials, Ecotoxicity Analyses of Nanomaterials		
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PSBTP 401-Practicals:

1. Biosynthesis and characterization of eco-friendly silver nanoparticles by using plant/leaf extracts/green tea
2. Synthesis and characterization of zinc sulfide nanoparticles by A reverse micelle method
3. Synthesis and characterization of Fluorescent Carbon Nanoparticles from Candle Soot and its 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

References:

1. Poinern, Gerrard Eddy Jai. A laboratory course in nanoscience and nanotechnology. CRC Press, 2014.
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4. Crookes-Goodson, W. J., Slocik, J. M., & Naik, R. R. (2008). Bio-directed synthesis and assembly of nanomaterials. Chemical Society Reviews, 37(11), 2403-2412
5. Chad A. Mirkin, Christof M. Niemeyer - Nanobiotechnology II_ More Concepts and Applications-Wiley-VCH (2007)
6. Christof M. Niemeyer, Chad A. Mirkin (Editors) - Nanobiotechnology_ Concepts, Applications and Perspectives-Wiley-VCH (2004)
7. Chad A. Mirkin, Christof M. Niemeyer - Nanobiotechnology II_ More Concepts and Applications-Wiley-VCH (2007)
8. Oded Shoseyov, Ilan Levy NanoBioTechnology_ BioInspired Devices and Materials of the Future (2008, Humana Press)
9. Textbook of Nanoscience and Nanotechnology by B.S. Murty, P. Shankar, Baldev Raj, B B Rath, James Murday
10. Arun Kumar - Nanomedicine in drug delivery-CRC Press _ Taylor & Francis (2013).
11. Yuliang Zhao, Zhiyong Zhang, and Weiyue Feng - Toxicology of Nanomaterials-Wiley-VCH (2016)
12. Diwan, Parag, and Ashish Bharadwaj, eds. The Nanoscope: Encyclopedia of Nanoscience and Nanotechnology. Pentagon Press, 2005. (Vol 1-6)

PSBT 402-OMICS AND SYSTEMS BIOLOGY

Course objective:	Bring awareness of the emerging fields of OMICS and Systems Biology, biological systems as a whole and how parts of a systems interact with each other To introduce the techniques involved in Genomics, Proteomics, transcriptomics, Lipidomics and Metabolomics. To describe the key features of human genome project To understand the applications of the different OMICS technology to screening, testing and treatment of human diseases . Perturbation of biological systems to study various responses in the biological systems using high throughput techniques. Introduction to the modelling systems , databases ,computational tools used in systems biology Data mining: The unit aims at introducing the concept of knowledge discovery process, data mining methods and various scientific application of data mining. The unit also explores application of systems biology in different field of health care.
Course outcome:	At the end of the course learners will be able to Understand how the data is generated by OMICS technologies to contribute to different databases. Understand , compare and contrast the techniques involved in Genomics, Proteomics, transcriptomics, Lipidomics and Metabolomics. Will be able to apply the different technologies of OMICS to the screening, testing and treatment of human diseases . Understand the structure and dynamics of a systems as a whole . Apply the different approaches to study systems biology by top down and bottom up approach. Introduction to concepts of knowledge discovery process and data mining methods. Understand the application of data mining in genomics , proteomics and development of tools in bioinformatics. Have the knowledge of applications of systems biology in development of personalized medicine, drug development.

Course Code	UNIT	OMICS AND SYSTEMS BIOLOGY	credits	lectures (hours)
PSBT 402	I OMICS- the OMICS technology , a broad outlook	Tools of Omics. Introduction to Epigenomics Human genome project- goals, conclusions and application. Structural and functional proteomics- protein- protein interaction and identification of interactions by various methods. Application of Proteomics and Genomics in human diseases –screening, testing and treatment of diseases. Metagenomics: concept, strategies, and applications in environmental biotechnology, agriculture and health	1	15
	II Transcriptomics, Lipidomics And Metabolomics	Introduction to Transcriptomics, Lipidomics And Metabolomics, Glycomics, Pharmacogenomics Techniques used in Lipidomics- Mass Spectroscopy, TLC, HPLC, GC and Capillary electrophoresis, MALDI. Technique used in Metabolomics- Mass Spectroscopy, Electrophoresis, chromatography- GC, LC & NMR. Technique used in Transcriptomics- next generation sequencing, northern blotting, DDRT-PCR, microarrays, gel free assays like biolayer interference, SPR. Applications of transcriptomics metabolomics and lipidomics in human diseases –screening, testing and treatment of diseases.(in clinical applications, personalised medicine, infectious diseases)	1	15
	III Introduction to systems biology	Systems biology towards systems level understanding of biological systems Systems structure, systems dynamics, systems design and control, systems project Models and Modelling systems in systems biology What is a model? Key properties of models, Basic of computational models, networks, data integration, standards, and model organism Perturbation of biological systems and ‘Omics’ as Quantitative high throughput experimental tools for systems biology Standards and formats for systems biology Computational Databases and software	1	15

		tools in systems biology. Biological networks: metabolic networks, gene regulatory networks, PPI networks, genetic interaction (GI) networks, and signaling networks	1	
	IV Data mining and application of systems biology	Introduction to Knowledge of discovery in databases (KDD) What is knowledge, need for KDD, KDD process outline, concept and goals. Data Mining methods: Statistics – classification, correlation, association analysis, regression, and clustering Machine learning –Symbolic and statistical approaches. Text mining, and Pattern evaluation. Data mining in scientific applications Application of systems biology : 1. Systems biology to systems medicine. 2. Application of systems biology in drug discovery and development 3. Systems biology and synthetic biology		15

PSBTP 402-PRACTICALS :

1. Gel electrophoresis of lipids (lipoproteins extracted from various sources) to separate and identify the lipid fraction
2. Preparation of report based on -Databases and data repositories used in systems Biology
3. Detection assay for gene expression using micro array and qRT –PCR (demonstration)
4. Identification of protein using analytical technique Mass spectroscopy (demonstration)

REFERENCES-

Sr no	Title of the book	Author	Publisher
1.	Bioinformatics and functional genomics (2003)	Jonathan Pevsner	John wiley & sons Publications
2.	Integration of omics approaches and systems biology for clinical applications	Antonia Vlahou, Harald Mischak, Jerome Zoidakis, Fulvio Magni.	Wiley publications
3.	Omic technologies : genomics, transcriptomics, proteomics and metabolomics.	Richard P. Horgan And Louise C. Kenny	Scientific advisory committee (sac) , the obstetrician and gynaecologist.
4.	Bioinformatics and functional	Jonathan Pevsner.	Wiley blackwell

	genomics, <i>third edition</i>		publications
5.	Concepts and techniques in genomics and proteomics-	Nachimuthu Saraswathy And Ponnusamy Ramalingam.	Biohealthcare publishing (oxford) limited
6.	Introduction to proteomics- <i>tools for the new biology- by</i>	Daniel C. Liebler,	Humana press totowa, nj
7.	Introduction to proteomics principles and applications	By Nawinmishra	John wiley & sons, inc., publication
8.	Multi-omics approaches to disease	Hasin et.,Al;	Genome biology (2017)
9.	The new science of metagenomics	Committee On Metagenomics: Challenges And Functional Applications, National Research Council, Board On Life Sciences	The national academies press. www.nap.edu
10.	Human molecular genetics 4th edition	Tom Strachan And Andrew Read	Garland science
11.	Systems biology a textbook, second edition	Edda Klipp, Wolfram Liebermeister, Christoph Wierling Axel Kowald	Wiley-vch publication
12.	Lipidomics-technologies and applications (2012)	Dr. Kim Ekroos	Wiley wch publications
13.	Topics in current genetics-metabolomics-a powerful tool in systems biology	Jens Nielsen · Michael C. Jewett (Eds)	Springer publications
14.	Foundations of systems biology. First edition	Hiraokikitano(2001)	MIT press, Cambridge
15.	Systems biology	Karthik Raman and Nagasuma Chandra,	Resonance □ February 2010
16.	A new approach to decoding life: systems biology	Trey Ideker	Article in annual review of genomics and human genetics · february 2001
17.	systems biology and synthetic biology (2009)	Pengcheng Fu, Sven Panke	Wiley publication
18.	Analysis of biological networks (2008)	Bjorn .Junker, Falk Schreiber	Wiley Interscience
19.	Knowledge discovery and data mining in biological databases	Vladimir Brus I C	The knowledge engineering review, vol. 14:3, 1999
20.	Computational systems biology	Andrieskreite, Roland Eils	Elsevier academic press
21.	Introduction To Biological Networks	Alpan Ravaland Animesh Ray	CRC press(2013)
22.	Advanced systems biology methods in drug discovery and translational biomedicine	Jun Zou	Biomed research international volume 2013

PSBT 403- Drug Discovery and Clinical Studies				
Course Objectives:	The objective of this course is to have a firm foundation in Drug Discovery and Clinical Studies. To provide students knowledge about Clinical Trial Design and Indian Regulations, Pharmacovigilance and Clinical Data Science.			
Course Outcomes:	By the end of the course the student will: Able to learn about drug discovery-design pathway using some in-silico tools. Able to understand the clinical trial design set up as well as they will gain information on rules-regulation and responsibilities in clinical studies.			
Course Code	Unit	Drug Discovery and Clinical Studies	Credit	Lectures
PSBT403	I Clinical Research Informatics in Drug Discovery	Introduction to the drug discovery & development • Source of drugs • Structural effects on drug action • Drugs derived from natural products • General principles of pharmacology • Drug development and testing process Approaches to new drug discovery • Computer-aided drug design • Identification of novel drug candidates and drug targets • Construction the signaling network of a drug using integer linear programming • Identification for druggable targets of a disease	1	15
	II Clinical Trial Design And Indian Regulations	Clinical Trial Design • Basic framework of clinical trial • Randomized clinical trials and different phases • Adaptive randomization methods • Seamless design • Internal pilot design • Design selection factors Regulations • The national regulatory body • Key documents in clinical research • Regulatory requirements for the conduct of clinical trials in India The Roles and Responsibilities of Stakeholders in the Sharing of Clinical Trial Data • Participants in clinical trials,	1	15

		• Investigators, • Research institutions and universities • Journals and Professional societies		
	III Pharmacovigilance	• Scope and purposes of pharmacovigilance • Adverse Drug Reactions (ADR) • ADR classification • Nature and mechanism of ADR • Concept of safety • Phases and types of DATA The process of Pharmacovigilance • Signal detection, evaluation and investigation, • Communication Methods of evaluating effectiveness of action International regulatory collaboration • WHO, CIOMS, ICH, ISoP, ISPE	1	15
	IV Clinical Data Science	• Data management in clinical research: An overview • Data Sources and Data Types • Standards in Healthcare Data • Research Data Stewardship for Healthcare Professionals • Preparing Data for Prediction Model Development • Prediction Modeling Methodology • Clinical Decision Support System	1	15

PSBTP 403-PRACTICALS:

1. A finding of a drug-gene interaction or potentially druggable category using The Drug Gene Interaction Database (DGIdb)
2. Recognition of binding patterns common to set of protein structures using ProBiS
3. Recognition of common spatial chemical binding patterns to a Set of Protein Structures using **Multiple** Alignment of Protein **B**inding Sites (MultiBind) tool and analysis using RasMol/Jmol
4. Computational protein-ligand docking using AutoDock (DEMO)

REFERENCES

Sr No	Title	Author	Print Details
1	Introduction to Basics of Pharmacology and Toxicology, Volume 1: General and Molecular Pharmacology: Principles of Drug Action, Chapter 3	Gerard Marshall Raj Ramasamy Raveendran, Editors	ISBN 978-981-32-9778-4 ISBN 978-981-32-9779-1 (eBook) https://oi.org/10.1007/978-981-32-9779-1
2	Basic & Clinical Pharmacology, 2017, Fourteenth Edition, Section I, Chapter 1.	Bertram G. Katzung, Editor	ISBN 978-1-259-64115-2 MHID 1-259-64115-5 ISSN 0891-2033
3	Software based approaches for drug designing and development: A systematic review on commonly used software and its applications, Bulletin of Faculty of Pharmacy, Cairo University 55 (2017) 203–210	Prasad G. Jamkhande, Mahavir H. Ghante, Balaji R. Ajgunde	http://dx.doi.org/10.1016/j.bfopcu.2017.10.001
4	Bioinformatics and Drug Discovery, Third Edition, (A Computational Platform and Guide for Acceleration of Novel Medicines and Personalized Medicine, Chapter 10)	Richard S. Larson, Tudor I. Oprea	https://doi.org/10.1007/978-1-4939-9089-4
5	Molecular docking studies, Chapter 5, Shodhganga		
6	Clinical Trial Designs, <u>Indian Dermatol Online J.</u> 2019 Mar-Apr; 10(2): 193–201.	<u>Brijesh Nair</u>	doi: 10.4103/idoj.IDOJ_475_18 PMCID: PMC6434767 PMID: 30984604
7	Experimental designs for small randomised clinical trials: an algorithm for choice,	Catherine Cornu et. al.,	doi: 10.1186/1750-1172-8-48 PMCID: PMC3635911 PMID: 23531234

	Orphanet J Rare Dis. 2013; 8: 48.		
8	Regulatory requirements for clinical trials in India: What academicians need to know, Indian J Anaesth 2017;61:192-9	Nithya J Gogtay, Renju Ravi, Urmila M Thatte	DOI: 10.4103/ija.IJA_143_17
9	Regulatory environment for clinical research: Recent past and expected future, Perspect Clin Res 2017;8:11-6.	Bhave A, Menon S	DOI: 10.4103/2229-3485.198551
10	National Academy Press, Committee on Strategies for Responsible Sharing of Clinical Trial Data; (Chapter 3, The Roles and Responsibilities of Stakeholders in the Sharing of Clinical Trial) Data, Board on Health Sciences Policy; Institute of Medicine. Washington (DC): <u>National Academies Press (US)</u> ; 2015 Apr 20.	The National Academies Press	International Standard Book Number-13: 978-0-309-31629-3
11	An Introduction to Pharmacovigilance, Second Edition	<i>Patrick Waller and Mira Harrison-Woolrych</i>	ISBN 9781119289753 (Adobe PDF)
12	Data management in clinical research: An overview, Indian J Pharmacol. 2012 Mar-Apr; 44(2): 168–172.	Binny Krishnankutty, Shantala Bellary, and Latha S. Moodahadu	doi: 10.4103/0253-7613.93842 PMCID: PMC3326906 PMID: 22529469
13	Fundamentals of Clinical Data Science	Pieter Kubben, Michel Dumontier Andre Dekker	ISBN 978-3-319-99712-4 ISBN 978-3-319-99713-1 (eBook) https://doi.org/10.1007/978-3-319-99713-1

PSBT 404-Scientific Writing and Food Biotechnology	
Course Objectives:	The objective of this course is: ☐ To develop skills for the processing and analysis of scientific data. ☐ To enable students to present their research results in the format of oral or poster presentations at conferences, to write scientific publications (theses, articles) and to prepare applications for scientific grants (research proposals). ☐ To inculcate good scientific writing practices.
Course Outcomes:	On completion of the course students will be able to: ☐ Think critically, organize and analyze scientific data. ☐ Develop advanced scientific writing skills to write research articles, reviews, thesis, and proposals and to make oral, poster or powerpoint presentations. Understand the best practices of scientific writing by adhering to research ethics and by avoiding plagiarism.

course code		Scientific Writing and Food Biotechnology	credits	lectures
PSBT 404	Unit I: Basic Scientific Writing and Plagiarism	Introduction to scientific writing. Basic scientific writing skills: style and language, spelling, grammar, syntax, jargon and sentence structure. Elements of a scientific paper: abstract, introduction, materials & methods, results, discussion, references and drafting titles. Scientific writing process: thinking, planning, rough draft, revision of content. Processing data & application of statistics Displaying data: text, table, graph and defining terms and abbreviations. Statistical analysis and tools for experimental data. Referencing software: Mendeley, Endnote. Plagiarism: Definition, Common types of plagiarism, Intentional and Unintentional plagiarism, Detection of plagiarism by anti-plagiarism tools (Turnitin, Duplichecker, Viper, Copyleaks), Penalties for plagiarism, Avoiding plagiarism.	1	15
	Unit II: Advanced Scientific Writing	Guidelines for Medical writing. Scientific writing skills: Writing a research paper for biomedical journal, Writing science research papers and articles, Writing a research proposal, Writing a research report, Writing popular reports, Writing thesis and dissertation, Writing clinical study reports. Presentation skills: Oral presentation, Poster Preparation & presentation, Powerpoint presentations. Research ethics, Scientific misconduct.	1	15
	Unit III: Food Biotechnology-Nutraceuticals	Nutraceuticals and functional foods Definition, characteristic features, and classification, phytonutraceuticals, Prebiotics and Probiotics, Sources (with examples e.g. microbes, plants, algae, animals), blue biotechnology , food security, food preservation, Chemopreservation Food	1	15

		processing (animal and sea food), food packaging		
	Unit IV: Food biotechnol ogy in manageme nt of health and disease	Applications of nutraceuticals in human health and nutrition- health effects of commonly used nutraceuticals and functional foods (case studies), Safety and Regulatory guidelines Nutraceuticls in management of health and disease Development of designer foods for specific chronic diseases Nutraceutical adjuvants	1	15

PSBT 404-Practicals

A) Practical: Scientific writing

- Exploration of various learning platforms in online courses listed below :
 - Online courses in fundamentals of Neuroscience from Harvard University <https://online-learning.harvard.edu/course/fundamentals-neuroscience-part-1-electrical-properties-neuron?delta=0>
 - Molecular Biology from MIT <https://ocw.mit.edu/courses/biology/7-28-molecular-biology-spring-2005/>
 - Introduction to Bioethics from Georgetown <https://bioethicsarchive.georgetown.edu/phlx101-02/course.html#units/introduction>
- Write a research proposal on any topic of your interest from the MSc syllabus. For research proposal contents and format refer to NSF guidelines.
https://www.nsf.gov/pubs/policydocs/pappg19_1/nsf19_1.pdf
For reference work use Mendeley Desktop.
<https://www.mendeley.com/guides/desktop>
- Complete an online course (Minimum 1 week) on the topic related to the biotechnology. Write a comprehensive report on the studied course contents.
 - Swayam <https://swayam.gov.in/>
 - NPTEL <https://nptel.ac.in/noc/>
 - MOOC <https://www.it.iitb.ac.in/frg/wiki/images/7/7b/Demo-PPT.pdf>
 - E-learning <https://www.bellevuecollege.edu/elearning/start/intro/>

B) Practical: (Food Technology - Nutraceuticals)

- Estimation of total sugars from food products (dairy, fruit juices, bakery)
- Determination of acid value of natural fats and oils.
- Determination of iodine number of fats and oils.

4. Estimation of vitamin B by HPLC (demonstration)
5. Study of nutraceuticals important plants like Zinziber, Curcuma, Alovera, Asparagus, Ocimum etc.
6. Estimation of antioxidant property of phytochemical by DPPH.
7. Qualitative test for tannins, phenols, isoflavones, alkaloids using TLC.
8. Estimation of food preservatives/additives (Parabens) from food sample by HPLC (demonstration).
9. Estimate Cholesterol contents in given sample by Zak's methods.
10. Estimation of bio-burden by viable counts.
11. Estimation of gluten from food sample.
12. To study nutritional components (protein, carbohydrate, secondary metabolites, lipids, vitamin C) of following: Bee honey, Mushrooms, Lentils, Soya, Dairy product, Amla, Papaya, Spinach

References:

1. Thomas, C George. (2019). Research Methodology and Scientific Writing 2nd edition.
2. Kumar, Ranjeet. (2011). Research methodology: a step-by-step guide for beginners 3rd edition.
3. Jennifer Peat, Elizabeth Elliott, Louise Baur, and Victoria Keena. (2002). Scientific Writing (BMJ Books).
4. J.R. Mathews & R.W. Mathews (2008) Successful Scientific Writing, 3rd Ed. Cambridge University Press.
5. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-3-structure-content-clinical-study-reports-step-5_en.pdf
6. https://www.emwa.org/documents/about_us/EMWAGuidelines.pdf
7. <https://www.otago.ac.nz/hedc/otago615367.pdf>
8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3510958/>
9. <http://medind.nic.in/iad/t02/i1/iadt02i1p21.pdf>
10. <https://intranet.birmingham.ac.uk/as/registry/policy/conduct/plagiarism/interactive-course.aspx>
11. <https://www.bowdoin.edu/dean-of-students/judicial-board/academic-honesty-and-plagiarism/common-types-of-plagiarism.html>
12. <https://www.ox.ac.uk/students/academic/guidance/skills/plagiarism?wssl=1>
13. <https://holyfamily.libguides.com/c.php?g=610218&p=4236572>
14. <https://plagiarismdetector.net>
15. <https://www.duplichecker.com>