CENTRE FOR TRANSLATIONAL AND CLINICAL RESEARCH

SCHOOL OF CHEMICAL AND LIFE SCIENCES SCIENCE

B.Sc.- M.Sc. INTEGRATED PROGRAMME(CLINICAL RESEARCH) SYLLABUS

CHOICE BASED CREDIT SYSTEM (CBCS)

EFFECTIVE FROM SESSION 2018-19

JAMIA HAMDARD
(Hamdard University)
New Delhi – 110062
www.jamiahamdard.edu

JAMIA HAMDARD

The History of Jamia Hamdard began with the establishment of a small Unani Clinic in the year 1906 by Hakeem Hafiz Abdul Majeed, a well known practitioner of Unani system of medicine. Hakeem Hafiz Abdul Majeed had a vision of making the practice of Unani medicine a scientific discipline so that Unani medicines could be dispensed in a more efficacious manner to patients. He gave the name “Hamdard” to his venture which means “sympathy for all and sharing pains”. His illustratious son, Hakeem Abdul Hameed, carried forward the philosophy and objectives of Hamdard in independent India.

For setting up a complex of research and educational institutions, Hakeem Abdul Hameed purchased a piece of land in Tughlaqabad area of South Delhi which was hardly inhabited in those times. The first institution in the Tughlaqabad campus was Institute of History of Medicine and Medical Research, whose foundation stone was laid on November 15, 1962 by Pandit Jawaharlal Nehru, the former Prime Minister of India.

In 1963, Indian Institute of Islamic studies was established and in the same year HamdardTibbi College was set up in GaliQasimJaan, Old Delhi. It was later shifted to Jamia Hamdard campus in 1980 to provide education in Unani Medicine.

In 1964, Hamdard National Foundation was created with a view to receive and disburse the profits earned by Hamdard Laboratories for charitable causes of education, medical relief and the advancement of knowledge.
In 1972, Hamdard College of Pharmacy was setup with the objective of providing education and training in all branches of pharmacy.

The year 1989 saw the fullfilment of the dream of Hakeem Abdul Hameed when JamiaHamdard was given the status of Deemed to be University by Ministry of Human Resource Development, Govt. Of India on 10th May, 1989. All the above named institutions set up by Hakeem Abdul Hameed and his associates were amalgamated into Jamia Hamdard. In a brief period of only 10 years it has evolved into an institution fulfilling the objects of Hamdard National Foundation.

Jamia Hamdard was inaugurated by Late Shri Rajiv Gandhi on August 01, 1989. Since then, Jamia Hamdard has progressed towards accomplishing the dream of Hakeem sahib. Currently, Jamia Hamdard is engaged in imparting high quality teaching and research in the disciplines of Allied Health Sciences, Pharmacy, Science, Medicine, Nursing, Management, Information Technology, Islamic studies and Social Sciences.

A great milestone was achieved when in 2012 Medical Council of India (MCI) approved MBBS programme in Hamdard Institute of Medical Sciences and Research (HIMSR) with annual intake of 100.

In 2009 Jamia Hamdard has launched a full-time comprehensive study programme, M.Sc. in Clinical Research through which students are trained to meet the demands of expanding health sector in India and abroad.

SCHOOL OF CHEMICAL AND LIFE SCIENCES

The School of Chemical and Life Sciences is one of the principal Schools which were amalgamated to create the crust of the University in 1989. Since the inauguration of University School of Chemical and Life Sciences has been in forefront of research and academic activities of Jamia Hamdard. All the Departments and Centres of the Schools are research intensive. Faculty members get funding for their research from all major governmental funding agencies. Every year a large number of Ph.D. degrees are awarded from the School. Faculty members and research scholars of the School publish their research work in highly cited journals. Thrust areas of research in the School of Chemical and Life Sciences are environment and health. The research objective is to understand the etiology of diseases at molecular level and relationships between nutrients and drugs. Modern bio-medical research tools and developments in the fields of Genetic Engineering, Genomics, Proteomics and Bio-informatics are being used to understand the cellular processes associated with health and diseases. The emerging concept of role of elements in health and effect of chemicals on environment and health and ecosystem including mitigation of their toxicity and carcinogenicity are other areas of research. Scientific evaluation of the efficacy of herbal medicine is being extensively pursued. The effect of environment on growth, structure and chemistry of plants, relationship between structure and function of proteins and enzymes, development of bio-molecules by r-DNA technology, regulation of gene expression, development of new generation vaccines and diagnostic probes, enhancement of secondary metabolites in medicinal plants, metabolomics, molecular biology of infectious diseases, biotransformation of medicinal plants for better yield of medicinal compounds and transgenics of valuable crops and medicinal plants are also being studied. Pre-clinical and clinical research and bioethics are other areas of research.

School has the following Departments and Centre

- Centre for Translational & Clinical Research
- Department of Biochemistry
- Department of Biotechnology
- Department of Botany
- Department of Chemistry
- Department of Medical Elementology& Toxicology

CENTRE FOR TRANSLATIONAL AND CLINICAL RESEARCH

The Centre for Translational & Clinical Research was has been in existence since 2009 as a Department of Clinical Research. In 2012 it was transformed as Centre and component of 'Translational Research' was also incorporated in its activities. The Centre imparts theoretical and practical training in all aspects of clinical research. It provides opportunity to individuals desirous of pursuing a career in expanding healthcare sector in India and abroad. According to industry sources, the clinical research industry in India will require more than 35000 new professionals in the coming few years. With domestic pharma industry surging ahead in India, global pharma moving more and more clinical trials to their Indian subsidiaries, and home grown contract research organization (CROs) growing day by day, the demand for clinical research professionals is expected to grow exponentially. Moreover, personnel involved in clinical research needs training in Good Clinical Practices (GCP) and ethics. The Centre offers a study programme of MSc in Clinical Research which takes care of all these aspects. The study programme is comprehensive based on both course work and research experience. It is broad-based multi-disciplinary study programme to prepare professionals in clinical research with training in the principles and methods of clinical research, clinical trials, epidemiology, health economics, biostatistics, bioethics, GCP and application of these principles to clinical research. The Department has established collaboration with Ranbaxy Laboratory Ltd., Max Health Care Institute Ltd., New Delhi and other leading clinical research organizations for practical training of the students. The Centre also organizes communication skills workshop for the students to train them in writing and presenting research data, clinical reports, grant applications and case study reports. Faculty includes internal faculty and faculty from industry and other academic institutions. There is a wet laboratory for behavioural and biochemical studies.

Regular Seminars and Workshop on relevant and contemporary topics are organized in collaboration with industry. Students participate in these events enthusiastically. These events provide them opportunity to meet professionals from industry and get an exposure to latest development in the field of clinical research.

B.Sc.-M.Sc. INTEGRATED PROGRAMME (CLINICAL RESEARCH)

B.Sc. (Clinical Research) is interdisciplinary study programme with right blend of basics of clinical research, pharmacology, clinical trials, biostatistics, drug regulatory affairs and ethics. The programme focuses on imparting knowledge and thorough understanding of the basic concepts in clinical trials. It provides multidisciplinary learning with eminent scientists from reputed Pharmaceutical Industries and Academia. The teaching and learning methods used in this programme include lectures, tutorials, practical hands-on training, seminars and workshops. In order to attain learning outcomes of the programme, assessments require students to integrate theory and apply it to practical aspects of clinical research.

CHOICE BASED CREDIT SYSTEM (CBCS)

ChoiceBasedCreditSystem(CBCS) is an internationally acknowledged system. The CBCS notonlyoffersopportunities andavenuestolearncoresubjectsbutalsoexploreadditionalavenuesoflearningbeyondth

e
coresubjectsforholisticdevelopmentofanindividual.TheCBCSprovideschoiceforstudents to selectfromthe prescribedcourses(core,electiveorminor orsoft skillcourses). CBCSoffersflexibilityforstudentsto studyat differenttimesandat differentinstitutions tocompleteonecourse(easemobilityofstudents).Creditsearnedatoneinstitutioncan betransferredtoanotherinstitution. TheCBCSfacilitates benchmarkingof selected courses withbestinternationalacademicpractices.

DIFFERENT COURSES UNDER CBCS

1. Core Courses (CC)

1.1 Discipline Core Course (DCC)

These are discipline specific papers.The course designed for papers under this category aim to cover the basics that a student is expected to imbibe in that particular discipline. DCCs should compulsorily be studied by a student as a core requirement.

1.2. Tutorials

It will be part of each course from the category of core discipline/generic specific paper.

1.3. Practicals

There will be one paper of practical/hands-on training in each semester except Semester VI.

2. Elective Courses (EC)

It is generally a course which can be chosen from a pool of courses and which may be very specific or specialized or advanced or supportive to the discipline/subject of study or which provides an extended scope or which enables an exposure to some other discipline/subject/domain or nurtures the candidate's proficiency/skill.

Elective courses may be of the following types.

2.1. Discipline Specific Elective Course (DSE)

Elective courses offered under the main discipline/subject of study is referred to as Discipline Specific Elective.

2.1.1 Project report/ Training report

An elective course designed to acquire special/advanced knowledge, such as supplement study/support study to a project work, and a candidate studies such a course on his own with an advisory support by a teacher/faculty member is called dissertation/project.Project work/Dissertation is considered as a special course involving application of knowledge in solving / analyzing /exploring a real life situation / difficult problem.

2.2. Generic Elective Course (GEC)

An elective course chosen from an unrelated discipline/subject, with an intention to seek exposure beyond discipline/s of choice is called a Generic Elective. The purpose

of this category of papers is to offer the students the option to explore disciplines of interest beyond the choices they make in Core and Discipline Specific Elective papers.

A core course offered in a discipline/subject may be treated as an elective by other discipline/subject and vice versa and such electives may also be referred to as Generic Elective.

3 Ability Enhancement Courses (AEC)

These courses are aimed at enhancing a student's knowledge base or skills which will lead to increased employability.

3.1. Ability Enhancement Compulsory Courses (AEC)

3.2. Skill Enhancement Courses (SEC)

USEFUL GLOSSARY

Academic Year: Two consecutive (one odd + one even) semesters constitute one academicyear.

ChoiceBasedCreditSystem(CBCS): TheCBCSprovideschoiceforstudentsto selectfromthe prescribedcourses(core,electiveorminor orsoft skillcourses).

Course:Usuallyreferredto,as'papers'isacomponentofaprogramme.Allcourses need notcarrythesame weight. The coursesshoulddefinelearningobjectivesandlearningoutcomes.Acoursemaybe designedtocompriselectures/tutorials/laboratory work/fieldwork/outreach activities/projectwork/vocationaltraining/viva/seminars/ termpapers/assignments/presentations/self-studyetc.ora combinationof someof these.

CreditBasedSemester System(CBSS): UndertheCBSS, the requirementfor awardingadegreeordiplomaorcertificateisprescribedinterms ofnumberof creditsto becompletedbythestudents.

CreditPoint:Itis the product of grade pointandnumber of creditsforacourse.

Credit:Aunit bywhich thecourseworkismeasured.Itdetermines thenumber of hours of instructionsrequired per week. One creditis equivalent to one hour of teaching (lectureor tutorial)or two hours of practicalwork/fieldworkper week.

Cumulative Grade Point Average (CGPA):Itisameasureof overallcumulative performanceofastudentoverallsemesters.The CGPAistheratiooftotalcreditpoints securedbyastudentinvariouscoursesinallsemestersandthesumofthetotalcredits of allcoursesin allthesemesters.Itisexpressed upto twodecimal places.

Grade Point:Itisanumericalweightallottedtoeachlettergradeona10-point scale.

LetterGrade: Itisanindexoftheperformanceofstudentsinasaidcourse.Gradesare denotedbylettersO,A+,A,B+,B,C,PandF.

Programme:Aneducationalprogrammeleadingtoawardofa Degree,diplomaor certificate.

SemesterGradePointAverage(SGPA):Itisameasureofperformanceofwork doneinasemester.Itisratiooftotalcreditpointssecuredbyastudentinvarious coursesregisteredinasemesterandthetotalcoursecreditstakenduringthatsemester. It shallbe expressed upto twodecimal places.

Semester:Eachsemesterwillconsistof15-18weeksofacademicworkequivalentto90 actualteachingdays.Theoddsemestermaybescheduledfrom JulytoDecemberand evensemesterfromJanuaryto June.

TranscriptorGradeCardorCertificate: Basedonthegradesearned,agrade certificate shall beissued toall the registered studentsaftereverysemester. Thegrade certificatewilldisplaythecoursedetails(code,title,numberofcredits,gradesecured) alongwith SGPA of that semesterandCGPAearnedtillthat semester.

B.Sc. (Clinical Research)

MATRIX OF COURSES AND CREDITS

Semester	CORE COURSES (CC) (14) Credits: Th:4, P:2	Ability Enhancement Compulsory Courses (AEC) (2) Credits: Th:2	Skill Enhancement Courses (SEC) (2) Credits: T:2	Discipline Specific Elective (DSE) (4) Credits: Th:4, P:2	Generic Electives (GE) (4) Credits: T:4, P:2	Credits 140
I	BCR CC01 (4 C) BCR CC01 TU (2 C)	AEC1: English Communication (2 C)			BCR GE01A(4C) OR BCR GE01B(4C)	20
	BCR CC2 (4 C)	AEC2: Environment Studies (2 C)			BCR GE01Tu (2C)	
II	BSC CC03 (4C)				BCR GE02A (4 C) OR BCR GE02B(4 C)	20
	BSC CC04 (4C)					
	BSC CC05 (4C)					
	BSC CC06 (4C)					
III	BCR CC 07 (4 C)		BCR SEC 01 (2 C) OR BCR SEC 02 (2C)		BCR GE 01 (4 C) OR BCR GE 02 (4C) OR BCR GE 03 (4C)	26
	BCR CC 08 (4 C)					
	BCR CC 09 (4 C)					
	BCR CC 10 (4 C)					
	BCR CC 07 P (4C)					
IV	BCR CC 02 PR (2 C) BCR CC 03 PR (2 C) BCR CC 04 PR (2 C) BCR CC 05 PR (2 C)		BCR SEC 03 (2C) OR BCR SEC 04 (2C)		BCR GE04 (3 C) OR BCR GE05 (3 C)	26
	BCR CC 06 PR (2 C)				BCR GE06 (3 C) OR BCR GE07(3 C)	
	BCR CC 11 (4C)					
	BCR CC 12 (4C)					
V	BCR CC 13 (4 C)			Any four of BCR DSE 01 (4C) BCR DSE 02 (4C) BCR DSE 03 (4C) BCR DSE 04 (4C) BCR DSE 05 (4C) BCR DSE 06 (4C)		24
	BCR DCC 13 PR (2C)			BCR DSE 07 PR(2C) Project		
VI	BCR CC 14 (4 C) BCR CC 15 (4 C) BCR CC 16 (4 C) BCR CC 17 (2 C)			BCR DSE 08Th/P (6C) Project report or BCR DSE 09 (6C) Training Report	Any two of BCR GEC 08 (2C) BCR GEC 09 (2C) BCR GEC 10 (2C)	26

					BBC GEC 602 Th (2C)	

DCC = Discipline Core Course

2. **DSE = Discipline Specific Elective Course**
3. **GEC = Generic Elective Course**
4. **AEC = Ability Enhancement Compulsory Courses**
5. **SEC = Skill Enhancement Courses**

B.Sc Clinical Research

Syllabus – Semester III

Centre for Translational and Clinical Research

List of courses/papers (credits are indicated in parenthesis)

Semester – III

1. Discipline Core Course (DCC) - compulsory

- BCR-CC07 : Pharmacology I (Credit – 4)
- BCR-CC08: Pathophysiology and Health Education I (Credit-4)
- BCR-CC09 : Drug Regulations (Credit-4)
- BCR-CC10: Fundamentals of Clinical Research (Credit-4)
- BCR-CC07 PR: Practical Pharmacology(Credit-4)

3. Skill Enhancement Courses (SEC)

Select any one course from the list provided below (2 Credit).

- BCR-SEC01: Computer Applications in Clinical Research (2 Credit).
- BCR-SEC02: Clinical Trial Documents (2 Credit).

3. Generic Elective Course (GEC)

Select any one course from the list provided below (3). May also be selected from the courses from the other Departments of School or from any other School of JamiaHamdard having credit of 4.

- BCR-GE01: Formulation Development (Credit-4)
- BCR-GE02: Bioinformatics (Credit-4)
- BCR-GE03: Clinical Biochemistry (Credit-4)

B.Sc. (Clinical Research)
Syllabus – Semester IV
Centre for Translational and Clinical Research

Semester – IV

1. Discipline Core Course (DCC) - compulsory

- BCR-CC11: Pharmacology II(Credit-4)
- BCR-CC12: Pathophysiology and Health EducationII (Credit-4)
- BCR CC-02 PR:Basics of chemistry(Credit-2)
- BCRCC-03 PR: Biomolecules
- BCR CC-04 PR: Cell Biology
- BCR CC-05 PR: Immunology
- BCR CC-06 PR: Enzymes And Proteins

3. Skill Enhancement Courses (SEC)

Select any one course from the list provided below (2).

- BCR-SEC03:Medical Records Management (2 credit).
- BCR-SEC-04: Monitoring of Clinical Trials (2 credit).

2. Generic Elective Course (GEC)

Select any two courses from the list provided below (6). May also be selected from the courses from the other Departments of School of JamiaHamdard having credit of 3.

BCR-GE04: Biopharmaceutics (3 credit)

OR

BCR-GE05: Pharmacoepidemiology (3 credit)
BCR-GE07: Medical Biostatistics (3credit)

OR

BCR-GE06 :Medical Microbiology (3 credit)

B.Sc. (Clinical Research)
Syllabus – Semester V
Centre for Translational and Clinical Research

Semester – V

1. Discipline Core Course (DCC) - compulsory

- BCR-CC13: Pharmacology – III (Credit-4)
- BCR-CC13 PR: Practical (2 credit)

3. Discipline Specific Elective Course (DSE)

- BCR-DSE01: Drug Regulatory Affairs (Credit 4)
- BCR-DSE02: Hospital and Community Medicine (Credit 4)
- BCR-DSE03: Clinical toxicology (Credit 4)
- BCR-DSE04: Clinical trial operations (Credit 4)
- BCR-DSE05: Alternative System of medicines and Clinical Research(Credit 4)
- BCR-DSE06: Regulatory and Methods of Toxicology (Credit 4)

A) Select any four courses from the list provided below (4 x 4 = 16).

B) Select any one of the following

- BCR –DSE 07PR: Any project related to above courses BCR DSE 01, 02, 03, 04, 05 and 06

B.Sc. (Clinical Research)
Syllabus – Semester VI
Centre for Translational and Clinical Research

Semester – VI

1. Discipline Core Course (DCC) - compulsory

- BCR-CC14: Pharmacology – IV (Credit-4)
- BCR-CC15: Hospital Pharmacy and Managment(Credit-4)
- BCR-CC16: ADR and Pharmacovigiliance(Credit-4)
- BCR-CC17: Packaging of formulations for CTs

2. Discipline Specific Elective Course (DSE)

Select any one of the following

- BCR DSE08Th/P : Project Report (Credit 6)
- BCR DSE 09Th/P: Training Report (Credit 6)

3. Generic Elective Course (GEC)

Select any one course from the list provided below (2 x 2=4 credits)

- BCR-GE08 : Medical Writing (Credit-2)
- BCR-GE09: Audits in Clinical Trials (Credit-2)
- BCR-GE10: Regulatory aspects of medical devices(Credit-2)

Select any onepractical course from the list provided below (2x1=2)

- BCR-GE02A PR Bioethics and IPR
- BCR-GE02APR Biotechnology and Human Welfare

BCR-CC07: Pharmacology I (Credit – 4)

Course objective: This module provides the understanding of drugs used in ANS, pharmacology of NSAIDS and drugs used as mydriatics and miotics. The aspects covered include information about mechanism of action, adverse drug reactions, and uses of drugs. In addition, recent updates on the drugs information to be studied.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I- Pharmacology of Autonomic Nervous System

- Cholinergic receptors, cholinergic drugs (parasympathomimetics, cholinomimetics, anticholinesterases).
- Anticholinergic drugs.
- Adrenoceptors, sympathomimetics, adrenoceptors blockers.
- Drugs action on autonomic ganglia (ganglionic stimulants, ganglion blocking agents).
- Neuromuscular blocking agents and centrally acting muscle relaxants.

UNIT II –Autocoids

- Histamine, Antihistaminics.
- Serotonin, agonists and antagonists.
- Arachidonic acid metabolites, NSAIDS

UNIT III - Drugs in Ocular Pharmacology

- Mydriatic and miotic agents and drugs used in glaucoma.

Suggested Readings

1.C.R.Craig and R.E.Stitzel: Modern Pharmacology 2. Theodore W.Rall, Alan S.Nies and Palmer Taylor: Goodman Gilman's : The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman. 3. D.R.Laurence and P.N.Bennett: Clinical Pharmacology. 4. K.D.Tripathi: Essentials of Medical Pharmacology. 5. R.S.Satoskar and S.D.Bhandarkar: Pharmacology and Pharmacotherapeutics. 6. F.S.K. Barar: Essentials of Pharmacotherapeuties. 7. H.P.Rang and M.M.Dale: Pharmacology

BCR-CC08: Pathophysiology and Health Education I (Credit – 4)

Course objective-This module provides the understanding of the pathophysiological changes in human body responsible for various diseases. In this module knowledge about various risk factors and symptoms of various diseases to be provided.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I- General Aspect of Pathophysiology

- Atrophy, necrosis, pain, irritation, inflammation, shock, allergy

UNIT II –Pathophysiology and Clinical AssessmentAutocoids

- Disorders of cells and tissues - hypoplasia, hyperplasia, hypertrophy, metaplasia, neoplasia
- Disorders of blood cells - leukopenia, leukemia, erythrocyte disorders (anemiapolycythemia), hemorrhagic diseases (thrombocytopenia, fibrinogen deficiency, purpura)
- Disorders of blood vessels and heart - atheroma, arteriosclerosis, aneurysms, thrombophlebitis, embolism, varicose veins, congestive cardiac failure, ischaemic heart disease, arrhythmia, hypertension, Burger's disease.
- Disorders of the respiratory tract - tonsillitis, bronchitis, bronchial asthma, cough.
- Disorders of the digestive tract -gastritis, peptic ulcers, pancreatitis, cirrhosis of the liver, jaundice

Suggested Readings

1. Kathleen J.W. Wilson: Anatomy and physiology in Health and Illness.
2. H.E.A. Mentz: Pathophysiology in Medical Science.
3. Thomos H. Kent, Michael N. Hart: Introduction to Human Disease.
4. Martha J. Miller: Pathophysiology- Principle of Disease.
5. Phillip J. Willians and James L. Burson: Industrial Toxicology.
6. P.K. Gupta and D.K. Salunkhe: Modern Toxicology.
7. B.C. Katzung: Basic and Clinical Pharmacology.

BCR-CC09: Drug Regulations(4 credits)

Course objective: This module provides the understanding of regulatory evolution for drugs to be studied. Knowledge about various acts passed in India to be provided.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I- Historical Background	
	● Drug legislation in India
UNIT II – Drug Laws	
	Drugs and cosmetic Act 1940, Rules 1945. ii) Pharmacy Act 1948. iv) Narcotic Drugs and Psychotropic Substances Act, and Rules there under. iii) Prevention of cruelty of animals act. v) Drugs and Magic Remedies (Objectionable Advertisements) Act 1954. vi) Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976. vii) Poison Act. viii) Factory Act. ix) Delhi shops and Establishment Act. x) Medical termination of pregnancy Act. xi) The Drug (price control) order. xii) The Insecticide Act. Xiii) Indian Patents Act as applicable to drugs and pharmaceuticals. xiv) AICTE Act, 1987.
Suggested Readings	
1	N. K. Jain: Pharmaceutical Jurisprudence and
2	2. S. P. Aggarwal
3	R. Khanna: Pharmaceutical Jurisprudence, Tata Publishers.

BCR-CC10: Fundamentals of Clinical Research (4 credits)			
Course objective: This module provides the understanding of the clinical trials and phases of trials. In addition ethical aspects of clinical research and type of clinical trials information to be provided.			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination

		25	75
UNIT I- History & Background of Origin of Clinical Research			
	● Thalidomide tragedy, Sulphanilamide disaster ● WMA Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects, ● The Belmont Report		
UNIT II – Fundamentals of Trial Design			
	● Randomized trial, open label study, double blind, single blind, matched pair study, cross over trial, case control study, cohort study, equivalence trials, superiority trials and non inferiority trials, sources and control of bias, Randomization, sample size and power.		
UNIT III – Phases in trial and Clinical Trial documents			
	● Phase I, II, III and IV trials, endpoints, inclusion and exclusion criteria, Protocol, ICF, CRF and TMF		
UNIT IV –Operation of Institutional Review Board (IRB) Independent Ethics Committee			
	● Defining Scope of IRB/IEC Authority, Responsibilities of IRB/IEC, Composition of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with IRB, IRB/IEC Records,		
Suggested Readings			
Clinical Drug Trials & Tribulations Ebooks by James Swarbrick • Clinical Research Coordinator Handbook Ebook by Deborah Rosenbaum, Michelle Dresser • Clinical Trial Medicine Ebook by Richard Chin, Bruce Y. Lee • Clinical Studies Management by Simon Cook • Clinical Trials – Ebooks by Duolao Wand, AmeetBakhaiRemedica • Good Clinical Practice by Josef Kolman, Paul Meng			

BCR-CC07 PR: Pharmacology I (PRACTICAL)

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

1. In-vitro simulation experiment
2. In-vivo experiments
3. Computer simulation experiments

SUGGESTED READINGS

1.C.R.Craig and R.E.Stitzel: Modem Pharmacology 2. Theodore W.Rall, Alan S.Nies and Palmer Taylor: Goodman Gilman's : The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman. 3. D.R.Laurence and P.N.Bennett: Clinical Pharmacology. 4. K.D.Tripathi: Essentials of Medical Pharmacology.

BCR-SEC01:COMPUTER APPLICATIONS IN CLINICAL RESEARCH(THEORY) (Credit -2)

Course objective: The objective of this module is to improve the student learning through the computer technology, software use and improve their concepts by browsing various useful sites. The following broad topics will be covered

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I A	**Elements of Computer Systems**
	Computer: Definition, Characteristics, Hardware & Software, Computer Organization. Operating Systems: Multi-tasking, Multi programming, Multiuser. Types of Operating System: MS-Windows, Unix/Linux, Mac OS. Database Models: Network, Hierarchical, Relational, Object Oriented. MS-Office: MS-Word, MS-Excel, MS-Power Point, MS-Access.
UNIT I B	
	ICT: meaning, advantages, disadvantages and uses, General abbreviations and terminology of ICT, Basics of internet and emailing, Use of internet in research works
UNIT II A Information Technology	
	Elements of Computer Network. Network Topologies: Ring, Bus, Star, Mesh, Hybrid. Internet, Intranet, WWW, URL, Email, HTTP, HTML, Website, Portal, Web Browser, E-Commerce, IP Address. Issues and Threats of Cyber & Information Security: Virus, Worms, Trojan, Malware, Ransom ware, Anti-Virus, Basics of Computer Trouble Shooting.
Unit II B	
	New developments in Information communication technology, cyber laws, Application BIOINFO

Suggested Readings

Epidemiology: Basis for Disease Prevention and Health Promotionby David DuncanCollier Macmillan publishers 5th edition
Clinical Epidemiology: The Essentialsby Robert H. Fletcher and Suzanne W. Fletcher; WHO Press;5TH Edition
Methods byBrian MacMahon and Thomas F. Pugh;Lippinkot William and Wilkins;2nd Edition

BCR-SEC02 (Credits-2) CLINICAL TRIAL DOCUMENTS			
Course objective: The objective of this module is to provide knowledge about various documents used in clinical trials. The following broad topics will be covered			
Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35
UNIT I-A	**Clinical Trial Documents**		
	Introduction to clinical trial documents, importance of CT documents, contents of protocol, ICF, CRF, Investigator's Brochure and Clinical Study report		
UNIT I B-Essential documents of clinical trial			
	Introduction to Essential documents, Importance, essential documents before the start of trial, essential documents during trial, essential documents after trial		
UNIT II A- Good Documentation practice			
	Definition of Good Documentation Practice, Importance of GDP in clinical trials, Guidelines for GDP		
UNIT II B Trial Master File			
	Trial master files (TMF), Importance of TMF in CT, Types of TMF, and components of TMF		
Suggested Readings			
E6-GCP guidelines			

BCR-GE01:FORMULATION DEVELOPMENT (Credit- 4)				
Course objective				
Credits		Contact hours	Marks – 100	
4		64	Internal assessment	Semester examination
			25	75
UNIT I-	**Powder as dosage form**			
	Powders Types of powders, their merits and demerits, classification of powders, compounding, storage and packaging of powders requiring special consideration like effervescent powders, bulk powders, dusting powders, insufflations, dentifrices and cachets.			
UNIT II- Liquid dosage forms				
	Monophasic: Liquid Dosage forms Preparation, merits, demerits, solubility and methods of increasing solubility. Storage and packaging of liquid formulations for internal and external use. B) Biphasic : Emulsions and Suspensions Emulsions – Definition, types and identification tests, merits and demerits, uses and classification of emulsifying agents and preparation and stability of emulsions. Suspensions – Definition, types, merits and demerits, use of suspending agents, flocculated and deflocculated suspensions, formulation and stability of suspensions. C) Sterile Dosage forms Definition, types, merits and demerits.			
UNIT III- Semi Solid Dosage Forms				
	Semi-Solid Dosage forms Ointments: Classification of ointments and ointment bases. Factors governing selection of an ideal ointment base, preparation, packaging, labeling and storage of ointments. Pastes, Jellies, Poultices: Formulation. Suppositories and Pesseries: Types, suppositories bases, displacement value, preparation, packaging, labeling and storage.			
UNIT IV	**Solid Dosage Forms**			
	A)Tablets Types of tablets, merits and demerits, preparation methods, equipments, storage, packaging and evaluation of tablets. B). Capsules Hard and soft gelatin capsules, merits and demerits, preparation, storage, packaging and evaluation of capsules.			
Suggested Readings				
1. Indian Pharmacopoeia, Govt. of India. 2. Remington's Pharmaceutical Sciences. 3. Nanda, Popli and Sharma: Current dispensing practices. 4. R.K.Khar and PratibhaNand: Dispensing Pharmacy, CBS Publishers, Delhi. 5. A.K. Gupta and S.S. Bajaj: Introduction to Pharmaceutics-II, 2nd Edition,CBS Publishers, New Delhi.				

6. Cooper and Gunn: Dispensing for pharmaceutical students, 12th Edition, CBS Publishers, Delhi.

BCR-GE02: BIOINFORMATICS (THEORY) (Credit- 4)			
Course objective: The objective of this module is to improve the student learning about Bioinformatics through the biological database, sequence alignment and genomics. The following broad topics will be covered			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75
UNIT I-	**Introduction to bioinformatics**		
	Computer fundamentals - programming languages in bioinformatics, role of supercomputers in biology. Historical background. Scope of bioinformatics - genomics, proteomics, computer-aided drug design (structure based and ligand-based approaches) and Systems Biology. Applications of bioinformatics.		
UNIT II-Biological databases and data retrieval			
	Introduction to biological databases - primary, secondary and composite databases, NCBI, nucleic acid databases (GenBank, EMBL, DDBJ, NDB), protein databases (PIR, Swiss-Prot, TrEMBL, PDB), metabolic pathway database (KEGG, EcoCyc, and MetaCyc), small molecule databases (PubChem, Drug Bank, ZINC, CSD). Structure viewers (RasMol, J mol), file formats.		
UNIT-III	**Sequence alignment and phylogenetic analysis**		
	Similarity, identity and homology. Alignment – local and global alignment, pairwise and multiple sequence alignments, alignment algorithms, amino acid substitution matrices (PAM and BLOSUM), BLAST and CLUSTALW. Construction of phylogenetic tree, dendrograms, methods of construction of phylogenetic trees - maximum parsimony, maximum likelihood and distance methods.		
UNIT – IV	**Protein structure prediction and Genomics**		
	Levels of protein structure. Protein tertiary structure prediction methods - homology modeling, fold recognition and *ab-initio* methods. Significance of Ramachandran map. Introduction to genomics, comparative and functional genomics, gene structure in prokaryotes and eukaryotes, gene prediction methods and tools.		

Suggested Readings

SUGGESTED READINGS

1. Bioinformatics: Sequence and Genome Analysis (2001), 1st ed., Mount, D.W. Cold Spring Harbor Laboratory Press (New York), ISBN: 0-87969-608-7.
2. Bioinformatics and Functional Genomics (2003), 1st ed., Pevsner, J., John Wiley & Sons, Inc. (New Jersey), ISBN: 0-47121004-8.
3. Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins (2005), 3rd ed., Baxevanis, A.D. and Ouellette, B.F., John Wiley & Sons, Inc. (New Jersey), ISBN: 0-47147878-4.
4. Bioinformatics – Principles and Applications (2008), 1st ed. Ghosh, Z. and Mallick, B., Oxford University Press (India), ISBN: 9780195692303.

BCR-GE03: CLINICAL BIOCHEMISTRY (Credit-4)

Course objective: The objective of this module is to improve the student learning various, biochemical tests, biochemical changes in human body and their reasons. The following broad topics will be covered

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I-	**Introduction**
	● Organization of clinical laboratory, Introduction to instrumentation and automation in clinical biochemistry laboratories safety regulations and first aid. General comments on specimen collection, types of specimen for biochemical analysis. Precision, accuracy, quality control, precautions and limitations. Collection of blood and storage **Exercises** Separation and storage of serum.
UNIT II- Evaluation of biochemical changes in diseases	

	● Basic hepatic, renal and cardiovascular physiology. Biochemical symptoms associated with disease and their evaluation. Diagnostic biochemical profile. ● **Assessment of glucose metabolism in blood** Clinical significance of variations in blood glucose. Diabetes mellitus. **Exercises** Estimation of blood glucose by glucose oxidase peroxidase method. ● **Lipid profile** Composition and functions of lipoproteins. Clinical significance of elevated lipoprotein. **Exercises** Estimation of triglycerides
UNIT III- Liver and kidney function tests	
	● **Exercises** Estimation of bilirubin (direct and indirect). ● **Renal function tests and urine analysis** Use of urine strip / dipstick method for urine analysis. ● **Exercise**s Quantitative determination of serum creatinine and urea.
UNIT IV	**Tests for cardiovascular diseases**
	● Involvement of enzymes in diagnostics of heart disease including aspartate transaminase, ● isoenzymes of creatine kinase and lactate dehydrogenase and troponin. **Exercises** ● Estimation of creatine kinase MB.
Suggested Readings	
1. Medical Laboratory Technology - a Procedure Manual for Routine Diagnostic Tests Vol. 2. I(2010), Mukherjee, K.L., Tata Mc Graw–Hill Publishing Company Limited (New Delhi). ISBN:9780070076594 / ISBN:9780070076631. 3. Medical Biochemistry (2005) 2nd ed., Baynes, J.W. and Dominiczak, M.H., Elsevier Mosby Ltd. (Philadelphia), ISBN:0-7234-3341-0. 4. Experimental Biochemistry: A Student Companion (2005) Rao, B.S. and Deshpande, V., IK International Pvt. Ltd. (New Delhi), ISBN:81-88237-41-8.	

BCR-CC12: PATHOPHYSIOLOGY AND HEALTH EDUCATION II (4 credit)		
Course objective: This module provides the understanding of the pathophysiological changes in human body responsible for various diseases. In this module knowledge about various risk factors and symptoms of various diseases to be provided.		
Credits	Contact hours	Marks – 100

4	64	Internal assessment	Semester examination
		25	75

UNIT I- Disorders of Urinary system, Nervous System, Eye and Bones

- Disorders of the urinary system - glomerulonephritis, renal calculi
- Disorders of the nervous system and special senses- Epilepsy, hypoxia, dementia, Parkinsons' disease, chorea, Alzheimer's disease, migrain, depression, schizophrenia
- Disorders of bone, joints and cartilages - Osteoporosis, gout, arthritis, rickettes.
- Disorders of eye - glaucoma and cataract

UNIT II – Health Education

- Spread and prevention of communicable disease- AIDS, sexually transmitted disease, small pox, measles, influenza, diphtheria, whooping cough, meningitis, tuberculosis, polio-myelitis, viral hepatitis, cholera, typhoid, diarrhea, amoebiasis, malaria, filariasis, rabies, tetanus, leprosy.

- Control of population explosion, national family planning program means of contraception (mechanical, chemicals, surgical, Immunological, physical and physiological).
- Immunization – various vaccines, toxoids and their uses.

Suggested Readings

1.C.R.Craig and R.E.Stitzel: Modem Pharmacology 2. Theodore W.Rall, Alan S.Nies and Palmer Taylor: Goodman Gilman's : The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman. 3. D.R.Laurence and P.N.Bennett: Clinical Pharmacology. 4. K.D.Tripathi: Essentials of Medical Pharmacology. 5. R.S.Satoskar and S.D.Bhandarkar: Pharmacology and Pharmacotherapeutics. 6. F.S.K. Barar: Essentials of Pharmacotherapeuties. 7. H.P.Rang and M.M.Dale: Pharmacology

BCR-CC11: Pharmacology II

Course objective: This module provides the understanding of drugs used in CNS, pharmacology of Diuretics, Drugs used in CVS disease and Drugs acting as blood forming agents. The aspects covered include information about mechanism of action, adverse drug reactions, and uses of drugs. In addition, recent updates on the drugs information to be studied

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination

		25	75

UNIT I- Drugs Acting on Central Nervous System

- i) Synaptic transmission in the CNS.
- ii) General anaesthetics, Dissociative and neurolept anaesthesia.
- iii) Hypnotics and sedatives.
- iv) Alcohol.
- v) Antiepileptics.
- vi) Psychopharmacological agent.
- vii) Antiparkinsonian drugs. .
- viii) Narcotic analgesics, opiodpoisoning and treatment.
- ix) CNS stimulants and Nootropic agents.
- x) Local anaesthetics.

UNIT II – **Drugs Acting on Cardiovascular System**

- Cardiac glycosides and positive ionotropic agents.
- Antiarrhythmic drugs.
- Antihypertensive drugs.
- Coronary vasodilators and drugs used in angina.
- Hypolipidemic drugs.
- Fibrinolytic agents.
- Nitric oxide.

UNIT III - **Drugs Acting on the Blood and Blood Forming Agents**

- Coagulants.
- Anticoagulants.
- Haematinics (iron, vitamin B12 and Folic acid).
- Plasma expanders.

UNIT IV - **Diuretics**

- Classification, Mechanism, side effects and uses

Suggested Readings

1.C.R.Craig and R.E.Stitzel: Modem Pharmacology 2. Theodore W.Rall, Alan S.Nies and Palmer Taylor: Goodman Gilman's : The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman. 3. D.R.Laurence and P.N.Bennett: Clinical Pharmacology. 4. K.D.Tripathi: Essentials of Medical Pharmacology. 5. R.S.Satoskar and S.D.Bhandarkar: Pharmacology and Pharmacotherapeutics. 6. F.S.K. Barar: Essentials of Pharmacotherapeuties. 7. H.P.Rang and M.M.Dale: Pharmacology

BCR-SEC03:Medical Records Management

Course objective: The course work is designed abreast the students with medical record management in a hospital set-up. The following broad topics will be covered			
Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35
UNIT 1: The Medical Records definition and contents			
1	● Definition & contents, Objectives ● Problem oriented medical record (POMR) ● Basic hospital records in detail, Obstetrics records, New born records ● Uses and values of medical records ● Functions of medical records department (MRD) ● Medical record professional duties and Responsibilities ● Medical Record Administrator and Medical Record Technician ● Medical Record Committee ● Medical staff and their responsibility for the Medical Record ● Medical Audit		
UNIT II: Electronic Health Records (EHR) – Definition			
	● Electronic Medical Records (EMR) Issues, Interoperability, Privacy, Social and organization Barriers, Technology limitation, Preservation of EMR, Benefits, obstacles to adoption, pictorial material, free text, structured text – the potions, optical mark reader (OMR), advantage of EHR over Paper Health records,		
Suggested Reading			
1	Health information and Management by Margaret A.Skuka by John Wiley & Sons 14TH March 2012		
2	Medical Records organization and management by GD Mogli;First Edition		

BCR-SEC04: Monitoring of Clinical Trial(Credits-2)		
Course objective: The course work is designed abreast the students with monitoring of Clinical Trial related activities and Good Documentation Practices. The following broad topics will be covered		
Credits	Contact hours	Marks – 50

2	32	Internal assessment	Semester examination
		15	35

UNIT I-A	**Monitoring and its Importance**
	What is monitoring, purpose of monitoring in clinical trials, On site monitoring, definition of SOP in trials, importance of SOPs in trials
UNIT I- BMonitoring Procedures	
	Monitoring procedure, Monitoring before trial, Monitoring of all trial related activities and documents during trial, monitoring during trial
UNIT II A Good Documentation Practices	
	Definition of Good Documentation Practice, Importance of GDP in clinical trials, Guidelines for GDP
UNIT – II B Quality Control Management	
	QA and QC in clinical trials, Total Quality Management, Clinical Quality Assurance unit in Clinical Trials set up
Suggested Readings	
E6-GCP guidelines	

BCR-GE04: Biopharmaceutics (Credit- 3)
Course objective: The course module is designed to provide the knowledge about pharmacokinetic parameters of drugs like absorption, distribution and bioavailability. The following broad topics will be covered

Credits	Contact hours	Marks – 75	
3	48	Internal assessment	Semester examination
		20	55

UNIT I-	**Biopharmaceutics**
	● Introduction to biopharmaceutics, definition, historical development of the subject, fundamental principles, concepts and its role in formulation development and clinical setting
UNIT II-A Drug Absorption	
	● Various mechanisms, factors affecting drug absorption-physicochemical, physiological and pharmaceutical.
UNIT II-B Drug disposition	
	● Distribution in blood, plasma -protein binding, application of drug-protein binding
UNIT III- Evaluation of Bioequivalence	
	● Determination of bioavailability and bioequivalence : Measures of bioequivalence study and single dose bioequivalence study and relevant statistics, review of regulatory requirements for conducting bioequivalence study ● Introduction to pharmacokinetics, importance in bioavailability and clinical practice. Concepts, definition and explanation of terminologies used.

Suggested Readings

1. J.G. Wagner: Text Book of Biopharmaceutics and Pharmacokinetics.
2. Shargel and Yu: Text Book of Biopharmaceutics and Pharmacokinetics (Prentice Hall).
3. Controlled drug bioavailability published by Wiley interscience.
4. Blanchard and Brodie: Principles and Perspective in drug bioavailability.
5. R.E. Notari: Biopharmaceutics and Pharmacokinetics

BCR-GE05: Pharmacoepidemiology (Credit -3)

Course objective: This module is designed to study various morbidity, mortality indicators, Pharmacoepidemiological studies and human genome projects. The following broad topics will be covered

Credits	Contact hours	Marks – 75

3	48	Internal assessment	Semester examination
		20	55

UNIT I-	
	● Measures of disease occurrence and disease association ● Morbidity indicators ● Mortality indicators ● Instruction in the research implications of evidence-based clinical medicine, including the specifications of diagnostic tests, screening tests, and prognostic tests.
UNIT II-	
	● Introduction to the concepts, principles, and use of molecular and genetic methods in epidemiology and clinical research ● Human Genome Project ● Meaning of race, ethnicity, social class, and culture, their effects on the conduct and interpretation of clinical research. ● Pharmacogenomics and its application in clinical research, GWAS
Unit III	● Pharmacoepidemiological studies

Suggested Readings

1.Epidemiology: Basis for Disease Prevention and Health Promotionby David DuncanCollier Macmillan publishers 5th edition
2.Clinical Epidemiology: The Essentialsby Robert H. Fletcher and Suzanne W. Fletcher; WHO Press;5TH Edition
3. Methods byBrian MacMahon and Thomas F. Pugh;Lippinkot William and Wilkins;2nd Edition

BCR-GE06:Medical Microbiology (Credit – 3)

Course objective: This Module is designed to provide knowledge about microorganisms, various sterility testing procedures, disinfectatnts and immunology. The following broad topics will be covered

Credits	Contact hours	Marks – 100	
3	48	Internal assessment	Semester examination
		20	55

UNIT I-	**Introduction**
	General classification of microorganisms and study of bacteria and viruses - nutrition, cultivation, isolation and identification. Effect ofmoisture, temperature, ion, light and pH on the growth of micro - organisms; bacteriological media; bacterial metabolism - EMP and TCA pathways.
UNIT II- Immuunology	
	Introduction, types of immunity, phagocytosis, antigens, antibodies, components; immune-systems humoral immunity, cellular immunity, privileged graft sites, graft host reaction; tolerance, immunogenetics; types of reactions and their application. General method of the preparation of bacterial vaccines, toxoids, viral vaccine, rickettsial vaccines, antitoxins, serum-immune, blood derivatives and other products relative to immunity. Interferon.
UNIT III A	**Disinfection**
	Classification and mode of action of disinfectants, factors influencing disinfection, dynamics of disinfection; disinfectants, antiseptics and their evaluation.
UNIT – III B	**Sterilization methods and Principles**
	Methods of sterilization- Physical, chemical, heat, radiation, gaseous, filtration. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization, sterility indicators.
UNIT-III C	**Sterility testing of pharmaceutical products**
	Sterility testing of products according to IP. Sterility testing of parenteral products - solids,liquids, ophthalmic and other sterile products according to the I.P.

Suggested Readings

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford

London.
2. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
3. Gilbert S.Banker and Christopher T. Rhodes: Modern Pharmaceutics.
4. Remington’s Pharmaceutical Sciences.

BCR-GE07: Medical Biostatistics (Credit- 3)			
Course objective: The aim of this module offers introduction to major biostatistical methods used in clinical research. Problem/Practical based learning will be followed throughout the module. The following broad topics will be covered.			
Credits	Contact hours	Marks – 75	
3	48	Internal assessment	Semester examination
		20	55
UNIT I			
	Null hypothesis, sources of variation, sampling, Data, Types of Data, Representation of Data		
UNIT II-			
	Measures of central tendency and Dispersion. Measures of Skewness and Kurtosis. Probability classical & axiomatic definition of probability, Theorems on total and compound probability, Elementary ideas of Binomial, Poisson and Normal distributions.		
UNIT III-			
	Confidence level, critical region, testing of hypothesis and standard error, large sample test and small sample test. Problems on test of significance, t-test, chi-square test for goodness of fit and analysis of variance (ANOVA) Correlation and Regression. Emphasis on examples from Biological Sciences.		
Suggested Readings			
1. Le CT (2003) Introductory biostatistics. 1st edition, John Wiley, USA 2. Glaser AN (2001) High Yield TM Biostatistics. Lippincott Williams and Wilkins, USA 3. Edmondson A and Druce D (1996) Advanced Biology Statistics, Oxford University Press. 4. Danial W (2004) Biostatistics: A foundation for Analysis in Health Sciences, John Wiley and Sons Inc.			

BCR-CC13: Pharmacology III (4 Credit)

Course objective: This module provides the understanding of drugs used for chemotherapy and vitamins. The aspects covered include information about mechanism of action, adverse drug reactions, and uses of drugs. In addition, recent updates on the drugs information to be studied

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I- Chemotherapy	
	● General principles of chemotherapy, General mechanism of action of chemotherapeutics agents. ii) Sulfonamides, Quinolones and other antibiotics (b-lactam antibiotic, aminoglycosides, macrolides, tetracyclines, chloramphenical, polypeptides).
UNIT II	**Chemotherapy II**
	● Antiprotozoal drugs. ● Antimalarials. ● Antiamoebics. ● Urinary antiseptics ● Antifungal and antiviral drugs. ● Anti-helmintics
UNIT III	**Antitubercular, Anticancer and Immunomodulator drugs**
	● Chemotherapy of tuberculosis and leprosy. ● Chemotherapy of cancer. ● Immunomodulators
UNIT IV– Vitamins	

Suggested Readings

Books Recommended Theory 1. C.R. Craig and R.E.Stitzel: Modem Pharmacology. 2. Goodman and Gilman's: The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman, Theodore W.Rall, Alan Nies and Palmer Taylor. 3. D.R. Laurence and P.N.Bennett: Clinical Pharmacology. 4. K.D.Tripathi: Essentials of Medical Pharmacology. 5. R.S.Satoskar and S.D.Rhandarkar, Pharmacology and Pharmacotherapeuties. 6. F.S.K. Barar: Essentials of Pharmacotherapeuties. 7. H.P. Rang and M.M. Dale: Pharmacology.

BCR-CC13 PR: Practicals (Credit- 2)

Course objective

In this module a basic orientation to Drug profiles, ICF and CRF preparation. Students will also be exposed to medication chart and lab investigation relevant to clinical research

Credits	Contact hours	Marks – 100	
2	32	Internal assessment	Semester examination
		15	35

UNIT I A

- Visits to hospital: Patient's history and demographics
- Medical record keeping
- Bioethics- do's and don'ts, confidentiality, cultural/social ethics

UNIT-I B

- Medication chart and ward rounds in hospital

UNIT I C

- ICF, PIL and CRF preparation

UNIT II

- Visit to research institute/CRO/SMO/National Medical Library

BCR-DSE01: Drug Regulatory Affairs(Credit- 4)

Course objective: To study the basics of the regulations of drugs, cosmetics, medical devices and biologics as per the Indian legislation. The primary goal of the course related to introduce the basic concepts of drug regulatory affairs with special emphasis on the Indian pharmaceutical legislations

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I-Drug regulatory authorities in India

- Introduction
- Organization and General Guidelines
- DCGI, CDSCO functions

UNIT II–Regulation and registration	
	● Regulation and registration of i) Drugs ii) Medical devices iii) Cosmetics iv) Biologics & Biotechnological products.
Unit III- Regulatory consideration for pre-clinical testing and clinical testing in India	
Unit IV - Regulation of generic pharmaceutical and bio similar products	
Suggested Readings	
1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare, Government of India. 2. Pharmaceutical Jurisprudence, G.K. Jani. 3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin 4. Medical Product Regulatory Affairs: Pharmaceutical, Diagnostics, Medical Devices – John J. Tobin and Gary Walsh. 5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus 6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.	

BCR-DSE02: Hospital and community Medicine (Credit – 4)			
Course objective: To study the basics of the hospital pharmacy, drug interactions, clinical pharmacy and drug distribution system. The primary goal of the course related to introduce the basic concepts of clinical pharmacy .			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75
UNIT IA	● Status of health delivery systems in India Definition and role of hospitals in the health delivery systems. Types of hospitals		
UNIT I B– Introduction to clinical pharmacy practice			
	● Definition and scope, common daily terminology used in the practice of medicine, functioning and working of clinical pharmacy unit, manpower requirements.		
Unit II A- Drug interactions of clinical important drugs			
	● Definition and Introduction, Mechanism of drug interactions, Drug - Drug Interactions with reference to Analgesics, Diuretics, Cardiovascular drugs, Gastrointestinal agents, Vitamins and Hypoglycemic drugs.		
Unit IIB- Drugs in clinical toxicity			

	● Introduction, general treatment of poisoning, systemic antidotes. Treatment of poisoning due to insecticides, heavy metals, narcotics, barbiturates, organophosphorous compounds
Unit III - Drug distribution system in Hospitals	
	● Out patients ii) In patients: Detailed discussion of (a) Unit dose dispensing (b) Floor ward stock system and satellite pharmacy services (c) Central sterile services, bed side pharmacy vi) Prepackaging.
Unit IV	● Maintenance of records of issue and use of narcotics and dangerous drugs, ward stock medicines and emergency drugs. ● Drug Information service and drug information bulletin
Suggested Readings	
1. Remington's Pharmaceutical Sciences. 2. W.E Hassan: Hospital Pharmacy. 3. Heifindal et al: Clinical Pharmacy & Therapeutics. 4. Allwood and Fell: Hospital Pharmacy. 5. P.C. Dandiya, R.K. Khar and N. Gumbani: Pharmacist year Book CBS Publisher. 6. PratibhaNand and R.K. Khar: Hospital & Clinical Pharmacy.	

BCR-DSE03: Clinical Toxicology (Credits-4)			
Course objective: To study the history of toxicology and different type of toxicants.			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75
UNIT I-	GENERAL PRINCIPLES		
	A. History of Toxicology B. Principles of Toxicology: Dose-Response Relationship C. Mechanisms of Toxicity D. General Principles of Clinical Toxicology		
UNIT II	Principles of Toxicology: Animal models as predictors of human toxicity		
UNIT III CURRENT TOPICS			
	A. Alcohols/Analgesics B. Health Risks of Tobacco and Marijuana C. Psychostimulants/Antidepressants D. Opioids		
UNIT IV			
	A) Chemical Carcinogens/Radiation B) Pulmonary/Inhalation Toxicants C) Pesticides D) Bacterial, Insect & Snake Toxins E) Heavy Metals		
Suggested Readings			
1. Regulatory Toxicology by Shayne C. Gad Taylor & Francis 2. Principles and Methods of Toxicology by A. Wallace Hayes			

BCR-DSE04: Clinical Trial Operations (Credit- 4)
Course objective: This module provides information for site selection, site conduct and site closeout of clinical trials along with the study of clinical trial project management.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I-	**Site Selection**
	Selection of Clinical trial sites, Clinical Investigators and making budget and vendor selection The roles and responsibilities of the following in CT: Sponsor, institution, Clinical Trial Coordinator, Clinical Investigator
UNIT II-	**Site Conduct**
	Site conduct: Recruitment, IP/IMP/Pharmacy file receipt and storage, CT site master file, Contingency planning to prepare for unexpected situations.
UNIT III	**Site Close Out**
	Suspending and premature termination of a trial Clinical study report, submission to ethics committee and regulatory agency
UNIT IV	**Project Management in Clinical Trials**
	Definition, Important components, Importance in CTs

Suggested Readings

ICH E6 guidelines

BCR-DSE05:Alternative System of medicines and Clinical Research (Credit-4)		
Course objective: To study the different system of medicine and role of clinical research in alternative system of medicine**.**		
Credits	Contact hours	Marks – 100

4	64	Internal assessment	Semester examination
		25	75

UNIT I-	
	Historical background of the different systems of medicines, Different traditional practices, Principles of prevention and treatment of diseases in alternative systems of medicine, Recent developments in the validation of different systems of medicine, Uses of medicinal plants and the utilization of different her
UNIT II	
	Clinical Research in alternative systems like Ayurveda, Unani
UNIT III	
	Herbal formulations Principles involved in Ayurveda, Sidha, Unani, Chinese and Homeopathic systems of medicines, preparation of Ayurvedic formulations like Aristas, Asava, Ghutika, Tailia, Churna, Avaleha, Ghrita and Bhasms; Unani formulations like Majooms, Safoofs
UNIT IV	
	Regulatory aspects and guidelines AYUSH

Suggested Readings

11.C.K. Kokate, P.P. Purohit and S.B. Gokhle: Pharmacognosy, NiraliPrakshan, Pune.
2. V.E. Tylor, L.R. Brady and S.B. Robbers: Pharmacognosy, K.M. Varghese Co. Bombay.
3 S.B.WagnerZgainsky: Plant Drug Analysis.
4. T.E. Wallis: Textbook of Pharmacognosy C.B.S. Publishers, Delhi

BCR-DSE06:Regulatory and Methods of Toxicology (Credit- 4)

Course objective: This module designed to study different regulatory guidelines for toxicity studies and animal models used for toxicity testing.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination

		25	75

UNIT I-	
	● **OECD guidelines** Introduction to various Organization for Economic Co-operation and Development (OECD) guidelines and their amendments for testing of toxicity and safety evaluation of chemicals. ● **Indian regulatory guidelines** Various Drug and Cosmetics Acts and their amendments, Schedule –Y, regulations pertaining to pre-clinical testing of drugs, regulations related to transport, storage and disposal of hazardous chemicals.
UNIT II-	
	Introduction, need of poison information centres, Poison control centres, Definition, chemical disasters, principles of disaster management. ICH and ICMR guidelines.
UNIT III	**ANIMAL MODELS OF TOXICITY TESTING**
	Importance of in vitro and in vivo testing of chemicals, Concepts and procedures of acute, chronic, subchronic toxicity testing, Mammalian models (rat, mouse, guinea pig, hamster and rabbit), Non-mammalian modes (daphnia, zebrafish), Basics of cell culture, different cell lines used in toxicological studies, Basics of toxicokinetics procedures.
UNIT – IV	● **Genotoxicity testing** Basic genetic concepts related to toxicity and carcinogenicity, Assay selection guidelines, Ames test, Single Cell Gel Electrophoresis (COMET) assay, Sister Chromatid Exchange, Micronucleus assay**.** ● **Carcinogenicity testing** Regulatory requirement for testing, Systemic approaches to testing, Rodent cancer bioassays, Cancer hazard and risk assessment
Suggested Readings	
Regulatory Toxicology by Shayne C. Gad Taylor & Francis 2. Principles and Methods of Toxicology by A. Wallace Hayes	

BCR-DSE07 PR: Project Report (Credit- 2)			
Course objective: This module designed to plan, execute and submit a project report. Project report should be 2000 words and must be related to translational and clinical research.			
Credits	Contact hours	Marks – 100	
2	32	Internal assessment	Semester examination
		15	35
Project related to any one of the following 1. BCR-DSE01 2. BCR-DSE02 3. BCR-DSE03 4. BCR-DSE04 5. BCR-DSE05 6. BCR-DSE06 The students should have undertaken the theory course			
Suggested Readings			
Pubmed, ScienceDirect Scopus			

BCR-CC14: Pharmacology IV(4 Credit)			
Course objective: This module is designed to study pharmacology of endocrine system with their drugs and classifications. All aspects related to Drugs mechanism of action, Adverse Drug Reactions and uses will be covered.			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75
UNIT I-	**Pharmacology of Endocrine System**		
	● Pituitary hormones. ● Thyroid - antithyroid drugs. ● Insulin, oral hypoglycemics and glucagons. ● Adrenocortical steroids and their antagonists. ● Sex hormones, contraceptives and drugs used in infertility. ● Drugs regulating calcium homoeostasis, bisphosphonates.Status of health delivery systems in India Definition and role of hospitals in the health delivery systems. Types of hospitals		
UNIT II- Bioassays			
	● General principles and methods of Bioassays. ● Official methods of bioassay of: Insulin, Heparin, Oxytocin, Vasopressin, ACTH, GIucagon, Gonadotrophin.		
UNIT III- Drugs Acting on Gastrointestinal System			
	● Purgatives. ● Antidiarrhoeal drugs. ● Antacids and treatment of peptic ulcers. ● Emetics and antiemetics. ● Prokinetic agents		
UNIT IV- Drugs Acting on Respiratory System			
	● Expectorants. ● Antitussive bronchodilators. ● Drugs used in common cold.		
Suggested Readings: Books Recommended Theory 1. C.R. Craig and R.E.Stitzel: Modem Pharmacology. 2. Goodman and Gilman's: The Pharmacological Basis of Therapeutics by Alfred Goodman Gilman, Theodore W.Rall, Alan Nies and Palmer Taylor. 3. D.R. Laurence and P.N.Bennett: Clinical Pharmacology. 4. K.D.Tripathi: Essentials of Medical Pharmacology. 5. R.S.Satoskar and S.D.Rhandarkar, Pharmacology and Pharmacotherapeuties. 6. F.S.K. Barar: Essentials of Pharmacotherapeuties. 7. H.P. Rang and M.M. Dale: Pharmacology			

BCR-CC15: Hospital Pharmacy and Management(4 Credit)			
Course objective: This module is designed to study personnel management, motivational theories, communication barriers and material management.			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75
UNIT-I Personnel Management and Industrial Relations			
	● Objectives and functions of personnel department, employment and development of personnel. Industrial relations: problems of labor management relations, causes of industrial disputes, remedies, industrial dispute act, trade union grievance and grievance handling procedure, causes of grievances, need for grievance procedure, grievance redressal machinery.		
UNIT II A Motivation			
	● Objectives, rules of motivation, motivation steps. Types of motivation, Financial and non-financial motivators. Theories of motivation: McGregor's Theory X and Y, Herzberg's time factor theory, McClelland's need for achievement theory, Vroom's expectancy theory, Behavioral theory, EmployeeCentered approach.		
Unit II B Communication			
	● Importance, nature of communication, types of communication- oral vs. written, media of communication. Barriers to communication. Communication failure. Achieving effective communication.		
Unit III A - Medical Stores			
	● Objectives, layout facilities; procedures for procurement of drugs and supplies from medical stores depot, manufacturer, distributor, local market, procedure and limits of emergency purchase.		
Unit III B - Pharmacy Therapeutics Committee			
	● Constitution and functions of Pharmacy therapeutics committee, hospital formulary system and its organization, functions and composition.		
Unit IV-A Materials management			
	● Materials handling, equipment, inventory management, economic ordering quantity, ABC analysis, value analysis, classification and codification of stores, obsolete, surplus and scrap management, lead time, inventory carrying costs, safety stock, solutions to problems relating to EOQ.		
Unit IV B - Drug Supply Planning and management			

	● Supply process and its pitfalls, planning for drug supply, planning models, steps to develop a formulary, predicting drug requirements, procurement cycle and its methods, designing training programs to improve pharmaceutical logistics.
Suggested Readings	
1. Remington's Pharmaceutical Sciences. 2. W.E Hassan: Hospital Pharmacy. 3. Heifindal et al: Clinical Pharmacy & Therapeutics. 4. Allwood and Fell: Hospital Pharmacy. 5. P.C. Dandiya, R.K. Khar and N. Gumbani: Pharmacist year Book CBS Publisher. 6. PratibhaNand and R.K. Khar: Hospital & Clinical Pharmacy.	

BCR-CC16: ADR and Pharmacovigilance (Credit- 4)
Course objective: This module is designed to provide information on Pharmacovigilance, basic tools for pharmacovigilance, drug monitoring and Pharmacovigilance role in drug regulation

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I-	
	● Introduction to Pharmacovigilance ● Definition and classification of ADRs ● Detection, reporting and causality assessment ● Pharmacovigilance in India and global perspective ● Pharmacovigilance methods, passive surveillance-spontaneous reports and case series ● Active surveillance-drug event monitoring and registries ● Basic tools used in pharmacovigilance ● Safety studies ● Importance of pharmacovigilance
UNIT II-	
	● Product surveillance and post marketing ● Signal detection and follow-up
UNIT III-	
	● Drug monitoring
UNIT IV-	
	● Pharmacovigilance in drug regulation
Suggested Readings	
Pharmacovigilance by Ronald D. Mann, Elizabeth Andrews; Wiley Blackwell;3RD Edition	

BCR-CC17: Packaging of formulations for CTs (Credit - 2)			
Course objective			
Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I-	**Packaging of formulations for CTs** Types of containers, materials used, closures, unit dose packaging, strip packaging materials, packaging of solid, parenterals, and ophthalmic dosage forms, stability aspects of packaging

	IP accountability for CTs:Storage, documentation and handling of IPs for CTs, IP requirement calculation, IP accountability at site
UNIT II	
	Archival of IPs, Batch manufacturing of IPs, Blinding, matching control, double dummy, randomization, GMP and CGMP for IP manufacturing.
Suggested Readings	
ICH E6 guidelines	

BCR DSE08 Th/P:Project Report

Course objective: The module will help the candidate in developing a research proposal and will give the understanding of the fundamentals involved in designing a research study. The following broad units will be covered.

Credits	Contact hours	Marks – 150	
6	96	Internal assessment	Semester examination
		50	100

Unit I:

	A project will be prescribed in the course structure in the 6th semester. Under this assignment a candidate shall be required to write a Dissertation/Drug Profile/Meta-analysis/Pharmacovigilance Report/Protocol Design/Standard Operating Procedure, of a minimum of 3000 words, on a topic allotted to him/her. Topics will be allotted in the 3rd Semester. The evaluation of dissertation shall be done at the final Examination by the Examiners as part of Viva-voce examination. Though for project work the topics shall be given in advance, the credits assigned for the project work shall be awarded at the end of 6th Semester. For project work, the Head of the Department shall call a meeting of the teachers of the Department and assign appropriate number of students to each teacher to act as the supervisor for project work. The student in consultation with the supervisor shall select a topic for the project work and inform the Head to the Department.

<table>
<tr><th colspan="5">BCR-GE08: Medical Writing (Credit – 2)</th></tr>
<tr><td colspan="5">In this module students will explore the basic skills of medical writing. Medical writing is an essential part of clinical research and drug development programme. The goal of this module is generally to provide overview in both medical science and writing fundamentals. Medical writing is the fast developing and exciting discipline that involves writing topics helpful for medical fraternity.In the end of this course the students will be able to write reports, narratives etc. The following broad topics will be covered in this module</td></tr>
<tr><td colspan="2">Credits</td><td>Contact hours</td><td colspan="2">Marks – 50</td></tr>
<tr><td colspan="2">2</td><td>32</td><td>Internal assessment</td><td>Semester examination</td></tr>
<tr><td colspan="2"></td><td></td><td>15</td><td>35</td></tr>
<tr><td colspan="5">Unit I:</td></tr>
<tr><td></td><td colspan="4">● Basic introduction to medical terminology and fundamentals of medical writing.
● Literature survey-Use of books and journals and internet.
● Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures.
● Research report and paper writing
● Plagiarism</td></tr>
<tr><td colspan="5">Unit II</td></tr>
<tr><td></td><td colspan="4">● Patient narrative preparation.
● Abstracts & manuscript.
● Writing of Clinical Study reports.
● Educational materials for subjects in clinical research
● Softwares relevant to medical writing</td></tr>
<tr><td colspan="5">Suggested Reading</td></tr>
<tr><td>1</td><td colspan="4">Guidelines for Reporting Health Research by David Moher Doughlas Altman BMJ books; August 2014</td></tr>
<tr><td>2</td><td colspan="4">Medical Writing: A Guide for Clinicians, Educators, and Researchers Second Edition; Springer 2011</td></tr>
<tr><td>3</td><td colspan="4">Medical writing a good practice guide by Justina-Orleans;WileyBlackwell 2012</td></tr>
</table>

BCR-GE09: Audits in Clinical Trial (Credit- 2)			
Course objective: In this module students will explore type of audits in clinical trials, what is the importance of audits and regulatory inspections.			
Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35
UNIT I-	**Audits and Inspections in CT**		
	Audits, its process and important aspects Types of audits Source document verification Good clinical practice and quality assurance Quality control vs. quality assurance		
UNIT II- **Auditors and their role in CT**			
	● Selection and Qualification of Auditors ● Auditing Procedures ● Regulatory Inspections		
Suggested Readings			
ICH E6 guidelines			

BCR-GE10:Regulatory aspects of medical devices (Credit -2)			
Course objective: This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.			
Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35
UNIT I-Medical Devices			

	● Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. ● History of Medical Device Regulation ● Classification of Medical Devices
UNIT II–Ethics	
	● Clinical Investigation of Medical Devices ● Clinical Investigation Plan for Medical Devices ● Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) ● Quality: Quality System Regulations of Medical Devices: ISO 13485 .
Suggested Readings	
1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus. 2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan. 3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh. 4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina. 5. Country Specific Guidelines from official websites	