The Kelkar Education Trust's
V. G. Vaze College of Arts, Science and Commerce (Autonomous)
Affiliated to University of Mumbai
(Re Accredited by NAAC with Grade A)

Revised Syllabus for MSc Biotechnology
Semester III & IV
Based on NEP-2020 Guidelines

To Be Implemented From
Academic Year 2024-25

MSc Biotechnology Course Structure

Semester III

Course	Title	Theory / Practical	Marks	Credits
MAJOR	Applied Virology and Microbiology	Theory	100	4
MAJOR	Applied Virology and Microbiology Practical	Practical	100	2
MAJOR	Environmental Biotechnology	Theory	100	4
MAJOR	Environmental Biotechnology Practical	Practical	100	2
MAJOR	Scientific Writing	Theory	100	2
ELECTIVE	Biologics and Regulatory Affairs	Theory	100	4
ELECTIVE	Molecular Enzymology and Enzyme Technology	Theory	100	4
RESEARCH PROJECT	RESEARCH PROJECT	Practical	100	4

MSc Biotechnology Course Structure

Semester IV

Course	Title	Theory / Practical	Marks	Credits
MAJOR	Nanobiotechnology	Theory	100	4
MAJOR	Nanobiotechnology Practical	Practical	100	2
MAJOR	Food Biotechnology	Theory	100	4
MAJOR	Food Biotechnology Practical	Practical	100	2
ELECTIVE	Drug Discovery & Clinical Studies	Theory	100	4
ELECTIVE	OMICS & Systems Biology	Theory	100	4
RESEARCH PROJECT	RESEARCH PROJECT	Practical	100	6

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. 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.

(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 & IV - 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	30
2.	**a.** Active participation in routine class instructional deliveries	05
	b Overall conduct as a responsible student, with respect to manners, skill in articulation, leadership qualities demonstrated through organizing co-curricular activities, etc.	05
	Total Marks	40

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

C. Research Project (4 credits in Sem III & 6 credits in Sem IV)

For semester III & IV students will 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.

M.Sc. BIOTECHNOLOGY

SEMESTER- III

Applied Virology & Microbiology	
Course Objectives	1. Students will be exposed to pandemic diseases, significance of epidemiology in studying various diseases and societal & economic issues related to such diseases**.** 2. Students will also learn details about emerging viral, bacterial, parasitic pathogens. 3. Students will learn advanced, automated methods for determining antimicrobial susceptibility, drug resistance and various aspects of biofilms.
Course Outcomes	1. Students will understand epidemiological principles in prevention, control and management of pandemic disease. 2. They will acquire understanding of antimicrobial resistance for management of drug resistance in population. 3. Students will understand the different aspects of biofilm and their management. 4. They will also get insights into latest development of diagnostics & therapeutics for such diseases.

Unit		Unit Details	Credits	Lectures
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 *Helicobacter pylori* Viruses as emerging pathogens / Diseases caused by viruses: HIV (AIDS), Chikungunya, Dengue, Parasites as emerging pathogens / Diseases caused by parasites: Malaria, *Entamoeba histolytica* (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

Applied Virology and Microbiology Practical 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 10th edition Gerald Tortora, Burdell Funke, Christine Case, Pearson Education Inc. Publication 2010
2	Basic Epidemiology R. Bonita, Bealglehole, T. Kjellstrom, 2nd 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 Kamtoh, 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, 10thedUniversities Press; Tenth edition, 2017
7	Koneman's Colour Atlas & Textbook of Diagnostic microbiology, 7th 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 Liviingston
9	Bailey and Scotts Diagnostic Microbiology Forbes, Sahem et al 12th ed, Moshby

Environmental Biotechnology				
Course Objectives:		This course aims to introduce learners to 1. latest concepts in environmental biotechnology, 2. various types of pollutions, monitoring, latest mitigation strategies and management of the same, 3. health hazards of pollution and waste, 4. solid waste management, 5. biodiversity concepts, data management and environmental monitoring.		
Course Outcomes:		At the end of the course, 1. students will be able to understand various concepts of environmental biotechnology, 2. latest development in the area, 3. and use of microbiological, molecular and analytical methods in environmental biotechnology.		
Unit		**Unit Details**	**Credits**	**Lectures**
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 & biomagnifcation for soil remediation. Phytostabilization - Contaminant removal, Soil cover, Rhizosphere modification, Geotextile capping solid waste; Industrial solid waste; Domestic solid waste; Agriculturalsolid 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 wetland, Mechanisms to remove pollutants from constructed wetlands	1	15
	IV Biodiversity & Environmental 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 inter-operatability, 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

ENVIRONMENTAL BIOTECHNOLOGY-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). *Sustainable air pollution management: theory and practice*. Springer.
2. Karl B. Schnelle & Charles A. Brown, (2002) Air pollution control technology Handbook. CRC Press
3. Singh, R. L. (Ed.). (2017). *Principles and applications of environmental biotechnology for a sustainable future*. Springer Singapore.
4. Enger, E. D., Smith, B. F., & Bockarie, A. T. (2000). *Environmental science: A study of interrelationships* (p. 434). Boston, MA: McGraw-Hill.
5. Rittmann, B. E., & McCarty, P. L. (2012). *Environmental biotechnology: principles and applications*. Tata McGraw-Hill Education.
6. Wainwright, M. (2012). *An introduction to environmental biotechnology*. Springer Science & Business Media.
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8. Pradhan, A. K., & Pradhan, N. (2015). Microbial biosurfactant for hydrocarbons and heavy metals bioremediation. In *Environmental Microbial Biotechnology* (pp. 91-104). Springer.
9. Rittmann, B. E., & McCarty, P. L. (2012). *Environmental biotechnology: principles and applications*. Tata McGraw-Hill Education.
10. Foin, T. C. (1976). *Ecological systems and the environment*. Houghton Mifflin.
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13. Maier, R. M., Pepper, I. L., & Gerba, C. P. (2009). *Environmental microbiology* (Vol. 397). Academic press.
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15. Gareth M. Evams et al., (2003) Environmental Biotechnology: Therory & Applications, Wiley.
16. Milton fingerman et al. (1999) Recent Advances in Marine Biotechnology Volume 3, AbeBooks Inc.
17. Upadhyay, L. S., & Verma, N. (2015). Role of Biosensors in Environmental Monitoring. In *Environmental Microbial Biotechnology* (pp. 77-90). Springer.
18. Geetha, S., & Gouthami, S. (2016). Internet of things enabled real time water quality monitoring system. *Smart Water*, *2*(1), 1.

Scientific Writing	
Course Objectives:	The objective of this course is: 1. To develop skills for the processing and analysis of scientific data. 2. 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). 3. To inculcate good scientific writing practices.
Course Outcomes:	On completion of the course students will be able to: 1. Think critically, organize and analyze scientific data. 2. Develop advanced scientific writing skills to write research articles, reviews, thesis, and proposals and to make oral, poster or powerpoint presentations. 3. Understand the best practices of scientific writing by adhering to research ethics and by avoiding plagiarism.

	Unit	Unit Details	credits	lectures
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**

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

<table>
<tr><th colspan="5">Biologics & Regulatory Affairs</th></tr>
<tr><td colspan="2">Course Objectives:</td><td colspan="3">1. To introduce learner to the basic concept of Biologics and Biosimilars, and its therapeutic uses.
2. To expose learner to the methodologies/steps involved in the production of Biologics/Biosimilars.
3. To educate learner with the nuances of characterization of Biosimilars with emphasis on Reference Biologic
4. To familiarize learner with the regulatory aspects of approval of a Biologic/Biosimilar</td></tr>
<tr><td colspan="2">Course Outcomes:</td><td colspan="3">At the end of the course, the learner will be:
1. Familiar with the basic concepts and significance of Biologics/Biosimilar in addition to having knowledge about its therapeutic applications
2. Knowledgeable in the steps involved in the production of Biologics/Biosimilars
3. Aware of the protocols/techniques required for characterization of the Biosimilar relative to the Reference Biologic.
4. Acquainted with the regulatory aspects of approval of a Biosimilars.</td></tr>
<tr><th colspan="2">Unit</th><th>Biologics & Regulatory Affairs
Unit details</th><th>Credits</th><th>Lectures</th></tr>
<tr><td></td><td>Unit 1

Introduction to Biologics and Biosimilars</td><td>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</td><td>1</td><td>15</td></tr>
</table>

	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, and downstream processing. Introduction to the concept of Biobetters vs Biosimilars	1	15
	Unit 3 **Character-ization 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

References

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 Regualtory 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).

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Molecular Enzymology and Enzyme Technology	
Course Objectives	1. 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. 2. Techniques of enzyme purification and its importance. 3. Need for enzyme engineering and its benefits and applications. 4. Role of enzymes as a diagnostic tool and for industrial applications. 5. Use of enzymes as Biosensors. 6. Enzyme deficiencies and use of enzymes as therapeutics.
Course Outcomes	At the end of the course the student will be: 1. aware of the enzyme kinetics, the catalytic power of an enzyme, changes in the active site, and the importance of the transition state. 2. The importance of obtaining enzymes in their pure form and the ways it can be achieved. 3. The need for and methods for enzyme engineering to enhance its activity or half-life. 4. The significance of enzymes as diagnostic tools, in therapy, industrial application and as biosensors; and the outcome of enzyme deficiencies.

Unit		Molecular Enzymology and Enzyme Technology	Credits	Lectures
	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 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.		15
	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, enzymes in cancer treatment, enzymes for fibrinolysis, enzymes used for various treatments and enzyme gene therapy.		15

REFERENCES:

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

12. https://docplayer.net/20937505- Protein-purification-nison-sattayasai-khon-kaen-university-thailand-1-introduction-2-extraction-of-protein.html
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14. _overview,_29155460.pdf
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M.Sc. BIOTECHNOLOGY

SEMESTER- IV

<table>
<tr><th colspan="5">- Nanobiotechnology</th></tr>
<tr><td>Course Objectives</td><td colspan="4">1. The course aims at providing a general and broad introduction to multi-disciplinary field of nanotechnology.
2. It will familiarize students with the synthesis and applications of nanomaterials in the field of medicine.
3. The course will also give an insight into systems where nanotechnology can be used to improve our everyday life.</td></tr>
<tr><td>Course Outcomes</td><td colspan="4">1. Students should be able to understand the basic science behind the properties of nanomaterials. and the
2. Students should be able to understand the principles behind advanced experimental techniques for studying nanomaterials.
3. Also understand the different aspects of nanomaterials,
4. And applications of nanomaterials.</td></tr>
<tr><td colspan="2">UNIT</td><td>Unit Details</td><td>Credits</td><td>Lectures</td></tr>
<tr><td rowspan="2"></td><td>I
Introduction to nanotechnology and nanomaterials</td><td>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. Nanorobotiocs devices of nature ATP synthase, the kinesin, myosin, dynein, flagella modulated motion.</td><td>1</td><td>15</td></tr>
<tr><td>II
Synthesis of Nanomaterials</td><td>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</td><td>1</td><td>15</td></tr>
</table>

	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 nanotechnology and Nanotoxicology	Applications of Nanomaterials. 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	1	15

NANOBIOTECHNOLOGY-Practicals:

1.
2. Biosynthesis and characterization of eco-friendly silver nanoparticles by using plant/leaf extracts/green tea
3. Synthesis and characterization of zinc sulfide nanoparticles by reverse micelle method
4. Synthesis and characterization of Fluorescent Carbon Nanoparticles from Candle Soot and its separation of using the Thin-Layer Chromatographic Method
5. Synthesis of alginate beads and investigation of citric acid release from a nanoshell coating of polymer
6. Antimicrobial activity testing of Nanoparticles/nanocomposites

References:

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Applications-Wiley-VCH (2007)
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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)
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- Food Biotechnology				
Course Objectives	1. To comprehend basic concepts of food sciences and properties of foods, and chemical and enzymatic factors affecting these properties. 2. To understand some emerging concepts in food technology. 3. To emphasize the concept of functional foods. 4. To explain the functional role and safety issues of food contaminants, food adulteration.			
Course Outcomes	1. Understand the fundamentals of food biotechnology. 2. Interpret the role of microorganisms and enzymes involved in various food formulations. 3. Highlight the concept of functional foods and different fermented foods. 4. Interpret the role, standard and law set by Indian and global regulatory authorities with respect to food quality control.			
UNIT		**Unit Details**	**Credits**	**Lectures**
	I Introduction to Food Biotechnology	Fermentative production of enzymes used in food industry; solid state fermentation; recovery of enzymes from natural sources; cheese making and whey processing, impact of enzyme technology (bioethanol, protein hydrolysates, bioactive peptides); enzymatic processing of fruit juices. Role of enzymes in baking, meat and meat processing; biosensors; enzymatic approach to tailor made fats; catabolic processes and oxygen-dependent reactions in food; use of lipases and reactions in organic solvents and two phases.	1	15
	II Food Biotechnology in management of health & disease	Applications of nutraceuticals in human health and nutrition- health effects of commonly used nutraceuticals and functional foods (case studies), Safety and Regulatory guidelines Nutraceuticals in management of health and disease. Development of designer foods for specific chronic diseases Nutraceutical adjuvants Nutrigenomics- Concept and examples.	1	15
	III Functional foods & 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 processing (animal and sea food), food packaging	1	15

	IV Food standards & Safety regulations	Salient features of Food Safety & Standards Act, 2006, Structure of FSSAI, Administrative set up at the State level. Roles and Responsibilities of different Food Safety Regulators, Food Safety Commissioner, Designated Officer, Food safety Officer, Adjudicating Officer Licensing and registration. Introduction to Food Safety, Food Contaminants (Microbial, Chemical, Physical), Food Adulteration (Common adulterants), Food Additives (functional role, safety issues), Food Packaging & labelling, Nutritional labelling, labelling requirements for pre-packaged food as per CODEX Role of WHO to improve evaluation of GM food FAO in India, Technical Cooperation programs, Biosecurity in Food and Agriculture.	1	15

Food Biotechnology- Practicals

1. Estimation of total sugars from food products (dairy, fruit juices, bakery)
2. Determination of acid value of natural fats and oils.
3. 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

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2. Murray Robert, Harper`s Biochemistry, 24th Ed, Prentice Hall International UK Ltd, 1990.
3. Swaminathan M., Essentials of Food and Nutrition, 2nd Ed, 1985, Ganesh and Co.
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7. Devlin, T.M., 1997, 4th Ed, Text Book of Biochemistry with Clinical Correlation, Wiley Liss Inc.
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9. Krause's Food, Nutrition and Diet Therapy, 10th Edition by Mahan, L.K. & Scott Stump, S. (2000), W.B. Saunders Ltd.
10. Nelson and Cox, 2000, Lehninger's Principles of Biochemistry, Worth Publishers.
11. Handbook of Nutraceuticals and Functional Foods Edited by Robert E.C. Wildman, Routledge Publishers.
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13. Methods of Analysis for Functional Foods and Nutraceuticals Edited by W. Jeffrey, Hursts, Routledge Publishers.
14. Nutraceutical beverages Chemistry, Nutrition and health Effects, Shahidi and Weerasinghe (Ed.), American Chemical Society, 2004.
15. Bioprocesses and Biotechnology for Functional Foods and Nutraceuticals, Jean - Richard Neeser & J. Bruce German, Marcel Dekker, Inc., 2004.
16. Ayurveda Aahar (Food / Diet)-Prof. P.H.Kulkarni.
17. Dietary Supplements and Functional Foods -Geoffrey P. Webb.
18. Introduction to the Chemical Analysis of Foods-S. Suzanne Nielsen.
19. Biotechnology, by H. J. Rehm and G. Reed, Vol 1-12, 2nd edition, VCH Publications, Germany.
20. Principles of fermentation Technology, Stanbury, Whitaker and Hall, Butterworth Heinemann (1997), Indian Edition.
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24. Bioprocess Engineering –basic concepts. Shuler and Kargi, Prentice Jall of India (2005).
25. Quality Management in Nutraceuticals, Chi Tang Ho & Quan Yi Zheng (Ed.), American Chem. Soc., 2002
26. Regulations and Quality: Pharmaceutical Manufacturing Handbook, Shayne Cox God (Ed.), Wiley Interscience 2008
27. Functional foods, designer foods, pharma foods, Nutraceuticals, Israel Goldberg (Ed.), Aspen publishers Inc., Gaithersburg, Maryland, USA, 1999.
28. Nutrition labeling handbook, Ralph Shapiro (Ed.), Marcel Dekker, N.Y., 1995
29. Dietary Supplements labeling-compliance review (third edition), James L. Summers (Ed.), Blackwell Publishing.
30. Manual of Industrial Microbiology and Biotechnology. 2nd ed. Demain and Davies (Ed.), ASM Press (1999).
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32. Food processing: Biotechnological Applications by Marvaha and Arora, 2000, Asiatech Publishers New Delhi.

-OMICS AND SYSTEMS BIOLOGY	
Course objective:	1. 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. 2. To introduce the techniques involved in Genomics, Proteomics, transcriptomics, Lipidomics and Metabolomics. 3. To describe the key features of human genome project. 4. To understand the applications of the different OMICS technology to screening, testing and treatment of human diseases. 5. Perturbation of biological systems to study various responses in the biological systems using high throughput techniques. 6. Introduction to the modelling systems, databases, computational tools used in systems biology 7. Data mining: The unit aims at introducing the concept of knowledge discovery process, data mining methods and various scientific applications of data mining. The unit also explores application of systems biology in different fields of health care.
Course outcome:	**At the end of the course learners will be able to** 1. Understand how the data is generated by OMICS technologies to contribute to different databases. 2. Understand, compare and contrast the techniques involved in Genomics, Proteomics, transcriptomics, Lipidomics and Metabolomics. 3. Will be able to apply the different technologies of OMICS to the screening, testing and treatment of human diseases. 4. Understand the structure and dynamics of a systems as a whole. 5. Apply the different approaches to study systems biology by top down and bottom up approach. 6. 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. 7. Have the knowledge of applications of systems biology in development of personalized medicine and drug development.

Course Code	UNIT	OMICS AND SYSTEMS BIOLOGY	credits	lectures (hours)
	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, and systems project. Models and Modelling systems in systems biology. What is a model? Key properties of models, Basics 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		
	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 applicationsApplication 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	1	15

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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, *third edition*		publications
5.	Concepts and techniques in genomics and proteomics-	Nachimuthu Saraswathy And Ponnusamy Ramalingam.	Biohealthcare publishing (oxford) limited
6.	Intrduction to proteomics- *tools for the new biology- by*	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

- 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 be 1. Able to learn about drug discovery-design pathway using some in-silico tools. 2. 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**
	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, 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

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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, Indian Dermatol Online J. 2019 Mar-Apr; 10(2): 193–201.	Brijesh Nair	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): National Academies Press (US); 2015 Apr 20.	The National Academies Press	International Standard Book Number-13: 978-0-309-31629-3
11	An Introduction to Pharmacovigilance, Second Edition	*Patrick Waller and* Mira *Harrison-Woolrych*	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