B.Sc (Hons) Biomedical Sciences
Preamble, Eligibility, Job Opportunities for the Course and Vertical Mobility for the Students

- The B.Sc. (Hons) Biomedical Sciences is likely to be started from the academic year 2024-2025 across a few selected colleges in the Telangana State.

- The course is interdisciplinary in nature. The syllabus has been designed to offer a comprehensive technical skill, domain knowledge in the area of biomedical sciences and make the students employable in the National Laboratories, Private Institutes, Government and Private Hospitals and Diagnostic Centers.

- **There are 8 Core Papers, 9 Elective Papers, 4Skill Enhancement papers, 1 Generic Elective paper, Project work, and Summer Internship.** The course has been designed to impart knowledge and technical skills to the students. Students will have hands-on training in medical lab techniques, epidemiological data analysis, biomedical, microbiological, genetical, besides Skill Enhancement courses.

- **Internship at the Pharma Industry, Diagnostic Centers/Hospitals and Biotech Companies:**At the end of the third year, students will undergo internship for a period of one year (two semesters). There will not be any theory classes during this period. However, students will submit the project report at the respective colleges at the end of 8th semester and credits will be allotted based on the quality of the project report that they prepare. Further, companies may not be able to provide any stipend during this period.

- It is mandatory for all the students to complete the project work and take up summer internship in recognized R&D institutions/Laboratories of repute / Universities/Hospitals/Pharma Industry/Biotech companies/diagnostic centres etc. **Generic Elective Course** has been designed to give exposure to the students in the discipline of Biomedical Sciences.

- **Eligibility Criteria:** Students who have passed the Intermediate Course with any Science streams such as Maths, Biology, Physics, Chemistry/ Biology, Physics, Chemistry/ Botany, Zoology, Chemistry/Biochemistry, Microbiology, Genetics, Biotechnology with Chemistry as compulsory subject are eligible/or its equivalent. The intake of students is purely based on merit basis at the Intermediate level.

- **Employment Opportunities:** The Biomedical Graduates can work as biomedical scientists, biotechnologists, clinical research associates, clinical scientists in the biochemistry, hematology, immunology, forensic scientist, microbiologist, Physician's associates, research scientist in life sciences, research scientist in medical sciences, scientific laboratory technician, toxicologist, crime scene investigator, genetic counselor, medical sales representative, medical science liaison officer, occupational hygienist, associate endocrinologist in the clinics, neuroscientist, scientific writer, teaching laboratory technician, medical lab diagnostic analyzer, health and biosafety executive in the government and private hospitals and in the intensive care units, biosafety officer

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for the disposal of municipal waste and workers, and biosafety officer for the disposal of hazardous waste in the National Research Organizations. Further, they can be also employed as:

- Executive in diagnostics
- Executive in preclinical testing
- Executive in clinical trails
- Executive in clinical data management (CDM)
- Executive in quality analysis(QA)
- Executive for Regulatory Affairs (RA)
- Executive as statistical programming
- Executive biologics quality analysis (QA) and testing (QA&T)

- **Mobility of the Students:** Student graduates either can seek jobs, or else for further studies they are eligible in any post graduate course such as M.Sc in Biomedical Science ,Chemistry, Bio Chemistry, Bioinformatics, Biotechnology, Environmental Science, Food and Nutrition, Food Technology, Forensic Science, Genetics, Home Science, Medical Biochemistry, Medical Microbiology, Medical Pharmacology, Medical Toxicology, Microbiology, Bioscience, or across any discipline in Life Sciences.

- **Students who get through B.Sc (Honours) degree are eligible to study MS abroad /Eligible for UGC/CSIR NET exam to join in PhD degree in any one of the disciplines mentioned above.**

Credits Proposed under the CBCS Scheme for

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B.Sc(Hons.)Biomedical Sciences Course (2024-2025)
Ability Enhancement Compulsory Course- AECC (Environmental Science/Basic Computers)

Courses		Papers	TotalCredits	Creditsforeachpaper/Semester					
				B.Sc.					
				I	II	III	IV	V	VI
Core CoursesDSC	Optional-1- Chemistry	4	20	5 (Chem)	5 (Chem)	5 (Chem)	5 (Chem)	-	-
	Optional 2--BMS 1	4	20	5 C-101	5 C-103	5 C-105	5 C-107	-	-
	Optional-3 BMS 2	4	20	5 C-102	5 C-104	5 C-106	5 C-108	-	-
Elective Courses DSE	Optional-1- Chemistry	2	10	-	-	-	-	5 (Chem)	5 (Chem)
	Optional-2-BMS 1	2	10	-	-	-	-	5 E-109 A/B	5 E-111 A/B
	Optional-3-BMS 2	2	10	-	-	-	-	5 E- 110 A/B	5 E-112 A/B
Language	English (FirstLanguage)	5	20	4	4	3	3	3	3
	SecondLanguage	5	20	4	4	3	3	3	3
AECC	Environ/ ComputerSkills	1	2	2	-	-	-	-	-
	Environ./Computers	1	2	-	2	-	-	-	-
SEC SkillEnhancementCourse SEC	SEC1	1	2	-	-	2 BMS-S301)	-	-	-
	SEC2	1	2	-	-	2 BMS-S301)	-	-	-
	SEC3	1	2	-	-	-	2 BMS-S301)	-	-
	SEC4	1	2	-	-	-	2 BMS-S301)	-	-
GE	OpenStream	1	4	-	-	-	-	4	-
Internship		1	4		VII & VIII semester internship				4
ProjectWork/Optional		1	4	-	-	-	-	-	4
TotalCreditsineachsemester				25	25	25	25	25	29
TotalCreditstill 6th semester				154					
Credits for Internship during the 7th and 8th Semesters		14	14	182					

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B.Sc (Hons.) Biomedical Sciences - Semester-WisePapers

SEMESTER-I

Paper I- Medical Biochemistry,Molecular Biology, Genetics, Microbiology(BMS-C101)
Paper II - Medical Endocrinology, Medical Diagnostics (BMS-C102)

SEMESTER-II

Paper III - Integrated Human Physiology, Anatomy, and Pathology (BMS-C103)
Paper IV - Applied Biostatistics for Pharmaceutical Sciences (BMS-C104)

SEMESTER-III

Paper V - Applied Immunology and Introduction to Biologics (BMS-C105)
Paper VI - Drug discovery, CDM and Statistical Programming (BMS-C106)

SEMESTER-IV

Paper VII - Pharmacology and Pharmacokinetics (BMS-C107)
Paper VIII - *In vitro* Assay Development and Drug Screening(BMS-C108)

SEMESTER-V

Elective Paper IX- Bioanalytical Techniques (BMS-E-109A) /Bioinformatics(BMS-E109B)
Elective Paper X- Biosafety and Infectious Diseases (BMS-E-110A) /Regulatory Affairs in Pharmacology and Toxicology (BMS-E110B)

SEMESTER-VI

Elective Paper- XI - Clinical Toxicology(BMS-E-111A) /Cancer Biology (BMS-E-111B)
Elective Paper-XII - Preclinical Drug Safety and Efficacy Analysis andPhysiologically Based Pharmacokinetic (PBPK) Modeling in Drug Discovery Development (BMS-E-112A)/Clinical Genetics (BMS-E-112B)
Elective Paper XIII - Biostatistics, Intellectual Property Rights and Entrepreneurship (BMS-E-113A)

SEMESTER VII and SEMESTER VIII

Project Work :Students will undertake Internship/Project work either at the Pharma Industry / Biotech Companies/ Diagnostic Centers / Corporate and Government Hospitals during the semesters VII and VIII. Students will submit the work at the respective colleges after the completion of the Internship. Stipend may be /or may not be provided to the students during this period. Credits will be allotted semester-wise for the Internship/project work.

Skill Enhancement Courses

Skill Enhancement Course - I - Clinical Biochemistry and Molecular Diagnostics (BMS-S301)
Skill Enhancement Course - II - InVitro and in Vivo Assay Developmentand Drug Screening (BMS-S302)
Skill Enhancement Course - III –Techniques in Forensic Science (BMS-S303)
Skill Enhancement Course - IV –DNA Fingerprinting (BMS-S304)
Generic Elective - Any Student Can Opt for this Elective Paper
(Other Than the Students from the Stream of Biomedical Sciences)

Title of the Paper - Fundamentals of Medical Diagnostics (only theory, no practicals)

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B.Sc(Hons.)Biomedical Sciences Programme
Proposed Structure of B.Sc Biomedical Sciences Programme
Eligibility of Teachers

Semester-I

Paper I -Medical Biochemistry,Molecular Biology, Genetics, Microbiology (BMS-C101)
(This paper will be taught by a faculty member with M.Sc or PhD in Biochemistry/Microbiology/Botany/Zoology/Biotechnology/Environmental Sciences degree)

Paper II - Medical Endocrinology, Medical Diagnostics (BMS-C102)
(This paper will be taught by any faculty member with MB.;BS or M.Sc or PhD in Biophysics/Biotechnology/Microbiology/Biochemistry/ degree)

Semester-II
Paper III - Integrated Human Physiology, Anatomy, and Pathology (BMS-C103)
(This paper will be taught by a faculty member with MB.;BS or M.Sc or PhD in Human Physiology/Human Anatomy/Human Pathology/Biochemistry/Microbiology/Genetics/Biotechnology degree)

Paper IV - Applied Biostatistics for Pharmaceutical Sciences (BMS-C104)
(This paper will be taught by a faculty member with B.Pharmacy/M.Pharmacy or M.Sc or PhD in Microbiology/Biotechnology/Genetics/Biochemistry/Zoology degree)

Semester III
Paper V- Applied Immunology and Introduction to Biologics(BMS-C105)
(This paper will be taught by any faculty member with M.Sc or PhD in Genetics/Zoology/Biotechnology/Biochemistry/Microbiology/B.Pharmacy/M.Pharmacy degree)

Paper VI- Drug discovery, Clinical Data Management (CDM) and Statistical Programming(BMS-C106)
(This paper will be taught by any faculty member with M.Sc or PhD in Statistics/P.G. Diploma in Bioinformatics/B.Tech or M.Tech Bioinformatics/Medical Biochemistry degree)

Semester-IV
Paper VII -Pharmacology and Pharmacokinetics(BMS-C107)
(This paper will be taught by any faculty member with MB.;BS or M.Sc or PhD in Pharmacology/B.Pharmacy or M.Pharmacy degree)

Paper VIII - *In vitro* Assay Development and Drug Screening (BMS-C108)
(This paper will be taught by any faculty member with a background on Human Pathology or a clinician with MB.;BS/or B.Pharmacy/M.Pharmacy/PhD in Pharmacy degree)

Semester-V
Elective Paper – IX- Bioanalytical Techniques (BMS-E109A) /Bioinformatics (BMS-E109B)
(These papers will be taught by any faculty member with M.Sc or PhD in Biophysics/Botany/Zoology/Biochemistry/Biotechnology/Microbiology/Genetics/P.G. Diploma in Bioinformatics/B.Tech or M.Tech/PhD in Bioinformatics)

Elective Paper –X - Biosafety and Infectious Diseases (BMS-E-110A) /Regulatory Affairs in Pharmacology and Toxicology (BMS-E110B)

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(These papers will be taught by any faculty member with MB.;BS/M.Sc or PhD in Genetics/ Microbiology/Biochemistry/B.Pharmacy/M.Pharmacy or PhD degree in pharmacy)

Semester-VI

Elective Paper – XI - Clinical Toxicology(BMS-E-111A) / Cancer Biology (BMS-E-111B)

(These papers will be taught by any faculty member with a background on Human Pathology/ clinician with MB;BS degree/M.Sc or PhD in Biochemistry/Microbiology/Genetics/B.Pharmacy orM.Pharmacy or PhD in Pharmacy)

Elective Paper – XII - Preclinical Drug Safety and Efficacy Analysis andPhysiologically Based Pharmacokinetic (PBPK) Modeling in Drug Discovery Development (BMS-E-112A)/Clinical Genetics (BMS-E-112B)

(These papers will be taught by a faculty member with M.Sc or PhD in Genetics/P.G. Diploma in Bioinformatics or B.Tech or M.tech or PhD in Bioinformatics)

Elective Paper – XIII –Biostatistics, Intellectual Property Rights and Entrepreneurship (BMS-E-113A)

(This paper can be handled by any faculty member with M.Sc or PhD in Genetics/Microbiology/Biochemistry/Biotechnology/Botany/Zoology/Biotechnology degree or Diploma in IPR).

SEMESTER VII and SEMESTER VIII

Project Work :Students will undertake Internship/Project work either at the Pharma Industry / Biotech Companies/ Diagnostic Centers / Corporate and Government Hospitals during the semesters VII and VIII. Students will submit the work at the respective colleges after the completion of the Internship. Stipend may be /or may not be provided to the students during this period. Credits will be allotted semester-wise for the Internship/project work.

Skill Enhancement Course - I - Clinical Biochemistry and Molecular Diagnostics (BMS-S301)
Skill Enhancement Course - II - InVitro and in Vivo Assay Developmentand Drug Screening (BMS-S302)
Skill Enhancement Course - III –Techniques in Forensic Science (BMS-S303)
Skill Enhancement Course - IV –DNA Fingerprinting (BMS-S304)

(The skill enhancement courses can be handled by Government and private hospitals, diagnostic centers, industries etc.)

Generic Elective - Any Student Can Opt for this Elective Paper (Other Than the Students from the Stream of Biomedical Sciences)

Title of the Paper - Fundamentals of Medical Diagnostics
(This paper will have only theory and no practical classes)

(This paper can be handled by Biochemistry/Microbiology/Biotechnology)

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Equipment Required for Conducting the B.Sc Biomedical Science Course in Telangana

1. Colorimeter
2. pH meter
3. Autoclave
4. Laminar Air Flow
5. Single Pan Balance
6. Refrigerator
7. -20 o C Freezer
8. Refrigerated Centrifuge
9. UV-VIS Centrifuge
10. Thermocycler (Bio-Rad or any other Standard Company)
11. Hot Air-Oven
12. Incubator Shaker
13. Gyratory Shaker
14. Air-Conditioners
15. Computers with basic minimum software
16. Submerged Electrophoretic Unit with Power Pack for Protein Separation
17. Gel Electrophoretic Unit with Power Pack for DNA and RNA separation
18. Pestles and Morters
19. Pipette Man (50 µl, 100 µl, 200 µl and 1000 µl) - All 3 quantities each
20. Clean Air Room
21. ELISA Reader
22. Gel Documentation System
23. Light Microscopes
24. Flourescent Microscope
25. Brightfoeld Microscope
26. Western Blotting Unit
27. Open-source statistical tools like R and Python (Jupyter Notebooks, Pandas, SciPy for statistical analysis).
28. Descriptive Statistical Analysis Using R, RStudio, Python to summarize pharmaceutical data sets with descriptive statistics and visualizations
29. SAS Programming software for Clinical Trials
30. OpenClinica or REDCap software for Clinical Data Management
31. BOD Incubator
32. Crime Scene Barricades
33. Forensic Light Source
34. Fume Hood
35. Microfuge
36. Paper Chromatographic Units
37. Specific forensic analytical equipment, like cyanoacrylate fuming chambers for lifting of latent fingerprints
38. Video Recording Facility

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Glassware, Plasticware, Stains and InterNet Facilities

1. Burettes, conical flasks, pipettes, measuring cylinders, Petri Dishes
2. Needles, Syringes, Gloves, Cotton, Small Glass Bottles for Collection of Blood samples
3. Pipette Tips, Eppendorf Tubes
4. Test tube Stands
5. White blood cell manual counter in specially designed chambers (Neubauer) or with automated counters
6. Glass slides with cover slips
7. Pen drives
8. Password Cracking Investigation Tools
9. HotSHOT DNA Extraction Kit or Dipstick DNA Extraction Kit
10. 5x HOT FIREPol® Blend Master Mix Ready To Load
11. PCR Grade Water
12. DNA barcoding Primer Mix
13. GelGreen® DNA Stain
14. 100 bp DNA Ladder
15. Protein Ladder
16. Giemsa stain

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B.Sc(Hons.)- Biomedical Sciences - Semester I - Theory
Paper I- Basics of Medical Biology (BMS-C101)
(Faculty Members are Requested to Orient the Students towards Biomedical Sciences)

Unit I –Role of Biomolecules in Medical Biology

(a) Proteins and Peptides

Introduction to amino acids, peptide bond and protein structure.
Composition and functions of hemoglobin, Ferritin, C- Reactive Protein (CRP) and Rheumatoid factor.
Peptide: Types, benefits and safety of peptides
Role of peptides in diagnostics
Peptides as therapeutic agents – current applications
Potential role of bioactive peptides in prevention and treatment of chronic diseases

(b). Enzymes as drugs and role in clinical medicine

Enzymes in pharmaceutical industry
Therapeutic application of enzymes
Proteolytic enzymes – Sources and benefits
Proteases in therapy
Role of proteolytic enzymes in disease prevention and medical biology
Diagnostic and therapeutic potential of protease inhibition

(c). Carbohydrates and Lipids

Carbohydrates: Basics of monosaccharides, disaccharides and polysaccharides.
Composition of glycogen.
Biomedical importance of Chitin, chitosan and Glycosaminoglycans.
Lipids: Classification of lipids and fatty acids.
Biological significance (MUFA & PUFA), Fate of dietary lipids.
Structure and functions of Cholesterol and Vitamin D.

(d). Nucleic acids as drug targets

Structure and composition of RNA and DNA
Classes of drugs that interact with DNA: DNA intercalators (amsacrine), Groove binders (netropsin), DNA alkylators(amines: mechlorethamine; nitrosoureas: carmustine)
Concept of antisense therapy

Unit II - Trancription:Eukaryotic transcription of mRNA, tRNA and rRNA

(a). Mechanism of Transcription

Basic transcription apparatus
Initiation, elongation and termination of transcription
Types of RNA polymerases, transcription factors
Inhibitors of transcription - rifampicin and α-amanitin

(b). Post-Transcriptional Modifications

Split Genes, Concept of introns and exons
RNA splicing, Spliceosomes and Self splicing introns
Alternative splicing and exon shuffling, mRNA transport
Post-Transcriptional Modifications – micro RNAs
miRNA, long non-coding RNA
PIWI Interacting RNAs
Role for DNA methylation on neurocognitive dysfunctions
Role of RNA methylation on neurocognitive dysfunctions

(c). - **Translation**

Mechanism of Translation

Features of genetic code and exceptions in some systems
Ribosome structure- rRNA and proteins
Charging of tRNA, aminoacyltRNAsynthetases
Proteins involved in initiation in prokaryotes
Proteins involved in the initiation of eukaryotes

(d). **Elongation and termination of polypeptides**

Fidelity of translation
Inhibitors of protein synthesis – tetracyclins, aminoglycosides
Chloramphenicol and aminoglycosides
Post-Translational Modifications
Phosphorylation, Acetylation, Hydroxylation, Methylation

Unit III-Variation in chromosomal number:

(a). **Mutations:** Mutagens (Physical and chemical). Types of mutations.
Gene mutations- Substitutions and Frame shift mutations
Molecular Basis of Gene mutations.

(b). **Chromosomal aberrations:** Numerical Variation in chromosomal number
Euploidy, Aneuploidy, Polyploidy.
Structural changes in chromosomes- Deletions, Duplications, translocations, inversions.
Significance of mutations.

(c). **Chromosomal abnormalities** in humans: Inborn errors in humans-Klinfelter's syndromes, Tuner's syndrome, Down's syndrome, Patau's syndrome.
Diagnosis genetic abnormalities (Amniocentesis).

(d). **Inherited human diseases:** Haemophilia, Sickle cell anemia
Muscular dystrophy (MD)
Cystic fibrosis

Unit – IV Principles of Diseases and Epidemiology

(a). **Relationship between Normal microbiota and host, Opportunistic microorganisms**
Nosocomial infections
Development and spread of infectious diseases
Invasion, pathogen, parasite, pathogenicity, virulence, carriers and their types

(b). **Bacterial and fungal diseases with reference to etiology, clinical symptoms**
Etiology of diseases
Clinical symptoms
Respiratory tract infections like Diphtheria and Tuberculosis

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(c). Gastrointestinal tract and urinary tract infections

Staphylococcal food poisoning and *E. coli* gastroenteritis
Microbiome and its role in human health
Probiotics and their role in human health
Urinary tract infections: gonorrhea and syphilis
Involvement of bacterial toxins or virulence factors in the Mechanisms of Pathogenesis
Viruses, viroids, prions

(d). General characteristics of viruses

Structure, isolation, cultivation and identification of viruses
Viral multiplication, one step multiplication curve
Lytic and lysogenic phages (lambda phage), concept of early and late proteins
Clinical virology with reference to HIV virus and hepatitis virus (life cycles)

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B.Sc(Hons.)– Biomedical Sciences - Practicals for the Semester I
Paper I - Medical Biochemistry, Molecular Biology, Genetics, Microbiology
(BMS-C101)
(All practical classes are compulsory for all papers)

An option to the students may be given to go to any Diagnostic Center for the Estimation of these Molecules if the Students are interested.

1. Estimation of total sugars by Anthrone, Amino acids by Ninhydrin method (Colorimetric or Spectrophotometric).
2. Estimation of urea from the blood or urine.
3. Demonstration of chromosomal banding techniques (C &Q).
4. Understanding about biosafety cabinet and Level-II Level III facilities
5. Staining and morphological characterization of *Aspergillus* species*Pencillium* species and *Saccharomyces* species
6. Demonstration of Pathogenic Bacterial Culture
7. Demonstration of Swab preparation from the throat and for DNA isolation from the Swab or Bacterial colonies
8. Detection and Diagnosis of Malaria, and Typhoid using the Rapid Kit Method
9. Diagnosis of *Corynebacterium diphtheria,Bordetella pertussis*, and COVID19 (Corona virus) detection by Real Time-PCR (RT-PCR)
10. Isolation of genomic DNA from blood/tissue
11. Demonstration of Polymerase Chain Reaction (PCR) technique.

B.Sc(Hons.)– Biomedical Sciences – Semester I - Suggested Books
Paper I - Medical Biochemistry, Molecular Biology, Genetics, Microbiology

1. Lehninger: Principles of Biochemistry, 5th edition (2008), David L. Nelson and Michael M. Cox; Prentice Hall Publishers, ISBN-13: 978-0321707338
2. Biochemistry, 4th edition (2003), Campbell, M. K. and Farrel, S. O.;Brooks/Cole, Cengage Learning (Boston), ISBN: 0030348498.
3. An Introduction to Practical Biochemistry, 3rd edition (1987), Plummer, McGraw-Hill College; ISBN-13: 978-0070841659.
4. Human Molecular Genetics, 3rd edition (2003) by Tom Strachan and Andrew Read; Garland Science Publishers, ISBN -13: 978-0815341826.
5. Concepts of Genetics, 10th edition, (2011). William S. Klug, Michael R. Cummings, Charlotte A. Spencer, Michael A. Palladino; Pearson Education, ISBN-13: 978-0321724120.
6. Principles of Genetics, 8th edition (2005), Gardner EJ, Simmons MJ, Snustad DP. John Wiley and Sons, Inc. ; ISBN-13: 978-9971513467.
7. Principles of Genetics, 6th edition (2011), Snustad DP and Simmons MJ, John Wiley and Sons, Inc; ISBN-13: 978-0470903599

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8. Microbiology: An Introduction, 9th edition (2008), Gerard J. Tortora, Berdell R. Funke, Christine L. Case; Benjamin Cummings. ISBN-13: 978-0321733603.
9. Prescott, Harley, and Klein's Microbiology, 8th edition, (2011), Joanne M. Willey, Linda M. Sherwood, Christopher J. Woolverton, McGraw Hill International. ISBN-13:978- 0071313674.
10. Bailey and Scott's Diagnostic Microbiology, 12th edition (2007), Betty A. Forbes, Daniel F. Sahm and Alice S. Weissfeld; Mosby Elsevier Publishers, ISBN-13: 978-0808923640.
11. Microbiology, 6th edition (1993), Pelczar, Chan and Krieg; McGraw Hill International, ISBN-13: 978-0070492585.
12. Brock Biology of Microorganisms, 13th edition (2010), Michael T. Madigan, John M. Martinko, David Stahl and David P. Clark, Pearsons, Benjamin Cummings, ISBN-13: 978- 0321649638.
13. Microbiology: A Laboratory Manual, 10th edition, (2013), James Cappuccino and Natalie Sherman, Benjamin Cummings. ISBN-13: 978-0321840226.
14. Molecular Biology of the Gene, 6th edition (2007), Watson, J. D., Baker T. A., Bell, S. P., Gann, A., Levine, M., and Losick, R; Benjamin Cummings Publishers, ISBN-13: 978- 0805395921.
15. Cell and Molecular Biology: Concepts and Experiments, 7th edition (2013), Gerald Karp. ; Wiley Publishers ISBN-13: 978-1118206737.

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B.Sc (Hons.) – Biomedical Sciences - Semester - I
PaperII - Medical Endocrinology, Medical Diagnostics (BMS-C102)

Unit – I - Introduction to Endocrinology

(a). Types of hormones
Functions of hormones in human body
Basic concepts about hypo and hyper secretion of hormones and their diseases
Types of endocrine cells: Alpha, Beta and Delta cells

(b). Pathways of hormonal synthesis
Hormone receptors / receptor biology
General mechanism of hormonal action

(c). Hormonal Assays
Hormonal assays and their clinical relevance
Disorder of growth and sexual differentiation

(d). Endocrine disorders in childhood and adolescence
Endocrine disorders during adolescence
Cushing's disease
Irregular menses, amenorrhea
Precocious puberty, premature thelarche

Unit II –Regulation of Glands and their secretion

(a). Structure, function and regulation of glands and their secretions:
Pituitary, Hypothalamus, Pineal, Thyroid, Parathyroid, Adrenal glands

(b). Insulin, Importance
Deficiency leading to Diabetes Mellitus
Insulin-receptor disorders
Inherited diabetes, insulin resistance (IR)
Thymus and Pancreas

(c). Hypothalamo – pituitary disorders
Autoimmune thyroid disorders
Hyperthyroidism - Graves' disease
Thyroidism and arrhythmia (irregular heartbeat), weight loss, protruding eyes and nervousness

(d). Reproductive hormone disorders and problems of menopause
Low estrogen including hot flashes, night sweats, poor sleep, vaginal dryness
The post-menopausal period and associated loss of bone density
Bone and mineral metabolism

Unit III - Fundamentals of Clinical Diagnostics

(a). Introduction to clinical laboratory principles and procedures
Concept of GLP and ISO labs
Quality control and laboratory safety
Regulation of diagnostic labs and accreditation methods
Guidelines for proper discard of biological waste and chemical wastes

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(b). Sample collection

Guidelines for sample collection
Transport
Preservation
Processing and analysis

(c). Blood and Phlebotomy

Composition and general function of blood
Description of blood cells - normal counts and function
Steps of blood coagulation, anticoagulants
Overview of phlebotomy (the surgical opening or puncture of a vein in order to withdraw blood)

(d). Hematology and other body fluid analysis

Hemoglobin estimation, anemia classification
Blood group ABO/Rh typingcomplications of mismatch transfusion, selection of donor, mandatory tests, comb's test, component separation, preservation and uses.
Analysis of Urine, Serum, Saliva andCerebrospinal fluid

Unit IV: Approaches to diagnosis of infectious diseases

(a). Sterilization Techniques

Physical methods
Chemical methods

(b). Molecular Diagnosis – An overview

Diagnosis of Bacterial and Viral Diseases using PCR and RT-PCR (Diphtheria, Pertussis, COVID-19 and others)
Bright field microscope, Fluorescence microscope
ELISA reader, Autoanalyser
UV-VIS Spectrophotometer
Gel Electrophoresis

(c). Isolation of bacteria from mixed culture

Study of morphological, cultural, biochemical characteristics of common bacterial pathogens
Observing Virus under the microscope
Isolation and identification of common microorganisms using microbiological, biochemical and PCR techniques

(d). Composition of culture media and Culture methods

Media for identification of pathogenic bacteria EMB agar
McConkey agar, Inoculation, incubation and purification methods in bacterial cultures
Preservation of bacterial culture

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B.Sc (Hons.) – Biomedical Sciences - Semester - I
Paper II - Medical Endocrinology, Medical Diagnostics (BMS-C102)
Practicals

1. Estimation of any one hormone
2. Demonstration of CT scan
3. Demondtration of dual-energy X-ray absorptiometry (DXA)
4. Demonstration of nuclear medicine studies
5. Demonstration of parathyroid or thyroid ultrasound
6. Estimation of troponin as a biomarker of choice for the detection of cardiac injury
7. Single or double radial immuno-diffusion test
8. Agglutination inhibition assay
9. Sandwich ELISA or Dot ELISA test
10. Widal test
11. Immunoprecipitation
12. Western Blotting
13. Differential and Total Leukocyte Counts

B.Sc (Hons.) – Biomedical Sciences - Semester - I
Paper II - Medical Endocrinology, Medical Diagnostics (BMS-C102)
Suggested Books

1. Text book of Endocrinology by Williams
2. Diabetes Mellitus by Joslin
3. Textbook of Diabetes by Holt's
4. Metabolic basis of inherited disease by Stanbury
5. The Thyroid by Ingbar
6. RIA – Principles and practices by Pillai and Bhandarkar
7. Reproductive Endocrinology by Speroff
8. Textbook of Clinical Chemistry by Tietz
9. Nutritive value of Indian Foods by Gopalan, ICMR
10. Endocrinology by Leslie J DeGroot
11. Pediatric Endocrinology by Hindmarsh and CGD BrooK
12. Metabolic Bone Diseases and Disorders of Mineral Metabolism
13. Immunology, 6th edition, (2006), J. Kuby et al, W.H. Freeman and Company, New York. ISBN-13: 978-1429202114.
14. Microbiology, 7th edition, (2008), Prescott, L., John Ii Harley, Donald A. Klein, McGraw Hill. ISBN-13: 978-0071102315.
15. Roitt's Essential Immunology, 12th edition, (2011), Wiley-Blackwell Science. ISBN-13: 978-1405196833.
16. An Introduction to Immunology, Immunochemistry and Immunobiology, 5th edition, (1988), Barrett, James T., Mosby Company, St. Louis. ISBN-13: 978-0801605307.
17. Immunology: An Introduction, 4th edition, (1994), Tizard, I.R., Saunders College Publishing, Philadelphia. ISBN-13: 978-0030041983.

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B.Sc (Hons) – Biomedical Sciences - Semester II - Theory
Paper III - Integrated Human Physiology, Anatomy, and Pathology
(BMS-C103)

Preamble: To create a consolidated and focused curriculum that merges key aspects of human physiology, anatomy, and pathology with an emphasis on relevance to healthcare and the pharmaceutical industry, we will integrate the most essential and complex topics from the given syllabi. This will ensure students grasp the fundamental and advanced principlesnecessary for roles in biomedical sciences, particularly those focusing on clinical research, drug development, and pathology.This merged syllabus provides a comprehensive view that bridges human physiology and pathology with a specific emphasis on areas critical to healthcare and pharmaceutical sectors, preparing students for advanced studies and professional roles in these fields.

Unit I - Human Anatomy and Physiology: Focus on Immunological and Hematological Systems

(a). Body organization and basics of the system

General anatomy, body planes, cavities, tissues, and an introduction to the immune system focusing on innate and adaptive immunity.

(b). Blood Composition and Hematopoiesis

Detailed study of blood components (WBC, RBC, platelets)
Hemoglobin structure, functions, and blood coagulation mechanisms

(c). Immune Response and Blood Disorders

Immune response phases, basic concepts of anemia
Sickle cell anemia, leukemia, and other hematological disorders

(d). Lymphoid System and Its Clinical Significance

Overview of lymphoid tissue, lymph system, blood groups,
And blood banking with relevance to transfusion medicine

Unit II - Nervous System and Sensory Organs: Physiology and Pathology

(a). Neurophysiology and Membrane Potentials

Structure and function of neurons, action potential, electrophysiology of ion channels and nerve impulse conduction

(b). Central and Peripheral Nervous System

Detailed anatomy and functions of the CNS and PNS
including the autonomic nervous system

(c). Neurotransmission and Neurological Disorders

Synapses, types of neurotransmitters, organization of the nervous system,
and basic aspects of neurological disorders

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(d). Sensory Systems and Disorders
Physiology of special senses (vision, hearing, taste, smell, touch),
and common disorders affecting these senses

Unit III - Musculoskeletal System and Associated Pathologies
(a). Muscle and Skeletal System Functionality
Functional anatomy of the muscular system, neuromuscular transmission
Muscle contraction mechanisms, and bone structure/function
Importance of calcium

(b). Muscle and Joint Disorders
Overview of muscular dystrophy, polymyositis
Myasthenia gravis, ALS, osteoporosis, and arthritis

(c). Wound Healing and Tissue Repair
Mechanisms of tissue regeneration, role of extracellular matrix, healing, and fibrosis

(d). Systemic Impact of Musculoskeletal Disorders
Detailed discussion on systemic lupus erythematosus
Sjogren's syndrome, and the genetic basis of musculoskeletal disorders

Unit IV - Pathological Mechanisms and Diagnostic Techniques
(a). Foundations of Human Pathology
Introduction to pathology, cellular adaptations, injury, death,
and responses including hyperplasia, hypertrophy, atrophy
Metaplasia, necrosis, and apoptosis

(b). Inflammation, Healing, and Chronic Diseases
Acute and chronic inflammation processes, healing,
Fibrosis, and granulomatous inflammation

(c). Principles of Hemodynamic and Nutritional Pathologies
Hemodynamic disturbances such as edema, hyperemia
Congestion, hemorrhage, and nutritional diseases

(d). Modern Diagnostic and Research Techniques
Advanced diagnostic and research techniques including immunofluorescence
PCR diagnostics, tissue processing
Staining of cells and tissues for various diseases

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B.Sc (Hons) – Biomedical Sciences
Semester II - Practicals
Paper III - Integrated Human Physiology, Anatomy, and Pathology (BMS-C103)

1. Estimation of hemoglobin and determination of blood groups.
2. Examination of blood smear preparations.
3. Analysis of nerve function tests and sensory response evaluations.
4. Muscle strength and fatigue testing.
5. Diagnostic imaging for bone and muscle disorders.
6. Biopsy techniques and histological analysis of pathological samples.
7. C-Reactive Protein (CRP) test
8. Venereal Disease Research Laboratory test (VDRL), and other relevant clinical tests

B.Sc (Hons) – Biomedical Sciences
Semester II – Suggested Books
Paper III - Integrated Human Physiology, Anatomy, and Pathology (BMS-C103)

1. Guyton and Hall Textbook of Medical Physiology by J.E. Hall
2. Robbins and Cotran Pathologic Basis of Disease by Vinay Kumar, Abul K. Abbas, Jon C. Aster
3. Principles of Anatomy and Physiology by Gerard J. Tortora and Bryan H. Derrickson
4. Pathophysiology: The Biologic Basis for Disease in Adults and Children by Kathryn L. McCance and Sue E. Huether

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B.Sc (Hons) – Biomedical Sciences
Semester II - Theory
Paper IV - Applied Biostatistics for Pharmaceutical Sciences (BMS-C104)

Objective: Equip students with the theoretical knowledge and practical skills in biostatistics necessary for analyzing and interpreting data in preclinical and clinical research settings within the pharmaceutical industry.To design a comprehensive undergraduate course in biostatistics tailored to meet the needs of those entering roles in biostatistics within clinical and non-clinical settings in the pharmaceutical industry, we will integrate the elements from both models provided. The course will focus on the statistical principles required for analyzing preclinical and clinical data, using both parametric and non-parametric tests, and will include practical applications relevant to the industry. This course design not only covers essential statistical techniques but also integrates practical applications using software tools relevant to the pharmaceutical industry, thus preparing students effectively for biostatistical roles in a regulatory, research, or clinical setting.

Unit 1- Foundations of Biostatistics and Data Analysis
(a). Introduction to Statistics in Pharma
Role and uses of statistics in pharmaceutical research
Basic statistical concepts; types of data

(b). Descriptive Statistics
Measures of central tendency (mean, median, mode)
Measures of dispersion (variance, standard deviation, range, coefficient of variation)

(c). Probability and Distributions
Basic probability concepts; common probability distributions
Applications to normal distribution

(d). Data Visualization
Construction and interpretation of graphs, histograms,
Pie charts, scatter plots, and semi-logarithmic plots

Unit II - Inferential Statistics and Hypothesis Testing
(a). Sampling Techniques
Simple random sampling and other sampling procedures
Sampling distributions of means and proportions

(b). Estimation and Hypothesis Testing
Point and interval estimation, hypothesis testing basics
Type I and II errors, significance levels

(c). Parametric and Non-Parametric Tests
Student t-tests, Chi-square tests, ANOVA

(d). Mann-Whitney U, Wilcoxon tests
Significance of the tests

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Unit III - Clinical Data Analysis and Experimental Design
(a). Clinical Study Design
Overview of case studies, observational studies
Interventional studies, parallel and crossover designs

(b). Experimental Design and Analysis
Concepts of randomized control trials, factorial design
Analysis of variance, Duncun's multiple range test

(c). Biostatistics in Clinical Trials
Statistical methods for design and analysis in clinical trials

(d). Dose-response studies, and bioequivalence

Unit IV- Regulatory Compliance and Reporting Theoretical Topics
(a). Regulatory Frameworks and Biostatistics
Understanding the role of biostatistics in meeting Food and Drug Administration (FDA)

(b). European Medicines Agency (EMA)
International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use(ICH) guidelines

(c). Report Writing and Data Presentation
Best practices in presenting data results and writing reports for regulatory submissions

(d). Emerging Trends in Biostatistics
Introduction to advanced methods like real-world data analysis
Predictive modeling

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B.Sc (Hons) – Biomedical Sciences
Semester II – Practical Exercises
Paper IV - Applied Biostatistics for Pharmaceutical Sciences (BMS-C104)

1. Statistical Software Training
2. Introduction to open-source statistical tools like R and Python (Jupyter Notebooks, Pandas, SciPy for statistical analysis).
3. Descriptive Statistical AnalysisUsing R or Python to summarize pharmaceutical data sets with descriptive statistics and visualizations
4. Applying Statistical Tests
5. Conducting parametric and non-parametric tests on sample data using R or Python.
6. Power and Sample Size Determination
7. Using software to calculate sample size and power for hypothetical studies
8. Designing a Clinical Study
9. Crafting a study design using software simulations to understand the implications of design choices
10. Analyzing Clinical Trial Data
11. Hands-on analysis of clinical trial data using SAS or an open-source alternative like R
12. Regulatory Submission Workshop
13. Creating a mock regulatory submission that includes statistical analysis reports using templates aligned with ICH guidelines.
14. Advanced Data Analysis Projects
15. Using advanced statistical models and real-world datasets to prepare analyses as would be required in industry settings.

B.Sc (Hons.) – Biomedical Sciences
Semester II – Suggested Books
Paper IV - Applied Biostatistics for Pharmaceutical Sciences (BMS-C104)

1. Biostatistics for the Biological and Health Sciences by Marc M. Triola and Mario F. Triola
2. Fundamentals of Biostatistics by Bernard Rosner
3. Design and Analysis of Experiments by Douglas C. Montgomery
4. Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines by Tom Brody
5. Applied Biostatistics for the Health Sciences, By Rossi Richard J
   ISBN 10-1119722691, ISBN 13-9781119722694, Medford, New York, USA
6. Biostatistics: An Applied Introduction for the Public Health Practitioner, By Bush Heather M
   ISBN:10-1111035148; ISBN 13: 9781111035143, EB-Books, Rockford, Illinois, USA

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B.Sc(Hons) - Biomedical Sciences
Semester III
Paper V – Applied Immunology and Introduction to Biologics (BMS-C105)

Preamble:Students will get job opportunities for Biomolecule development and testing.
To further enrich the syllabus for a focus on biomoleculardrugs research, including monoclonal antibodies (mAbs), messenger RNA (mRNA), and nucleotide drugs, while incorporating fundamental immunology in each unit, we will expand the existing curriculum. Each unit will start with a fundamental topic in immunology, linking it to the advanced applications and techniques relevant to biopharmaceuticals. This approach ensures a solid grounding in immunological principles while exploring their application in drug discovery and development.

Unit I - Immunobiology of Biopharmaceuticals

(a). Overview of Immunology
Introduction to the immune system, focusing on the distinctions and roles of innate and adaptive immunity, and their relevance to biopharmaceutical interventions. Antigen and antibody concept, Types of immunoglobulins.

(b). Advanced Concepts of the Immune System
Importance of the immune system in biopharmaceuticals
Innate vs. adaptive immunity: implications for drug targeting and delivery
Active and passive immunity: therapeutic applications in biologic drug design
Immune Cells and Biopharmaceuticals

(c). Hematopoiesis and its relevance to the production of therapeutic antibodies
Role of T and B lymphocytes, NK cells, monocytes, and macrophages in response to biopharmaceuticals
Dendritic cells: from immune response to antigen presentation in vaccine strategies
Immune Organs and Biomolecule Interaction
The role of thymus and bone marrow in the development of therapeutic cells and vaccines
Lymph nodes, spleen, MALT, GALT, SALT: sites of action for targeted drug delivery

(d). Recognition Systems in Biopharmaceuticals
Pattern recognition receptors (PRRs): Targeting mechanisms in drug design
The role of PRRs in identifying pathogen-associated molecular patterns (PAMPs) from therapeutic nucleotides, Transplantation immunology.

Unit II - Mechanisms of Action of Biopharmaceuticals

(a). Immune Effector Mechanisms
Understanding how macrophages, neutrophils, and the complement system contribute to pathogen clearance and how these mechanisms are harnessed or modified by biopharmaceuticals.

(b). Immune Effector Functions and Drug Action
Mechanisms of macrophages and neutrophils in the context of drug-induced immune responses
Complement system: Harnessing pathways for targeted drug delivery and therapy

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(c). **Immune Modulation by Biopharmaceuticals**
Biological consequences of complement activation in monoclonal antibody therapies
Inflammatory responses: Modulation by biopharmaceuticals and implications for efficacy and safety.
Adaptive Immune Response to Biomolecules
Design of vaccines and monoclonal antibodies using epitope mapping and antigen design
MHC interactions with peptide drugs and implications for therapeutic efficacy

(d). **Antigen Presentation and Response Modulation**
Antigen processing and presentation pathways: Key to effective vaccine design
Mixed Lymphocyte Reactions (MLRs) in evaluating
immune compatibility of gene therapies

Unit III - Design and Development of Monoclonal Antibodies and Nucleotide Therapeutics

(a). **B Cell and Antibody Basics**
The process of B cell maturation, antibody generation, and class switching, which is crucial for understanding how therapeutic antibodies are developed and function.

(b). **Humoral Responses to Therapeutic Biomolecules**
Development and function of monoclonal antibodies: From B cells to hybridoma technology
Antibody diversity and its importance in developing effective therapies

(c). **Monoclonal Antibody Engineering**
Monoclonal vs. polyclonal antibodies in clinical use
Abzymes and immunotoxins: Advanced concepts in antibody engineering
Cellular Immunity in Therapeutic Applications
T cell responses to biomolecular drugs: Understanding cell-mediated immunity in drug efficacy
Engineering T cells for therapeutic applications,including CAR-T cell therapies

(d). **Cytokine Involvement in Drug Therapies**
Role of cytokines in modulating therapeutic responses
Interferons and interleukins as drug targets and therapy enhancers

Unit IV - Analytical Techniques and Regulatory Considerations for Biomolecule Drugs

(a). **Immunological Assays and Techniques**
Overview of various immunological assays used in the analysis and characterization of biopharmaceuticals, including ELISA, flow cytometry, and Western blotting.

(b). **Immunoassays in Drug Development**
Techniques in antigen-antibody recognition: ELISA, Western blotting for biopharmaceutical analysis

(c). **Advanced Imaging and Characterization**
Flow cytometry, immunofluorescence, and immunoelectron microscopy in the characterization of therapeutic molecules
Regulatory and Ethical Considerations
Vaccine and therapeutic approval processes
Understanding regulatory requirements
Ethical considerations in the use of biopharmaceuticals, especially in gene and cell therapies

(d). **Practical Challenges and Case Studies**
Case studies on successful biopharmaceutical development
Challenges in the development and implementation of biopharmaceutical therapies

B.Sc(Hons.)- Biomedical Sciences
Semester III - Practicals
Paper V – Applied Immunology and Introduction to Biologics (BMS-C105)

1. Hybridoma technology and monoclonal antibody production.
2. Using ELISA to measure drug efficacy and immune response.
3. Flow cytometry techniques to analyze T cell activation.
4. CRISPR/Cas9 in developing targeted gene therapies.
5. Protein engineering for improved antibody specificity.
6. Animal models for testing mRNA vaccine efficacy.
7. T-cell receptor engineering workshops.
8. Case studies on FDA-approved biopharmaceuticals.
9. Advanced biostatistics for analyzing clinical trial data.
10. Ethical debate on the use of genetic therapies in humans.
11. Practical sessions on regulatory documentation preparation.
12. Workshops on designing nucleotide-based drugs.
13. Immunofluorescence techniques for studying drug interactions at the cellular level.
14. Pharmacokinetic modeling of biopharmaceuticals.
15. In vitro assays for testing immune modulation by new drug candidates.

B.Sc(Hons.)- Biomedical Sciences
Semester III - Reference Books
Paper V – Applied Immunology and Introduction to Biologics (BMS-C105)

1. Janeway'sImmunobiology by Kenneth Murphy
2. Monoclonal Antibodies: Principles and Practice by James W. Goding
3. Molecular Biotechnology: Principles and Applications of Recombinant DNA by Bernard R. Glick and Jack J. Pasternak
4. Practical Immunology by Frank C. Hay and Olwyn M. R. Westwood
5. The Antibody Molecule by Anthony R. Rees

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B.Sc (Hons.) – Biomedical Sciences
Semester III – Theory
Paper VI - Drug discovery, Clinical Data Management (CDM) and Statistical Programming (BMS-C106)

Context:

Clinical Data Management (CDM), Tables, Figures, and Listings (TFL), Analysis of Data Model (ADaM), and Statistical Software Suite (SAS) programming in the context of pharmaceutical filings, it is essential to cover a range of topics that provide a foundational understanding as well as practical skills. These topics will equip professionals to handle data effectively for clinical trials and regulatory submissions, ensuring compliance with industry standards and guidelines.

Importance:

This comprehensive training plan covers the essentials for professionals involved in the statistical programming and data management aspects of clinical trials, preparing them for effective contributions to pharmaceutical filings. For practical training in the fields of Clinical Data Management (CDM), Tables, Figures, and Listings (TFL), Analysis Data Model (ADaM), and SAS programming, it's important to incorporate exercises that simulate real-world scenarios that professionals might encounter in clinical research and pharmaceutical filings.Alongside these practical exercises, it is also recommend some free and academic software tools that can be utilized for hands-on training, particularly beneficial for students and professionals without access to commercial software.

Unit I- Clinical Data Management (CDM)

(a). CDM is crucial for ensuring the accuracy and integrity of data collected during clinical trials

Introduction to Clinical Data Management
Overview of CDM in clinical research
Roles and responsibilities of a clinical data manager

(b). Data Management Plan (DMP)

Creating and maintaining a DMP
Essential elements and documentation in DMP
Case Report Form (CRF) Design
Principles of CRF design
Electronic Data Capture (EDC) systems like Medidata Rave and Oracle Clinical

(c). Data Collection and Entry

Data collection methods
Procedures for data entry and validation
Data Cleaning and Query Management
Data validation and cleaning processes
Managing queries and discrepancies
Data Coding
Medical coding with dictionaries such as MedDRA and WHO Drug

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(d). Database Lock and Data Archiving
Procedures for database lock
Strategies for data storage and retrieval
Regulatory Compliance and Audits
Understanding of FDA, EMA guidelines for clinical data
Preparing for audits and inspections

Unit II - Tables, Figures, and Listings (TFL)
(a). TFL are key outputs for clinical study reports.
Principles of TFL Preparation
Overview of TFL in clinical reporting
Standards and best practices

(b). Introduction to SAS Programming
Basic and advanced SAS programming skills
Using SAS for data manipulation and analysis

(c). Graphs and Data Visualization
Producing clinical graphs using SAS
Statistical graphics procedures in SAS

(d). Reporting Standards
CDISC standards including SDTM and ADaM
Regulatory requirements for TFL

Unit III - Analysis Data Model (ADaM)
(a). ADaM datasets are designed to support statistical analysis and reporting
Overview of ADaM Standards
Purpose and principles of ADaM
Relationship between SDTM and ADaM

(b). Creating ADaM Datasets
Basic Data Structure (BDS)
Subject-Level Analysis Dataset (ADSL)

(c). Implementing ADaM Conventions
Traceability and derivations
Compliance with CDISC guidelines

(d). Use Cases and Examples
Practical exercises for creating ADaM datasets
Preparing datasets for common statistical analyses

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Unit IV - SAS Programming for Clinical Trials

(a). SAS is the industry standard for analyzing clinical trial data

SAS Basics and Data Manipulation

Data step programming

PROC SQL for data management

(b). Statistical Procedures

Commonly used PROCs like **PROC MEANS**, **PROC FREQ**, **PROC UNIVARIATE**, etc.

Advanced procedures for mixed models, survival analysis, etc

Macros and Automation

Developing and using SAS macros

Automation techniques in SAS

(c). Clinical Data Interchange Standards Consortium (CDISC) Implementation

Creating Study Data Tabulation Model (SDTM) and Analysis Data Management (ADaM) datasets using SAS

Validation and compliance checks

Reporting and Documentation

Generating reports with PROC REPORT and PROC TABULATE

Documentation practices for reproducibility and audit trails

(d). Additional Elements

Case Studies and Real-World Examples: Provide practical scenarios that mimic real-world tasks and challenges

Hands-On Sessions and Exercises: Essential for understanding the application of theoretical concepts

Updates on Latest Trends and Software: Include training on new regulations, versions of standards (like updates in CDISC), and software tools

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B.Sc (Hons) – Biomedical Sciences- Semester III
Practical Topics for Hands-On Training
Paper VI–Drug Discovery, Clinical Data Management (CDM) and Statistical Programming (BMS-E-106)

This comprehensive training plan covers the essentials for professionals involved in the statistical programming and data management aspects of clinical trials, preparing them for effective contributions to pharmaceutical filings. For practical training in the fields of Clinical Data Management (CDM), Tables, Figures, and Listings (TFL), Analysis Data Model (ADaM), and SAS programming, it's important to incorporate exercises that simulate real-world scenarios that professionals might encounter in clinical research and pharmaceutical filings.Alongside these practical exercises, it is also recommend some free and academic software tools that can be utilized for hands-on training, particularly beneficial for students and professionals without access to commercial software.

1. Clinical Data Management (CDM):
   CRF Design and Setup: Using a free EDC tool, design a Case Report form based on a given clinical study protocol
2. Data Validation Rules Development: Write and test data validation rules to ensure the quality and consistency of clinical data
3. Database Lock Scenario: Simulate the steps leading to a database lock, including data cleaning, query resolution, and final checks
4. Tables, Figures, and Listings (TFL) - Creating Statistical Tables: Generate demographic tables, efficacy endpoints, and safety tables as per a given protocol using statistical software
5. Graphical Data Representation: Develop figures such as Kaplan-Meier survival plots, time-series plots, and histograms to represent clinical trial data
6. Mock Clinical Study Report: Compile a mock clinical study report including all necessary TFL components
7. Analysis Data Model (ADaM) - ADaM Dataset Creation: From provided SDTM datasets, create ADaM datasets (ADSL, BDS) using specified analysis criteria
8. Analysis Ready Datasets: Prepare datasets specifically tailored for pre-specified statistical analysis, ensuring traceability back to SDTM datasets.
   Replicating Analysis Results: Using ADaMdatasets, replicate analysis specified in statistical analysis plans or publications
9. SAS Programming for Clinical Trials: Data Manipulation: Using SAS-like environments, perform complex data manipulations and transformations typical in preparation for statistical analysis
10. Macro Programming: Write SAS macros to automate repetitive tasks in data cleaning and analysis.Statistical Analysis Simulation: Conduct statistical analyses commonly required in clinical trials such as t-tests, chi-square tests, ANOVA, and regression analysis.

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Free and Academic Software for Hands-On Training

1. R and R Studio:
R: A free software environment for statistical computing and graphics, which can be used as an alternative to SAS for statistical analysis.
RStudio: A powerful IDE for R. It provides tools to help users write code, navigate files, visualize data, and manage projects.

2. Python: Python: A versatile programming language that can be used for statistical data analysis, data manipulation, and visualization.
Jupyter Notebook: An open-source web application that allows you to create and share documents that contain live code, equations, visualizations, and narrative text.

3. PSPP: PSPP: A free alternative to SPSS, PSPP is used for statistical analysis of sampled data. It can perform descriptive statistics,
T-tests, ANOVA, and linear regression.

4. OpenClinica or REDCap for Clinical Data Management: OpenClinica: Offers community versions that can be used for designing studies, capturing data, and managing clinical data.
REDCap: A secure web application for building and managing online surveys and databases, widely used in the academic research community

5. CDISC Express (for SAS-like processing in Excel): CDISC Express: A free tool that converts clinical data into CDISC SDTM using Microsoft Excel.

6. ClinovoClinCapture: ClinCapture: An open-source EDC system that can be used for capturing and managing clinical trial data.
These free tools and practical exercises provide a solid foundation for learners to gain hands-on experience in the various aspects of clinical research data handling, analysis, and reporting. Such training will be invaluable for academic purposes and entry-level professional development in the pharmaceutical and biotechnology industries.

Continuous Assessment: Include graded assignments, lab reports, quizzes, and a final project focused on developing a comprehensive preclinical testing proposal based on ICH guidelines.
This course design aims to provide a robust educational foundation that aligns closely with industry requirements for preclinical safety and efficacy analysis roles, ensuring students are job-ready upon graduation.

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B.Sc (Hons) – Biomedical Sciences
Semester IV – Theory
Paper VII - Pharmacology and Pharmacokinetics (PPK) (BMS-C107)

Objective: Designing a curriculum to suit an in vitro biologist role within drug discovery and the broader pharmaceutical industry requires a focus on both theoretical knowledge and practical skills that are crucial for high-throughput screening, assay development, and the evaluation of drug efficacy and safety using in vitro systems.

Unit I - Biopharmaceutics
(a). Introduction to Biopharmaceutics
Principles and importance of pharmacology

(b). Absorptionofdrugsfromgastrointestinaltract

(c). DrugDistribution

(d). DrugElimination

Unit II - Pharmacokinetics
(a). IntroductiontoPharmacokinetics

(b). Mathematicalmodel
Druglevelsinblood

(c). Pharmacokineticmodel

(d). Compartmentmodels
Pharmacokineticstudy

Unit III - Onecompartmentopenmodel
(a). Intravenous Injection (Bolus)
Intravenous Infusion
Multicompartment model
Twocompartmentopenmodel
IVbolus,IVinfusionandoraladministration

(b). Multiple–DosageRegimens
RepetitiveIntravenousinjections–OneCompartmentOpenModel
RepetitiveExtravasculardosing– OneCompartmentOpenmodel
MultipleDoseRegimen–TwoCompartmentOpenModel

(c). NonlinearPharmacokinetics
Introduction
FactorscausingNon-linearity

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(d). Michaelis-Mentonmethodofestimatingparameters
Significance of the method

Unit IV - NoncompartmentalPharmacokinetics

(a). StatisticalMomentTheory

(b). MRTforvariouscompartmentmodels
PhysiologicalPharmacokineticmodel

(c). BioavailabilityandBioequivalence
Introduction, Importance of bioavailability and bioequivalence

(d). Bioavailabilitystudyprotocol
MethodsofAssessmentofBioavailability

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B.Sc (Hons.) – Biomedical Sciences
Semester IV – Practicals
Paper VII - Pharmacology and Pharmacokinetics (PPK) (BMS-C107)
Practicals: Practicals should be conducted by usingPK Sim software (Free software)

B.Sc (Hons.) – Biomedical Sciences
Semester IV – Suggested Books
Paper VII - Pharmacology and Pharmacokinetics (PPK) (BMS-C107)

1. BiopharmaceuticsandClinicalPharmacokineticsby,MiloGibaldi
2. Remington'sPharmaceuticalSciences,ByMackPublishingCompany,Pennsylvania.
3. Pharmacokinetics:ByMiloGlbaldiDonald,R.MercelDekkerInc.
4. HandBookofClinicalPharmacokinetics,ByMiloGibaldiandLauriePrescottbyA DISHealth SciencePress.
5. BiopharmaceuticsandPharmacokinetics;ByRobertFNotari
6. Biopharmaceutics;BySwarbrick
7. BiopharmaceuticsandPharmacokinetics-ATreatise,ByD.M.BrahmankarandSunilB.Jaiswal,VallabhPrakashanPitampura, Delhi
8. Cilincal Pharmacokinetics,ConceptsandApplications: ByMalcolm RowlandandThomas,N. Tozen,LeaandFebrger,Philadelphia,1995.
9. Dissolution,BioavailabilityandBioequivalence,ByAbdouH.M,Mack,Publishing Company,Pennsylvania1989.
10. Biopharmaceutics andClinicalPharmacokinetics-Anintroduction4th editionRevisedandexpandedbyRebortFNotariMarcelDekkerInn,NewYorkand Basel,1987.
11. EncyclopediaofPharmaceuticalTechnology,Vol13,JamesSwarbrick,James ,C.Roylan,MarcelDekkerInc,NewYork 1996.
12. BiopharmaceuticsandClinicalPharmacokineticsby,MiloGibaldi
13. Remington'sPharmaceuticalSciences,ByMackPublishingCompany,Pennsylvnia.
14. Pharmacokinetics:ByMiloGlbaldiDonald,R.MercelDekkerInc.
15. HandBookofClinicalPharmacokinetics,ByMiloGibaldiandLauriePrescottbyA DISHealth SciencePress.
16. BiopharmaceuticsandPharmacokinetics;ByRobertFNotari
17. Biopharmaceutics;BySwarbrick
18. BiopharmaceuticsandPharmacokinetics-

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ATreatise,ByD.M.BrahmankarandSunilB.Jaiswal,VallabhPrakashanPitampura, Delhi

19. Cilincal Pharmacokinetics,ConceptsandApplications: ByMalcolm RowlandandThomas,N. Tozen,LeaandFebrger,Philadelphia,1995.
20. Dissolution,BioavailabilityandBioequivalence,ByAbdouH.M,Mack,Publish ingCompany,Pennsylvania1989.
21. Biopharmaceutics andClinicalPharmacokinetics-Anintroduction4th editionRevisedandexpandedbyRebortFNotariMarcelDekkerInn,NewYork andBasel,1987.
22. EncyclopediaofPharmaceuticalTechnology,Vol13,James Swarbrick,James,C.Roylan,MarcelDekkerInc,NewYork 1996.
23. Essentials of Medical Pharmacology, 7th edition (2010), K.D. Tripathi, Jaypee Brothers, ISBN:9788184480856.
24. Pharmacology, 7th edition (2011), H.P. Rang, M.M. Dale, J.M. Ritter and P.K. Moore, Churchill Livingstone. ISBN: 9780702045042.
25. Hand book of Experimental Pharmacology, 4th edition (2012), S.K. Kulkarni, VallabhPrakashan, 2012. ISBN 13: 9788185731124.
26. Medical Pharmacology, 7th Edition, (2021), Dr. PadmajaUdaykumar, CBS Publishers and Distributors, Private Limited.
27. Pharmacology for Medical Undergraduates, Paperback, 2018, First Edition, Dr. Prasan R Bhandari (Author).

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B.Sc (Hons.) Biomedical Sciences
Semester IV– Theory
Paper VIII - In Vitro Assay Development and Drug Screening(BMS-C108)

Job Opportunities: In Vitro Biologist/Scientist / ADME scientist / Invitro toxicologist / in vitro safety scientist.

Objective: Designing a curriculum to suit an in vitro biologist role within drug discovery and the broader pharmaceutical industry requires a focus on both theoretical knowledge and practical skills that are crucial for high-throughput screening, assay development, and the evaluation of drug efficacy and safety using in vitro systems. Here's how to structure a comprehensive unit:

Aim: Equip students with essential skills and knowledge for a role in drug discovery, emphasizing in vitro techniques for screening and evaluating potential therapeutic compounds.

This curriculum is designed to provide a robust framework for training aspiring in vitro biologists, equipping them with the necessary theoretical background and practical skills to thrive in drug discovery roles within the pharmaceutical industry. The practical exercises and recommended textbooks support a deep understanding of current technologies and standards, preparing students for real-world challenges in the field.

Unit I –Drug Discovery

(a). Principles of Drug Discovery and In Vitro Assays

Drug Discovery Process

Overview of the drug discovery pipeline from target identification through to clinical trials

Integration of in vitro studies in drug development phases

(b). Basics of In Vitro Assays

Understanding different types of in vitro assays (e.g., biochemical, cell-based assays) and their applications in drug discovery

Selection and validation of appropriate assays for target molecules

(c). Cell Biology in Drug Discovery

Role of cell culture in drug discovery including primary cells, continuous cell lines, and the use of stem cells

Techniques for culturing, maintaining, and banking cells.

(d). Receptor-Ligand Interactions

Mechanisms of drug action at the receptor level, including agonism

Antagonism, and allosteric modulation

Unit II -Advanced Assay Technologies and High-Throughput Screening

(a). High-Throughput Screening (HTS)

Overview of HTS technologies, automation, and miniaturization in drug discovery
Strategies for developing HTS assays and handling large data sets

(b). Biochemical Assays
Detailed exploration of enzyme assays, binding assays,
and functional assays to evaluate drug-target interactions

(c). Phenotypic verses Target-Based Screens
Comparisons of screening strategies, advantages and disadvantages,
and their implications for drug discovery

(d). Data Analysis and Hit Validation
Techniques for analyzing screening data
Hit confirmation, and the role of statistics in validating hits

Unit III -Safety, Toxicity, and Regulatory Compliance
(a). Toxicity of drugs
Toxicology in Drug Discovery
Introduction to in vitro toxicology and its role in assessing drug safety early in the discovery process

(b). Regulatory Aspects of In Vitro Testing
Understanding global regulatory requirements, including guidelines from the Food and Drug Administration (FDA)
European Medicines Agency (EMA), and International Council for
Harmonisation of Technical Requirements for Registration of Pharmaceuticals
For Human Use (ICH)related to in vitro testing

(c). ADME Studies Using In Vitro Methods
Techniques and methodologies for assessing drug metabolism
and potential drug-drug interactions in vitro

(d). Predictive Toxicology
Use of computational models and in vitro systems to predict in vivo toxicity

Unit IV - Alternatives, Modelling, and Pharmacokinetics
(a). Alternatives to animals
Ethics and Alternatives to Animal Testing
Ethical considerations in drug discovery and the use of in vitro methods as alternatives to in vivo tests
(b). Emerging Technologies in Assay Development
Use of novel technologies such as CRISPR, organ-on-a-chip,
2D and 3D culture of Human tissues in drug screening

(c). Pharmacodynamics and Pharmacokinetics
Basic principles affecting the bioactivity, absorption,
distribution, metabolism, and excretion (ADME) of drugs

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(d). Introduction to Physiological Based Pharmacokinetic (PBPK) Modeling
Accuracy and importance of the modeling

B.Sc (Hons.) Biomedical Sciences
Semester IV – Practical
Paper VIII - In Vitro Assay Development and Drug Screening(BMS-C108)

1. Cell Culture Techniques
2. Fundamental cell culture operations, aseptic techniques, and cell line maintenance.
3. Assay Development
4. Designing and optimizing a cell-based assay to measure drug effects on cell proliferation.
5. High-Throughput Screening Setup
6. Setting up and running a mini-HTS project, including data collection and initial analysis.
7. Phenotypic Screening
8. Conducting a phenotypic drug screening using live-cell imaging to assess drug effects on cellular behavior
9. Toxicity Screening
10. Conducting in vitro toxicity tests (e.g., MTT assay for cytotoxicity).
11. PBPK modelling for Bioaviability prediction using PK-Sim and MoBi, complete tutorials.
12. ADME Profiling
13. Using in vitro assays to evaluate the metabolic stability of a compound

B.Sc (Hons.) Biomedical Sciences - Semester IV – Suggested Books
Paper VIII - In Vitro Assay Development and Drug Screening
(BMS-C108)

1. In Vitro Toxicology by Gad Shayne
2. High-Throughput Screening in Drug Discovery edited by JörgHüser
3. Pharmacology Principles and Applications by FulgaSigurta
4. Cell Culture Technology for Pharmaceutical and Cell-Based Therapies edited bySadettinOzturk and Wei-Shou Hu
5. The Laboratory Rat by Patrick Sharp and Marie C. La Regina

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B.Sc(Hons.)Biomedical Sciences
Semester V - Theory
Elective Paper-IX-Bioanalytical Techniques (BMS-E109A)

Unit I – Spectrophotometry and Centrifugation Techniques

(a). UV-visible spectrophotometry

UV and Visible spectra, Beer-Lamberts law and its limitations
Colorimetry and spectrophotometry, Molar extinction coefficient
Principle of fluorimetry
Applications with examples

(b). Infra-red spectroscopy

Principle of infrared spectroscopy
Identification of exchangeable hydrogen,number of hydrogen bonds,tautomeric forms
Applications with examples

(c). Magnetic resonance spectroscopy

Basic theory of Nuclear Magnetic Resonance (NMR)
Chemical shift, medical applications of NMR
Mass spectrometry (MS) (Matrix assisted Laser Desorption Ionization Time of Flight) (MALDI-TOF)
Applications with examples

(d). Centrifugation

Principle of centrifugation techniques
Svedberg equation, differential and density gradient centrifugation
Preparative and analytical ultracentrifugation
Fractionation of cellular components using centrifugation

Unit II - Chromatography and Electrophoresis techniques

(a). Chromatographic techniques-I

Introduction and principles of chromatographic techniques
Paper chromatography
Thin layer chromatography
Gel filtration (molecular sieve) chromatography
Applications with examples

(b). Chromatographic techniques-II

Ion exchange Chromatography
Affinity chromatography
HPLC
Applications with examples

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(c). Electrophoresis techniques-I

Principle of electrophoresis
Native PAGE
SDS-PAGE
Isoelectric Focusing
Two-Dimensional Electrophoresis
Applications with examples

(d). Electrophoresis techniques-II

Agarose gel electrophoresis
Pulse Field Gel Electrophoresis
Blotting techniques
Applications with examples

Unit III - Hydrodynamic methods and Molecular Biophysics

(a). Viscosity

Methods of measurement of viscosity
Specific and intrinsic viscosity
Relationship between viscosity and molecular weight
Measurement of viscoelasticity of DNA

(b). Flow Cytometry

Basic principle of flow cytometry
Cell sorting using Flow Cytometry
FACS
Detection strategies in flow cytometry
Applications with examples

(c). Basic Thermodynamics

Concept of entropy, enthalpy, free energy change, heat capacity
Forces involved in biomolecular interactions with examples: configuration versus conformation
Van der Waals interactions, electrostatic interactions, stacking interactions, hydrogen bond and hydrophobic effect

(d). Protein folding

Thermodynamic and kinetic basis of protein folding, protein folding problem (Levinthal's paradox), and role of molecular chaperones in cellular protein folding
Basics of molecular and chemical chaperones, protein mis-folding and aggregation
Diseases associated with protein mis-folding

Unit IV – Microscopy and RadioactiveTracer techniques

(a). Light Microscopy

Simple and compound microscope
Phase contrast microscopy
Dark field and polarization microscopy
Applications with examples

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(b). Fluorescence microscopy

Fluorescence microscopy
Confocal microscopy: imaging live cells
FACS
FRET, FRAP
Applications with examples

(c). Electron microscopy

Scanning electron microscopy
Transmission electron microscopy
Sample preparation for electron microscopy
Applications with examples

(d). Tracer techniques

Stable and radioactive isotopes
Half-life and emission spectra of biologically useful isotopes: ^{2}H, ^{3}H, ^{14}C, ^{18}O, ^{32}P, ^{35}S and ^{125}I
Isotopes used for labelling proteins (^{3}H ^{14}C, ^{35}S, ^{125}I) and nucleic acids (^{3}H, ^{32}P)
Detection of radioactivity by Scintillation counting, Autoradiography and GM counter
Radiation hazards and safe disposal of radio activity waste

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B.Sc (Hons.) Biomedical Sciences
Semester V - Practicals
Elective Paper–IX–Bioanalytical Techniques (BMS-E109A)

1. Effect of different solvents on UV absorption spectra of proteins.
2. Study of structural changes of proteins at different pH using UV spectrophotometry.
3. Study of structural changes of proteins at different temperature using UV spectrophotometry.
4. Determination of melting temperature of DNA.
5. Study the effect of temperature on the viscosity of a macromolecule (Protein/DNA).
6. Use of viscometry in the study of ligand binding to DNA/protein.
7. Crystallization of enzyme lysozyme using hanging drop method.
8. Analysis, identification and comparison of various spectra (UV, NMR, MS, IR) of simple organic compounds.

B.Sc (Hons.) Biomedical Sciences
Suggested Books - Semester V
Elective Paper–IX–Bioanalytical Techniques (BMS-E109A)

1. Physical Biochemistry: Principles and Applications, 2nd edition (2009), David Sheehan, John Wiley. ISBN-13: 978-0470856031.
2. Physical Biochemistry: Applications to Biochemistry and Molecular Biology, 2nd edition (1982), David Freifelder, W.H. Freeman and Company. ISBN-13: 978-0716714446.
3. Physical Chemistry: Principles and Applications in Biological Sciences, 4th edition (2001), I. Tinoco, K. Sauer, J.C. Wang and J.D. Puglisi, Prentice Hall, ISBN-13: 978-0130959430.
4. Molecular Biology of the Gene, 7th edition (2007), Watson, J. D., Baker T.A., Bell, S. P., Gann, A., Levine, M., and Losick, R, Benjamin Cummings Publishers, ISBN-13: 978- 0805395921.
5. Biophysics, 1st edition (1983), W. Hoppe, W. Lohmann, H. Markl and H. Ziegler, SpringerVerlag, ISBN-13: 978-3540120834.
6. The Physics of Proteins: An introduction to Biological Physics and Molecular Biophysics, 1st edition (2010), H. Frauenfelder, S.S. Chan and W.S. Chan, Springer, ISBN-13: 978- 1441910431.
7. Principles of Instrumental Analysis, 6th edition (2006), D.A. Skooget. al., Saunders College Publishing. ISBN-13: 978-0495012016.
8. Principles of Physical Biochemistry, 2nd edition (2005), K.E. Van Holde, W.C. Jhonson and P. Shing Ho, Prentice Hall Inc. ISBN-13: 978-0130464279.
9. Biophysical Chemistry, 1st edition (1980), C.R. Cantor, P.R. Schimmel, W.H. Freeman andCompany. ISBN-13: 9780716711889.
10. Crystallography Made Crystal Clear: Guide for Users of Macromolecular Models, 3rd edition (2010), Gale Rhodes, Academic Press. ISBN: 9780080455549.
11. Introduction to Protein Structure, 2nd edition (1999), C. Branden and J. Tooze, Garland Publishing, ISBN-13: 978-0815323051.

B.Sc (Hons.) – Biomedical Sciences
Semester V - Theory
Elective Paper - XI – Bioinformatics (BMS-E203A)

Unit I – Biological databases

(a). Introduction to Bioinformatics and Biological databases
Types of databases – Primary Nucleic Acid Databases
NCBI, DDBJ and EMBL

(b). Primary Protein data Banks
Secondary Protein databanks
Composite Datbases

(c). Genomic, Proteomic and Other Databases
Data storage and retrieval
File Format (Genebank, DDBJ, FASTA, PDB)

(d). Organellar Databases
Search Engines for Literature
Viral Genome database

Unit II – Biological Squence Analysis

(a). Sequence analysis tools and the basic concepts
Basic concepts sequence similarity, identity and homology
Pairwise sequence alignment tools (BLAST)

(b). Dotlet and Dotlet examples
Protein sequences and interpretation of the results

(c). Multiple Sequence Alignment tools
Global and local alignment tools
CLUSTAL Omega tool

(d). Sequence Similarity Search
NCBI Blast
Basic Local Alignment Search Tool (BLAST)
Fast Adaptive Shrinkage Threshold Algorithm (FASTA)

Unit III – Phylogeny - Basic concepts

(a). Basic concepts in Phylogeny
Concepts in Taxonomy and its relation to Phylogeny
Software tools used in preparing Phylogenic Trees
Importance of phylogenic tree construction

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(b). **Gene Identification and Protein Modeling**
Gene Identification
Identification of introns and exons
Identification of Promoter Sequences using software tools
What is GenID

(c). **What is protein modeling**
Motifs, Profiles (PSSM)
Profile based searches using PSI-BLAST, PHI-BLAST

(d). **An overview of protein modeling**
Ribbon model of a protein

Unit IV - Predict Protein software

(a). **Concepts of protein structure and drug – protein interaction**
Motif finding tools

(b). **TMHMM tool**
TMHMM is a web server for predicting membrane protein topology based on a statistical Model called the Hidden Markov Model (HMM)

(c). **Creation of 3-D models of proteins**
Importance of 3-D models of proteins

(d). **Drug Designing**
Basic concepts of drug designing using the software tools
Applications in new drug discovery

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B.Sc – Biomedical Sciences
Semester V - Elective Paper – XI – Bioinformatics (BMS-E203A)
Practicals

1. Retrieval of information from Biological Databases (Nucleotide and Protein)
2. Dot Plots, Global and Local Sequence Alignment Tools
3. Finding Homology sequences
4. Finding Distant Relationships
5. FASTA, BLAST, BLASTN, BLASTP, BLASTX, DELTA BLAST
6. Multiple sequence Alignment: ClustalW and ClustalX
7. MEME SUITE – Motif Finding Sequence Analysis Tools
8. PROSITE-Expasy, Interproscan
9. Creation of 3-D structure of a protein (Ribbon model)

B.Sc – Biomedical Sciences
Semester V - Elective Paper - XI - Bioinformatics (BMS-E203A)
Suggested Books

1. **Introduction to Bioinformatics, By S. Sundararajan and Balaji**
   ISBN-13: 978-8174934734
2. **Principles of Biological Databases**
   By P.B. KaviKishor and L.N. Chavali
   Himalaya Publishing House, Mumbai
   Year of Publication 2013, ISBN-13:978-9350976920 ISBN-10: 9350976927
3. **Bioinformatics – A Beginner's Guide**
   By Jean Michel Claverie, Cedric Notredame,
   Wiley India Pvt., Ltd. Publishers, Year of Publication: 2003
   ISBN-10. 8126503807; ISBN-13.978-8126503803
4. **Bioinformatics – Basic Methods and Applications**
   By N. Mendiritta, P. Rastogi and S.C. Rastogi
   Year of Publication: 2013, ISBN-13:978-8120347854
5. **Bioinformatics: Sequence and Genome Analysis**
   By David W. Mount
   CBS Publishers, Second Edition
   Year of Publication: 2004, ISBN-13:978-0879697129
6. **Biological Sequence Analysis: Probabilistic Models of Proteins and Nucleic Acids**
   By R. Durbin, S. Eddy, A. Krogh, G. Mitehison
   Cambridge University Press
   Seventh Printing: 2002, ISBN 0 521 62041 4 (hard cover)

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B.Sc (Hons.) – Biomedical Sciences
Syllabus for the Semester VI – Theory
Elective Paper X – Biosafety and Infectious Diseases (BMS-E110A)

Unit I – Biosafety

(a). Introduction to biological safety cabinets

Primary containment for biohazards biosafety levels of specific microorganisms
Recommended biosafety levels for infectious agents and infected animals
Zoonotic diseases

(b). Biosafety guidelines

Government of India definition of genetically modified organism (GMOs)
Living modified organisms (LMOs)
Roles of institutional biosafety committee
Review committee on genetic manipulation (RCGM)
Genetic engineering approval committee (GEAC) for GMO applications in food and agriculture

(c). Environmental release of genetically modified organisms (GMOs)

The GM-food debate and biosafety assessment procedures for biotech foods
and related products, including transgenic food crops
Genetically modified bacteria

(d). Case studies of relevance

Biosafety assessment of pharmaceutical products such as drugs/vaccines etc.

Unit II – Infectious and Radioactive Material

(a). Handling and transportation of GM, infectious and radioactive materials

Risk analysis, risk assessment
Risk management and communication

(b). Overview of national regulations

Relevant international agreements including Cartagena Protocol
Biosafety management
Key to the environmentally responsible use of biotechnology
Ethical implications of biotechnological products and techniques
Social and ethical implications of biological weapons
Bioterrorism

Unit III - Concept of social science

(a). Basic concepts of social science

Reason to apply its principles to study cause of health problems and suggest appropriate
Intervention / solution to problem

(b). Foundation of Bioethics

Definition, historic evolution, codes and guidelines, universal principles
Codes, Covenants, Declarations and Guidelines

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(c). Bioethics and Clinical Ethics

Define the term "Bioethics" in relation to profession, society, and biomedicine
Learning about gradation of moral and ethical norms from simpler to higher levels
Describe the sanctity of human life and the need to preserve human life
Issues related to prenatal screening of embryos
Ethical aspects of illegal abortions
Clinical trials (Phase I/II/III/IV) and studies related to it

(d). Women health ethics

Vulnerability of women with respect to health care
Examination and screening of women for disease
Social issues like domestic violence and female genital mutilation and abortion

Unit IV: Critical care ethics

(a). Medical errors and Negligence

Medical error and medical negligence difference
Remedies against medical negligence
Protection and compensation related to it

(b). History and need for Intensive Care Unit (ICU) care

Functioning and ethical principles of an ICU care
Triage and futility, end of life care
Ethical principles related to withholding treatment and withdrawing treatment (euthanasia)
Legal position regarding policies in ICU and handling of conflicts in the ICU

(c). Care in HIV, AIDS and COVIDcases

Basics of HIV infection, identify ethical issues in clinical practice of HIV medicine and its prevention
Hazard to healthcare workers

(d). Segregation and Disposal of Biowaste and Biowaste Management
Research ethics related to HIV

Ethical use of animals in the laboratory

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B.Sc(Hons.)- Biomedical Science - Semester V– Practicals
Elective Paper X – Biosafety and Infectious Diseases (BMS-E110A)

1. A case study on segregation and handling of biological waste
2. A case study based on removal of selective marker in a DNA vaccine.
3. A case study on clinical trials of drugs in India with emphasis on ethical issues.
4. A case study on women health ethics.
5. A case study on medical errors and negligence.
6. A case study on critical care ethics at point of care.
7. A case study on ethical issues in clinical practice of AIDS.
8. A case study on handling and disposal of radioactive waste.
9. A case study based on terminator seeds.

B.Sc(Hons.)- Biomedical Science - Semester V
Suggested Books
Elective Paper X – Biosafety and Infectious Diseases (BMS-E110)

1. Bioethics and Biosafety, 1st edition (2008), M. K Sateesh, I K International Pvt Ltd, ISBN13: 978-8190675703.
2. The Cambridge Textbook of Bioethics, 1st edition (2008), Peter A. Singer and A. M. Viens; Cambridge University Press, ISBN-13: 978-0511545566.
3. Foundation of Bioethics, 2nd edition (1996), E. H Tristram; Oxford University Press, ISBN13: 9780195057362.
4. Social science: An introduction to the study of society, 14th edition (2010), Hunt, E. F.,and Colander, D. C. ; Peason/Allyn and Bacon, Boston, ISBN-13: 978-020570271.
5. Principles of Biomedical Ethics, 6th edition (2011), Beauchamp Tl, Childress JF; Oxford University Press, 2001. ISBN-13: 978-0195143317.
6. A Companion to Bioethics, 2nd edition (2012), Helga Kuhse, Peter Singer; John Wiley and Sons, ISBN-13: 978-1444350845.
7. Bioethics: An Introduction to the History, Methods, and Practice, 1st edition (1997), Nancy Ann SilbergeldJecker, Albert R. Jonsen, Robert A. Pearlman; Jones and Bartlett Learning, ISBN-13: 978-0763702281.
8. Genetically Modified Organisms and biosafety, 1st edition (2004), Tomme Young. ISBN13: 978-2831707983.
9. Environmental Safety of Genetically Engineered Crops, 1st edition (2011), Rebecca Grumet, James F. Hancock, Karim M. Maredia, CholaniWeebadde, Michigan State University Press ISBN-13: 978-1611860085.
10. Biosafety and Bioethics, 1st edition (2006), Rajmohan Joshi; Isha Books ISBN-13: 978-8182053779.
11. Bioethics and biosafety in biotechnology, 1st edition (2007), V. Sreekrishna; New Age International (P) Ltd., ISBN-13: 978-8122420852.

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B.Sc (Hons.) – Biomedical Sciences
Semester V – Theory
Elective Paper X - Regulatory Affairs in Pharmacology and Toxicology(BMS-E110B)

Objective: To enhance the curriculum for training in pharmaceutical drug safety and efficacy analysis, incorporating a comprehensive understanding of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines is critical. These guidelines ensure that the pharmaceuticals developed are of high quality, safe, and effective, and they streamline regulatory approval processes across regions. Here's how to integrate an overview of ICH guidelines, with a special focus on toxicology, safety, and efficacy, into the existing curriculum chapters.

Integration into Existing Syllabus: This integration ensures that students and professionals understand not only the scientific and practical aspects of drug development but also the critical regulatory environment in which they operate. By focusing on ICH guidelines throughout the course, participants are prepared to contribute effectively in international and multicultural pharmaceutical settings, equipped with knowledge that transcends local regulatory boundaries. This prepares them comprehensively for roles in the global pharmaceutical industry, ensuring their expertise is both current and relevant to international standards.

Unit I - Fundamental Concepts in Pharmacology and Toxicology
(a). Introduction to ICH Guidelines
History and objectives of the ICH
Overview of ICH structure, membership, and the harmonization process

(b). ICH Guidelines for Quality
Basic principles of ICH

(c). Q-series, focusing on Q1A-Q1F
(Stability testing), Q2 (analytical validation), and Q3 (impurities guidelines)

(d). Importance of pharmacological tests in drug release

Unit II - Advanced Assay Development and Validation
(a). Assay development ICH

(b). Guidelines for Method Validation (Q2)

(c). Detailed discussions on the validation of analytical procedures

(d). Types of validation studies, and required documentation

Unit III - Preclinical Drug Safety and Efficacy Testing
(a). ICH Guidelines for Preclinical Safety (S-Series)
ICH S1A-S1C: Guideline on the need for carcinogenicity studies

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(b). ICH S3A-S3B: Pharmacokinetics and toxicokinetics guidelines
ICH S4: Duration of chronic toxicity testing

(c). ICH S5: Reproductive toxicology considerations
ICH S7A and S7B: Safety pharmacology studies for human pharmaceuticals

(d). ICH Guidelines for Efficacy (E-Series)
ICH E8: General considerations for clinical trials
ICH E6 (R2): Good Clinical Practices
Focus on the design conduct, recording, and reporting of clinical trials

Unit IV - Regulatory Compliance and Future Technologies
(a). Detailed Exploration of Regulatory Frameworks
Comprehensive review of the regulatory impact of ICH guidelines
on global drug development and approval processes

(b). Special emphasis on ICH harmonization benefits and challenges

(c). ICH and Innovations in Drug Development

(d). Examination of how ICH guidelines are adapting to or influencing
emerging technologies and methodologies in drug development such as predictive toxicology and alternative efficacy models

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B.Sc (Hons.) – Biomedical Sciences
Semester V – Practicals
Elective Paper X - Regulatory Affairs in Pharmacology and Toxicology (BMS-E110B)

1. **Case Studies:**
   Analysis of how ICH guidelines influence the design and implementation of stability studies and quality assessments

2. **Workshop on Analytical Validation**
   Hands-on training in developing, validating, and documenting analytical methods in accordance with ICH Q2

3. **Toxicology and Safety Pharmacology Workshops:**
   Design and execution of toxicology and safety pharmacology studies following ICH guidelines

4. Preparing documentation and reports for regulatory submissions based on ICH S-Series.

5. **Regulatory Filing Simulations:**Creating mock regulatory submissions that meet ICH guideline requirements, particularly focusing on nonclinical and clinical aspects

6. Discussion on real-world cases and interpretation of guidelines in practical scenarios

B.Sc (Hons.) – Biomedical Sciences
Semester V – Suggested Books
Paper X - Regulatory Affairs in Pharmacology and Toxicology (BMS-E110B)

1. Curtis D. Klaassen (Editor), Cassarett and Doull's Toxicology: The Basic Science of The Poisons, 7th edition (2008), McGrawHill Medical. ISBN: 9780071470513.

2. Klaassen and Whatkins, Cassarett and Doull's Essentials of Toxicology, 2nd edition (2010), McGraw Hill Publisher. ISBN-13: 978-0071622400.

3. John Timbrell, Introduction to Toxicology, 3rd edition (2001), Taylor and Francis Publishers. ISBN 13: 9780415247627.

4. Stine Karen and Thomas M Brown, Principles of Toxicology, 2nd edition (2006), CRC Press. ISBN-13: 978-0849328565.

5. Frank C Lu and Sam Kacow, Lu's Basic Toxicology: Fundamentals Target Organ and Risk Assessment, 5th edition (2009), Informa Health Care. ISBN: 9781420093117.

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B.Sc - Biomedical Sciences
Semester VI – Theory
Elective Paper XI – Clinical Toxicology (BMS-E111A)

Unit I - Introduction

(a) History and Overview

Historical developments, Evolution, Modern applications and Interdisciplinary nature, Importance in public health, environmental protection, and pharmaceuticals

(b) Classification of Toxic Substances and Definition

Classification based on chemical nature, mechanism of action, and target organ/system; Definitions of toxicity, hazard, risk, and exposure assessment

(c) Toxic Exposure and Response

Factors influencing toxic exposure - duration, frequency, dose, and route of exposure; Routes of exposure - inhalation, dermal, oral, and systemic absorption; Sites of toxic action- local effects vs. systemic effects; Xenobiotics and their effects on different organ systems

(d) Types of Toxic Responses and Interactions

Acute vs. chronic toxicity- immediate vs. delayed effects; Types of toxic responses- cytotoxic, genotoxic, neurotoxic, immunotoxic, and carcinogenic; Interactions between xenobiotics - synergistic, additive, antagonistic effects; Mechanisms of tolerance and addiction in toxicology

Unit II - Evaluation of Toxicity

(a) Evaluation of Toxicity

Linear, non-linear, threshold, and non-threshold dose-response relationships; Understanding the shape and significance of dose-response curves

(b) Assumptions in Deriving Dose Response

Assumptions underlying dose-response relationships and their implications; Parameters including LD50 (lethal dose), LC50 (lethal concentration), TD50 (toxic dose), and therapeutic index; Interpretation of these parameters in toxicological assessments

(c) Mechanism of Toxicity

Delivery of Toxicants to Target Sites -Absorption, distribution, metabolism, and excretion (ADME) of toxicants; Factors influencing toxicant bioavailability and distribution in the body

(d)Formation and Detoxification of Ultimate Toxicants

Mechanisms Involved in the formation of ultimate toxicants: Metabolic activation of pro-toxicants into reactive intermediates - role of biotransformation enzymes (Phase I and Phase II) in toxicant activation and detoxification.

Detoxification of ultimate toxicants - cellular defense mechanisms against toxic insult; Role of antioxidants, conjugation reactions, and efflux transporters in detoxification processes

Unit III - Fate of Xenobiotics in Human Body

(a) Absorption, Distribution, and Fate of Xenobiotics

Processes of absorption and distribution of xenobiotics in the body; Factors influencing the absorption and distribution of xenobiotics

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(b). Excretion and Metabolism of Xenobiotics
Biotransformation of toxic substances - Phase I reactions: oxidations, hydrolysis, reductions - Phase II reactions: conjugation reactions; Role of biotransformation in detoxification and activation of xenobiotics; Susceptibility of liver to toxicants and its implications

(c) Human Exposure to Toxic agents
Types of toxic agents and their effects - pesticides, arsenic, mercury, asbestos; Accidental overuse of medicines and its consequences.
Reversibility and Irreversibility of toxic agents-understanding the potential for recovery or permanent damage from toxic exposure;
Toxicokinetics and Toxicodynamics of Drugs; Pharmacokinetic and pharmacodynamic aspects of drug toxicity.
Mechanisms of action and resultant toxicities of xenobiotics; Organic and inorganic xenobiotics - food additives, industrial chemicals, pollutants, and their toxicological implications

(d). Metals and Pesticide toxic agents
Toxic Metals -Lead, arsenic, fluoride, and their toxicological profiles; Pesticides – Types- organophosphates, carbamates, organochlorines, bipyridyl compounds, anticoagulant pesticides

Unit IV - Eco-toxicology
(a). Concepts of Ecotoxicology
Introduction to Ecotoxicology - Definition and scope of ecotoxicology, Understanding the interactions between pollutants and ecosystems; Avian and aquatic Toxicology - toxicological studies focusing on birds and aquatic organisms

(b). Movement and Effect of Toxic Compounds in Food Chain
Case Studies - DDT, Mercury, and other persistent organic pollutants; Bioaccumulation and Biomagnification processes; Consequences of toxicant accumulation in ecosystems

(c). Management of poisoned patients
Management of Poisoned Patients - assessment, diagnosis,
and treatment of acute and chronic poisonings
Clinical methods to decrease absorption -administration of activated charcoal,
gastric lavage, and other techniques to reduce absorption

(d). Enhanced excretion of toxicants
Enhanced excretion of toxicants from the body
Induction of diuresis, hemodialysis, and other methods to enhance elimination
Use of antidotes - antidotes for common toxins and their mechanisms of action

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Biomedical Sciences – Semester VI
Elective Paper - Practicals
Elective Paper XI – Clinical Toxicology (BMS-E111A)

1. Solvent extraction and functional group identification (eg. mixture consisting of benzoic acid, beta-napthol and napthelene).
2. Dissolved oxygen measurement using Winkler's method.
3. Assessment of Biological Oxygen Demand (BOD).
4. Quantitative estimation of residual chlorine in water samples.
5. Determination of total water hardness using EDTA.
6. Measurement of acid value in oil samples.
7. Estimation of formaldehyde content in a given sample.
8. Calculation of LD50 value of insecticide.
9. Assessment of Chemical Oxygen Demand (COD) in water samples.

Biomedical Sciences – Semester VI
Elective Paper
Suggested Books – Elective Paper XI – Clinical Toxicology (BMS-E111A)

1. Curtis D. Klaassen (Editor), Cassarett and Doull's Toxicology: The Basic Science of The Poisons, 7th edition (2008), McGrawHill Medical. ISBN: 9780071470513.

2. Klaassen and Whatkins, Cassarett and Doull's Essentials of Toxicology, 2nd edition (2010), McGraw Hill Publisher. ISBN-13: 978-0071622400.

3. John Timbrell, Introduction to Toxicology, 3rd edition (2001), Taylor and Francis Publishers. ISBN 13: 9780415247627.

4. Stine Karen and Thomas M Brown, Principles of Toxicology, 2nd edition (2006), CRC Press. ISBN-13: 978-0849328565.

5. Frank C Lu and Sam Kacow, Lu's Basic Toxicology: Fundamentals Target Organ and Risk Assessment, 5th edition (2009), Informa Health Care. ISBN: 9781420093117.

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B.Sc - Biomedical Sciences
Syllabus for the Semester VI – Theory
Elective Paper XI - Cancer Biology (BMS-E111B)

Unit I - Cancer cells
(a). Basic aspects of cancer cells verses normal cells
Definition of cancer, Prevalence of cancer, Properties of cancer cells
Examples of cancer susceptibility syndromes

(b). Causative factors of cancer: Symptoms of cancer, Life style and dietary factors that cause cancer, Hormonal factors that cause cancer,Cancer risks, DNA and RNA viruses

(c). Malignant tumours
Definition of primary and secondary cancer
Sporadic cancers, hereditary cancers,Immune suppression-related cancers

(d). Cancer tissue types and histological/immunochemical examination
Solid tumors, Blood cancer, Histopathological examination,Immunohistochemistry

Unit II - Diagnosis
(a). Morphological examination
Basic aspects of cancer cell imaging,Hematological malignancies
Image analysis using artificial intelligence and machine learning

(b). Epidemiology and Biopsies:
Epidemiological data and their interpretation,Molecular epidemiology
Biopsy and its types,Clinical examination of cancer cells

(c). Flowcytometric diagnosis
Concepts of flow cytometry
Flow cytometry – Diagnosis of blood and other cancers

(d). Radiological examination of cancer
Mammography
Digital and 3-D mammography
Lymph node mapping

Unit III - Cancer pathways and genetics of cancer
(a). Molecular basis of carcinogenesis
Cell cycle and cancer
Oncogenes and their mutation
DNA Repair pathways and Genetic variations in cancer

(b). Apoptosis
Apoptotic pathways affecting growth and differentiation
P53 and apoptosis
Autophagy, Necrosis

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(c). Signal transduction pathways in tumor biology
Small molecular second messengers
(Cyclic AMP, lipid messengers, and free radical signaling)
Ligands and receptors
Regulation of protein kinases and phosphatases in cancer biology
Multiprotein complexes
Signaling networks

(d). Tumor suppressor genes
Tumour suppressor genes in immune regulation
Functions of tumour suppressor genes
Telomerase and its maintenance for therapeutic target
P53, INK4, PTEN as suppressor genes

Unit IV - Cancer and treatment
(a). Importance of cancer classification
Cancer screening
Molecular classification of cancer
Adenocarcinoma
Squamous cell carcinoma

(b). Tumour, Node, Metastasis (TNM)
TNM systems,Types of staging,Stage grouping
Cancer progression, clonal heterogeneity and metastasis

(c). Chromosomal abnormalities and cancer
Chromosomal abnormalities in solid tumours
Chromosomal abnormalities in blood cancer
Whole chromosomal aneuploidy and cancer

(d). Treatment
Biological therapy
Chemotherapy, Laser therapy
Thermotherapy, Alternative medicine
Cancer and personalized medicine based on mutations/Single nucleotide polymorphism
Treatment challenges: drug resistance and cancer relapse

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B.Sc(Hons.)- Biomedical Sciences - Semester VI - Practicals
Elective Paper XI - Cancer Biology(BMS-E111B)

1. Handling of case study of breast cancer tissue
2. Interpretation of 3-D mammography
3. Handling of case study of lung cancer tissue
4. Interpretation of histological tissues of normal and cancer cells
5. Biomarkers for tumour tissues
6. Chromosomal abnormalities in cancer affected tissues (Slides)
7. Mutation screening in the genome sequencing of tumour tissues
8. Identification of Single Nucleotide Polymorphism (SNPs) in cancer affected tissues
9. Collection of biopsy and its observation under microscope
10. Interpretation of epidemiological data

B.Sc(Hons.)- Biomedical Sciences
Semester VI – Suggested Books
Elective Paper XI - Cancer Biology(BMS-E111B)

1. **Biology of Cancer**
   Second International, Student Edition by Robert A. Weinberg, NORTON
   Publisher: Norton, Year of Publication: 2014, ISBN: 9780815345282
2. **The Basic Science of Oncology**
   By Lea Harrington, Ian Tannock, Richard Hill and Dave Cescon
   Publisher: McGraw Hill, Sixth Edition, Year of Publication: 2021
   ISBN-10: 1259862070
3. **The Biological Basis of Cancer**
   By Ivan Damjanov, Robert G. McKinnell
   Publishers: Cambridge
   Year of Publication: 2006
4. **Principles of Cancer Biology**
   By: Lewis J. Kleinsmith
   Year of Publication: 2016
   Publisher: Pearson Education India Pvt. Ltd.
5. **Oxford Textbook of Cancer Biology (Hardback)**
   By Pezzella et al.
   Publishers: Oxford University Press
   Year of Publication: 2020.

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B.Sc (Hons.) – Biomedical Sciences
Semester VI – Theory
Elective Paper-XII - Preclinical Drug Safety and Efficacy Analysis and Physiologically Based Pharmacokinetic (PBPK) Modelingin Drug Discovery Development (BMS-E-112A)

Course Implementation Notes

Objective: Gain deep insights into the development, optimization, and validation of in vitro and in vivo assays relevant to drug safety and efficacy. Integrating the given topics into a cohesive undergraduate-level course on preclinical safety and efficacy studies in pharmaceuticals requires a well-structured approach that spans both theoretical knowledge and practical applications. This course will aim to prepare students for industry roles that require expertise in both in vitro and in vivo assay development and testing.The objective is to explore regulatory frameworks and the impact of future technologies on drug development, focusing on compliance and innovative approaches to drug testing.

Aim: Understand basic and advanced principles of pharmacology and toxicology, focusing on drug interactions, ADME processes, and the foundational knowledge required for ICH compliance.Learn to conduct and interpret comprehensive preclinical safety and efficacy tests, utilizing both traditional and innovative methods.

Blended Learning Approach: Combine lectures with hands-on laboratory work, case studies, and group projects to enhance understanding and application of theoretical knowledge.

Industry Collaboration: Involve industry professionals as guest lecturers or advisors to provide insights into current trends and challenges.

Unit 1: Foundations of Pharmacology and Toxicology

(a). Basic Principles of Pharmacology and Toxicology

Introduction to pharmacodynamics, pharmacokinetics

ADME, toxicokinetics, and toxicodynamics

(b). Drug-Receptor Interactions

Mechanisms and quantitative models of how drugs interact with biological receptors

(c). In Vitro and In Vivo Assays

Overview of assay types, applications, advantages, and limitations

ICH Guidelines Overview

(d). Introduction to the structure, objectives, and key documents of the ICH

ICH Guidelines for Quality (Q-Series)

Focus on stability testing, analytical validation, and impurities

Unit II - Assay Development and Validation

(a). Development, optimization, and validation of in vitro and in vivo assays relevant to drug safety and efficacy

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(b). Advanced Assay Design
Techniques for developing robust in vitro and in vivo models
Validation and Quality Control
Understanding validation parameters and regulatory guidelines for assay validation

(c). ICH Guidelines for Method Validation (Q2)
Detailed validation requirements for analytical procedures
Regulatory Compliance in Assay Development
How ICH guidelines affect assay design and validation

(d). Emerging Technologies in Assay Development
Innovations like organ-on-a-chip and high-throughput screening methods

Unit III -Preclinical Drug Safety and Efficacy Testing
(a). Comprehensive Toxicology Testing
Guidelines and methodologies for various toxicology tests

(b). Efficacy Testing in Drug Development
Designing studies and interpreting results for drug efficacy

(c). ICH Guidelines for Preclinical Safety (S-Series)
Detailed study of ICH guidelines related to safety and pharmacology

(d). Pharmacometrics and Its Role
Use of pharmacometric techniques in safety and efficacy prediction
ICH Guidelines for Efficacy (E-Series)
Understanding clinical trial design and GCP guidelines

Unit IV - Regulatory Compliance and Innovation
(a). Global Regulatory Environments
Detailed exploration of how ICH guidelines integrate with global regulatory practices

(b). Documentation and Reporting for Regulatory Submissions
Techniques for preparing comprehensive documentation for regulatory bodies

(c). Advances in Drug Testing Technologies
The role of AI, digital tools, and predictive models in drug development
Alternative Methods and Ethical Considerations
Discussion on reducing animal testing and ethical implications

(d). Case Studies and Real-World Applications
Examination of how companies integrate ICH guidelines into their development processes

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B.Sc (Hons.) – Biomedical Sciences
Semester VI – Practicals
Elective Paper-XII - Preclinical Drug Safety and Efficacy Analysis and Physiologically Based Pharmacokinetic (PBPK) Modeling in Drug Discovery Development (BMS-E-112A)

1. Laboratory Safety and Basic Techniques
2. Introduction to GLP, handling of chemicals, and basic care of laboratory animals
3. Hands-on Assay Development and Validation
4. Design and execution of assays, quality control measures, and compliance documentation.
5. Conducting Toxicological and Pharmacological Testing

PBPK modelling for Bioaviability prediction using PK-Sim and MoBi, complete tutorials

6. Practical execution of tests, data analysis, and report preparation according to ICH guidelines
7. Regulatory Compliance Workshops
8. Simulations of regulatory filings, adherence to ICH guidelines, and handling real-world scenarios.

B.Sc (Hons.) – Biomedical Sciences
Semester VI – Suggested Books
Elective Paper-XII - Preclinical Drug Safety and Efficacy Analysis and Physiologically Based Pharmacokinetic (PBPK) Modelingin Drug Discovery Development (BMS-E-112A)

1. PBPK Modeling and Simulations: Principles, Methods, and Applications in the Pharmaceutical Industry. By Dr. Sheila Annie Peters. ISBN: 978-1-119-49768-4. September 2021.
2. Biopharmaceutics Modeling and Simulations: Theory, Practice, Methods, and Applications. By Kiyohiko Sugano
   ISBN: 978-1-118-35432-2 July 2012.
3. Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations, 2nd Edition
   By Sara E. Rosenbaum (Editor)
   ISBN: 978-1-119-14318-5 November 2016.
4. Principles of Drug Discovery
   by Padmajakore (Author), SubhashBodhankar, Year of Publication 2022
5. Drug Discovery and Development, Third Edition Paperback – Import, 30 June 2021
   by James J. O'Donnell (Editor), James T. O'Donnell (Editor), John Somberg (Editor), Vincent Idemyor (Editor)

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B.Sc(Hons.)Biomedical Sciences
Syllabus for the Semester – VI– Theory
Elective Paper - XII - Clinical Genetics (BMS-E – 112B)

Unit 1-The Human Genome

(a) **Human chromosome structure and types,**
Karyotyping analysis of human chromosomes and its significance

(b) **Human Mitochondrial genome organisation**
Human nuclear genome organisation- gene size and density, organisation of protein coding genes; Gene families (globin gene family, histone gene family,etc) pseudogenes.Non-coding sequences, Repetitive elements

(c) Human Genome variation- DNA sequence variants, genetic polymorphisms, gene duplication and evolution ; Functional Genomics: Transcriptomics, Epigenomics and Proteomics

(d) Applications of genomics in research, Society and public health: Comparative genomics, Pharmacogenomics, Clinical genomics, DNA fingerprinting and forensics, Nutrigenomics

Unit 2-Gene Transmission in Families

(a) Pedigree analysis in monogenic traits- Autosomal dominant inheritance, recessive inheritance (consanguinity and inbreeding), X-linked dominant, X-linked recessive, Y-linked, sex-influenced and sex-limited disorders

(b) Pedigree analysis- Maternal inheritance of disorders caused by mutations in the mitochondrial genome (homoplasmy and heteroplasmy)

(c) Factors affecting pedigree pattern- penetrance (complete and incomplete), variable expressivity, anticipation, genomic imprinting (Prader-Willi Syndrome, Angelman Syndrome), Mosaicism (mosaics, chimeras)

(d) Genotype and phenotype correlation-genetic heterogeneity (allelic and locus), phenotypic heterogeneity; Segregation analysis of monogenic conditions- Complete and Incomplete ascertainment; Multifactorial inheritance- Threshold model, Heritability, Twin studies in genetic analysis

Unit 3-Genetics and Molecular Basis of Human Disorders

(a) Molecular basis of human chromosome anomalies: Numerical and Structural chromosomal Disorders

(b) Inherited disorders due to defects of: Amino acid metabolism,
Lipid metabolism
Carbohydrate metabolism and Purine metabolism

(c) Inherited disorders due to defects in: membrane transport (Cystic fibrosis) and receptor proteins (Familial Hypercholesterolemia), structural proteins (DMD and BMD) and Collagen disorders (Osteogenesisimperfecta)

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(d) Single gene disorders- Hemoglobinopathies (Sickle cell disease, Thalassemia) and Complex genetic diseases – Hypertension, Diabetes mellitus, Coronary Artery Disease

Unit 4- Genetic testing and Counseling

(a) Prenatal screening (Indications, Invasive methods and Non-invasive techniques, Detection of cytogenetic, biochemical and genetic defects in fetal samples) and Neonatal Screening (PKU, Galactosemia, SCA and Congenital hypothyroidism)

(b) Preclinical screening: Adult onset diseases (Alzheimer's, HD and FHCL), Disease susceptibility for complex diseases (CAD, T2DM and RA) , Heterozygote detection and population screening (Thalassemia, Cystic Fibrosis, DMD, Fragile– X syndrome, Hemophilia)

(c) Methods and approaches for genetic testing: biochemical assays, chromosomal analysis, molecular tests (detection for known and unknown mutations
Analysis of dynamic mutations and gene expression analysis

(d) Genetic counseling: Indications for and purpose; information gathering for Medical Genetic evaluation (Basic components of Medical History
Past medical history, social and family history) and construction of pedigrees-estimation of recurrence risk
Legal and ethical considerations,psychological counseling, Patient education
Risk communication and decision making

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B.Sc(Hons.)Biomedical Sciences
Semester VI - Syllabus for the Practicals
Elective Paper - XII - Clinical Genetics (BMS-E – 112B)

1. Karyotyping and G-banding of Human chromosomes
2. Screening for Barr bodies
3. Separation of haemoglobin variants by electrophoresis
4. Diagnosis of diseases by PCR-based methods
5. RT-PCR analysis for identification of disease gene expression
6. New born screening-PKU/ other
7. Triple marker test
8. Construction of pedigrees and identification of mode of inheritance of a trait.
9. Problems on Genetic counseling and risk assessment
10. Analysis of genome data

B.Sc(Hons.)Biomedical Sciences
Semester VI – Suggested Books
Elective Paper - XII - Clinical Genetics (BMS-E – 112B)

1. Connor and Smith. Essentials of Medical Genetics, Blackwell-1993
2. Davies Human. Genetic Disease Analysis, IRL-1993
3. Emery and Mueller. Elements of Medical Genetics, ELBS-1992
4. Jorde et al. Medical Genetics, Elsevier-1998
5. Pasternak. An Introduction to Molecular Human Genetics, Fritzgerald-2000
6. Strachan and Read. Human Molecular Genetics,Wiley-2011
7. Vogel andMotulsky. Human Genetics, Springer-1997
8. Thompson and Thompson Genetics in Medicine (7th Edition), Nussbaum, Mclnnes, Willard 6. Robert et al., (2015)
9. Gardner, A. and Davies, T. (2009) Human Genetics-Scion Publishing, 2nd Edition. 10. Lewis, R. (2008) Human Genetics: Concepts and Applications, McGraw-Hill Publishing, New York, 8th Edition.

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B.Sc Biomedical Sciences
Semester VI – Syllabus for Theory
Elective Paper – XIII – Biostatistics, Intellectual Property Rights and Entrepreneurship (BMS-E113A)

Unit I - Introduction to Biostatistics

(a). Importance of statistics in biology and medical sciences
One way classification
Analysis of variance (ANOVA)
One-way, and two-way analysis

(b). Single factor ANOVA
Two factor ANOVA with unequal and equal replication
Principles and Design of Experiments
Randomization
Replication and Local control

(c). Introduction to population genetics
Importance of population genetics in the context of biomedical sciences
Significance of the population genetics and its relavence
Population genetics and random mating
Genetical variance and correlations
Elston-Stewart algorithm for calculation likelihood

(d). Linkage and Alleles
Estimation of recombination fraction
Multiple alleles and blood types
Inheritance of quantitative traits
Maximum likelihood methods of estimation
Sex linked genes
Autopolyploid

Unit II -Correlation and regression

(a). Definition of correlation and regression
Scatter diagram
Karl Pearson's coefficient of correlation

(b). Regression
Definition of regression
Lines of regression
Regression coefficients

(c). Probability
Probability and probability distributions
Random experiment, Trial, Sample space
Sample point and different types of events

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(d). Mean, Median, Standard error

Definitions of mean, Median and Standard Error (SE)
Standard deviation
Student t-test, Chi square

Unit III -Intellectual Property Rights (IPR), Patents, Trademarks, Copyrights

(a). Overview of Intellectual Property Rights (IPR)

Need for IPR, IPR in India
Rationale for IPR, Types of IPR, Industry proprietary

(b). Patents

Definition of a patent, Patent application process
Drafting and filing of a patent, National and International patents
Patentable and non-patentable inventions
Process and Product patent, Legal requirements for patents
Granting of patents, Exclusive rights of a patent
Infringement of a patent

(c). Trademark

Purpose and rights of trademark
Signs used as trademarks-type, Trademark filing, trademark registration
Protectable matter and Protection of trademark

(d). Copyrights and Geographical Indication of Goods

Rights and protection covered by copyrights
Fundamentals of copyright law
Copyright ownership issues, Infringement of copyrights
Why and how GI needs protection
Indian GI act

Unit IV – Entrepreneurship in Biomedical Sciences

(a). Preparation of the project proposals for financial assistance

Aim and objectives of the project proposal
Identification of the gap or unmet need of the product
Preparation of detailed project report
Market survey and key strategies for market penetration
Preparation of prototypes and deliverables

(b). Start-up Business and Hand-holding for small Business Entrepreneurships

Identification of potential areas
Start-up in the preparation of diagnostic kits
Start-up in the establishment of diagnostic centers
Start-up for in vivo assay of the drug toxicity and drug screening
Start up for the in vitro assay of the drug toxicity and drug screening

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(c). Government funding agenciesand BioNEST

Translation research in biomedical sciences
Vision and mission of start-up loans
Bioincubators Nurturing Entrepreneurship for Scaling Technologies (BioNEST)
BioNEST compendium and the scheme to create globally competent bioincubation facilities
Incubation centers and utilization of facilities therein

(d). Funding from DBT-BIRAC/SIBRI and other agencies

Small Business Innovation Research Initiative (SBIRI) scheme
Biotechnology Industry Research Assistance Council (BIRAC)
BIRAC initiative, Launching Entrepreneurial Driven Affordable Products (LEAP) fund and the aims of such schemes
Biotechnology Industry Partnership Programme (BIPP)

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B.Sc (Hons.) Biomedical Sciences
Semester VI – Practicals
Elective Paper – XIII – Biostatistics, Intellectual Property Rights and Entrepreneurship (BMS-E113A)

1. Construction of discrete and continuous frequency distribution
2. Preparation of graph on X- and Y-axis
3. Construction of Bar diagram
4. Histogram, Pie diagram, Frequency curve and frequency polygon
5. Formula and calculation of mean, median, and mode
6. Geometric mean, and harmonic mean for grouped and ungrouped data
7. Calculation of Standard error, standard deviation, student t test, chi square, mean deviation, Standard deviation
8. Formula and calculation of absolute measures of dispersion
9. Formula and calculation of relative measures of dispersion

SEMESTER VII and SEMESTER VIII

Project Work :
Students will undertake Internship/Project work either at the Pharma Industry / Biotech Companies/ Diagnostic Centers / Corporate and Government Hospitals during the semesters VII and VIII. Students will submit the work at the respective colleges after the completion of the Internship. Stipend may be /or may not be provided to the students during this period. Credits will be allotted semester-wise for the Internship/project work.

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B.Sc (Hons.) Biomedical Sciences
Semester VI – Suggested Books
Elective Paper – XIII – Biostatistics, Intellectual Property Rights and Entrepreneurship (BMS-E113A)

1. **Introduction to Biostatistics**
   By Pranab Kumar Benerjee
   S. Chand Publications, New Delhi
2. **Biostatistics**
   By Sudhir Kumar Pundir
   ISBN: 9789354661808, Available at Amazon
3. **Biostatistics – Perspectives in Healthcare Research & Practice**
   By B.L. Verma, G.D. Shukla, and R.N. Srivastava
   Year of Publication 2016, Available at Amazon
   ISBN: 979812390161.
4. **Fundamentals of Epidemiology and Statistics**
   By ShyamSundarDeepti
   ISBN: 9788123925844, Available at Amazon
5. **Biostatistics in Health Research**
   By ShouvikChoudury and Uttam Kumar Roy
   Year of Publication: 2023.
   Available: Amazon

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B.Sc(Hons.)– Biomedical Sciences
Skill Enhancement Course - I
Clinical Biochemistry and Molecular Diagnostics (BMS-S301)
(There will not be any theory classes, Only Practical classes will be conducted)

Unit – I. Fundamentals of Clinical Diagnosis

(a). Sterilization Techniques (only practicals)

Physical methods (by autoclaving)
Chemical methods (using alcohol or sodium hypochlorite)
Introduction to clinical laboratory principles and procedures.
Concept of GLP and ISO labs, quality control and laboratory safety.
Regulation of diagnostic labs and accreditation methods.

(b). Clinical biochemistry

General overview of blood banking, blood typing/ Blood grouping,
CBP, Blood screening in transfusion medical lab
Guidelines for collection transport, preservation processing and analysis of specimen.
Urine analysis, basic hematology,
Diabetic screening,
Kidney/Renal function tests, Liver Function Tests.

(c). Overview of phlebotomy (the surgical opening or puncture of a vienin order to withdraw blood).

Immune-serology and clinical microbiology
Guidelines for proper discard of biological waste and chemical wastes
Principles and applications of important instruments used in the diagnostic laboratory
Biological safety cabinets (Class I, II, III)

(d). Molecular Diagnosis – An overview

Diagnosis of Bacterial and Viral Diseases using PCR and RT-PCR machines
(Diphtheria, Pertussis, COVID-19 and others)
Bright field microscope
Fluorescence microscope
ELISA reader
Autoanalyser
UV-VIS Spectrophotometer
Gel Electrophoresis
Image analysis **(Scans)**

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(b). Composition and use of important differential media

Media for identification of pathogenic bacteria EMB agar

McConkey agar, TCBS agar and Salmonella-Shigella agar and blood culture media (any two)

Enumerate the microbial load on the selected fresh produce from major outlets.

Isolate and identify the common microorganisms present on their surface using microbiological, biochemical and PCR techniques.

(c). Classification of culture media and quality control of culture media.

Inoculation, incubation and purification methods in bacterial cultures

Preservation of bacterial culture. Rapid identification system

Continuous monitoring of culture systems: Detection of Bacteria and other microorganisms in BACTEC 9240 Blood Culture Bottles

Use of conventional microbiological tools supplemented by most modern analytical techniques including PCR for enumeration

(d). Isolation and identification of microbes (mainly on fresh produce)

Setting up of a "Gold Standard" method, concepts of accuracy (efficiency)

Precision, sensitivity, specificity, reliability of diagnostic tests

Prevalence, positive predictive value and negative predictive value

Unit III - Immunoserology: Principles and Application(only practicals)

(a). Antigen-antibody interaction and its use in diagnosis

Detection and diagnosis of common diseases: Widal and typhi dot test for typhoid

(b). Acylatedhaemoglobin in Diabetes, TSH levels in Thyroid condition

Malaria antigen in Malaria, Types of Malaria, Rapid diagnostic kit tests

(c). NS1 antigen in Dengue, Chikungunya (any two three immune diagnostic tests)

Concepts of Immune response (Explain the concepts).

Loop-mediated Isothermal Amplification (LAMP)-based diagnostic methods

(d). Techniques to be discussed: ELISA - direct, indirect

Competitive and sandwich ELISA

Co-immunoprecipitation for protein-protein interaction studies

Unit IV - Medical Cytogenetics

(a). Become familiar with major techniques used in clinical cytogenetics

Culture of peripheral blood and preparation of metaphase chromosomes

Chromosome banding and karyotyping

Human cytogenetics and its application to medicine

(b). Cell culture and harvest

Chromosome banding and staining, chromosome identification

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Cytogenetics nomenclature, chromosome abnormalities and aberrations
Chromosomal syndromes, classification of genetic disorders

(c). Clinical Genetics

Integration of genetic diagnostic services with other healthcare services
Clinical Genetics, Prenatal Diagnosis, Infertility, Cancer Cytogenetics
Issues related to the interpretation of normal and abnormal chromosomal variation (with the help of photographs or slides)

(d). Chromosomal Abnormalities

Mosaicism, aneuploidy and other chromosomal rearrangements
ISCN nomenclature
Abnormalities of chromosome number (monosomy, trisomy, triploidy)
Partial aneuploidy, microdeletion/contiguous gene syndromes
Abnormal chromosomes

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Following skills will be imparted at the end of this course which may enhance their employability

1. Students will demonstrate the knowledge of how to procure reliable information from a spectrum of sources such as Web, Popular media, and Scientific Publications.

2. Students will acquire skills at different diagnostic settings and hence their employability skills will enhance.

3. Students will demonstrate the knowledge of how to generate data and put it in a proper format and then communicate the results of their scientific investigation to a Scientific Journal.

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B.Sc (Hons.) Biomedical Sciences
Skill Enhancement Course - I
Clinical Biochemistry and Molecular Diagnostics (BMS-S301)
Suggested Books

1. Bailey and Scott's Diagnostic Microbiology, 12th edition (2007), Betty A. Forbes, Daniel F. Sahm and Alice S. Weissfeld; Mosby Elsevier Publishers, ISBN-13: 978-0808923640.

2. Medical Laboratory Technology Methods and Interpretations Volume 1 and 2, 6th edition (2009), RamnikSood; Jaypee Brothers Medical Publishers, ISBN-13: 978-8184484496.

3. Current Protocols in Human Genetics, 1st edition (1994), Dracopoli and Nicolas C. Dracopoli; John Wiley and Sons, Inc., ISBN-13: 978-0471034209.

4. Molecular Cloning: A Laboratory Manual, 4th edition (2012), Michael R. Green and Joseph Sambrook; Cold Spring Harbor Laboratory Press, ISBN-13: 978-1936113422.

5. Microbiology: A Laboratory Manual, 10th edition (2013), James Cappuccino and Natalie Sherman, Benjamin Cummings, ISBN-13: 978-0321840226.

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B.Sc (Hons.) Biomedical Sciences
Skill Enhancement Course - II
In Vitro and in Vivo Assay Development and Drug Screening(BMS-S302)
(There will not be any theory classes, Only Practical classes)

1. Human Cell Culture Techniques
2. Fundamental cell culture operations, aseptic techniques, and cell line maintenance.
3. Assay Development for screening the drugs
4. Designing and optimizing a cell-based assay to measure drug effects on cell proliferation
5. High-Throughput Screening Setup
6. Setting up and running a mini-HTS project, including data collection and data analysis
7. Phenotypic Screening
8. Conducting a phenotypic drug screening using live-cell imaging to assess drug effects on cellular behavior
9. Drug toxicity screening
10. Conducting in vitro toxicity tests (e.g., MTT assay for cytotoxicity)
11. PBPK modelling for Bioaviability prediction using PK-Sim and MoBi, complete tutorials
12. ADME Profiling
13. Using in vitro assays to evaluate the metabolic stability of a compound
14. Testing the drugs in animal models (in vivo)

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B.Sc(Hons.)– Biomedical Sciences
Skill Enhancement Course - III
Techniques in Forensic Science (BMS-S303)
(There will not be any theory classes, Only Practical classes)

Unit I -Crime Scene Investigation(All practical classes)

(a). Introduction to Forensic Science Principles
Documentation of crime scene by photography
Sketching and field notes

(b). Simulation of a crime scene for training
To lift footprints from crime scene

(c). Forensic science laboratory and its organization and service
Tools and techniques in forensic science

(d). Branches of forensic science
Causes of crime
Role of modus operandi in criminal investigation

Unit II - Types of injuries and death

(a). Types of injuries
Case studies to depict different types of injuries and death

(b). Classification of injuries and their medico-legal aspects
Method of assessing various types of deaths

(c). Forensic Chemistry and Ballistics
Comparison of bullets and cartridges in museum Laboratory

(d). Separation of nitro compounds (explosives) by thin layer chromatography
To perform the preliminary examination of blood in a given sample
Unit Classification of fire arms and explosives
Introduction to internal, external and terminal ballistics
Chemical evidence for explosives

Unit III - Forensic Graphology

(a). Identification and comparison of handwriting characters
To perform thin layer chromatography of ink samples
General and individual characteristics of handwriting

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Examination and comparison of handwritings
Analysis of ink of various samples

(b). Forensic Toxicology
Forensic toxicology-An overview
Instruments used in forensic toxicology
Identification techniques of common toxins, drugs, pesticides

(c). Volatile poisons, vegetable poisons, mushroom poisons etc., inthe given biological samples and available at crime scene
Widely used death investigations
Witnesses at the crime scene
Role of the toxicologist, significance of toxicological findings

(d). Fingerprint analysis
Forensic biometrics
Fingerprint scanning
Investigation method for developing fingerprints by Iodine crystals
To observe the effects of surface temperature on fingerprints

Unit IV - Fundamental principles of fingerprinting

(a). Principles of fingerprinting
Classification of fingerprints
Development of finger print as science for personal identification

(b). DNA Fingerprinting
Purpose, Procedure, and How it is Used?
DNA isolation in minimal available biological samples
PCR amplification on target DNA and DNA profiling
Identification of the criminal using DNA fingerprinting

(c). Principle of DNA fingerprinting
Principles involved in DNA fingerprinting
Application of DNA profiling in forensic medicine

(d). Cyber Forensic Investigation
Introduction to Cyber Security
Digital Evidence Collection Laboratory
E-Mail Investigation, E-Mail Tracking, IP Tracking
E-Mail Recovery, Recovering deleted evidences
Password Cracking Investigation Tools
eDiscovery, WhatsApp Messages, Evidence Preservation
Search and Seizure of Computer Hard Disks, Pen Drives

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Skill Enhancement Course – III
Techniques in Forensic Science (BMS-S303)
Suggested Books

1. An introduction to Scientific and Investigative Techniques, 3rd edition (2009), James SH, Nordby JJ and Bell S; CRC Press, ISBN-13: 978-1420064933.
2. Practical Forensic Microscopy: A laboratory manual, 1st edition (2008), Barbara Wheeler and Lori J Wilson; Bios Scientific Publisher, ISBN-13: 978-0470031766.
3. Forensic Handwriting Identification: Fundamentals, Concepts and Principals 1st edition (2000) Ronald N. Morris, Academic press ISBN-13: 978-0125076401
4. Handbook of Firearms and Ballistics: Examining Interpreting Forensic Science by Brian J Heard 2nd edition (2008), John Wiley and Sons ISBN-13: 978-0470694602.
5. Principles of Forensic Medicine and Toxicology, 1st edition (2011) Rajesh Bardale; Jaypee Brothers Medical Pub, ISBN-13: 978-9350254936.
6. Practical Crime Scene Processing and Investigation, 2nd edition (2011), Ross M Gardner, CRC press ISBN-13: 978-1439853023.
7. Forensic Medicine and Toxicology: Oral, Practical AndMcq, 3rd edition (2006), Karmakar, Jaypee Brothers, ISBN-13:978-8171797350.
8. Fundamentals of Forensic Science, 2nd edition (2010), Houck, M.M. and Siegel, JA; Academic Press, ISBN-13: 978-0123749895.
9. Criminalistics - An Introduction of Forensic Science, 10th edition (2010), Prentice Hall Inc; ISBN-13: 978-0135045206.

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B.Sc(Hons.)Biomedical Sciences
Skill Enhancement Course – IV
DNA Fingerprinting (BMS-S304)

BMS-S303 **Practical Syllabus (30hrs)** **Credits 2**

Unit I: DNA Profiling **(15 hrs)**

(a). DNA finger printing
Various steps involved in DNA profiling. Y-DNA testing
Mitochondrial DNA testing (mt DNA testing)

(b). DNA Polymorphism and the concept of molecular markers
Characteristic features of markers
Types of molecular Markers-RFLP, RAPD, AFLP, SSR, ISSR, SSR, SNP
Advantage and disadvantages of different types of molecular markers

(c). DNA Barcoding: Concepts of DNA barcoding
Methods and protocols of DNA barcoding
Advantages of DNA barcoding.
Application for preparation of barcoding library, identify and classify
Living organisms, identifications of various products and adulterants

(d) Application of DNA fingerprinting- Forensic science, medicine, paternity testing
Ancestry estimates, Genetic testing. DNA databases- Combined DNA Index System (CODIS)
Bioethics in DNA fingerprinting

Unit II: Techniques DNA Finger Printing **(15 hrs)**

(a). DNA sample preparation: Sample sources for DNA
Collection and preservation of biological samples for DNA testing
Issues in samples- Degraded DNA, contamination, mixed samples and low copy number
Legal standards for admissibility of DNA profiling

(b). DNA Isolation:DNA isolation from biological samples (blood, tissue, hair, tooth Saliva and bones)
Preparation of buffers
Recent methods for isolation of DNA, Recent methods of DNA quantification and quality check

(c). Qualitative analysis of isolated DNA using electrophoresis
Restriction enzymes and Restriction digestion
Separation of DNA by Electrophoresis.Agarose Gel electrophoresis- Principle, methodology
Gel scoring and data analysis
Application of Agarose Electrophoreses in molecular biology

(d). DNA amplification by PCR: Polymerase Chain Reaction (PCR)- Introduction, Principle
Primer designing, detailed procedure of PCR
Different types of PCR. Rt PCR
Factors affecting PCR, Application of PCR in biological research

B.Sc (Hons.) Biomedical Sciences
Skill Enhancement Course - IV
DNA Fingerprinting (BMS-S304)
Suggested Books

1. **DNA Fingerprinting: Advancements and Future Endeavors**
   Editors: HirakRanjan Dash, PankajShrivastava
   Publisher: Springer, Singapore, Year of Publication: 2018.
   https://doi.org/10.1007/978-981-13-1583-1.
   Hardcover ISBN978-981-13-1582-4
2. **Handbook of DNA profiling.**
   Editors: HirakRanjan Dash, PankajShrivastava, José Antonio Lorente
   Publisher: Springer, Singapore, Year of Publication: 2022.
   https://doi.org/10.1007/978-981-15-9364-2.
   eBook ISBN978-981-15-9364-2.
3. **Forensic DNA Typing: Principles, Applications and Advancements**
   Editors: PankajShrivastava, HirakRanjan Dash, Jose A. Lorente, Jahangir Imam
   Publishers: Springer Nature, Singapore, Year of Publication: 2020.
   https://doi.org/10.1007/978-981-15-6655-4.
   Hardcover ISBN978-981-15-6654-7.
4. **Advancements in Forensic DNA Analysis**
   Editors:HirakRanjan Dash, Kelly M. Elkins, Noora Rashid Al-Snan
   Publishers: Springer Nature, Singapore
   ISBN Number: ISBN-13-9789819961948, Year of Publication 2023
5. **DNA barcoding and Molecular Phylogeny**
   Editors:SubrataTrivedi, HasiburRehman, ShaliniSaggu, ChellasamyPanneerselvam, Sankar K. Ghosh
   Publishers: Springer Nature, Singapore
   ISBN Number: ISBN3030500756, 9783030500757, Year of Publication 2020
6. **DNA barcodes: Methods and Protocols**
   Editors: W. John Kress and David L. Erickson
   Publisher: Humana Totowa, New Jersey, USA
   Hardcover ISBN978-1-61779-590-9, Year of Publication 2012

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B.Sc(Hons.)Biomedical Sciences
Generic Elective Course
Fundamentals of Medical Diagnostics (BMS-GE401)

(Students across all disciplines can opt for this paper, other than from Biomedical Sciences)
(There will be only theory classes, but not practical classes)

Unit – I- Fundamentals of Clinical Diagnostics

(a). Introduction to clinical laboratory principles and procedures
Concept of GLP and ISO labs
Quality control and laboratory safety
Regulation of diagnostic labs and accreditation methods
Guidelines for proper discard of biological waste and chemical wastes

(b). Sample collection
Guidelines for sample collection
Transport
Preservation
Processing and analysis

(c). Blood and Phlebotomy
Composition and general function of blood
Description of blood cells - normal counts and function
Steps of blood coagulation, anticoagulants
Overview of phlebotomy (the surgical opening or puncture of a vein in order to withdraw blood)

(d). Hematology and other body fluid analysis
Hemoglobin estimation, anemia classification
Blood group ABO/Rh typingcomplications of mismatch
transfusion, selection of donor, mandatory tests, comb's test, component separation, preservation and uses.
Analysis of Urine, Serum, Saliva andCerebrospinal fluid

Unit II:Approaches to diagnosis of infectious diseases

(a). Sterilization Techniques
Physical methods
Chemical methods

(b). Molecular Diagnosis – An overview
Diagnosis of Bacterial and Viral Diseases using PCR and RT-PCR
(Diphtheria, Pertussis, COVID-19 and others)
Bright field microscope, Fluorescence microscope
ELISA reader, Autoanalyser
UV-VIS Spectrophotometer
Gel Electrophoresis System

(c). **Isolation of bacteria from mixed culture**
Study of morphological, cultural, biochemical characteristics of common bacterial pathogens
Observing Virus under the microscope
Isolation and identification of common microorganisms using microbiological, biochemical and PCR techniques

(d). **Composition of culture media and Culture methods**
Media for identification of pathogenic bacteria EMB agar
McConkey agar, Inoculation, incubation and purification methods in bacterial cultures
Preservation of bacterial culture

Unit III - Immunoserology: Principles and Application

(a). **Antigen-antibody interaction and its use in diagnosis**
Detection and diagnosis of common diseases: Widal and typhi dot test for typhoid

(b). **Glycosylated hemoglobinin Diabetes, TSH levels in Thyroid condition**
Malaria antigen in Malaria, Types of Malaria, Rapid diagnostic kit tests

(c). **NS1 antigen in Dengue, Chikungunya**
Concepts of Immune response (Explain the concepts)
Loop-mediated Isothermal Amplification (LAMP)-based diagnostic methods

(d). **ELISA (Enzyme-Linked ImmunoSorbent Assay)**
Direct and Indirect ELISA
Competitive and sandwich ELISA

Unit IV - Medical Cytogenetics

(a). **Basics of clinical cytogenetics**
Culture of peripheral blood and preparation of metaphase chromosomes
Chromosome banding and karyotyping
Human cytogenetics and its application in medicine

(b). **Cell culture and harvest**
Chromosome banding and staining, chromosome identification
Cytogenetics nomenclature, chromosome abnormalities and aberrations
Chromosomal syndromes, classification of genetic disorders

(c). **Clinical Genetics**
Integration of genetic diagnostic services with other healthcare services
Clinical Genetics, Prenatal Diagnosis, Infertility, Cancer Cytogenetics

(d). **Chromosomal Abnormalities**
Mosaicism, aneuploidy and other chromosomal rearrangements
ISCN nomenclature
Abnormalities of chromosome number (monosomy, trisomy, triploidy)
Partial aneuploidy, microdeletion/contiguous gene syndromes
Abnormal chromosomes

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