

# SRI BALAJI VIDYAPEETH

(Deemed to be University Declared u/s 3 of UGC act 1956)

Accredited by NAAC with 'A' Grade

Pondicherry - 607402.

[www.sbv.ac.in](http://www.sbv.ac.in)

**MAHATMA GANDHI MEDICAL COLLEGE & RESEARCH  
INSTITUTE, PONDICHERRY**

**SHRI SATHYA SAI MEDICAL COLLEGE & RESEARCH INSTITUTE,  
KANCHEEPURAM DT**



**FACULTY OF ALLIED HEALTH SCIENCES**

**B.Sc. CLINICAL RESEARCH**

**2019 -2020 ONWARDS**

**FIRST, SECOND & THIRD YEAR SYLLABUS AND REGULATIONS**

**CHOICE BASED CREDIT SYSTEM (CBCS) PATTERN SYLLABUS**

**(As approved in the Academic Council at the meeting held on 22-05-2019)**

**Revisit of the syllabus and Examination pattern**

**(As approved in the Academic Council at the meeting held on 28-09-2020)**

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## FOREWORD

In recent years, several innovative and need based undergraduate courses in the realms of Faculty of Allied Health Sciences have been promulgated. These courses are primarily oriented towards augmenting the Core academic courses in the Health Care sector.

Although, Allied Health Science courses are in place at several institutes county wide, mention must be made of the fact that only a few Health Science Universities offer courses in Allied Health Sciences under a holistic umbrella. It is in the fitness of things that Allied Health Science courses are being offered in Nodal and Thrust areas at Sri Balaji Vidyapeeth starting from Certificate programme through Doctoral studies.

The Undergraduate programme of Allied Health Science courses leading to B.Sc degree has been very carefully planned taking all the three components into due consideration, namely academics, patient care and research. Competency assumes great importance as the graduates coming out of these programmes would either directly or indirectly assist the Clinicians in day to day activities.

With this in view, the thrust has been laid on a common syllabus for all B.Sc programmes during the first year of study. These subjects offered in the first year are oriented Basic Medical Sciences, besides English as a mode of communication which is vital for affording Global Placements to our successful candidates. Furthermore all programmes are designed in Choice Based Credit System (CBCS) made to suit the convenience of the students. The proficiency and competence of the Undergraduates is fortified by the promulgation of a unique internship cum research programme.

I wish all students success in their studies and career.

**Prof. N. Ananthakrishnan**

*Dean - Faculty, SBV*

# **POLICY ON COURSES OFFERED UNDER FACULTY OF ALLIED HEALTH SCIENCES**

## **PREAMBLE**

Sri Balaji Vidyapeeth, Deemed to be University, established under Section 3 of UGC Act, 1956, Accredited by NAAC with A Grade offers various courses under the Faculty of Medicine, Faculty of Dentistry, Faculty of Nursing Sciences and Faculty of Allied Health Sciences.

"Allied Health Professions are a distinct group of health professionals who apply their expertise to prevent disease transmission, diagnose, treat and rehabilitate people of all ages and all specialties. Together with a range of technical and support staff they may deliver direct patient care, rehabilitation, treatment, diagnostics and health improvement interventions to restore and maintain optimal physical, sensory, psychological, cognitive and social functions." - Organization of International Chief Health Professions Officers (ICHPO).

In March 2011, the Ministry of Health and Family Welfare nominated the Public Health Foundation of India (PHFI) as its technical partner and constituted the National Initiative for Allied Health Sciences (NIAHS) secretariat with a mandate to develop a framework to improve allied health training, education and regulation in the country. (Yet to be notified by Government of India).

Sri Balaji Vidyapeeth has introduced several innovative need based courses under the Faculty of Allied Health Sciences at Undergraduate and Postgraduate levels keeping in mind the initiative of Ministry of Health & Family Welfare, Government of India. In an era marked by expanding global job opportunities, these courses are bound to create an awareness among the students to suit themselves in the Health Care Team. Curricula have been designed in an objective manner and are aimed at cognitive, affective and psychomotor domains of learning. Furthermore all courses are designed in Choice Based Credit System (CBCS) made to suit the convenience of the students.

The Undergraduate courses mainly concentrate in creating professionals who form the part of the Health Care Team. The role of these professional is to ably assist the doctor in treatment as well as prognosis and in many a times form the core professional of the team. The proficiency and competence of the Undergraduates is fortified by the promulgation of a unique internship cum research programme.

The Postgraduate courses mainly aim at shaping a graduate into a full professional. Also these postgraduate courses help the graduates as well as the postgraduates to acquire specific skills on various adjunct therapies and techniques.

## **SUPPLY AND DEMAND**

The starting of the new courses will entirely depend on

- a. Demand for the course as seen by the enrolment at other institutes.
- b. Employability after the qualification.

At present, the shortage of quality human resources is one of the major challenges faced by the public health domain in India. To redress the imbalance in human resources, the Working Group on Medical Education Training and Manpower Training of the Planning Commission (1984) prioritized training of para-professional and auxiliary personnel as follows:

- Training and development of auxiliary health professionals
- Training and development of para-health professionals
- Basic and pre-service/induction training in health care and health management
- Continuing education in health profession education.

Many new health occupations (Physician's Assistant, Optometrists, Medical Imaging Technologists, and Laboratory Technologists etc) have access over several common features in Allied Health Sciences including Basic Medical Sciences which are being effectively addressed. These processes have received support from administrators who are constantly searching for economic qualified and quality labor.

Service users are becoming more empowered through the consumerism of health, which has resulted in better access to information and user-consultation in service development and delivery. Each of these factors has the potential to influence the roles of existing professional groups and presents a challenge to workforce planners. In India, students are not aware of all the allied health courses available in the medical education system. Their career choices are generally influenced by their parents and peer groups, who themselves are unaware of the prospects in this area. By understanding that an entry-level position is just a first step, youth can realistically plan for their future and have a better understanding of what is needed for long-term success. This approach also benefits employers who need a steady inflow of workers at all levels of their organization.

#### **POLICY ON ELIGIBILITY, ADMISSION, & COURSE DURATION OF UG DEGREE COURSES**

At Sri Balaji Vidyapeeth, we empower the departments of all the constituent colleges to contribute to the development of innovative, need, value based and job oriented courses taking into considerations the interests of the stakeholders.

**The Undergraduate Degree courses (B.Sc.)** are presently being offered under the Choice Based Credit System (CBCS) mode as per the Guidelines of UGC. The duration of the course will be Three years with a compulsory internship of 1 year (Non Stipendiary) in any of the tertiary health care institute of the University/ Trust. The proficiency and competence of the Undergraduates is fortified by the promulgation mandatory for appearing at the University Examinations. The maximum time limit for completion of the course will be Six years. However, the Dean / Principal, AHS has the discretionary powers to extend the course duration on valid grounds (Health, Maternity, Natural Disaster, etc.).

The First year of B.Sc. (AHS) courses will be common for all the disciplines. Though the disciplines will be provisionally allotted at the time of admission itself, upon

successful completion of the First year the candidates may opt for a change in the discipline or the college which will be permitted depending on the vacancy and on merit based on the First year marks.

### **Fourth year - Internship Programme**

One-year compulsory internship in various intensive care units, outpatient departments, research center under Sri Balaji Vidyapeeth during which the students get to hone the skills and knowledge acquired in the three years of study. This year ensures their readiness to approach a patient in any setting. The students should also complete a short duration project (in their areas of interest) and also maintain and submit a log book. The degree will be awarded only upon the successful completion of the course including the internship period. The one-year compulsory internship includes postings at the respective department.

### **Eligibility for Admission**

A candidate seeking admission in the B.Sc. Allied Health Sciences courses shall be completing the age of 17 years as on December of the admission year. The candidate shall have passed the Higher Secondary Examinations conducted by the State Board or the Central Board or its equivalent. The candidate should have studied English as one of the papers and passed the same. The candidate should have had Biology, Physics & Chemistry and have passed the same in their qualifying Examinations. Mathematics as a subject is mandatory for B.Sc. Optometry, Medical Imaging Technology and Clinical Research.

The candidate should have secured 50 percent as aggregate in the subjects of English, Biology, Physics and Chemistry at the Higher Secondary Examinations. A relaxation of 5 percent in the minimum required (50%) shall be awarded to the candidates belonging to SC/ ST communities and physically challenged candidates (Disability more than 40%). The candidates seeking relaxation should necessarily submit the relevant certificates issued by the concerned Government authorities while applying for the course and mention about the same in their application.

### **Lateral Entry**

Candidates who have Diploma of Two years in the concerned subject from a recognized University can seek Lateral Entry to the second year of the concerned courses provided that they have studied Anatomy, Biochemistry, Physiology, Microbiology and Pathology as individual papers during their Diploma Course.

**Note:** The candidates who have completed their Diploma Course through Distance Education modes are not eligible to seek admission through Lateral Entry mode.

**Shorter intrinsic training programmes** of duration few weeks to a month or so will be conducted by the departments under the Supervision of the concerned HOD / Dean / Principal.

### **POLICY ON CHANGE OF NAME/DATE OF BIRTH**

The name and date of birth of candidates will be registered in the records of the University as given in their H.S.C. Mark Statement/Transfer Certificate only. No request will be considered later, to correct the spelling of the name of the candidates.

The parents and candidates are requested to verify and confirm these entries in the H.S.C. Mark Statement / Transfer Certificate at the time of receipt of the same. Once admitted to a course of study in the University, date of birth as furnished in the HSC/School record of student and submitted to the University at the time of admission, shall be taken as final proof and no subsequent request for change of date of birth will be entertained by the University at any time under any circumstance, either during the course of study or after the completion of such study. The student should take utmost care while entering their details in SBV GARUDA portal at the time of their registration. They are responsible for any data mismatch at later stage.

Every student shall give an undertaking to this effect duly countersigned by his/her parent or guardian at the time of admission.

### **PAYMENT OF TUITION AND OTHERFEES**

Every student shall pay tuition fee and other fee, as prescribed by the University, within the due date notified. The fees are subject to revision as per rules of the University. All fees, once paid to the University, will not be refunded or adjusted for any other purpose under any circumstance.

### **RULES FOR DISCONTINUANCE FROM COURSE OF STUDY**

Where any student applies for discontinuance, or without any application discontinues on his/her own, from the course to which he/she has been admitted to, for any reason, either after the cut-off date prescribed by the statutory authorities/ University for admission to the first year of the course concerned or where the seat is rendered vacant without having any chance of being filled up with any other candidate from waiting list etc., such students will have to remit the tuition fee and other applicable fees for the 'Entire/Remaining Course Period'. Unless and until payment of all the prescribed fees for the entire/remaining course period is made to the University account, such student shall not be entitled to any certificate including transfer certificate, mark sheets etc., to be issued by the College/ University and to get back his/her original certificates deposited with the University at the time of admission. All students and parent will be required to furnish a declaration agreeing to the above said conditions at the time of admission.

### **POLICY ON RAGGING**

Ragging is strictly prohibited in the University Campus. Sri Balaji Vidyapeeth strictly enforces anti-ragging measures and the campus is free from any form of ragging. Any violation will be dealt with according to the law in force and as per directives of the Supreme Court of India. The University has adopted the –Medical Council of India (Prevention and Prohibition of ragging in Medical College / Institutions) Regulations, 2009 and –UGC Regulations on curbing the menace of Ragging in Higher Educational

Institutions, 2009 and these Regulations shall be applicable to all students. These Regulations are available in the University Website.

### **IMPORTANT NOTE**

All admissions are subject to fulfillment of all the prescribed eligibility conditions by the candidate. If it is found either at the time of admission or at a later stage, that the candidate has given false information/forged certificates or concealed material information, his/her admission shall be cancelled and the student shall be dismissed from the college immediately.

The University reserves the right to change the curriculum, course structure and the rules relating to admission, examinations, fee structure, refunds, etc.

All disputes arising in the interpretation and implementation of the provisions will be referred to the Vice-Chancellor of Sri Balaji Vidyapeeth and Vice-Chancellor's decision shall be final and binding.

In respect of matters relating to or arising out of this prospectus the jurisdiction shall lie in Puducherry alone.

### **FUTURE PLANS**

It is planned to conduct an informal market survey and start AHS Certificate & M.Sc courses.



## OUTLINE OF THE CHOICE BASED CREDIT SYSTEM (CBCS) FOR UNDERGRADUATE DEGREE PROGRAMME

**Credit System Credit System (CBCS):** The CBCS provides choice for students to select from the prescribed courses (core, elective or minor or soft skill courses). This is to enhance the quality and mobility of the students within and between the Universities in the country and abroad.

### Credit hours

16 Theory classes = 1 credit

32 Practical/Tutorial/Clinical training/Research project = 1 credit

Subjects	Credits
Each core subjects	6 Credits
Ability Enhancement Compulsory course (AECC)	2 Credits
Skill Enhancement course (SEC)	2 Credits
Generic Elective course ( GE)	4 Credits
Discipline Electives (DE)	4 Credits

**Core course:** A Hard core course may be a Theory, Practical (lab), clinical rotation/field work or Research Project Work which are compulsory component studied by candidate to complete the requirement of their programme.

**Discipline Elective (DE) Course:** An elective course which is supportive or related to the discipline/subject (i.e. supportive to core course) is called a Discipline Elective (DSE) Course.

**Generic Elective (GE) Course:** An elective course which is unrelated to the discipline/subject (i.e. unrelated to core course) to expand their knowledge chosen by a candidate is called a Generic Elective.

**Skill Enhancement Courses (SEC):** This course chosen by candidate which provides additional value-based and skill-based knowledge to increase their employability.

**NPTEL/ SWAYAM / MOOC/ Other value-added online courses**

COLLEGES	PROGRAMMES WHICH INVOLVE CREDIT TRANSFER
Mahatma Gandhi Medical College and Research Institute & Shri Sathya Sai Medical College and Research Institute	B. Sc. (AHS)

Each Undergraduate student of B.Sc (AHS) is recommended to earn a minimum of **EIGHT credits** from the online courses offered through SWAYAM - NPTEL - MOOCs platform during their Course period. It is to be noted that the student earns the credit prior to the starting of their internship.

PROGRAMME	DESIRABLE CREDITS	NUMBER OF COURSES
B.Sc. (AHS)	Minimum - 8 credits	Minimum - 4 Maximum - 6

It is required of the Undergraduate students (B.Sc - AHS) that in addition to their curricular requirement of the programme, it is recommended for enhancing job opportunities for the student to earn minimum of prescribed credits from the online courses offered through SWAYAN - NPTEL - MOOCs platform that will be transferred into the students' Statement of Marks, issued during the final year of their study. This has to be completed prior to the starting of their internship programme and students have to be informed that **those who do not earn the minimum credits prescribed by SBV, it will be mentioned NIL for the details on credits transferred from ONLINE courses in their FINAL year statement of marks issued by SBV.**

#### **Credit points during Internship**

For the 16 UG Internship programmes, there is a Minimum of 40 Credit points to a maximum of 45 Credit points which the students have to obtain. Credit points will be assessed based on the student's satisfactory attendance, performance in the Clinical /Camp postings / Seminars /Presentation of the logbook & Research project.

### **CRITERIA FOR UNIVERSITY EXAMINATIONS**

#### **Eligibility / Maximum Duration for the Award of the Degree**

- a) The candidates shall be eligible for the bachelor degree when they have undergone the prescribed course of study for a period of not less than four years (3 Years + 1 Year Internship) in an institution approved by the university and have passed the prescribed examination in all subjects.
- b) A student who does not meet the minimum attendance requirement in a year must compensate the inadequacies before appearing examination.

#### **To reaffirm the passing minimum in the University Examinations for all the Undergraduate courses offered under the Faculty of Allied Health Sciences.**

- A candidate shall secure a minimum of 50% aggregate in University Core theory/ Elective theory Exams and Internal Assessment put together.
- A candidate shall secure a minimum of 50% aggregate in University Practical and Internal Assessment put together.
- For Skill based electives, a candidate shall secure a minimum of 50% aggregate in University Practical cum Viva Exams and Internal Assessment put together.

#### **Retotaling / Revaluation and Grace Mark**

There is no provision for **Retotaling / Revaluation for AHS programme.**

**Grace marks** up to a maximum of five marks may be awarded at the discretion of the university to a student who has failed and shall be distributed among the failed subjects.

## SCHEME OF EXAMINATION

- 1) **Attendance Requirements:** 80% hours of learning in each Core Subjects / Electives / Practical's / Postings for appearing for the university exams.
- 2) **Minimum marks required to be eligible for University Examination:** 35% marks in the internal assessment (Theory / Practical) are required for the candidate to be eligible to appear in the University Examinations.
- 3) **Passing Minimum:** 50% aggregate both in theory and practical's including internal assessment marks is required for a candidate to pass in the University Examinations.
- 4) **Submission of Record Note Books for practical examinations**  
Candidates appearing for practical examinations should submit bonafide Record Note Books prescribed for practical examinations, otherwise the candidates shall not be permitted to appear for the practical examinations.

## GRADING

Marks obtained by candidate	Equivalent grade letter	Grade descriptor	Grade point
85 % & above	O	Outstanding	10
75-84	A+	Excellent	9
65-74	A	Very good	8
60-64	B+	Good	7
55-59	B	Above average	6
50-54	C	Average pass	5
49 & below	F	Reappear	0
	AB	Absent	0

A student obtaining **Grade F** shall be considered failed and will be required to reappear in the examination.

### Conversion formula for Percentage to CGPA

Percentage divided by 9.5 = CGPA

### Award of Class

#### Class division will be based on CGPA grade

- ≥ 7.8 grade point = Distinction Division
- ≥ 6.8 and < 7.7 grade point = First class Division
- ≥ 6.3 and < 6.7 grade point = Second class Division
- ≥ 5.2 and < 6.2 grade point = Third class Division
- < 5.2 and below - Fail

Computation of SGPA and CGPA will be in accordance with the UGC Guidelines & Recommendations. It is a measure of overall cumulative performance of a student over all exams. The CGPA is the ratio of total credit points secured by a student in various courses in all exams and the sum of the total credits of all courses in all the University exams. It is expressed up to two decimal places.

**Cumulative Grade Point Average (CGPA):** It is a measure of overall cumulative performance of a student over all exams. The CGPA is the ratio of total credit points secured by a student in various courses in all exams and the sum of the total credits of all courses in all the University exams. It is expressed up to two decimal places.

**Grade Point:** It is a numerical weight allotted to each letter grade on a 10-point scale.

**Transcript:** Based on the credits earned, a transcript shall be issued to all the registered students after the completion of the program indicating the hours of study and structure of the curriculum delivery as prescribed in his/her curriculum and completed by the student. The transcript will display the course details, including course code, title, and number of credits, hours and type of contact hours in a semester.

### INTERNAL ASSESSMENT

1. Continuous Internal Assessment (CIA) for all AHS programs with a minimum of 4 Assessments per year.
2. Internal Assessment will be done in each subject according to the scheme of examinations. The IA marks will be on the basis of performance in the assignment, class tests and practical test in the clinical areas.

### Evaluation of Clinical Rotation

Lab, Clinical cum Community postings - To conduct practical's or viva based on the Heads of the concerned department's decision and the total 100 marks to be sent to COE through proper channel to find a place in the transcript.

### Question Paper Pattern

The following question paper patterns shall be followed for CBCS pattern syllabi for the candidates admitted from the academic year 2019-20 onwards.

### CORE SUBJECTS

For **UG NON-SEMESTER COURSES** - Each Core Subjects University Exam carries -100 marks of 80(Theory) + 20 (IA marks) which consists of

Theory - 80 marks			
I	Essay-type questions of either / or type -(like 1.a (or) 1.b)	2 (of either / or type)	2 x 10=20
II	Short answer questions	6 ( *1 choice)	5 x 6=30
II	Very Short answer questions	12 ( *2 choice)	10 x 3=30

The University duration of 80 marks - 3 Hours For courses having Section A & Section B Subjects

For **Section A & Section B Subjects** University Exam carries - 50 marks for each Section consisting of 40 (Theory marks) + 10 (IA marks)

Theory - 40 marks			
I	Essay-type questions of either / or type -(like 1.a (or) 1.b)	1 (of either / or type)	1 x 10 = 10
II	Short answer questions	5 ( *2 choice)	3 x 6= 18
II	Very Short answer questions	5 ( *1 choice)	4 x 3 = 12

## **ELECTIVE SUBJECTS**

For all UG NON SEMESTER **COMPULSORY, GENERIC & DISCIPLINE** Elective University Exam papers carries- 50 marks of 40 (Theory)+10 (IA marks) which consists of

<b>Theory - 40 marks</b>			
I	Short answer questions	5 ( *3 choice)	5 x 6=30
II	Very Short answer questions	5 ( *2 choice)	5 x 2=10

\* Number of choices given

- For **SKILL BASED ELECTIVES** from 2019-20 batch onwards all UG AHS courses will have 40 marks as university Practical cum Viva examination & 10 marks as Internal Assessment = 50 marks.
- 50 marks of the **COMPULSORY, GENERIC, DISCIPLINE & SKILL BASED ELECTIVES** which will be converted to 100 marks in the transcript.

### **CONDONATION FOR SHORTAGE OF ATTENDANCE**

Condonation of shortage of attendance in aggregate up to 10% in each Year may be granted by the college Academic Committee and as per regulations of university.

## **PROGRAM OUTCOME (PO) - B.SC CLINICAL RESEARCH**

**CR-PO1:** Performs the duty as a Technologist, with leadership qualities having a good written & communication skills and also skilled at computer applications including E-library

**CR-PO2:** To gain knowledge about laboratory safety precautions, biomedical waste management adhering to the environmental needs of the society, and preventing the spread of infectious diseases

**CR-PO3:** Understanding the structure and functions of different organs in normal human body.

**CR-PO4:** To learn the general Biochemistry, Microbiology and Pathology, gaining expertise in Clinical Laboratory practices.

**CR-PO5:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CR-PO6:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CR-PO7:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial participants

**CR-PO8:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CR-PO9:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CR-PO10:** Develop the key skills and knowledge needed to operate an effective drug safety program.

**CR-PO11:** To identify various life style disorders and with due counselling & guidance advising the patients with proper diet, hygiene and Yoga to keep the body, mind, soul and behavior healthy.

**I YEAR**

**FACULTY OF ALLIED HEALTH SCIENCES**

**SRI BALAJI VIDYAPEETH**

**(Deemed to be University)**

**Accredited by NAAC with 'A' Grade**

**COMMON SYLLABUS FOR ALL FIRST YEAR B.Sc. ALLIED HEALTH SCIENCES**

**CORE SUBJECTS**

1. Anatomy
2. Physiology
3. Biochemistry
4. Pathology & Microbiology

**ELECTIVES**

**Ability Enhancement compulsory course (AECC)**

1. English

**Skill enhancement course (SEC) - Choose any TWO**

1. Culinary Skills for optimal nutrition
2. Enhancing soft skill & personality
3. Basics of Yoga & Practice
4. Speaking effectively

**Generic Elective Course (GEC) - Choose any ONE**

1. Basics of Hospital Administration
2. Counseling and Guidance
3. Lifestyle Disorders



## SCHEME OF CREDIT BASED ACADEMIC CURRICULUM

Faculty Code	Category	Course Title	Hours					Credits				
			Theory	Practical	Tutorials	Lab training	Total hours	Lecture (L)	Practical	Tutorials	Lab training	Credits
AHS	Core theory CCT	Subjects										
AHS	CCT-1	Anatomy	80		32			5		1		6
AHS	CCT-2	Physiology	80		32			5		1		6
AHS	CCT-3	Biochemistry	80		32			5		1		6
AHS	CCT-4	Pathology	40		16			5		1		6
AHS		Microbiology	40		16							
AHS	Lab training CCT 1 to 4					192					6	6
AHS	AECC	English	16	34				1	1			2
AHS	SEC - 1-3	Student's choice	16	32				1	1			2
AHS	SEC - 1-3	Student's choice	16	32				1	1			2
AHS	GEC 1-3	Student's choice	64					4				4
			<b>432</b>	<b>98</b>	<b>128</b>	<b>192</b>	<b>850</b>	<b>27</b>	<b>3</b>	<b>4</b>	<b>6</b>	<b>40</b>

## SCHEME OF EXAMINATION AHS - I YEAR BASIC SCIENCES

Papers	Subject	Theory		Practical		Theory	Practical	Grand Total (900)	Min marks to pass % (450)
		UE	IA	UE	IA	UIA*	UIA*		
CCT-1	Anatomy	80	20					100	50
CCT-2	Physiology	80	20					100	50
CCT-3	Biochemistry	80	20					100	50
CCT-4	Pathology	40	10					100	50
	Microbiology	40	10						
CCT -LT	Lab training Core 1 to 4						100	100	50
AECC	Ability enhancement Compulsory Course- English	80	20					100	50
SEC	Skill enhancement Course	80	20					100	50
SEC	Skill enhancement Course	80	20					100	50
GEC	Generic elective	80	20					100	50

**\*UIA - University Internal Assessment only for Lab Trainings (No Final University Examination).**

**Passing criteria** -50 % aggregate both in theory and practical's including internal assessment marks

For all elective course, 40 marks for university theory and Practical cum Viva examination & 10 marks as Internal Assessment = 50 marks which will be converted to 100 marks in the transcript

# **ANATOMY**

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES - ANATOMY**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: ANATOMY</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 80 Hrs</b>
<b>DURATION OF TUTORIAL SESSIONS</b>	<b>: 32 Hrs</b>
<b>DURATION OF LAB TRAINING</b>	<b>: 40 Hrs</b>
<b>EXAMINATION</b>	<b>: 100 Marks (80 U + 20IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 3 Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE DESCRIPTION**

The course is designed to assist students to acquire knowledge of the normal structure of human body and its functions. To ensure that the students understand the alteration in anatomical structure and function in disease in the practice of accident and emergency care technology.

**OBJECTIVES**

At the end of the course, the student will be able to

1. Describe the anatomical terms, organization of human body and structure of cell, tissue, membranes and glands.
2. Describe the structure and functions of bones and joints.
3. Describe the structure and functions of systems in body. Have knowledge about Applied Anatomy

**COURSE OUTCOMES FOR ANATOMY**

At the end of the course, students will be able to...

**AN-AHS-CO1:** Explains the Gross and Microscopic structure of human body.

**AN-AHS-CO2:** Explains the normal structure and integration of the functions of the organs and systems on basis of the structure of Human body.

**AN-AHS-CO3:** Explains the clinical correlation of the organs and structures involved and interprets the anatomical basis of the disease presentations.

**AN-AHS-CO4:** Knows about the General development of human body.

**AN-AHS-CO5:** Outlines the knowing of the hard & soft structures of the body.

UNIT	TITLE	THEORY + TUTORIALS (80 + 32)HOURS
I	<p><b>(a) INTRODUCTION TO HUMAN BODY AS AWHOLE</b></p> <ul style="list-style-type: none"> <li>• Terms of location, positions and planes</li> <li>• Cell and its organelles</li> <li>• Epithelium - Definition, classification, description with examples and functions.</li> <li>• Glands-Classification, description of Serous and Mucous glands with examples.</li> <li>• Basic tissues - Classification with examples.</li> </ul> <p><b>(b) LOCOMOTION AND SUPPORT</b></p> <ul style="list-style-type: none"> <li>• Cartilage - Different types with examples and Histology.</li> <li>• Bone - Classification, Names of bone cells, parts of Long bone, Microscopy of Compact bone, Names of all bones, Vertebral column, Intervertebral disc, Fontanelles of Fetal Skull.</li> <li>• Joints-Classification of Joints with examples, Synovial Joints (in detail for Medical Imaging Technology students)</li> <li>• Muscular system: Classification of Muscular tissue and histology.</li> <li>• Names of the muscles of the body.</li> </ul>	20 + 8
II	<p><b>UNIT (a) CARDIO VASCULAR SYSTEM</b></p> <ul style="list-style-type: none"> <li>• Heart Size, Location, Chambers - Exterior &amp; Interior - conducting System and Valves</li> <li>• Blood supply of heart</li> <li>• Systemic &amp; Pulmonary circulation</li> <li>• Branches of Aorta, Common Carotid artery, Subclavian artery, Axillary artery, Brachial artery, Superficial Palmar arch, Femoral artery and Internal Iliac artery.</li> <li>• Peripheral pulse</li> <li>• Inferior Venacava, Portal vein and Porto systemic anastomosis.</li> <li>• Great Saphenous vein</li> <li>• Dural Venous Sinuses</li> <li>• Lymphatic System - Cisterna Chyli and Thoracic duct.</li> <li>• Names of regionallymphatics, axillary and inguinal lymph nodes in brief.</li> </ul> <p><b>(b) RESPIRATORY SYSTEM</b></p> <ul style="list-style-type: none"> <li>• Parts of Respiratory System, Nose, Nasal Cavity, Larynx, Trachea, Lungs, Broncho pulmonary segments</li> <li>• Histology of Trachea, Lung and Pleura</li> <li>• Names of Para nasal air sinuses</li> </ul>	20 + 5
III	<p><b>(a) GASTRO- INTESTINAL SYSTEM - (10 +5hrs)</b></p> <ul style="list-style-type: none"> <li>• Parts of GIT, Oral cavity (Tongue, Tonsil, Dentition, Pharynx, Salivary glands, Waldeyer's ring)</li> <li>• Oesophagus, Stomach, Small &amp; Large Intestine, Liver, Gall Bladder, Pancreas</li> </ul> <p><b>(b) URINARY SYSTEM - - (5hrs)</b></p> <ul style="list-style-type: none"> <li>• Kidney, Ureter, Urinary bladder, Male &amp; Female Urethra</li> </ul>	10 + 5

IV	<p><b>(a) REPRODUCTIVE SYSTEM - (10 +2hrs)</b></p> <ul style="list-style-type: none"> <li>• Parts of Male Reproductive system, Testis, Vas deferens, Epididymis, Prostate</li> <li>• Parts of Female Reproductive System, Uterus, Fallopian tubes, Ovary</li> <li>• Mammary gland</li> </ul> <p><b>(b) ENDOCRINE GLANDS - (5hrs)</b></p> <ul style="list-style-type: none"> <li>• Names of all Endocrine glands in detail on Pituitary Gland, Thyroid Gland, Parathyroid gland and Suprarenal Gland.</li> </ul>	10 + 5
V	<p><b>NERVOUS SYSTEM - (15 +2 hrs)</b></p> <ul style="list-style-type: none"> <li>• Cerebrum, Cerebellum, Mid brain, Pons, Medulla Oblongata, Spinal cord with spinal nerve</li> <li>• Meninges, Ventricles and Cerebrospinal fluid</li> <li>• Names of Basal nuclei</li> <li>• Blood Supply of Brain</li> <li>• Cranial Nerves</li> </ul>	10 + 5
VI	<p><b>(a) EMBRYOLOGY</b></p> <ul style="list-style-type: none"> <li>• Spermatogenesis and Oogenesis</li> <li>• Ovulation, Fertilization</li> <li>• Fetal Circulation</li> <li>• Placenta</li> </ul> <p><b>(b) COURSE SPECIFIC TOPICS</b></p> <ul style="list-style-type: none"> <li>• Skin</li> <li>• Eye</li> <li>• Arterial System and Venous Drainage System in detail</li> </ul>	10 + 4

#### LAB TRAINING (40 hrs)

- Histology of Types of Epithelium
- Histology of Serous, Mucous and Mixed Salivary gland
- Histology of the types of Cartilage
- Demo of all bones showing parts, radiographs of normal bones & Joints
- Histology of Skeletal (TS & LS), Smooth and Cardiac muscle
- Demonstration of Heart and Vessels of the body
- Histology of Large artery, Medium sized artery and vein, Large Vein
- Microscopic appearance of Large and Medium sized Artery and Vein, Large Vein
- Demonstration of all muscles of the body
- Pericardium
- Histology of Lymph node, Spleen, Tonsil and Thymus
- Demonstration of parts of Respiratory system
- Normal Chest radiograph showing Heart shadows
- Histology of Lung and Trachea
- Normal Angiograms
- Histology of Lymphatic tissues
- Radiographs of Abdomen - IVP, Retrograde cystogram
- Demonstration of parts of the Urinary system and Histology of Kidney, Ureter and Urinary bladder

- Demonstration of Male and Female Pelvis with organs in situ.
- Histology of Male and Female Reproductive organs
- Histology of Pituitary, Thyroid, parathyroid and Suprarenal glands
- Histology of peripheral nerve and optic nerve.
- Demo of all parts of brain

#### METHODS OF TEACHING

- Lecture cum discussion
- Demonstration
- Lab visit
- Practical work record

#### METHODS OF EVALUATION

- Written Test
- Laboratory observation Book
- Assignments
- Oral Presentations

#### REFERENCE BOOKS

- Cohen, Memmler: Structure & Function of Human Body, Lippincott Williams & Wilkins; Tenth edition(2012)
- Waugh: Ross & Wilson Anatomy & Physiology in health and illness Penguin Books Ltd(2010)
- Tortora: Anatomy & Physiology, John Wiley & Sons(2012)

#### B.Sc. ALLIED HEALTH SCIENCES - ANATOMY - BLUE PRINT

Unit No.	Unit	Weightage	Marks Allotted	Knowledge / Recall			Understanding			Application		
				LAQ	SAQ	VSAQ	LAQ	SAQ	VSAQ	LAQ	SAQ	VSAQ
1	I	14 %	12	...	1	1	---	---	1	---	---	---
2	II	20 %	16	1		1	1*		----	---	---	1
3	III	20 %	15	1*	1	1	--	1	----	---	---	1*
4	IV	20 %	16	--	--	1	1	1*	1*	---	----	1
5	V	14 %	12	---	1	---	---	--	1	---	---	1
6	VI	12 %	9	---	1	---	---	--	1	---	---	--

## LONG ANSWER QUESTIONS

S.No	Unit wise	Type of Question	Question has to ask
1	CVS / Respiratory System / GIT	Knowledge / Understanding	2
2	Urinary system / Reproductive system / Endocrine system	Knowledge / Understanding	2

## SHORT ANSWER QUESTIONS

S. No	Unit wise	Type of Question	Question has to ask
1	Unit - I	Recall	1
2	Unit - II	Understanding	-
3	Unit - III	Understanding + Recall	2
4	Unit - IV	Understanding / Recall	1
5	Unit - V	Understanding	1
6	Unit - VI	Understanding / Recall	1

## VERY SHORT ANSWER QUESTIONS

S.No	Unit wise	Type of Question	Question has to ask
1	Unit - I	Understanding / Recall	2
2	Unit - II	Understanding + Recall	2
3	Unit - III	Understanding + Recall + Application	2
4	Unit - IV	Understanding + Recall + Application	3
5	Unit - V	Understanding + Application	2
6	Unit - VI	Understanding / Application	1

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 100 marks.

Long Answer Questions	: 2 X 10 = 20 marks (Choice 2 out of 4)
Short Answer Questions	: 5 X 6 = 30 marks (Choice 5 out of 6)
Very Short Answer Questions	: 10 X 3 = 30 marks (Choice 10 out of 12)
TOTAL	= Theory 80 + IA 20 = 100marks



**MODEL QUESTION PAPER**  
**FIRST YEAR B.Sc. ALLIED HEALTH SCIENCES**  
**ANATOMY**

**Time:3 Hours**

**Maximum Marks:80**

Illustrate your answers with suitable diagrams where ever necessary.

**LONG ANSWER QUESTIONS - (Write any Two) (2 X 10 =20)**

1. (A) Explain the Gross features of Right atrium. (OR)  
(B) Explain the Gross features of Stomach.
2. (A) Explain the Gross features of Kidney. (OR)  
(B) Explain the Gross features of Thyroid gland.

**SHORT ANSWER QUESTIONS - (Write any Five) (5 x 6=30)**

1. Discuss the Classification of joints with its examples.
2. Discuss the boundaries and contents of superior Mediastinum.
3. Discuss the gross features of Right lung.
4. Discuss the external & internal features of 2<sup>nd</sup> part of Duodenum.
5. Discuss the location, external features of urinary bladder.
6. Discuss the supports of uterus.

**VERY SHORT ANSWER QUESTIONS - (Write any Ten) (10 x3 =30)**

1. Write a note on Sesamoid bone.
2. Trace the conducting system of Heart.
3. List out the paranasal air sinuses.
4. Write a note on Pancreatic duct.
5. List out the parts & functions of extra hepatic biliary apparatus.
6. Write a note on Trigone of urinary bladder.
7. Enumerate the Ovarian follicles.
8. Enumerate the hormones of Adrenal gland.
9. Enumerate the layers of Scrotum.
10. List out the meningeal layers & its modifications.
11. Structure of thin skin.
12. Write a note on Fertilization

# PHYSIOLOGY

**SYLLABUS FOR I YEAR  
B.Sc. ALLIED HEALTH SCIENCES - PHYSIOLOGY**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: PHYSIOLOGY</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 80 Hrs</b>
<b>DURATION OF TUTORIAL SESSIONS</b>	<b>: 32 Hrs</b>
<b>DURATION OF LAB TRAINING</b>	<b>: 38 Hrs</b>
<b>THEORY EXAMINATION</b>	<b>: 100 Marks (80 U + 20IA)</b>
<b>UNIVERSITY PRACTICAL EXAMINATION</b>	<b>: NIL</b>
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 3 Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE DESCRIPTION**

The course is designed to assist students to acquire the knowledge of the normal physiology of various human body systems and understand the alteration in physiology in disease and practice of accident and emergency care technology

**COURSE OBJECTIVES**

At the end of the course, the student will be able to

- Describe the physiology of cell, tissues, membranes and glands.
- Describe the physiology of blood and functions of heart.
- Demonstrate blood cell count, coagulation, grouping, Hb; BP and Pulse monitoring
- Describe the physiology and mechanism of respiration.
- Demonstrate Spirometry
- Describe the physiology of Excretory system

**COURSE OUTCOMES FOR PHYSIOLOGY**

At the end of the course, students will be able to...

**PHY-AHS-CO1:** Understand normal structure and functioning of the organs and organ systems of the body

**PHY-AHS-CO2:** Understand the regulatory mechanisms in normal and physiological variations.

**PHY-AHS-CO3:** Understand age-related physiological changes in the organ functions that reflect normal growth and development.

**PHY-AHS-CO 4:** Understand the physiological basis of diseases.

**PHY-AHS- CO 5:** Interpret laboratory data pertaining to normal function of organ and organ system.

UNIT	TITLE	THEORY + TUTORIALS (80+32) HOURS
I	<p><b>a. General physiology (5 + 2hrs)</b></p> <ul style="list-style-type: none"> <li>• Structure and functions of cell and cell organelles</li> <li>• Transport across cell membrane</li> <li>• Homeostasis: definition and feedback mechanisms</li> </ul> <p><b>b. Hematology (10 + 2hrs)</b></p> <ul style="list-style-type: none"> <li>• Composition and function of blood and body fluids</li> <li>• Plasma proteins and their functions</li> <li>• RBC: morphology, production, functions and fate</li> <li>• Anemia: etiological &amp; morphological classification</li> <li>• Immunity : Types, mechanism of immune response</li> <li>• Hemostasis and anticoagulants</li> <li>• Blood groups: Types, cross matching and clinical importance</li> </ul>	15 + 4
II	<p><b>Cardiovascular physiology (10 + 5 hrs)</b></p> <ul style="list-style-type: none"> <li>• Functional anatomy</li> <li>• Conductive system of heart: origin, spread of cardiac impulse</li> <li>• Properties of cardiac muscle</li> <li>• ECG: leads, principles of normal recording. Normal waves and interpretations</li> <li>• Cardiac cycle</li> <li>• Heart sounds, Physiological basis of murmur</li> <li>• Cardiac output: definition, factors affecting, factors regulating and its measurement</li> <li>• Blood pressure: total pressure, lateral pressure, importance of different pressure, measurements, factors controlling BP</li> <li>• Shock: definition &amp; types.</li> </ul>	10 + 5
III	<p><b>Respiratory physiology (10 + 5 hrs)</b></p> <ul style="list-style-type: none"> <li>• Functional anatomy</li> <li>• Mechanism of respiration</li> <li>• Lung volumes and capacities: definition, normal values, measurements and clinical importance</li> <li>• Transport of gases: oxygen and carbon dioxide</li> <li>• Control of respiration: neural and chemical regulation.</li> <li>• Dyspnoea, Asphyxia, cyanosis, periodic breathing</li> <li>• Hypoxia : definition and types</li> </ul>	10 + 5
IV	<p><b>a. Gastro-intestinal physiology (5 hrs)</b></p> <ul style="list-style-type: none"> <li>• GI secretions: saliva, gastric juice, pancreatic juice, liver &amp; gallbladder</li> <li>• GI motility: deglutition, gastric motility and emptying,</li> </ul>	15 + 3

	<p>intestinal motility</p> <ul style="list-style-type: none"> <li>• GI hormones: Gastrin, Secretin, CCK - PZ, motilin, Inhibin</li> </ul> <p><b>b. Renal physiology (10 + 3 hrs)</b></p> <ul style="list-style-type: none"> <li>• Nephrons: structure, types and functions</li> <li>• Juxta glomerular apparatus</li> <li>• RBF: definition, normal values, factor affecting</li> <li>• GFR: definition, normal values factor affecting and factors regulating, measurement.</li> <li>• Renal handlings of solutes : Na<sup>+</sup> , Cl<sup>-</sup> ,Glucose, water (diuretics, diuresis), H<sup>+</sup>, ammonia</li> <li>• Renin-angiotensin- aldosterone mechanism</li> <li>• Concentration of urine - countercurrent multiplier and countercurrent exchanger.</li> <li>• Micturition</li> <li>• Renal dialysis</li> </ul>	
V	<p><b>a. Endocrine physiology (10 + 3hrs)</b></p> <ul style="list-style-type: none"> <li>• Pituitary gland: hormones secreted and their functions, applied: dwarfism, gigantism, Diabetes Insipidus.</li> <li>• Thyroid gland: hormones secreted and their functions, applied: hypothyroidism, hyperthyroidism</li> <li>• Parathyroid gland: hormones secreted and their functions</li> <li>• Adrenal gland: hormones secreted and their functions</li> <li>• Pancreas: hormones secreted and their functions, applied: Diabetes Mellitus</li> </ul> <p><b>b. Reproductive physiology (5 + 2hrs)</b></p> <ul style="list-style-type: none"> <li>• Male reproductive system: spermatogenesis ,endocrine functions of testis</li> <li>• Female reproductive system: oogenesis, ovulation, functions of estrogen and progesterone.</li> <li>• Menstrual cycle: ovarian cycle, uterine cycle, hormonal changes, abnormalities of menstruation</li> <li>• Contraception</li> </ul>	15 + 5
VI	<p><b>a. Nerve-Muscle physiology (5 + 5 hrs)</b></p> <ul style="list-style-type: none"> <li>• Neurons: structure, types, properties, degeneration and regeneration</li> <li>• Neuromuscular junction: transmission of impulse and its clinical applications</li> <li>• Skeletal muscle: structure , muscle proteins, contraction&amp; relaxation, types of contraction</li> </ul> <p><b>b. Central nervous system (5 + 3hrs)</b></p> <ul style="list-style-type: none"> <li>• Organization of nervous system</li> <li>• Synapse: types, functions</li> <li>• CSF :functions</li> <li>• Cerebral cortex: Broca`s area and their functions</li> <li>• Cerebellum: lobes &amp;function</li> <li>• Basal ganglia: nucleus &amp; functions, Parkinsonism</li> </ul>	15 + 10

	<ul style="list-style-type: none"> <li>• Hypothalamus: functions</li> </ul> <p><b>c. Special senses (5 + 2 hrs)</b></p> <ul style="list-style-type: none"> <li>• Vision: Errors of refraction, visual pathway and effects of lesion</li> <li>• Hearing: functions of middle ear, Conductive deafness and nerve deafness.</li> <li>• Smell and taste: receptors and pathways</li> </ul>	
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### **LAB TRAINING (38 hrs)**

- Hemoglobinometry
- White Blood Cell Count
- Red Blood Cell Count
- Determination of Blood Groups
- Leishman's Staining and Differential WBC Count
- Determination of Packed Cell Volume
- Erythrocyte Sedimentation Rate(ESR)
- Determination of Clotting Time, Bleeding Time
- Recording of Blood pressure
- Auscultation for Heart sounds
- Artificial Respiration
- Determination of Vital capacity.

#### **METHODS OF TEACHING**

- Lecture cum discussion
- Demonstration
- Lab visit
- Practical work record

#### **METHODS OF EVALUATION**

- Written Test
- Laboratory observation Book
- Assignments
- Oral Presentations

#### **REFERENCE BOOKS**

1. Basics of Medical Physiology D.Venkatesh /H.H.Sudhakar Wolters Kluwer Third Edition.
2. Waugh: Ross & Wilson Anatomy & Physiology in health and illness Penguin Books Ltd (2010).
3. Principles of Physiology, Singh (H).

## PHYSIOLOGY - BLUEPRINT

Unit	Systems	Marks	Weightage (%)	Question type		
				LAQ (2 out of 4 )	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	General physiology	15	19%			2+1*
	Hematology			1*	1	1
II	Cardiovascular physiology	16	20%	1	1	
III	Respiratory physiology	16	20%	1	1	
IV	Gastro-intestinal physiology	12	15%		1	1+1*
	Renal physiology			1*		1
V	Endocrine physiology	12	15%		1	1
	Reproductive physiology					1
VI	Nerve-Muscle physiology	09	11%			1
	Central nervous system				1*	1
	Special senses					1

**Note:** \* represents question of choice

- The duration of Examination (University) is Three (3) hours.
- The total marks for the University Examination will be 100marks.
  - Long Answer Questions : 2 X 10 = 20 marks (Choice 2 out of 4)
  - Short Answer Questions : 5 X 6 = 30 marks (Choice 5 out of 6)
  - Very Short Answer Questions : 10 X 3 = 30 marks (Choice 10 out of 12)
  - TOTAL = Theory 80 + IA 20 = 100mark

**MODEL QUESTION PAPER**  
**FIRST YEAR B.Sc. ALLIED HEALTH SCIENCES**  
**PHYSIOLOGY**

**Total marks: 80**

**Duration: 3hours**

**LONG QUESTION ANSWER**

**(2 X 10 =20)**

1. a) Define Erythropoiesis? Describe its stages. Mention the factors influencing it. (OR)  
b) Define blood pressure. Write its normal range. Briefly explain short term regulation mechanism of blood pressure.
2. a) Explain how oxygen is transported in blood. Explain oxygen dissociation curve. List the factors shifting this curve to right&left.(OR)  
b) Define Glomerular filtration rate (GFR). Write its normal value. Explain the factors affecting it.

**SHORT QUESTION ANSWER - Answer any 5**

**(5 X 6 =30)**

1. Define hemostasis. Briefly explain blood clotting mechanism.
2. Define cardiac output. Give its normal value. Describe the factors regulating it
3. Draw normal spirogram indicating static lung volumes and capacities.
4. Briefly explain the mechanism of HCl secretion in stomach.
5. Name the anterior pituitary hormones. Briefly explain functions of growth hormones.
6. Briefly describe stages of Spermatogenesis.

**VERY SHORT ANSWER - Answer any 10**

**(10 X 3=30)**

1. Write the functions of Golgi apparatus
2. Briefly explain osmosis
3. Briefly describe the function of Na<sup>+</sup> K<sup>+</sup> ATPase pump
4. What are anticoagulants? Name any two.
5. Write any 3 functions of saliva
6. Name any two GI hormones. Write any one function of them.
7. Name the cells of Juxta glomerular apparatus & mention their function
8. List the 3 functions of thyroid hormone
9. Name natural contraceptive methods
10. Classify muscle proteins
11. Classify glial cell. Write any two functions of it.
12. What is myopia? How it is corrected



# **BIOCHEMISTRY**

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES - BIOCHEMISTRY**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: BIOCHEMISTRY</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 80hrs</b>
<b>DURATION OF TUTORIAL SESSIONS</b>	<b>: 32hrs</b>
<b>DURATION OF LAB TRAINING</b>	<b>: 38Hrs</b>
<b>THEORY EXAMINATION</b>	<b>: 100 marks (80 U + 20IA)</b>
<b>UNIVERSITY PRACTICAL EXAMINATION</b>	<b>: Nil</b>
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 3 hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE DESCRIPTION**

The course is designed to assist students to acquire the knowledge of the normal biochemical functioning of human body and alterations.

**OBJECTIVES**

At the end of the course, the student will be able to

1. Identify the basic principles of biochemistry.
2. Synthesize the knowledge of these principles in various situations.

**COURSE OUTCOMES FOR BIOCHEMISTRY**

At the end of the course, students will be able to...

**BIO-AHS-CO1:** Correlate the integration of various aspects of biomolecules and its lab diagnosis

**BIO-AHS-CO2:** Explain biochemical basis and rationale of clinical laboratory tests for inborn errors of metabolism, and interpret the results.

**BIO-AHS-CO3:** Correlate the results of these investigations with the primary disorders of each human body system.

**BIO-AHS-CO4:** Follow good clinical laboratory practice as well as to handle the biological samples collected

**BIO-AHS-CO5:** Learn how to collect the samples and to process it for diagnostic purposes

UNIT	TITLE	THEORY + TUTORIALS (80 +32 ) HOURS
I	<p><b>(i) INTRODUCTION TO BIOCHEMISTRY</b></p> <ul style="list-style-type: none"> <li>• Biophysical aspects of Biochemistry: Theory of acids and bases, Ionization of acids, Dissociation of water, Hydrogen ion concentration and concept of pH, Dissociation of acids and bases, Basic concepts in Acidosis and Alkalosis (Respiratory and Metabolic)</li> <li>• Concept of buffering, Definition of buffers and Buffering Capacity, Chemical and Physiological buffers, Henderson Hassel Balch equation and pH - pK relationship,</li> <li>• Glass electrode and determination of pH, Acid Base titration.</li> </ul> <p><b>ii) PROTEINS</b></p> <ul style="list-style-type: none"> <li>• Proteins: Chemistry, Classification, properties and biomedical importance of Proteins.</li> <li>• Hydrolytic products of proteins</li> <li>• Classification of Amino acids and important properties</li> </ul> <p><b>iii) ENZYMES</b></p> <ul style="list-style-type: none"> <li>• Definitions of Catalyst, Enzymes, Apo enzyme, Coenzyme, Holoenzyme, Cofactors and prosthetic group</li> <li>• Active site</li> <li>• Systematic classification of Enzymes</li> <li>• Factors influencing Enzyme kinetics</li> <li>• Enzyme units</li> </ul>	18 + 6
II	<p><b>i) CARBOHYDRATES</b></p> <ul style="list-style-type: none"> <li>• Carbohydrates: Chemistry, Classification, properties and biomedical importance of carbohydrates.</li> </ul> <p><b>ii) NUCLEOPROTEINS</b></p> <ul style="list-style-type: none"> <li>• Purine and Pyrimidine bases</li> <li>• Ribose and Deoxy Ribose</li> <li>• Definition of Nucleosides and Nucleotides</li> <li>• Structure of DNA</li> <li>• Types of RNA</li> <li>• Biologically significant Nucleotides</li> </ul>	15 + 5
III	<p><b>LIPIDS</b></p> <ul style="list-style-type: none"> <li>• Definition of Fats and Oils</li> <li>• Classification of Lipids</li> <li>• Saturated and Unsaturated Fatty acids</li> <li>• Properties of Lipids</li> <li>• Biomedical importance of Lipids with special reference to Phospho Lipids, Glycolipids and Cholesterol.</li> </ul>	15 + 7
IV	<p><b>ENERGY METABOLISM AND NUTRITIONAL BIOCHEMISTRY</b></p> <ul style="list-style-type: none"> <li>• Calorific value, Respiratory Quotient, Resting Metabolic expenditure, Specific dynamic action</li> <li>• Energy requirements</li> <li>• Complex Carbohydrates and Role of Dietary fiber</li> <li>• Essential Fatty acids</li> <li>• Essential amino acids</li> </ul>	20 + 6

	<ul style="list-style-type: none"> <li>• Positive and Negative Nitrogen balance</li> <li>• Protein Energy Malnutrition</li> <li>• Biochemical functions of Vitamins</li> <li>• Biochemical functions of major and trace elements</li> </ul>	
V	<p><b>(i) CLINICAL CHEMISTRY</b></p> <ul style="list-style-type: none"> <li>• Serum Osmolality: Significance and measurement</li> <li>• Electrophoresis: Principles, Methodology and Diagnostic significance</li> <li>• Principles and applications of Paper Chromatography</li> <li>• Simple tests to identify Carbohydrates, Lipids and Proteins in biological fluids</li> <li>• Qualitative estimation of Glucose, Proteins, Cholesterol, Urea, Creatinine and Uric acid and their diagnostic significance</li> </ul> <p><b>(ii) ENVIRONMENTAL CHEMISTRY</b></p> <ul style="list-style-type: none"> <li>• Definition of Pollutants</li> <li>• Impact of Terrestrial, Water and air pollutants</li> <li>• Bio pesticides Chemistry, Metabolic Transformation in the living system and role in Chemical Pathology</li> <li>• Influence of Non-Biodegradable domestic utility items and its role in metabolic disorders</li> <li>• Carcinogens and mutagens: qualitative and molecular pathology involved in mutagenesis and carcinogenesis</li> <li>• Plastics and its impacts on Society</li> <li>• Biomedical Waste and its management</li> </ul>	12 + 8

#### LAB TRAINING (38 hrs)

- Simple Color reactions of Carbohydrates and Proteins
- Qualitative estimations of Glucose, Urea, Creatinine, Total Protein and Cholesterol
- Normal constituents of Urine
- Abnormal (pathological) Urine
- Glucose Tolerance Test and its significance
- Demonstration of Electrophoresis and Interpretation of important clinical conditions based on Electrophoresis appearance
- Demonstration of Paper Chromatography and its utility in the diagnosis of inborn errors of metabolism

#### METHODS OF TEACHING

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

## METHODS OF EVALUATION

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

## REFERENCE BOOK

1. Essential of Biochemistry for B.Sc. Nursing Students Harbanslal, first edition.
2. Biochemistry U.Sathya Narayana, U.Chakrapani, fifth edition

### B.Sc. ALLIED HEALTH SCIENCES - BIOCHEMISTRY (I Year) BLUE PRINT

Unit No.	Weight age	Marks Allotted	Knowledge/ Recall			Understanding			Application		
			LAQ (10)	SAQ (6)	VSAQ (3)	LAQ (10)	SAQ (6)	VSAQ (3)	LAQ (10)	SAQ (6)	VSAQ (3)
I	30 %	25		1	1	1	1				
II	20%	19	1		2			1			
III	15%	12	1*	1	2						
IV	15 %	9	1*	1*	2			1			
V	20%	15		1	1 + 1*		1	1*			

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 80 marks.

Long Answer Questions : 2X 10 marks = 20 marks (Choice 2 out of 4)

Short Answer Questions : 5X 6 marks = 30 marks (Choice 5 out of 6)

Very Short Answer Questions : 10 X 3 marks = 30 marks (Choice 10 out of 12)

TOTAL = Theory 80 + IA 20 = 100marks

**MODEL QUESTION PAPER**  
**FIRST YEAR B.Sc. ALLIED HEALTH SCIENCES**  
**BIOCHEMISTRY**

**TIME: 3 HOURS**

**MAXIMUM MARKS:80**

**A. Long answer question**

**(2 X10=20)**

1. a) Write in detail about the Hetero polysaccharides and mention its importance.

**(Or)**

b) How is acid base balance maintained in the body?

2. a) Define and classify Lipids with suitable examples.

**(Or)**

b) Write in detail about the RDA, dietary sources, and biochemical role and deficiency manifestations of folic acid.

**B. Short answer questions -Answer any 5 questions**

**(5X 6=30)**

1. Mention dietary sources and functions of cholesterol

2. Define Chromatography & write any 4 applications

3. Classify Carbohydrates with a suitable example

4. Classify Enzymes systematically by providing one example under each class.

5. Define carcinogen and name any three agents that cause carcinogenesis.

6. List down the sources, regulation and functions of Calcium

**C. Very Short answer questions -Answer any 10 questions**

**(10 x 3=30)**

1. Define Respiratory quotient

2. Define buffer

3. List any two functions of trace elements.

4. List any two impacts of plastics on society

5. Mention the essential fatty acids and its importance

6. List any 2 functions of phospholipids

7. Name one test to identify plasma proteins and urea.

8. Define osmolality

9. Mention any one cardiac glycoside with its function

10. Draw a neat labeled diagram of DNA

11. Define mutarotation

12. List any two functions of Fat soluble vitamin

# **GENERAL MICROBIOLOGY**

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES - GENERAL MICROBIOLOGY**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: GENERAL MICROBIOLOGY</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 40 hrs</b>
<b>DURATION OF TUTORIAL SESSIONS</b>	<b>: 16 hrs</b>
<b>DURATION OF LAB TRAINING</b>	<b>: 38 Hrs</b>
<b>EXAMINATION</b>	<b>: 50 marks (40 U+10 IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE DESCRIPTION**

The course is designed to assist students to acquire understanding of fundamentals of microbiology and identification of microorganisms. It also provides opportunities for practicing infection control measures in hospital setting.

**COURSE OBJECTIVES**

At the end of the course, the student will be able to:

1. Identify common disease producing microorganisms
2. Explain the basic principles of microbiology and their significance in health and disease. Demonstrate skill in handling specimens.
3. Explain various methods of disinfection and sterilization
4. Identify the role of the nurse in hospital infection control system.

**COURSE OUTCOMES FOR GENERAL MICROBIOLOGY**

At the end of the course, students will be able to...

**MIC-AHS-CO1:** Sterilize the articles with physical and chemical methods

**MIC-AHS-CO2:** Perform with suitable culture media, methods for growth of the bacteria and perform staining techniques for identification of bacteria

**MIC-AHS-CO3:** Learn the structure, function of immune system and immunity by its antigen-antibody reactions

**MIC-AHS-CO4:** Learn the how to collect & process the specimen for the diagnostic purposes

**MIC-AHS-CO5:** Learn about the identification of fungal infections from clinical specimens and various antifungal agents used for the fungal infections.

**MIC-AHS-CO6:** Learn the laboratory diagnosis of Parasitic and Viral infections

**MIC-AHS-CO7:** Learn about the treatment and post exposure prophylaxis (PPE) of viral infections



UNIT	TITLE	THEORY + TUTORIALS (40 +16) HOURS
I	<b>GENERAL BACTERIOLOGY</b> <ul style="list-style-type: none"> <li>□ Historical introduction Classification of Microorganisms based on size, shape and structure</li> <li>□ Anatomy &amp; Physiology of Bacteria : Nutrition, Growth</li> <li>□ Microscopy, staining techniques &amp; Culture media, culture methods</li> <li>□ Sterilization (physical &amp; chemical methods) Infection</li> </ul>	8 + 2
II	<b>IMMUNOLOGY</b> <ul style="list-style-type: none"> <li>□ Immune response</li> <li>□ Immunity</li> <li>□ Hyper sensitivity, Autoimmunity</li> <li>□ Complement</li> <li>□ Antigen antibody reactions</li> </ul>	7 + 2
III	<b>SYSTEMATIC BACTERIOLOGY</b> <ul style="list-style-type: none"> <li>□ Introduction : Collection transport &amp; processing of bacteriological clinical specimen in general</li> <li>□ Pyogenic cocci</li> <li>□ Spore bearing bacilli Clostridium + Bacillus</li> <li>□ Enterobacteriaceae- E.coli, Klebsiella, Salmonella, Shigella</li> <li>□ Vibrio, Pseudomonas</li> </ul> <b>MYCOLOGY</b> <ul style="list-style-type: none"> <li>□ Introduction, classification of fungi, laboratory diagnosis in general</li> <li>□ Fungi of medical importance- Opportunistic fungi</li> </ul>	8 + 3
IV	<b>BASICS OF PARASITOLOGY</b> <ul style="list-style-type: none"> <li>□ Introduction to Parasitology, Classification, Protozoa-I - Entamoeba histolytica</li> <li>□ Protozoa-II, Plasmodium spp.</li> <li>□ Cestodes: general, T.solium &amp; T.saginata, E.granulosus</li> <li>□ Nematodes: Introduction &amp; Classification <ul style="list-style-type: none"> <li>- Intestinal -Ascaris, Ancylostoma, Strongyloides</li> <li>- Tissue-W.bancrofti</li> </ul> </li> </ul>	7 + 3
V	<b>VIROLOGY</b> <ul style="list-style-type: none"> <li>□ Classification &amp; General properties of Viruses, Virus Host interactions &amp; Lab diagnosis in general</li> <li>□ DNA Viruses : Pox viruses &amp; Adenoviruses, Herpes viruses</li> <li>□ Hepatitis virus, HIV</li> <li>□ Rabies , Polio, Arbo viruses common in India - Dengue, Chikungunya , Japanese encephalitis, KFD</li> </ul>	6 + 4
VI	<b>HOSPITAL INFECTION AND CONTROL</b> <ul style="list-style-type: none"> <li>□ Causative agents and methods of transmission</li> <li>□ Systematic investigation of hospital infection</li> <li>□ Prevention and control of Hospital infections</li> <li>□ Environmental Hazards resulting from biomedical waste and preventive measures.</li> </ul>	4 + 2

## LAB TRAINING (38 hrs)

- Introduction & visit to microbiology lab + Morphology of bacteria + Identification of bacteria (Culture plates & Basic biochemical reactions)
- Gram stain, Acid fast Stain
- Spotters , Instruments, Culture media inoculated & un inoculated
- Applied Immunology(Bacterial)
- Serological tests - CRP, ASO, RPR, Widal Applied Immunology (Virology) Serological tests: HIV, HBsAg( Rapid Tests)
- Stool Examination for eggs + Parasitology specimens

### METHODS OF TEACHING

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

### METHODS OF EVALUATION

1. Written Test
2. Laboratory Observation Book
3. Assignments
4. Oral Presentations

### REFERENCE BOOKS

1. Ananthnarayan R: Textbook of Microbiology.(2017)
2. Pommerville J. C: Fundamentals of Microbiology. Jones and Bartlett learning(2013)
3. ApurbaSastry, SandhyaBhat. Essentials of Microbiology.
4. Text book of Concise Microbiology by C.P.Baveja, Latest edition

**BLUE PRINT - B.Sc ALLIED HEALTH SCIENCES -GENERAL MICROBIOLOGY (I Year)**

Unit No.	Unit	Weightage (%)	Marks Allotted	Knowledge/ Recall			Understanding			Application		
				LAQ (10)	SAQ (6)	VSAQ (3)	LAQ (10)	SAQ (6)	VSAQ (3)	LAQ (10)	SAQ (6)	VSAQ (3)
I	GENERAL BACTERIOLOGY	8	3	1*								1
II	BASICS OF IMMUNOLOGY	15	6			1*		1				
III	SYSTEMATIC BACTERIOLOGY	25	10				1				1*	
IV	BASICS OF PARASITOLOGY& MYCOLOGY	22	9					1				1
V	VIROLOGY	22	9		1							1
VI	HOSPITAL INFECTION AND CONTROL	8	3		1*				1			
	<b>TOTAL</b>	<b>100</b>	<b>40</b>									

The duration of Examination (University) is One and Half (1 ½) hours.

The total marks for the University Examination will be 40marks.

Long Answer Questions : 1X10mark = 10 marks (Choice 1 out of2)

Short Answer Questions : 3X6marks = 18 marks (Choice 3 outof5)

Very Short Answer Questions : 4 X3 marks = 12marks (Choice 4 out of5)

TOTAL = 40 marks

**MODEL QUESTION PAPER**  
**FIRST YEAR B.Sc. ALLIED HEALTH SCIENCES**  
**GENERAL MICROBIOLOGY**

**Time: 1½Hours**

**Maximum Marks: 40**

Illustrate your answers with suitable diagrams wherever necessary.

**(A) Long answer questions** **(1 X 10=10)**

1. Describe the commonly used chemical disinfectants and their applications in the hospital.

**(OR)**

2. Classify Mycobacterium. Give an account on pathogenesis and laboratory diagnosis of pulmonary tuberculosis. Add a note on BCG vaccine.

**(B) Short answer questions -Answer any 3 questions marks** **(3 X6=18)**

1. Define immunity. Describe acquired immunity.

2. Types of HAI & mention the causative agents.

3. Name the UTI cause bacteria. How to collect urine & laboratory diagnosis of *E.coli*.

4. Life cycle of malaria parasite in human.

5. Write about Modes of transmission of HIV.

**(C) Very Short answer questions -Answer any 4 questions** **(4 x3 =12)**

1. Mention different color coded bags for biological waste management used in hospital with the viruses.

2. Prophylaxis of hepatitis B.

3. List FOUR bacteria causing wound infection.

4. Name the opportunistic fungi.

5. Name four arbo viral diseases common in India.

# **GENERAL PATHOLOGY**

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES - GENERAL PATHOLOGY**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: GENERAL PATHOLOGY</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 40hrs</b>
<b>DURATION OF TUTORIAL SESSIONS</b>	<b>: 16hrs</b>
<b>DURATION OF LAB TRAINING</b>	<b>: 38Hrs</b>
<b>EXAMINATION</b>	<b>: 50 marks (40 U + 10IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: IYEAR</b>

**COURSE DESCRIPTION**

To make the student to understand pathology laboratory reports, the normal ranges of investigations, severity and specificity of disease conditions which will help him perform International Classification of diseases to clinical pertinence.

**COURSE OBJECTIVES**

On completion of this subject, the student will be able to:

- Differentiate between symptoms and diseases
- Understand the needs of mandatory diagnostic procedures
- Demonstrate an understanding of the pathology of common diseases
- Understand various pathology laboratory reports
- Know about the possibilities and consequences of nosocomial infections, needle prick injuries etc., in a health care facility

**COURSE OUTCOMES FOR GENERAL PATHOLOGY**

At the end of the course, students will be able to...

**PAT-AHS-CO1:** Learns the pathophysiology of disease and its causes and progression

**PAT-AHS-CO2:** Learns the etiologies, the pathogenesis, and the host response specific to a particular organ system

**PAT-AHS-CO3:** Learn about lab investigations and techniques in Hematology.

**PAT-AHS-CO4:** Learns to perform cross matching, coombs test, blood grouping and TTI

**PAT-AHS-CO5:** Learns the diagnosis of disease based on the laboratory analysis of bodily fluids

UNIT	TITLE	THEORY + TUTORIALS (40 +16) HOURS
I	<b>GENERAL PATHOLOGY (12 +3 HOURS)</b> Basic Concepts in Cellular Adaptions <ul style="list-style-type: none"> <li>• Cell injury and Cell death</li> <li>• Over view of Cellular adaption</li> </ul> Basic Principles in Inflammatory Process <ul style="list-style-type: none"> <li>• General features of acute and Chronic inflammation repair.</li> <li>• NEOPLASIA</li> <li>• Definition of Neoplasia</li> <li>• Differences between Benign and Malignant tumors</li> <li>• Nomenclature</li> </ul>	10 + 5
II	<b>HAEMATOLOGY</b> <b>Structure and functions of Blood cells</b> <ul style="list-style-type: none"> <li>• Objective use of anticoagulants</li> <li>• Mechanisms of Haemostasis</li> <li>• Tests to monitor Coagulation</li> <li>• Blood Grouping and Blood Bank (Basic aspects on Blood Components)</li> <li>• Basic concepts in Anemia</li> <li>• Basic Concepts of Leukemia</li> </ul>	10 + 3
III	<b>BIOMEDICAL WASTE MANAGEMENT AND ENVIRONMENTAL PATHOLOGY</b> <ul style="list-style-type: none"> <li>• Biomedical waste management from perspectives of Pathology</li> <li>• Environment and Disease - Smoking hazards, Asbestosis and Silicosis Occupational Exposure</li> </ul>	5 + 2
IV	<b>CLINICAL PATHOLOGY</b> <ul style="list-style-type: none"> <li>• Collection, transport, preservation and processing of Clinical Specimen</li> <li>• Clinical Pathology of specialized Body Fluids(CSF), Synovial fluid, Pleural Fluid</li> <li>• Urine Examination(Urinalysis)</li> </ul>	5 + 2
V	<b>OVERVIEW OF SYSTEMIC PATHOLOGY</b> <ul style="list-style-type: none"> <li>• Rheumatic Heart Disease ineffective endocarditic, atherosclerosis, IHD - Basic Concepts.</li> <li>• Lungs : Pneumonia, COPD, Asthma, ARDS - Basic Concepts</li> <li>• Gastrointestinal tract - Peptic Ulcer, Carcinoma Stomach, Carcinoma Colon -Basic Concepts.</li> <li>• Liver: Hepatitis, Cirrhosis, Gall Bladder -basic</li> </ul>	10 + 4

	<p>Concepts.</p> <ul style="list-style-type: none"> <li>• Brain Tumor.</li> <li>• Kidney - Renal Calculi, Hydronephrosis, renal Tumor - Basic Concepts.</li> <li>• FGT - Leiomyoma, Endometrial hyperplasia, Endometrial Cancer, Cervical Cancer -Basic Concepts.</li> <li>• FGT - Ovarian Tumor classifications - Basic Concepts.</li> <li>• Breast - Benign and Malignant tumors - Basic Concepts</li> <li>• Bone Tumors - Basic Concepts</li> </ul>	
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### **LAB TRAINING (38 hrs)**

1. Blood Grouping and Rh typing
2. Urine Routine
3. Hb, TLC,DLC
4. Gross Specimens
5. Slides

#### **METHODS OF TEACHING**

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### **METHODS OF EVALUATION**

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### **REFERENCE BOOK**

1. Culling Histopathology techniques
2. Bancroft Histopathology techniques
3. Todd & Sanford Clinical Diagnosis by laboratory method
4. Dacie & Lewis - Practical Haematology
5. RamanicSood, Laboratory Technology (Methods and interpretation) 4<sup>th</sup>Ed.



**B.Sc. ALLIED HEALTH SCIENCES - PATHOLOGY (I Year)-BLUE PRINT**

Unit No.	Unit	Weightage	Marks Allotted	Knowledge/ Recall			Understanding			Application		
				LAQ (10)	SAQ (6)	VSAQ (3)	LAQ (10)	SAQ (6)	VSAQ (3)	LAQ (10)	SAQ (6)	VSAQ (3)
I	a) BASIC CONCEPTS IN CELLULARADAPTIONS b) BASIC PRINCIPLES IN INFLAMMATORY PROCESS c) NEOPLASIA	37.5%	15	1*	2	1	-	1*	1*	-	-	-
II	HAEMATOLOGY	22.5%	9	-	1	1	-	-	-	-	-	-
III	BIOMEDICAL WASTE MANAGEMENT AND ENVIRONMENTAL PATHOLOGY	7.5%	3	-	-	-	-	-	1	-	-	-
IV	CLINICAL PATHOLOGY	7.5%	3	-	1*	1	-	-	-	-	-	-
V	OVERVIEW OF SYSTEMIC PATHOLOGY	25%	10	1	-	-	-	-	-	-	-	-

The Duration of Examination (University) is One and Half hours (1 ½) hours.

The total marks for the University Examination will be 40 marks.

Lon Answer Questions : 10X1marks = 10 marks (Choice 1 out of 2)

Short Answer Questions : 3 X6marks = 18 marks (Choice 3 out of5)

Very Short Answer Questions : 4 X3marks = 12 marks (Choice 4 out of5)

TOTAL = 40 marks

**MODEL QUESTION PAPER  
FIRST YEAR B.Sc. ALLIED HEALTH SCIENCES  
GENERAL PATHOLOGY**

**Time: 1½Hour**

**Maximum Marks: 40**

Illustrate your answers with suitable diagrams wherever necessary.

**(A) Long Answer Questions**

**(1X10=10)**

1. Mention the types of necrosis with examples

(Or)

2. Describe about Myocardial infarction

**(B) Short Answer Question**

**(3X6=18)**

**Answer any THREE of the following**

1. Tabulate the difference between Benign and Malignant tumors

2. Define anemia. Mention types of anemia, on the basis of Etiology.

3. Explain the mode of spread of tumors in brief.

4. Explain granulomatous inflammation with a neat labeled diagram

5. Describe the method of collection, transport and preservation of CSF

**(C) Very Short Answer Questions**

**(4X3=12)**

**Answer any FOUR of the following**

1. Define Apoptosis.

2. Enumerate two colors coding for various biomedical waste disposal with examples.

3. Define cross matching

4. Mention two types of Necrosis.

5. Define Pneumonia.

# **I YEAR ELECTIVE COURSES**

**SYLLABUS FOR I YEAR  
B.Sc. ALLIED HEALTH SCIENCES  
ABILITY ENHANCEMENT COMPULSORY COURSE (AECC) - ENGLISH**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: ENGLISH</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 34hrs</b>
<b>EXAMINATION</b>	<b>: 100 marks (80 U + 20 IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE OUTCOMES FOR ENGLISH**

**ENG-CO1:** Speak and write grammatically correct sentences in English

**ENG-CO2:** Develop effective writing skills needed for clinical task

**ENG-CO3:** Build fluency in English needed for clinical tasks

**SYLLABUS  
(THEORY& PRACTICALS = 16 +34 Hours)**

**COURSE DESCRIPTION**

This course is designed to build spoken and written English competency of the students needed to function effectively in academic setup.

**OBJECTIVES**

On completion of this subject, the student will be able to:

1. Speak and write grammatically correct sentences in English.
2. Develop effective writing skills.
3. Build fluency in English

**UNIT: I GRAMMAR**

1. Remedial Grammar : Parts of speech; Types of sentences, question tags
2. Modal verbs;
3. Tenses
4. Concordance

**UNIT: II VOCABULARY**

1. Word formation - prefixes and suffixes
2. Medical terminology
3. Words often misused or confused
4. Idioms and phrases

**UNIT: III WRITING SKILLS**

1. Letter writing - permission, leave and other official letters
2. Note making methods
3. Jumbled sentences -cohesion
4. Paragraph Writing

**UNIT: IV SPOKEN COMMUNICATION**

1. Pronunciation of commonly mispronounced words
2. Day today conversation
3. Telephonic conversations
4. Group Discussions

**UNIT: V LISTENING AND READING SKILLS**

1. General Listening and reading comprehension

**Textbook Recommended**

1. Effective English Communication by Krishna Mohan and Meenakshi Raman, Tata McGraw - Hill Publishing Company Limited, New Delhi.
2. English for Colleges and Competitive Exams by Dr. R. Dyvadatham, Emerald Publishers.

**SYLLABUS FOR I YEAR  
B.Sc. ALLIED HEALTH SCIENCES  
SKILL BASED ELECTIVE COURSE (SBEC) - CULINARY SKILLS FOR  
OPTIMAL NUTRITION**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: CULINARY SKILLS FOR OPTIMAL NUTRITION</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16 Hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32Hrs</b>
<b>PRACTICAL EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY THEORY EXAMINATION</b>	
<b>DURATION OF EXAMINATION</b>	<b>: 1 ½ Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT: IYEAR</b>	

**COURSE OUTCOMES**

**NUTRI-CO1:** Understand the basic food groups, their nutrient composition and function for balanced healthy diet for people of all ages & patients on dietary management for healthy life.

**THEORY & PRACTICALS (DURATION 16 + 32 Hours)**

**UNIT-I INTRODUCTION TO FOODS AND NUTRITION**

- Food-Definition of foods, nutrition and nutrients characteristics of good health
- Relation of nutrition to good health-optimal nutrition, malnutrition and over nutrition
- Classification of foods based on major nutrient content
- Food selection-factor responsible for food selection

**UNIT-II FOODS GROUPS**

- Basic four and five food groups-cereals, millets pulses, fruits and vegetables, fats and oils, sugar and jaggery.
- Foods and nutrients, Functions of food- energy yielding, body building and protective foods, balanced diet, vegetarian and non-vegetarian foods
- Functional Foods-Dietary supplements
- Food Adulterations-Common adulterants and method of identification, nutrition labeling and food standards

**UNIT-III METHODS OF COOKING, PRESERVATION AND SENSORY EVALUATION**

- Principles and techniques of sensory evaluation, Interpretation tools
- Cooking methods-moist heat, dry heat advantages and disadvantages, changes during cooking, nutrient preservation while cooking
- Preservation techniques advantages and disadvantages

#### **UNIT-IV NUTRITIONAL REQUIREMENTS AND MEAL PLANNING**

- Basic nutritional requirements through different stages of life cycle, basic principles of meal planning, revisiting concept of balanced diet.

#### **PRACTICALS**

- Introduction to cutlery and crockery
- Introduction to weights and measures
- Art of table setting
- Market survey on food labeling
- Preparation of few commonly consumed cereal preparation
- Preparation of few commonly consumed pulse dishes
- Vegetable cooking without nutrient loss
- Preparation and display of fruits salads
- A day's menu for an adult sedentary worker
- A day's menu for an 8-monthold infant
- Nutritious snacks for preschooler
- Nutritious lunch for school going boys and girl
- Consistency modified menu for an 80-year-old
- Simple test to identify food adulteration
- Sensory evaluation of prepared items

#### **METHODS OF TEACHING**

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### **METHODS OF EVALUATION**

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### **Reference book**

1. Srilakshmi.B. : Food science; seventh edition(2012)
2. Jacqueline B .Marcus :Culinary Nutrition: The science and practice of healthy cooking:(2014)

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES**  
**SKILL BASED ELECTIVE COURSE (SBEC) - ENHANCING SOFT SKILL & PERSONALITY**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: Enhancing soft skill &amp; personality</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16Hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32Hrs</b>
<b>PRACTICAL EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY THEORY EXAMINATION</b>	
<b>DURATION OF EXAMINATION</b>	<b>: 1 ½ Hrs.</b>
<b>YEAR</b>	<b>: I YEAR</b>

**COURSE OUTCOMES**

**ESSP-CO1:** Foster healthy attitude and develop effective inter and intra personal skills to be an effective team worker in both academic and professional setup.

**LEARNING OBJECTIVES**

This course is designed to equip the students with essential soft skills needed for workplace and improve personality.

**SYLLABUS**

**UNIT: I ASPECTS OF COMMUNICATION**

1. Importance of communication, Process, Barriers
2. Nonverbal Communication

**UNIT: II SPEAKING**

1. Opening and Closing conversations
2. Introductions and Address Systems
3. Expressing Courtesy
4. Giving Compliments and replying to Compliments
5. Presentation Skills
6. Telephonic conversation and telephone etiquette

**UNIT - III PRESCRIBED READING**

1. White washing the Fence - Episode from Tom Sawyer by Mark Twain
2. Bacon's Essays: - Of Goodness and goodness of nature

**UNIT - IV WRITING**

1. Letter writing - Letter of Complaints, Inviting and Declining an invitation
2. Memos and Email
3. Editing- Grammar, Spelling & Punctuation, Use of Dictionary & Thesaurus.



## **UNIT - V SOFT SKILLS**

1. Active Listening Skills
2. Assertive Skills
3. Negotiation and Persuasive Skills
4. Interview Skills

### **Reference Books**

1. Communication Skills for Engineers and Scientists by Sangeeta Sharma and Binod Mishra, PHI Learning Private Limited, New Delhi.
2. English and soft skills by S.P. Dhanavel, Orient Black Swan
3. Effective English Communication by Krishna Mohan and Meenakshi Raman, Tata McGraw -Hill Publishing Company Limited.
4. Technical Communication - Principles and Practice, by Meenakshi Raman and Sangeetha Sharma, II edition, Oxford University Press.

### **Learning Outcome**

This course is designed to help the students to

- Foster healthy attitude.
- Develop effective inter and intra personal skills to be an effective team worker.
- Communicate effectively in both academic and professional setup

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES**  
**SKILL BASED ELECTIVE COURSE (SBEC) - SPEAKING EFFECTIVELY**

**NAME OF THE SUBJECT PAPER : SPEAKING EFFECTIVELY**

**DURATION OF THEORY CLASSES : 16Hrs**

**DURATION OF PRACTICAL SESSIONS : 32Hrs**

**PRACTICAL EXAMINATION : 50 Marks (40 U + 10 IA)**

**NO UNIVERSITY THEORY EXAMINATION**

**DURATION OF EXAMINATION : 1 ½ Hrs.**

**YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT: I YEAR**

**COURSE OUTCOMES**

**SPEAK-CO1:** Speak and write grammatically correct sentences in English and Build fluency in English needed for clinical tasks.

**LEARNING OBJECTIVES**

- Advance the students intellectual curiosity, competency and skills in preparation for employment
- Develop critical thinking, creativity and effective communication

**SYLLABUS**

**1. Communication Skills**

- Importance of Communication skills in Public health; Communication process; Methods of communication; Types of communication: Verbal and Non-verbal; Impediments to effective communication; Feedback

**2. Oral Presentation Skills**

- Preparation and planning; Structure; Audio-visual aids; Creating interest and establishing a relationship with the audience; Body language; Voice and pronunciation; Review

**3. Writing skills**

- Writing a scientific paper; Writing a proposal; Structure of an article; References and literature review; Peer-review process-Publication bias; International guidelines for publication in journals; Professional Ethics

**4. Leadership in Public health**

- Leadership styles and trait; Motivation skills; Interpersonal communication skills; Problem solving skills; Decision making skills; Management skills; Communication Skills

## **5. Manuscript writing**

- Writing introduction, objectives, methodologies, major finding, discussion, conclusion and recommendation

## **6. Seminar presentations**

- Use of computers present data and information on recent topics

## **LEARNING OUTCOMES**

At the completion of the course, the students will-

- Develop good written and oral communication abilities
- Develop an understanding of team building and leadership skills
- Develop knowledge regarding capacities needed to work independently within diverse work environments

## **TEXT BOOKS**

1. Professional Writing Skills, A self-paced training Programme by Janis Fisher Chan and Diane Lutovich.
2. Speaking Your Mind: Oral Presentation and Seminar Skills By Rebecca Stott, Tory Young, Cordelia Bryan Contributor Rebecca Stott, Tory Young, Cordelia Bryan.

**SYLLABUS FOR I YEAR  
B.Sc. ALLIED HEALTH SCIENCES  
SKILL BASED ELECTIVE COURSE (SBEC) - BASICS OF YOGA AND PRACTICE**

NAME OF THE SUBJECT PAPER	: BASICS OF YOGA AND PRACTICE
DURATION OF THEORY CLASSES	: 16Hrs
DURATION OF PRACTICAL SESSIONS	: 32Hrs
PRACTICAL EXAMINATION	: 50 Marks (40 U + 10 IA)
NO UNIVERSITY THEORY EXAMINATION	
DURATION OF EXAMINATION	: 1 ½ Hrs
YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT	: I YEAR

**SYLLABUS & COURSE OUTCOMES FOR BASICS OF YOGA & PRACTICE (YOGA)**

**YOGA CO1:** Understand the respiratory system, types of breathing and benefits of meditation.

Unit	TIME(HRS)	CONTENT
1	1	Introduction to Yoga philosophy, psychology and lifestyle
2	1	A brief outline of the history of Yoga.
3	1	Cultivation of correct psychological attitudes
4	1	Asanas : Definition, Types, scope and limitations of Asanas
5	1	Pranayamas and their significance in Yogic curriculum, Types & phases of Pranayama.
6	1	Dharna and Dhyana as the keys to unlocking human potential.
7	1	Study of various aspects of Yoga: Kriyas, Bandhas, Mudras
8	1	Yoga defined as –Integration   and –Harmony
9	1	Meaning of the term –Positive Health
10	1	Yoga, a tool to restore homeostasis
11	1	Integration of Yoga into Health Professions Education
12	1	Order of teaching the Yogic practices; Do's and Dont's of specific Yoga techniques.
13	2	Applied aspects of Yoga in various human activities like therapeutics, education and sports
14	2	Introduction to yogic concept of health and disease

## **Unit 15: Introduction to Yogic techniques: Methods and practices (32 hours)**

### **Asanas (26 hrs):**

- Aruna Surya Namaskar
- Ardha - Padmasana/Padmasana
- ArdhakatiChakrasana
- PadaHasta
- PavanaMuktasana
- Trikona
- Navasana
- Ardha -Shalabhasana
- Shalabhasana
- Makarasana
- Bhujangasana
- Dhanurasana
- Vakrasana
- Vrikshasana
- Ushtrasana
- Gomukasana
- Yoga Mudra.
- Natarajasana
- Chakra sana
- Sarvangasana
- Matsyasana
- Halasana
- Shavasana

### **Pranayama (6 hrs)**

- Vibhaga Pranayama
- Pranava Pranayama
- Savitri Pranayama
- Chandra and SuryaNadi Pranayama
- Nadi-Shuddhi
- Sheetali and Sitkari

## **TEXT BOOKS**

- Dayanidy G and Bhavanani AB. CYTER Practical Book. Pondicherry, India: Dhivyananda Creations;2016.
- A primer of Yoga Theory - Dr Ananda Balayogi Bhavanani, Dhivyananda Creations,Pondicherry-13
- Fundamentals of Yoga History- Compilation by Meena Ramanathan
- Basic Hatha Yoga lessons (Tamil) - Dr Ananda Balayogi and Meena Ramanathan, Puducherry

## **BOOKS RECOMMENDED FOR STUDIES AND REFERENCE**

1. A yogic approach to stress-Dr Ananda Balayogi Bhavanani, Ananda Ashram, Pondicherry
2. Asana, Pranayama, Mudra and Bandha. Swami Satyananda, Bihar School of Yoga,Monger
3. ASANAS : WHY? AND HOW? - byShri. O.P. Tiwari.Kaivalyadhama,Lonavla.
4. Hatha Yoga practices of the Gitananda tradition by Dr Ananda Balayogi Bhavanani
5. Ramanathan Meena. Applied Yoga: Applications of Yoga in Different Fields of Human Activities. 3<sup>rd</sup>Ed; Pondicherry, India: Sri BalajiVidyapeeth;2018
6. PRANAYAMA - by Swami Kunalayananda. Kaivalyadhama, Lonavla.
7. Yoga and sports- Swami Gitananda and Meenakshi Devi, Ananda Ashram, Pondicherry.

**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES**  
**GENERIC ELECTIVE COURSE (GEC) - BASICS OF HOSPITAL ADMINISTRATION**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: BASICS OF HOSPITAL ADMINISTRATION</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 64Hrs</b>
<b>THEORY EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ HRS</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE OUTCOMES**

**HSM CO1:** To familiarizes students with the basics concepts, policies of hospital management regarding the occupational safety, organizational behavior & quality management.

**COURSE OBJECTIVES**

- To provide orientation about the hospital functions
- To familiarize students with the basics concepts of hospital management

**THEORY (DURATION 64 Hours)**

**UNIT: I ORGANISATION OF A HOSPITAL AND ITS DEPARTMENTS**

1. Organogram
2. Vision, Mission & Values, Logo
3. Patient Service Points - Clinical & Non-Clinical (OPD's, A&E, MHC, Wards, ICU's, OT's, etc.)
4. Scope of Services (Medical & Supportive Services)

**UNIT: II HOSPITAL POLICIES & PROCEDURES**

1. Registration Process
2. OP/IP Billing
3. Admission Process
4. Discharge Process
5. Financial counseling
6. Visitors Policy
7. Feedback forms.

**UNIT: III MEDICAL RECORDS MANAGEMENT/LEGAL ASPECTS**

1. Types of Medico legal cases
2. SOP's for handling MLC

3. Medical Records -Forms, consents, registers used in hospitals

#### **UNIT: IV QUALITY MANAGEMENT**

1. Quality - Brief Introduction
2. Code of Conduct for health care professionals
3. Patient rights &responsibilities
4. Incident Reporting
5. Quality indicators
6. List of Licenses to be obtained to run a Hospital College
7. Accreditation-ISO/NABH/JCI

#### **UNIT: VOCCUPATIONAL SAFETY**

1. Biomedical Waste Management
2. Hospital Spill Management
3. Usage of PPE
4. Emergency Codes
5. Fire Safety Management
6. Hospital Infection Control

#### **UNIT: VI ORGANISATIONAL BEHAVIOUR**

1. Communication with patients/health care professionals
2. Grooming standards
3. Time Management
4. Grievance Handling, Interdisciplinary Committee
5. Leadership

#### **LEARNING OUTCOMES**

Students will have an overview of hospital functions, processes and patient management.



**SYLLABUS FOR I YEAR**  
**B.Sc. ALLIED HEALTH SCIENCES**  
**GENERIC ELECTIVE COURSE (GEC) - COUNSELING AND GUIDANCE**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: COUNSELING AND GUIDANCE</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 64Hrs.</b>
<b>EXAMINATION</b>	<b>: 50 Marks (40 U +10IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ Hrs.</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE OUTCOMES**

**CG CO1:** To assess a person's needs and understand their personal characteristics that will help in personal growth, wellbeing and improving their relationships with others.

**LEARNING OBJECTIVES**

- To understand theoretical foundations of counseling psychology
- To examine briefly the major perspectives of Counselling and to apply based on the client's needs
- To assess one's own needs and motivations and personal characteristics that will help in personal growth and wellbeing.
- To understand basic counseling skills as practiced by an effective counsellor.
- To discuss special settings and populations where Counselling could be effectively used.
- To explore ethical and legal issues for the practice of counseling profession.

**SYLLABUS**

**UNIT I:**

Introduction and definition of Counselling and Guidance, Counsellor Preparation, Qualifications, Qualities, Legal and Professional ethics

**UNIT- II:**

Different approaches to counselling, goals in counselling, role and functions of the counsellor.

**UNIT- III:**

Micro skills in Counselling- relationship building strategies and methods: Opening techniques, attending skills- verbal and non-verbal communication, Listening skills:

Open questions and closed questions, Encouragement, Paraphrasing, Reflection, Summarization, influencing skills-Reframing, genuineness and Self-disclosure.

**UNIT-IV:**

Macro skills in Counselling, empathy, advanced empathy, Confrontation & challenging, Resistance, transference and counter-transference

**UNIT-V:**

Counselling situations and Counselling across life-span.

**Learning Outcome**

At the end of this course, the students will be able to:

Demonstrate basic knowledge in counseling (concepts, theories, ethical issues, basic skills, etc.)

**SYLLABUS FOR I YEAR  
B.Sc. ALLIED HEALTH SCIENCES  
GENERIC ELECTIVE COURSE (GEC) - LIFESTYLE DISORDERS**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: LIFESTYLE DISORDERS</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 64Hrs</b>
<b>EXAMINATION</b>	<b>: 50 Marks (40 U +10IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ Hrs.</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: I YEAR</b>

**COURSE OUTCOMES**

**LD CO1:** To understand the relevance, significance and implications of lifestyle disorders for the betterment of human life quality.

**THEORY (64 Hours)**

**UNIT I Modern Life style disorders**

Desk bound and sleeping habits, junk food, anxiety. Food poisoning, Acidity.

**UNIT II Dietary disorders**

Food groups and concept of a balanced diet, obesity, metabolic syndrome, hypertension- their causes and prevention through dietary and lifestyle modifications

**UNIT III Social health problems**

Smoking, alcoholism, drug dependence and Acquired Immune Deficiency Syndrome (AIDS).

**UNIT IV Gastrointestinal disorders**

Stomach disorders-Gastritis, Ulcer, Amoebiasis, Constipation, piles  
Common ailment- cold, cough, fevers, diarrhea, constipation- their causes and dietary

**LEARNING OUTCOMES**

To understand the relevance, significance and implications of lifestyle disorders for the betterment of human life quality

**Text Books**

1. Text book of Clinical Biochemistry-Carl.A. Burtis and EdwardR.Ashwood
2. Text Book of Medical Biochemistry-Dr.M.N.Chatterjee and Rane Shinde

**Reference Books**

1. P. Singh MD. Textbook of Nutrition and Health; First Ed; 2008; Academic Excellence  
Biochemistry with Clinical Correlation- Thomas M.Devl

**II YEAR**

**B.Sc - CLINICAL RESEARCH**  
**FACULTY OF ALLIED HEALTH SCIENCES**  
**SRI BALAJI VIDYAPEETH**  
**(Deemed to be University)**  
**Accredited by NAAC with 'A' Grade**

**II-YEAR**

**CORE SUBJECTS**

1. Basics Of Clinical Pharmacology& Clinical Research
2. Ethics In Clinical Research &Clinical Trial Documentation
3. Pharmacovigilance

**ELECTIVES**

**Ability Enhancement compulsory course (AECC)**

1. Environmental studies

**Skill enhancement course (SEC) - Choose any TWO**

1. Good Clinical Laboratory practice
2. Computer Applications
3. Library and E-resource
4. Public Health and Hygiene

**Generic Elective Course (GEC) - Choose any ONE**

1. Basic Psychology
2. Sociology
3. Entrepreneurship essentials

## AHS Course Content Second year B.Sc. Clinical Research (CR)

Faculty code	Category	Course title	Hours					Credits				
			Theory	Practical	Tutorials	Clinical training	Total hours	Lecture	Practical	Tutorials	Clinical training	Total credits
AHS	Core theory CR	Subjects										
AHS	CR -5	Basics Of Clinical Pharmacology& Clinical Research	64	64				4	2			6
AHS	CR -6	Ethics In Clinical Research &Clinical Trial Documentation	80		32			5		1		6
AHS	CR-7	Pharmacovigilance	80		32			5		1		6
AHS	CR-CT 1	Clinical Training CR 5 to 7				384					12	12
AHS	AECC	Environmental Science	16	34				1	1			2
AHS	SEC - 1-3	Student's choice	16	32				1	1			2
AHS	SEC - 1-3	Student's choice	16	32				1	1			2
AHS	GEC - 1-3	Student's choice	64					4				4
			<b>432</b>	<b>98</b>	<b>128</b>	<b>192</b>	<b>850</b>	<b>27</b>	<b>3</b>	<b>4</b>	<b>6</b>	<b>40</b>

## SCHEME OF EXAMINATION

Papers	Subject	Theory		Practical		Theory	Practical	Grand total 900	Min marks to pass % (450)
		UE	IA	UE	IA	UIA*	UIA*		
CR -5	Basics Of Clinical Pharmacology& Clinical Research	80	20	80	20			200	100
CR -6	Ethics In Clinical Research &Clinical Trial Documentation	80	20					100	50
CR-7	Pharmacovigilance	80	20					100	50
CR-CT 1	Clinical Training CR 5 to 7						100	100	50
AECC	Ability enhancement Compulsory Course - Environmental Science	80	20					100	50
SEC	Skill enhancement Course	80	20					100	50
SEC	Skill enhancement Course	80	20					100	50
GEC	Generic elective	80	20					100	50

For all elective course, 40 marks for university theory and Practical cum Viva examination & 10 marks as Internal Assessment = 50 marks which will be converted to 100 marks in the transcript.



# **BASICS OF CLINICAL PHARMACOLOGY & CLINICAL RESEARCH**

## PAPER- CR-5 - BASICS OF CLINICAL PHARMACOLOGY & CLINICAL RESEARCH

Duration of Theory Classes	: 64 Hrs
Duration of Practical/Tutorial Sessions	: 64Hrs
Theory Examination	: 100 Marks (80 U + 20 IA)
University Practical Examination	: 100 Marks
Duration of Theory Examination	: 3 Hrs
Year in which Subject Paper is taught	: II Year

### COURSE DESCRIPTION

This course covering the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics. The course focuses on the following core principles of pharmacology: pharmacokinetics; drug metabolism and transport; drug therapy in special populations; assessment of drug effects; drug discovery and development; pharmacogenomics and pharmacotherapy.

### OBJECTIVES

1. To provide an in-depth look at drug absorption, distribution, metabolism and excretion.
2. To describe the impact of age, pregnancy, and disease on pharmacokinetics.
3. To describe the basic principles in the assessment of drug effects.
4. To describe the process of drug discovery and development.
5. Provide an overview of clinical pharmacotherapy including pharmacogenomics and medication safety.

### PROGRAM OUTCOMES

**CRPO1:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CRPO2:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CRPO3:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial participants

**CRPO4:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CRPO5:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CRPO6:** Develop the key skills and knowledge needed to operate an effective drug safety program.

### COURSE OUTCOMES

At the end of the course the student should be able to

**CO1:** Understand the basic concepts of Clinical Pharmacology including bioequivalence and rational therapeutics

**CO2:** Gain in-depth knowledge about the fundamentals of clinical research

**CO3:** Understand the basics of drug discovery and development process

**CO4:** Describe the various screening methods for evaluation of crude drugs including types of toxicity testing

### COURSE CONTENT

UNIT	TITLE	THEORY+TUTORIAL (64 HOURS)
I	<p><b>INTRODUCTION TO PHARMACOLOGY</b></p> <ul style="list-style-type: none"> <li>• Definitions, source of drugs, pharmacological classification of drugs, routes of drug administration</li> </ul> <p><b>PHARMACOKINETICS</b></p> <ul style="list-style-type: none"> <li>• Absorption of drugs: Phases &amp; routes of drug transfer from G.I absorption in to systemic circulation, Nature of cell membrane, passage of drug across cell membrane, Oral drug absorption, factors influencing drug absorption &amp; bioavailability.</li> <li>• Distribution of drugs: Physiological factors of distributions, apparent volumes of distributions, protein binding of drugs, kinetics of protein bindings, clinical significance of drug-protein binding &amp; factors affecting distribution of drugs.</li> <li>• Biotransformation of drugs: Need for drug biotransformation, drug metabolizing organs, drug metabolizing enzymes, Phase I &amp; II reactions, factors affecting biotransformation of drugs, Bio-pharmaceutics drug disposition classification system.</li> <li>• Elimination of drugs: Renal excretion of drugs, concept of clearance &amp; factors affecting renal excretion &amp; clearance, Non-linear pharmacokinetics.</li> </ul>	15 HOURS

II	<p><b>PHARMACODYNAMICS</b></p> <ul style="list-style-type: none"> <li>Mechanism of drug action, relation between the drug concentration &amp; effect, receptor, structural &amp; functional families of receptors, classification of receptors, Therapeutic Drug Monitoring (TDM), Therapeutic Index (TI).</li> </ul> <p><b>BIOAVAILABILITY &amp; BIOEQUIVALENCE</b></p> <ul style="list-style-type: none"> <li>Definition, purpose of bioavailability studies, relative &amp; absolute bioavailability, method of assessing bioavailability &amp; bioequivalence studies, design &amp; evaluation of bioequivalence studies, In-vitro drug dissolution testing models, biopharmaceutical classification system (BCS) &amp; clinical significance of bioequivalence studies.</li> </ul> <p><b>RATIONAL THERAPEUTICS &amp; TOXICITY</b></p> <ul style="list-style-type: none"> <li>Rational use of drugs, drug-drug interactions, drug-food interactions, drug-herb interactions, drug overdose &amp; drug abuse</li> </ul>	17 HOURS
III	<p><b>INTRODUCTION &amp; FUNDAMENTALS</b></p> <ul style="list-style-type: none"> <li>Development of pharmaceutical industry, nature of disease &amp; purpose of therapy. Therapeutic modalities and basics of pharmaco-economics</li> </ul>	4 HOURS
IV	<p><b>DRUG DISCOVERY</b></p> <ul style="list-style-type: none"> <li>Introduction- Drug discovery process, general principles &amp; case histories - Stages of drug discovery - Trends in drug discovery &amp; project planning - Choosing the project- Strategic issues, Un-met medical needs, market considerations, scientific &amp; technical issues, patent situation &amp; operational issues. - Choosing the target- Introduction &amp; scope for new drug targets, conventional strategies for finding new drug targets, new strategies for identifying new drug targets, travelling the genomes - Target validation- Pharmacological &amp; genetic approaches.</li> </ul>	10 HOURS
V	<p><b>DRUG DEVELOPMENT</b></p> <ul style="list-style-type: none"> <li>Introduction &amp; nature of drug development, components of drug development, interface between discovery &amp; development. New drug discovery process- purpose, main steps involved in new drug discovery process, timelines of each steps, advantages and purposes of each steps, ethics in clinical research, unethical trials, thalidomide tragedy, Phase-I, II, III, IV trials. Principles of sampling -Inclusion and exclusion criteria -Methods of allocation and randomization -Informed consent process in brief - Monitoring treatment outcome -Termination of trial -Safety monitoring in clinical trials, Preclinical toxicology: General principles, Basic terminology used in clinical research: Types of clinical trials, single blinding, double blinding,</li> </ul>	10 HOURS

	open access, randomized trials and their examples, interventional study, ethics committee and its members, cross over design, etc...and Institution Ethics Committee / Independent Ethics Committee Data Management in clinical Research. Pharmaceutical developments: Route of administration & dosage forms, pre-formulation studies, solubility & dissolution rate, stability, novel drug delivery system. - Patenting & intellectual property in drug development: patent specification, requirements for patentability, filing patent applications.	
VI	<p><b>PHARMACOGNOSY &amp; PHARMACOLOGICAL SCREENING</b></p> <ul style="list-style-type: none"> <li>Introduction to medicines derived from natural sources, source &amp; classification of crude drugs. Various methods of evaluation of crude drugs, secondary metabolites &amp; its medicinal values, nutraceuticals&amp; ethno pharmacology. Toxicity- acute, sub-acute &amp; chronic toxicity, animal toxicology, pharmacological screening of medicinal product- Analgesic, anti-inflammatory, hepato-protectivity, anti-diabetic, antiviral, anticancer, antioxidant &amp; microbiological screening.</li> </ul>	<b>8 HOURS</b>

#### **METHODS OF TEACHING**

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### **METHODS OF EVALUATION**

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### **TEXT BOOKS**

1. Essential of medical pharmacology by KD Tripathi, 7<sup>th</sup> edition,2013.
2. Clinical Pharmacology, Scientific book agency, Laurence, DR and BennetPN.
3. Textbook of Clinical Research -VikasDhikav-2016
4. Drug discovery & clinical research - SK Gupta -2011
5. ICMR - Regulatory requirement for drug development & Clinical research,ICMRPublication,2013

## BLUE PRINT

UNIT	SYSTEMS	WEIGHTAGE %	MARKS ALLOTTED (TOTAL 80)	LAQ (2 out of 4)	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	Introduction to Pharmacology	30.80	25	1	1	3
II	Pharmacodynamics	26.25	21	2*	2+1*	3+1*
III	Introduction and fundamentals of clinical research	11.25	9		1	1
IV	Drug discovery	16.2	13	1		1+1*
V	Drug development	11.25	9		1	1
VI	Pharmacognosy and pharmacological screening	3.75	3			1
	<b>Total</b>		<b>80</b>			

*Note: \* represents question of choice*

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 100 marks.

Long Answer Questions : 2 X 10 = 20 marks (Choice 2 out of 4)

Short Answer Questions : 5 X 6 = 30 marks (Choice 5 out of 6)

Very Short Answer Questions: 10 X 3 = 30 marks (Choice 10 out of 12)

TOTAL = Theory 80 + IA 20 = 100 marks

### PAPER- CR-5- BASICS OF CLINICAL PHARMACOLOGY & CLINICAL RESEARCH

#### MODEL QUESTION PAPER

**TIME: 3 HOURS**

**MAXIMUM MARKS: 80**

**I. Long answer questions**

**(2 x10 = 20)**

1. a) Explain in detail about mechanism of drug action, concentration and effect of receptors. (OR)
  - b) Methods of allocation and randomization
2. a) Explain in detail about classification of drugs.(OR)
  - b) Describe about Therapeutic Drug Monitoring

**II. Short answer questions -Answer any 5 questions marks**

**(5 X 6 =30)**

1. Purpose of bioavailability studies
2. Factors influencing drug absorption
3. Toxicity testing
4. Thalidomide tragedy
5. PHASE 0 clinical trial
6. Reproductive toxicity

**III. Very Short answer questions -Answer any 10 questions**

**(10x3 = 30)**

1. What is a lead compound?
2. Define half-life of a drug
3. What are the types of blinding?
4. Define Teratogenicity.
5. Post marketing surveillance
6. Two clinical significance of drug-protein binding
7. Define bioavailability
8. Therapeutic Index
9. Define pharmacokinetics
10. List 2 types of adverse drug reaction and give example for each
11. List 2 advantages of intramuscular route
12. Define toxicology

# **ETHICS IN CLINICAL RESEARCH & CLINICAL TRIAL DOCUMENTATION**



## PAPER- CR- 6- ETHICS IN CLINICAL RESEARCH & CLINICAL TRIAL DOCUMENTATION

Duration of Theory Classes	: 80Hrs
Duration of Practical Sessions	: 32Hrs
Theory Examination	: 100 Marks (80 U + 20 IA)
University Practical Examination	: NIL
Duration of Theory Examination	: 3 Hrs
Year in which Subject Paper is taught : II Year	

### COURSE DESCRIPTION

This course is offered to anyone interested or involved in the ethics of clinical research with human subjects. Participants represent multiple disciplines including research teams, IRB members, physicians, psychologists, nurses, social workers, administrative staff, students, and others.

### OBJECTIVES

1. Utilize a systematic framework for evaluating the ethics of a clinical research protocol.
2. Apply appropriate codes, regulations, and other documents governing the ethical conduct of human subject research to their own research.
3. Discuss controversial issues relating to human subject research, including Phase 1 research, randomization, children in research, international research, etc.
4. Identify the critical elements of informed consent and strategies for implementing informed consent for clinical research.
5. Describe the purpose, function, and challenges of IRBs.
6. Appreciate the experience of human subjects who have participated in research protocols.

### PROGRAM OUTCOMES

**CRPO1:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CRPO2:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CRPO3:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial participants

**CRPO4:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CRPO5:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CRPO6:** Develop the key skills and knowledge needed to operate an effective drug safety program.

## COURSE OUTCOMES

At the end of the course the student should be able to

**ECRCTDCO1:** Understand the basics of the ethics in clinical research, different types of ethical codes & develop their knowledge about regulatory issues of clinical research & trial management.

**ECRCTDCO2:** Gain knowledge about the institutional review board

**ECRCTDCO3:** Attain the skill of writing a proper informed consent forms

**ECRCTDCO4:** Understand and acquire skills in the preparation of Investigators Brochure

**ECRCTDCO5:** Design a proper study protocol for different phases and types of clinical trial

**ECRCTDCO6:** Understand the benefits in implementation and monitoring of the standard operating procedures in clinical trials

**ECRCTDCO7:** Prepare various essential documents required for a clinical trial and understand the procedure of recording, handling and storing them.

## COURSE CONTENT

UNIT	TITLE	THEORY+TUTORIAL (80+32HOURS)
I	<p><b>INTRODUCTION AND FUNDAMENTALS</b> History, Ethical theories and foundation, moral principles that apply values and judgments in the context of clinical trials. Misconduct in Clinical Trials, Conflict of interest, patients case studies, Selection of Investigators,, confidentiality of Clinical data, Safety Monitoring, Standard of care, Continued Access, Compensation and Transparency.</p> <p><b>PRINCIPLES OF RESEARCH ETHICS</b> Four fundamental principles medical ethics: Respect for autonomy, Beneficence, Non Malfeasance, Justice. Other principals include Privacy and Confidentiality, preservation of life issues, Social Responsibility and Gender issues, vulnerable population, loyalty and trust, Respects and dignity. Application of principles of medical ethics to preclinical, Clinical and Post Clinical aspects in Medical Research.</p>	<b>10 + 4 HOURS</b>

II	<p><b>ETHICAL CODES</b>  Declaration of Helsinki, Nuremberg codes, ICMR code of ethics, Indian Council of Medical Research Ethical Guidelines (ICMR) for Biomedical Research, Council for International Organizations of Medical Sciences (CIOMS) guidelines - International Commission on Harmonization - Good Clinical Practices (ICH-GCP) guidelines [ ICH &amp; its composition: E6-GCP principles], Indian GCP guidelines, CPCSEA guidelines</p> <p><b>INSTITUTIONAL REVIEW BOARD AND INFORMED CONSENT</b>  Ethics committee, need for IRB, Composition of IRBs, Type of IRBs, setting IRB in an institution, Process of IRB review, Activities of IRB, Types of review: Full review expedited review, continuing review.</p> <p>Criteria for IRB Approval, disapproval, require modification, safeguards of the research participant. Categories of research that require IRB approval, Protocol FWA approval through OHRP (office of Human Research subject Protection), Indemnity for ethic committee members, IRB agreements, Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP).Concept of Informed consent, components of informed consent- Information, conformation, voluntariness, Elements of consent form (12 elements).Process of obtaining informed consent, Translation, Legally Authorized Representative (LAR), impartial witness</p>	12 + 6 HOURS
III	<p><b>CLINICAL TRIAL APPLICATION REQUIREMENTS</b>  Investigational New drug (IND): Classifications, IND application submission check list, FDA IND review check list , IND application process, Information for sponsors-investigator submitting IND, IND forms and instructions New Drug Application(NDA): Pre NDA meeting, NDA submission Check list, FDA NDA review check list: Abbreviated New drug Application(ANDA): ANDA content, ANDA Submission check list , FDA ANDA review check list , ANDA process for generic drugs, guidance documents for ANDAs, ANDA forms and electronic submissions Orphan Drugs Application:</p>	16 + 8 HOURS

	<p>Submission check list, FDA orphan drug review check list, FDA documents.</p> <p><b>INVESTIGATOR’S BROCHURE</b> Confidentiality Statement, Summary, Introduction, Physical, Chemical, and Pharmaceutical Properties and Formulation, Nonclinical Studies, Nonclinical Pharmacology, Pharmacokinetics and Product Metabolism in Animals, Toxicology, Effects in Humans, Pharmacokinetics and Product Metabolism in Humans, Safety and Efficacy, Marketing Experience, Summary of Data and Guidance for the Investigator</p> <p><b>STUDY PROTOCOL</b> The contents of a trial protocol should generally include the topics: General Information, Background Information, Trial Objectives and Purpose, Trial Design, Selection and Withdrawal of Subjects, Treatment of Subjects, Assessment of Efficacy, Assessment of Safety, Biostatistics, Direct Access to Source Data/Documents, Quality Control and Quality Assurance, Ethics, Data Handling and Record Keeping, Financing and Insurance, Publication Policy, Supplements, CASE REPORT FORMS (CRF) &amp; E- CRF Study Title, Inclusion Criteria, Exclusion Criteria, Patient Screening, Admission /discharge procedure, Visit wise, Period wise, Laboratory Analysis, Vital signs, Diet restriction, Concomitant medication, withdrawal/drop out details, Adverse Events Form, Serious Adverse Event Form</p>	
IV	<p><b>INFORMED CONSENT FORM/ASSENT FORM</b> Study title, What is the purpose of research, The study design, Study Procedures, Women of childbearing potential, Possible risks, Possible benefits, Compensation, Possible benefits to other people, The alternatives you have, Cost to the participant, Confidentiality of the information of subject/patient, decision to participate/ not participate, Withdrawal of the consent, Right to new information, Contact persons, Patient consent form, Patient Information Sheet, Patient visit diary</p> <p><b>CLINICAL STUDY REPORT</b> Title Page, Synopsis, List Of Abbreviations And Definitions Of Terms, Ethics, Investigators And Study Administrative Structure,</p>	12 + 8 HOURS

	<p>Introduction, Study Objectives, Investigational Plan, Study Patients, Efficacy Evaluation, Efficacy Evaluation, Discussion And Overall Conclusions, Tables, Figures and Graphs Referred, Reference List, Appendices</p> <p>STANDARD OPERATING PROCEDURES (SOP) IN CLINICAL TRIALS Need of SOPs, What is SOPs, Benefits of SOPs, different types of SOPs, SOP Writing SOPs and Guideline, Implementation and monitoring of SOPs, Change control</p>	
V	<p><b>ESSENTIAL DOCUMENTS</b></p> <p>Importance of Essential Documents</p> <p>Pre Study Document: Investigators Brochure, Financial aspects of the trial, Approval letter from the IRB, IRB Composition etc</p> <p>During the Study Documents: Updates on medical/laboratory/technical procedure tests, Investigational product(s) accountability at site, Subject enrolling log, Audit certificate etc.</p> <p>Post Study Documents: Final report by investigator to IRB, Final report by investigator to regulatory authorities, Clinical study report to document results and interpretation etc,</p> <p>Others: Study Completion documents, Study Termination/closure documents</p>	<b>14 + 6 HOURS</b>

#### **METHODS OF TEACHING**

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### **METHODS OF EVALUATION**

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### **TEXT BOOKS**

1. Textbook of Clinical Research -VikasDhikav- 2016
2. Guideline for Good Clinical Practice - ICH.

## BLUE PRINT

UNIT	SYSTEMS	WEIGHTAGE %	MARKS ALLOTTED (TOTAL 80)	LAQ (2 out of 4)	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	Introduction and fundamentals	2.5	22	1	1	2+1*
II	Ethical codes	11.2	9	1*	1	1
III	Institutional review board and informed consent	42.5	34	1+1*	2+1*	4+1*
IV	Informed consent form/assent form	15	12		1	2
V	Essential documents	3.75	3			1
	<b>Total</b>		<b>80</b>			
<i>Note: * represents question of choice</i>						

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 100 marks.

Long Answer Questions : 2 X 10 = 20 marks (Choice 2 out of 4)

Short Answer Questions: 5 X 6 = 30 marks (Choice 5 out of 6)

Very Short Answer Questions: 10 X 3 = 30 marks (Choice 10 out of 12)

TOTAL = Theory 80 + IA 20 = 100 marks

### PAPER- CR- 6- ETHICS IN CLINICAL RESEARCH & CLINICAL TRIAL DOCUMENTATION

#### MODEL QUESTION PAPER

**TIME: 3 HOURS**

**MAXIMUM MARKS: 80**

**A. Long answer questions**

**(2 x10 = 20)**

1. a) Explain in detail about ethical codes.(OR)  
b) Detail about Compensation in clinical trials
2. a) Describe the importance of essential documents.(OR)  
b) Describe the Institutional ethics committee composition

**B. Short answer questions -Answer any 5 questions**

**(5X 6 =30)**

1. Orphan Drugs Application
2. Clinical Trial Design
3. Benefits of SOPs
4. Waiver of consent
5. Malfeasance
6. Vulnerable population

**C. Very Short answer questions -Answer any 10 questions**

**(10x 3 = 30 )**

1. Respect of autonomy
2. Name 2 national bioethics organizations
3. Drug safety monitoring board
4. What is vulnerability?
5. Schedule M III
6. Fast track approval
7. Expedited review
8. What is a source document?
9. Trial initiation monitoring report
10. List the pre study - essential documents
11. Master randomization list
12. Screen failure log.

# PHARMACOVIGILANCE



## SYLLABUS -PAPER CR-7 - PHARMACOVIGILANCE

Duration of Theory Classes	: 80Hrs
Duration of Practical Sessions	: 32Hrs
Theory Examination	: 100 Marks (80 U + 20 Ia)
University Practical Examination	: NILL
Duration of Theory Examination	: 3 Hrs
Year in which Subject Paper is taught	: II Year

### COURSE DESCRIPTION

Focus will be on drug safety monitoring, in accordance with national and international legislation and guidelines, as well as proactive strategies for risk management to improve patient safety.

### OBJECTIVES

On completion of this course, the student will be able to:

1. Critically appraise the principles of pharmacovigilance practice and the regulatory framework for clinical drug safety
2. Distinguish safety reporting requirements in the pre-marketing, peri-approval, and post-marketing continuum
3. Categorise the seriousness, expectedness, and causality of adverse events
4. Identify EU risk management plan (RMP) requirements and USA risk evaluation and mitigation strategies (REMS)
5. Discuss methods for signal detection and data mining, and apply the principles of pharmaco epidemiology

### PROGRAM OUTCOMES

**CRPO1:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CRPO2:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CRPO3:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial participants

**CRPO4:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CRPO5:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CRPO6:** Develop the key skills and knowledge needed to operate an effective drug safety program.

## COURSE OUTCOMES

At the end of the course the student should be able to

**PVCO1:** Understand the basic concepts and importance of ADR monitoring and Post marketing surveillance

**PVCO2:** Gain in-depth knowledge and skills on the best way to collect and report adverse events and perform causality assessment

**PVCO3:** Outline the methods of signal detection and data mining in

pharmacovigilance **PVCO4:** Prepare the reports of periodic safety update report

(PSUR) **PVCO5:** Understand the functioning of the National Pharmacovigilance Centre

## COURSE CONTENT

UNIT	TITLE	THEORY+TUTORIAL (80+32HOURS)
I	<b>THE BASIS OF PHARMACOVIGILANCE</b> Introduction - Key Definition, History of pharmacovigilance, Legal Basis(India, EU and United States) - Ethical Oversight Concern and Confidentiality - Mechanism of ADR - Non clinical safety evaluation and Adverse events in Phase Trials.	16 + 6
II	<b>FUNDAMENTALS AND PRINCIPLES OF DRUG SAFETY AND TOXICOLOGY</b> Introduction and Fundamentals: Classification of adverse reactions, common mechanisms, predisposing factors, Management of safety procedures, Assessment and Challenges: Drug Reactions, Drug Interactions, Over dosage, Dependence, addiction, Assessment of Violation, Drug withdrawal errors, bias, Quality control procedures, Quality Maintenance, Standard Utility Procedures.	15 + 8
III	<b>ADE/ADR</b> The epidemiology of preventable adverse drug events: Incidence, preventability, and impact of Adverse Drug Events (ADEs) and potential ADEs, Adverse drug events and medication errors: detection and classification of ADEs according to preventability, ameliorability, disability, severity, stage, compensation issues	12 + 7
IV	<b>RISK MANAGEMENT &amp; SIGNAL DETECTION</b> Crisis Management: Evaluation of Risk Management in Clinical Trials, Confidentiality issues, Monitoring Strategies: Tactics and operations for Government Organization, Clinical Research Organization, and contract organization. Methods in Post market surveillance, safety studies, Pharmacovigilance, Data Management Statistical methods for signal detection - Statistical methods of evaluating - Pharmacovigilance Data - Data mining in Pharmacovigilance-Signal Detection	16 + 7
V	<b>SURVEILLANCE OF REACTION</b> Surveillance of reactions through charts, laboratory, prescription	15 + 4

<p>data, and administrative databases, or screening by computer systems to identify signals.</p> <p><b>INDIVIDUAL CASE SAFETY REPORT (ICSR) AND PERIODIC DRUG SAFETY REPORT</b></p> <p>Data base used in ICSR Process flow of ICSR - Medwatch3500, CIOMS 1 form , MedDRA</p> <p>Safety narrative writing and medical assessment - Quality control and Quality assurance in ICSR. PSUR of Indian Drug Control General of India - PSUR, Surveillance for Medical Devices</p> <p><b>PHARMACOVIGILANCE PROGRAM IN INDIA</b></p> <p>Rules and Regulation of PVG Centre - Function of PVG centre</p>	
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#### METHODS OF TEACHING

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### METHODS OF EVALUATION

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### TEXT BOOKS

1. Textbook of Pharmacovigilance - SK Gupta -2011

#### BLUE PRINT

UNIT	SYSTEMS	WEIGHTAGE %	MARKS ALLOTTED (TOTAL 80)	LAQ (2 out of 4)	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	Basis of Pharmacovigilance	7.5	6		1*	2
II	Fundamental and principles of drug safety and toxicology	23.75	19	1	1	1+1*
III	ADE/ADR	15	12		1	2
IV	Risk management and signal detection	15	12	1*	1	2
V	Surveillance of reaction	38.75	31	1+1*	2	3+1*
	Total		80			
<i>Note: * represents question of choice</i>						

**PAPER CR-7- PHARMACOVIGILANCE**

**MODEL QUESTION PAPER**

**TIME: 3 HOURS**

**MAXIMUM MARKS: 80**

**A. Long answer questions**

**(2 X 10 =20)**

1. a) Explain the fundamentals and principles of drug safety and toxicology. (OR)  
b) Detail about crisis management cycle in pharmacovigilance
2. a) Describe the organization, responsibilities and registration procedure for approval of drug products. (OR)  
b) Explain about needs & objectives of pharmacovigilance.

**B. Short answer questions -Answer any 5 questions**

**(5 X 6 =30)**

1. Methods of signal detection
2. Serious adverse event
3. Pharmacological classification of ADR
4. Applications of MedDRA
5. PSUR
6. ADR Reporting system

**C. Very Short answer questions -Answer any 10 questions**

**(10x3 = 30)**

1. Medical error
2. Post registration safety study
3. Define Signal
4. SUSAR
5. What is Vigiflow?
6. Spontaneous reporting
7. Type B reactions
8. Define Adverse event
9. Define Pharmacovigilance
10. Define idiosyncrasy
11. Give examples for teratogenicity
12. Rechallenge

# **II YEAR ELECTIVE COURSES**

**II YEAR ELECTIVE COURSE CONTENT  
ABILITY ENHANCEMENT COMPULSORY COURSE (AECC)  
ENVIRONMENTAL STUDIES**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: ENVIRONMENTAL STUDIES</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16 hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32 hrs</b>
<b>EXAMINATION</b>	<b>: 100 marks (80 U + 20 IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: II YEAR</b>

**SYLLABUS**

**UNIT-I (Renewable and Non – renewable resources)**

The multidisciplinary nature of environmental studies – Definition, scope and importance – Need for public awareness.

- 1 Forest resources: Use and over-exploitation, deforestation, case studies. Timber extraction, mining, dams and their effects on forests and tribal people.
- 2 Water resources: Use and over-utilization of surface and ground water, floods, drought, conflicts over water, dams-benefits and problems.
- 3 Mineral resources: Use and exploitation, environmental effects of extracting and using mineral resources, case studies.
- 4 Food resources: World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity, case studies.
- 5 Energy resources: Growing energy needs, renewable and non-renewable energy resources, use of alternate energy sources, case studies.
- 6 Land resources: Land as a resource, land degradation, man induced Landslides, soil erosion and desertification. Role of an individual in conservation of natural resources. Equitable use of resources for sustainable lifestyles.

**UNIT-II (Ecosystems)**

Concept of an ecosystem - Structure and function of an ecosystem Producers, consumers and decomposers – Energy flow in the ecosystem-Ecological succession- Food chains, food webs and ecological pyramids –Introduction, types, characteristic features, structure and function of the following ecosystem:

- Forest ecosystem
- Grassland ecosystem
- Desert ecosystem
- Aquatic ecosystems (Ponds, streams, lakes, rivers, ocean estuaries)

**UNIT-III (Biodiversity and its conservation)**

Introduction – Definition: genetics, species and ecosystem diversity

- Biogeographically classification of India
- Value of Biodiversity: Consumptive use, productive use, social, ethical aesthetic and option values

- Biodiversity at global, national and local levels
- India as a mega- diversity nation
- Hot-spots of biodiversity-Threats to biodiversity: habitat loss, poaching of wildlife, man wildlife conflicts
- Endangered and endemic species of India
- Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity

#### **UNIT-IV (Environmental Pollution)**

Definition- causes, effects and control measures of:

- Air pollution
- Water pollution
- Soil pollution
- Marine pollution
- Noise pollution
- Thermal pollution
- Nuclear pollution
- Solid waste Management: causes, effects and control measures of urban and industrial wastes – role of an individual in prevention of pollution –Pollution case studies – Disaster management: floods, earthquake, cyclone and landslides.

#### **UNIT-V**

Social Issues and the Environment: From unsustainable to sustainable development – Urban problems and related to energy – Water conservation, rain water harvesting, watershed management –Resettlement and rehabilitation of people; its problems and concerns. Case studies - Environmental ethics: issues and possible solutions climate change, global warming, acid rain, ozone layer depletion, nuclear accidents and holocaust.

- Wasteland reclamation – Consumerism and waste products –Environmental Protection Act – Air ( Prevention and Control of Pollution) Act – Water ( Prevention and control of Pollution) Act – Wildlife Protection Act – Forest Conservation Act - Issues involved in enforcement environmental legislation – Public awareness
- Human Population and the Environment: Population growth, variation among nations – Population explosion – Family welfare Programmes – Environment and human health- Human Rights - Value Education- HIV/ AIDS - Women and Child Welfare- Role of Information Technology in Environment and Human Health – Case Studies.

#### **FIELD WORK**

1. Visit to local area to document environmental assets- river/ forest/ grassland / hill / mountain
2. Visit to a local polluted site - Urban / Rural / Industrial / Agricultural
3. Study of common plants, insects, birds
4. Study of simple ecosystems- pond, river, hill slopes, etc.

**TEXT BOOKS RECOMMENDED**

1. Agarwal, K.C. Environmental Science, Nidi Publishers.
2. BharuchaErach, The Biodiversity of India, Mapin Publication.
3. Brunner RC, Hazardous waste incineration, McGraw Hill Publishers.
4. Iaclhav H, Environmental Protection and Laws, Himalaya Publication.
5. Odum EP, fundamentals of Ecology, WB Sannders Publication.

**TEACHING LEARNING ACTIVITIES**

The course content in Environmental Studies will be covered by:

1. Interactive Lectures
2. Group Discussions
3. Field Visits



**SKILL- BASED ELECTIVE COURSES - II YEAR**  
**GOOD CLINICAL LABORATORY PRACTICE**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: Good Clinical Laboratory practice</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16 Hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32 Hrs</b>
<b>PRACTICAL EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY THEORY EXAMINATION</b>	
<b>DURATION OF EXAMINATION</b>	<b>: 1 ½ Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: II YEAR</b>

**THEORY & PRACTICALS (DURATION 16 + 32 Hours)**

**Learning Objective**

- To understand the relevance, importance and basic concepts of good laboratory practices
- To apply the knowledge to become familiar with the basic laboratory skills

**UNIT I: INTRODUCTION**

Introduction to Bioethics and Biosafety. Biosafety Guidelines and Regulations. Legal and Socio-economic Impacts of Biotechnology. Use of Genetically Modified Organisms and their Release in the Environment. Hazardous Materials used in Biotechnology their Handling and Disposal.

**UNIT II: GOOD LABORATORY PRACTICE PRINCIPLE**

Test Facility Organization and Personnel: Management responsibility, Study directors responsibility, safety measures and personal responsibility. Quality assurance program. Facilities: Test System Facilities, Facilities for Handling test and Reference Substances. Archive Facilities. Waste Disposal, Animal Care Facilities, Animal Supply Facilities.

**UNIT III: STANDARDIZED OPERATING PROCEDURES**

Definition, Initiation of SOP, Preparation of SOP, Administration, Distribution and Implementation. Maintenance of laboratory records. Formatting SOP, Reagent/materials certification, Certification of analysts, Certification of laboratory facilities, Documentation and maintenance of record.

**UNIT IV: DATA REPORTING AND STORAGE**

Performance of study, Study plan, Conduct of study, Reporting of results. Archival storage of records and reports.

**Learning Outcome**

- To understand the implications of good laboratory practices

**SKILL- BASED ELECTIVE COURSES - II YEAR  
COMPUTER APPLICATIONS**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: COMPUTER APPLICATIONS</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16 Hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32 Hrs</b>
<b>PRACTICAL EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY THEORY EXAMINATION</b>	
<b>DURATION OF EXAMINATION</b>	<b>: 1 ½ Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: II YEAR</b>

**THEORY & PRACTICALS (DURATION 16 + 32 Hours)**

**UNIT - I - Introduction to Computers**

- Concepts of Computers
- Hardware and software trends and technology
- Classification of computers
- Application of computers in Laboratories

**UNIT - II - Operating System**

- Introduction
- Types of operating systems
- Windows

**UNIT - III -Multimedia**

- Types and uses
- Computer aided teaching and testing

**UNIT – IV -Internet**

- Introduction to Internet
- Use of Internet and e- mail
- Statistical packages

## LIST OF PRACTICAL EXERCISES

1. Computer operating systems like MS-DOS and WINDOWS
2. Study of software packages like Chem Draw, Tinker and Microsoft package. Unit - Typing text in MS word- manipulating text- formatting the text - using different font sizes, bold, italics, Bullets and numbering - pictures, file insertion - aligning the text and justify - choosing paper size - adjusting margins- header and footer, inserting page numbers in a document - printing a file with options - using spell check and grammar - find and replace mail merge - inserting tables in a document.

**Creating table in MS - Excel** - cell editing - using formulas and functions - manipulating data with excel - using sort function to sort numbers and alphabets - drawing graphs and charts using data in excel - auto formatting - inserting data from other worksheets  
**Preparing new slides using MS- POWER POINT** - inserting slides - slide transition and animation - using templates - different text and font sizes - slides with sounds - inserting clip arts, pictures, tables and graphs - presentation using wizards.

**Internet-** using search engine - Google search - Exploring the text Explorer and Navigator - uploading and downloading of files and images E mail ID creation - sending messages - attaching files in E- mail

## TEACHING LEARNING ACTIVITIES

The course content in Computer Applications will be covered by:

1. Interactive Lectures
2. Lab

**SKILL- BASED ELECTIVE COURSES - II YEAR**  
**Library and E-resource**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: Library and E-resource</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16 Hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32 Hrs</b>
<b>PRACTICAL EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY THEORY EXAMINATION</b>	
<b>DURATION OF EXAMINATION</b>	<b>: 1 ½ Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: II YEAR</b>

**THEORY & PRACTICALS (DURATION 16 + 32 HOURS)**

**Course Objectives**

- To enable the students to understand at different levels of information systems in the society and their functions.
- To enable the students apply their knowledge in various library practice.
- To enable the students to understand the basic concepts of the Health Sciences.

**UNIT: 1**

Evolution, growth and development of LIS in India-current trends.

Type of libraries: Academic, Public and special Libraries (Health Science Libraries).

**UNIT: 2**

Library concepts & Legislation: Five laws of Library science, Professional ethics of librarian, Delivery of books and newspaper act/Intellectual Property/Plagiarism.

**UNIT: 3**

Library Association and International Bodies: Library Association -ILA, IASCIC, ALA, IFLA and UNESCO, SALIS, MLAI (Medical Library Association of India).

**UNIT: 4**

Library Rules & Regulation, Stock Verification, Annual Reports, Budgets, Library buildings, furniture, equipment's.

## **SKILL- BASED ELECTIVE COURSES - II YEAR PUBLIC HEALTH AND HYGIENE**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: Public Health and Hygiene</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 16 Hrs</b>
<b>DURATION OF PRACTICAL SESSIONS</b>	<b>: 32 Hrs</b>
<b>PRACTICAL EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY THEORY EXAMINATION</b>	
<b>DURATION OF EXAMINATION</b>	<b>: 1 ½ Hrs</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: II YEAR</b>

### **THEORY & PRACTICALS (DURATION 16 + 32 Hours)**

#### **Learning objectives**

- To understand the concepts, significance and relevance of public health and hygiene
- To understand the health hazards as associated with public health and hygiene

#### **I Introduction**

Definition and Concept of Public Health, historical aspects, public health system in India and in the rest of world

#### **II Aspects of health**

Indicators of health, Determinants of Health, (Social, Economic, Cultural, Environmental, Education, Genetics, Food and Nutrition). Burden and prevention of disease. Environmental health- sanitation, air, water pollution, waste management. Mental health.

#### **III Epidemiology**

Introduction, principles and concepts, study design, analysis methods, presentation and interpretation of epidemiological data

#### **IV Hygiene concepts**

Definition, importance, personal hygiene, medical hygiene, food hygiene, industrial hygiene.

**Learning outcomes**

- To understand public health and hygiene issues, their relevance and significance as can be practiced in real-life situations.

**Text Books**

1. Introduction to Public Health, Raymond L. Goldsteen, Karen Goldsteen, David G. Graham, 2011, Springer publishing company
2. Introduction To Community Health Nursing, KasturiSundarRao, 4th edition, Bi Publications Pvt Ltd
3. Concepts of Epidemiology, Raj S Bhopal, 2002, Oxford University press

**Reference Books**

1. A Treatise On Hygiene And Public Health, BirendraNathGhosh, 9th edition, Calcutta Scientific Publishing Co
2. An Introduction to Public Health, Caryl Thomas, 1949, John Wright and SonsLtd.,

## GENERIC ELECTIVE COURSES - II YEAR BASIC PSYCHOLOGY

NAME OF THE SUBJECT PAPER	: Basic Psychology
DURATION OF THEORY CLASSES	: 64 Hrs
EXAMINATION	: 50 Marks (40 U + 10 IA)
NO UNIVERSITY PRACTICAL EXAMINATION	
DURATION OF THEORY EXAMINATION	: 1 ½ Hrs
YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT	: II YEAR

### THEORY (64 Hours)

#### LEARNING OBJECTIVES

After completing the course the student can able to

- To identify the emerging specialties
- To understand the behavior and mental processes
- How the theories and principles of psychology may be applied to individual, societal and global issue
- Explain the application of psychology in Allied Health Sciences

#### Unit I: Introduction

Introduction to applied Psychology, Scientific methods in Psychology, Application of Psychology: Psychology in Industry, community, family, education, health, self development, Human relations. Scope of psychology with special relevance to Allied Health Sciences.

#### Unit II: various cognitive processes and their application

Factors affecting learning, Importance of studying Psychology of learning in relation to Allied Health Sciences

Memory and forgetting, Kinds of remembering, the nature of forgetting, Improving memory, relevance to Allied Health Sciences

Intelligence, Normal distribution of intelligence levels, Intelligence Testing, Intelligence tests, Uses and abuses of intelligence tests, relevance of intelligence and aptitude for Allied Health Sciences

#### Unit-III: Life style, Health, Stress and Coping Behavior

Cultural evolution, Life style choices and consequences, Healthy and Unhealthy life styles. Nutrition, Physical fitness, Smoking and Drinking. Stress and Health, The biological basis of stress, Stress and Physical functioning, Coping with stress, Adjustment a lifelong process. Cognitive appraisal and Stress, Stressful life styles,

Coping with everyday stress, Sources of stress, Coping styles and Strategies, Stress inoculation training.

#### **Unit IV : Psychology of Vulnerable Individuals**

Psychology of the challenged, types of disability, effects of disability, psychology of women, women and health, dealing with alcoholics and their families, post-traumatic stress disorder, psychology of the sick and ill, how patients react to chronic illness, effects of illness and hospitalization

#### **REFERENCE BOOKS**

1. Clifford T. Morgan, Richard a. King, John R. Weis and John Schopler, –Introduction to Psychologyll - 7th Edition. Tata McGraw Hill Book Co. New Delhi, 1993.
2. Ernest R. Hillgard, Richard C. Atkinson, Rita L. Atkinson, –Introduction to Psychologyll 6th Edition, Oxford IBH publishing Co. Pvt. Ltd., New Delhi, 1975.
3. Baron.A. Robert, Psychology, Pearson Education Vth Ed., 2002
4. Psychology -the science of behavior -fifth edition 1982-Neil Carson-William Bulkist- Allyn and Bacon.



## GENERIC ELECTIVE COURSES - II YEAR SOCIOLOGY

NAME OF THE SUBJECT PAPER	: SOCIOLOGY
DURATION OF THEORY CLASSES	: 64 Hrs
EXAMINATION	: 50 Marks (40 U + 10 IA)
NO UNIVERSITY PRACTICAL EXAMINATION	
DURATION OF THEORY EXAMINATION	: 1 ½ Hrs
YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT	: II YEAR

### THEORY (64 Hours)

#### Unit 1: Sociology: Discipline and Perspective

- Thinking Sociologically
- Emergence of Sociology, Sociology as a science; Sociology and Common Sense
- Some Basic Concepts: Association; Aggregates: Community, Categories, Groups and its Forms; Status and Role; Norms and Values.
- Individual and Society; Socialization: Concept and Agencies; Culture -meaning and characteristics; Types of culture - popular, elitist, folk, and consumer cultures; Pluralism and Multiculturalism, Culture and Personality.

#### Unit 2: Sociology and Other Social Sciences

- Sociology and Social Anthropology
- Sociology & Psychology
- Sociology & History

#### Unit 3: Human Society

- Social Institutions and Social Processes
  - Social control: meaning, agencies and mechanisms
  - Conformity and Deviance.
  - Social Change, definition, factors, Social Mobility
1. Anthony Giddens : Sociology
  2. G. Rocher: A General Introduction to Sociology
  3. George Ritzer. Encyclopaedia of sociology
  4. Harry M. Johnson Sociology

## **GENERIC ELECTIVE COURSES - II YEAR ENTREPRENEURSHIP ESSENTIALS**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: Entrepreneurship essentials</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 64 Hrs</b>
<b>EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>NO UNIVERSITY PRACTICAL EXAMINATION</b>	
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 ½ Hrs.</b>
<b>YEAR IN WHICH THE SUBJECT PAPER IS TAUGHT</b>	<b>: II YEAR</b>

### **THEORY (64 Hours)**

#### **LEARNING OBJECTIVES**

- To understand the fit between you and your entrepreneurial ambitions
- To find a problem worth solving
- To identify your customers
- To develop a solution for your customers' problems and problem solution
- To build and demonstrate an MVP
- To structure a business model around the problem, customer, and solution and present your Business Model Canvas

#### **UNIT - I ORIENTATION**

What is entrepreneurship - myths about entrepreneurship - impact of an entrepreneur and social entrepreneurship - wealth building and making an impact

#### **IDEA/PROBLEM**

What is a business opportunity and how to identify it - Methods for finding and understanding problems - (Observation, Questioning, DT, Jobs to be done (JTBD) - Introduction to Design Thinking - Process and Examples - Generate ideas that are potential solutions to the problem identified.

#### **UNIT - II**

##### **CUSTOMER**

The difference between a consumer and a customer (decision maker); Market Types, Segmentation and Targeting, Defining the personas; Understanding Early Adopters and Customer Adoption Patterns - Identify the innovators and early adopters for start-up - Basics of Lean Approach and Canvas; Types of Business Models (b2b; b2c)

## **UNIT - III**

### **BUSINESS MODEL AND VALIDATION**

Introduction to Risks; Identify and document your assumptions (Hypotheses); Identify the riskiest parts of Plan - Develop the Solution Demo - Sizing the Opportunity - Building an MVP (Minimum Viable Product)

## **UNIT - IV**

### **MONEY AND TEAM**

Revenue Streams: Basics of how companies make money - Understand income, costs, gross and net margins - Identify primary and secondary revenue streams - Pricing and Costs - Financing Your New Venture - Team Building: Role of a good team in a venture's success; What to look for in a team; How do you ensure there is a good fit? Defining clear roles and responsibilities

## **UNIT - V**

### **MARKETING AND SALES**

Positioning - channels and strategy - sales planning - Importance of project management to launch and track progress - Understanding time management, workflow, and delegation of tasks - Business regulation: Basics of business regulations of starting and operating a business - Importance of being compliant and keeping proper documentation

## **LEARNING OUTCOMES**

- This course will give the students the foundational experience of the entire cycle of entrepreneurship, through a combination of theory and practice.
- Students will learn what it takes to be an entrepreneur, recognizing business opportunities and the basics to create launch and manage new businesses.
- The participating students will create a \_campus venture' or a "real" venture of their own to practice the concepts taught during the program. The course is built in a modular fashion such that colleges can tailor their offerings to cover either the entire offering (idea to an MVP) or limit to building a business model.

# III YEAR

**B.Sc - CLINICAL RESEARCH**  
**FACULTY OF ALLIED HEALTH SCIENCES**  
**SRI BALAJI VIDYAPEETH**  
**(Deemed to be University)**  
**Accredited by NAAC with 'A' Grade**

**III YEAR**

**CORE SUBJECTS**

1. Clinical Trials : Design And Regulations
2. Clinical Data Management & Biostatistics
3. Medical Writing

**Discipline Elective Course (DEC) - Choose any TWO**

1. Biomedical Waste Management
2. Palliative care
3. Air borne infection control
4. Biochemistry & Molecular Biology

**AHS COURSE CONTENT THIRD YEAR B.SC. CLINICAL RESEARCH (CR)**

Faculty code	Category	Course title	Hours					Credits				
			Theory	Practical	Tutorials	Clinical training	Total hours	Lecture	Practical	Tutorials	Clinical training	Total credits
AHS	Core theory CR	Subjects										
AHS	CR -8	Clinical Trials: Design And Regulations	64	64				4	2			6
AHS	CR -9	Clinical Data Management & Biostatistics	64	64				4	2			6
AHS	CR-10	Medical Writing	80		32			5		1		6
AHS	CR-CT 2	Clinical Training CR 9 to 10				448					14	14
AHS	DE 1-8	Student's choice	64					4				4
AHS	DE 1-8	Student's choice	64					4				4
			<b>336</b>	<b>128</b>	<b>32</b>	<b>448</b>	<b>944</b>	<b>21</b>	<b>4</b>	<b>1</b>	<b>14</b>	<b>40</b>

## SCHEME OF EXAMINATION

Papers	Subject	Theory		Practical			Grand total (800)	Min pass marks (400)
		UE	IA	UE	IA	UIA*		
CR -8	Clinical Trials : Design And Regulations	80	20	80	20		200	100
CR -9	Clinical Data Management & Biostatistics	80	20	80	20		100	50
CR-10	Medical Writing	80	20				200	100
CR-CT 2	Clinical Training CR 8 to 10					100	100	50
DEC	Discipline elective	80	20				100	50
DEC	Discipline elective	80	20				100	50

# **CLINICAL TRIALS: DESIGN AND REGULATIONS**



## PAPER CR -8: Clinical Trials: Design And Regulations

Name of the paper	: Clinical Trials: Design and Regulations
Duration of Theory Classes	: 64Hrs
Duration of Practical Sessions	: 64Hrs
Theory Examination	: 100 Marks (80 U + 20 IA)
University Practical Examination	: 100 Marks
Duration of Theory Examination	: 3 Hrs
Year in which Subject Paper is taught	: III Year

### COURSE DESCRIPTION

Clinical trials play a pivotal role in evidence-based medicine. This course will provide an introduction to the scientific, statistical, and ethical aspects of clinical research. Topics will include basic principles and current methodologies used in the design, implementation, and analysis of clinical trials, including first-in-human studies (dose-finding, safety, proof of concept, and Phase I), Phase II, Phase III, and Phase IV studies. All aspects of the development of a study protocol will be addressed, including criteria for the selection of participants, assignment of study treatments, endpoints, randomization procedures, sample size determination, data analysis, adverse event reporting, and protocol compliance monitoring. The ethical issues that arise at each phase of new biomedical product development will also be explored.

### OBJECTIVES

1. Describe study designs and their limitations
2. Identify scientific and practical issues associated with the planning of a clinical research study
3. Manage protocol structure, outline, timeline, and amendments
4. Discuss requirements for protection of human research subjects
5. Review statistical issues in design and analysis of clinical research studies
6. Develop a basic statistical understanding (e.g., qualitative and quantitative data, sample size determination, and interim analysis)

### PROGRAM OUTCOMES

**CRPO1:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CRPO2:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CRPO3:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial

participants

**CRPO4:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CRPO5:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CRPO6:** Develop the key skills and knowledge needed to operate an effective drug safety program.

### COURSE OUTCOMES

At the end of the course the student should be able to

**CTDRCO1:** Understand and explain the various phases of clinical trials

**CTDRCO2:** Explain the roles and responsibilities of clinical trial study team

**CTDRCO3:** Understand the basics and acquire skills in the preparation of various clinical trial documents

**CTDRCO4:** Develop the skill of writing a proper trial monitoring report

Gain in depth knowledge about the regulations in clinical trials with special emphasis to the Indian regulatory guidelines

### COURSE CONTENT

UNIT	TITLE	THEORY+TUTORIAL (64 HOURS)
I	<b>INTRODUCTION AND FUNDAMENTAL OF CLINICAL TRIALS</b> Introduction to clinical trials, definition & terminology used in clinical trials & phases of clinical trials (0, I, II, III, IV)	12 HOURS
II	<b>CLINICAL TRIAL STUDY TYPE</b> Parallel, cross-over, adaptive, sequential, group/cluster & factorial designs Selection of controls (historical, placebo), Equivalence, non-inferiority & superiority trials Bio-equivalence & bio-availability studies, Blinding & biases in clinical trials, Advantages of factorial design & its comparison to latin square randomized designs, Fractional factorial designs, split-plot technique, and nested designs. <b>CLINICAL TRIALS OPERATIONS I</b> <b>CLINICAL TRIAL STUDY TEAM</b> Roles & responsibilities of: Investigator, co-investigator, study co-ordinator, sponsor, monitor, contract research organisation, site management organisation, vendors (central lab, translation companies, logistics) IRB/IEC role & responsibility <b>CLINICAL TRIAL OPERATIONS II</b> <b>CLINICAL TRIAL DOCUMENTS:</b> Guidelines to the preparation of documents: Preparation of synopsis and protocols, Preparation of Investigator Brochure, Preparation of Informed Consent Document, Preparation of case report forms, Preparation of clinical study reports and	14 HOURS

	<p>summaries, Preparation of contracts and agreements, Preparation of the diary cards</p> <p><b>CLINICAL TRIAL START-UP ACTIVITIES:</b>  Site Feasibility Studies, Site/Investigator selection, Vendor selection, Pre-study visit, ICF/PIS translation, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission, Investigational Product procurement and Storage, Filing procedures, Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up</p> <p><b>CLINICAL TRIAL MONITORING AND CLOSE-OUT:</b>  Preparation for monitoring visit, Conduct of monitoring visit, Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications etc.  Safety reporting, Monitoring visit reporting and follow-up, Close-Out visit, Study related documents collection, Archival requirement, IP reconciliation and destruction, Close-Out visit report</p>	
III	<p><b>AUDIT AND DOCUMENTATIONS</b>  Quality Assurance and Quality Control in Clinical Trials, Types of audits, Audit criteria, Audit process, Responsibilities of stake holders in audit process, Audit follow-up and documentation, Fraud and misconduct management.</p>	10 HOURS
IV	<p><b>INTRODUCTION AND FUNDAMENTALS</b>  Concept &amp; historical development of pharmaceutical product registration. - Industry &amp; FDA liaisons.</p> <p><b>INDIAN REGULATION IN CLINICAL TRIALS</b>  Laws and Acts: An introduction of following laws with regard to drug product design, manufacture and distribution in India (with latest amendments):  SCHEDULE Y, a. Drugs and Cosmetics Act 1940 and its rules 1945. b. National Pharmaceutical Pricing Authority (NPPA) c. Intellectual property rights - Indian patent Act and its rules, Law of Copyright and Designs, Law of Trademark and Geographical indications. d. Patent Procedure in India.</p> <p><b>CDSKO (CENTRAL DRUG STANDARD CONTROL ORGANIZATION)</b>  Organization, Responsibilities and Registration Procedures for approval of drug products. Approval procedures (clinical trials), timelines for approval, CDSKO guidelines (Approval of Clinical trials) Indian Common Technical Document, Serious Adverse Events Reporting, Indian GCP guidelines.</p>	16 HOURS
V	<p><b>REGISTRATION REQUIREMENTS</b>  Forms, Clinical Trial Registration, Test License, Commercial Import License, Sale License, Manufacture License, Certificate of Pharmaceutical Product (CoPP)  BA/ BE: Bioavailability and Bioequivalence Requirements, BCS classification of Drugs, Documentation Requirements for Bioequivalence study for export Applications.</p>	12 HOURS

	REGULATORY REQUIREMENTS: For import and product registration of New Drugs, DCGI & RCGM requirements, Generics, Medical Devices, Biologics, Herbals, Cosmetics & Fixed Dose Combinations, Export of drugs, traditional drugs, Narcotics, etc.	
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#### METHODS OF TEACHING

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### METHODS OF EVALUATION

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### TEXT BOOKS

Textbook of Clinical Research -VikasDhikav- 2016

#### BLUE PRINT

UNIT	SYSTEMS	WEIGHTAGE %	MARKS ALLOTTED (TOTAL 80)	LAQ (2 out of 4)	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	Introduction and fundamental of clinical trials	11.25	9		1	1
II	Clinical trial study type	31.25	25	1	1+1*	3+1*
III	Audit and documentations	16.25	13	1		1+1*
IV	Introduction and fundamentals of regulatory affairs of clinical trials	29.55	24	2*	2	4
V	Registration requirements	11.25	9		1	1
	Total		80			

*Note: \* represents question of choice*

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 100 marks.

Long Answer Questions : 2 X 10 = 20 marks (Choice 2 out of 4)

Short Answer Questions : 5 X 6 = 30 marks (Choice 5 out of 6)

Very Short Answer Questions: 10 X 3 = 30 marks (Choice 10 out of 12)

TOTAL = Theory 80 + IA 20 = 100 marks

**PAPER CR-8 - CLINICAL TRIALS: DESIGN AND  
REGULATIONS  
MODEL QUESTION PAPER**

**TIME: 3 HOURS**

**MAXIMUM MARKS: 80**

**A. Long answer questions**

**(2 X 10=20)**

1. a) Describe the preparation of documents, contracts and agreements of clinical data. (OR)

b) Ethical issues related to organ recipients

2. a) Describe the infrastructures of clinical data management. (OR)

b) Detail about Drugs and Cosmetics Act

**B. Short answer questions -Answer any 5 questions**

**(5 X 6= 30)**

1. Cross-over clinical trials

2. Non-inferiority trials

3. Bio-equivalence studies

4. Split-plot technique

5. Pre-study visit

6. Archival requirement

**C. Very Short answer questions -Answer any 10 questions**

**(10 X 3= 30)**

1. Mention any 2 essential services offered by CRO

2. Roles & responsibilities of co-investigator

3. Double blind trial

4. Mention any 2 important roles of CDSCO

5. Close-Out visit

6. Phase 0 trial

7. Advantages of nested design

8. Site initiation visit

9. Causes of vulnerability

10. What is schedule Y?

11. Facility audit

12. What is ane-CRF?

# **CLINICAL DATA MANAGEMENT & BIostatISTICS**

## PAPER CR-9 - CLINICAL DATA MANAGEMENT & BIostatISTICS

Duration of Theory Classes	: 64 Hrs
Duration of Practical Sessions	: 64 Hrs
Theory Examination	: 100 Marks (80 U + 20 IA)
University Practical Examination	: 100 Marks
Duration of Theory Examination	: 3 Hrs
Year in which Subject Paper is taught	: III Year

### COURSE DESCRIPTION

This course presents critical concepts and practical methods to support planning, collection, storage, and dissemination of data in clinical research. Introduction to Biostatistics provides an introduction to selected important topics in bio statistical concepts and reasoning. This course represents an introduction to the field and provides a survey of data and data types. Specific topics include tools for describing central tendency and variability in data; methods for performing inference on population means and proportions via sample data; statistical hypothesis testing and its application to group comparisons; issues of power and sample size in study designs; and random sample and other study types. While there are some formulae and computational elements to the course, the emphasis is on interpretation and concepts.

### OBJECTIVES

Upon completion of the course, students are able to:

1. Recognize and give examples of different types of data arising in public health and clinical studies
2. Interpret differences in data distributions via visual displays
3. Calculate standard normal scores and resulting probabilities
4. Calculate and interpret confidence intervals for population means and proportions
5. Interpret and explain a p-value
6. Select an appropriate test for comparing two populations on a continuous measure, when the two sample t-test is not appropriate
7. Understand and interpret relative risks and odds ratios when comparing two populations
8. Understand why survival (timed to event) data requires its own type of analysis techniques
9. Describe different kinds of studies
10. Understand confounding and interaction in studies

## PROGRAM OUTCOMES

**CRPO1:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CRPO2:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CRPO3:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial participants

**CRPO4:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CRPO5:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CRPO6:** Develop the key skills and knowledge needed to operate an effective drug safety program.

## COURSE OUTCOMES

At the end of the course the student should be able to

**CDMBRCO1:** Learn the procedures that are followed for entering, verifying, validating & further reviewing of the gathered data during a clinical trial.

**CDMBRCO2:** Appreciate the importance of collecting & validating clinical trial data

**CDMBRCO3:** Acquire knowledge about the basics of bio statistical and epidemiologic methods involved in conducting clinical research.

**CDMBRCO4:** Identify various study designs, settings, and databases that are useful in the evaluation of clinical interventions.

**CDMBRCO5:** Develop a hypothesis with a data set and perform appropriate statistical tests of the hypothesis.

**CDMBRCO6:** Use database management and statistical software to organize and analyze data.

## COURSE CONTENT

UNIT	TITLE	THEORY+TUTORIAL (64 HOURS)
I	<b>INTRODUCTION TO CLINICAL DATA MANAGEMENT</b> Definition, types of data, computer system validations, clinical data management process flow diagrams & roles & responsibilities of CDM personnel, Code of Ethics for CDM professionals , CRF design considerations: Data cleaning issues, Data processing issues, Revisions to the CRF, Quality assurance for CRFs, SOPs on CRF design, Reuse and refine CRF modules - The data management plan, Revising the DMP, Using plans with CROs, Quality assurance and DMPs, SOPs for DMPs and study files, Using data management plans, CDM and case record form (CRF), needs of CRF users, standardization of CRFs, guidelines for designing CRF	<b>10 HOURS</b>



II	<b>DATABASE DESIGN &amp; BUILD</b> Making design decisions, High-impact fields, Tall-skinny format, versus short-fat format, Using standards , Quality assurance for database design, Standard operating procedures for database design, Responsibilities in database design	7 HOURS
III	<b>CLINICAL DATA MANAGEMENT PROCESS</b> <ul style="list-style-type: none"> <li>• Study setup: A plan for validation, Specification and building, Testing, Moving to production Change control, Setup for EDC systems, Quality assurance, SOPs for study setup, Setup is programming</li> <li>• Entering data: Transcribing the data, dealing with problem data, Modifying data, Quality control through database audits, SOPs for data entry, Enter quality</li> <li>• Tracking CRF pages and corrections: Goals of tracking, CRF workflow, Tracking challenges, Missing pages reports, Tracking query forms, CROs and tracking, SOPs for tracking, tracking throughout the process.</li> <li>• Data Capture: Definition, paper based and electronic data capture, dataflow in paper CRFs and e-CRFs, tools for data capture, advantages and disadvantages of paper CRF/ e-CRF</li> <li>• Data Coding: Definition, data quality, coding significance, coding dictionaries, Coding symbols for a thesaurus of adverse reaction terms (COSTART), problems with Coding data, special search categories, coding of AE data</li> <li>• Cleaning data: Identifying discrepancies, managing discrepancies, Resolving queries, Quality assurance and quality control, SOPs for discrepancy management</li> <li>• Managing laboratory data: Storing lab data, Storing units, Ranges and normal ranges, Checking result values, Using central labs, Using specialty labs, Loading lab data, Quality assurance, SOPs for processing lab data, Taking lab data seriously</li> <li>• Collecting adverse event data: Collecting AEs, Coding AE terms, Reconciling SAEs, Quality assurance and quality control, SOPs for AE data, Impact on data management, Creating reports and transferring data, Specifying the contents, Standard and ad hoc reports, Data transfers, Review of printed reports and presentations, SOPs for reports and transfer</li> <li>• Locking studies: Final data and queries, Final QC, Locking and unlocking, Time to study lock, After study lock, Quality assurance, SOPs for study lock, Reducing time to study lock.</li> </ul>	14 HOURS
IV	<b>CLINICAL DATA MANAGEMENT- INFRASTRUCTURES</b> <ul style="list-style-type: none"> <li>• <b>Standard operating procedures and guidelines:</b> What is an SOP?, SOPs for data management, Creating standard procedures, Complying with standard procedures, SOPs on</li> </ul>	15 HOURS

	<p>SOPs, SOP work never ends</p> <ul style="list-style-type: none"> <li>• <b>Training:</b> Who gets trained on what?, How to train, Training records, SOPs on training, Allotting time for training - Controlling access and security: Account management, Access control, SOPs and guidelines for account</li> <li>• <b>Working with CROs:</b> Defining responsibilities, Auditing CROs, Oversight and interaction, SOPs for working with CROs, Benefiting from CROs.</li> </ul> <p><b>CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)</b>  Introductions, importance of CTMS, regulatory compliance, validation, functions &amp; accounts of CROs using CTMS &amp; CTMS modules, Overview of Data management Software(s)</p>	
V	<p><b>BIostatistics for Clinical Trials</b></p> <ul style="list-style-type: none"> <li>• <b>FUNDAMENTALS OF BIostatistics</b>  Definition, Types of Statistical Methods, Populations and Samples, Sources, Types and Classification of Data, Measurement Scales, Organization of Data-Frequency Distribution-Graphic Methods, Descriptive Statistics</li> <li>• <b>PROBABILITY AND SAMPLING DISTRIBUTIONS</b>  Probability Theory-Trials, Events, Sample Space, Definition of Probability  Probability Distributions: Binomial, Poisson and Normal distributions and their applications, Central limit theorem and its applications, Sampling Distribution- Definitions of Sampling Distribution and Standard Error.</li> <li>• <b>ANALYSIS OF EFFICACY DATA</b>  Parametric and Non- Parametric Test- Principle of testing statistical significance. Test for Mean(s), Tests for paired and unpaired samples. Rank testing. Statistical Power and Sample Size.</li> <li>• <b>ANALYSIS OF SAFETY DATA</b>  Parametric and Non- Parametric Test- Principle of testing statistical significance: Test for Proportions(s), Tests for paired and unpaired samples.</li> <li>• <b>CORRELATION AND REGRESSION</b>  Correlation - Simple and Rank Correlations - Regression - Simple, Multiple, Poisson and Cox Regression.</li> <li>• <b>SURVIVAL ANALYSIS</b>  Introduction, Definition of Survival Time, Hazard Rate, Censoring, Truncation, Types of Censoring, Estimation of Survival Time by Life Table Method and Kaplan Meier Method, Comparison of Survival Time by Log - Rank Test.</li> <li>• <b>INTERIM ANALYSIS</b>  Introduction, Monitoring, Group - Sequential design and Continuous Statistical Techniques</li> <li>• <b>EQUIVALENCE TESTING</b>  Introduction, Equivalence Testing, Validity of Equivalence Trials</li> </ul>	18 HOURS

**METHODS OF TEACHING**

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

**METHODS OF EVALUATION**

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

**TEXT BOOKS**

1. ABC of Research Methodology and Applied Biostatistics - 2009 by M.N. Parikh, NithyaGogtay

**BLUE PRINT**

UNIT	SYSTEMS	WEIGHTAGE %	MARKS ALLOTTED (TOTAL 80)	LAQ (2 out of 4)	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	Introduction to clinical data management	3.75	3			1
II	Data base design and build	11.25	9		1	1
III	Clinical data management process	11.25	9	1*	1	1
IV	Clinical data management - infrastructures	32.50	26	2		2
V	Fundamentals of biostatistics	41.25	33	1*	3+1*	5+2*
	<b>Total</b>		<b>80</b>			
<i>Note: * represents question of choice</i>						

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 100marks.

Long Answer Questions : 2 X 10 = 20 marks (Choice 2 out of 4)

Short Answer Questions : 5 X 6 = 30 marks (Choice 5 out of 6)

Very Short Answer Questions: 10 X 3 = 30 marks (Choice 10 out of 12)

TOTAL = Theory 80 + IA 20 = 100 marks

**PAPER CR-9- CLINICAL DATA MANAGEMENT & BIostatISTICS**  
**MODEL QUESTION PAPER**

**TIME: 3 HOURS**

**MAXIMUM MARKS: 80**

**A. Long answer questions**

**(2 X 10 =20)**

1. a) Define clinical trials. Write in detail phases and terminology used in clinical Trials. (OR)  
b) Detail about Types of Statistical Methods
2. a) Explain in detail about regulatory affairs in clinical trials.(OR)  
b) Explain in detail about guidelines for designing CRF

**B. Short answer questions -Answer any 5 questions**

**(5 X 6 = 30)**

1. SOP for entry & tracking of data
2. Advantages and disadvantages of paper CRF
3. Data Coding significance
4. Data management Software
5. Measures of Central tendency
6. Non- Parametric Test
7. Statistical Power and Sample Size
8. Hazard Rate

**C. Very Short answer questions -Answer any 10 questions**

**(10x3 = 30)**

1. Auto-encoding
2. What is oracle clinical?
3. Coding of AE data
4. Data locking/freezing
5. Binomial Distribution
6. Definition of Survival Time
7. Types of Censoring
8. Audit trial
9. Tools for data capture
10. Double entry
11. What is COSTART?
12. Clinical trial portal

# **MEDICAL WRITING**

## PAPER CR-10- MEDICAL WRITING

Duration of Theory Classes	: 80Hrs
Duration of Practical Sessions	: 32Hrs
Theory Examination	: 100 Marks (80 U + 20 IA)
University Practical Examination	: NIL
Duration of Theory Examination	: 3 Hrs
Year in which Subject Paper is taught	: III Year

### COURSE DESCRIPTION

Becoming a Medical Writer is a lucrative and stimulating career for this decade" With the fast pace development in science and technology and increasing awareness and interest of general public in these developments, both scientific writing and medical journalism has gained lot of importance. Presenting the scientific and medical information in an easy format is very important. BII has obtained a position of the premier institution for training the professional for this upcoming field.

### OBJECTIVES

1. To give professional an insight into the various aspects of scientific/ medical writing and will help the writers to make a positive contribution to the medical world, through their documentation.
2. To enabling the professional with the skills to express the results of new inventions and discoveries in a scientifically approved manner.
3. To imparting professional with technical details of writing observations and results of clinical trials, regulatory submissions, and marketing or promotional literatures.

### PROGRAM OUTCOMES

**CRPO1:** Develop knowledge about the basic concepts, skills and techniques required to work in the clinical research field.

**CRPO2:** Accumulate the knowledge and develop skills in the planning and management of clinical research including practices related to the organization, execution and monitoring of clinical trials.

**CRPO3:** Describe the established clinical trial regulations and guidelines, and ensure that the clinical trials are conducted ethically and in ways that respect the rights of clinical trial participants

**CRPO4:** Adequately trained to effectively prepare various essential documents of clinical trial and develop the skills in writing and critiquing research manuscripts

**CRPO5:** Apply the fundamental concepts of biostatistics in the field of clinical research

**CRPO6:** Develop the key skills and knowledge needed to operate an effective drug safety program.

### COURSE OUTCOMES

At the end of the course the student should be able to

**MWCO1:** Prepare clinical trial documents and medico- regulatory documents

**MWCO2:** Construct a drug monograph and other marketing related documents

**MWCO3:** Demonstrate skills in communicating results of research in abstract and presentation forms

**MWCO4:** Demonstrate skills in writing and critiquing research manuscripts.

### COURSE CONTENT

UNIT	TITLE	THEORY+TUTORIAL (80+32HOURS)
I	<b>BASICS OF MEDICAL WRITING</b> Style for accurate & readable medical writing - Writing in plain English - Referencing - Words in conventional positions & punctuation signals, choosing words by weight, familiarity & accuracy, round about phrasing, borrowing from Latin & other languages. - Structure of medical writing groups - Background, skills & educations of medical writing team. - Team approach to medical writing	20 + 8
II	<b>MEDICO - CLINICAL TRIAL DOCUMENTS</b> Synopsis & protocols for clinical trials - IRB/IEC approval documents - Regulatory submission & approval of clinical trial documents - Study feasibility questioner preparation - Investigator undertaking letter - Preparation of informed consent form - Preparation of Trial master file (TMF), Site master file (SMF) & Central trial master file (CTMF). - Site Initiation Visit kit (SIB) preparation - Log sheet & templates for conducting clinical trial - Preparation of monitoring visit & report - Clinical study report E3 format - Safety narrative writing - Investigator brochure - Consolidated standards of reporting trials (CONSORT) preparation	23 + 8
III	<b>MEDICO-REGULATORY DOCUMENTS ( 20 HOURS + 8 TUTORIALS)</b> Regulation of the drug process - Filing of Investigational New Drug Application (IND) for India & global regulatory. - Approval for New Drug Application (NDA) for India & global. - Preparations	20 + 8

	of Abbreviated & Supplemental New Drug Application (ANDAs & SNDAs) - Preparation & submission of Dossier- CTD & e-CTD for registration of pharmaceutical products (ICH-CTD module 1 - 5, Indian CTD & other regulatory CTD) - Preparation of Biological License Applications (BLA) - Medical device approval process (Indian, FDA & other regulatory) - Preparation of global labelling changes of pharmaceutical products (CCDS, CPLP & CCSI)	
IV	<b>MEDICO- MARKETING DOCUMENTS</b> Preparation of drug monograph - Supportive documents for drug promotion - Prescribing information - Leave-Behind-Letter (LBL) - Training material for field force - Slides & poster for presentations - Preparation material for Continuing Medical Education (CME) programme	10 + 4
V	<b>PUBLICATION DOCUMENTS</b> 7 + 4 Types of publication documents - Manuscripts in scientific journals - Authorship & ethical issues - Critical review of literature	7 + 4

#### METHODS OF TEACHING

1. Lecture cum discussion
2. Demonstration
3. Lab visit
4. Practical work record

#### METHODS OF EVALUATION

1. Written Test
2. Laboratory observation Book
3. Assignments
4. Oral Presentations

#### TEXT BOOKS

1. Medical writing in drug development: A practical guide for pharmaceutical research by Robert J Bonk, First edition. Rutledge



## BLUE PRINT

UNIT	SYSTEMS	WEIGHTAGE %	MARKS ALLOTTED (TOTAL 80)	LAQ (2 out of 4)	SAQ (5 out of 6)	VSAQ (10 out of 12)
I	Basics of medical writing	15	12		1	2
II	Medico clinical trial documents	27.5	22	1	1+1*	2
III	Medico regulatory documents	15	12	1*	1	2+1*
IV	Medico marketing documents	15	12	1*	1	2+1*
V	Publication documents	27.5	22	1	1	2
	Total		80			

*Note: \* represents question of choice*

The duration of Examination (University) is Three (3) hours.

The total marks for the University Examination will be 100marks.

Long Answer Questions : 2 X 10 = 20 marks (Choice 2 out of 4)

Short Answer Questions : 5 X 6 = 30 marks (Choice 5 out of 6)

Very Short Answer Questions: 10 X3 = 30 marks (Choice 10 out of 12)

TOTAL = Theory 80 + IA 20 = 100 marks

### PAPER CR-10 - MEDICAL WRITING

#### MODEL QUESTION PAPER

**TIME: 3 HOURS**

**MAXIMUM MARKS: 80**

**A. Long answer questions**

**(2 X10 = 20)**

1. a) Explain in detail about approval for new drug application for India and global.(OR)  
b) Explain in detail about consolidated standards of reporting trials preparation
2. a) Describe the documents prepared for publications.(OR)  
b) Describe the requirements for writing research articles.

**B. Short answer questions -Answer any 5 questions**

**(5 X6 = 30)**

1. Types of medical writing
2. Site master file
3. Types of publication documents
4. Regulatory medical writing
5. SAE reconciliation
6. Educational medical writing

**C. Very Short answer questions -Answer any 10 questions**

**(10x3 = 30)**

1. Name 2 organization for medical writers
2. What is a review article?
3. PSUR
4. Mention 2 important goals of medical writing
5. CONSORT
6. Leave-Behind-Letter
7. Spontaneous reporting
8. Types of referencing styles
9. What is a case report?
10. Safety narrative writing
11. ANDA
12. Types of publication document

# **DISCIPLINE ELECTIVE - III YEAR**

**SBV DEEMED TO BE UNIVERSITY - FACULTY OF ALLIED HEALTH SCIENCES**  
**B.Sc. CLINICAL RESEARCH**  
**Discipline Elective I - Biomedical Waste Management**

<b>NAME OF THE SUBJECT PAPER</b>	<b>: Biomedical Waste Management</b>
<b>DURATION OF THEORY CLASSES</b>	<b>: 64 Hrs</b>
<b>THEORY EXAMINATION</b>	<b>: 50 Marks (40 U + 10 IA)</b>
<b>PRACTICAL EXAMINATION</b>	<b>: NIL</b>
<b>DURATION OF THEORY EXAMINATION</b>	<b>: 1 1/2 Hrs</b>

### **Course Description**

The increasing number of Biomedical wastes (BMW) being generated is becoming a serious problem to hospitals and has significant adverse impacts on public health and occupational health if improperly handled. Biomedical waste requires utmost care in handling, collection, processing, and disposal due to inherent hazards of the waste. The basic goal of the course is to provide the fundamentals of and biomedical wastes and various aspects of their management right from generation through collection and disposal. Special emphasis will be given to the system approach to managing these wastes to meet regulatory requirements.

### **Learning Objectives**

- To sensitize the students about health care waste and its impact on health and environment.
- Acquaint the students to existing legislation, knowledge, and practices regarding health care waste.

### **Learning Outcomes**

At the end of the course the student will be able to

- Possess the knowledge on the sources of generation, of hazardous and non-hazardous waste in health care settings and research laboratories.
- Demonstrate understanding on the environmental and occupation hazards of improper BMW management.
- Understand the good practices for a systematic approach in the management of BMW
- Gain knowledge in various management strategies and technological solutions in BMW management, treatment, and disposal.
- Be familiar with the applicable legislations and regulations for treatment and disposal.

## **SYLLABUS**

### **1. Introduction to Hospital Waste**

- Definition Classification of hospital wastes
- Types and composition: Types of solids, liquids, sharps, blood and blood tissue, radioactive material, biological and chemical material
- Hospital effluents: Nature and composition, Levels of Generation in a small clinic, nursing home, small and large hospitals, Storage of hospital waste; Types of bags and containers used for storage

### **2. Biomedical Waste Management Guideline**

- Requirement
- Documentation of Biomedical waste types and guidelines
- Bio-medical wastes (Management & Handling) Rules, 1998; and amendments

### **3. Principles of Biomedical Waste Management**

- Segregation of biomedical waste
- Handling and transport of hospital waste: Authorization and accidental spilling
- Methods / treatments required for disposal of pathogens
- Waste disposal methods
- Techniques of waste management
- Protocols for HW management

### **4. Waste prevention**

- Waste reduction activities
- Waste recycling

### **5. Biomedical Waste Treatment Facility**

- Introduction, location, land requirements
- Coverage area, types of equipment
- Infrastructure requirements
- Record keeping
- Waste collection, transport and storage facilities
- Precautions required

## **TEXTBOOKS**

1. Sustainable Biomedical Waste Management, P. K. Behera, 2nd Edition. 2008
2. Biomedical Waste Management, R. Radhakrishnan, 1st Edition, 2005
3. The Environmental Protection Act, 1986.

## MODEL QUESTION PAPER

TIME: 1 1/2 HOURS

MAXIMUM MARKS: 40

**(A) Short Answer (Answer any Five)**

**(5x6=30)**

1. Explain the different categories of biomedical waste.
2. Explain the different sources of health-care wastes and how the hospitals handle them.
3. What are the various guidelines given by WHO for safe health-care waste management?
4. Write the principles of hospital hazards management. Explain the various types of infections.
5. How does the color-coding help in medical waste management? Explain with examples.

**(B) Very Short Answer (Any six)**

**(5x2=10)**

1. How will you classify healthcare waste?
2. What are waste sharps?
3. Who is at risk from health-care waste?
4. Write few rules governing the disposal of medical wastes?
5. Why is segregation important?
6. How sharps are disposed?
7. List some non-infectious wastes in hospital.
8. What is chemical disinfection?

## B.Sc. CLINICAL RESEARCH

### Discipline Elective II -BIOCHEMISTRY AND MOLECULAR BIOLOGY

NAME OF THE SUBJECT PAPER : BIOCHEMISTRY AND MOLECULAR BIOLOGY

DURATION OF THEORY CLASSES : 64 Hrs

THEORY EXAMINATION : 50 Marks (40 U + 10 IA)

PRACTICAL EXAMINATION : NIL

DURATION OF THEORY EXAMINATION : 1 1/2 Hrs

## SYLLABUS

### UNIT-I: NUCLEO PROTEIN

- Purine and Pyrimidine bases, Ribose and Deoxy Ribose, Definition of Nucleosides and Nucleotides, Biologically significant Nucleotides
- Nucleic acids as genetic information carriers - experimental evidence e.g. action spectrum, genetic information, Hershey-chase experiment etc.
- Modes of replication, details of Meselson and Stahl experiment, semi conservative replication.

### UNIT -II

- Genetic code - Evidence for a triplet code, properties of the code - sequential, ubiquitous, degenerative, wobble hypothesis, nonsense codon
- Mechanism of translation
- Mechanism of transcription, Regulation of transcription, Post translational processing
- Rates of eukaryotic and prokaryotic protein synthesis

### UNIT-III: DEOXY RIBONUCLEIC ACID

- Physical properties of DNA - 5' - 3' direction, size range location, isolation, base composition, base equivalent, secondary structure, base pairing, Tertiary structures.
- DNA replication - properties of DNA dependent DNA polymerases I, II, III and their role in DNA replication
- DNA Repair systems

### UNIT-IV: RIBONUCLEIC ACID

- Physical properties of RNA-classes of RNA-structure, methods of isolation and fractionation of RNA-primary, secondary and tertiary structures
- Rapid RNA sequencing techniques

### UNIT-V

- Polymerase Chain Reaction (PCR)
- Recombinant DNA technology and its applications

## Discipline Elective III - Palliative care

NAME OF THE SUBJECT PAPER	: Palliative care
DURATION OF THEORY CLASSES	: 64 Hrs
THEORY EXAMINATION	: 50 Marks (40 U + 10 IA)
UNIVERSITY PRACTICAL EXAMINATION	: NIL
DURATION OF THEORY EXAMINATION	: 1 1/2Hrs

### Course Description

This virtual one-day course is designed to offer physicians, nurses, social workers and other clinicians the information and skills needed to provide high quality palliative care to patients with serious illnesses in a variety of practice settings. It addresses the assessment and management of current challenges in palliative care, including the physical, psychological, social, and spiritual/existential sources of suffering experienced by patients and their families.

### Learning objectives

Upon completion of this activity, participants will be able to:

Access and manage physical, psychological, social, and spiritual/existential sources of suffering for patients and their families dealing with serious illnesses or towards the end of life

- Develop practical strategies for discussing patient fears, hopes, goals, and wishes for care in the face of serious illness and at the end of life, including balancing hope and honesty in discussing treatment options and dealing with the ethical, psychosocial and spiritual issues that arise
- Improve the access to quality palliative care for all people with serious illness regardless of setting, diagnosis, prognosis or age
- Describe key issues and principles of pain management with opioids, including equianalgesic dosing, common side effects, addiction, tolerance, and dependence

### Learning Outcomes

- Interactive learning formats include: Q&A, panel presentations, and case based discussions and ask the expert sessions.
- The course is designed to change both learner competence and performance in practice for primary and specialty palliative care practitioners.

## SYLLABUS CONTENT

### 1. Basic principles (20 Hrs)

- Definitions of palliative care; general palliative care; specialist palliative care
- Evolving nature of palliative care over the course of illness
- Re-adaptation and rehabilitation
- Personal qualities and attributes of palliative medicine

### 2. Physical care (20 Hrs)

- Initial Assessment - detailed history and examination
- Management of life limiting, progressive disease
- Management of vaginal discharge and bleeding
- Diagnosis of rectovaginal, rectovesical and vesicovaginal fistulae
- Management of Urgency and dysuria/anuria



**3. Psychosocial care (20 Hrs)**

- Social and Family Relationships
- Communication with patients and relatives
- Psychological responses of patients and carers to life-threatening illness and loss
- Attitudes and responses of doctors and other professionals
- Patient and family finance

**4. Culture, language, religion and spirituality (5 Hrs)**

**5. Ethics (10 Hrs)**

- Theoretical ethics, applied ethics

**6. Legal framework, teamwork and management (5 Hrs)**

**MODEL QUESTION PAPER**

**TIME: 1 1/2 HOURS**

**MAXIMUM MARKS: 40**

**(A) Short Answer (Answer any two)**

**(5x6=30)**

1. Indications and importance of providing palliative care
2. Principles of palliative care
3. Distinguish between palliative care and hospice care
4. Non pharmacological management for pain under palliative care
5. Psychosocial factors influencing palliative care

**(B) Very Short Answer (Any six)**

**(5x2=10)**

1. Signs of physiological death
2. Stages of palliative care
3. Definition of palliative care
4. Rehabilitation versus palliative care
5. Palliative care under hospital settings
6. Phases of rehabilitation
7. Pharmacotherapy for pain for patients under palliative care
8. Importance of palliative care

## DISCIPLINE ELECTIVE -V: AIR BORNE INFECTION CONTROL

NAME OF THE SUBJECT PAPER	: AIR BORNE INFECTION CONTROL
DURATION OF THEORY CLASSES	: 64 HOURS
DURATION OF TUTORIAL SESSION	: NIL
THEORY EXAMINATION	: 50 MARKS (40 U+ 10 IA)
DURATION OF THEORY EXAMINATION	: 1 1/2 HOURS
PRACTICAL EXAMINATION	: NIL

### Learning Objectives

- Describe how pathogenic organisms may be spread in healthcare settings.
- Identify the factors which influence the outcome of an exposure to pathogenic organisms in healthcare settings.
- List strategies for prevention of transmission of pathogenic organisms.
- Describe how infection prevention concepts are applied in a professional practice

## SYLLABUS

### UNIT - 1 : Transmission and control of infection in healthcare setting

- Introduction
- Pathogen or infectious agent
- Portal of entry
- Reservoir
- Transmission
- Common vehicle to transmit the infections and
- Transmission of infections.

### UNIT - 2 : Factors Influencing the Outcome of Exposures

- Host Factors
- Pathogen or Infectious Agent Factors
- Environmental Factors

### UNIT - 3 : Methods to prevent the spread of pathogenic organisms in healthcare settings

- Respiratory Hygiene/Cough Etiquette: these measures apply to patients, visitors, and healthcare workers with signs of respiratory infection.
- Safe injection practice
- For patients infected with organisms other than blood borne pathogens
- Control of routes of transmission

### UNIT - 4 : Standard precautions

- Hand hygiene
- Use of PPE whenever there is an expectation of possible exposure to blood or body fluid

# QUESTION BANK

# B.Sc. AHS I YEAR

## PAPER-1: ANATOMY

### UNIT: 1 GENERAL ANATOMY

#### HUMAN CELL

Q. NO	TOPICS	TYPE
1.	Discuss the Cell & its Organelles.	SAQ

#### EPITHELIUM

Q.NO	TOPICS	TYPE
1.	Classification of Epithelium with its examples.	SAQ
2.	Draw the neat label diagram of Simple epithelium with its examples.	SAQ
3.	Draw the neat label diagram of Compound epithelium with its examples.	SAQ
4.	Write a note on Goblet cell.	VSAQ
5.	Write a note on Basement membrane of epithelium.	VSAQ

#### GLANDS

Q.NO	TOPICS	TYPE
1.	Classification of Glands with its examples.	SAQ
2.	Discuss the Microscopic structure of Mucous / Serous / Mixed salivary gland with its examples.	SAQ

#### CARTILAGE

Q.NO	TOPICS	TYPE
1.	Discuss the Microscopic structure of Hyaline cartilage / Elastic cartilage / White fibro cartilage with its examples.	SAQ
2.	Classification of Cartilage with its examples.	VSAQ
3.	Write a note on Perichondrium.	VSAQ

#### BONE

Q.NO	TOPICS	TYPE
1.	Classification of Bones with its examples.	SAQ
2.	Draw & Discuss the Microscopic structure of Compact bone (T.S)	SAQ
3.	Discuss the blood supply of long bone.	SAQ
4.	List out the bones in region wise.	SAQ
5.	State the parts of growing long bone.	VSAQ
6.	State the parts of adult long bone.	VSAQ
7.	Write a note on Periosteum.	VSAQ
8.	Write a note on carpal bones.	VSAQ
9.	Write a note on Sesamoid bone.	VSAQ
10.	Write a note on Fontanellae of fetal skull.	VSAQ
11.	Write a note on Haversian system of compact bone.	VSAQ
12.	List out the structural differences between the Bone & Cartilage.	VSAQ

#### JOINTS

Q.NO	TOPICS	TYPE
1.	Classification of Joints with its examples.	SAQ
2.	Classification of Synovial joint with its examples.	SAQ
3.	Discuss the structure of synovial joint.	SAQ

4.	Classification of Cartilagenous joint with its examples.	SAQ
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### MUSCULAR TISSUE

Q.NO	TOPICS	TYPE
1.	Draw & Discuss the Microscopic structure of Skeletal muscle / Cardiac muscle / Smooth muscle with its examples.	SAQ
2.	Classification of muscular tissue with its examples.	VSAQ
3.	State the muscles of mastication & its nerve supply.	VSAQ
4.	List out the microscopic structural differences between the types of muscles.	VSAQ

### SKIN

Q.NO	TOPICS	TYPE
1.	Draw & Discuss the Microscopic structure of Thick / Thin skin.	SAQ
2.	Classification / Types of skin with its example.	VSAQ
3.	List out the structural differences between the types of skin.	VSAQ

## UNIT: 2 CARDIOVASCULAR SYSTEMS

### MEDIASTINUM

Q.NO	TOPICS	TYPE
1.	Definition, location & general boundary / outline boundary of Mediastinum.	SAQ
2.	Discuss the boundaries & contents of Superior mediastinum.	SAQ
3.	Discuss the boundaries & contents of Inferior mediastinum.	SAQ

### HEART

Q.NO	TOPICS	TYPE
1.	Explain the gross features of Right atrium under following headings - a) Definition, b) location, c) external features, d) internal features, e) Function, f) arterial supply.	LAQ
2.	Describe the Blood supply of Heart.	LAQ
3.	Discuss the location & External features of Heart.	SAQ
4.	Discuss the Valves of Heart. (A.V -valve & Semilunar valve)	SAQ
5.	Discuss the Systemic & Pulmonary circulation of Heart.	SAQ
6.	Discuss the Right coronary artery / Left coronary artery under following headings - a) Origin, b) course, c) branches.	SAQ
7.	Write a note on Apex of Heart.	VSAQ
8.	List out the chambers & great blood vessels of Heart.	VSAQ
9.	Trace the conducting system of Heart.	VSAQ
10.	State the definition, layers, sinuses & nerve supply of Pericardium.	VSAQ

### BLOOD VESSELS

Q.NO	TOPICS	TYPE
1.	Describe the Portal vein under following headings - a) Definition, b) formation, c) location, d) course, e) branches, f) Parts, g) Tributaries.	LAQ
2.	Explain the Cavernous sinus under following headings - a) Definition, b) location, c) measurement, d) extension, e) relations,	LAQ

	f) Tributaries, g) communications.	
3.	Parts & branches of Aorta	SAQ
4.	Discuss the origin, course, parts & branches of Subclavian artery.	SAQ
5.	Discuss the origin, course, parts & branches of Axillary artery.	SAQ
6.	Discuss the origin, course & branches of Brachial artery.	SAQ
7.	Discuss the origin & branches of Internal iliac artery.	SAQ
8.	Discuss the origin, course & branches of External carotid artery.	SAQ
9.	Discuss the origin, parts, course & branches of Internal carotid artery.	SAQ
10.	Classification of Dural venous sinuses.	SAQ / VSAQ
11.	Enumerate the branches of Brachial artery.	VSAQ
12.	State the branches of Radial & Ulnar artery.	VSAQ
13.	State the branches of Femoral artery.	VSAQ
14.	List out the sites of Peripheral pulse.	VSAQ
15.	List out the sites of Porto caval anastomosis.	VSAQ
16.	State the formation, course & termination of Great saphenous vein / Short saphenous vein.	VSAQ
17.	Write a note on Cysterna chyli.	VSAQ
18.	Formation, location & branches of Superficial palmar arch / Deep palmar arch.	VSAQ

### UNIT: 3 RESPIRATORY SYSTEM

Q.NO	TOPICS	TYPE
1.	Explain the <b>Larynx</b> under following headings - a) Definition, b) location, c) extension, d) measurement, e) Skeletal framework, f) function.	LAQ
2.	Explain the <b>Lung</b> under following headings - a) Definition, b) location, c) coverings, d) weight & Colour, e) external features, f) medial surface impression, g) hilum, h) Root of lung, i) blood supply, j) note on Bronchopulmonary segments.	LAQ
3.	Discuss the definition, formation & structures opening in the Lateral wall of nose.	SAQ
4.	Discuss the definition, extension, measurement, external feature of Trachea.	SAQ
5.	Discuss the definition, layers, parts of layers, recesses, nerve supply of Pleura.	SAQ / VSAQ
6.	State the parts of Respiratory system.	VSAQ
7.	Enumerate the structures forming the Nasal septum.	VSAQ
8.	Write a note on Carina.	VSAQ
9.	Write a note on Bronchopulmonary segments.	VSAQ
10.	List out the Para nasal air sinuses.	VSAQ
11.	Enumerate the muscles of Respiration & state its nerve supply.	VSAQ

### UNIT: 4 DIGESTIVE SYSTEMS

Q.NO	TOPICS	TYPE
1.	Describe the <b>Tongue</b> under following headings - a) Definition, b) location, c) parts, d) external features, e) muscles, f) Nerve supply.	LAQ
2.	Explain the <b>Pharynx</b> under following headings -	LAQ

	a) Definition, b) location, c) extension, d) sub-division, e) Muscles forming the pharynx, f) nerve supply.	
3.	Explain the <b>Stomach</b> under following headings - a) Definition, b) location, c) capacity, d) measurement, e) External features, f) Parts, g) relations, h) blood supply.	LAQ
4.	Describe the <b>Duodenum</b> under following headings - a) Definition, b) location, c) parts, d) measurement, e) external features, f) Internal features (2 <sup>nd</sup> part), g) blood supply.	LAQ
5.	Explain the <b>Liver</b> under following headings - a) Definition, b) location, c) Colour, d) weight, e) external features, f) Relations, g) bare area, h) Porta hepatis, i) blood supply, j) function.	LAQ
6.	Explain the <b>Pancreas</b> under following headings - a) Definition, b) location, c) anatomical & functional parts, d) measurement, e) Colour, f) external features, g) relations, h) Duct of pancreas, i) Blood supply.	LAQ
7.	Discuss the location & external features of Tongue.	SAQ
8.	Discuss the parts, muscles of Tongue & state its nerve supply.	SAQ
9.	Discuss the location, external features, parts & blood supply of stomach.	SAQ
10.	Discuss the external & internal features of the 2 <sup>nd</sup> part of Duodenum.	SAQ
11.	Discuss the <b>Caecum</b> under following headings - a) Definition, b) location, c) measurement, d) types, e) external features, f) Internal features, g) blood supply.	SAQ
12.	Discuss the <b>Appendix</b> under following headings - a) Definition, b) location, c) parts, d) measurement, e) position, f) Blood supply.	SAQ
13.	Discuss the characteristic features / cardinal features of Large intestine.	SAQ
14.	Discuss the Extra hepatic biliary apparatus under following headings - a) Definition, b) parts, c) measurement, d) function, e) Note on gall bladder.	SAQ
15.	Discuss the definition, location, origin, course & branches of Coeliac trunk.	SAQ
16.	List out the parts of Digestive system.	VSAQ
17.	State the parts & papillae of Tongue.	VSAQ
18.	State the nerve supply of Tongue.	VSAQ
19.	Enumerate the muscles of Tongue.	VSAQ
20.	State the extension & sub-divisions of Pharynx.	VSAQ
21.	State the extension & constrictions of Esophagus.	VSAQ
22.	List out the structural differences between the Jejunum & Ileum.	VSAQ
23.	State the location & types of Caecum.	VSAQ
24.	State the location / parts & position of Appendix.	VSAQ
25.	Write a note on Porta hepatis.	VSAQ
26.	Write a note on bare area of Liver.	VSAQ
27.	Write a note on Pancreatic duct.	VSAQ
28.	Enumerate the parts & function of Biliary apparatus.	VSAQ
29.	Classification of Salivary glands.	VSAQ
30.	State the branches of Superior mesenteric artery.	VSAQ
31.	State the branches of Inferior mesenteric artery.	VSAQ

32.	State formation of Marginal artery / artery of Drummond.	VSAQ
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### UNIT: 5 URINARY SYSTEM

Q.NO	TOPICS	TYPE
1.	Explain the Kidney under following headings - a) Definition, b) location, c) measurement, d) Colour, e) external features, f) Hilum, g) relations, h) coverings, i) internal features, j) Blood supply.	LAQ
2.	Explain the Urinary bladder under following headings - a) Definition, b) location, c) shape, d) measurement, e) capacity, f) External features, g) relations, h) supports, i) Internal features (Trigone of urinary bladder), j) blood supply, k) role.	LAQ
3.	Discuss the location & relations of Kidney.	SAQ
4.	Discuss the extension, parts, measurement, constrictions & blood supply of Ureter.	SAQ
5.	Discuss the external features & supports of Urinary bladder.	SAQ
6.	State the parts of Urinary system.	VSAQ
7.	Write a note on hilum of kidney.	VSAQ
8.	State the extension, parts & constrictions of ureter.	VSAQ
9.	Write a note on Trigone of urinary bladder.	VSAQ
10.	State the definition, extension & parts of Male urethra.	VSAQ
11.	Write a note on Female urethra.	VSAQ

### UNIT: 6 REPRODUCTIVE SYSTEMS

#### MALE REPRODUCTIVE SYSTEM

Q.NO	TOPICS	TYPE
1.	Explain the Testis under following headings - a) Definition, b) location, c) measurement, d) shape, e) external features, f) Coverings, g) internal features, h) functions, i) blood supply.	LAQ
2.	Describe the Prostate gland under following headings - a) Definition, b) location, c) shape, d) measurement, e) shape, f) External features, g) lobes, h) coverings, i) blood supply.	LAQ
3.	Discuss the location, external features, layers & blood supply of Scrotum.	SAQ
4.	Discuss the External & internal features of Testis.	SAQ
5.	Discuss the External features, lobes & coverings of Prostate.	SAQ
6.	State the parts of Male Reproductive system.	VSAQ.
7.	Enumerate the layers of Scrotum & state its nerve supply.	VSAQ.
8.	State the parts & role of Epididymis.	VSAQ.
9.	State the coverings of Testis & Prostate.	VSAQ.
10.	State the coverings & contents of Spermaticcord.	VSAQ.

#### FEMALE REPRODUCTIVE SYSTEM

Q.NO	TOPICS	TYPE
1.	Explain the Mammary gland under following headings - a) Definition, b) location, c) extension, d) shape, e) structures / features, f) Blood supply.	LAQ
2.	Explain the Uterus under following headings - a) Definition, b) location, c) shape, d) measurement, e)	LAQ



	external features, f) Positions, g) relations, h) supports, i) blood supply.	
3.	Discuss the Gross structure of Mammary gland.	SAQ
4.	Discuss the location & external features of Uterus.	SAQ
5.	Discuss the location, position & supports of Uterus.	SAQ
6.	Discuss the external & internal features of Ovary.	SAQ
7.	State the parts of Female Reproductive system.	VSAQ
8.	State the parts & role of Fallopian tube.	VSAQ
9.	Enumerate the ovarian follicles.	VSAQ
10.	State the parts & positions of Uterus.	VSAQ

#### UNIT: 7 ENDO CRINE SYSTEM

Q.NO	TOPICS	TYPE
1.	Describe the <b>Thyroid gland</b> under following headings - a) Definition, b) location, c) hormones, d) peculiarities, e) external features, f) Parts, g) relations, h) coverings, i) blood supply, j) Functions.	LAQ
2.	Explain the <b>Pituitary gland</b> under following headings - a) Definition, b) location, c) shape, d) measurement, e) external features & hormones, f) Blood supply.	LAQ
3.	Explain the <b>Suprarenal gland</b> under following headings - a) Definition, b) location, c) measurement, d) external features, e) Internal features, f) hormones, g) blood supply.	LAQ
4.	Discuss the external features of Thyroid gland, state its coverings & blood supply.	SAQ
5.	Discuss the external features & hormones of Pituitary gland.	SAQ
6.	Discuss the external & internal features of Suprarenal gland & state its hormones.	SAQ
7.	List out the Endocrine glands.	VSAQ
8.	Classification of Endocrine glands.	VSAQ
9.	State the location & blood supply of Thyroid gland.	VSAQ
10.	State the location & hormones of Pituitary gland.	VSAQ
11.	State the location & hormones of Parathyroid gland.	VSAQ

#### UNIT: 8 NERVOUS SYSTEM

Q.NO	TOPICS	TYPE
1.	Classification of Nervous system.	SAQ
2.	Discuss the Cerebrum under following headings - a) Definition, b) location, c) external features.	SAQ
3.	Discuss the external features & blood supply of Cerebrum.	SAQ
4.	Discuss the Supero-lateral surface of Cerebrum.	SAQ
5.	Discuss the Cerebellum under following headings - a) Definition, b) location, c) nucleus, d) functions, e) blood supply.	SAQ
6.	Discuss the Spinal cord under following headings - a) Definition, b) location, c) extension, d) measurement, e) coverings, f) Blood supply.	SAQ
7.	Discuss the extension & external features of Spinal cord.	SAQ
8.	Discuss the location & external features of Midbrain.	SAQ
9.	Discuss the location & external features of Pons.	SAQ
10.	Discuss the location & external features of Medulla oblongata.	SAQ
11.	Discuss the blood supply of Brain.	SAQ

12.	Discuss the formation of Circle of Willis.	SAQ
13.	Classification of Cranial nerves.	SAQ / VSAQ
14.	State the parts of Brain.	VSAQ
15.	Write a note on Sulci & Gyri.	VSAQ
16.	State the location & nucleus of Cerebellum.	VSAQ
17.	State the layers of Meninges & its space.	VSAQ
19.	State the layers of meninges & its modification.	VSAQ
18.	State the modification of Spinal meninges.	VSAQ
20.	Enumerate the cranial nerves emerges from Midbrain / Pons / Medulla oblongata.	VSAQ
21.	List out the Cranial nerves.	VSAQ
22.	List out the Basal nuclei	VSAQ
23.	State the location & parts of Corpus callosum.	VSAQ

#### UNIT: 9 GENERAL EMBRYOLOGY

Q.NO	TOPICS	TYPE
1.	Discuss the stages of Spermatogenesis.	SAQ
2.	Discuss the stages of Oogenesis.	SAQ
3.	Discuss the Placenta under following headings - a) Definition, b) external features, c) functions.	SAQ
4.	Write a note on Fertilization & state its phases.	VSAQ
5.	Write a note on Implantation.	VSAQ
6.	Write a note on Ovulation.	VSAQ

## PAPER 2 - PHYSIOLOGY

### UNIT - I

#### GENERAL PHYSIOLOGY

##### Very short answer questions (VSAQ)

1. Draw labeled diagram of human cell and mention any four functions of cell organelles.
2. Explain one function of
  - a) Mitochondria, b). Golgi apparatus
  - c) Endoplasmic reticulum d) Ribosome
3. Give two differences between mitosis and meiosis.
4. Name the phases of mitosis
5. Name different types of intercellular connections?
6. Classify various mechanisms of transport across cell membrane.
7. Describe different mechanism of passive transport across the cell membrane
8. Describe different mechanism of active transport across the cell membrane
9. Define osmosis. Give examples.
10. Define symport. Give one example.
11. Define antiport. Give one example.
12. Define homeostasis. Name the types of feedback mechanisms involved in homeostasis with one example.
13. Briefly explain negative feedback mechanisms with examples.
14. Briefly explain positive feedback mechanisms with examples.
15. Give normal values of i) Intracellular fluid (ICF), ii) Extracellular fluid (ECF), iii) plasma and iv) Interstitial fluid

#### HEMATOLOGY (BLOOD)

##### Long answer questions (LAQ)

1. What is erythropoiesis? Describe the stages and factors influencing it.
2. What is anemia? Describe the types of anemia. Give the blood picture in each of them.
3. What is immunity? Explain its types.
4. Explain the mechanism of hemostasis.
5. Explain intrinsic and extrinsic mechanisms of blood clotting.
6. Name the blood group systems. Explain the basis for its classification. Add a note on its clinical importance.

##### Short answer questions (SAQ)

1. Briefly describe the composition of blood.
2. Write the functions of blood.
3. List the plasma proteins. Write its functions.
4. What is Erythropoiesis? List its stages.
5. Define anemia with types. Explain iron deficiency anemia.
6. Briefly explain ABO and Rh system.
7. Erythroblastosis fetalis.
8. Define hemostasis with stages.
9. Name the clotting factors.
10. Define immunity. What are its types?

### Very short answer questions (VSAQ)

1. Classifications of WBC.
2. Functions of neutrophil.
3. What is Phagocytosis?
4. Functions of eosinophil.
5. Functions of basophil.
6. Functions of lymphocytes.
7. Functions of red blood cell (RBC).
8. Write the normal values of hemoglobin in adults male and female.
9. Functions of hemoglobin.
10. Functions of platelets.
11. What is hemophilia?
12. What is anticoagulant?
13. Name any two anticoagulants.
14. Name the blood group systems.
15. Define Landsteiner's law.  
Mismatch transfusion.

## UNIT - II

### CARDIOVASCULAR SYSTEM

#### Long answer questions (LAQ)

1. Define cardiac cycle. Explain with the help of a diagram the mechanical and pressure changes during cardiac cycle.
2. Draw a labelled diagram showing the innervations of heart. Describe the regulation of heart rate.
3. Define blood pressure. Give its normal values. Write the factors controlling blood pressure.
4. Define cardiac output and cardiac index. Give its normal values. Describe the factors regulating cardiac output.
5. What is shock? What are its types? Discuss the cardiovascular compensatory changes that occur during shock.

#### Short Answer Questions (SAQ)

1. Write the difference between pulmonary and systemic circulation.
2. Briefly describe the conducting system of heart.
3. Draw labeled diagram of conducting system of heart.
4. List out the properties of cardiac muscle. Briefly explain any two properties.
5. Draw a normal Lead II ECG indicating its waves and segments.
6. Define blood pressure (BP). What are the components of it and write its normal range.
7. List the factors affecting blood pressure
8. Define cardiac cycle. List the events during cardiac cycle.
9. Define shock. Name its types.
10. Briefly explain the types of heart sounds.

### **Very Short Answer Questions (VSAQ)**

1. Write any two differentiating points between pulmonary and systemic circulation.
2. Define blood pressure.
3. What is systolic blood pressure? Write its normal value.
4. What is diastolic blood pressure? Write its normal value.
5. Define pulse. Write its normal range.
6. Write any two differences between tachycardia and bradycardia.
7. Define cardiac output. Write its normal values.
8. Define stroke volume. Write its normal values.
9. What is electrocardiogram (ECG)?
10. List any four properties of cardiac muscle.

### **UNIT III**

#### **RESPIRATORY SYSTEM**

#### **Long answer questions (LAQ)**

1. Describe the mechanics of breathing.
2. Explain oxygen transport in the blood. Describe the oxygen dissociation curve.
3. Discuss the transport of carbon dioxide in the blood.
4. Name the respiratory centers. Explain the neural regulation of respiration.
5. Classify hypoxia. Describe the types with suitable examples.

#### **Short answer questions (SAQ)**

1. Briefly explain the mechanism of inspiration.
2. Briefly explain the mechanism of expiration.
3. Draw labeled diagram of pontine and medullary respiratory centers.
4. Briefly explain the transport of oxygen in the blood.
5. Briefly explain the transport of carbon dioxide in the blood.
6. Draw labeled diagram of normal spirogram indicating lung volume and capacities.
7. Define and give normal values of lung volumes.
8. Define and give normal values of lung capacities.
9. What is surfactant? Give its function.
10. Define hypoxia. List its various types.
11. Classify and explain any one type of hypoxia.

#### **Very short answer questions (VSAQ)**

1. Name the inspiratory muscles.
2. Name the expiratory muscles.
3. Name the respiratory and non-respiratory functions of lungs.
4. Write any four functions of respiratory system.
5. Function of surfactant.
6. Name the respiratory centers.
7. Normal values of lung volumes.
8. Normal values of lung capacities.
9. Draw labeled diagram of respiratory center.
10. List the types of hypoxia.
11. Vital Capacity.
12. What is dead space?
13. What is hypoxia?

14. What is dyspnea?
15. What is cyanosis?
16. What is periodic breathing?

#### **UNIT - IV**

#### **IV - GASTRO-INTESTINAL PHYSIOLOGY**

##### **Long Answer Questions (LAQ)**

1. Describe the phase and control of deglutition. Add a note on its applied importance.
2. Write the composition of saliva? Describe the regulation of salivary secretion. Discuss its functions.
3. Describe the composition and phases of gastric secretion. Briefly explain the HCl secretion in stomach.
4. Describe the phases of pancreatic secretion.

##### **Short Answer Questions (SAQ)**

1. Give the composition and functions of saliva?
2. Give composition and functions of gastric secretion?
3. Briefly explain mechanism of HCl secretion
4. Give composition and functions of pancreatic secretion?
5. Briefly explain entero-hepatic circulation with neat diagram.
6. Briefly explain the functions of liver.
7. Classify gastro intestinal (GI) hormones and write its actions of any two hormones.
8. Peptic ulcer.

##### **Very Short Answer Questions (VSAQ)**

1. What is mastication?
2. What is deglutition?
3. Write any four functions of saliva.
4. Write any four functions of liver.
5. Functions of pancreatic juice.
6. Name any four GI hormones.
7. Functions of gastrin.
8. Functions of secretin.
9. Functions of cholecystokinin pancreozymin.
10. What are the movements of stomach?
11. What are the movements of small intestine?
12. What are the movements of large intestine?
13. Write any four functions of bile.
14. What is the difference between liver and gall bladder bile?

#### **UNIT - IV**

#### **RENAL PHYSIOLOGY (EXCRETORY SYSTEM)**

##### **Long Answer Questions (LAQ)**

1. Describe the mechanism of urine formation.
2. Define GFR (Glomerular filtration rate). Write its normal values. Briefly explain the factors affecting GFR.
3. Describe the Structure and functions of juxta glomerular apparatus

4. Draw a labeled diagram showing nerve supply to the urinary bladder. Explain the mechanism of micturition. What is a neurogenic bladder?
5. Describe the role of counter current multiplier and exchange system in concentrating urine.
6. Discuss the role of different buffer systems in regulation of acid - base balance.

#### **Short Answer Questions (SAQ)**

1. Briefly explain the functions of kidney.
2. Briefly explain the formation of urine.
3. Briefly explain mechanism behind voiding of urine.
4. Define GFR (Glomerular filtration rate). Write its normal values. List the factors affecting GFR.
5. What is the normal renal blood flow? How is it measured?
6. List the Special features of renal blood flow.
7. List any three differences between Cortical and Juxtamedullary nephrons.
8. Draw a labeled diagram of juxtaglomerular apparatus. What are its functions?
9. With a flow chart and suitable diagram, indicate the process of micturition reflex.
10. Briefly explain the role of ADH (Anti-diuretic hormone) on kidney?
11. Briefly explain renal dialysis.

#### **Very Short Answer Questions (VSAQ)**

1. Draw labeled diagram of a nephron.
2. Draw labeled diagram of filtration membrane
3. Write any four functions of kidney.
4. Functions of macula densa and Juxtaglomerular cells
5. What are the steps of urine formation?
6. Give one substances used to measure GFR and renal plasma flow.
7. What is micturition reflex?
8. What is cystometrogram?
9. Filtration fraction.
10. Define renal clearance.
11. Name the types of renal clearance.
12. List any three differences between cortical and medullary nephrons.
13. What is diuresis?
14. What is diuretics?
15. Name any two diuretics.
16. Give two functions of skin?

### **UNIT - V**

#### **V - ENDOCRINE PHYSIOLOGY**

#### **Short Answer Questions (SAQ)**

1. List the anterior pituitary (Adenohypophysis) hormones. Give any two hormone functions.
2. Mention the physiological role of GH (Growth hormone). Add a note on its hyper and hypo secretion.
3. Name the posterior pituitary hormones. Give their functions.
4. Name the adrenal cortical and medullary hormones. Mention the functions of glucocorticoids.
5. Mention the functions of aldosterone.

6. Name the thyroid hormones. Write its functions.
7. Name the hormones synthesized by pancreas. Mention their role in maintaining blood glucose.
8. Explain the actions of hormones on hyperglycemia and hypoglycemia.

#### **Very Short Answer Questions (VSAQ)**

1. Name any four hypothalamic hormones.
2. Name the anterior pituitary (Adenohypophysis) hormones.
3. List the posterior pituitary (Neurohypophysis) hormones
4. What is diabetes mellitus? What are its types?
5. What is the difference between gigantism and acromegaly?
6. What is dwarfism?
7. Name the thyroid hormones.
8. Write any two functions of thyroid hormones.
9. What is Grave's disease?
10. What is myxedema?
11. What is cretinism?
12. What is the difference between myxedema and cretinism?
13. Functions of parathormone.
14. Functions of mineralocorticoids (Aldosterone).
15. Functions of glucocorticoids.
16. What is Cushing's syndrome?
17. What is Addison's disease?
18. What is the difference between diabetes mellitus and diabetes insipidus?
19. Name the hormones secreted by pancreas.
20. Name the diabetogenic and antidiabetogenic hormones.
21. Functions of insulin.
22. Functions of glucagon.
23. What is diuresis? What are its types?
24. Functions of adrenal medullary hormone.
25. What is fight or flight response?

#### **V- REPRODUCTIVE SYSTEM**

##### **Short answer questions (SAQ)**

1. What is spermatogenesis? Mention its stages.
2. Briefly explain the ovarian cycle.
3. Briefly explain ovulation with hormonal regulations.
4. What is menstrual cycle? Briefly explain its phases.
5. Briefly explain any two female contraceptive methods.
6. List the contraceptive methods in male and female.
7. Explain the IUCD (Intrauterine contraceptive device).
8. List the functions of estrogen.
9. List the functions of progesterone.

##### **Very short answer questions (VSAQ)**

1. Write any two functions of testosterone.
2. What is menarche and menopause?
3. What is menstrual cycle?
4. List the placental hormones.
5. List the functions of Follicular stimulating hormone (FSH).
6. List the functions of sertoli cells



7. Functions of placenta.
8. Name the factors influencing spermatogenesis.
9. What is fertilization?

## **UNIT - VI**

### **NERVE MUSCLE PHYSIOLOGY**

#### **Short answer questions (SAQ)**

1. Draw the labeled diagram of neuromuscular junction (NMJ).
2. Briefly explain the ionic basis of action potential in a neuron.
3. Briefly explain the steps of neuromuscular transmission of signal impulse.
4. With the help of a flow chart, depict the steps of muscle contraction.
5. Briefly explain the excitation - contraction coupling in a skeletal muscle
6. Write any four differences between skeletal, cardiac and smooth muscles.
7. Myasthenia gravis

#### **Very short answer questions (VSAQ)**

1. Describe the structure of a neuron.
2. Give the normal value of resting membrane potential of i) motor neuron and ii) skeletal muscle.
3. Give normal resting membrane potential of neuron and skeletal muscle.
4. List any two properties of nerve fibers.
5. Name any two neuromuscular blocking agent
6. Draw the structure of sarcomere
7. Name the muscle proteins.
8. List any four properties of skeletal muscle.
9. Rigor mortis

## **VI - CENTRAL NERVOUS SYSTEM (CNS)**

#### **Short answer questions (SAQ)**

1. Briefly explain the divisions of nervous system.
2. With a flow chart and suitable diagram briefly explain the synaptic transmission of excitatory postsynaptic potential (EPSP).
3. With a flow chart and suitable diagram briefly explain the synaptic transmission of inhibitory postsynaptic potential (IPSP).
4. Briefly explain the functions of cerebral cortex.
5. What are the functions of cerebellum?
6. What are the functions of basal ganglia?
7. What are the functions of hypothalamus?

#### **Very short answer questions (VSAQ)**

1. Name any four properties of synapse.
2. Write any two functions of thalamus.
3. Functions of medulla oblongata.
4. Functions of cerebro spinal fluid (CSF).
5. Name any two neurotransmitters.
6. Name any four hypothalamic hormones.
7. Name the anterior pituitary (Adenohypophysis) hormones.
8. List the posterior pituitary (Neurohypophysis) hormones

## **VI - SPECIAL SENSES**

#### **Short answer questions (SAQ)**

1. Trace the visual pathway with a neat labeled diagram
2. Explain the errors of refraction
3. Trace the auditory pathway with a neat labeled diagram

4. Functions of Middle ear.
5. Trace the olfactory pathway.

**Very short answer questions (VSAQ)**

1. Name the receptors for vision, smell, taste and hearing.
2. Functions of eye
3. List the primary colors of vision
4. Accommodation reflex.
5. What are the functions of rods and cones in eye?
6. Explain the terms ageusia, hypogeusia, dysgeusia.
7. Name the primary taste sensations

# PAPER-3: BIOCHEMISTRY

## UNIT-I: INTRODUCTION TO BIOCHEMISTRY

### Long answer questions

(10 marks)

1. How is acid base balance maintained in the body?
2. Write in detail about Acid base disorders

### Short Questions

(6 marks)

1. Discuss the different buffer system of acid base homeostasis.
2. What is the normal PH of blood? How is it maintained?
3. Explain the role of lungs in acid base system
4. Glass electrode and determination of pH
5. Explain the Metabolic acidosis & Metabolic alkalosis
6. Explain the Respiratory acidosis & Respiratory alkalosis
7. Role of kidney in the regulation of blood pH
8. Biochemical assessment of acid base balance

### Very Short answer questions:

(3 marks)

1. Define pH. What is the normal values of blood & urine PH
2. Define buffer and give 2 examples.
3. Define acid/ base with example
4. Write any 2 conditions for acid base imbalance.
5. What is Henderson Hasselbalch equation
6. Define Anion gap with example
7. List out any 2 causes & symptoms for Respiratory acidosis & alkalosis
8. List out any 2 causes & symptoms for Metabolic acidosis & alkalosis
9. Define isoelectric PH.

## PROTEINS

### Long answer questions

(10 marks)

1. Define proteins & detail in classification of Proteins with suitable examples
2. Describe the different levels of protein structure in detail with suitable diagram

### Short Questions

(6 marks)

1. What are Essential amino acids & mention its clinical significance
2. Mention any five biologically important peptides & its clinical role
3. Define Protein denaturation & causes, characteristics with example
4. Classify amino acids in detail with example.
5. Explain Transamination & Give one example.
6. Functions of plasma proteins
7. Define Electrophoresis & its clinical significance
8. Define Chromatography & its clinical significance
9. Explain the secondary structural organization of proteins
10. Mention the hydrolytic products of proteins
11. Precipitation reactions of protein
12. Define peptide bond formation & characteristics of peptide bond
14. Determination protein structure
15. Biological functions of amino acids
- 16 Biological functions of proteins.

**Very Short answer questions:****(3 marks)**

1. Name any 4 agents causing denaturation of protein
2. Name any 2 defense & buffer proteins
3. Name the Sulphur containing essential amino acid & functions.
4. Explain oxidative deamination with example
5. Explain decarboxylation with example
6. Mention the Properties of proteins
7. Name the conjugated protein with example
8. Name the derived protein with example
9. Define A:G ratio
10. Nutritional classes of proteins with example
11. Define zwitterion
12. Fibrous & globular proteins

**ENZYMES****Long answer questions****(10 marks)**

1. Classify enzymes? Explain any 4 factors affecting the enzymes activity
2. Explain the different types of enzyme inhibition with suitable examples

**Short Notes****(6 marks)**

1. How are enzymes classified and give one example for each class?
2. Explain factors affecting enzyme activity
3. Mention the clinical applications of enzymes and how they are useful in diagnosis of disease
4. Explain the features of active site of enzyme
5. Explain the competitive inhibition with suitable example
6. Explain the non-competitive inhibition with suitable example
7. What are the Co-enzymes & Explain the features with example
8. Explain the regulation of enzyme activity
9. Define Iso-enzyme? Give two examples and its importance in clinical diagnosis
10. Explain the types of specificity

**Very Short answer questions****(3 marks)**

1. Define Enzymes & Catalyst
2. Define Active site
3. What is Co-enzymes, mention any 2 examples with significance.
4. Define Enzyme unit
5. Define Apo enzyme & Holoenzymes
6. What is Suicide Inhibition
7. List any 3 Therapeutic uses of enzymes.
8. Plasma enzymes
9. Define km
10. Koshland's induced fit theory
11. Fischer's template theory
12. Prosthetic groups
13. Examples of Metalloenzymes & Metal activated enzymes

## UNIT II - CARBOHYDRATES

### Long answer questions

(10 marks)

1. Write in detail about the Polysaccharides and mention its importance.
2. Properties of Monosaccharides
3. Define Carbohydrates & detail in classification of carbohydrates with examples
4. Explain the reaction of Monosaccharides.

### Short Questions

(6 marks)

1. Define carbohydrate and classify with examples
2. Write a note on Mucopolysaccharides & mention one function of each
3. Differentiate between Glycogen and Starch
4. Define Mutarotation
5. List out the functions of carbohydrates
6. Explain the Clinical importance of monosaccharides
7. Properties of monosaccharides
8. Explain Homopolysaccharides & mention their function
9. Write a note on Disaccharides
10. Define glycosides? Name any 3 glycosides & mention their function

### Very Short answer questions

(3marks)

1. What is heparin? Mention its composition & function
2. List any 2 reducing sugars
3. List any 4 functions of glycoprotein
4. Difference between glycoprotein & proteoglycan
5. Why is sucrose a non-reducing sugar
6. Mention the clinical application of Inulin & Dextran
7. Difference between reducing and non-reducing sugars
8. Define invert sugar
9. What is cellulose? Mention its function
10. Note on Anomers
11. Define Epimers with examples
12. Biological importance of mannitol
13. Optical isomerism with examples.
14. Define amino sugars with examples
15. Define glycosides

## NUCLEIC CHEMISTRY

### Short Answer Questions

(6 marks)

1. List any 5 synthetic analog bases and mention its function
2. Short notes on types of RNA & mention its function
3. Define nucleoside and nucleotide by giving suitable examples.
4. Describe the structure of t-RNA and mention its function
5. List the important functions of nucleotides
6. Give a detailed account on Secondary structure of DNA
7. Difference between DNA and RNA
8. Difference between Purines and Pyrimidines

**Very Short Answer Questions****(3 marks)**

1. Name the purine and pyrimidine bases of DNA & RNA
2. Differentiate Ribose and Deoxy ribose.
3. Name any 4 minor bases
4. Draw a neat labeled diagram of DNA
5. Mention the types of DNA and give 3 points each
6. What are the biological important bases and its function
7. Define Chargaff's rule
8. Functions of nucleic acid
9. What is ribosomal RNA
10. Draw a neat labeled diagram of t-RNA

**UNIT III - LIPIDS****Long answer questions****(10 marks)**

1. what are lipids? classify them. Give biological significance of lipids.
2. what are fatty acids? classify them. Give biological significance of polyunsaturated fattyacids
3. Explain the phospholipids with examples and its function.

**Short Questions****(6 marks)**

1. Explain in detail about Sphingomyelins & their function
2. Write a short note on Micelles, Bio membranes
3. Write a short note on Sphingophospholipids
4. Write a short note on Liposomes
5. Write a short note on Triacylglycerol
6. What is saturated fatty acid and give three examples with biological significance
7. What are prostaglandins? Mention their function
8. What is unsaturated fatty acid? Explain the types and biological significance
9. Write a short note on Properties of fatty acids
10. Write a short note on Essential Fatty Acids?
11. Write a short note on Trans fatty acids
12. Write a short note on cholesterol
13. Describe briefly about the classifications of lipids with suitable examples
14. What are the compounds formed from cholesterol?
15. Write in detail about the lipoprotein & its functions

**Very Short answer questions****(3 marks)**

1. Lung surfactant
2. Saponification number
3. Iodine number
4. Acid number
5. What are Apo Lipoproteins?
6. Respiratory Distress Syndrome (RDS)
7. Define halogenation
8. What is rancidity of lipids?
9. Omega 3 Fatty acids
10. Cardiolipin
11. Free Fatty Acids

12. Leukotriene's (LTs)
13. Thromboxane's (Tx)
14. Write the products formed due to complete hydrolysis of triacylglycerol
15. What is cephalin

#### UNIT IV - ENERGY METABOLISM AND NUTRITIONAL BIOCHEMISTRY

##### Long answer questions

(10 marks)

1. Write in detail about the RDA, dietary sources, biochemical role and deficiency manifestations of folic acid/ vitamin B12/ calcium /iron
2. Explain the RDA, dietary sources, biochemical role and deficiency manifestations of vitamin A/ vitamin D/ vitamin C/ vitamin K

##### Short Notes

(6 marks)

1. List out the clinical significance of Vitamin E/ Vitamin K
2. Coenzymes & functions of any 1 B-complex vitamin (Thiamine/ Riboflavin/ Niacin/Pyridoxine/ Folic acid etc.)
3. Explain the Vitamin E has selenium sparing action.
4. Discuss the steps involved in digestion & absorption of calcium/ phosphorous / iron
5. How plasma calcium level is regulated
6. Functions of copper/ selenium/ zinc
7. Role of proteins in diets
8. Describe protein energy malnutrition
9. Nutritional value of protein
10. Dietary role of different lipids
11. Dietary fiber
12. Thermogenic effect of food
13. Obesity
14. Define nitrogen balance & Mention the factor that causes positive & negative nitrogen balance
15. Define BMR & factor affecting BMR
16. What are Essential Amino Acids? Mention their clinical importance
17. Explain the RDA, sources, biochemical role and deficiency of sodium / potassium
18. What are Essential Fatty Acids? Mention their clinical importance.

##### Very Short answer questions

(3marks)

1. Write any 3 causes for Tetany
2. Define Heme proteins/ non heme proteins
3. Hemochromatosis/ Hemosiderosis
4. Iron deficiency anemia
5. Wilson's disease
6. Fluorosis
7. Define balanced diet
8. Define calorific values & Its significance
9. Define Respiratory quotient
10. What is Glycemic index
11. What is pellagra
12. Ceruloplasmin

## UNIT V CLINICAL CHEMISTRY

### Short Notes

(6marks)

1. Detail account on basic principle, methodology and diagnostic significance of electrophoresis.
2. Detail account on basic principle, methodology and diagnostic significance of paper chromatography
3. Short notes on Osmolality, significance and measurement.
4. write about the different types of electrophoresis & application of each type
5. Explain the method of cholesterol /urea /glucose estimation
6. write about the different types of electrophoresis & application of each type

### Very Short answer questions

(2 marks)

1. Define Osmolality/ Osmolarity
2. Write the principle of (GOD-POD) method
3. List any 3 simple test to identify Carbohydrates, lipids and proteins
4. Mention the normal values of glucose/ cholesterol/ protein/ urea/ creatinine
5. Define osmolal gap
6. what is Rf value
7. Write the principle of Molisch test /Benedict's test
8. List out the normal/ abnormal constituents of urine

## ENVIRONMENTAL CHEMISTRY

### Short Notes

(6 marks)

1. Explain in detail about biomedical waste management
2. Write short notes on air pollution
3. Write short notes on Acid Rain.
4. Write short notes on carbon monoxide
5. Write short notes on mutagenesis.
6. Explain in detail about bio pesticides & its types
7. Explain briefly about the harm full effects of plastics to human health

### Very Short answer questions

(3marks)

1. Define pollutants & give 2 examples
2. What are biomedical wastes?
3. Name five categories of bio pesticides
4. Write about biological water borne disease
5. What are the problems caused by plastics?
6. Name some chemicals causing water borne disorders
7. What is Bio-degradable & Non-biodegradable Waste?
8. Define greenhouse effects
9. What is Ames test?
10. What is meant by carcinogens, and list any three chemicals causing carcinogens
11. What is biosafety?



## PAPER 4A - GENERAL MICROBIOLOGY

### UNIT -I : GENERAL BACTERIOLOGY

#### 10 MARKS

1. Discuss the methods of collection and transportation of specimens.
2. Define the terms sterilization, disinfection and antisepsis. Name various agents used for sterilization and discuss the role of hot air oven in sterilization.
3. Define the terms sterilization. Discuss the role of moist heat in sterilization and their sterility control methods.
4. Discuss the various types of disinfectants and discuss the role of halogens in chemical disinfection.

#### 6 MARKS

1. Write a short note on contribution of Louis Pasteur.
2. Write a short note on contribution of Robert Koch.
3. Write a short note on contribution of Edward Jenner.
4. Write a short note on Koch postulates.
5. Tabulate the difference between prokaryotes and Eukaryotes .
6. Draw a labeled diagram of a bacterial cell. Describe the cell wall of bacteria.
7. Draw a labeled diagram of Autoclave. Describe the structure and functioning.
8. Draw a labeled diagram of Hot air oven. Describe the structure and functioning.
9. Tabulate the difference between differentiate between flagella and fimbria .
10. Write a short note on spores.
11. Describe bacterial growth curve.
12. What are culture media? Classify and discuss them in brief.
13. Discuss in detail anaerobic methods of cultivation of bacteria.
14. Discuss the methods of preservation of microorganisms.
15. Write a short note on phenols as disinfectant.
16. Write a short note on Aldehydes as disinfectant.
17. Write a short note on Antimicrobial sensitivity testing.
18. Discuss the methods of collection and transportation of specimens.
19. Outline the steps in Gram staining and interpretation.
20. Outline Ziehl-Neelsen staining procedure and interpretation.
21. Name the different types of hospital wastes and discuss in detail the methods of disposal of hospital wastes

#### 3 MARKS

1. Write four functions of bacterial cell wall.
2. Write four differences between gram positive & gram negative bacterial cell wall.
3. What is protoplast & spheroplast.
4. What are the functions of capsule.
5. How will you classify bacteria based on position of flagella.
6. Write four examples of spore producing bacteria.
7. Write four examples of capsule producing bacteria.
8. Write four examples of capnophilic bacteria.
9. Write four examples of strict aerobic bacteria.
10. Write four examples of strict anaerobic bacteria.

11. Write four examples of microaerophilic bacteria.
12. Define sterilization .
13. Define disinfectant .
14. Name the types of filters and their uses.
15. What is cold sterilization.
16. Define inspissation.
17. What is an agar? write its role in preparation of media.
18. Name four selective media.
19. Name four differential media.
20. Name four transport media.
21. Write the composition of TSI agar.
22. Write the principles of catalase test.
23. Write the principles of oxidase test.
24. Name the two motile and non-motile organisms

## UNIT -2 : IMMUNOLOGY

### 6 MARKS

1. Discuss the mechanism of innate and acquired immunity.
2. What is hypersensitivity? Classify hypersensitivity reactions? Describe in detail about type I reactions.
3. Discuss the principle and clinical applications of immunofluorescence technique.
4. Discuss the principle and clinical applications of ELISA technique.
5. Describe the structure and functions of Ig M, Ig G & Ig A.
6. Write a short notes on autoimmunity.
7. Discuss about delayed type hypersensitivity.
8. Describe about phagocytosis process.
9. Herd immunity.
10. Type III Hypersensitivity.

### 3 MARKS

1. Write the difference between active & passive immunity.
2. Define Immunity.
3. Write two examples of each , live attenuated bacterial & viral vaccines.
4. Write two examples of each , killed bacterial & viral vaccines
5. Write four difference between live & killed vaccines.
6. Define hapten.
7. What is heterophile antigen? write two examples.
8. Write two uses of ELISA.
9. Define hypersensitivity.
10. Difference between immediate and delayed type of hypersensitivity.
11. Define autoimmunity

## UNIT -3 SYSTEMIC BACTERIOLOGY

### 10 MARKS

1. Discuss the pathogenicity and laboratory diagnosis of *Staphylococcus aureus*.
2. Name various organism causing sore throat and discuss in detail the laboratory diagnosis of diphtheria.
3. Classify Streptococci. Discuss the pathogenesis and lab diagnosis of *S.pyogenes*.

4. Classify the Clostridia of medical importance. Describe the pathogenesis, laboratory diagnosis of gas gangrene.
5. Classify Mycobacteria. Give an account on pathogenesis and laboratory diagnosis of pulmonary tuberculosis. Add a note on BCG vaccine.
6. Discuss the morphology, pathogenesis and laboratory diagnosis of syphilis.
7. Discuss in detail about pathogenesis and laboratory diagnosis of enteric fever.
8. List the diarrhea causing bacteria. Write in detail about pathogenesis and laboratory diagnosis of *vibrio*.

### 6 MARKS

1. Name four causative agents of enteric fever and explain about WIDAL test.
2. Name the UTI causing bacteria. How to collect urine & laboratory diagnosis of *E.coli*.
3. Describe about Toxin produced by *staphylococcus aureus*.
4. Discuss about prophylaxis of diphtheria.
5. Difference between *Streptococcus viridians* & *Streptococcus pneumoniae*.
6. Coagulase test.
7. Tetanus.
8. Explain about morphology and pathogenicity of *Bacillus anthracis*.
9. Classification of shigella and explain the antigenic structure and toxins produced by *Shigella*.
10. Weil's diseases.
11. Laboratory diagnosis of syphilis
12. Discuss the pathogenicity of Chlamydia.

### 3 MARKS

1. Name the pigments produced by *Pseudomonas*.
2. Name two toxins produced by *Clostridium tetani*.
3. Define Asepsis.
4. Enumerate any four diseases caused by *Streptococcus pyogenes*.
5. Gas gangrene.
6. Name four first line drugs used to treat tuberculosis infections.
7. List four species of *Shigella*.
8. List the cultivation methods of leprae.
9. MRSA.
10. ASO
11. CRP
12. Non -gonococcal urethritis (NGU).
13. Name two selective media for *V.cholera*
14. Significant bacteriuria.
15. Meningitis .
16. Selective medium of Salmonella
17. VDRL and RPR.
18. Name two transport and enrichment media for *V.cholerae*.
19. What are coliform bacilli? write two examples.
20. Actinomycosis
21. List the atypical mycobacteria.
22. Ghon's focus.
23. BCG vaccine
24. Name the two beta hemolytic bacteria.

25. Mantoux test.

#### UNIT -4 : VIROLOGY

##### 10 MARKS

1. Name two RNA viruses. Name four methods of transmission of Hepatitis B virus infection in man. Mention the schedule of Hepatitis B vaccination.
2. Mention the modes of transmission of HIV in humans. Draw a neat diagram of HIV and label the parts. List the tests available for the confirmation of HIV in the microbiology laboratory.
3. Describe the laboratory diagnosis and prophylaxis of poliomyelitis.
4. Explain the laboratory diagnosis and prophylaxis of Rabies.

##### 6 MARKS

1. Describe the serological markers of Hepatitis B virus.
2. Describe the prophylaxis of polio virus.
3. Complications of dengue virus.
4. Write a short note on adenovirus.
5. Infectious mononucleosis.
6. List the opportunistic infections in AIDS patient.

##### 3 MARKS

1. Name four DNA virus.
2. Name four RNA virus
3. Haemorrhagic causing virus.
4. MMR vaccine.
5. Draw a neat labeled diagram of HIV.
6. Rabies vaccine.
7. List the cultivation methods of virus.

#### UNIT -5: PARASITOLOGY

##### 6 MARKS

1. Difference between amoebic and bacillary dysentery.
2. Describe the life cycle of *Entamoeba histolytica*.
3. Describe the life cycle of *Giardia lamblia*
4. Describe the life cycle of *Malaria*
5. Describe the life cycle of *hookworm*
6. Describe the life cycle of *Roundworm*
7. Lab diagnosis of Plasmodium.
8. Describe the lab diagnosis of parasitological samples.

##### 3 MARKS

1. Morphology of *E. histolytica*.
2. Black water fever.
3. Vectors.
4. Morphology of Leishmania.
5. Peripheral blood smear of Malaria.
6. Dog tapeworm.
7. *Cysticercus bovis*.
8. *Cysticercus cellulose*.
9. *Microfilaria*.

## UNIT -6: MYCOLOGY

### 6 MARKS

1. Discuss the laboratory diagnosis of fungal infections.
2. Write a short notes on zygomycosis.
3. Aspergillosis
4. Describe about systemic mycoses.
5. Cryptococcosis - Lesions caused & Laboratory diagnosis.
6. Discuss the opportunistic mycoses.
7. Describe the morphology & cultural characteristics of Dermatophytes.
8. Describe the morphology& cultural characteristics of *Candida albicans*

### 3 MARKS

1. SDA
2. Name two selective culture media for *Candida* spp.
3. Name two selective culture media for *Cryptococcus* spp.
4. What is germ tube test.
5. Mention four fungal laboratory contaminants .
6. Name four dimorphic fungus.
7. Name two examples of yeast.
8. Name four opportunistic fungus.
9. Name four superficial mycoses.
10. Mycetoma

## UNIT -7: HOSPITAL INFECTION CONTROL

### 6 MARKS

1. Biomedical waste management.
2. Write a short note on universal precaution.
3. Write a short note on universal precaution.
4. Mode of transmission of infections.
5. Write short note on the vaccines recommended for health care workers.
6. Recall the procedure to be followed for sharp injury to health care workers.
7. Describe the prevention of Nosocomial infections.

### 3 MARKS

1. Define segregations.
2. List four infectious waste.
3. Define land filling.
4. What is HICC? List two roles of HICC.
5. List two techniques used for the treatment of infectious waste.
6. Define universal precautions.
7. Define PPE.
8. List four methods to control the Hospital acquired infections.

## PAPER 4B - GENERAL PATHOLOGY

### LONG ANSWER

(10 MARKS )

1. Mention the types of necrosis with two example each
2. Mention the types of cellular adaptations with one example each
3. Mention the types of cell injury and describe the changes seen in each type
4. Describe the morphological alterations in reversible cell injury
5. Describe the morphological alterations in irreversible cell injury

### SHORT ANSWERS

(6 MARKS )

1. Tabulate the differences between exudate and transudate
2. Tabulate the differences between benign and malignant tumor
3. Define Gangrene. Mention the types of gangrenes with one example each
4. Mention the factors that influence wound healing and repair
5. Tabulate the differences between acute and chronic inflammation
6. Describe the principle chemical mediators of inflammation
7. Tabulate the differences between necrosis and apoptosis
8. Write a short note on apoptosis
9. Describe causes and morphological features of chronic inflammation
10. Explain granulomatous inflammation with a neat labeled diagram
11. Tabulate the differences between dry and wet gangrene
12. Explain mode of spread of tumors in brief
13. Adverse effects of smoking
14. Write a short note on asbestosis
15. Write a short note on silicosis

### VERY SHORT ANSWERS

(3 MARKS)

1. Define apoptosis. Mention two examples.
2. List the cardinal signs of acute inflammation
3. Define acute inflammation reaction and mention its outcome
4. Define chronic inflammation and give 2 examples
5. Mention the components of granulation tissue
6. Mention the parts of microscope
7. Give 2 examples of granulomatous inflammation
8. Define neoplasia
9. Define hypertrophy. Give 2 example
10. Define atrophy. Give 2 example
11. Define hyperplasia. Give 2 example
12. Define metaplasia. Give 2 example
13. Define reversible cell injury and mention two features
14. Define phagocytosis.
15. Define Virchow triad

### HAEMATOLOGY

#### SHORT ANSWERS

(6 MARKS )

1. Define anemia. Mention the types of anemia on the basis of etiology.
2. Classify leukemia. Mention general features of acute leukemia.
3. Enumerate various color codings of various biomedical waste disposal with 4 examples

4. Describe the collection, transport, preservation and processing of clinical specimen
5. Describe the structure and function of different types of WBC'S with a neat labeled diagram
6. Write a short note on occupational health hazards.
7. Describe mechanism of homeostasis
8. Describe various types anticoagulant and its uses with its color coding
9. Explain microscopic examination of urine samples.
10. Describe the method of collection, transport, preservation of CSF.
11. Write short note on Coomb's test
12. Define anemia . Mention the general clinical features and basic interpretation of anemia.
13. Classify hemolytic anemia and mention in brief the laboratory findings

#### **VERY SHORT ANSWERS**

**(3 MARKS )**

1. Define Landstenier's Law
2. Define blood group
3. Mention the normal platelet count and function of platelets.
4. Mention the types of transfusion transmitted infection
5. Mention 2 causes of Eosinophilia.
6. Mention 2 causes of Neutrophilia.
7. Mention 4 preservative of urine and its indication
8. Define cross matching
9. Mention Principle of major cross matching
10. Mention Principle of minor cross matching
11. Write about the principle of benedicts test.
12. Write about biomedical waste management.

#### **SYSTEMIC PATHOLOGY**

##### **LIVER**

1. Define Cirrhosis. (3M)
2. Describe in detail about viral hepatitis. (6M)
3. Mention the various stages of alcoholic liver disease (3M)
4. Describe in detail about gall stones. (6M)
5. Write about the etiology, pathogenesis and clinical features of chronic cholecystitis. (10M)

##### **BRAIN TUMOURS**

1. Classify brain tumours (3M)

##### **KIDNEY**

1. Mention the types of renal calculi. (3M)
2. Describe the clinical features of renal stones. (3M)
3. Define hydronephrosis (3M)
4. Classify renal tumours. (3M)

##### **BONE TUMOURS**

1. Classify bone tumours (3M)
2. Give two examples of benign bone tumors. (3M)
3. Give two examples of malignant bone tumours (3M)

## **FEMALE GENITAL TRACT**

1. Classify ovarian tumours(3M)
2. Describe the types of endometrial hyperplasia and risk factors associated with it.(6M)
3. Write a short note on risk factors for endometrial cancer.(6M)
4. Describe the etiopathogenesis and risk factors for cervical cancer.(10M)

## **BREAST**

1. Describe the risk factors and clinical features of breast carcinoma.(10M)
2. Give 2 example of benign breasts tumour (3M)
3. Give 2 example of malignant breast tumours.(3M)

## **CARDIOVASCULAR SYSTEM**

### **RHEUMATIC HEART DISEASES**

1. Enumerate the modified Jones criteria for rheumatic heart disease(6M)

### **INFECTIVE ENDOCARDITIS**

1. List the causative organisms for infective endocarditis(3M)
2. Enumerate the Dukes criteria for infective endocarditis.(6M)

### **ARTHEROSCLEROSIS**

1. Enumerate the risk factors for atherosclerosis.(6M)
2. Mention two complications of atherosclerosis ( 3M)\
3. Mention the types of Ischemic heart disease. (3M)
4. Write in detail about myocardial infarction. (10M)

## **RESPIRATORY SYSTEM**

### **LUNG INFECTIONS**

1. Describe the various Stages of Pneumonia.(6M)
2. Define Pneumonia.(6M)

### **COPD**

1. Define emphysema.(3M)
2. Define chronic bronchitis.(3M)
3. Define broncheactasis.(3M)
4. Tabulate the differences between chronic bronchitis and emphysema.(6M)
5. Mention various systemic effects of smoking ( 3M)

### **ASTHMA**

1. Describe the etiopathogenesis and clinical features of bronchial asthma.(6M)
2. Define ARDS(3M)
3. Give 2 examples for conditions associated with ARDS.(3M)

## **GASTROINTESTINAL SYSTEM**

1. Enumerate the clinical features of peptic ulcer.(3M)
2. Describe the Risk factors and clinical features of carcinoma stomach.(10M)
3. Describe the Risk factors and clinical features of carcinoma colon.(10M)



**ABILITY ENHANCEMENT COMPULSORY ELECTIVES  
AECC-1- ENGLISH QUESTION BANK**

**UNIT-1 - GRAMMAR**

**Six Mark Questions**

1. Define grammar, Explain the types of grammar with example.
2. What do you mean by noun and Explain its type with examples?
3. Write a brief note on types of sentences with examples.
4. How many types of tenses are there?

**Two Mark Questions**

1. Define verb.
2. Define Adjective with example.
3. Define Adverb with example.
4. Define Gerund and preposition.
5. What do you mean by conjunction and interjection?
6. How many types of tenses are there?
7. He Said, "My father is ill".(Change the sentence into indirect speech)
8. He said to her, "Where are you going"? (Change the sentence into indirect speech)
9. They said that they can't live without water.(change the sentence into direct speech)
10. Radha said, "I am very busy now".(Change the sentence into indirect speech)
11. She says that she is a little bit nervous.(change the sentence into direct speech)
12. You are busy, \_\_\_\_\_? (Fill the sentence with suitable question tag)
13. Helmet makes driving safe, \_\_\_\_\_? (Fill the sentence with suitable question tag)
14. Dogs cannot fly, \_\_\_\_\_? (Fill the sentence with suitable question tag)
15. She was talking, \_\_\_\_\_?(Fill the sentence with suitable question tag)
16. He won't come today\_\_\_\_?(Fill the sentence with suitable question tag)
17. He \_\_\_\_\_ (drink)tea every morning. (Fill the sentence with suitable tense)
18. I enjoy\_\_\_\_\_(read) at a cafe.(Fill the sentence with suitable tense)
19. We\_\_\_\_\_(see) a film last night.(Fill the sentence with suitable tense)
20. They went home, after they\_\_\_\_\_(finish) their work.(Fill the sentence with suitable tense)
21. I\_\_\_\_\_(stay) here till you return.(Fill the sentence with suitable tense)
22. I\_\_\_\_\_ do it tomorrow. (Fill the sentence with modal verb)
23. \_\_\_\_\_ you help me with the house work, please? (Fill the sentence with modal verb)
24. I \_\_\_\_\_ speak English.(Fill the sentence with modal verb)
25. The doctor\_\_\_\_\_ see you now.(Fill the sentence with modal verb)
26. He \_\_\_\_\_ be the love of my life.(Fill the sentence with modal verb)
27. All\_\_\_\_\_ submit your notebook.(Fill the sentence with modal verb)
28. Seetha loves Rama. (Change the sentence to passive voice)
29. The story has been read by me. (Change the sentence to active voice)
30. Do you speak English well? (Change the sentence to passive voice)
31. Open the door (Change the sentence to passive voice)
32. Let the T.V be watched by them. (Change into active voice)
33. He admitted his guilt. (Change the simple sentence into complex sentence)
34. In-spite of his hard work, he failed. (Change the simple sentence into compound sentence)

35. It was raining, but they went out. (Change the compound sentence into simple sentence)
36. He failed to prove that he was innocent. (Change the complex sentence into simple sentence)
37. If you do not work hard, you will fail. (Change the complex sentence into compound sentence)
38. Everest is \_\_\_\_\_ highest mountain in the world. (Fill up with the suitable article)
39. The rose is \_\_\_\_\_ beautiful flower. (Fill up with the suitable article)
40. \_\_\_\_\_ umbrella is useful in rain. (Fill up with the suitable article)
41. Do you play \_\_\_\_\_ Piano? (Fill up with the suitable article)
42. \_\_\_\_\_ unicorn is a special creature. (Fill up with the suitable article)
43. Red \_\_\_\_\_ danger. (Fill up with suitable prepositions)
44. I acted \_\_\_\_\_ him. (Fill up with suitable prepositions)
45. Mr. Kumar is \_\_\_\_\_ the office. (Fill up with suitable prepositions)
46. I am ready \_\_\_\_\_ help. (Fill up with suitable prepositions)
47. Put it \_\_\_\_\_ (Fill up with suitable prepositions)
48. Bharath is the cleverest of all the boys in the class. (Identify the degrees of comparison)
49. Seetha is taller than Geetha. (Identify the degrees of comparison)
50. Hyderabad is not so hot as Chennai. (Identify the degrees of comparison)
51. I am not so strong as he. (Identify the degrees of comparison)
52. Mumbai is bigger than Hyderabad. (Identify the degrees of comparison)

## UNIT-2 : VOCABULARY

### Six Mark Questions

1. Define vocabulary and explain its types.
2. How to improve our vocabulary.
3. Write the uses of Dictionary.

### Two Mark Questions

1. Use a prefix to make the word meaningful:  
Possible
2. Use a prefix to make the word meaningful:  
Legal
3. Use a suffix to make the word meaningful:  
Beauty
4. Use a suffix to make the word meaningful:  
Clever
5. Use a suffix to make the word meaningful:  
Danger
6. Give the antonym:  
Weak
7. Give the antonym:  
Open
8. Give the antonym:  
Narrow
9. Give the antonym:  
Expand
10. Give the antonym:  
Superior

11. Give the synonym:

Incredible

12. Give the synonym:

Ecstatic

13. Give the synonym:

Rest

14. Give the synonym:

Behavior

15. Give the synonym:

Tired

16. Use the following idioms / phrases into sentence:

In black and white

17. Use the following idioms / phrases into sentence:

Get away

18. Use the following idioms / phrases into sentence:

Come forward

19. Use the following idioms / phrases into sentence:

Break down

20. Use the following idioms / phrases into sentence:

Look after someone

21. Write any two words miss used or confused?

22. Define Homophones.

23. Use the homophonic words in the sentences.

Write & right

24. Use the homophonic words in the sentences.

Whole & hole

25. Use the homophonic words in the sentences.

Weight & wait

26. Use the homophonic words in the sentences.

Sell & cell

27. Use the homophonic words in the sentences.

Sum & some

### UNIT-3 : WRITING SKILLS

(Six Mark Questions)

1. Make a precise of the following passage and suggest a heading:

Effective speaking depends on effective listening. It takes energy to concentrate on hearing and to concentrate on understanding what has been heard. Incompetent listeners fail in a number of ways. First, they may drift. Their attention drifts from what the speaker is saying. Second, they may counter. They find counter-arguments to whatever a speaker may be saying. Third, they compete. Then, they filter. They exclude from their understanding those parts of the message which do not readily fit with their own frame of reference. Finally, they react. They let personal feelings about a speaker or subject override the significance of the message which is being sent. What can a listener do to be more effective? The first key to effective listening is the art of concentration. If a listener positively wishes to concentrate on receiving a message his chances of success are high. It may need determination. Some speakers are difficult to follow, either because of voice problems or because of the form in which they send a message. There is then a particular need for the determination of a listener to concentrate on what is being said. Concentration is helped by alertness. Mental alertness is helped by physical alertness. It is not simply physical fitness, but also positioning of the body, the limbs and the head. Some people also find it helpful to their concentration if they hold the head slightly to one side. One

useful way for achieving this is intensive note-taking, by trying to capture the critical headings and sub-headings the speaker is referring to. Note-taking has been recommended as an aid to the listener. It also helps the speaker. It gives him confidence when he sees that listeners are sufficiently interested to take notes; the patterns of eye-contact when the note-taker looks up can be very positive; and the speaker's timing is aided-he can see when a note-taker is writing hard and can then make effective use of pauses. Posture too is important. Consider the impact made by a less competent listener who pushes his chair backwards and slouches. An upright posture helps a listener's concentration. At the same time it is seen by the speaker to be a positive feature amongst his listeners. Effective listening skills have an impact on both the listener and the speaker.

**2. Make a precise of the following passage and suggest a heading:**

Despite all the research every one of us catches cold and most of us catch it frequently. Our failure to control one of the commonest of all ailments sometimes seems ridiculous. Medical science regularly practises transplant surgery and has rid whole countries of such killing diseases as Typhus and the Plague. But the problem of common cold is unusually difficult and much has yet to be done to solve it. It is known that a cold is caused by one of a number of viral infections that affect the lining of the nose and other passages leading to the lungs but the confusing variety of viruses makes study and remedy very difficult. It was shown in 1960 that many typical colds in adults are caused by one or the other of a family of viruses known as rhinoviruses, yet there still remain many colds for which no virus has as yet been isolated. There is also the difficulty that because they are so much smaller than the bacteria which cause many other infections, viruses cannot be seen with ordinary microscopes. Nor can they be cultivated easily in the bacteriologist's laboratory, since they only grow within the living cells of animals or plants. An important recent step forward, however, is the development of the technique of tissue culture, in which bits of animal tissue are enabled to go on living and to multiply independently of the body. This has greatly aided virus research and has led to the discovery of a large number of viruses. Their existence had previously been not only unknown but even unsuspected. The fact that we can catch a cold repeatedly creates another difficulty. Usually, a virus strikes only once and leaves the victim immune to further attacks. Still, we do not gain immunity from colds. Why? It may possibly be due to the fact that while other viruses get into the bloodstream where antibodies can oppose them, the viruses causing cold attack cells only on the surface. Or it may be that immunity from one of the many different viruses does not guarantee protection from all the others. It seems, therefore, that we are likely to have to suffer colds for some time yet.

**3. Make a precise of the following passage and suggest a heading:**

There is nothing more frustrating than when you sit down at your table to study with the sincerest of intentions and instead of being able to finish the task at hand, you find your thoughts wandering. However, there are certain techniques that you can use to enhance your concentration. "Your concentration level depends on a number of factors," says Samuel Ghosh, a social counsellor. "In order to develop your concentration span, it is necessary to examine various 2 facets of your physical and internal environment," she adds. To begin with one should attempt to create the physical environment that is conducive to focussed thought. Whether it is the radio, TV or your noisy neighbours, identify the factors that make it difficult for you to focus. For instance, if you live in a very noisy neighbourhood, you could try to plan your study hours in a nearby library. She disagrees with the notion that people can concentrate or study in an environment with distractions like a loud television, blaring music etc. "If you are distracted

when you are attempting to focus, your attention and retention powers do not work at optimum levels,” cautions Ghosh. “Not more than two of your senses should be activated at the same time,” she adds. What that means is that music that sets your feet tapping is not the ideal accompaniment to your books. Also do not place your study table or desk in front of a window. “While there is no cure for a mind that wants to wander, one should try and provide as little stimulus as possible. Looking out of a window when you are trying to concentrate will invariably send your mind on a tangent,” says Ghosh. The second important thing, she says, is to establish goals for oneself instead of setting a general target and then trying to accomplish what you can in a haphazard fashion. It is very important to decide what you have to finish in a given span of time. The human mind recognizes fixed goals and targets and appreciates schedules more than random thoughts. Once your thoughts and goals are in line, a focussed system will follow. She recommends that you divide your schedule into study and recreation hours. When you study, choose a mix of subjects that you enjoy and dislike and save the former for the last so that you have something to look forward to. For instance, if you enjoy verbal skill tests more than mathematical problems, then finish Maths first. Not only will you find yourself working harder, you will have a sense of achievement when you wind up. Try not to sit for more than 40 minutes at a stretch. Take a very short break to make a cup of tea or listen to a song and sit down again. Under no circumstances, should one sit for more than one and a half hours. Short breaks build your concentration and refresh your mind. However, be careful not to overdo the relaxation. It may have undesired effects.

**4. Make a precise of the following passage and suggest a heading:**

Research has shown that the human mind can process words at the rate of about 500 per minute, whereas a speaker speaks at the rate of about 150 words a minute. The difference between the two at 350 is quite large. So a speaker must make every effort to retain the attention of the audience and the listener should also be careful not to let his mind wander. Good communication calls for good listening skills. A good speaker must necessarily be a good listener. Listening starts with hearing but goes beyond. Hearing, in other words is necessary but is not a sufficient condition for listening. Listening involves hearing with attention. Listening is a process that calls for concentration. While, listening, one should also be observant. In other words, listening has to do with the ears, as well as with the eyes and the mind. Listening is to be understood as the total process that involves hearing with attention, being observant and making interpretations. Good communication is essentially an interactive process. It calls for participation and involvement. It is quite often a dialogue rather than a monologue. It is necessary to be interested and also show or make it abundantly clear that one is interested in knowing what the other person has to say. Good listening is an art that can be cultivated. It relates to skills that can be developed. A good listener knows the art of getting much more than what the speaker is trying to convey. He knows how to prompt, persuade but not to cut off or interrupt what the other person has to say. At times the speaker may or may not be coherent, articulate and well organized in his thoughts and expressions. He may have it in his mind and yet he may fail to marshal the right words while communicating his thought. Nevertheless, a good listener puts him at ease, helps him articulate and facilitates him to get across the message that he wants to convey. For listening to be effective, it is also necessary that barriers to listening are removed. Such barriers can be both physical and psychological. Physical barriers generally relate to hindrances to proper hearing whereas psychological barriers are more fundamental and relate to the interpretation and evaluation of the speaker and the message.

**5. Make a precise of the following passage and suggest a heading:**

The term dietary fibres refers collectively to indigestible carbohydrates present in plant foods. The importance of these dietary fibres came into the picture when it was observed that the people having diet rich in these fibres, had low incidence of coronary heart disease, irritable bowel syndrome, dental caries and gall stones. The foodstuffs rich in these dietary fibres are cereals and grains, legumes, fruits with seeds, citrus fruits, carrots, cabbage, green leafy vegetables, apples, melons, peaches, pears etc. These dietary fibres are not digested by the enzymes of the stomach and the small intestine whereas most of other carbohydrates like starch and sugar are digested and absorbed. The dietary fibres have the property of holding water and because of it, these get swollen and behave like a sponge as these pass through the gastrointestinal tract. The fibres add bulk to the diet and increase transit time in the gut. Some of these fibres may undergo fermentation in the colon. In recent years, it has been considered essential to have some amount of fibres in the diet. Their beneficial effects lie in preventing coronary heart disease, and decreasing cholesterol level. The fibres like gums and pectin are reported to decrease postprandial (after meals) glucose level in the blood. These types of dietary fibres are recommended for the management of certain types of diabetes. Recent studies have shown that the fenugreek (Methi) seeds, which contain 40 per cent gum, are effective in decreasing blood glucose and cholesterol levels as compared to other gum containing vegetables. Some dietary fibres increase transit time and decrease the time of release of ingested food in colon. The diet having less fibres is associated with colon cancer and the dietary fibres may play a role in decreasing the risk of it. The dietary fibres hold water so that stools are soft, bulky and readily eliminated. Therefore, high fibre intake prevents or relieves constipation. The fibres increase motility of the small intestine and the colon and by decreasing the transit time there is less time for exposure of the mucosa to harmful toxic substances. Therefore, there is a less desire to eat . and the energy intake can be maintained within the range of requirement. This phenomenon helps in keeping a check on obesity. Another reason in helping to decrease obesity is that the high-fibre diets have somewhat lower coefficients of digestibility. The dietary fibres may have some adverse effects on nutrition by binding some trace metals like calcium, magnesium, phosphorus, zinc and others and therefore preventing their proper absorption. This may pose a possibility of nutritional deficiency especially when diets contain marginal levels of mineral elements. This may become important constraints on increasing dietary fibres. It is suggested that an intake of 40 grams dietary fibres per day is desirable.

6. Write a letter to your uncle thanking him for the birthday present he had sent for you.
7. Write a letter to your mother about your daily routine.
8. Write a letter to your younger brother who has grown very weak. Suggest ways how he can improve his health.
9. Write a letter to your younger brother who has grown very weak. Suggest ways how he can improve his health.
10. Write a letter to your father requesting him to buy you a cycle.
11. Write an application to your Principal requesting him to grant leave. Also mention reason/reasons.
12. You are Nirmal/Nirmala, a student of Government High School, Gurgaon. Write an application to the Principal of your school, requesting him to allow you full fee concession.

13. Write an application to the Principal of your school to allow you to change your section.
14. You have lost your library card. Write a letter to the librarian to issue you a duplicate card.
15. Write a letter to the Chairman of the Municipal Board regarding insanitary conditions of the locality you live in.

**Rearrange the following jumbled sentences to meaningful sentences:**

1. are machines/to think/robots/that use/a computer brain
2. are sent/computer brain/in the robot's parts/messages/from the/to motors
3. can be/to do/of work/robots/programmed/many kinds
4. is the/computer science/concerned with/robotics/field/and engineering/creating robots

**Two Mark Questions**

1. How is note making important in your profession?
2. How many types of letters are there?
3. Define skimming.

**UNIT-4 : SPOKEN COMMUNICATION**

**Six Mark Questions**

1. Write a Dialogue between a shopkeeper and a customer.
2. Write a Dialogue between two friends on the topic of air pollution.
3. Write a Dialogue between two new comers in college campus.
4. Write a Dialogue between a Nurse and a doctor.
5. Write a Dialogue between a student and a teacher.
6. Why is phonetics important in studying English.
7. Write a conversation two friends discussing about the online classes.
8. Describe a brief note on group discussion.
9. What are the good qualities of debater?

**Two Mark Questions**

1. Write a short note on hazards of cell phone usage?
2. Describe your favorite friend.
3. Define pronunciation.
4. Define intonation.
5. Write any two words in British English and American English.
6. Define debate.

**UNIT-5 : LISTENING AND READING SKILLS**

**Six Mark Questions**

1. Read the following and answer the questions given below

"I Have a Dream" is a public speech delivered by American civil rights activist Martin Luther King Jr. during the March on Washington for Jobs and Freedom on August 28, 1963, in which he calls for an end to racism in the United States and called for civil and economic rights. Delivered to over 250,000 civil rights supporters from the steps of the Lincoln Memorial in Washington, D.C., the speech was a defining moment of the civil rights movement.

Beginning with a reference to the Emancipation Proclamation, which freed millions of slaves in 1863, King observes that: "one hundred years later, the Negro still is not free". Toward the end of the speech, King departed from his prepared text for a partly improvised peroration on the theme "I have a dream", prompted by Mahalia Jackson's cry: "Tell them about the dream, Martin!" In this

part of the speech, which most excited the listeners and has now become its most famous, King described his dreams of freedom and equality arising from a land of slavery and hatred. Jon Meacham writes that, "With a single phrase, Martin Luther King Jr. joined Jefferson and Lincoln in the ranks of men who've shaped modern America". The speech was ranked the top American speech of the 20th century in a 1999 poll of scholars of public address.

Q1. What issues does Martin Luther King's speech address?

1. Continuation of racism
2. End to racism and civil and economic rights
3. Civil rights
4. Civil War

Q2. What pushes King to speak: "I have a dream"?

1. He reads out the Emancipation Proclamation
2. He is prompted by Mahalia Jackson
3. He is overwhelmed by the crowd
4. Lincoln had asked him to give the speech.

Q3. From the last paragraph, give one word for "to leave"

1. Departed
2. Proclamation
3. Improvised
4. Address

Q4. What is the name of Martin Luther King's famed speech?

1. The Emancipation Proclamation
2. An Improvisation
3. A Peroration
4. I Have a Dream

Q5. In front of whom does King speak?

1. The civil rights supporters
2. His friends
3. Lincoln
4. The Negroes

**Read the following and answer the questions given below**

Conflict had existed between Spain and England since the 1570s. England wanted a share of the wealth that Spain had been taking from the lands it had claimed in the Americas.

Elizabeth I, Queen of England, encouraged her staunch admiral of the navy, Sir Francis Drake, to raid Spanish ships and towns. Though these raids were on a small scale, Drake achieved dramatic success, adding gold and silver to England's treasury and diminishing Spain's supremacy. Religious differences also caused conflict between the two countries. Whereas Spain was Roman Catholic, most of England had become Protestant. King Philip II of Spain wanted to claim the throne and make England a Catholic country again. To satisfy his ambition and also to retaliate against England's theft of his gold and silver, King Philip began to build his fleet of warships, the Spanish Armada, in January 1586.

Philip intended his fleet to be indestructible. In addition to building new warships, he marshaled 130 sailing vessels of all types and recruited more than 19,000 robust



soldiers and 8,000 sailors. Although some of his ships lacked guns and others lacked ammunition, Philip was convinced that his Armada could withstand any battle with England.

The martial Armada set sail from Lisbon, Portugal, on May 9, 1588, but bad weather forced it back to port. The voyage resumed on July 22 after the weather became more stable.

The Spanish fleet met the smaller, faster, and more maneuverable English ships in battle off the coast of Plymouth, England, first on July 31 and again on August 2. The two battles left Spain vulnerable, having lost several ships and with its ammunition depleted. On August 7, while the Armada lay at anchor on the French side of the Strait of Dover, England sent eight burning ships into the midst of the Spanish fleet to set it on fire. Blocked on one side, the Spanish ships could only drift away, their crews in panic and disorder. Before the Armada could regroup, the English attacked again on August 8.

Although the Spaniards made a valiant effort to fight back, the fleet suffered extensive damage. During the eight hours of battle, the Armada drifted perilously close to the rocky coastline. At the moment when it seemed that the Spanish ships would be driven onto the English shore, the wind shifted, and the Armada drifted out into the North Sea. The Spaniards recognized the superiority of the English fleet and returned home, defeated.

**Q1. Sir Francis Drake added wealth to the treasury and diminished Spain's \_\_\_\_.**

- unlimited power
- unrestricted growth
- territory
- treaties

**Q2. King Philip recruited many \_\_ soldiers and sailors.**

- warlike
- strong
- accomplished
- timid
- inexperienced

**Q3. The \_\_ Armada set sail on May 9, 1588.**

- complete
- warlike
- independent
- isolated

**Q4. The two battles left the Spanish fleet \_\_\_\_.**

- open to change
- triumphant
- open to attack
- defeated
- discouraged

**Q5. The Armada was \_\_ on one side.**

- closed off
- damaged
- alone
- circled

## **2. Read the following and answer the questions given below**

Opera refers to a dramatic art form, originating in Europe, in which the emotional content is conveyed to the audience as much through music, both vocal and

instrumental, as it is through the lyrics. By contrast, in musical theater an actor's dramatic performance is primary, and the music plays a lesser role. The drama in opera is presented using the primary elements of theater such as scenery, costumes, and acting. However, the words of the opera, or libretto, are sung rather than spoken. The singers are accompanied by a musical ensemble ranging from a small instrumental ensemble to a full symphonic orchestra.

1. It is pointed out in the reading that opera ----.
  - A) has developed under the influence of musical theater
  - B) is a drama sung with the accompaniment of an orchestra
  - C) is not a high-budget production
  - D) is often performed in Europe
  - E) is the most complex of all the performing arts
  
2. We can understand from the reading that ----.
  - A) people are captivated more by opera than musical theater
  - B) drama in opera is more important than the music
  - C) orchestras in operas can vary considerably in size
  - D) musical theater relies above all on music
  - E) there is argument over whether the music is important or the words in opera
  
3. It is stated in the reading that ----.
  - A) acting and costumes are secondary to music in musical theater
  - B) many people find musical theater more captivating than opera
  - C) music in musical theater is not as important as it is in opera
  - D) an opera requires a huge orchestra as well as a large choir
  - E) opera doesn't have any properties in common with musical theater.

**Read the following passage and answer the questions given below.**

Dolphins are regarded as the friendliest creatures in the sea and stories of them helping drowning sailors have been common since Roman times. The more we learn about dolphins, the more we realize that their society is more complex than people previously imagined. They look after other dolphins when they are ill, care for pregnant mothers and protect the weakest in the community, as we do. Some scientists have suggested that dolphins have a language but it is much more probable that they communicate with each other without needing words. Could any of these mammals be more intelligent than man? Certainly the most common argument in favor of man's superiority over them that we can kill them more easily than they can kill us is the least satisfactory. On the contrary, the more we discover about these remarkable creatures, the less we appear superior when we destroy them.

1. It is clear from the passage that dolphins ----.
  - A) don't want to be with us as much as we want to be with them
  - B) are proven to be less intelligent than once thought
  - C) have a reputation for being friendly to humans
  - D) are the most powerful creatures that live in the oceans
  - E) are capable of learning a language and communicating with humans
  
2. The fact that the writer of the passage thinks that we can kill dolphins more easily than they can kill us ----.

- A) means that they are better adapted to their environment than we are
- B) shows that dolphins have a very sophisticated form of communication
- C) proves that dolphins are not the most intelligent species at sea
- D) does not mean that we are superior to them
- E) proves that Dolphins have linguistic skills far beyond what we previously thought

3. One can infer from the reading that ----.

- A) dolphins are quite abundant in some areas of the world
- B) communication is the most fascinating aspect of the dolphins
- C) dolphins have skills that no other living creatures have such as the ability to think
- D) it is not usual for dolphins to communicate with each other
- E) dolphins have some social traits that are similar to those of humans.

**Read the following and answer the questions given below.**

Naval architects never claim that a ship is unsinkable, but the sinking of the passenger-and-car ferry Estonia in the Baltic surely should have never have happened. It was well designed and carefully maintained. It carried the proper number of lifeboats. It had been thoroughly inspected the day of its fatal voyage. Yet hours later, the Estonia rolled over and sank in a cold, stormy night. It went down so quickly that most of those on board, caught in their dark, flooding cabins, had no chance to save themselves: Of those who managed to scramble overboard, only 139 survived. The rest died of hypothermia before the rescuers could pluck them from the cold sea. The final death toll amounted to 912 souls. However, there were an unpleasant number of questions about why the Estonia sank and why so many survivors were men in the prime of life, while most of the dead were women, children and the elderly.

1. One can understand from the reading that ----.

- A) the lifesaving equipment did not work well and lifeboats could not be lowered
- B) design faults and incompetent crew contributed to the sinking of the Estonia ferry
- C) 139 people managed to leave the vessel but died in freezing water
- D) naval architects claimed that the Estonia was unsinkable
- E) most victims were trapped inside the boat as they were in their cabins

2. It is clear from the passage that the survivors of the accident ----.

- A) helped one another to overcome the tragedy that had affected them all
- B) were mostly young men but women, children and the elderly stood little chance
- C) helped save hundreds of lives
- D) are still suffering from severe post-traumatic stress disorder
- E) told the investigators nothing about the accident

3. According to the passage, when the Estonia sank, ----.

- A) there were only 139 passengers on board
- B) few of the passengers were asleep
- C) there were enough lifeboats for the number of people on board
- D) faster reaction by the crew could have increased the Estonia's

chances of survival  
E) all the passengers had already moved out into the open decks

**6. Medical report writing.**

You are a staff nurse in the psychiatry ward. Mr. Rammohan aged 40 was admitted in your ward with the complaint of Dengue. Write a report of this to your clinical instructor.

**7. Medical report writing.**

You are a staff nurse in the psychiatry ward. Ms. Lalitha aged 34 was admitted in your ward with the complaint of Alzheimer disorder (memory loss). Write a report of this to your clinical instructor.

**8. Medical report writing.**

You are a staff nurse in the psychiatry ward. Mr. Ranjith aged 50 was admitted in your ward with the complaint of Obsessive compulsive disorder. Write a report of this to your clinical instructor.

**9. Medical report writing.**

You are a staff nurse in the special ward. Mrs. Jaya Priya aged 30 was admitted in your ward with the complaint of Diarrhea. Write a report of this to your clinical instructor.

**10. Medical report writing.**

You are a staff nurse in the psychiatry ward. Mr. Vijay aged 20 was admitted in your ward with the complaint of Anxiety disorder. Write a report of this to your clinical instructor.

11. Write a Comprehensive Report on the outbreak of Covid-19 in your Locality.

12. Write a Comprehensive Report on the outbreak of Malaria in your Locality.

13. Write a Comprehensive Report on the outbreak of Dengue in your Locality.

14. Write a Comprehensive Report on the outbreak of Cholera in your Locality.

15. Write a Comprehensive Report on the outbreak of Pneumonia in your Locality.

**Two Mark Questions**

1. How to make effective reading?
2. What are the types of reading?
3. Why medical report writing is important in your profession?
4. What are the skills you should have for successful Telephone conversation.

## II YEAR

### **Paper -5: Basic of Clinical Pharmacology and Clinical Research**

#### **UNIT - 1: Introduction to Pharmacology**

##### **Essay**

1. Enumerate the routes of drug administration with examples for each. Write the advantages and disadvantages of each route

##### **6 MARKS**

1. Sublingual route of drug administration with example. What are its advantages
2. Transdermal route of drug administration with example. Write two of its advantages
3. Explain parenteral routes of drug administration. Write two advantages and two disadvantages for any one route.
4. What are the factors that govern the choice of route of administration. Explain about local routes

##### **3 MARKS**

1. Give example of a drug given through subcutaneous route. Write one advantage.
2. Give an example for a drug given intra dermally.
3. Write one advantage and disadvantage for rectal route of drug administration with an example.

#### **UNIT - II Pharmacokinetics**

##### **Essay**

1. What is Biotransformation? Give examples of Biotransformation reactions

##### **6 MARKS**

1. Explain the kinetics of elimination
2. Explain volume of distribution. What is the significance of plasma protein binding?
3. Explain passive diffusion and specialized transport
4. What is microsomal enzyme induction and what are its consequences
5. What is microsomal enzyme inhibition and what are its consequences
6. Explain first order and zero order kinetics with examples
7. What is Biological half life ( $t_{1/2}$ ) mention its significance

##### **3 MARKS**

1. What is loading dose
2. What is maintenance dose
3. Two methods to prolong drug action
4. What is plateau principle
5. Give example for first order kinetics
6. Give example for zero order kinetics.
7. What is plasma half life

#### **UNIT - III : Pharmacodynamics**

##### **Essay**

1. Explain the concept of therapeutic drug monitoring. Briefly outline where TDM is required and not required

**6 MARKS**

1. Enzymes as receptors. Explain
2. Describe the role of ion channels as receptors
3. Explain Competitive and non competitive antagonism
4. Write briefly about agonist, antagonist, partial agonist, inverse agonist with examples
5. Explain synergism with examples
6. Explain the various types of antagonism with examples
7. What is potency and efficacy of a drug? Explain it with a diagram

**3 MARKS**

1. What is synergism
2. Give example of physiological antagonism
3. Give example for chemical antagonism
4. What is supra additive effect
5. What is inverse agonist
6. What is partial agonist. Give example
7. Define receptor

**UNIT - IV: Bioavailability and bioequivalence****Essay**

1. What is Bioavailability? Mention its significance. Explain the factors affecting the bioavailability of drugs.

**6 MARKS**

1. Explain the concept of Bioequivalence with examples
2. Study designs in BA/BE studies
3. Sample size calculation in BA/BE studies
4. Outline the regulations for conducting BA/BE studies
5. Outline BA/ BE studies in special situations.
6. Bio analysis in BA/BE studies.

**3 marks**

1. Two factors affecting the bioavailability of drugs
2. Define bio equivalence
3. What is clinical equivalence
4. What is pharmaceutical equivalence
5. What is chemical equivalence

**UNIT - V : Rational therapeutics and Toxicity****6 MARKS**

1. Explain about cumulative toxicity, tachyphylaxis, secondary effect, superinfection, mutagenicity
2. Write in short about Idiosyncrasy with an example
3. What are the general principles in management of toxicity with drugs
4. Performance enhancers in sports
5. Explain substance abuse with its ill effects on health
6. Explain few drug interactions and their beneficial effects
7. Explain few drug interactions and their adverse effects
8. Explain rational prescribing and its benefits
9. Explain irrational prescription and its impact.

10. Write the mechanism of drug interactions
11. Explain hypersensitivity reactions and its management

**3 MARKS**

1. Define teratogenicity with an example
2. Give example for an idiosyncratic reaction
3. What is drug allergy. Give an example
4. What is secondary effect
5. What is toxic effect
6. What is teratogenicity. Give an example
7. What is phototoxicity and what is photo allergy

**UNIT - IV : Introduction and fundamentals of clinical research**

**Essay**

1. Explain in detail about good manufacturing practice (GMP )

**6 MARKS**

1. What are the implications of pharmacoeconomics on health and disease.
2. Write in brief about the types of pharmacoeconomic studies.
3. What are the various methodologies in pharmacoeconomic studies.
4. What are the scope and objectives of pharmacoepidemiology
5. What are the reasons to perform pharmacoepidemiology studies.
6. Mention the epidemiological study designs
7. Explain documentation in GMP

**UNIT -VII : Drug discovery**

**Essay**

1. What are the various phases of clinical trials. Explain each stage in brief.

**6 MARKS**

1. What are the various types of clinical trials
2. Explain phase 0 clinical trials
3. What is post marketing surveillance
4. Explain randomization in clinical trials.
5. Use of placebo in clinical trials
6. Informed consent
7. Types of bias in clinical trials
8. What are the advantages and disadvantages of placebo controlled trials
9. Clinical trials in Indian scenario. What are the pros and cons.
10. Explain some pharmacokinetic drug variations
11. Explain few pharmacodynamic drug variations
12. What is the role of personalized medicine. What are its implications

**3 MARKS**

1. Allocation concealment
2. Types of blinding
3. What is single arm study
4. What is a parallel design study
5. What is placebo

## **UNIT - VIII : Drug development**

### **Essay**

1. What are the steps in new drug discovery process. Explain about preclinical studies
2. What is the constitution of ethical committee. What are its roles and responsibilities in conducting a clinical trial
3. What are the roles and responsibilities of Institutional animal ethics committee in preclinical trials

### **6 MARKS**

1. Preclinical animal studies
2. Euthanasia
3. 4 R in animal studies
4. Unethical clinical trials
5. Cross over design
6. Novel drug delivery systems
7. Patenting and intellectual property in drug development.
8. New drug delivery in cancer chemotherapy

### **3 MARKS**

1. List two placebo
2. Enlist two types of blinding
3. Give two examples of trial designs
4. What is AMES test
5. List two methods of euthanasia
6. List four commonly used laboratory animals
7. What is a screening trial
8. What is quality of life trial
9. What is treatment trial
10. What is prevention trial
11. What is diagnostic trial
12. What is ANDA
13. What is microdosing in clinical trial
14. Name two novel drug delivery system
15. Name two newer insulin delivery system

## **UNIT - IX : Pharmacognosy and pharmacological screening**

### **6 MARKS**

1. Reverse pharmacology and its implications
2. What are the various methods of evaluation of crude drugs
3. Explain toxicity testing in animals
4. Screening of Analgesic drugs
5. Screening of Anti-inflammatory drugs
6. Screening method for hepato-protective drugs
7. Screening method for anti-diabetic drugs
8. Screening method for antiviral drugs
9. Screening method for Anti-cancer drugs
10. Screening for anti-oxidant effects
11. Role of ethnopharmacology and traditional medicines in cure of disease



### **3 MARKS**

1. List few drugs obtained by reverse pharmacology
2. Give two examples of ethnopharmacological studies
3. Define ethnopharmacology

## **Paper 6 : Ethics in clinical research and clinical trial documentation Introduction and Fundamentals**

### **10 Marks**

1. Introduction to Research Ethics. Add a note on the Conflict of Interest in a Clinical Trial and its Ethical Considerations.
2. What is Misconduct in Clinical Trials? What are the principles to be adhered to during the conduct of clinical trial?

### **6 marks**

1. What are the standards of Care in Clinical Research?
2. Brief note on Data Collection, Confidentiality of Clinical Data.
3. What is Compensation in Clinical Trial? When and Who is eligible to receive compensation in clinical trial? Mention the details of Calculation of Compensation in a Clinical Trial related event in the trial participant?

### **3 marks**

1. Define Transparency in Clinical Trial
2. Mention two criteria for Selection of Investigators for a Clinical Trial

## **Principles of Research Ethics**

### **10 Marks**

1. What are the Fundamental principles of Medical Ethics? Explain each principle with a quote of an example.

### **6 marks**

1. Who are vulnerable population in Clinical Research? Mention any 2 incidents involving vulnerable population in the past?
2. Brief note on Application of principles of Medical Ethics to Preclinical Research.
3. Brief note on Application of principles of Medical Ethics to Clinical Research
4. Brief note on Application of principles of Medical Ethics to Post Clinical Aspects in Medical Research
5. What are the Social Responsibilities of the Investigator in initiating a Clinical Research?

## **Ethical Codes**

### **3 marks**

1. What is Declaration of Helsinki? Mention any two principles which came to act after this Declaration.
2. What is Nuremberg Code? Mention any two principles under this Code.
3. What is ICMR Code of Ethics?
4. When was the first ICMR Ethical Guidelines for Biomedical Research enacted? Mention any two changes or modification of Ethical Guidelines done in the recent version of this guidelines .
5. What is CIOMS? When did the latest version of CIOMS guidelines come into act?
6. What are CPCSEA Guidelines? Mention the fundamentals of the CPCSEA guidelines.

## **Institutional Review Board and Informed Consent**

### **10 Marks**

1. What is Ethics Committee? What are the needs for IRB, and the Composition of IRB and the need for IRB in an Educational Institution?
2. What are the types of IRB and the Composition of each type of IRB?
3. Mention the ICMR Risk level Categorization and explain the category of research under each risk level.
4. What are the components of Informed Consent Documentation? Add a note on Legally authorized Representative (LAR). Who is Impartial Witness for Informed Consent Document?

### **3 marks**

1. What is indemnity form for Ethics Committee members?
2. What is Translation Certificate for the Informed Consent Documents?

## **Clinical Trial Application Requirements**

### **10marks**

1. What is Investigational New Drug (IND)? Classify IND? Explain in detail the submission of application for a Clinical Trial related to an IND.
2. What is New Drug Application (NDA)? Mention the contents of the Check list for Submission and Review of New Drug Application.
3. What are the details of FDA Orphan Drug Submission and review Check list?

## **Investigators Brochure**

### **10 Marks**

1. What is Investigators Brochure? What are the Components of the Investigators Brochure? Explain the key concepts of Pharmacokinetics and Product Metabolism in Animals and the Toxicological effects in Humans in Non-clinical studies?
2. Explain the key concepts of Pharmacokinetics and Product Metabolism in Humans and the Marketing Experience of the Investigator in the Clinical Research.

### **3 Marks**

1. Define Safety and Efficacy in Trial Participants in a Clinical Trial. Give one example to each concept.

## **Study Protocol**

### **10 Marks**

1. List the contents of the Trial Protocol.

### **6 Marks**

1. How do we mention in general the details for the withdrawal of the study participants in between the study in a study protocol?
2. Brief note on Inclusion Criteria for the study participants.
3. Brief note on Exclusion Criteria for the Study participants.
4. Brief note on Statistical Analysis of the data and categorization of the data for the statistical analysis in a study protocol
5. Adverse events/Serious Adverse Events in a Study: Occurrence, Monitoring, Compensation and Forms to be submitted during the review process.

### **Informed Consent Form/Assent Form**

#### **6 marks**

1. What is the purpose of research in a vulnerable population? What are the possible risks and benefits and compensation for any untoward events in the vulnerable category?
2. What are the clauses to be mentioned related to the Confidentiality of the details of the study participants in the Informed Consent form?
3. What is Assent Form? Categorize the Assent form and the Witness for the Assent form in the Study Participation.
4. What is Patient Information Sheet (PIS) form? What are the details to be included in them? Who are the Contact persons in the Study in general involving vulnerable and non-vulnerable population?
5. Brief note on Withdrawal of the Consent and Right to new information during the study process.
6. Brief note on Patient visit Diary and its significance.

### **Clinical Study Report**

#### **10 marks**

1. Components of the Clinical Study Report to be submitted after the completion of the study. Mention any five abbreviations commonly used in the Clinical Trial. Design a Flow chart for an investigational plan in the Clinical Trial with an example.
2. What are SOPs? What are the different types and Benefits of SOPs?
3. What are the guidelines for implementation and monitoring of SOPs in a Clinical trial

### **Essential Documents**

#### **10 marks**

1. List the pre-study documents. Explain in detail the Composition of IRB. What are the Components of the Approval letter from the IRB and the necessity of each detail in the IRBs Approval Letter?
2. List the Study Documents. What is Site Monitoring during the Clinical Trial? Mention the Documents reviewed by the Site Monitoring Committee.
3. List the Post Study Documents. Mention the Contents of the Final Clinical Trial Report to be submitted by the Investigator to the Regulatory Authorities?

#### **6 Marks**

1. Brief note on the Contents of Study Completion Documents to be submitted to the Regulatory Authorities. Add a note on the Indian Clinical Trial Regulatory Bodies who monitor a Clinical Trial.
2. Brief note on the Contents of the Study Termination Documents submitted to the Regulatory Authorities.
3. Brief note on the contents of the Study Completion Documents submitted to the Regulatory Authorities.

## PAPER 7: PHARMACOVIGILANCE

### Unit 1: The basis of Pharmacovigilance

#### 3 Marks

1. Define pharmacovigilance
2. Thalidomide tragedy
3. Types of ADRs
4. Severity of ADRs
5. Purpose of Pharmacovigilance
6. Augmented adverse drug reaction
7. Unpredictable adverse drug reaction

#### 6 Marks

1. Legal basis of Pharmacovigilance
2. Needs and objectives of Pharmacovigilance
3. Ethical concern and confidentiality in Pharmacovigilance
4. Non clinical safety evaluation and adverse events in phase trials

#### 10 Marks

1. Discuss in detail about the basis of Pharmacovigilance: History and legal basis of it.

### Unit 2: Fundamentals and Principles of Drug Safety and Toxicology

#### 3 Marks

1. Classification of ADRs
2. De-challenge test
3. Re-challenge test
4. Difference between side effects and toxicity
5. Drug addiction
6. Define Idiosyncrasy
7. Examples for Teratogenecity

#### 6 marks

1. Rawlin - Thompson classification of ADRs
2. Causal - effect Relationship
3. Drug withdrawal errors
4. Drug dependence
5. Quality control procedures in drug safety
6. Drug interactions
7. Bias encountered in drug safety and toxicology

#### 10 marks

1. Explain the fundamentals and principles of drug safety and toxicology

### Unit 3: ADE/ADR

#### 3 Marks

1. Define Adverse drug event
2. Define Adverse effect
3. Define Adverse Drug Reaction
4. Unpredicatable ADR
5. Type A Adverse drug reaction

6. Serious adverse drug event
7. What is Vigiflow
8. Spontaneous reporting
9. SUSAR

**6 Marks**

1. Adverse drug events and medication errors
2. Classification of ADEs according to severity
3. Causality assessment of ADRs
4. ADR monitoring centres
5. ADR reporting methods
6. ADR form in India
7. Vigiflow

**10 marks**

1. Define and classify adverse drug reaction. Add a note on different ADR reporting methods and ADR monitoring centre
2. Classify and Explain with examples a different categories of ADRs

**Unit 4: Risk management and Signal Detection**

**3 Marks**

1. Define CRO
2. Signal detection in Pharmacovigilance
3. Define Clinical Research Organisation
4. Define Signal
5. Post registration safety study
6. Post marketing surveillance

**6 Marks**

1. Data mining in Pharmacovigilance
2. Signal detection methods
3. Crisis management cycle in Pharmacovigilance
4. Methods involved in Post marketing surveillance
5. Statistical methods of evaluating Pharmacovigilance data

**10 Marks**

1. Discuss in detail about the evaluation of Risk Management in Clinical Trials, Confidentiality issues, monitoring strategies. Add a note on statistical methods for Signal Detection.
2. Describe the organisation responsibilities and registration procedure for approval of drug products.

**Unit 5: Surveillance of reaction**

**3 Marks**

1. ADR Surveillance
2. Purpose / need for Surveillance if reaction
3. Administrative databases in surveillance

**6 Marks**

1. Different methods followed for the surveillance of ADR
2. Screening by computer systems to identify signals.
3. Surveillance of reaction through prescription data.

## **Unit 6: Individual Case Safety Report (ICSR) and Periodic Drug Safety Report**

### **3 marks**

1. Define ICSR
2. Define PSUR
3. Define SUSAR
4. CIOMS
5. Medwatch
6. DCGI

### **6 Marks**

1. Quality control and Quality assurance in ICSR
2. PSUR
3. Data base used in ICSR process flow of ICSR
4. Surveillance for medical devices
5. Applications of MedDRA

### **10 marks**

1. Explain in detail about the Database used in ICSR process flow, Safety narrative writing and medical assessment in ICSR. Add a note on PSUR and SUSAR.

## **Unit 7: Pharmacovigilance Programme of India (PvPI)**

### **3 marks**

1. What is PvPI?
2. PvPI mission
3. Objectives of PvPI
4. Committees under NCC
5. Regional centres under PvPI
6. NPP and PvPI

### **6 Marks**

1. Objectives and Goals of PvPI
2. Pharmacovigilance Programme of India
3. Rules and regulations in PVG centre
4. Functions of PVG centre
5. UMC in PVG

### **10 Marks**

1. What is PvPI? Discuss in detail about the Rules and regulations in PVG centre; Functions of PVG centre. Add a note on PvPI.

## III YEAR

### **PAPER 8 CLINICAL TRIALS: DESIGN AND REGULATIONS**

#### **Unit 1**

##### **Short notes**

1. Phases of clinical trials (0, I, II, III, IV)
2. Micro dosing
3. Multicentric trials
4. Post Marketing surveillance
5. PSUR
6. Therapeutic exploratory trials

##### **VSAQ**

1. What is NDA
2. What are the two types of phase 2 trials?

#### **Unit 2**

##### **Essay**

1. Write an essay on the different types of study designs in a clinical trial

##### **Short notes**

2. Placebo
3. Bioavailability & Bioequivalence studies
4. Blinding
5. Bias in clinical research
6. Randomization

##### **VSAQ**

1. Mention any two types of blinding
2. Mention any two types of bias in clinical trials

#### **Unit 3**

##### **Clinical trials operation 1**

1. Explain the role of Sponsor/Principle investigator/contract research organization

##### **Short notes**

1. Mention the role of contract research organization in clinical trial studies
2. Mention the role of IRB in clinical trials

##### **VSAQ**

1. Mention any two responsibilities of investigator
2. Mention any two responsibilities of sponsor
3. Mention any two responsibilities of Site management organization in conducting clinical trials

#### **Unit 4**

1. Write an essay on how to prepare a protocol for a Phase III clinical trial for a new antihypertensive drug

##### **Short notes**

1. Investigator's brochure
2. Informed consent form
3. Prestudy visit
4. Clinical trial agreement

5. Write briefly on the procurement and storage of IP
6. Write briefly about the procedures involved in Trial site monitoring
7. Explain the process involved in safety reporting

## **Unit 5**

### **Essay**

1. Explain briefly the types of audits and the responsibilities of the stakeholders in the audit process.

## **Unit 6**

### **Short Notes**

1. Explain the process involved in registration of a new investigational product with the regulatory body.

## **Unit 7**

### **Short Notes**

1. Write a note on NPPA
2. write the Indian scenario of applying for a patent

## **Unit 8**

### **Short Notes**

1. Explain the functions and responsibilities of CDSCO
2. Explain the latest procedure in reporting a Serious Adverse Event with CDSCO.
3. Write a note in Indian GCP guidelines.

## **Unit 9**

### **Short notes**

1. Clinical trial registration
2. Explain the procedure involved in obtaining a test license/ commercial import license/ manufacture license/ sale license
3. Explain the requirements to conduct BA/BE studies in india
4. Explain the procedure involved in Import/marketing and storage of Narcotics.



## PAPER 9 CLINICAL TRIAL DATA MANAGEMENT AND BIOSTATISTICS

### UNIT - 1: Introduction to clinical data management

#### Essay

1. Clinical data management (CDM) process flow diagram. Roles and responsibility of CDM personnel.
2. Guidelines for designing case record form

#### 6 MARKS

1. Code of ethics for clinical data management professionals
2. Quality assurance for case report forms (CRF), SOPs on CRF design
3. Roles and responsibility of clinical data management personnel

#### 3 MARKS

1. Data cleaning issues
2. Data processing issues
3. Revisions to the case report form

### UNIT - II Data base design and build

#### Essay

1. Quality assurance for database design and standard operating procedures for database design

#### 6 MARKS

1. Responsibilities of data base design
2. Tall skinny format versus short-fat format in database design

#### 3 MARKS

1. High impact fields in data base design
2. Tall skinny format in database design
3. Short-fat format in database design

### UNIT - III : Clinical data management process

#### Essay

1. Explain in detail about the clinical data management process and the setup for electronic data capture systems
2. Write in detail about the data coding and data cleaning.
3. Describe about the various tools for data capture. Explain the advantages and disadvantages of paper versus e-CRFs.

#### 6 MARKS

1. Explain the advantages and disadvantages of paper versus e-CRFs.
2. SOPs for discrepancy management
3. Explain the process of data entry in clinical data management.
4. Setup for electronic data capture systems
5. Dealing with problem data
6. Data coding

#### 3 MARKS

1. Locking studies in clinical data management process
2. COSTART
3. Coding of adverse event data
4. SOPs for study lock

## **UNIT -IV: Clinical data management - infrastructures**

### **Essay**

1. Write in detail about standard operating procedures and its guidelines.
2. What is the role of clinical data management with respect to CROs

### **6 MARKS**

1. SOPs on SOP
2. Clinical data management: infrastructure

### **3 Marks**

1. Standard operating procedure
2. Uses of SOPs
3. Disadvantages of SOPs

## **UNIT - V: Clinical trial management system**

### **Essay**

1. Write in detail about the functions and importance of Clinical trial management system.
2. Write about the regulatory compliance, validation, functions and accounts of contract research organisation using clinical trial management system modules.

### **6 MARKS**

1. Data management software's
2. Clinical trial management system modules
3. Functions of Clinical trial management system

### **3 MARKS**

1. Two important functions of clinical trial management system

## **UNIT - VI : Fundamentals of biostatistics**

### **Essay**

1. Write in detail about sources, types and classification of data. Write about measurement scales
2. Explain in detail about descriptive statistics and its uses.

### **6 MARKS**

1. Types of data
2. Data presentation
3. Measures of central tendency
4. Measures of variation

### **3 MARKS**

1. Mean
2. Mode
3. Median
4. Standard deviation
5. Variance
6. Range
7. Interquartile-range

## **UNIT - VII: Probability and sampling distribution**

### **Essay**

1. What are the types of sample distribution? Explain each with an example and application.

### **6 MARKS**

1. Poisson distribution
2. Binomial distribution
3. Standard error
4. Central limit theorem and its application

### **3 MARKS**

1. Sample space
2. Definition of probability
3. P-value
4. Normal distribution

## **UNIT - VIII: Analysis of efficacy data**

### **Essay**

1. Principles of testing statistical significance. Parametric versus non-parametric tests in statistics
2. Write in detail about sample size calculation and statistical power

### **6 MARKS**

1. Tests for paired and unpaired samples
2. Sample size calculation
3. Principles of testing statistical significance
4. Tests for proportions

### **3 MARKS**

1. List the softwares available for sample size calculation
2. List the values needed for sample size calculation
3. Tests for paired samples
4. Tests for unpaired samples

## **UNIT IX : Correlation and regression**

### **Essay**

1. Explain in detail about correlation and regression analysis of the clinical study data.

### **6 MARKS**

1. Poisson and cox regression
2. Simple versus multiple regression

### **3 MARKS**

1. Briefly explain Correlation
2. Briefly explain Regression
3. Types of correlation
4. Types of regression

## **UNIT - X : Survival analysis**

### **Essay**

1. Explain in detail about survival analysis with special mention about log-rank test.
2. Explain in detail about interim analysis. Briefly describe about sequential design technique.

### **6 MARKS**

1. Equivalence testing and validity of equivalence trials
2. Estimation of survival time by life table method
3. Estimation of survival time by Kaplan Meier method

### **3 MARKS**

1. Hazard rate
2. Types of censoring
3. What is truncation in survival analysis

## **Paper 10 - Basics of medical writing**

### **Essay**

1. Discuss in detail the format of writing a scientific paper

### **6 MARKS**

1. What are the ethics in writing a scientific paper?
2. Discuss the rules of citation in a scientific paper.
3. Team approach to medical writing
4. Structure of medical writing group

### **3 MARKS**

1. Round about phrasing
2. Name two important goals of medical writing
3. What is a case report

### **Unit: 2 - Medico - Clinical trial documents.**

#### **Essay**

1. Write in detail about the IRB/IEC approval documents.

#### **6 Marks**

1. Elements of research protocol
2. Regulatory guidelines for submission & approval of clinical trials.
3. Informed consent form
4. Investigator Brochure
5. CONSORT Statement

#### **3 Marks**

1. Essential items of informed consent form
2. Importance of investigator brochure
3. Advantage of CONSORT statement

**Unit: 3 - Medico - regulatory Documents**

**ESSAY**

1. Preparation and submission of Dossier- CTD and e-CTD for pharmaceutical products.
2. Write in detail regarding biological license applications

**6 MARKS**

1. Investigational new drug application (IND)
2. Safety narrative writing
3. ANDA & SNDA
4. ICH - CTD module 1 - 5
5. Approval process for medical devices in India

**3 Marks**

1. List four medico-regulatory documents
2. Spontaneous reporting
3. PSUR

**Unit: 4- Medico marketing Documents**

**Essay**

1. Write in detail about drug monograph

**6 marks**

1. Components of drug monograph

**3 marks**

1. Leave behind letter
2. Preparation material for continuing medical education programme

**Unit: 5- Publication Documents**

**Essay**

1. Describe the documents prepared for publications

**6 marks**

1. Guidelines for authorship of an article
2. Vancouver reference system
3. Authorship & plagiarism in scientific journals

**3 marks**

1. Types of referencing style.
2. Types of publication document
3. What is a review article?