KAHER

M.Sc in Clinical Research Syllabus

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Pre-amble;

Scope of Clinical Research in India and abroad: India has been involved in clinical research for the past many years and is now on its way to becoming a major hub for it. There is a growing need for clinical researchers in the health industries (pharmaceutical, biotechnology/medical device companies, research institutes, hospitals) involved in the development of new drugs and therapies. This program trains students in conducting The billion dollar industry is already witnessing high demand for qualified professionals. There is a massive need for clinical research professionals in this fast-growing field. Clinical research makes an interesting career option with a great scope for professional growth. To build a career in clinical research, basic education in this field is necessary.

About Clinical Research

A branch of medical science, clinical research is related to the effectiveness and testing of medications, diagnostic products, medical devices and treatment procedures for human use. These can be used for a disease's treatment, prevention, diagnosis or for relief. Clinical research refers to the comprehensive bibliography of biology, drugs, and devices. It is a fast growing discipline in India as the country's large population and lower costs allow multinationals to establish research facilities here.

Career Opportunities:

There is a huge demand for qualified and trained Clinical Research Professionals. Clinical Research as well as pharmaceutical industries are rapidly expanding in India, creating exciting opportunities for trained professionals. During the last 5 years it has increased from Rs. 20 crores to more than Rs. 100 crores. It is expected that Clinical Research industry would require more

than 50,000 jobs in clinical research with the demand increasing steadily. There is always a shortage of trained manpower in India where there are about 500-1000 investigators; while US has 50,000 investigators (Source, FICCI).

It is projected that India will need at least 10,000 investigators to meet the present requirement. With the implementation of product patent regime from 2005, many international pharmaceutical companies and CROs have set up their R&D base in India leading more number of clinical trials and thereby the job opportunities.

Monitors or Clinical Research Associates (CRAs):

CRAs play a very important role in monitoring and overseeing the conduct of Clinical trials in meet international/national guidelines as also national regulatory requirements.

Clinical Research Managers (CRMs). Their role is usually within the clinical or medical departments of a Company or in a Contract Research Organization.

Investigators:

Investigators are the ones who are directly responsible for recruitment and treatment of patients in a Hospital setting and are usually medically qualified personnel.

Site Co-ordinators:

Site Co-ordinators play a role in a hospital setting, by co-ordinating the study with the Chief Investigator.

EMERGING TRENDS IN CLINICAL RESEARCH

Clinical research, a critical component of pharma R&D, ensures a quicker and better return on investment. It also helps organizations deliver better and safer care for patients.

Three promising trends in clinical research present big opportunities for the industry at large:

1. Risk-based monitoring
2. The “Big Data” revolution
3. Applications that improve organizational performance

These trends lead to reduced costs, lower risk and a faster time-to-market

ORDINANCE, SCHEME & SYLLABUS FOR M.Sc in Clinical Research

Course Title: **M.Sc in Clinical Research**.

Type of Course: Two years post-graduate course

Medium of instruction: English

Course Fees: As per University norms

Pattern: Semester wise

Award of the Degree: Degree will be awarded for those passing in all the semesters as per rules and regulations.

3.1 DURATION OF THE COURSE: The duration of the course shall be for two academic years, with each academic year of two semesters. Each semester extends for 6 months duration from the date of commencement of the course.

3.2 Total Intake: 10 Students

3.3 ELIGIBILITYFOR ADMISSION:

3.3.1Candidates wishing to apply for the course need to fulfill the following eligibility criteria:

- Minimum eligibility needed for applying to the course is Graduation completed from a recognized university with a minimum aggregate score of 50% (Aggregate of three/four years for graduate degree holders) (45% for SC/ST/OBC candidates) at the level of graduation
- The successful completion of graduation from a recognized university in any of:

➢ Health sciences [Medicine, Dental, Pharmacy, Nursing, Ayurveda, Homeopathy, Unani etc.]

➢ Life science graduates [biotechnology, botany/zoology, Biochemistry, Pharmacology, Microbiology, Toxicology, etc.]

- Post-graduates in the above disciplines can also apply

3.3.2Selection Procedure:

To maintain high academic standard, university gives due importance to the quality of students enrolled. To ensure this, the selection of individual student will undergo the following procedure:

- Written examination
- Personal interview

3.4Attendance and progress:

3.4.1 A candidate is required to put in **at least 80% attendance** in individual courses considering theory and practical separately**.**

3.4.2 The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

3.5. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, practical classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

3.6. Credit assignment:

3.6.1. Theory and Practical/Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lectures (L) and Practical (P) courses consist of hours spent in the laboratory/Practical assignments. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a **multiplier of one (1) for lecture and a multiplier of half (1/2) for practical (laboratory)/Assignment hours**. Thus, for example, a theory course having four lectures per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory/assignment hours per week throughout semester carries a credit of 1/2. The contact hours of seminars, assignments and research work shall be treated as that of practical courses for the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly, the contact hours of journal club, research work presentations and discussions with the supervisor shall be considered as theory course and multiplied by 1.

Minimum credit requirements:

3.7. Academic work

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club, Discussion with the supervisor, Research work presentation and Dissertation shall be maintained by the department / teaching staff of respective courses.

3.8 ELIGIBILITYFOR APPEARING IN EXAMINATION:

(a) Only such candidates who are approved from the Head of the Academic Institution in proof of his/her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each, shall be eligible for appearing at the M.Sc in Clinical Research examination.

(b) A candidate can have a relaxation of 10% attendance on medical ground by producing a certificate from medical officer of government hospital and a 5% relaxation by the vice-chancellor on request

M.Sc in Clinical Research Course Scheme of Instruction

Table – 1: List of M.Sc Clinical Research subjects and their Code

I Semester Theory

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	MCR-I-1 T	Human Anatomy and Physiology	04	04
2.	MCR-I-2 T	Pathophysiology	04	04
3.	MCR-I-3 T	Pharmacology	04	04
4.	MCR-I-4 T	Communication skills and Business English	02	02
Total			**14**	**14**

I Semester Practical

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	MCR-I-1 P	Human Anatomy and Physiology	06	03
2.	MCR-I-2 P	Pharmacology	06	03
Total			**12**	**06**
Total of theory and practical			**26**	**20**

II Semester Theory

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	MCR-II-1 T	Drug development and Regulations	04	04
2.	MCR-II-2 T	Clinical Research	04	04
3.	MCR-II-3 T	Research Methodology and Applied Biostatistics	04	04
Total			**12**	**12**

II Semester Practical

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	MCR-II-1 P	Drug development and Regulations	06	03
2.	MCR-II-2 P	Clinical Research	06	03
Total			**12**	**06**

Total of theory and practical	**24**	**18**

***Synopsis development**

III Semester Theory

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	**MCR-III-1 T**	Pharmacovigilance and Safety Monitoring	04	04
2.	**MCR-III-2 T**	Pharmacoepidemiology & Pharmacoeconomics	04	04
3.	**MCR-III-3 T**	Seminar – I/Journal club	04	04
Total			**12**	**12**

III Semester Practical

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	**MCR-III-1 P**	Pharmacovigilance and Safety Monitoring	06	03
2.	**MCR-III-2 P**	Pharmacoepidemiology & Pharmacoeconomics(Assignments/ Exercises)	06	03
3.	**MCR-III-3 P**	Research project/Dissertation work	12	06
Total			**24**	**12**
Total of theory and practical			**36**	**24**

IV Semester

Sl. No.	Subject Code	Name of the Subject	Prescribed Hours	Credits
1.	**MCR-IV-1 P**	Seminar – II /Journal club	04	04
2.	**MCR-IV-2 P**	Research project/Dissertation work and submission	32	16
Total			**36**	**20**

Distribution of Hours and Credits for M.Sc in Clinical Research

Sl. No.	Semester	Theory		Practical		Total Hours	Total credits
		Hours	Credits	Hours	Credits		
1.	**I**	14	14	12	06	**26**	**20**
2.	**II**	12	12	12	06	**24**	**18**
3.	**III**	12	12	20	10	**36**	**24**
4.	**IV**	-	-	36	20	**36**	**20**
	Total					**118**	**82**

Scheme of examination

Table – 1: Schemes for internal assessments and end semester examinations

I Semester Theory

Sl. No	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-I-1 T	Human Anatomy and Physiology	20	1 Hr	80	3 Hrs	100
2.	MCR-I-2 T	Pathophysiology	20	1 Hr	80	3 Hrs	100
3.	MCR-I-3 T	Pharmacology	20	1 Hr	80	3 Hrs	100
4.	MCR-I-4 T	Communication skills and Business English	20	1 Hr	80	3 Hrs	100
		Total	**80**		**320**		**400**

I Semester Practical

Sl. No.	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-I-1 P	Human Anatomy and Physiology	20	1 Hr	80	3 Hrs	100
2.	MCR-I-2 P	Pharmacology	20	1 Hr	80	3 Hrs	100
		Total	**40**		**160**		**200**

II Semester Theory

Sl. No.	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-II-1 T	Drug development and Regulations	20	1 Hr	80	3 Hrs	100
2.	MCR-II-2 T	Clinical Research	20	1 Hr	80	3 Hrs	100
3.	MCR-II-3 T	Research Methodology and Applied Biostatistics	20	1 Hr	80	3 Hrs	100
		Total	**60**		**240**		**300**

II Semester Practical

Sl. No.	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-II-1 P	Drug development and Regulations	20	1 Hr	80	3 Hrs	100
2.	MCR-II-2 P	Clinical Research	20	1 Hr	80	3 Hrs	100
		Total	**40**		**160**		**200**

III Semester Theory

Sl. No.	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-III-1T	Pharmacovigilance and Safety Monitoring	20	1 Hr	80	3 Hrs	100
2.	MCR-III-2T	Pharmacoepidemiology & Pharmacoeconomics	20	1 Hr	80	3 Hrs	100
3.	MCR-III-3T	Evaluation Seminar-I (Synopsis of project)	-	-	50	1 Hr	50
Total			**40**		**210**		**250**

III Semester Practical

Sl. No.	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-III-1 P	Pharmacovigilance and Safety Monitoring	20	1 Hr	80	3 Hrs	100
2.	MCR-III-2 P	Pharmacoepidemiology & Pharmacoeconomics (Assignments/Exercises)	50	1 Hr	-	-	-
3.	MCR-III-3 P	Research project	--		--		---
Total			**70**		**80**		**150**

IV Semester

Sl. No.	Subject Code	Name of the Subject	Sessional Exams		End-Semester Exams		Total Marks
			Marks	Duration	Marks	Duration	
1.	MCR-IV-1 P	Evaluation seminar – II	**50**	**1 Hr**	-	-	50
2.	MCR-IV-2 P	Viva-voce & Dissertation Presentation	--		100	3 Hrs	100
Total			50		**100**		**150**

Grand Total Marks: 600 + 500 + 400 + 150 = 1650

Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical sessional examinations is given in the table. The average marks of two sessional exams shall be computed for internal assessment as per the requirements given in tables.

Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in a course of M.Sc. programme if he/she secures at least 50% marks in that particular course including internal assessment.

Carry forward of marks

In case a student fails to secure the minimum 50% in any Theory or Practical course as specified in 12, then he/she shall reappear for the end semester examination of that course. However his/her marks of the Internal Assessment shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

Improvement of internal assessment

A student shall have the opportunity to improve his/her performance only once in the sessional exam component of the internal assessment. The re-conduct of the sessional exam shall be completed before the commencement of next end semester theory examinations.

Re-examination of end semester examinations

Reexamination of end semester examination shall be conducted as per the schedule given in table 3. The exact dates of examinations shall be notified from time to time.

Table – 3: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I and III	November / December	May / June
II and IV	May / June	November / December

Allowed to keep terms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in ATKT rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I and II semesters till the III semester examinations. However, he/she shall not be eligible to attend the courses of IV semester until all the courses of I, II and III semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to IV semesters within the stipulated time period as per the norms.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Such rules are also applicable for those students who fail to register for examination(s) of any course in any semester.

Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in Table – 4.

Table – 4: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter grade	Grade point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

The student who remains absent for any end semester examination, shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtained in all the courses by the student during the semester. For example, if a student takes five courses (Theory/Practical) in a semester with credits C1, C2, C3 and C4 and the student's grade points in these courses are G1, G2, G3 and G4, respectively, and then students' SGPA is equal to:

$$CGPA = \frac{C1S1 + C2S2 + C3S3 + C4S4}{C1 + C2 + C3 + C4}$$

where C1, C2, C3,…. is the total number of credits for semester I,II,III,…. and S1,S2, S3,….is the SGPA of semester I,II,III,…. .

Declaration of class: The class shall be awarded on the basis of CGPA as follows:

- **FIRST CLASS WITH DISTINCTION = CGPA OF. 7.50 AND ABOVE**
- **FIRST CLASS = CGPA OF 6.00 TO 7.49**
- **SECOND CLASS = CGPA OF 5.00 TO 5.99**

Project work

All the students shall undertake a project under the supervision of a teacher in Semester III to IV and submit a report. 4 copies of the project report shall be submitted (typed & bound copy not less than 75 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). The projects shall be evaluated as per the criteria given below.

Internal Evaluation seminar-II marks 50 Marks

Evaluation of Project Presentation:

Final Presentation of work	50 Marks
Communication skills	30 Marks
Question and answer skills	20 Marks

Total: 150 Marks

Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the M.Sc Clinical Research program shall not be eligible for award of ranks. Moreover, the candidates should have completed the M.Sc Clinical Research program in minimum prescribed number of years, (two years) for the award of Ranks.

Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

Revaluation/ Re-totaling of answer papers

There is no provision for revaluation of the answer papers in any examination. However, the candidates can apply for re-totaling by paying prescribed fee.

Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying prescribed fees.

SYLLABUS

SEMESTER: I

MCR-I-1 T: HUMAN ANATOMY AND PHYSIOLOGY THEORY
(75 Hours)
Theory: 3 Hrs/ Week

Scope and Objectives:
This course is designed to impart a fundamental knowledge on the structure and functions of the human body.
It also helps in understanding definition of various terms used in Anatomy and Physiology with brief introduction to disorders of the various body systems.
Objectives: Upon completion of this course the student should be able to
1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.

Detailed syllabus and lecture wise schedule

1. a. Introduction to human body: **12 Hrs**
Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.
b. Structure of cell – its components and their functions.
Elementary tissues: Elementary tissues of the body, i.e. epithelial tissue, muscular tissue, connective tissue and nervous tissue.

2. Skeletal System and joints: **10 Hrs**
Skeletal System: Structure and functions of Skelton.
Classification of joints and their functions, Joint disorders.
Structure of skeletal muscle: Names, positions, attachments and functions of various skeletal muscles. Physiology of neuromuscular junction, physiology of muscle contraction.

3. Cardiovascular System: **12 Hrs**
a) Anatomy and functions of heart

b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation).
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders:
Hypertension, Hypotension, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

4. Respiratory system: **05 Hrs**
a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases

5. Urinary System: **06 Hrs**
Various parts of urinary system and their functions.
structure and functions of kidney.
Physiology of urine formation.
Definition of some disorders of renal diseases and management of edema.

6. Central Nervous System: **10 Hrs**
Anatomy and physiology of various parts of central nervous system.
Brain and its parts, functions and reflex action.
Autonomic nervous system - Anatomy & functions of sympathetic & parasympathetic N.S.

7. Sensory Organs: **05 Hrs**
Elementary knowledge of structure and functions of the organs of taste, smell, ear, eye and skin. Physiology of pain

8. Digestive System: **10 Hrs**
Names of various parts of digestive system and their functions.
Physiology of digestion and absorption. Definition of some disorders of GIT.

9. Endocrine System: **03 Hrs**
Endocrine glands and Hormones. Location of glands, their hormones and functions. Pituitary, Thyroid. Adrenal and Pancreas

10. Reproductive system: Anatomy and physiology of Reproductive system. **02 Hrs**

Books recommended: (Latest editions)

Tortora G.J. and Anagnodokos N.P.; Principles for Anatomy and Physiology; Harper andRow Publishers N.Y.

Goyal R.K.; A Text Book of Experimental Physiology; B.S. Shah Prakashan

Course materials:

Text books

a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.

b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

a.Guyton arthur, C. Physiology of human body. Publisher: Holtsaunders.

b.Chatterjee,C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.

c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H. d. Gray's anatomy. Publisher:Churchill Livingstone, London.

PRACTICALS (50 hours) 3Hrs/week

1**.** List of Experiments:

1. Study of tissues of human body

(a) Epithelial tissue. (b) Muscular tissue.

2. Study of tissues of human body

(a) Connective tissue. (b) Nervous tissue.

3. Study of appliances used in hematological experiments.

4. Determination of W.B.C. count of blood.

5. Determination of R.B.C. count of blood.

6. Determination of differential count of blood.

7. Determination of (a) Erythrocyte Sedimentation Rate. (b) Hemoglobin content of Blood. (c) Bleeding time & Clotting time.

8. Determination of (a) Blood Pressure. (b) Blood group.

9. Study of various systems with the help of charts, models & specimens

(a) Skeleton system appendicular skeleton.

(b) Cardiovascular system.

(c) Respiratory system.

(e) Digestive system.

(f) Urinary system.

(g) Nervous system.

(h) Special senses.

(i) Reproductive system.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune Anderson Experimental Physiology, Latest edition, Publisher: NA

MCR-I-2T: PATHOPHYSIOLOGY (THEORY) (75 Hours)

Theory: 3 Hrs/ Week

1. Scope of the Subject: This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subjects of pharmacy.

2. Objectives of the Subject: Upon completion of the subject student shall be able to –

a. describe the etiology and pathogenesis of the selected disease states;

b. name the signs and symptoms of the diseases; and
c. mention the complications of the diseases.

Text books (Theory)

a. Pathologic basis of disease by- Cotran, Kumar, Robbins
b. Text book of Pathology- Harsh Mohan c. Text book of Pathology- Y.M. Bhinde

Reference books (Theory)

a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

Detailed syllabus and lecture wise schedule

Chapters:

1 Basic principles of cell injury and Adaptation: **12 Hrs**

a) Causes, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage) and morphology of cell injury-Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia)

2 Inflammation: **10 Hrs**

a) Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation
b) Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

3 Diseases of Immunity: **06 Hrs**

a) Introduction to T and B cells
b) MHC proteins or transplantation antigens
c) Immune tolerance -

4 Hypersensitivity: **12 Hrs**

Types, significance, Allergy due to food, chemicals and drugs.
Autoimmunity - Criteria for autoimmunity, mechanism of autoimmunity, Types, Transplantation and immunologic tolerance, mechanism of rejection of allograft.
- Acquired immune deficiency syndrome (AIDS), Amylodosis

5. **Cancer:** etiology and pathogenesis of cancer, differences between benign and malignant tumors, Histological diagnosis of malignancy, classification of tumors, general biology of tumors, metastasis. **07 Hrs**

6. Shock: Types, mechanism, stages and management **03 Hrs**

7. **Pathophysiology of some common diseases** **25 Hrs**

a. Parkinsonism **b.** Schizophrenia **c.** Depression and mania **d.**Hypertension, **e.** Stroke (ischaemic and hemorrhage) **f.** Angina, CCF, Atherosclerosis, Myocardial infarction **g.** Diabetes Mellitus **h.** Peptic ulcer and inflammatory bowel diseases **i.** Cirrhosis and Alcoholic liver diseases

j. Acute and chronic renal failure **k.** Asthma and chronic obstructive airway diseases **l.** Anaemia **m.** Infectious diseases: Meningitis,Typhoid, Leprosy, Hepatitis, Tuberculosis, Urinary tract infections

MCR-I-3T: PHARMACOLOGY – I (THEORY) (75 Hours)
Theory: 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) – a. understand the pharmacological aspects of drugs falling under the above mentioned chapters; b. handle and carry out the animal experiments; c. appreciate the importance of pharmacology subject.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
d. Shargel and Leon.

Text books (Practical):

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b.Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.

Detailed syllabus and lecture wise schedule: Title of the topic

1. General Pharmacology and mechanism of drugs action **12 Hrs**

a) Introduction, definitions and scope of pharmacology
b) Routes of administration of drugs
c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
d) Pharmacodynamics
e) Factors modifying drug effects

Note: The term Pharmacology used here refers to the classification, mechanism of action, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration

2. Pharmacology of drugs acting on ANS **12 Hrs**

a) Adrenergic and antiadrenergic drugs
b) Cholinergic and anticholinergic drugs
c) Neuromuscular blockers
d) Mydriactics and miotics
e) Drugs used in myasthenia gravis
f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system **10 Hrs**

a) Anti-hypertensives
b) Anti-anginal drugs
c) Anti-arrhythmic drugs
d) Drugs used for therapy of Congestive Heart Failure
e) Drugs used for hyperlipidaemias

4. Pharmacology of drugs acting on Central Nervous System **10 Hrs**

a) General and local anesthetics
b) Sedatives and hypnotics
c) Anticonvulsants
d) Analgesic and anti-inflammatory agents
e) Psychotropic drugs

5. Pharmacology of Drugs acting on Respiratory tract **10 Hrs**

a) Bronchodilators
b) Mucolytics
c) Expectorants
d) Antitussives
e) Nasal Decongestants

6. Pharmacology of Hormones and Hormone antagonists **08 Hrs**

a) Thyroid and Anti-thyroid drugs
b) Insulin, Insulin analogues and oral hypoglycemic agents
c) Sex hormones and oral contraceptives

7. **Chemotherapy of microbial diseases**: **12 Hrs**

a) Anti- tubercular agents, Antifungal agents, antiviral drugs, anti-leprotic drugs.
b) Chemotherapy of protozoal diseases, Anthelmintic drugs.
c) Chemotherapy of cancer.

PRACTICAL (50 hours)

3 Hrs. /Week

The first six of the following experiments will be done by the students while the remaining will be demonstrated by the teacher.

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. Effect of potassium and calcium ions, acetylcholine and adrenaline on frog's heart.
6. Effect of acetyl choline on rectus abdomens muscle of frog and guinea pig ileum.
7. Effect of local anaesthetics on rabbit cornea.
8. Effect of mydriatics and miotics on rabbit's eye.
9. To study the action of strychnine on frog.
10. Effect of hypnotics in mice.

MCR-I-4T: Communication skill and Business English (50Hrs/week)
Theory: 2 Hrs. /Week

1. Scope: In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. Objectives: Upon completion of the course, the student shall be able to –
   a. know the business and professional practice management skills in community pharmacies; b. Listening, writing and speaking skills;
   c. Application of the said skills in communicating and providing the community Pharmacy services to patients.

Text Books:

1. Lesiker Raymond.V and Maire E, HatleyBasic Business Communication, New york, Tata McGraw Hill
2. Hamplyons Liz & Ben Heasley , Study writing, Cambridge, Cambridge University Press
3. Beaumont Digty and Colin, Granger, English Grammer, An International reference practice book, London, Heinmann
4. Elison John, The right word at the right time A guide to the English language and how to use it The Reader's Digest
5. Selva Rose, Career English for nurses, Orient Longman Pvt. Ltd.,Hydrabad,

1. Introduction to communication 10 Hrs

a) The communication process
b) Verbal & nonverbal communication
c) Interpersonal communication
d) Relationships & communication
e) Small group communication
f) Public speaking
g) Informative speech presentations
h) Persuasive speech presentations

2.LISTENING SKILLS **10 Hrs**

a) What is listening?
b) Types of Listening
c) Objectives
d) Active Listening- an Effective Listening Skill
e) Note Taking Tips
f) Barriers for Good Listening
g) Purpose of Listening
h) Outlines and Signposting
i) Gambits

3.COMMUNICATION SKILLS- SPEAKING SKILLS **05 Hrs**

a) Definition
b) Barriers of Communication
c) Types of Communication
d) Know What You Want To Say

4.COMMUNICATION SKILLS IN ENGLISH **10 Hrs**

a) The Importance of English
b) English as the First or Second language
c) Uses of English
d) Other Uses of English
e) Importance of Reading
f) Definition of Reading
g) Levels of Reading
h) Requirements of Reading
i) Types of Reading
j) Techniques of Reading
k) Academic Reading Tips
l) Exercise

5. WRITING SKILLS **15 Hrs**

a) What is writing?
b) The Sentence
c) The Phrase
d) Kinds of Sentences
e) Parts of Sentence
f) Parts of Speech
g) Articles
h) Types of Sentences
i) Time Management Tips

j) Test Preparation Tips
k) Tips for Taking Exams
l) What is a Paragraph?
m) Construction of Paragraph
n) Linkage and Cohesion
o) Example
p) Exercise
q) Academic Essay Writing
r) Thesis
s) Procedure for Thesis Approval and Deposit
t) Summary
u) Precise Writing
v) Report Abstracts
w) Letter Writing
x) Memo
y) Cover Letter
z) Resume writing

Semester: II

MCR-II-1T: Drug development and Regulations 75 Hrs/week
Theory: 3 Hrs/Week

1. **Scope of the Subject:**
2. **Objectives of the Subject :**

RECOMMENDED BOOKS: Theory

1.Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone c.

2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes

Reference books:

1. Recent Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2013, 2017.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000, 2014, 2017. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green,March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. SecondEdition, Jan 2000, Wiley Publications

Detailed syllabus and lecture wise schedule

1. Drug development process **10 Hrs**

- Investigational new drug development
- New drug development
- Abbreviated New Drug Development
- 505 b(2) application for drug development-Hatch Waxman Act

2. Clinical drug development phases **10 Hrs**

- Phase 0 studies
- Phase I and subtype studies (single ascending, multiple ascending, dose escalation,methods, food effect studies, drug – drug interaction, PK end points
- Phase II studies (proof of concept or principle studies to establish efficacy)
- Phase III studies (Multi ethnicity, multinational, registration studies)
- Phase IV studies (Post marketing authorization studies; pits and practices?)

Bridging studies and pilot studies
Requirements in clinical research

3. Requirements in clinical research **10 Hrs**

Good clinical practice (ICH GCP E6), Clinical trial materials (Documentation, Investigational drugs, logistical materials)

4.Ethical issues in clinical research **10 Hrs**

- Ethics committees, constitution and practices
- Declaration of Helsinki and Informed consent process
- Liability and indemnity in clinical trials (Insurance and Indemnity: roles and responsibility)
- Misconduct and Fraud in clinical research
- Ethics and clinical trials in special population
- Ethics in clinical research publication; publication policy, Canadian guidelines.

5. Safety Monitoring in Clinical Trials (ICH E2) **10 Hrs**

- Adverse event and serious adverse event reporting in clinical trials; emphasis On SUSARs, managing and reporting of events.

6. Analysis and reporting in clinical trials (ICH E3 and E9) **10 Hrs**

- Statistics in clinical trials
- Clinical study reports – structure and content
- Baseline data, figures and tables presentation in reporting
- Critical appraisal of clinical study report
- Reporting clinical trials in common technical document
- Electronic reporting in clinical trials

7. Regulations Governing Clinical Trials **10 Hrs**

- Clinical Research regulations in India – CDSCO guidelines, ICMR guidelines
- Clinical trial application requirements in India- IND, ANDA, AADA and NDA.
- USFDA regulations to conduct drug studies
- Clinical Research regulations in UK – Medicines and Healthcare Products Regulatory Agency (MHRA)
- Clinical Research regulations in Europe (EMEA).

Practicals:

Suggested List of Practicals: 3Hrs/week

Total: 50 Hrs

1. Introduction to Pharmacoepidemiology
2. Measurement of outcomes in PE
3. Concept of Risk in PE
4. Drug Utilization Review
5. Spontaneous Reporting System
6. Prescription event Monitoring
7. Record Linkage system
8. Introduction to Pharmacoeconomics
9. Pharmacoeconomics Evaluation
10. Applications of Pharmacoeonomics

MCR-II-2 T: Clinical Research **75 Hrs/week**

Theory: 3 Hrs. /Week

1. **Scope of the Subject:**

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives of the study: Upon completion of this course it is expected that students shall be able to:

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

RECOMMENDED BOOKS: Theory

1.Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone c.

2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes

Reference books:

1. Recent Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2013,2017.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000, 2014, 2017. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications

Detailed syllabus and lecture wise schedule

1. Historical Perspectives: **06 Hrs**

- Nuremberg Code Study,
- The Belmont Report
- The declaration of Helsinki
- Origin and Principles of International Conference on Harmonization - GoodClinical Practice (ICH-GCP) guidelines

2. Informed Consent Process: **06 Hrs**

- Ethical principles governing informed consent process
- Structure and content of a Patient Information Sheet
- Structure and content of an Informed Consent Form
- The process of taking informed consent and documentation

3. Types and Designs used in Clinical Research: **08 Hrs**

Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification),Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)

4. Clinical Trial Study team: **06 Hrs**

Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization, Site management Organizations.

5. Clinical trial Documents: **08 Hrs**

Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Dairy Cards

6. Clinical Trial Start up activities: 06 Hrs

Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission, Site initiation visit,

02 Hrs

7. Investigational Product: Procurement and Storage of investigation product

8. Preparation and conduct of monitoring visit: 10 Hrs

Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up **Close-Out visit:** Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

9. Quality Assurance and Quality Control in Clinical Trials: 05 Hrs

Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management

10. Clinical Data Management 06 Hrs

Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: 12 Hrs

Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Central lab, IVRS, source data.

Data cleaning, managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing

Practicals:

Suggested List of Practical: Total: 50 Hrs 3Hrs/week

3. To prepare and submit **Informed Consent Process (ICF) for the following population 15 Hrs**

- Geriatric Patients

- Paediatric patients
- Psychiatric patients
- Unconscious patients

4. To prepare and submit dummy **patient information sheet** (PIS) **for the below mentioned population** **15 Hrs**
   - Geriatric Patients
   - Paediatric patients
   - Psychiatric patients
   - Unconscious patients
5. To prepare and submit the **standard operating procedures(SOP)** for procurement and storage filing of Investigational product**(IP)** **10 Hrs**
6. To prepare and submit **e-CRF**(Electronic Case Report Form) for dummy clinical data **10 Hrs**

MCR-II-3 T: Research Methodology & Applied Biostatistics **75 Hrs/week?**

Theory: 3 Hrs. /Week

1. **Scope of the Subject:**

2. Objectives of the study:

RECOMMENDED BOOKS: Theory

4. Clinical Epidemiology, Brian Haynes, David L Sackett, 3rd edition, Lippincott publications

5. Quantitative Methods for Health Research, Nigel bruce, Daniel Pope, John Wiley and Sons,Ltd

1 **Research Methodology**

a) Types of clinical study designs: Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study

Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 **Applied Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Construction and labeling of graphs, histogram, piecharts, scatter plots, semi algorithmic plots.

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean. Incidence and prevalence, relative risk, attributable risk

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) **Basics of statistical softwares:** SPSS, Epi Info, SAS

SEMESTER: III

MCR-III-1 T:

Pharmacoepidemiology and Pharmacoeconomics

Theory: 3 Hrs/Week

1. **Scope of the Subject:**This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes.
2. **Objectives of the Subject :**Upon completion of this course it is expected that students shall be able to:

- Understand the various epidemiological methods and their applications understand the fundamental principles of Pharmacoeconomics.
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

RECOMMENDED BOOKS: Theory

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.

2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.

3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
5. Graker, Dennis. Pharmacoeconomics and outcomes.
6. Walley, Pharmacoeconomics.
7. Relevant review articles from recent medical and pharmaceutical literature

1. **Pharmacoepidemiology:** **45 Hrs**

a.Definition and scope: Origin and evaluation of Pharmacoepidemiology, need for pharmacoepidemiology, aims and applications.

b.Measurement of outcomes in Pharmacoepidemiology: Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

c.Concept of risk in pharmacoepidemiology: Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

d.Pharmacoepidemiological methods:

Includes theoretical aspects and practical study of various methods: case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

e.Sources of data for Pharmacoepidemiological studies:

Ad Hoc data sources and automated data systems.

Selected special applications of Pharmacoepidemiology: Studies of vaccine safety, hospital pharmacoepidemiology

2. Phrmacoeconomics: **25 Hrs**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation: Outcome assessment and types of evaluation Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics **05 Hrs**

Software and case studies

Suggested List of Practical AssignmentsAssignment: Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

1. Assignments on Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio with the help of examples (Two)
2. Assignments on study of various Pharmacoepidemiological with the help of case studies for individual methods (Four)
3. Assignments on various Pharmacoeconomic outcome analysis with the help of case studies for individual methods (Four)

Cost – minimization, cost- benefit, cost – effectiveness, cost utility methods 4. Assignments on Special applications of the softwares used

MCR-III-2 T: Pharmacovigilance and Safety Monitoring
Theory: 3 Hrs/Week
Scope of the Subject:
RECOMMENDED BOOKS: Theory

1.Pharmacovigilance: **20 Hrs**

Introduction to Pharmacovigilance and safety monitoring
a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
c. Reporting, evaluation, monitoring, preventing & management of ADRs
d. Global and IndianPharmacovigilance System

2.Pre-Marketing Methodologies in Pharmacovigilance **15 Hrs**

Post-Marketing Methodologies in Pharmacovigilance
Sources and Documentation of Individual Case Safety Reports (ICSRs)
Medical dictionary (MedDRA) and Medical aspects in Pharmacovigilance
Medical Information System
Special cases in Pharmacovigilance
Standard operating procedures in Pharmacovigilance

3.Safety Monitoring in Clinical Trials: **13 Hrs**

Pharmacovigilance Database And Signal Detection Tools
Risk –benefit assessment and management in PharmacovigilanceCompliance monitoring and Pharmacovigilance inspections
Ethics Committee – Schedule Y

4. Pharmacovigilance communications **10 Hrs**

Case triage
Case entry
Case processing

5. Global regulatory requirements and guidelines in Pharmacovigilance **10 Hrs**

Regulatory submissions (E2b, MHRA, FDA)
Periodic Safety Update Reports (PSUR,s) For Marketed Drugs (ICH E2C)
Schedule Y - ICMR

Practicals:

Suggested List of Practicals: 50Hrs **3Hrs/week**

1. To assess causality for the given case of ADR (Adverse Drug Reaction) and submit using the appropriate scale **12 Hrs**
1. To assess Probability for the given dummy case of ADR (Adverse Drug Reaction) and submit using the appropriate scale **12 Hrs**
2. To assess **and submit** Severity for the given dummy case of ADR **10 Hrs**
3. To prepare **and submit** the Reporting of SAE(Using the appropriate forms) **10 Hrs**
4. To prepare and **submit SOP(Standard Operating Procedures)** for **ADR reporting** **06 Hrs**