Baba Farid University of Health Sciences

Ordinances & Syllabus

M.Sc. Clinical Research
(2 Years Degree Programme)

Faridkot -151203

Ordinances
M.Sc. Clinical Research

1. Duration of Course:

Duration of Master of Science in Clinical Research shall be of two years.

2. Eligibility for admission

a) This course shall be open to a candidate who have passed B. Pharmacy/MBBS/BDS/BAMS/B.Sc.(Nursing) or equivalent examination from a Statutory Institution/University.

OR

b) Any other examination recognized by the Board of Management of this University as an equivalent course / examination thereto, from time to time.

3. Medium of Instructions

The medium of instruction during the course and examinations shall be English.

4. Examination Schedule:

4.1 The examination shall be held twice a year in the months of May/June and November/December or on such other dates as may be decided by the Board of Management on the recommendation of Faculty of Medical Sciences and Academic Council.

4.2 Normally, the University shall conduct not more than two examinations in a year, for any subject, with an interval of not less than four and not more than six months between the two examinations.

4.3 The last date by which examination forms and fee must reach the Controller of Examinations/Registrar shall be as follows : -

Examinations	without late fee	with late fee of Rs.200/-	with late fee of Rs.500/-	with late fee of Rs.1500/-
May/June	March 1	March 15	March 31	April 15
Nov./Dec.	Sept. 15	Sept. 30	Oct. 15	Oct. 31

Note: Vice-Chancellor may permit acceptance of examination form and fee ten days before the commencement of examination with a late fee of Rs.2000/-. The fee structure is revisable by the University from time to time.

5. **First year M.Sc. Clinical Research**

a) The First Year M.Sc. Clinical Research shall be open to a person who has been enrolled for one academic year preceding the examination in a Colleges/Institutions affiliated to this University.

b) submitted his/her name to the Controller of Examination/Registrar by the Head of the Research Centre/Institution/College with the following certificates:-

i) of having attended separately in theory and practical/clinical not less than 75% percent of the lectures delivered and practicals conducted in each of the subjects prescribed for the examination provided that deficiency in the number of lectures delivered and practicals conducted may be condoned by the Head of the Research Centre/Institution/College to the extent of 10% of the lectures delivered.

ii) of having secured at least 35% marks of the total marks fixed for internal assessment in each subject, separately, in order to be eligible to appear in all University examinations.

iii) of good moral character.

Note: 1) Internal Assessment shall be submitted to the University at least two weeks before the commencement of theory examinations or within one week from the issuance of Roll Numbers by the University. All the colleges shall adopt uniform criteria for Internal Assessment as follows:-

a) Attendance above 90% to be acknowledged with 10% extra weightage for Internal Assessment.

b) At least two tests to be held in each year in addition to the pre-final (send up) examination. The Internal Assessment should be the average of all awards of these tests taken together.

c) **Criteria for calculation of Internal Assessment**

ii)	House Examinations	- 80%
iii)	Attendance (above 90%)	- 10%
iv)	Subject assessment (candidate's conduct and extra curricular participation)	- 10%

d) Additional mandatory requirement for Internal Assessment to be observed by all colleges.

i) All test marks obtained by candidates will be displayed on Notice Boards of respective departments as and when they are awarded.

ii) All computations of Internal Assessment of the entire class made by the HOD of the department shall be displayed on the notice board of the department showing individual test marks, advantage of all tests, attendance advantage and subjective assessment and the total Internal Assessment thus derived for at least one week before sending the awards to the Principal's office.

iii) Professor Incharge/HOD preparing Internal Assessment shall certify that the detailed assessment of the entire class has been

displayed on the department Notice Board for at least one week prior to its being submitted for onward transmission to the University and that adequate opportunity has been given to all the students to file any objections and that the same have been addressed satisfactory.

iv) The Principal forwarding the Internal Assessment to the University shall countersign the above referred certificate of the HOD/Professor Incharge preparing the Internal Assessment.

e) The re-appear/fail students will be re-assessed every time for the purpose of Internal Assessment.

2) If a candidate fulfils the condition laid down in clause 5 (b) (i), (ii) and (iii) above for one or more subject (s) he/ she may be allowed to take the examination in such subject (s) in which he/ she fulfils the requirements.

3) Every candidate before appearing in Second Year Examination must have cleared House Examination securing at least 50 percent marks in both theory as well as practical separately.

c) The First Year M.Sc. Clinical Research shall be held in the by the University in the following subjects:-

Subject Code/Paper	Paper	Max. Marks		Total
		Theory	Internal Assessment	
MSCCR-01/ Paper - I	Patent, Intellectual property rights, Research Methodology and Biostatistics	80	20	100
MSCCR-02/ Paper - II	Basics of Clinical Research	80	20	100
MSCCR-03/ Paper – III	Pharmacokinetics, Bio-availability and Bio-equivalence (BA/BE) studies	80	20	100
MSCCR-04/ Paper – IV	Clinical trials: Design and regulations	80	20	100
MSCCR-05/ Paper – V	Methods in Biological Evaluation of Drugs, Pharmaco-vigilance and Pharmaco-epidemiology	80	20	100
MSCCR-06/ Paper – VI	Herbal Formulation Development Technology	80	20	100
MSCCR-07/ Paper - VII	Skill Development*	80	20	100

***Note:** There shall be no University examination for the subjects of Skill Development. Examination will be conducted at College level and marks will be sent to University for final inclusion in the result.

i) Each theory paper shall be of three hours duration.

ii) The minimum number of marks to pass the examination shall be 50% in theory including Internal Assessment in each subject separately.

iii) The candidate who will absent himself/herself from the examination will be deemed to have been failed in the examination.

iv) A candidate who passes in one or more subjects shall be exempted from appearing in these subject at a subsequent examination, but the candidate must pass the examination in a maximum of four attempts, failing which he/ she will not be allowed to continue his studies.

v) A candidate who fails in more than three subjects will not be promoted to second year class.

vi) A candidate, who fails in three subjects maximum in his/her 1st attempt, shall be permitted to attend classes in Second Year M.Sc. Clinical Research. However, he/she will be allowed to appear in Second Year M.Sc. Clinical Research Viva-Voce examination only after passing all the subjects of First Year M.Sc. Clinical Research.

6. **The Second Year M.Sc. Clinical Research shall be open to a person**

a) who has been enrolled for two academic year preceding the examination in a Colleges/Institutions affiliated to this University.

b) submitted his/her name to the Controller of Examination/Registrar by the Head of the Research Centre/Institution/College with the following certificates:-

i) of having attended research work not less than 75% percent, which may be condoned by the Head of the Research Centre/Institution/College to the extent of 10% of the attendance.

ii) of having secured at least 50% marks of the total marks fixed for internal assessment, in order to be eligible to appear in the Second Year MSc. Clinical Research examinations.

iii) of good moral character.

iv) Must have submitted thesis on following guidelines:-

a) Every candidate shall submit a thesis plan to the University within one month from the declaration of result of First Year examination.
b) Every candidate shall carry out work on an approved research project under the guidance of a recognized PG Teacher, the results of which shall be written up and submitted in the form of a thesis by the candidate.
c) Thesis shall be submitted to the University through Head of the Research Centre/College/Institution two months before completion of second year.
d) The Vice-Chancellor may allow a candidate to submit the thesis within one month after the date fixed for the purpose with the prescribed late fee.
e) The thesis shall embody the results of the candidate's own research and/or experience and shall contain precise reference to the publications quoted, and must attain a good standard and shall be satisfactory in literary presentation

and in other respects and should end with a summary embodying conclusions arrived at by the candidate. The thesis shall be typewritten on one side of the paper (size 11" x 8 ½") with margins of 1½" on each side, bound, indicating on the outside cover its title and the name of the candidate.

f) vi) The thesis shall be examined by a minimum of two examiners, one internal and one external examiner. Normally the Viva-voce examination will be conducted by the same examiner who has evaluated the Thesis. However, in exceptional circumstances another examiner may be called for this purpose. The candidates who have submitted the thesis in University will be allowed to appear in the Viva-Voce examination. However, the result shall be declared only on receipt of the thesis acceptance from both the examiners.

g) The internal examiner shall send only report to the University after evaluation of thesis and the evaluated copy will be deposited in the college library for reference of the students. The external examiner shall also send copy of the thesis along with the report to the University. The University shall keep two copies in the University Library for reference of the students.

Note: If a candidate fulfils the condition laid down in clause 6 (a) & (b) above may be allowed to take the Second Year MSc. Clinical Research examination.

7. The Viva-voce in the Second Year MSc. Clinical Research Examination shall be held in May/June and the supplementary within six months of the Annual Examination, as under:-

Subject Code/Paper	Subject	Marks			
		Marks in Thesis	Internal Assessment/ Journal Club	Marks for Viva-voice	Total
MSCCR-08/ Paper - 8	Project Work/Thesis/ Dissertation	300	100	200	600

i) The minimum number of marks to pass the examination shall be 50% in Thesis, Internal Assessment/Journal Club and Viva-voce separately.

ii) The candidate who will absent himself/herself from the examination will be deemed to have been failed in the examination.

iii) The candidate who has completed two years course and has failed in the Thesis/Viva-voce examination may appear again in a subsequent examination. However, a candidate who fails to pass the MSc. Clinical Research within a period of four years of his/her admission shall not be allowed to continue his/her studies.

8) Number of Examinations

The examination shall be conducted twice a year in May/June and November/December or on such dates as determined by the University from time to time.

9) Grace Marks:

There shall be no provision for grace marks.

10. Board of Examiners

i) There shall be four examiners – two internal and two external.

ii) Professor & Head of the Department shall be the Convener and first examiner. The second Internal Examiner will be appointed by annual rotation from amongst the Professors/Associate Professors/Assistant Professor who fulfills the criteria of PG teacher. In case of non-availability of Professors/Associate Professors/Assistant Professor in the department the teacher who fulfils the minimum requirements to be an examiner may be appointed as Internal Examiner.

iii) The examiners shall be appointed by the University from the teachers working in the Medical Colleges affiliated to it, preferably from the colleges where this course is being run, on the recommendations of the Board of Studies in Medical Sciences and Faculty of Medical Sciences.

11. Paper setting and moderation of Question Papers:

The University may get each paper set from External Examiner only. The moderation of question papers may be got done under the directions of the Vice-Chancellor, if necessary.

12. Evaluation of Answer Books:

The answer books shall be got evaluated by putting fictitious roll numbers thereon or spot evaluation (table marking) or any other method under the directions of the Vice-Chancellor.

13. Declaration of Result and minimum pass marks:

A candidate shall be declared successful only when his thesis has been accepted and the candidate has obtained a minimum of 50% marks in Thesis, Internal Assessment and Viva-voce separately.

A successful candidate on the basis of theory and Thesis/Viva-voce marks taken together shall be classified as under: -

Second Class : A candidate obtaining 50% or more marks but less than 60% marks
First Class : A candidate obtaining 60% or more marks
First Class with Distinction : A candidate obtaining 80% or more marks

14. Award of Degree

Each successful candidate shall be awarded a degree of M.Sc. Clinical Research.

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SYLLABUS

M.SC CLINICAL RESEARCH

Instructions to Paper Setter

Note: 1) The question paper covering the entire course shall be divided into two sections. Each section to be attempted in a separate answer book and to be evaluated by separate examiners.

2) In each section there shall be 8 questions of 5 marks each and total weight-age being 40 marks

Section A **(Max. marks 40)**

Section B **(Max. marks 40)**

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR – 01, Paper – I
Patent, Intellectual property rights, Research Methodology and Biostatistics

UNIT-I: The Indian Patents Act 1970 and Indian patents (Amendments) Act 2005 and issue related to Patents, Importance, parts of patent, type of patent, provisional application, Oppositions, Patent infringement, Patent search engines

UNIT-II: Introduction to INTELLECTUAL PROPERTY RIGHTS (IPR) and patent OVERVIEW OF INTELLECTUAL PROPERTY, meaning of Intellectual Property?, types of intellectual creations COPYRIGHT Introduction, Area covered by copyright, types of rights covered by copyright, economic rights, moral rights, need of protection of copyright RELATED RIGHTS Introduction, distinction between related rights and copyright , the rights granted to the beneficiaries of related rights, need for protection of related rights? TRADEMARKS Introduction, kind of signs used as trademarks, types of trademark, function of a trademark, protecting trademark, protection provided by a trademark, GEOGRAPHICAL INDICATIONS Introduction, difference between a geographical indication and a trademark, protecting geographical indication, need for protection of geographical indications INDUSTRIAL DESIGNS Introduction, protecting industrial designs, protection provided by industrial designs, territorial restrictions to industrial design protection, need for protection of industrial designs?

UNIT III: PATENTS What is a patent?, kind of inventions protected by patent, protecting inventions, granting process of a patent, rights provided by patent, patent protection. UNFAIR COMPETITION Unfair competition, relationship between unfair competition and intellectual property laws ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS Infringement of intellectual property rights, Enforcement Measures, EMERGING ISSUES IN INTELLECTUAL PROPERTY, Protection of biotechnological inventions, traditional knowledge, the issue of genetic resources related to IP

UNIT-IV: Brief introduction of: Paris conventional, World Trade Organization, WIPO and GATT, US Patent System and European Patent System

UNIT-V: Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research, Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey. Selecting a problem and preparing Research proposals

UNIT-VI: The Research Report Paper writing/ thesis writing.

UNIT-VII: Biostatistics in clinical trials: Introduction, Probability, Regression, Biostatistics and Various statistical methods i.e. null hypothesis, t- Test, Regression analysis, ANOVA, Chi-square etc Parametric and Non-parametric tests

UNIT- VIII: Optimization Techniques- Design of experiments, Factorial designs Grid search technique, Response surface methodology, contour plots, etc.

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR -02, PAPER - II
Basics of Clinical Research

Unit I: Introduction to Drug Discovery and drug Development, Basic pharmacology and clinical research : Basic conceptual knowledge about receptors, drugs, preclinical studies, pharmacodynamic, pharmacokinetic (ADME), drug interactions, clinical research, Introduction to pharmacoeconomics.

Unit II: Clinical trials-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.

-Introduction and designing
-Various phases of clinical trials
-Post Marketing surveillance – methods
-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

Unit III: Pre clinical toxicology: General principles, Systemic toxicology (Single dose and repeat dose toxicity studies), Carcinogenicity, Mutagenicity, Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity, animal toxicity requirements.

Unit IV: Basic terminology used in clinical research: Types of clinical trials, single blinding, double blinding, 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

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR -03, PAPER - III
Pharmacokinetics, Bio-availability and Bio-equivalence (BA/BE) studies

Unit I: Clinical Pharmacokinetics: Introduction to clinical pharmacokinetics, Steady-state pharmacokinetic. Linear and non-linear pharmacokinetics. Absorption: Definition, Mechanism of absorption, Factors influencing the absorption. Distribution: Definition, Binding of drugs, Physiological barriers, Drug disposition, Factors affecting the distribution. Metabolism: Definition, Phase-I and Phase-II metabolism with examples. Excretion: Definition, Clearance, Renal clearance, Hepatic clearance, Factors affecting the excretion of drugs.

Unit II: Drug Interactions: Definition, Epidemiology, Mechanism of drug interactions, Drugfood interactions. Adverse Drug Reaction: Epidemiology, Definition and Classification, Predisposing factors, Types of ADRs and their mechanism, Detection and Monitoring of ADR, Identification of ADR. Therapeutic Drug Monitoring : Introduction, When and why TDM is required? Necessity of the TDM, Indications for TDM, Protocol for TDM, TDM of selected drugs used in the following disease conditions: cardiovascular disease, CNS conditions etc.

Unit-III: Bioavailability studies: Introduction, Defination, objectives, factors affecting bioavailability, types: absolute vs relative, single vs multiple dose studies, healthy voluntiers vs patient studies, measurement of bioavailability, drug dissolution rate and Bioavailability, invitro-invivo correlation, methods for enhancement of bioavailability

Unit-IV: Bioequivalence: Introduction, Defination, Bases for Determining Bioequivalence Design and Evaluation of Bioequivalence Studies Analytical Methods, Reference Standard, Extended-Release Formulations, Combination Drug Products,Study. Designs: Fasting Study, Food Intervention Study, Multiple-Dose (Steady-State) Study Crossover Designs, Replicated Crossover Design, Evaluation of the Data, Pharmacokinetic Evaluation of the Data, Statistical Evaluation of the Data, Analysis of Variance (ANOVA), Two One-Sided Tests Procedure, Example Bioequivalence, Study Submission and Drug Review Process, Waivers of In-Vivo Bioequivalence Studies (Biowaivers) Dissolution Profile Comparison, The Biopharmaceutics Classification System (BCS), Solubility, Permeability, Dissolution, Drug Products for Which Bioavailability or Bioequivalence May Be Self-Evident, Generic Biologics, Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution, Approved Drug Products with Therapeutic Equivalence Evaluations

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR -04, PAPER - IV
Clinical trials: Design and regulations

Unit I: Types of clinical trials

Unit II: Design and organization of phase-I, phase-II, phase-III, phase-IV trials

Unit III: Various regulatory requirements in clinical trials, Schedule Y, ICMR guidelines etc.
Documents in clinical study
Investigator Brochure (IB), Protocol & Amendment in Protocol , Case Report Form (CRF), Informed Consent Form (ICF) , Content of Clinical Trial Report
Essential Documents in Clinical Trial
Good Clinical Practice: ICH guidelines
Indian GCP guidelines (CDCSO guidelines)
ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y

Unit IV: Study of various clinical trials (completed or ongoing)
Clinical Trial Application in India
Import & Export of Drug in India
Investigational New Drug application (IND)
Abbreviated New Drug Application (ANDA)
New Drug Application (NDA)

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR -05, PAPER - V
Methods in Biological Evaluation of Drugs, Pharmacovigilance and Pharmacoepidemiology

Unit-I: Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies.

Biological evaluation of drugs--Screening and evaluation (including principles of screening, development of models for diseases : In vivo models / In vitro models / cell line study) techniques of the following:

1. Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
2. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.

Unit –II: Drugs used in Peptic Ulcer, Respiratory disorders, and Endocrine disorders. Anti fertility agents and diuretics.

Unit-III: Pharmacovigilance: Scope, definition and aims of pharmacovigilance Adverse drug reactions – Classification, mechanism, predisposing factors and causality assessment. Role of clinical pharmacist in Reporting, evaluation, monitoring, prevention and management of ADR, Adverse drug reaction reporting and monitoring, Drug induced diseases

Unit-IV: Pharmacoepidemiology: Definations: epidemiology, Disease distribution, disease determination, disease frequency, Aims of epidemiology, Difference between epidemiology and clinical medicines, Epidemiological approach, Measurements in epidemiology, (rates, ratios, and proportions)

Measurement of mortality: international death certificate, limitations and use of mortality data, mortality rates and ratios, crude death rates, specific death rates, case fatality ratio, proportional mortality ratio, survival rate, standardize rates, direct standardization, indirect standardization,

Measurement of morbidity: Incidence, Prevalence, uses of prevalence, relationship between incidence and prevalence,

Epidemiological methods: Descriptive epidemiology:

Time distributions: Short term fluctuations: Types of Epidemics- single exposure/point source exposure epidemics, continuous exposure epidemics, propagated epidemics, slow epidemics, Periodic fluctuations, Long term fluctuations

Place Distributions: International variance, National variance, Rural-Urban variations, Local distributions, Person distributions.

Analytical epidemiology: Case control study: Selection of cases, selection of controls, matching, measurements of exposure, analysis, odds ratio, bias in case control study., advantages, disadvantages and some examples of case control study

Cohort study: Concept, framework, prospective and retrospective cohort study, combination of prospective and retrospective cohort study, elements of cohort study, relative risk, attributable risk, advantages, disadvantages and examples of cohort study.

Experimental epidemiology: Randomized controlled trials: Protocol, selecting reference and populations, randomization, manipulation, follo-ups, assessment, study designs in randomized trials like parallel and cross over study, Types of randomized controlled trials: clinical trial, preventive trials, risk factor trials, cessational trials, trial of aeitiological agents

Non-randomized trials: uncontrolled trials, natural experiments, before and after comparison studies

Ethical principles in pre-clinical studies and clinical trials, History, its Principles

Roles & Responsibility of various clinical trial personnel as per ICH GCP and ICMR guidelines like Sponsor, Investigator, Monitor, Auditors.

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR -06, PAPER - VI
Herbal Formulation Development Technology

Unit I:

Methods of Preparation of Extracts: Principles of extraction and selection of suitable extraction method. Different methods of extraction including maceration, percolation, hot continuous extraction, pilot scale extraction, microwave method and supercritical fluid extraction with their merits and demerits. Purification and Recovery of Solvents.

Standardization of Herbal Raw materials and Extracts: Standardization of herbal raw materials including Pharmacognostical, physical, chemical and biological methods with examples. Standardization of herbal extracts, physical, chemical and spectral analysis. Qualitative and Quantitative estimation of active principles from standardized extracts by HPTLC. Biological standardization -Pharmacological screening of herbal extracts and Microbiological evaluation of herbal extracts. Toxicology studies of herbal extracts.

Unit II:

Chromatographic separation techniques: Chromatographic techniques used in qualitative and quantitative study of phytochemicals. TLC, column chromatography, Flash chromatography, HPLC, and solid phase extraction. Their principles, operation, and application to the plant derived products.

Non-chromatographic separation techniques: Chemical derivatisation-based separation methods, fractional crystallization, centrifugation, Froth-floatation technique.

Unit III:

Evaluation of Drugs: Concept, considerations, parameters and methods of quality control for medicinal plant materials as per various pharmacopoeia and other guidelines. Preparation of monograph of crude drug. Comparative study of IP, European Pharmacopoeia, BP / Ayurvedic Pharmacopoeia of India / Ayurvedic formulary of India and WHO guidelines.

Unit IV:

Herbal drug standardization: Fundamentals and comparative account of multi-component, multi-target phytotherapy and single-molecule, single-target concept of modern medicine. Conventional methods used in herbal drug standardization and their limitations. Sources of variation in chemical make-up of plant derived drugs: genotypic, ecotypic and biotypic variations and variations resulting during processing and storage. System biology approach for quality control of herbal drugs, DNA micro-array technique.

Analysis of Ayurvedic Formulations and crude drugs with references to: Identity, purity and quality of crude drugs. Determination of pesticide residues, determination of arsenic and heavy metals, determination of microorganisms, determination of microbial load in crude drugs. Identification of aflatoxins in crude drugs. Quality assurance in herbal drug industry, concept of GMP and ISO-9000.

Formulation development and quality assurance of herbal drugs: Difficulties in development of herbal formulations and possible remedies to overcome these problems. Formulation of dried extracts, solid and liquid dosage forms and their quality control using physical parameters. Stabilization and stability of herbal formulations, preservation of liquid formulations. Applications of Novel drug delivery systems for phytochemicals. Quality assurance in breeding, cultivation, harvesting, post harvesting, processing and storing of medicinal plants.

Unit V:

Nutraceuticals and Cosmeceutical: Concept of nutritional requirements at different age, sex and in different conditions like normal, diseases, pregnancy etc. Different types of additives used. Herbs used in cosmetics

Unit VI: Ethno medicinal documentation of medicinal plants to be useful for preparation of herbal formulation to cure the ailments in human beings. Traditional approach of herbal formulation and its scientific exploration. Recent trends in poly-herbal medicines. Global regulatory status of herbal drugs. Clinical study of plant derived medicine.

SYLLABUS

FIRST YEAR

M.SC CLINICAL RESEARCH

MSCCR -07, PAPER - VII
Skill Development

1.	Hospital training (Clinical skills)	(20)
2.	Tutorial assessment (Group discussion skills)	(20)
3.	Journal Club assessment (Analysis skills)	(20)
4.	Seminar presentation (Teaching skills)	(20)
5.	Attendance in Conference/ Seminar/Workshop/ Training/Symposium (Interactive skills)	(20)

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Subject: Copy of paras of the Minutes of the 45th meeting of the Board of Management held on 14.10.2016 at 02:30 pm in the Committee Room, State Institute of Health & Family Welfare Complex, SAS Nagar (Mohali)

~~14.~~ 19. Considered the recommendations of the Academic Council made in its 25th meeting held on 30.08.2016 vide para-15 and after some discussion it was **RESOLVED**: To approve that Guide: Student Ratio for PG Paramedical Courses i.e. M.Sc./ Master in Hospital & Healthcare Administration (MHHA), etc. will be 1:3 under the Faculty of Medical Sciences. It was informed by Vice-Chancellor that the recommendations are within the prerogative of the University and no approval is required from the Central Council/body(s).