REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

POST GRADUATE COURSE IN PHARMACY

PHARMACEUTICS

Course code:276

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1 Title of course:

Master of Pharmacy in Pharmaceutics

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Postgraduate, and Doctoral).

2.3 Medium of instruction:

Medium of instruction shall be in English

2.4 Course outline

a) M.Pharm Part – I course of study consists of two subjects namely *one compulsory* and *one optional*

course of study for each branch have been divided into *one compulsory* subject and *three specialization* subjects. The *compulsory subject* consist of two subjects papers – a theory paper and a practical paper.

The *specialization subject* consists of three theory paper (Paper I, Paper II, Paper III) with one practical paper for each respective theory paper.

b) M.Pharm Part – II course of study consists of a thesis written on the basis of regular research work durig the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M.Pharm Part – II course and has satisfactorily conducted the two seminars during the period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary.

The candidate shall be eligible to submit their thesis only after passing M.Pharm Part – I examination.

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All M.Pharm Part –II students have to present two seminars relevant to their subject specialization including recent advances before submission of thesis.

2.5 Duration

Duration of the course:

a) The duration of the M.Pharm course shall be of two academic years full time with each academic year spread over a period of not less than 365 working days.
b) The study of M. Pharm course shall be of annual system, which includes M.Pharm (Part-I) extending for 12 months from the commencement of the academic term and M.Pharm (Part-II) of another 12 months duration.
c) At the end of M.Pharm (Part-I) there shall be a university examination of M.Pharm (Part-I). At the end of M.Pharm (Part-II) the candidate shall submit a dissertation on the topic approved by the university.

2.6 Syllabus

As given under "Content of each subject in each year" (clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7 Total number of hours

As in "Content of each subject in each year"(clause 2.10)

2.8 Branches if any, with definition:

As in "Content of each subject in each year"(clause 2.10)

2.9 Teaching-Learning method:

As in "Content of each subject in each year"(clause 2.10)

2.10 Content of each subject in each year

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS

(Compulsory to all branches of M. Pharm course)

THEORY 75hrs [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY 5hrs

Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and colour relationship. The chromophore concept, absorption laws and limitations.

Woodward –Fischer rules for calculating absorption maxima. Modern instrumentation - design and working principle. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

2. INFRA RED SPECTROSCOPY 5hrs

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy. Recent advances in IR spectroscopy, including FT-IR, ATR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY 10hrs

Fundamental principles of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to the interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13} NMR. Nuclear overhauser effect, C^{13} NMR spectra, their presentation, characteristics, interpretation examples and applications.

4. MASS SPECTROSCOPY 12hrs

Basic principles and brief outline of instrumentation, Ionisation types: Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Hyphenation of MS with other analytical instruments (LC-MS, GC-MS) and applications in Pharmacy.

5. CHROMATOGRAPHIC TECHNIQUES 9hrs

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY 4hrs

Instrumentation, packed open tubular columns, Column efficiency parameters, resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY **4hrs**

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative and microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection, and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY **3hrs**

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS **3hrs**

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER **2hrs**

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STATISTICAL ANALYSIS **10hrs**

Introduction, significance of statistical methods, normal distribution, probability, Degree of freedom, standard deviation, correlation, variance, accuracy, precision, Classification of errors, reliability of results, confidence interval, Test for statistical Significance; students T-TEST, F-test, Chi-square test, correlation and regression.

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation
2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.

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7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

BRANCH-D- PHARMACEUTICS MPH.D-I

(PAPER- I) FORMULATION TECHNOLOGY

Theory (3hrs/wk) (75 hrs)

1. Formulation, Design, manufacturing and quality control of solid dosage forms- Tablets and Capsules
2. Formulation of parenteral products - Formulation and manufacture of small volume and large volume parenterals, containers and their evaluation.
3. Controlled release drug delivery system Concept, drug properties relevant to controlled release- formulation, mechanism, microencapsulation, oral. *In-vitro-in-vivo* correlation.
4. Controlled drug delivery modules
    a. Insulin pump, elementary osmotic pump system a few examples GIT – Floating Drug delivery and Mucoadhesive systems, modules for GIT, implants, IUD system.
    b. Transdermal drug delivery system, Nasal drug delivery systems
5. Colloidal drug delivery system – microemulsion, Liposomes, Nano particles. Formulation, evaluation and their applications. Gene delivery and protein drug delivery.
6. Drug Targeting – concept, different approaches – use of physical, chemical and biological methods.
7. Pharmaceutical Inhalation Aerosols – Targeting to lungs – chemical and biochemical consideration, mechanism, Design and development of inhalation drug delivery systems
8. Chemistry of antigens, vaccines-production, standardization and storage. Modern vaccine technologies. Monoclonal antibody based pharmaceuticals. Interferons and Interleukins
9. Biotechnology products – detailed study of production of Humulin, Humatrop, activase , Hepatitis –B Vaccine, proteases and other biotechnology products. Storage and handling of biotechnology products.

MPH.D-II (PAPER- II) BIOPHARMACEUTICS AND PHARMACOKINETICS

Theory (3hrs/week)

1. Overview of fundamental principles in biopharmaceutics and pharmacokinetics. Biopharmaceutical classification system.
2. Compartment models – one compartment open, multi compartment open, nonlinear kinetics – multiple dosing, physiological models, loading and maintenance dose, dosing time interval. Wagner-Nelson and Loo-Reigelman methods. Mean residence Time.
3. Effects of rate determining parameters on controlled release of drugs. Polymer solubility, solution solubility, partition coefficient, polymer diffusivity, thickness of hydrodynamic diffusion layer, Drug loading dose, surface area.
4. Clinical Pharmacokinetics-Applications of Pharmacokinetic data in dose adjustment and individualization of therapy. An overview of the software relevant to pharmacokinetic studies
5. Bio-availability studies – bioavailability of single dose and multiple dose administrations, comparative bioavailability studies and analysis.
6. Biopharmaceutics of injectable medications; physico chemical and physiological factors affecting drug absorption, application of pharmacokinetics to biopharmaceutic investigations, pharmacokinetic models.
7. Preformulation studies – introduction, organoleptic properties, Particle size, particle shape, surface area, solubility dissolution, parameters affecting absorption, Stability. Polymorphism – crystal properties
8. Gene expression and recombinant DNA technology, Gene therapy. - -an overview

MPH. D-III (PAPER- III) INDUSTRIAL PHARMACY

(Theory 3hrs/week)

1. Characterisation of raw materials. Excipient compatibility.
2. Polymer science and application – Introduction and definitions, types of polymers, Pharmaceutical applications, polymers as thickening agents, viscosity, solvent selection, fabrication technologies.
3. Optimization techniques in Pharmaceutics, formulation and processing – Optimization parameters
4. Stability of drugs, effect of temp, humidity, light and pH, stability studies stability loss, overage and shelf life – design for short term and long term stability studies of dosage forms, statistical considerations.
5. Production Management and Documentation: Documentation – relevance and importance, statutory requirement and procedure for documentation, Schedule U, critical examination of documents. ISO 9000 series, Label control. Intellectual Property Rights. Total quality management and productivity, guide to pharmaceutical manufacturing facilities, materials management and cost control.
6. Regulatory requirements as per ICH, WHO and FDA guidelines. Schedule Y.
7. Patent laws, NDA & ANDA- general considerations, specific requirements, content and format.
8. cGMP : definition, Schedule M, cGMP in manufacturing, processing, packaging and holding of drugs, control of components, containers and closures, production and process controls, packaging and labelling controls, premises, design, construction, maintenance, equipment, warehousing.
9. Pilot Plant Scale Up Techniques: Significance of pilot plant scaleup phase from laboratory procedures to routine production procedures. Discussion on important parameters such as formula and equipment, product uniformity and stability. Raw materials and process, physical layouts, personnel requirements and reporting responsibilities.
10. Industrial Safety: Industrial hazards due to fire, accidents, mechanical and electrical equipments, chemical and pharmaceuticals. Monitoring and prevention systems (safety measures).
11. Pharmaceutical process validation- regulatory basis for process validation, prospective process validation, retrospective validation, validation of solid dosage forms, Transdermal process validation
12. Fermentation Technology– Design & Operation of Industrial fermentor– Development of industrial micro-organisms. Advances in Screening, batch culture, continuous

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culture and kinetics, precursors, inducers, repressors. Manufacture of pharmaceutical products by fermentation- antibiotics, vitamins, Industrial alcohol, citric acid, lactic acid.

PRACTICALS--- BRANCH (PHARMACEUTICS)

MPH. D-IV

PHARMACEUTICS PRACTICALS

(12 hrs/wk)

a) Formulation Technology:

1. Study of effect of various new type of binding agents on the properties of tablets
2. Formulation and evaluation of semi-solid dosage forms using different bases
3. Formulation and comparative evaluation of coated and uncoated tablets (marketed) of various categories. Similarity factor.
4. Protocol preparation for
    a) Liquid antacid preparation.
    b) Multivitamin tablet/capsule
    c) Skin ointments / creams.
    d) Injection containing antibiotics.
    e) Sustained release preparations
5. Preparation of albumin microspheres and their particles size characterization
6. Preparation of matrix tablets using various polymers and studying their release pattern.
7. Preparation and evaluation of microcapsules by different microencapsulation techniques
8. Preparation and evaluation of wax embedded microspheres
9. Preparation and evaluation of Reservoir type devices (eg.) PEG Ethylcellulose in chloroform/dichloromethane as the coating material
10. Validation of sterilization procedures
11. Evaluation of disinfectants
12. Evaluation of Antibiotics

b) Biopharmaceutics and Pharmacokinetics:

1. Study on the diffusion of drugs through various polymer membranes.
2. Preparation and study on the *in-vitro* dissolution of various sustained action products and comparison with marketed products.
3. Preparation of various polymer films, containing different drugs and studying the film characteristics and release patterns.
4. Study of *in-vitro* one compartment and two compartment models.

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5. The diffusion study of drugs using natural/artificial membranes and various diffusion media.
6. Study of Transdermal delivery of drugs from various dosage forms and use of absorption enhancers.
7. Determination of pharmacokinetic parameters using given data of plasma level-urine level time profile. Wagner-Nelson, Loo Reigelmann methods, MRT, Loading and Maintenance doses, dosing interval.
8. Study of effects of parameters on controlled release of drugs.
9. Study of IVIVC.
10. Characterisation of polymers- Solubility, Acidity/Alkalinity, loss on drying, UV/Visible spectroscopy

c) Industrial Pharmacy:

1. Accelerated stability studies on formulations and drugs with respect to temperature, moisture & light.
2. Determination of rate and order of decomposition of drugs like aspirin, vitamins.
3. Evaluation of packaging materials like glass, plastic and rubber
4. Study on characterization of raw materials flow and consolidation properties, True density, Bulk density, compressibility, particle size, surface area.
5. Fermentation studies

2.11. No: of hours per subject

As given under "Content of each subject in each year "(clause 2.10)

2.12. Practical training

As given under "Content of each subject in each year " (clause 2.10)

2.13. Records

To be maintained for all Practical Work

2.14. Dissertation:

Standard format of dissertation

a) Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized guide. The results of such a work shall be submitted in the form of a dissertation.

b) Synopsis shall be forwarded to University, for information within 3 months from the starting of 2nd year.

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c) The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results
6. Discussion
7. Conclusion
8. Summary
9. References
10. Tables
11. Annexure

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed conventional (Times New Roman) font, size 12-point, 10 to 12characters per inch must be used with 1.5 line spacing on one side of the bond paper (A4size, 8.27" x 11.69") All margins should be consistently 25mm in width and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of M. Pharm Part II term.

Change of dissertation topic / guide – rules

The decision regarding change of title/guide shall be taken as per the Institute research committee recommendations and the same can be intimated to the University.

2.15. Speciality training, if any

As per "Teaching, learning methods " and "Content of each subject in each year " above.

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2.16. Project work to be done if any

Thesis

1. Every candidate shall carry out work on an assigned research project under the guidance of a recognised Postgraduate Teacher, the result of which shall be written up and submitted in the form of a Thesis.

2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least one month before the examination.

3. The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

2.17. Any other requirements [CME, Paper Publishing etc.]

As per the instruction of HoD of concerned Department

2.18. Prescribed/recommended textbooks for each subject

Compulsory subject

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.
3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Textbook of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

Specialized subjects

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann...

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2. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
3. Physical Pharmacy; By Alfred martin
4. Bentley's Textbook of Pharmaceutics – Rawbins.
5. . Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
6. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
7. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
8. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
9. Applied production and operations management; By Evans, Anderson, Sweeney and Williams
10. Remington's Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.
11. Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc
12. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
13. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.
14. Biopharmaceutics; By Swarbrick.
15. Biopharmaceutics and Pharmacokinetics- A Treatise; By D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.
16. Clinical Pharmacokinetics, Concepts and Applications; By Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.
17. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
18. Controlled and Novel Drug Delivery; By N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
19. Controlled Drug Delivery - Concepts and Advances; By S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002
20. Pharmaceutical Dosage forms, disperse system: Volume 1, By Herbert A.Libermann et.al, Marcel Dekker, Inc.
21. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.
22. Bentley's Textbook of Pharmaceutics; By E.A.Rawlins, ELBS Publications.
23. General Microbiology:R.Y.Stainer.
24. Essentials and applications of microbiology: Judy Kandal
25. Microbiology:Pelczar,Reid and Chan
26. Genetics of Antibiotic producing Microorganisms: G.Sermonti
27. Topley & Wilson:Volumes I to IV
28. Genes V and VI: Lewin Benjamin
29. Virology: Fields
30. Immunology: Weir

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31. The Actinomycetes: Waksman S

2.19 Reference books

1. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
2. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann
3. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann
4. Modern Pharmaceutics; By Gillbert and S. Banker
5. Remington's Pharmaceutical Sciences
6. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
7. Novel Controlled Drug Delivery - Fundamentals and Applications, 2nd edition; By Joseph R.Robinson and Vincent H.L.Lee
8. drug delivery system; By Y.w.Chien, Marcel Dekker, Inc. .
9. Microencapsulation and Related Drug Process; By Patric B. Daisy
10. Pharmaceutical Preformulations; By J.J. Wells
11. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
12. Dissolution, Bioavailability and Bioequivalence; By Abdou.H.M., Mack Publishing Company, Pennsylvania, 1989.
13. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.
14. Encyclopedia of controlled delivery; By Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester / Weinheim
15. Immunology: Ivan Roitt, Johnathan Bronstoff, David Male .
16. Microbial Genetics:David Freifelder
17. Animal cell culture: Ian Frshney .
18. Medical Microbiology: Mackie and McCartney.

2.20. Journals

All Pharmacy and related medical Journals

2.21. Logbook

Registers to be maintained

3. EXAMINATIONS

3.1. Eligibility to appear for exams

a. Attendance, conduct and condonation option:

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M. Pharm Part I examination.

No condonation of attendance is permitted.

b. Internal assessment

Candidates obtaining minimum of 50% marks separately in both theory and practical shall be eligible for appearing in University examination

3.2. Schedule of Regular/Supplementary exams

There will be two examinations one regular and one supplementary in an academic year. The supplementary examinations shall be conducted within 6 months after declaration of results.

3.3. Scheme of examination showing maximum marks and minimum marks

University Examination:

M. Pharm Part I Examination:-

I. Theory:

There shall be 4 theory papers (including compulsory paper) each of 3 hours duration each carrying 100marks.

II. Practical:

There shall be practical examination for the compulsory subject (MCS-II) of 6 hours duration including viva voce. The marks for the practical examination are out of 100, which are distributed as follows:

Distribution of marks for Compulsory subject (MCS-II) practical examination

Synopsis	20
One Major Experiment	40
One Minor Experiment	25
Basic Spectral Analysis	15
Total	100
Viva Voce	25

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The practical examination of the 3 different papers in the specialization subject are to be conducted separately. Duration of the practical examination for the three different papers together is 3×6 hrs = 18hrs, including Viva-voce. Viva voce is also conducted separately for the three papers in specialization subject. The marks distribution is as follows in each paper.

Distribution of marks for specialization subject practical examination

Synopsis	20
Experiment/s	80
Total	100
Viva-voce	25

Distribution of marks and hours for theory and practical examination

Subject	Theory				Practical					Total
	Duration	Exam	Sessional	Total	Duration	Exam	Sessional	Viva-voce	Total	
Compulsory subject										
Modern Analytical and Research Methods	3hrs	100	50	150	6hrs*	100	25	25	150	300
Specialization subjects										
Paper I	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper II	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper III	3hrs	100	50	150	6hrs*	100	25	25	150	300
Total										**1200**

*** including viva voce**

Scheme of evaluation

Evaluation system for M. Pharm Part I is Centralized Double valuation by examiners from outside University and within University. The averages of marks of the two examinations are taken as the mark of the theory paper. If the variation in total marks obtained in two valuations is more than 15%, the paper should undergo a third valuation, and the average of aggregate of the nearest two will be counted. M.

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Pharm Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

No re-evaluation is permitted, only re-totaling can be allowed on request by the candidate.

Criteria for pass & Re- appearance in case of failure

I. M. Pharm Part I Examination:-

i. For passing the university examination, a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination individually and overall aggregate of 50% marks, including Sessional marks in each theory paper and in the case of practical examination including viva-voce and Sessional marks.

ii. If a candidate fails in any of the theory papers or practical papers in the examination of compulsory subject or in the specialization subject, he/she has to appear again in the compulsory subject or in that paper/s of the specialization subjects including the theory and practical as the case may be.

II. M. Pharm Part II Examination:-

(A) Submission of thesis and Distribution of marks:

a. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M. Pharm Part -2 course. The candidate shall be eligible to submit their thesis only after passing M. Pharm Part-1 examination.

b. Any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year, after discussion in Institutional research committee.

c. The dissertation should be submitted one month in advance to the II year M. Pharm examinations duly signed by the respective guide and the same has to be forwarded to the Controller of Examinations through the Principal of the College.

M. Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Four copies of the thesis duly certified by the supervising teacher shall be submitted to the University one month before by the candidate either in printed or typewritten form through the Head of the institution before the last date prescribed by the University.

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The distributions of marks for evaluation of M. Pharm part II dissertation work is as follows:

M. Pharm part II examination is of total marks 500, which has been divided into as shown in the table

Distribution of marks for M. Pharm part II examination

Thesis	300
Oral	100
Seminar	100
Total	500

(B) Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University within an examination center. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with duration of about 30 minutes, which is followed by a viva voce.

(C) Evaluation of thesis and criteria for pass

Any candidate who secures less than 50% of the total marks, he/she has to reappear based on the evaluation report of the examiners, before maximum duration of course (four years)

3.4 Papers in each year:

S.No.	Code. No	Title
Compulsory Subject		
1.	MCS-I	Modern Analytical and Research Methods
BRANCH D: PHARMACEUTICS		
2.	MPH.D-I	Formulation Technology
3.	MPH.D-II	Biopharmaceutics and Pharmacokinetics
4.	MPH.D-III	Industrial Pharmacy

3.5 Details of theory exams

There shall be 4 theory papers (including compulsory paper) each of three hours duration each carrying 100 marks

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3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

Modern Analytical and Research Methods (Common for all branches)

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. What are the principles of spin-spin decoupling and describe any three methods. Discuss the factors affecting chemical shift with suitable examples.

2. Explain the principle and instrumentation of gas chromatography. Derive the Beer-Lamberts law and explain its deviations.

Short Essays: **(6 X 10 = 60)**

3. Explain the principle, instrumentation and sample handling techniques in infrared spectroscopy.

4. Discuss the principle and Instrumentation of atomic absorption spectroscopy.

5. Explain the principle involved in assay of riboflavin, thiamine and quinine by fluorimetry. Mention the transitions involved in fluorescence.

6. Explain briefly about resolution in mass spectrophotometer and MC-Lafferty rearrangement.

7. Compare TLC & HPTLC on the basis of its principle and mention its pharmaceutical applications.

8. Explain briefly about Miller's indices. How will you calculate mean, median, mode and students T-test.

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QP Code: **Reg No: ……**

First Year M. Pharm Degree Examinations– September 2014 (2011Scheme)

(Pharmaceutics)

Paper I – Formulation Technology

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1. Define microencapsulation. Mention its advantages and disadvantages. Explain in details of conservation phase separation process.

2. Discuss formulation and manufacturing of parentral implants and its limitations. Add a note on its pharmaceutical applications.

Short Essays: **(6x10=60)**

3. Explain the different types of granulation process. Mention the types of equipments used for compression.

4. Explain the benefits and limitation of transdermal drug delivery systems. Add a note on their formulation.

5. Explain the use of liposome as drug delivery system with examples of drug and its evaluation.

6. Discuss the production of human insulin by recombinant technology.

7. Explain the standardization and storage of biological products.

8. Discuss the mechanism of buccal absorptions. Mention the examples of drug that can be delivered by mucosal drug delivery system.

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QP Code: **Reg No: ……**

First Year M. Pharm Degree Examinations– September 2014 (2011 Scheme)

(Pharmaceutics)

Paper II – Biopharmaceutics and Pharmacokinetics

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1. Explain flip-flop model. What are the various methods for estimation of absorption rate stant. Explain the method of residuals.

2. Discuss and compare the various approaches available for the pharmacokinetic analysis of experimental data following intravenous infusion in one compartment model.

Short Essays: **(6x10=60)**

3 .Explain Wagner-Nelson method. Mention its merits and demerits.

4. What is capacity limited kinetics. Explain the causes of non-linearity. Discuss the application of Michaelis- menton equation in non-linearity.

5. Discuss the methods used to assess the bioavailability of dosage form.

6. Serum concentrations of a new antibiotic after oral administration in a capsule dosage form are given below. Calculate MRT and Half life of the capsule

Time in hrs	0.102	0.303	0.5		1.5					
Conc mg/ml	0.05	0.29	0.59	2.3	3.5	5.9	5.5	1.1	0.11	0.42

7. Describe the process of renal excretion of drugs and the factors influencing it. Add a note on adjustment of doses in renal impairment.
8. Elaborate the production of hepatitis B vaccine using r-DNA technology.

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QP Code: **Reg No: ……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

(Pharmaceutics)

Paper III – Industrial Pharmacy

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1. Explain stability studies for tablets. What do you mean by short-term and long-term stability studies. Add a note on over ages

2. What are polymers. Classify polymers with important pharmaceutical applications

Short Essays: **(6x10=60)**

3. Explain ISO 9000 series for quality system

4. Discuss the monitoring and prevention of fire and electrical hazards

5. Explain the pilot plant scale up studies of solid dosage forms

6. Describe pharmaceutical process validation in detail

7. Explain the production of streptomycin by fermentation

8. Describe briefly intellectual property rights and patents

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3.7 Internal assessment component

Sessional Examination:

I. Theory:

The Sessional marks for the compulsory subjects and for each specialization subjects are 50; out of which 40 marks are awarded for Sessional examination.10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, confidence in the topic and defense performances.

There shall be minimum 3 Sessional examinations in each of the three papers of specialization M. Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be two evaluation seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

Marks distribution for compulsory and specialization subjects in Theory

Theory	Marks
Written examination	40
Seminar	10
Total	50

II. Practical:

Compulsory subject:

The Sessional marks for the compulsory subject are 25, of which 20 are awarded for daily assessment and 5 marks for practical Sessional examination.

Specialization subjects:

The marks for practical in each paper of the specialization subject are 25. 20 marks are awarded for daily assessment in each paper and 5 marks are awarded for the Sessional practical examination conducted towards the end of the academic year.

Marks distribution for compulsory and specialization subjects in Practical

Practical	Marks
Practical Examination	05
Daily assessment	20
Total	25

The daily assessment is done on the basis of followingcriteria. -Assembly of equipments

- Use of instruments -Manipulative skills -Precision and Accuracy -Cleanliness

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- Interpretation of data and results
- Preparation of protocols, case presentation, case study analysis
- Record maintenance
  (Whichever applies)

3.8 Details of practical/clinical practical exams

Each practical paper shall be of 6 hours duration carrying 100 marks each.

Practical examination shall be conducted to test the knowledge and competence of the candidates for making valid and relevant observations based on the experimental/Laboratory studies and his ability to perform such studies as are relevant to his subject.

3.9 Number of examiners needed (Internal & External) and their qualifications

A post graduate (PG) degree in M. Pharm shall be eligible as teacher.

A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.

A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.

A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

3.10 Details of Viva: Division of marks

M. Pharm Part I Examination

The Oral examination shall be thorough and shall aim at assessing the candidates knowledge and competence about the subject, investigative procedures, technique and other aspects of the speciality, which form a part of the examination.

The Oral examination marks: 25 marks

M. Pharm Part II Examination

Thesis:

The Oral examination marks: 100 marks

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4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

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REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

POST GRADUATE COURSE IN

PHARMACEUTICAL CHEMISTRY

Course Code: 277

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1 Title of course:

Master of Pharmacy in Pharmaceutical Chemistry

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Postgraduate, and Doctoral).

2.3 Medium of instruction:

Medium of instruction shall be in English

2.4 Course outline

a) M.Pharm Part – I course of study consists of two subjects namely *one compulsory* and *one optional*

course of study for each branch have been divided into *one compulsory* subject and *three specialization* subjects. The *compulsory subject* consist of two subjects papers – a theory paper and a practical paper.

The *specialization subject* consists of three theory paper (Paper I, Paper II, Paper III) with one practical paper for each respective theory paper.

b) M.Pharm Part – II course of study consists of a thesis written on the basis of regular research work durig the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M.Pharm Part – II course and has satisfactorily conducted the two seminars during the period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary.

The candidate shall be eligible to submit their thesis only after passing M.Pharm Part – I examination.

All M.Pharm Part –II students have to present two seminars relevant to their subject specialization including recent advances before submission of thesis.

2.5 Duration

Duration of the course:

a) The duration of the M.Pharm course shall be of two academic years full time with each academic year spread over a period of not less than 365 working days.

b) The study of M. Pharm course shall be of annual system, which includes M.Pharm (Part-I) extending for 12 months from the commencement of the academic term and M.Pharm (Part-II) of another 12 months duration.

c) At the end of M.Pharm (Part-I) there shall be a university examination of M.Pharm (Part-I). At the end of M.Pharm (Part-II) the candidate shall submit a dissertation on the topic approved by the university.

2.6 Syllabus

As given under "Content of each subject in each year" (clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7 Total number of hours

As in "Content of each subject in each year"(clause 2.10)

2.8 Branches if any, with definition:

As in "Content of each subject in each year"(clause 2.10)

2.9 Teaching-Learning method:

As in "Content of each subject in each year"(clause 2.10)

2.10 Content of each subject in each year

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS

(Compulsory to all branches of M. Pharm course)

THEORY 75hrs [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY 5hrs

Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and colour relationship. The chromophore concept, absorption laws and limitations.

Woodward –Fischer rules for calculating absorption maxima. Modern instrumentation - design and working principle. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

2. INFRA RED SPECTROSCOPY **5hrs**

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy. Recent advances in IR spectroscopy, including FT-IR, ATR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY **10hrs**

Fundamental principles of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to the interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13} NMR. Nuclear overhauser effect, C^{13} NMR spectra, their presentation, characteristics, interpretation examples and applications.

4. MASS SPECTROSCOPY **12hrs**

Basic principles and brief outline of instrumentation, Ionisation types: Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Hyphenation of MS with other analytical instruments (LC-MS, GC-MS) and applications in Pharmacy.

5. CHROMATOGRAPHIC TECHNIQUES **9hrs**

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY **4hrs**

Instrumentation, packed open tubular columns, Column efficiency parameters, resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY **4hrs**

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative and microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection,

and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY 3hrs

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS 3hrs

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER 2hrs

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STATISTICAL ANALYSIS 10hrs

Introduction, significance of statistical methods, normal distribution, probability, Degree of freedom, standard deviation, correlation, variance, accuracy, precision, Classification of errors, reliability of results, confidence interval, Test for statistical Significance; students T-TEST, F-test, Chi-square test, correlation and regression.

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation
2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.
7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

MPH. B-I (Paper-I)

ADVANCED MEDICINAL CHEMISTRY

Max 75hrs (3hrs/week)

A: DRUG DESIGN (max 40hrs)

1. Introduction to drug design and discovery. Conventional methods of drug design: Lead, discovery of lead, lead optimization, pharmacophoric identification and Analog design: Bioisosterism in drug design, rigid analogs, alteration in chain length, branching, ring size, alteration in stereochemistry, fragmentation of a lead molecule. Peptidomimetics in drug design, Topliss decision tree analysis.

   6hrs

2. Structure activity relationships in drug design. Qualitative versus quantitative approaches, advantages and disadvantages; Random screening, nonrandom screening, drug metabolism studies, clinical observations, Structure based drug design, ligand based drug design. **6hrs**

3. QSAR: Electronic effects; Hammett equation, Lipophilicity effects; Steric Effects; Taft Equation, Free Wilson Analysis, Hansch Analysis; Experimental and theoretical approaches for the determination of physico-chemical parameters. 3D QSAR approach, generation of 3D coordinates conversion of 2D structures in to 3D form.

   8hrs

4. A brief study of molecular biology of receptors, drug receptor theories including receptor binding assays. Molecular modeling, energy minimization, geometry optimization, conformational analysis, global conformational minima determination; automated methods of conformational search. Advantages and limitations of molecular modeling softwares. Molecular docking and dynamics: Rigid docking, flexible docking, manual docking; autodocking, receptor mapping, pharmacophor matching, de Novo design. **10hrs**

5. Combinatorial Chemistry. Introduction, Solid Phase Synthesis, Liquid Phase Synthesis, Methods of Parallel and Mixed Combinatorial Synthesis, Deconvolution and High Throughput Screening, library synthesis on resin beads, peptide synthesis, parallel synthesis, tea bag method, pin method. **6hrs**

6. Informatics methods in drug design:General approaches to Bioinformatics, cheminformatics, genomics, proteomics, chemogenomics, pharmainformatics; ADME databases, chemical biochemical and pharmaceutical databases. **4hrs**.

B: MEDICINAL CHEMISTRY (max 35 hrs)

A detailed study of classification, chemistry, mechanism of action, SAR, Synthesis of two drugs from each class, uses and recent advances of the following classes of drugs:

1. Antiviral agents including Anti- HIV agents. (3hrs)
2. Antineoplastic agents (4hrs)
3. Antihypertensive agents (4 hrs)
4. Prostaglandins, Leukotrienes and other Eicosanoids. (3hrs)
5. Antihyperlipidemic agents. (3hrs)
6. Gastrointestinal agents including drugs used in Peptic Ulcer. (4hrs)
7. Immunosuppressants and immunostimulants. (3hrs)
8. Anti Parkinsonism agents and agents for Alzheimer's disease. (3hrs)
9. Gene Therapy in cancer and other chronic disease (4hrs)
10. Radiosensitizers and radioprotective agents. (4hrs)

MPH-B-II (PAPER-II)

ADVANCED ORGANIC CHEMISTRY

Theory (3 hrs/week)

1. Bonding and electron distribution: Localized and delocalized bonding (including aromaticity), heterocyclic rings exhibiting aromaticity. Bonding weaker than Covalent: hydrogen bonding, addition complex, electron donor-acceptor complexes, crown ethers, inclusion compounds and clathrate compound, acids and bases and effect of structure on their reactivity.

6hrs

2. Introduction to stereo chemistry: Chiral compounds, molecules with one chiral Center, molecules with a chiral axis, molecules with a chiral plane of symmetry, molecules with two or more chiral centers, characterization of enantiomers by chiroptical method. **6hrs**

3. Asymmetric synthesis- Chiral induction, factors controlling selectivity, chiral reagents, catalyst and solvents (include industrially used); kinetic resolution, double asymmetric

induction, acyclic diastereo selection, asymmetric amplification. Asymmetric synthesis of amino acids and betalactams. **6hrs**

4. Chemistry of electron sources: general ranking of electron sources, nonbonding electrons, electron rich sigma bond, electron rich pi-bonds and simple pi-bonds, aromatic rings. **6hrs**

5. Electron acceptors: general ranking of electron acceptors, electron deficient species, weak single bonds, polarized multiple bond, mechanisms and methods of determining; thermodynamic and kinetic requirement for reaction–methods of determining reaction mechanism. **6hrs**

6. Stability and reactivity of reaction intermediates, ion stability, solvation and media effect. Ranking of stability and trends (structure, lone pair stabilization, pi-bondstabilization, hyper conjugation). Ranking of electron donor groups. Ranking of electron withdrawing groups. Pka rule. **6hrs**

7. Study of mechanism and reactivity, stereochemistry of the following organic reactions. Aliphatic nucleophilic and electrophilic substitutions. Aromatic electrophilic and nucleophilic substitutions. Free radical substitution. Addition to carbon-carbon and carbon-hetero multiple bond Elimination reactions. Rearrangements involving carbon to carbon, carbon to nitrogen, carbon to oxygen, nitrogen to carbon, oxygen to carbon. **6hrs**

8. Principles of synthetic planning, logic centered molecular synthesis; dislocation, synthetic tree, synthons, logical imposition of boundary conditions, directed associated approach. Structure functionality relationship; functionality and unsaturation levels. Polar reactivity analysis; control elements, consonant and dissonant circuits. Protocol for synthetic design. Retrosynthesis. **7hrs**

9. Photochemistry: Exited state and ground state, Franck and Condon principles, Jablonski diagram, singlet and triplet state photo sensitization, forbidden transitions, types of excitations, photolytic cleavage, the fate of excited molecules, physical and chemical processes, determination of photochemical mechanisms. **7hrs**

10. Generation, fate and biological significance of electron deficient species, carbocations, carbenes, carbanions, free radicals, nitrenium ions and nitrenes. Mechanisms (include stereochemistry) of oxidation- reduction reactions-Birch reduction, Meerwin Pondroff's reduction, Oppeneaur Oxidation, Wolf Kishner reduction and catalytic hydrogenation.

6hrs

11. Alkylation: Enolates: Regio and stereo selective enolate generation, "O" versus "C"-alkylation, effects of solvents, counter cation and electrophiles, symbiotic effects. Thermodynamically and kinetically controlled enolate formation. Enamines and metallo-enamines: Regioselective in generation, applications in controlling the selectivity of alkylation.

7hrs

12. Catalysis: Introduction, phase transfer catalysis in anhydride, epoxide, ester, nitryl, sulphide formation, ester hydrolysis and reduction reaction. **6hrs**

MPH.B-III (PAPER III)

CHEMISTRY OF NATURAL PRODUCTS

Theory (3hrs/wk)

1. General methods of isolation and separation of plant constituents, qualitative reactions for the detection of plant constituents. Applications of GLC, HPLC, HPTLC and Counter current distribution to separation and analysis of plant constituents. Application of IR, H^1 NMR, C^{13} NMR, ESR, Mass spectroscopy in the structural determination of natural products.

10hrs

2. Alkaloids: - Introduction, chemical classification, General isolation and purification Methods, Constitution of morphine, reserpine and quinine. **8hrs**

3.Steroids: - Introduction, nomenclature, stereochemistry, structural elucidation of cholesterol, ergosterol, diosgenin and cardiac glycosides. Synthesis of Progesterone from diosgenin.

10hrs

4. Flavonoids: - Chemistry of Rutin and quercetin. **4hrs**

5. Terpenoids:- Classification, general structural elucidation of terpenoids. Constitution of citral, terpineol, camphor and abietic acid. **9hrs**

6. Coumarins :- Structural determination of Xanthotoxins and Psoralene. **6hrs**

7. Carotenoids:- Chemistry of carotenes, conversion of beta carotene to vitamin A, constitution of vitamin A. **6hrs**

8. Herbal drugs:- Introduction and evaluation of herbal drugs for antidiabetic, hepatoprotective, diuretic, antidiarrheal, antiulcer, wound healing, cardiovascular, anti-inflammatory, analgesic, antipyretic, antifertility, antioxidant, antiviral and antitumour properties. Identification of biomarkers and fingerprinting of herbal drugs. **10hrs**

9. Chemistry of natural products having cosmetic value. **2hrs**

10. Marine natural products with therapeutic potential. **2hrs**

11. Isolation and characterization of important neutraceuticals. **2hrs**

12. WHO guidelines for evaluation of safety and efficacy of herbal medicines. **3hrs**

13. Role of natural products in new drug development. **3hrs**

MPH.B- IV

PHARMACEUTICAL CHEMISTRY PRACTICALS

(12 hrs/wk)

I, II, III - each (4hrs/wk)

I. ADVANCED MEDICINAL CHEMISTRY

a) Drug Design:

1. Demonstration on molecular graphics, molecular docking, Small molecule generation
2. Workshop on QSAR: Hansch analysis, pKa values, Free Wilson Analysis
3. Workshop on retrosynthetic methods, proposing different routes and reaction conditions.

b) Medicinal Chemistry:

1. Synthesis and Characterization of drug / organic compounds involving more than two steps.
2. Synthesis of compounds of medicinal interest (Atleast six)
    a. Benzimidazole.
    b. Benzotriazole.
    c. 2, 3 diphenylquinoxaline.
    d. Oxadiazole.
    e. Thiadiazole
    f. 3-methyl-1-phenyl-5-pyrazolone
    g. 2-methyl-3,1-benzoxacin-4-one
    h. Isatin
    i. Busulfan
    j. Sulphanilide/ sulphapyridine
    k. Isoniazid
    l. Risocaine

II. ADVANCED ORGANIC CHEMISTRY

1. Study of spectral interpretation of selected compounds using UV, IR, NMR and Mass spectra

2. To perform the following reactions of synthetic importance

a) Clemmenson reduction.

b) Meerwin-Pondroff's reduction.

c) Grignard reaction.

d) Benzyllic acid rearrangement.

e) Beckmann rearrangement.

f) Photochemical reaction.

III. CHEMISTRY OF NATURAL PRODUCTS

1. Isolation of active principles from natural sources like alkaloids, terpenes, steroids,

Eg: - Piperine from Black pepper
-Citral from lemongrass oil.
-Asiaticoside from Centella asiatica.
-Beta- sitosterol from Sida acuta.

Conversion of Diosgenin to progesterone.

2. Isolation and characterization of active principles, including neutraceuticals from natural sources, including UV, IR spectroscopic analysis and TLC

Eg: Eugenol from clove
Curcumin from turmeric
Hesperidine from orange peel
Embelin from Embelica ribes
Pectin from orange peel
Epicatechin from Cahew kernel outer covering
Borswellic acid from Borswellia Serrata.

3. Workshop on various strategies to new lead identification and optimization from natural products.

4. Degradation reaction of following products and the identification of degraded intermediates by micro TLC and qualitative tests

Eg: (a) Atropine (b) Caffeine (c) Ephedrine.

2.11. No: of hours per subject

As given under "Content of each subject in each year "(clause 2.10)

2.12. Practical training

As given under "Content of each subject in each year " (clause 2.10)

2.13. Records

To be maintained for all Practical Work

2.14. Dissertation:

Standard format of dissertation

a) Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized guide. The results of such a work shall be submitted in the form of a dissertation.

b) Synopsis shall be forwarded to University, for information within 3 months from the starting of 2nd year.

c) The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results
6. Discussion
7. Conclusion
8. Summary
9. References
10. Tables
11. Annexure

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure.

It should be neatly typed conventional (Times New Roman) font, size 12-point, 10 to 12characters per inch must be used with 1.5 line spacing on one side of the bond paper (A4size, 8.27" x 11.69") All margins should be consistently 25mm in width and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of M. Pharm Part II term.

Change of dissertation topic / guide – rules

The decision regarding change of title/guide shall be taken as per the Institute research committee recommendations and the same can be intimated to the University.

2.15. Speciality training, if any

As per "Teaching, learning methods " and "Content of each subject in each year " above.

2.16. Project work to be done if any

Thesis

1. Every candidate shall carry out work on an assigned research project under the guidance of a recognised Postgraduate Teacher, the result of which shall be written up and submitted in the form of a Thesis.

2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least one month before the examination.

3. The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

2.17. Any other requirements [CME, Paper Publishing etc.]

As per the instruction of HoD of concerned Department

2.18. Prescribed/recommended textbooks for each subject

Compulsory subject

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.

3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Textbook of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

Specialized subjects

1. R.B.Silverman, "The Organic Chemistry of Drug Design and Drug Action" Academic press Inc., San Diego, 1992.
2. Schueler, Chemobiodynamic and Drug Design.
3. Martin, Y., QSAR, 1978.
4. Kubiny's, QSAR.
5. Holtje. Sippl., Rognan and Folkers, Molecular Modeling.
6. P.K. Larsen, Tommy and U.Madsen, Textbook of Drug Design and Discovery.
7. T.J. Perun and C.L. Propst, Computer Aided Drug Design.
8. Robert GCK,ed., " Drug Action at the Molecular Level" University Prak Press Baltimore.
9. Martin YC. "Quantitative Drug Design" Dekker, New York.
10. Lien EJ. SAR "Side effects and Drug Design" Dekker, New York.
11. Ariens EJ "Drug Design" Academic Press New York.
12. Olson EC "Computer Assisted Drug Design" American Chemical SocietyACS Symposium Series 112.
13. Pope & Perruuns "Computer Aided Drug Design" Academic Press New York.
14. Fischer Janos, Ganellin C. Robin "Analogue-based drug Discovery, Wiley-VCH Verlag Gmb H & Co. KG &A.
15. Pandi, Veerapandian "Structure based drug design New York Marcel Dekker, inc., 1997.
16. Paul S. Charifson, Practical Application of Computer Aided Drug Design Marcel Dekker Inc, New York.
17. G Vurter & Mark Gardner, Molecular Modelling & Drug Design Mac Milan Press Ltd 1994.

18. Smith HJ, Williams H, eds, “Introduction to the principles of Drug Design” Wright Boston.
19. J. March “Advanced Organic chemistry, Reaction mechanisms and structure”, John Wiley and sons, N.Y.
20. E.S.Gould, Hold Rinchart and Winston “Mechanism and Structure in Organic Chemistry”, NewYork.
21. Delgado JN, Remers WA eds “Wilson & Gisvolds’s Text Book of Organic Medicinal & Pharmaceutical Chemistry” Lippincott, New York.
22. A guide to mechanisms in Organic Chemistry – Peterskyes (Orient Longman, New Delhi).
23. R.A. Aitken and S.M.Kilengi “Asymmetric synthesis”, Ed., Blackie Academic and professional London, 1992.
24. Lednicer, The Organic Chemistry of Drug Synthesis, Volume I to V.
25. Ariens E.J: Medicinal Chemistry Series.
26. Ellis and West: Progress in Medicinal Chemistry Series.
27. Butterworther: Progress in Medicinal Chemistry Series.
28. Stuart Warren: Organic Synthesis – The Disconnection Approach (John Wiley &Sons).
29. Comprehensive Medicinal Chemistry – Series – I-VI (Academic Press).
30. Stephen R. Wilson & Anthony W. Czarn, Combinational Chemistry – Synthesis and Applications.
31. Reactive intermediates in organic chemistry – Tandom and Gowel.
32. Molecular reaction and Photochemistry – C.H. Depuy and O.L.Chapman.
33. Heterocyclic Chemistry: Vol. I, II, III: R. R. Gupta, M. Kumar and M. Gupta.
34. Heterocyclic Chemistry: Joules and Mills.
35. Modern heterocyclic Chemistry: L. A. Paquette (Benjamin).
36. Modern Methods of Plant Analysis- Peech and Tracey.
37. Phytochemistry Volume I and II by Miller. 24. Chemistry of Natural Products by S. V. Bhat.
38. Trease and Evans, Pharmacognosy, 15th Edition.
39. Recent Advances in Phytochemistry Volume I to IV.
40. Natural Product Chemistry- Nakanishi Gggolo.
41. Organic Chemistry of Natural Products- Volume I and II by Chatwall.
42. Organic chemistry of Natural Products Volume I and II by O. P. Agarwal.
43. Remington’s Pharmaceutical Sciences- 20th Edition.
44. Indian Pharmacopoeia.

2.19. Reference books

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
4. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
5. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
6. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
7. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
8. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
9. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.
10. Foye W "Principles of Medicinal chemistry 'Lea & Febiger'.
11. Abraham D.J., ed., Burger's Medicinal Chemistry & Drug Discovery, Vol.-I-VI, John Wiley & sons, New Jersey.
12. Ford M.E., Catalysis of organic reactions, Marcel Dekker Inc., New York.
13. Laszlo Kurti, Barbara Czako, Strategic Applications of Name reaction in Organic Synthesis, Elsevier, Academic Press, New York.
14. Eliel, E.L., Stereochemistry of Carbon compounds. MC. Graw Hill Book Company, Inc.NewYork.

    I.L. Finar "Organic Chemistry" Vol I and II. ELBS, Sixth ed., 1995

2.20. Journals

All Pharmacy and related medical Journals

2.21. Logbook

Registers to be maintained

3. EXAMINATIONS

3.1. Eligibility to appear for exams

a. Attendance, conduct and condonation option:

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M. Pharm Part I examination.

No condonation of attendance is permitted.

b. Internal assessment

Candidates obtaining minimum of 50% marks separately in both theory and practical shall be eligible for appearing in University examination

3.2. Schedule of Regular/Supplementary exams

There will be two examinations one regular and one supplementary in an academic year. The supplementary examinations shall be conducted within 6 months after declaration of results.

3.3. Scheme of examination showing maximum marks and minimum marks

University Examination:

M. Pharm Part I Examination:-

I. Theory:

There shall be 4 theory papers (including compulsory paper) each of 3 hours duration each carrying 100marks.

II. Practical:

There shall be practical examination for the compulsory subject (MCS-II) of 6 hours duration including viva voce. The marks for the practical examination are out of 100, which are distributed as follows:

Distribution of marks for Compulsory subject (MCS-II) practical examination

Synopsis	20
One Major Experiment	40
One Minor Experiment	25
Basic Spectral Analysis	15
Total	100
Viva Voce	25

The practical examination of the 3 different papers in the specialization subject are to be conducted separately. Duration of the practical examination for the three different papers together is 3×6 hrs = 18hrs, including Viva-voce. Viva voce is also conducted separately for the three papers in specialization subject. The marks distribution is as follows in each paper.

Distribution of marks for specialization subject practical examination

Synopsis	20
Experiment/s	80
Total	100
Viva-voce	25

Distribution of marks and hours for theory and practical examination

Subject	Theory				Practical					Total
	Duration	Exam	Sessional	Total	Duration	Exam	Sessional	Viva-voce	Total	
Compulsory subject										
Modern Analytical and Research Methods	3hrs	100	50	150	6hrs*	100	25	25	150	300
Specialization subjects										
Paper I	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper II	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper III	3hrs	100	50	150	6hrs*	100	25	25	150	300
Total										**1200**

*** including viva voce**

Scheme of evaluation

Evaluation system for M. Pharm Part I is Centralized Double valuation by examiners from outside University and within University. The averages of marks of the two examinations are taken as the mark of the theory paper. If the variation in total marks obtained in two valuations is more than 15%, the paper should undergo a third valuation, and the average of aggregate of the nearest two will be counted. M.Pharm

Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

No re-evaluation is permitted, only re-totaling can be allowed on request by the candidate.

Criteria for pass & Re- appearance in case of failure

I. M. Pharm Part I Examination:-

i. For passing the university examination, a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination individually and overall aggregate of 50% marks, including Sessional marks in each theory paper and in the case of practical examination including viva-voce and Sessional marks.

ii. If a candidate fails in any of the theory papers or practical papers in the examination of compulsory subject or in the specialization subject, he/she has to appear again in the compulsory subject or in that paper/s of the specialization subjects including the theory and practical as the case may be.

II. M. Pharm Part II Examination:-

(A) Submission of thesis and Distribution of marks:

a. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M. Pharm Part -2 course. The candidate shall be eligible to submit their thesis only after passing M. Pharm Part-1 examination.

b. Any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year, after discussion in Institutional research committee.

c. The dissertation should be submitted one month in advance to the II year M. Pharm examinations duly signed by the respective guide and the same has to be forwarded to the Controller of Examinations through the Principal of the College.

M. Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Four copies of the thesis duly certified by the supervising teacher shall be submitted to the University one month before by the candidate either in printed or typewritten form through the Head of the institution before the last date prescribed by the University.

The distributions of marks for evaluation of M. Pharm part II dissertation work is as follows:

M. Pharm part II examination is of total marks 500, which has been divided into as shown in the table

Distribution of marks for M. Pharm part II examination

Thesis	300
Oral	100
Seminar	100
Total	500

(B) Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University within an examination center. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with duration of about 30 minutes, which is followed by a viva voce.

(C) Evaluation of thesis and criteria for pass

Any candidate who secures less than 50% of the total marks, he/she has to reappear based on the evaluation report of the examiners, before maximum duration of course (four years)

3.4 Papers in each year:

S.No.	Code. No	Title
Compulsory Subject		
1.	MCS-I	Modern Analytical and Research Methods
BRANCH B : Pharmaceutical Chemistry		
2.	MPH.B-I	Advanced Medicinal Chemistry
3.	MPH.B-II	Advanced Organic Chemistry
4.	MPH.B-III	Chemistry of Natural Products

3.5 Details of theory exams

There shall be 4 theory papers (including compulsory paper) each of three hours duration each carrying 100 marks

3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

Modern Analytical and Research Methods (Common for all branches)

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. What are the principles of spin-spin decoupling and describe any three methods. Discuss the factors affecting chemical shift with suitable examples.

2. Explain the principle and instrumentation of gas chromatography. Derive the Beer-Lamberts law and explain its deviations.

Short Essays: **(6 X 10 = 60)**

3. Explain the principle, instrumentation and sample handling techniques in infrared spectroscopy.

4. Discuss the principle and Instrumentation of atomic absorption spectroscopy.

5. Explain the principle involved in assay of riboflavin, thiamine and quinine by fluorimetry. Mention the transitions involved in fluorescence.

6. Explain briefly about resolution in mass spectrophotometer and MC-Lafferty rearrangement.

7. Compare TLC & HPTLC on the basis of its principle and mention its pharmaceutical applications.

8. Explain briefly about Miller's indices. How will you calculate mean, median, mode and students T-test.

****

QP Code: **Reg. No.:……**

M Pharm Degree (Part I) Examinations – Pharmaceutical Chemistry

(Model Question Paper)

Paper II – Advanced Medicinal Chemistry

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20=40)**

1.Discuss recent advances in cancer therapy. Classify anti viral drugs. Explain the mechanism of action and synthesis of one drug from two different classes.

2.Give classification mechanism of action and S R of anti hypertensive agents. Drugs used in neuro degenerative disorders.

Short Essays: **(6x10=60)**

3.Explain how radio sensitizers are used in drug therapy

4.Discuss the agents used in management of tuberculosis. Explain the concept of multiple drug resistance in tuberculosis.

5.Discuss the chemistry of β lactam antibiotics. Steroidal anti inflammatory agents

6.Explain about anti hyperlipidemic agents. Give synthesis of any two drugs.

7.What are tranquillizers . Give SAR of phenothiazine derivatives. give an account of thiazide diuretics.

8.Write the important classes of anti malaraial agents and give synthesis of amodiaquine and chloroquine

QP Code: **Reg. No.:……**

M Pharm Degree (Part I) Examinations – Pharmaceutical Chemistry

(Model Question Paper)

Paper III – Advanced Organic Chemistry

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20=40)**

1.Explain localized and delocalized bonds with examples. Explain generation fate and biological significance of free radicals.

2.Write notes on (4X5=20)

Oppeneaur oxidation Wolf Kishner reduction

Birch reduction Meerwin Pondroff's reduction

Short Essays: **(6x10=60)**

3.Discuss various methods of determining organic reaction mechanisms.

4.Discuss in detail the various mechanisms involved in the addition to carbon carbon multiple bonds.

5.Explain in detail about retro synthetic analysis. Explain hyper conjugation with examples.

6.Discuss the phase transfer catalysis and its applications in reduction reactions.

7.Give a detail account of carbocations and carboanions.

8.Explain the mechanism of aromatic electrophilic substitution reaction. Write the basic theory of photochemical reactions and mention its applications.

☆

QP Code: **Reg. No.:……**

M Pharm Degree (Part I) Examinations – Pharmaceutical Chemistry

(Model Question Paper)

Paper IV –Chemistry of Natural Products

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20=40)**

1.Define alkaloids . Give the methods of isolation of alakaloids. Elucidate the structure of quinine

2.Write the applications of IR, NMR and MASS Spectroscopy in the structural elucidation of natural products. Explain the importance of GLC and HPLC in separation

Short Essays: **(6x10=60)**

3.Explain the chemistry of :

- Rutin Carotenes

4.Elucidate the structure of Cholestrol

5.Outline the synthesis :

- Progesterone
- Reserpine

6.Write a note on role of natural products in new drug development. Explain the constitution of vitamin A.

7.Write in detail the role of recombinant DNA technology. Write about the isolation and characterization of important neutraceuticals.

8.Define terpenoids and elucidate the structure of camphor

☆

3.7 Internal assessment component

Sessional Examination:

I. Theory:

The Sessional marks for the compulsory subjects and for each specialization subjects are 50; out of which 40 marks are awarded for Sessional examination.10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, confidence in the topic and defense performances.

There shall be minimum 3 Sessional examinations in each of the three papers of specialization M. Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be two evaluation seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

Marks distribution for compulsory and specialization subjects in Theory

Theory	Marks
Written examination	40
Seminar	10
Total	50

II. Practical:

Compulsory subject:

The Sessional marks for the compulsory subject are 25, of which 20 are awarded for daily assessment and 5 marks for practical Sessional examination.

Specialization subjects:

The marks for practical in each paper of the specialization subject are 25. 20 marks are awarded for daily assessment in each paper and 5 marks are awarded for the Sessional practical examination conducted towards the end of the academic year.

Marks distribution for compulsory and specialization subjects in Practical

Practical	Marks
Practical Examination	05
Daily assessment	20
Total	25

The daily assessment is done on the basis of followingcriteria. -Assembly of equipments

- Use of instruments -Manipulative skills -Precision and Accuracy -Cleanliness

- Interpretation of data and results
- Preparation of protocols, case presentation, case study analysis
- Record maintenance
  (Whichever applies)

3.8 Details of practical/clinical practical exams

Each practical paper shall be of 6 hours duration carrying 100 marks each.

Practical examination shall be conducted to test the knowledge and competence of the candidates for making valid and relevant observations based on the experimental/Laboratory studies and his ability to perform such studies as are relevant to his subject.

3.9 Number of examiners needed (Internal & External) and their qualifications

A post graduate (PG) degree in M. Pharm shall be eligible as teacher.

A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.

A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.

A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

3.10 Details of Viva: Division of marks

M. Pharm Part I Examination

The Oral examination shall be thorough and shall aim at assessing the candidates knowledge and competence about the subject, investigative procedures, technique and other aspects of the speciality, which form a part of the examination.

The Oral examination marks: 25 marks

M. Pharm Part II Examination

Thesis:

The Oral examination marks: 100 marks

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

POST GRADUATE COURSE IN

PHARMACOGNOSY & PHYTOCHEMISTY

Course Code:278

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1 Title of course:

Master of Pharmacy in Pharmacognosy & Phytochemistry

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Postgraduate, and Doctoral).

2.3 Medium of instruction:

Medium of instruction shall be in English

2.4 Course outline

a) M.Pharm Part – I course of study consists of two subjects namely *one compulsory* and *one optional*

course of study for each branch have been divided into *one compulsory* subject and *three specialization* subjects. The *compulsory subject* consist of two subjects papers – a theory paper and a practical paper.

The *specialization subject* consists of three theory paper (Paper I, Paper II, Paper III) with one practical paper for each respective theory paper.

b) M.Pharm Part – II course of study consists of a thesis written on the basis of regular research work durig the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M.Pharm Part – II course and has satisfactorily conducted the two seminars during the period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary.

The candidate shall be eligible to submit their thesis only after passing M.Pharm Part – I examination.

All M.Pharm Part –II students have to present two seminars relevant to their subject specialization including recent advances before submission of thesis.

2.5 Duration

Duration of the course:

a) The duration of the M.Pharm course shall be of two academic years full time with each academic year spread over a period of not less than 365 working days.

b) The study of M. Pharm course shall be of annual system, which includes M.Pharm (Part-I) extending for 12 months from the commencement of the academic term and M.Pharm (Part-II) of another 12 months duration.

c) At the end of M.Pharm (Part-I) there shall be a university examination of M.Pharm (Part-I). At the end of M.Pharm (Part-II) the candidate shall submit a dissertation on the topic approved by the university.

2.6 Syllabus

As given under "Content of each subject in each year" (clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7 Total number of hours

As in "Content of each subject in each year" (clause 2.10)

2.8 Branches if any, with definition:

As in "Content of each subject in each year"(clause 2.10)

2.9 Teaching-Learning method:

As in "Content of each subject in each year"(clause 2.10)

2.10 Content of each subject in each year

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS

(Compulsory to all branches of M. Pharm course)

THEORY 75hrs [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY 5hrs

Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and colour relationship. The chromophore concept, absorption laws and limitations.

Woodward –Fischer rules for calculating absorption maxima. Modern instrumentation - design and working principle. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

2. INFRA RED SPECTROSCOPY 5hrs

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy. Recent advances in IR spectroscopy, including FT-IR, ATR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY 10hrs

Fundamental principles of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to the interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13} NMR. Nuclear overhauser effect, C^{13} NMR spectra, their presentation, characteristics, interpretation examples and applications.

4. MASS SPECTROSCOPY 12hrs

Basic principles and brief outline of instrumentation, Ionisation types: Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Hyphenation of MS with other analytical instruments (LC-MS, GC-MS) and applications in Pharmacy.

5. CHROMATOGRAPHIC TECHNIQUES 9hrs

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY 4hrs

Instrumentation, packed open tubular columns, Column efficiency parameters, resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY 4hrs

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative and microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection,

and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY 3hrs

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS 3hrs

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER 2hrs

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STATISTICAL ANALYSIS 10hrs

Introduction, significance of statistical methods, normal distribution, probability, Degree of freedom, standard deviation, correlation, variance, accuracy, precision, Classification of errors, reliability of results, confidence interval, Test for statistical Significance; students T-TEST, F-test, Chi-square test, correlation and regression.

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation
2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.
7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

BRANCH C - PHARMACOGNOSY & PHYTOCHEMISTRY

MPH-C-I (PAPER-I)

PHYTOCHEMISTRY

Theory 3 hrs/wk (75 hrs)

1) Biogenetic pathways for the production and chemistry of the following Phytopharmaceuticals

Alkaloids – tropane, indole, quinoline, isoquinoline, phenanthrene, alkaloidal amines
Glycosides- Anthraquinone, saponins, cardiac glycosides
Steroids, Flavanoids-biosynthesis general **15**

2) Significance of chemotaxonomical studies with special reference to therapeutically important plant products. **03**

3) Methods of extraction, isolation, purification and estimation of the following plant Constituents

a) Tropane alkaloids
b) Indole alkaloids- ergot, Rauwoifia, Nux vomica
c) Anthraquinone glycosides
d) Cardiac glycosides
e) Flavanoids
f) Ginsenosides
g) Artemisinin
h) Taxol **15**

Different methods of extraction of phytochemicals and preparation of extracts.
Separation and isolation techniques for Phytochemicals

4) Sources, chemistry and pharmacological actions of terpenoids and carotenoids **05**

5) Chemistry of proteins and peptides, methods of separation and analysis **05**

6) Natural products as leads for new drugs. Approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further development **03**

7) Neutraceuticals, herbal cosmetics and phytoestrogens - sources, chemistry and uses **05**

8) SAR of phytochemicals with examples, introduction to docking studies **03**

9) Different methods of standardization of crude drugs including, organoleptic, microscopical, physical and chemical methods, quantitative microscopy, biological screening, DNA fingerprinting **08**

10) Application of chromatographic and spectroscopic methods of standardization for quality control and assay of crude drugs and herbal formulations. **05**

11) Drugs and pharmaceuticals from marine sources- sources, extraction, constituents, description and uses. **08**

MPH-C-II (PAPER-II)

CULTIVATION AND PROCESSING OF DRUGS

Theory 3 hrs/wk (75 hrs)

1. Biodiversity conservation. Endangered species of plants. **08**
2. Plant breeding and Germ plasm conservation **05**
3. Extrinsic factors affecting yield and quality of constituents – altitude, light, temperature, moisture, irrigation, rainfall. Intrinsic factors affecting cultivation **08**
4. Soil management, classification of soils **04**
5. Fertilizers, manures, biofertilizers **05**
6. Plant growth regulators **07**
7. Mineral supplements- micro and macronutrients **05**
8. Crop quality improving methods – chemodemes, hybridization, mutation, Polyploidy **08**
9. WHO guidelines on good agricultural practices for medicinal plants.WHO guidelines for herbal drugs including standards for pesticide residues and aflatoxins **10**
10. Problems and recent trends in pest management. Biopesticides, pheromones, juvenile hormones **05**
11. Commercial cultivation of the following plants with reference to Indian conditions –Senna, Clove, Cardomom, Cinchona, Vanilla, Saffron, Ashwagandha **10**

MPH-C-III (PAPER-III)

APPLIED PHARMACOGNOSY

Theory 3 hrs/wk (75 hrs)

1) Biological screening of hepatoprotective , antifertility, antimalarial, anti-inflammatory, antimicrobial, anticancer, antidiabetic, immunomodulatory, and adaptogenic activity , effects on CNS, CVS and GIT of herbal drugs. **10**

2) Development of herbal formulations. Problems encountered in the manufacture of herbal formulations. GMP for herbal drug formulations.General standards for formulation of complimentary (alternative) system of medicine with special reference to Ayurveda **10**

A review of current status of medicinal plants in alternative system of medicines and general standards for Ayurvedic formulations

3) Plant products and high thoroughput screening. **03**

4) Adverse effects of herbal drugs. **02**

5) Determination of shelf life of herbal formulations, development of evaluation methods, use of markers in herbal drug Standardization **04**

6) Patents for phytochemicals and herbal formulations **02**

7) Herb drug interactions **02**

8) Introduction to preparation and uses of phytosomes **03**

9) Principles of plant genetics gene mutation, genetic mapping, molecular maps of plant genomes, uses of PCR in gene mapping, plant chromosome analysis
Genetics factors affecting plants and their constituents, transgenic medicinal plants gene transfer methods and applications of transgenic plants **10**

10) Gene recombination and basis of plant breeding, DNA recombinant technology
Use of DNA markers and DNA hybridization **05**

11) A detailed study of plant tissue culture and its application in pharmacognosy, laboratory requirements and general techniques, tissue culture media.

Callus culture, meristem culture, organ culture, anther and microspore culture, liquid cell suspension culture, pollen culture, protoplast fusion, hairy root culture, immobilized plant cell culture, immobilization techniques and synthetic seeds **10**

12) Secondary metabolism in tissue cultures with emphasis on production of medicinal agents and its impact on pharmacy. Screening and selection of high yielding cell lines **03**

13) Effect of cultural practices, precursors and elicitors on production of biomedicinals. **02**

14) Biotransformation, bioreactors for pilot and large scale cultures of plant cells. Cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures. **05**

15) Applications of fermentation technology, Industrial fermentation **04**

MPH-C-IV

PHARMACOGNOSY AND PHYTOCHEMISTRY PRACTICALS

(12 hrs/wk)

a) Phytochemistry:

1. Extraction of phytochemicals from fresh and dried plants
2. Isolation and purification of constituents
3. Spectral studies of phytochemicals
4. Chromatographic studies of plant extracts
5. Estimation of constituents and official herbal preparations by different analytical Techniques
6. Extraction of volatile constituents

b) Cultivation and Processing of Drugs:

1. Experiments on cultivation of medicinal plants
2. Use of fertilizers and manures in cultivation
3. Effect of plant growth regulators on the yield and quality of constituents
4. Collection and preservation of locally available medicinal plants

c) Applied Pharmacognosy:

1. Preparation of herbal formulations including cosmetics
2. Evaluation of traditional herbal formulations
3. Standardisation of herbal formulations using various analytical techniques
4. Simple in vitro screening of extracts and formulations for biological activity
5. Experiments in plant tissue culture using different media

6. Different methods of sterilization of explants
7. Simple experiments in fermentation
8. Observation of different stages of cell division

2.11. No: of hours per subject

As given under "Content of each subject in each year "(clause 2.10)

2.12. Practical training

As given under "Content of each subject in each year "(clause 2.10)

2.13. Records

To be maintained for all Practical Work

2.14. Dissertation:

Standard format of dissertation

a) Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized guide. The results of such a work shall be submitted in the form of a dissertation.

b) Synopsis shall be forwarded to University, for information within 3 months from the starting of 2nd year.

c) The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results
6. Discussion
7. Conclusion
8. Summary
9. References

10. Tables
11. Annexure

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed conventional (Times New Roman) font, size 12-point, 10 to 12characters per inch must be used with 1.5 line spacing on one side of the bond paper (A4size, 8.27" x 11.69") All margins should be consistently 25mm in width and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of M. Pharm Part II term.

Change of dissertation topic / guide – rules

The decision regarding change of title/guide shall be taken as per the Institute research committee recommendations and the same can be intimated to the University.

2.15. Speciality training, if any

As per "Teaching, learning methods " and "Content of each subject in each year " above.

2.16. Project work to be done if any

Thesis

1. Every candidate shall carry out work on an assigned research project under the guidance of a recognised Postgraduate Teacher, the result of which shall be written up and submitted in the form of a Thesis.

2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least one month before the examination.

3. The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

2.17. Any other requirements [CME, Paper Publishing etc.]

As per the instruction of HoD of concerned Department

2.18. Prescribed/recommended textbooks for each subject

Compulsory subject

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.
3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Textbook of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

Specialized subjects

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2. Jean Bruneton, Pharmacognosy and Phytochemistry of medicinal plants Techniques and Documentation, Lavoiser, 1995.
3. Wickery, M.L., Secondary Plant Metabolism, MC Millan Press, London.
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5. Vinod D. Rangari, Pharmacognosy and Phytochemistry, Career publication, Nashik.
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8. Nakanishi K., Chemistry of Natural Products, Kodausha Book Publishing Company, Osaka (Japan).
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22. Dewick, Medicinal Natural Products, A Biosynthetic Approach.
23. Atal, C.K., Kapur, B.M., Cultivation and Utilization of Medicinal and Aromatic Plants, R.R.L. Jammu.
24. Farooqui, A.A., Sreeramu, B.S., Cultivation of Medicinal and Aromatic Plants University press, 2001.
25. Yoganasimhan, S.N., Medicinal Plants of India, 1st Edition, Interlive Publishing Pvt. Ltd.
26. Medicinal and Aromatic Plant abstracts (MAPA) CSIR, New Delhi.
27. Wallis, T.E., Text Book of Pharmacognosy.
28. Indian Herbal Pharmacopoeia.
29. Bruneton Jean, Pharmacognosy and Phytochemistry of Medicinal Plants.
30. Kaufmann, Natural Products from Plants, CRC Press, New York.
31. Butler, M., Poucher's Perfumes, Cosmetics and Soaps.
32. Panda, Herbal Soaps and Detergents.
33. Vimladevi, Text Book of Cosmetics.
34. D'Amelio, Botanicals, A Phytocosmetic Desk reference
35. Practical Pharmacognosy Dr. C.K.Kokate
36. Agarwal, S.s. and Paridhavi.M, Herbal Drug Technology, Orient Longman Pvt Ltd, Hyderabad.

2.19 Reference books

1. Pharmacognosy by Brady &Tyler.E.
2. Pharmacognosy by T.E.Wallis.
3. Pharmacognosy by C.S. Shah & Qadery.
4. Pharmacognosy by M.A. Iyengar.

2.20. Journals

All Pharmacy and related medical Journals

2.21. Logbook

Registers to be maintained

3. EXAMINATIONS

3.1. Eligibility to appear for exams

a. Attendance, conduct and condonation option:

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M. Pharm Part I examination.

No condonation of attendance is permitted.

b. Internal assessment

Candidates obtaining minimum of 50% marks separately in both theory and practical shall be eligible for appearing in University examination

3.2. Schedule of Regular/Supplementary exams

There will be two examinations one regular and one supplementary in an academic year. The supplementary examinations shall be conducted within 6 months after declaration of results.

3.3. Scheme of examination showing maximum marks and minimum marks

University Examination:

M. Pharm Part I Examination:-

I. Theory:

There shall be 4 theory papers (including compulsory paper) each of 3 hours duration each carrying 100marks.

II. Practical:

There shall be practical examination for the compulsory subject (MCS-II) of 6 hours duration including viva voce. The marks for the practical examination are out of 100, which are distributed as follows:

Distribution of marks for Compulsory subject (MCS-II) practical examination

Synopsis	20
One Major Experiment	40
One Minor Experiment	25
Basic Spectral Analysis	15
Total	100

Viva Voce	25

The practical examination of the 3 different papers in the specialization subject are to be conducted separately. Duration of the practical examination for the three different papers together is 3×6 hrs = 18hrs, including Viva-voce. Viva voce is also conducted separately for the three papers in specialization subject. The marks distribution is as follows in each paper.

Distribution of marks for specialization subject practical examination

Synopsis	20
Experiment/s	80
Total	100
Viva-voce	25

Distribution of marks and hours for theory and practical examination

Subject	Theory				Practical					Total
	Duration	Exam	Sessional	Total	Duration	Exam	Sessional	Viva-voce	Total	
Compulsory subject										
Modern Analytical and Research Methods	3hrs	100	50	150	6hrs*	100	25	25	150	300
Specialization subjects										
Paper I	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper II	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper III	3hrs	100	50	150	6hrs*	100	25	25	150	300
Total										**1200**

*** including viva voce**

Scheme of evaluation

Evaluation system for M. Pharm Part I is Centralized Double valuation by examiners from outside University and within University. The averages of marks of the two examinations are taken as the mark of the theory paper. If the variation in total marks

obtained in two valuations is more than 15%, the paper should undergo a third valuation, and the average of aggregate of the nearest two will be counted. M. Pharm Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

No re-evaluation is permitted, only re-totaling can be allowed on request by the candidate.

Criteria for pass & Re- appearance in case of failure

I. M. Pharm Part I Examination:-

i. For passing the university examination, a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination individually and overall aggregate of 50% marks, including Sessional marks in each theory paper and in the case of practical examination including viva-voce and Sessional marks.

ii. If a candidate fails in any of the theory papers or practical papers in the examination of compulsory subject or in the specialization subject, he/she has to appear again in the compulsory subject or in that paper/s of the specialization subjects including the theory and practical as the case may be.

II. M. Pharm Part II Examination:-

(A) Submission of thesis and Distribution of marks:

a. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M. Pharm Part -2 course. The candidate shall be eligible to submit their thesis only after passing M. Pharm Part-1 examination.

b. Any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year, after discussion in Institutional research committee.

c. The dissertation should be submitted one month in advance to the II year M. Pharm examinations duly signed by the respective guide and the same has to be forwarded to the Controller of Examinations through the Principal of the College.

M. Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Four copies of the thesis duly certified by the supervising teacher shall be submitted to the University one month before by the

candidate either in printed or typewritten form through the Head of the institution before the last date prescribed by the University.

The distributions of marks for evaluation of M. Pharm part II dissertation work is as follows:

M. Pharm part II examination is of total marks 500, which has been divided into as shown in the table

Distribution of marks for M. Pharm part II examination

Thesis	300
Oral	100
Seminar	100
Total	500

(B) Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University within an examination center. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with duration of about 30 minutes, which is followed by a viva voce.

(C) Evaluation of thesis and criteria for pass

Any candidate who secures less than 50% of the total marks, he/she has to reappear based on the evaluation report of the examiners, before maximum duration of course (four years)

3.4 Papers in each year:

S.No.	Code. No	Title
Compulsory Subject		
1.	MCS-I	Modern Analytical and Research Methods
BRANCH C - PHARMACOGNOSY & PHYTOCHEMISTRY		
2.	MPH.C-I	Phytochemistry
3.	MPH.C-II	Cultivation and Processing of Drugs
4.	MPH.C-III	Applied Pharmacognosy

3.5 Details of theory exams

There shall be 4 theory papers (including compulsory paper) each of three hours duration each carrying 100 marks

3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

Modern Analytical and Research Methods (Common for all branches)

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. What are the principles of spin-spin decoupling and describe any three methods. Discuss the factors affecting chemical shift with suitable examples.

2. Explain the principle and instrumentation of gas chromatography. Derive the Beer-Lamberts law and explain its deviations.

Short Essays: **(6 X 10 = 60)**

3. Explain the principle, instrumentation and sample handling techniques in infrared spectroscopy.

4. Discuss the principle and Instrumentation of atomic absorption spectroscopy.

5. Explain the principle involved in assay of riboflavin, thiamine and quinine by fluorimetry. Mention the transitions involved in fluorescence.

6. Explain briefly about resolution in mass spectrophotometer and MC-Lafferty rearrangement.

7. Compare TLC & HPTLC on the basis of its principle and mention its pharmaceutical applications.

8. Explain briefly about Miller's indices. How will you calculate mean, median, mode and students T-test.

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QP Code: 105330 **Reg No: ……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

(Pharmacognosy & Phytochemistry)

Paper I - Phytochemistry

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1.Outline the biosynthetic pathway of cardiac glycosides.

2.Explain the different methods of standardization of crude drugs. Add a note on the DNA fingerprinting technique in characterization of herbal drugs.

Short Essays: **(6x10=60)**

3.Methods of isolation, purification and estimation of flavonoids

4.Illustrate the structure activity relationship of tropane alkaloids

5.everse pharmacology technique in drug discovery.

6.Extraction and estimation of ginsenosides.

7.Biosynthesis and medicinal importance of anthraquinones

8.Explain the sources, chemistry and uses of phytoestrogens.

QP Code: 106330 **Reg No: ……..**

First Year M. Pharm Degree Examinations– September 2014 (2011Scheme)

(Pharmacognosy & Phytochemistry)

Paper II - Advanced Pharmacognosy

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1.Explain germplasm conservation in detail.

2.Explain the WHO guidelines for good agricultural practices.

Short Essays: **(6x10=60)**

3. Explain the profile for commercial cultivation of senna.

4.Discuss briefly about soil management for cultivation of medicinal plants

5.Elaborate the role of plant growth regulators.

6.Explain the role of hybridization in improving the quality of crop with suitable examples.

7.Macro and micronutrients needed for cultivation of medicinal plants.

8.iscuss the role of pesticides in the cultivation of medicinal and aromatic plants. Explain briefly about bio pesticides.

QP Code: 107330 **Reg No: ……**

First Year M. Pharm Degree Examinations– September 2014

(2011 Scheme)

(Pharmacognosy & Phytochemistry)

Paper III - Applied Pharmacognosy and Plant Biotechnology

Time: 3 hrs

Maximum Marks: 100

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1.Describe the role of biotransformation and immobilization in the production of secondary metabolites of medicinal importance.

2.Explain the good manufacturing practices in the development of herbal formulations.

Short Essays: **(6x10=60)**

3.Methods of screening medicinal plant extracts/formulations for anti inflammatory activity.

4.Explain the effects of herbal drugs on GIT.

5.Procedures for patenting of herbal drugs.

6.DNA recombinant techniques and its significance.

7.Effect of various elicitors in the production of bio-medicinals

8.Applications of fermentation technology in pharmaceutical industry

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3.7 Internal assessment component

Sessional Examination:

I. Theory:

The Sessional marks for the compulsory subjects and for each specialization subjects are 50; out of which 40 marks are awarded for Sessional examination.10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, confidence in the topic and defense performances.

There shall be minimum 3 Sessional examinations in each of the three papers of specialization M. Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be two evaluation seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

Marks distribution for compulsory and specialization subjects in Theory

Theory	Marks
Written examination	40
Seminar	10
Total	50

II. Practical:

Compulsory subject:

The Sessional marks for the compulsory subject are 25, of which 20 are awarded for daily assessment and 5 marks for practical Sessional examination.

Specialization subjects:

The marks for practical in each paper of the specialization subject are 25. 20 marks are awarded for daily assessment in each paper and 5 marks are awarded for the Sessional practical examination conducted towards the end of the academic year.

Marks distribution for compulsory and specialization subjects in Practical

Practical	Marks
Practical Examination	05
Daily assessment	20
Total	25

The daily assessment is done on the basis of followingcriteria. -Assembly of equipments

- Use of instruments -Manipulative skills -Precision and Accuracy -Cleanliness

- Interpretation of data and results
- Preparation of protocols, case presentation, case study analysis
- Record maintenance
  (Whichever applies)

3.8 Details of practical/clinical practical exams

Each practical paper shall be of 6 hours duration carrying 100 marks each.

Practical examination shall be conducted to test the knowledge and competence of the candidates for making valid and relevant observations based on the experimental/Laboratory studies and his ability to perform such studies as are relevant to his subject.

3.9 Number of examiners needed (Internal & External) and their qualifications

A post graduate (PG) degree in M. Pharm shall be eligible as teacher.

A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.

A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.

A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

3.10 Details of Viva: Division of marks

M. Pharm Part I Examination

The Oral examination shall be thorough and shall aim at assessing the candidates knowledge and competence about the subject, investigative procedures, technique and other aspects of the speciality, which form a part of the examination.

The Oral examination marks: 25 marks

M. Pharm Part II Examination

Thesis:

The Oral examination marks: 100 marks

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

POST GRADUATE COURSE IN PHARMACY

M.Pharm –Pharmaceutical Analysis

Course Code: 279

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1 Title of course:

Master of Pharmacy in Pharmaceutical Analysis

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Postgraduate, and Doctoral).

2.3 Medium of instruction:

Medium of instruction shall be in English

2.4 Course outline

a) M.Pharm Part – I course of study consists of two subjects namely *one compulsory* and *one optional*

course of study for each branch have been divided into *one compulsory* subject and *three specialization* subjects. The *compulsory subject* consist of two subjects papers – a theory paper and a practical paper.

The *specialization subject* consists of three theory paper (Paper I, Paper II, Paper III) with one practical paper for each respective theory paper.

b) M.Pharm Part – II course of study consists of a thesis written on the basis of regular research work durig the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M.Pharm Part – II course and has satisfactorily conducted the two seminars during the period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary.

The candidate shall be eligible to submit their thesis only after passing M.Pharm Part – I examination.

All M.Pharm Part –II students have to present two seminars relevant to their subject specialization including recent advances before submission of thesis.

2.5 Duration

Duration of the course:

a) The duration of the M.Pharm course shall be of two academic years full time with each academic year spread over a period of not less than 365 working days.
b) The study of M. Pharm course shall be of annual system, which includes M.Pharm (Part-I) extending for 12 months from the commencement of the academic term and M.Pharm (Part-II) of another 12 months duration.
c) At the end of M.Pharm (Part-I) there shall be a university examination of M.Pharm (Part-I). At the end of M.Pharm (Part-II) the candidate shall submit a dissertation on the topic approved by the university.

2.6 Syllabus

As given under "Content of each subject in each year"(clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7 Total number of hours

As in "Content of each subject in each year"(clause 2.10)

2.8 Branches if any, with definition:

As in "Content of each subject in each year"(clause 2.10)

2.9 Teaching-Learning method:

As in "Content of each subject in each year"(clause 2.10)

2.10 Content of each subject in each year

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS

(Compulsory to all branches of M. Pharm course)

THEORY 75hrs [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY 5hrs

Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and colour relationship. The chromophore concept, absorption laws and limitations.

Woodward –Fischer rules for calculating absorption maxima. Modern instrumentation - design and working principle. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

2. INFRA RED SPECTROSCOPY **5hrs**

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy. Recent advances in IR spectroscopy, including FT-IR, ATR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY **10hrs**

Fundamental principles of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to the interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13} NMR. Nuclear overhauser effect, C^{13} NMR spectra, their presentation, characteristics, interpretation examples and applications.

4. MASS SPECTROSCOPY **12hrs**

Basic principles and brief outline of instrumentation, Ionisation types: Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Hyphenation of MS with other analytical instruments (LC-MS, GC-MS) and applications in Pharmacy.

5. CHROMATOGRAPHIC TECHNIQUES **9hrs**

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY **4hrs**

Instrumentation, packed open tubular columns, Column efficiency parameters, resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY **4hrs**

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative and microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection, and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY **3hrs**

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS **3hrs**

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER **2hrs**

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STATISTICAL ANALYSIS **10hrs**

Introduction, significance of statistical methods, normal distribution, probability, Degree of freedom, standard deviation, correlation, variance, accuracy, precision, Classification of errors, reliability of results, confidence interval, Test for statistical Significance; students T-TEST, F-test, Chi-square test, correlation and regression.

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation
2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.

7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

MPH. A-I (PAPER I) ADVANCED PHARMACEUTICAL ANALYSIS

THEORY 75 Hours [3hrs/week]

1. A detailed study of the principles and techniques involved in the analysis of pharmaceutical formulation containing
   a. Sulphonamides.
   b. Barbiturates – i.e., Barbituric acid derivatives and Xanthine derivatives.
   c. Steroids such as Adrenocortical steroids, Progesterone, Androgens and Cholesterol.
   d. Vitamins like Vitamin A, B1, B2, B12, C & E.
   e. Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin.

   20 hrs

2. General methods of quality control of the following as per Indian Pharmacopoeia.

   i. Tablets ii. Capsules iii. Liquid orals iv. Parenterals v. External preparation.

   15 hrs

3. A detailed study on immunological assays, ELISA, Immunoblotting, Immunofluorescence, Immunoaffinity, Radioimmunoassay, and Radiotracer Techniques and the use of these techniques in Pharmaceutical analysis. **4 hrs**

4. Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis.
   1. 2, 6- dichloroquinone chloride.
   2. 1, 2 -naphthaquinone-4-sulphonate.
   3. 3-methyl-1,2 - benzothiazoline hydrazine hydrochloride [MBTH]
   4. Folin Ciocalteau Reagent.
   5. p-dimethyl amino benzaldehyde [PDAB]
   6. p-dimethyl amino cinnamaldehyde [PDMAC]
   7. 2, 3, 5-triphenyl tetrazolium salt.
   8. N, 1-naphthyl ethylene diamine.
   9. 2, 4-dinitro phenyl hydrazine.
   10. Ninhydrin reagent. **6hrs**

5. Analysis of drugs originating from genetic engineering, vaccines, sera and toxoids.

   8hrs

6. Validation and calibration of various instruments used for drug analysis, such as UV Visible spectrophotometer, IR spectrophotometer, spectroflourimeter, HPTLC, and HPLC.

4 hrs

7. Principles and procedures involved in quantitative determination of the following groups
(a) Hydroxyl (b) Aldehyde (c) Ketone (d) Ester (e) Amine.

4hrs

8. Identification and quantitative determination of preservatives, antioxidants, colouring materials, emulsifiers, and stabilizers in pharmaceutical formulation.

8 hrs

9. Microbiological assay of vitamins, antibiotics and LAL test.

4 hrs

10. Quality control of radio pharmaceuticals and radio chemical methods of analysis.

2 hrs

MPH. A-II (PAPER II)

QUALITY CONTROL &QUALITY ASSURANCE

THEORY 75 Hours [3hrs/week]

1. Concept of TQM, GLP, GMP (orange guide), ISO 9000, ISO 14000, ISO 18000 and NABL. Concept of validation, types of validations, protocols for process validation, validation of equipments and procedures.

10hrs

2. Organisation and personnel, responsibilities, training and hygiene.

3hrs

3. Premises: Location, design, plan, layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

3hrs

4. Equipments: Selection, purchase specification, maintenance, sterilization of an area [TP and STP]

3hrs

5. Raw materials: Purchase specification, maintenance of stores, selection of vendors, controls on raw materials. **3hrs**

6. Manufacture of and control on dosage forms, manufacturing documents, master formula, batch formula records, standard operating procedure, Quality audits of manufacturing processes and facilities.

6hrs

7. Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

5hrs

8. Packing and labelling controls, line clearance, reconciliation of labels, cartons and other packing material, types and tests assuring quality of glass, types of plastics used, permeation, leaching, sorption, chemical reaction, biological tests, modification of plastics by drugs, different types of closure and closure liners, film wrappers, blister packs, bubble packs, shrink handling, foil/plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes. Quality control of packing material and filling equipment.

18hrs

9. Quality control laboratory: Responsibility, good manufacturing practice, routine controls, instruments, protocols, non clinical testing, controls in animal house, application of computer in Quality control laboratory.

3hrs

10. Protocols of analysis, preparation of analytical report and documentation. Data generation and storage, quality control documentation, retention samples, record quality audits, stability testing, and determination of shelf life.

3hrs

11. Finished products: Quality review, quality audit, batch release documentation.

3hrs

12. Warehousing: Good warehousing practice, material management.

3hrs

13. Distribution: Distribution of records, handling of returned goods, recovered materials and reprocessing.

3hrs

14. Complaints and recalls: Evaluation of complaints, recall procedures, related records and documents. **3hrs**

15. Waste disposal, scrap disposal, procedure and records. **3hrs**

16. WHO Certification, globalization of Drug industry, Introduction to Export of drugs and Import policy, Patent regime.

3hrs

MPH. A-III (PAPER III)

PHARMACEUTICAL AND CLINICAL ANALYSIS

THEORY 75 Hours (3hrs/week)

1. Analysis of drugs from biological samples, including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting the extraction of drugs.

6hrs

2. A brief study of principles and procedures involved in Therapeutic Drug Monitoring (TDM). A detailed discussion on the methods of estimation of drugs implicated in TDM such as Phenobarbitone, Phenytoin, Carbamazepine, Ethosuximide, Digoxin, Lidocaine, Quinidine, Procainamide, Methotrexate, Theophylline and Antidepressants.

12hrs

3. A detailed discussion on DOPE tests and methods for the estimation of anabolic steroids and drugs of abuse in blood/urine.

5hrs

4. Concept of analytical and bioanalytical method development of drugs and dosage forms using various instruments like UV-VIS spectrophotometer, Spectrofluorimeter, HPTLC, HPLC and LC-MS.

6hrs

5. A detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action. ICH guidelines for impurity and related substances determination in drugs. General method of analysis of chemical constituents of food, identification of common adulterants, water analysis including pesticide residue in water.

8hrs

6. Stability testing of formulation and shelf life prediction. ICH guidelines for stability studies of drugs.

6hrs

7. WHO guidelines for the assessment of quality, safety and efficacy of herbal drugs, protocols and procedures for systematic evaluation, standardization and Fingerprint profiles of herbal drugs using HPTLC.

8hrs

8. Analysis of various types of raw materials used in cosmetics. Analysis of cosmetics in finished form such as skin care products, baby care products, dental products, personal hygiene products, colour cosmetics and ethnic products. Indian Standard Specification [ISI] laid down for sampling and testing various cosmetics in the finished form by the Bureau of Indian Standards. Toxicity testing in cosmetics. Legislation of cosmetic products. **24hrs**

MPH. A- IV

PHARMACEUTICAL ANALYSIS PRACTICALS

(12 hrs/wk)

I, II, III - each (4hrs/wk)

I. Advanced Pharmaceutical Analysis

1. Use of spectrophotometer for the analysis of Pharmacopoeial compounds and their Formulation.
2. Assay of official compounds by fluorimetry: Quinine, Codeine, Thiamine, and Riboflavin.
3. Quantitative analysis of drugs in multicomponent dosage forms.
4. Quantitative determination of the following groups: hydroxyl, carbonyl, and amino groups.
5. HPLC analysis of drugs.
6. Quality control test for tablets, capsules, injections, ointments and suppositories.
7. Detection and determination of preservatives, antioxidants and colouring materials in pharmaceuticals.
8. Sterility testing of areas
9. Monograph analysis of Pharmacopoeial compounds used as raw materials

II. Quality Control & Quality Assurance

1. Development of analytical profiles for newer drugs.
2. Calibration of glass wares. Testing of containers, closures, liners, glass, plastics used for packing. Testing of packing material, cartons, aluminium foils, strip packing, blister packing, ampoules, vials, etc.
3. Preparation of process protocols, SOP etc.

III. Pharmaceutical and Clinical Analysis

1. Screening of commonly encountered poisons in biological fluids. (Qualitative)
2. Quality control of some cosmetics.
3. Microbiological evaluation of waste water.
4. Analysis of drugs in biological fluids.
5. Dissolution study of simple and modified release solid dosage form.
6. Accelerated stability studies of some drugs.
7. General methods of analysis of chemical constituents of food.

2.11. No: of hours per subject

As given under "Content of each subject in each year "(clause 2.10)

2.12. Practical training

As given under "Content of each subject in each year " (clause 2.10)

2.13. Records

To be maintained for all Practical Work

2.14. Dissertation:

Standard format of dissertation

a) Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized guide. The results of such a work shall be submitted in the form of a dissertation.

b) Synopsis shall be forwarded to University, for information within 3 months from the starting of 2nd year.

c) The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results

6. Discussion
7. Conclusion
8. Summary
9. References
10. Tables
11. Annexure

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed conventional (Times New Roman) font, size 12-point, 10 to 12characters per inch must be used with 1.5 line spacing on one side of the bond paper (A4size, 8.27" x 11.69") All margins should be consistently 25mm in width and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of M. Pharm Part II term.

Change of dissertation topic / guide – rules

The decision regarding change of title/guide shall be taken as per the Institute research committee recommendations and the same can be intimated to the University.

2.15. Speciality training, if any

As per "Teaching, learning methods " and "Content of each subject in each year " above.

2.16. Project work to be done if any

Thesis

1. Every candidate shall carry out work on an assigned research project under the guidance of a recognised Postgraduate Teacher, the result of which shall be written up and submitted in the form of a Thesis.

2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least one month before the examination.

3. The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

2.17. Any other requirements [CME, Paper Publishing etc.]

As per the instruction of HoD of concerned Department

2.18. Prescribed/recommended textbooks for each subject

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.
3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Text book of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

2.19 Reference books

1. Spectrophotometric identification of Organic Compounds, Robert M. Silverstein et al.
2. Principles of Instrumental Analysis by Donglas A. Skoog, James J. Leary.
3. Pharmaceutical Analysis-Modern Methods by James W. Munson.
4. Instrumental Methods of Analysis- Hobert H.Willard.
5. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics.
6. Organic Spectroscopy- William Kemp
7. Techniques and practice of Chromatography - Raymond P.W.Scott.
8. Application of Absorption Spectroscopy of Organic compounds by John Dyer
9. Liquid Chromatography-Mass Spectrometry, W.M.A. Niessen, J.Van der Greef.
10. Organic Chemistry by I.L. Finar.
11. Comprehensive Pharmacy Review by Leon Shargel, Alan H. Mutnick, Paul F.Souney, Larry N. Sawnson.
12. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel et al.
13. Indian Pharmacopoeia.
14. Practical HPLC method development by Lloyd R. Snyder et al.
15. Indian Standard Institution (BIS).

16. Text Book of Pharmaceutical Analysis-K.A. Connors.
17. Quantitative Analysis of Drugs – D.C. Garreth.
18. Vogel's Textbook of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney, 5th edition, ELDS, 1991.
19. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
20. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
21. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
22. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
23. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
24. QA manual by D.H. Shah , Galaxy printers, New Delhi.
25. ICH guidelines.
26. Research guideline for evaluating the safety and efficacy of herbal medicines WHO publications.
27. Modern Practice of Gas Chromatography by Robert L. Grob and Eugene F. Barry.
28. Analytical Methods for Therapeutic Drug Monitoring and Toxicology: by Q. Alan Xu and Timothy. L. Madden.
29. Harry's Cosmeticology – Wilkinson, Moore, seventh edition, George Godwin, 1982.
30. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
31. Indian Standard Toothpaste specification, second revision, BIS, New Delhi.
32. Indian Standard specification for hair creams, first revision, BIS, New Delhi.
33. U.S FDA Guidance for Industry-Bioanalytical Method Validation.
34. A Handbook of Bioanalysis and Drug Metabolism by Gary Evans.
35. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989.
36. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
37. Guidelines on c-GMP and Quality of Pharmaceutical Products, S. Iyer.

2.20. Journals

All Pharmacy and related medical Journals

2.21. Logbook

Registers to be maintained

3. EXAMINATIONS

3.1. Eligibility to appear for exams

a. Attendance, conduct and condonation option:

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M. Pharm Part I examination.

No condonation of attendance is permitted.

b. Internal assessment

Candidates obtaining minimum of 50% marks separately in both theory and practical shall be eligible for appearing in University examination

3.2. Schedule of Regular/Supplementary exams

There will be two examinations one regular and one supplementary in an academic year. The supplementary examinations shall be conducted within 6 months after declaration of results.

3.3. Scheme of examination showing maximum marks and minimum marks

University Examination:

M. Pharm Part I Examination:-

I. Theory:

There shall be 4 theory papers (including compulsory paper) each of 3 hours duration each carrying 100marks.

II. Practical:

There shall be practical examination for the compulsory subject (MCS-II) of 6 hours duration including viva voce. The marks for the practical examination are out of 100, which are distributed as follows:

Distribution of marks for Compulsory subject (MCS-II) practical examination

Synopsis	20
One Major Experiment	40
One Minor Experiment	25
Basic Spectral Analysis	15
Total	100

Viva Voce	25

The practical examination of the 3 different papers in the specialization subject are to be conducted separately. Duration of the practical examination for the three different papers together is 3×6 hrs = 18hrs, including Viva-voce. Viva voce is also conducted separately for the three papers in specialization subject. The marks distribution is as follows in each paper.

Distribution of marks for specialization subject practical examination

Synopsis	20
Experiment/s	80
Total	100
Viva-voce	25

Distribution of marks and hours for theory and practical examination

Subject	Theory				Practical					Total
	Duration	Exam	Sessional	Total	Duration	Exam	Sessional	Viva-voce	Total	
Compulsory subject										
Modern Analytical and Research Methods	3hrs	100	50	150	6hrs*	100	25	25	150	300
Specialization subjects										
Paper I	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper II	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper III	3hrs	100	50	150	6hrs*	100	25	25	150	300
Total										**1200**

*** including viva voce**

Scheme of evaluation

Evaluation system for M. Pharm Part I is Centralized Double valuation by examiners from outside University and within University. The averages of marks of the two examinations are taken as the mark of the theory paper. If the variation in total marks

obtained in two valuations is more than 15%, the paper should undergo a third valuation, and the average of aggregate of the nearest two will be counted. M. Pharm Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

No re-evaluation is permitted, only re-totaling can be allowed on request by the candidate.

Criteria for pass & Re- appearance in case of failure

I. M. Pharm Part I Examination:-

i. For passing the university examination, a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination individually and overall aggregate of 50% marks, including Sessional marks in each theory paper and in the case of practical examination including viva-voce and Sessional marks.

ii. If a candidate fails in any of the theory papers or practical papers in the examination of compulsory subject or in the specialization subject, he/she has to appear again in the compulsory subject or in that paper/s of the specialization subjects including the theory and practical as the case may be.

II. M. Pharm Part II Examination:-

(A) Submission of thesis and Distribution of marks:

a. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M. Pharm Part -2 course. The candidate shall be eligible to submit their thesis only after passing M. Pharm Part-1 examination.

b. Any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year, after discussion in Institutional research committee.

c. The dissertation should be submitted one month in advance to the II year M. Pharm examinations duly signed by the respective guide and the same has to be forwarded to the Controller of Examinations through the Principal of the College.

M. Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Four copies of the thesis duly certified by the supervising teacher shall be submitted to the University one month before by the

candidate either in printed or typewritten form through the Head of the institution before the last date prescribed by the University.

The distributions of marks for evaluation of M. Pharm part II dissertation work is as follows:

M. Pharm part II examination is of total marks 500, which has been divided into as shown in the table

Distribution of marks for M. Pharm part II examination

Thesis	300
Oral	100
Seminar	100
Total	500

(B) Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University within an examination center. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with duration of about 30 minutes, which is followed by a viva voce.

(C) Evaluation of thesis and criteria for pass

Any candidate who secures less than 50% of the total marks, he/she has to reappear based on the evaluation report of the examiners, before maximum duration of course (four years)

3.4 Papers in each year:

S.No.	Code. No	Title
Compulsory Subject		
1.	MCS-I	Modern Analytical and Research Methods
BRANCH A : PHARMACEUTICAL ANALYSIS		
2.	MPH.A-I	Advanced Pharmaceutical Analysis
3.	MPH.A-II	Quality Control &Quality Assurance
4.	MPH.A-III	Pharmaceutical and Clinical Analysis

3.5 Details of theory exams

There shall be 4 theory papers (including compulsory paper) each of three hours duration each carrying 100 marks

3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

Modern Analytical and Research Methods (Common for all branches)

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. What are the principles of spin-spin decoupling and describe any three methods. Discuss the factors affecting chemical shift with suitable examples.

2. Explain the principle and instrumentation of gas chromatography. Derive the Beer-Lamberts law and explain its deviations.

Short Essays: **(6 X 10 = 60)**

3. Explain the principle, instrumentation and sample handling techniques in infrared spectroscopy.

4. Discuss the principle and Instrumentation of atomic absorption spectroscopy.

5. Explain the principle involved in assay of riboflavin, thiamine and quinine by fluorimetry. Mention the transitions involved in fluorescence.

6. Explain briefly about resolution in mass spectrophotometer and MC-Lafferty rearrangement.

7. Compare TLC & HPTLC on the basis of its principle and mention its pharmaceutical applications.

8. Explain briefly about Miller's indices. How will you calculate mean, median, mode and students T-test.

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QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– July 2015 (2011 Scheme)

(Pharmaceutical Analysis)

Paper I – Advanced Pharmaceutical Analysis

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. Explain the quantification of hydroxyl and ketone functional group present in Pharmaceuticals (10 + 10)
2. What are preservatives and classify them. Explain the quantitative procedure for any two (2 + 4 + 7 + 7)

Short Essays: **(6 X 10 = 60)**

3. Explain the evaluation techniques including principle of formulation containing steroids
4. Discuss the practice and concept behind microbiological assay of antibodies
5. Describe the procedure for calibration and validation of HPLC
6. What is immunofluorescence. How does it employed in pharmacy
7. Discuss the application of ninhydrine and 2,6-dichloroquinone chloride in estimation of pharmaceuticals
8. Discuss the QC test for any one of the external preparation

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QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– July 2015 (2011 Scheme)

(Pharmaceutical Analysis)

Paper II – Quality Control and Quality Assurance

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. Explain in detail validation of equipment. Explain the location, design & layout, construction and control of contamination of manufacturing premises.
2. Explain in detail (a) raw material purchase specification (b) maintenance of stores (c) standard operating procedure for coating of tablets and membrane filtration

Short Essays **(6 X 10 = 60)**

3. Discuss in detail (a) reconciliation of labels (b) master and batch formula record
4. Discuss about the quality control tests for plastic containers and closures
5. Explain quality review of finished product and preparation of analytical record
6. Explain the procedure involved in handling complaints and recalls
7. Explain (a) reprocessing (b) waste disposal records
8. Explain salient features of GMP

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QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– July 2015 (2011 Scheme)

(Pharmaceutical Analysis)

Paper III – Pharmaceutical and Clinical Analysis

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. Explain ICH guideline for stability of drugs and WHO guidelines for the assessment of safety and efficacy of herbal pharmaceutical products
2. Explain the concept involved in analytical method development using HPLC. What are the methods for the analysis of pesticide residue in water

Short Essays: **(6 X 10 = 60)**

3. What are the different biological samples available for analysis of drugs. Explain the different methods for extracting drugs from them
4. Explain the toxicity testing in cosmetics
5. Explain the different methods for the estimation of 'drugs of abuse' in blood / urine
6. Explain the specifications laid down for sampling and testing various cosmetics in finished form by the bureau of Indian standards
7. Explain the principle involved in the therapeutic drug monitoring. Explain the methods for the estimation of carbamazepine and phenobarbitone for TDM
8. Explain the effect of related substances and impurity on drug stability

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3.7 Internal assessment component

Sessional Examination:

I. Theory:

The Sessional marks for the compulsory subjects and for each specialization subjects are 50; out of which 40 marks are awarded for Sessional examination.10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, confidence in the topic and defense performances.

There shall be minimum 3 Sessional examinations in each of the three papers of specialization M. Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be two evaluation seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

Marks distribution for compulsory and specialization subjects in Theory

Theory	Marks
Written examination	40
Seminar	10
Total	50

II. Practical:

Compulsory subject:

The Sessional marks for the compulsory subject are 25, of which 20 are awarded for daily assessment and 5 marks for practical Sessional examination.

Specialization subjects:

The marks for practical in each paper of the specialization subject are 25. 20 marks are awarded for daily assessment in each paper and 5 marks are awarded for the Sessional practical examination conducted towards the end of the academic year.

Marks distribution for compulsory and specialization subjects in Practical

Practical	Marks
Practical Examination	05
Daily assessment	20
Total	25

The daily assessment is done on the basis of followingcriteria. -Assembly of equipments

- Use of instruments -Manipulative skills -Precision and Accuracy -Cleanliness

- Interpretation of data and results
- Preparation of protocols, case presentation, case study analysis
- Record maintenance
  (Whichever applies)

3.8 Details of practical/clinical practical exams

Each practical paper shall be of 6 hours duration carrying 100 marks each.

Practical examination shall be conducted to test the knowledge and competence of the candidates for making valid and relevant observations based on the experimental/Laboratory studies and his ability to perform such studies as are relevant to his subject.

3.9 Number of examiners needed (Internal & External) and their qualifications

A post graduate (PG) degree in M. Pharm shall be eligible as teacher.

A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.

A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.

A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

3.10 Details of Viva: Division of marks

M. Pharm Part I Examination

The Oral examination shall be thorough and shall aim at assessing the candidates knowledge and competence about the subject, investigative procedures, technique and other aspects of the speciality, which form a part of the examination.

The Oral examination marks: 25 marks

M. Pharm Part II Examination

Thesis:

The Oral examination marks: 100 marks

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

POST GRADUATE COURSE IN

PHARMACOLOGY

Course Code: 280

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1 Title of course:

Master of Pharmacy in Pharmacology

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Postgraduate, and Doctoral).

2.3 Medium of instruction:

Medium of instruction shall be in English

2.4 Course outline

a) M.Pharm Part – I course of study consists of two subjects namely *one compulsory* and *one optional*

course of study for each branch have been divided into *one compulsory* subject and *three specialization* subjects. The *compulsory subject* consist of two subjects papers – a theory paper and a practical paper.

The *specialization subject* consists of three theory paper (Paper I, Paper II, Paper III) with one practical paper for each respective theory paper.

b) M.Pharm Part – II course of study consists of a thesis written on the basis of regular research work durig the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M.Pharm Part – II course and has satisfactorily conducted the two seminars during the period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary.

The candidate shall be eligible to submit their thesis only after passing M.Pharm Part – I examination.

All M.Pharm Part –II students have to present two seminars relevant to their subject specialization including recent advances before submission of thesis.

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2.5 Duration

Duration of the course:

a) The duration of the M.Pharm course shall be of two academic years full time with each academic year spread over a period of not less than 365 working days.

b) The study of M. Pharm course shall be of annual system, which includes M.Pharm (Part-I) extending for 12 months from the commencement of the academic term and M.Pharm (Part-II) of another 12 months duration.

c) At the end of M.Pharm (Part-I) there shall be a university examination of M.Pharm (Part-I). At the end of M.Pharm (Part-II) the candidate shall submit a dissertation on the topic approved by the university.

2.6 Syllabus

As given under "Content of each subject in each year"(clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7 Total number of hours

As in "Content of each subject in each year"(clause 2.10)

2.8 Branches if any, with definition:

As in "Content of each subject in each year"(clause 2.10)

2.9 Teaching-Learning method:

As in "Content of each subject in each year"(clause 2.10)

2.10 Content of each subject in each year

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS

(Compulsory to all branches of M. Pharm course)

THEORY 75hrs [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY 5hrs

Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and colour relationship. The chromophore concept, absorption laws and limitations.

Woodward –Fischer rules for calculating absorption maxima. Modern instrumentation - design and working principle. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

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2. INFRA RED SPECTROSCOPY **5hrs**

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy. Recent advances in IR spectroscopy, including FT-IR, ATR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY **10hrs**

Fundamental principles of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to the interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13} NMR. Nuclear overhauser effect, C^{13} NMR spectra, their presentation, characteristics, interpretation examples and applications.

4. MASS SPECTROSCOPY **12hrs**

Basic principles and brief outline of instrumentation, Ionisation types: Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Hyphenation of MS with other analytical instruments (LC-MS, GC-MS) and applications in Pharmacy.

5. CHROMATOGRAPHIC TECHNIQUES **9hrs**

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY **4hrs**

Instrumentation, packed open tubular columns, Column efficiency parameters, resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY **4hrs**

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative and microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection,

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and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY 3hrs

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS 3hrs

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER 2hrs

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STATISTICAL ANALYSIS 10hrs

Introduction, significance of statistical methods, normal distribution, probability, Degree of freedom, standard deviation, correlation, variance, accuracy, precision, Classification of errors, reliability of results, confidence interval, Test for statistical Significance; students T-TEST, F-test, Chi-square test, correlation and regression.

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation
2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.
7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

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BRANCH –E PHARMACOLOGY

MPH- E-I (PAPER - I)

PHARMACOLOGICAL SCREENING METHODS AND

DRUG DEVELOPMENT

3hrs/wk

1. Principles of experimental pharmacology. Different laboratory animals in pharmacological research, routes of drug administration to laboratory animals and collections of biological samples, breeding of laboratory animals, euthanasia. CPCSEA guidelines for laboratory animal facility and animal welfare requirements, limitation of animal testing, Transgenic animals

05

2. Principles of toxicity evaluations. Different aspects of acute, chronic and special toxicity studies. LD50, ED50, TD50, IC50 determination. ICH Ethics and animal experimentation, recommendations, guidelines and regulatory agencies- CPCSEA, OECD. OECD guidelines for toxicity evaluations .In vitro screens for specific toxicities.

05

3. Bioassays-Basic principles of bioassay, experimental models and designs employed in biological standardization, official bioassays, bioassays of Antihaemophillic fraction, Heparin Sodium, Diphtheria anti toxin, Anti rabies vaccine.

05

4. Microbial assay of antibiotics. Screening for antimicrobial activity.

03

5. Receptor- radio ligand binding assays: general principles and techniques of radio ligand binding assays ,specific assay design for adrenoreceptors ,dopamine receptors, histamine receptors GABA and benzodiazepine receptors , Principle and methods of ELISA, FPIA, Apoenzyme Reactivation Immunoassay.

05

6. Evaluation of kinetics of new drugs. Bioavailability studies.models

05

7. Pharmacological models employed in the screening of new drugs belonging to the following categories (invivo & in vitro models):Analgesics and drugs used in Arthritis and neuropathic pain, Antiinflammatory agents ,anti-psychotics, Anxiolytics, Antidepressants , Nootropics, Antiparkinsonian agents, Antiepileptics, Local anaesthetics , Skeletal muscle relaxants and neuromuscular blockers .Drugs affecting memory, Drugs for Alzheimer's disease, Antiatherosclerotic agents,, Antihypertensive agents, Antianginal agents, Antiarrhythmic agents and agents used in sudden cardiac death, Drugs for myocardial infarction, Drugs in cardiac failure and cardiac myopathies, Antiplatelet and thromolytic agent, Antimigraine agents,

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Anticancer agents, Antidiabetics, Antiulcer agents, Antiasthmatic agents, Antiemetics, Drugs affecting reproductive system, Antifertility agents , Diuretics, Drugs used in inflammatory bowel disease, Hepatoprotective agents, Antiobesity agents, Drugs used in erectile dysfunction, Antiviral agents, Antimalarial agents, Dermatological

agents and experimental models in skin pharmacology Invitro and invivo evaluation of drugs influencing immune system., Biochemical estimation of free radical scavengers.

17

8. Biostatistics. & Research methodology- Selection of study groups,Study designs and variables, Blinding, confounding and randomization, Various statistical methods. Methods of collection of data, classifications and graphical representation of data. Binomial and normal probability distribution. Polygon, histogram, measure of central tendency. Significance of statistical methods, probability, degree of freedom, measures of variation - Standard deviation, Standard error. Sampling, sample size and power. Statistical inference and hypothesis. Tests for statistical significance: student t-test, Chi-square test, confidence level, Null hypothesis. Linear regression and correlation. Analysis of Variance (one way and two way). Factorial designs (including fraction factorial design). Theory of probability, Permutation and Combination, Ratios, Percentage and Proportion. Two way ANOVA and Multiple comparison procedures. Non-parametric tests, Experimental design in clinical trials, Statistical quality control, Validation, Optimization techniques and Screening design. Correlation and regression, least square method, significance of coefficient of correlation, nonlinear regression.

10

9.Drug development process: Clinical trials, definition, types of clinical trial, choice of patients, exclusion criteria, inclusion criteria, ethical and legal aspects of clinical trials, methods of randomization, size, documentation monitoring management of clinical trial, clinical trial registry of India, phase 1,phase 11, phase 111 and phase 1V studies, design, safety evaluation, guidelines as per ICMR, WHO and Drugs control authorities, preparation of IND/NDAs, post marketing surveillance of drugs, statistical designs in clinical trials, data analysis techniques and presentation skills **05**

10. Alternatives to screening procedures Cell culture and cell line techniques
Types, sourcing maintenance, propagation and preservation of cell lines, Design and equipment for the cell culture laboratory, quality control considerations. Applications of cell culture and good cell banking practices.

Patch clamp techniques, different in vitro models **05**

11. Drug discovery: strategies and approaches employed in drug discovery, basic concept of combinatorial chemistry, High throughput screening, lead selection & optimization. Insilico systems for assessing toxicity and pharmacokinetics. Docking-a brief description,

05

12. Genomics: Impact of human genome sequence on the discovery of newer pharmacological agents, basic concepts and applications of bioinformatics and proteomics in drug discovery.

05

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MPH.E-II (PAPER-II)

BIOCHEMICAL & MOLECULAR PHARMACOLOGY

3hrs/wk

1. Biochemical mechanisms of cell injury, reactive oxygen species, oxido reductive stress, antioxidant defence mechanisms.

05

2. Biochemical mechanisms of acute and chronic inflammation, apotosis and necrosis, mediators of inflammation.

05

3. Programmed celldeath (Apotosis): physiological and pharmacological implications and therapeutic potentials of apotosis.

4. Endogenous bioactive molecules:

a. **Cytokines and Chemokines**: Classification, physiology, pharmacology, pathological and therapeutic implications of various cytokines and chemokines.

b. **Cell adhesion molecules and Matrix proteins**: Biology of cell adhesion molecules and matrix proteins, their role in various disease processes, and potential target sites to develop newer agents. Glycoproteins11b/IIIa receptor antagonists and anti-integrin therapy.

c.**Growth factors:** Biology and therapeutic potentials of various growth factors.

Pharmacology of Erb B receptors, cardiac and vascular remodeling.

d. **Biology of vascular endothelium**: Biology of EDRF, EDCF, and EDHF, pharmacology of endothelins and nitric oxide. Clinical implications of endothelial dysfunctions.

e. **Neuropeptides**: Biological functions, pharmacological implications, and their antagonists and therapeutic potentials of the following neuropeptides:.Neuropeptide Y Calcitonin gene-related peptide(CGRP), Substance P, Cholecytokinin.

f. **Transport proteins**: Classification and biology of ATP binding cassette (ABC) transport super family. Multidrug resistance (mdr) proteins, Cystic fibrosis trans membrane regulator (CFTR)

g. **Neurosteroids**

h. Arachidonic acid metabolites, cox-2 regulators and their role in inflammation

i. Atrial peptides

j. Oxygen intermediates, antioxidants and their therapeutic implications.

10

5. Chronobiology and Chiral biology: Basic concepts and clinical potentials of chronobiology and chiral configuration.

01

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6. Introduction to pharmacogenetics and pharmacogenomics, chrono pharmacology.

05

7. **Molecular biology:** Cell and its components, plasma membrane its structure and functions, the nucleus, cell growth and division, molecular organisation and behaviour of the genome. Cell motility and excitation, cell differentation. Molecular basis of mutations. Biology and pathophysiology of cancer, diabetes, Thalessemia, cystic fibrosis, Hemophilia & other diseases-Physiological manifestations and symptoms. Cell ageing

06

8. **MOLECULAR GENETICS**: Introduction to genetics, structure of DNA, DNA replication and transcription, enzymes involved in replication, isolation of DNA, RNA, etc. Gene sequencing and mutation.Plymerase Chain Reaction and analysis of DNA sequences.

06

9. **GENE REGULATION AND EXPRESSION:** Regulation of gene activity in prokaryotes and eukaryotes. Principles of regulation, E. coil lactose system, tryptophan operon, autoregulation, feedback inhibition, gene family, gene amplification, regulation of trancsription and processing, translational control, gene rearrangement.

06

10. **TECHNIQUES OF GENE ANALYSIS:** Southern blotting, Northern and Western blotting, gene probes.

05

11. **GENETIC DISORDERS:** Single gene disorders and molecular pathology, molecular genetics and common diseases. autoimmune diseases, cancer, cardiovascular diseases, nervous disorder.

06

12. **GENETIC ENGINEERING:** Introduction, mutagenisis, cutting and rejoining. Polymerase chain reaction Isolation and amplification of genes, gene expression and general introduction to genomics.

05

13. **Genetic recombination:** Transfer of characters, genetic recombination, phage crosses, gene transfer Mechanisms, plasmids, insertion of phage chromosomes, transduction, transformation.

05

14. **Gene cloning:** Cloning vectors, cloning techniques, cloning strategies, cloning of eukaryote gene. Therapeutic protein expression, Transgenic animals, engineered gene expression,second generation protein program design, examples of engineered proteins of therapeutic potential. Applications of recombinant DNA technology.

06

15. **Immunotoxins**: Biology, pharmacology, therapeutic potentials of immunotoxins.

05

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MPH –E-III (PAPER-III) RECENT ADVANCES IN PHARMACOLOGY (3hrs/wk)

1. **Molecular mechanisms of drug action,** Receptor occupancy , drug receptor interaction, forces binding the drug to the receptors, targets for drug binding, kinetics and quantitative aspects of drug receptor interactions, drug antagonism, stereo selectivity of drug action. Cellular signaling systems including G proteins, phosphatidyl inositol cyclic nucleotides, Calcium and calcium binding proteins, phospholipase.

07

2. **Pharmacology of receptors**: Classifications, cellular signaling systems, and pharmacology of agonist and antagonist and modulators of the following receptor types: Excitatory amino acid receptors, Kinin receptors. Purinoreceptors
GABA and benzodiazepine receptors, Neurosteroid receptors
Cannabinoid receptors, Melatonin receptors

Adrenergic receptors, Cholinergic receptors

07

3. **Ion channel and their modulators**: Classification and biology of potassium, calcium, and chloride channels, pharmacology of their modulators.

05

4. **Novel target sites**: Physiological functions, pharmacological implications and therapeutic potential of following target sites:

a) Rho kinase
b) Phosphoinositide 3-kinase
c) Akt (protein kinase)
d) Caspase
e) Poly(ADP-ribose)polymerase(PARP)
f) Peroxisome proliferators activator receptors
g) AMP activated protein kinases
h) Protein kinases
i) Phosphodiesterases

09

5. **Nucleic acid therapies**: Basic concepts and clinical potentials of gene therapy, oligonucleotide therapy, aptamer therapy and ribozyme therapy.

05

6. Stem cell therapeutics: Biology of stem cell and their potentials in various disorders.

05

7. Ethical issues: Ethical issues related to stem cells, human cloning, genetic counseling, foeticide, and surrogated parenthood.

05

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8. Gene therapy- Gene transfer technologies (viral and non-viral vectors), clinical applications of gene therapy, disease targets for gene therapy.
Pharmacokinetics and pharmacodynamics of peptides and protein drugs.
Immunogenecity of protein drugs.

08

9. Immunopharmacology:

a) Basic principles- cells of immune system, specific and non specific immunity, antigens, antigen- antibody binding immunoglobulins, humoral immune response, cellular immune response, control of immune response, complement system
b) Pharmacological aspects of clinical conditions involving immunological mechanisms- Hypersensitivity, delayed hypersensitivity, immunomodulators, current concept in the therapy and research of drugs for AIDS, Tissue transplantation (immunosuppressants and immunoenhancers), cancer, vaccines and sera, anti-fertility drugs and vaccines, drug allergy
c) Immunomodulators of indigenous origin (plants)
d) Fc Receptors: Introduction, structure and function of antibodies, confirmation of antibodies, Fc8R family, Proteins, transcripts and genes: Gene, structure and actions of high affinity. Fc receptor for immunoglobulin E. binding factors. E. Fc – receptor mediated killing. Fc – receptor on T and B lymphocytes, Immunoglobulin binding factors 07

10. Free radicals and therapeutic agents- generation of free radicals, role of free radicals in etiology of various diseases, protective activity of certain important anti-oxidants.

03

11. Nutraceuticals- Concept, regulatory requirements and clinical uses

03

12. Recent developments in chemotherapeutic agents: mechanism of action, mechanism of anti-microbial resistance.

05

13. Anti-sense agents

03

14. Pharmaco-epidemiology and pharmacoeconomics, essential drug list, rational drug use, national drug policy

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PHARMACOLOGY PRACTICALS

12hrs/wk

a) Pharmacological Screening methods and Drug Development:

1. Animal handling and techniques as per CPSCEA guidelines
    i. Breeding data, Housing, Maintenance, Animal feeds
    ii. Study of basic animal techniques, injection og drugs, collection of blood samples, feeding of animals
    iii. Techniques of euthanasia,
    iv. Anaesthesia in animals
    v. Sacrificing animals
2. Evaluation/ Screening of drugs for the following activity. (use different models) Hypnotic activity, Locomotor activity, Anti-psychotic activity, Muscle relaxant activity, Analgesic activity, Anti-inflammatory activity, Anti-convulsant activity, Anti-anxiety activity (Four different models),Anti-parkinsonoan activity, Antidementia- Learning & Memory, Anti-diabetic activity, Diuretic activity, Anti- ulcer, intestinal motility, anti-diarrhoeal activity, Local anaesthetic activity, Anti-histaminic activity, Anti-pyretic activity, Anti-fertility activity.
3. Evaluation of anti-microbial activity & Anti biotic assays
4. Recording of blood pressure and respiration in anaesthetized animals.
5. Any other activity using newer animal models.
6. Preparation of protocol for human experiment/ clinical trials
7. Preparation of 'Informed Consent Form' for human experiments
8. Evaluation of fixed dose combinations and Rational Drug Therapy.

b) Biochemical and Molecular Pharmacology:

1. Anti-oxidant/ free radical scavengers estimation in blood, saliva, tissue homogenates in normal, after drug challenge, and in diseased.
2. Renal function test- nephrotoxic drugs/ diseased
3. Liver function test- hepatotoxic drugs/ diseased
4. Measurements of inflammatory mediators- inflammation and effect of anti-inflammatory drugs
5. Evaluation of anti-inflammatory activity – HRBC method
6. Pharmacokinetic studies:
    i. Bioavailability and Bioequivalent studies.
    ii. Intestinal absorption studies- simple sac method, everted sac method
    iii. Drug metabolism- induction and inhibition studies
    iv. Drug distribution, protein binding studies
    v. Drug excretion studies.
7. Cell cultures preparation and maintenance: Chick embryo fibroblast Lymphocyte culture.

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8. Protein separation and isolation using gel electrophoresis.
9. DNA isolation, sequencing and PCR techniques.
10. Estimation of protein and nucleic acids.
11. RNA isolation from yeast.
12. Mutagenicity testing using mouse bone marrow micronucleus test.
13. *In vitro* cell cultures and toxicity testings
14. *In vitro* cell cultures and drug evaluation for various activities

c) Recent Advances in Pharmacology:

1. Physiological salt solution, preparation, maintenance, modifications
2. Preparation of drug solutions and storage
3. Biological standardization of drugs like Histamine, Acetylcholine, 5 - HT, Oxytocin, DTC
4. Experiments for studying the effects of Histamine,Acetyl Choline, 5HT, adrenaline and noradrenaline alone and in the presence of antagonist on suitable isolated tissue preparations.
5. Cumulative Dose response curve- guinea pig tracheal chain
6. Estimation of PA2 values of various antagonists under suitable isolated tissue preparations
7. Drug potentiation and drug antagonism (competitive & non-competitive) –using isolated tissue preparations
8. Effect of Calcium channel blockers- isolated tissue preparations.
9. Phrenic nerve diaphragm of rat- Effect of drugs on neuro muscular junction
10. Experiments on CVS:
    a. General screening procedure of vasodilators
    b. Effect of various drugs on isolated heart preparations on various animal models under normal, arrhythmic and hypo dynamic conditions.

11 Experiments on toxicology:
    a. Acute toxicity tests.
    b. Determination of LD50, ED50
    c. Subacute and chronic toxicity tests
    d. Gross behavioural studies
    e. Pyrogen testing

12. Record of blood pressure and respiration of anaesthetized animals (dog, rat) and identification of unknown drug based on response.
13. Computer Assisted Learning- Designing programmes for various experiments Computer based illustration and data presentation.

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2.11. No: of hours per subject

As given under "Content of each subject in each year " (clause 2.10)

2.12. Practical training

As given under "Content of each subject in each year "(clause 2.10)

2.13. Records

To be maintained for all Practical Work

2.14. Dissertation:

Standard format of dissertation

a) Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized guide. The results of such a work shall be submitted in the form of a dissertation.

b) Synopsis shall be forwarded to University, for information within 3 months from the starting of 2nd year.

c) The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results
6. Discussion
7. Conclusion
8. Summary
9. References
10. Tables
11. Annexure

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure.

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It should be neatly typed conventional (Times New Roman) font, size 12-point, 10 to 12characters per inch must be used with 1.5 line spacing on one side of the bond paper (A4size, 8.27" x 11.69") All margins should be consistently 25mm in width and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of M. Pharm Part II term.

Change of dissertation topic / guide – rules

The decision regarding change of title/guide shall be taken as per the Institute research committee recommendations and the same can be intimated to the University.

2.15. Speciality training, if any

As per "Teaching, learning methods " and "Content of each subject in each year " above.

2.16. Project work to be done if any

Thesis

1. Every candidate shall carry out work on an assigned research project under the guidance of a recognised Postgraduate Teacher, the result of which shall be written up and submitted in the form of a Thesis.

2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least one month before the examination.

3. The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

2.17. Any other requirements [CME, Paper Publishing etc.]

As per the instruction of HoD of concerned Department

2.18. Prescribed/recommended textbooks for each subject

Compulsory subject

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.

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3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Textbook of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

Specialized subjects

1. Genetics. Of Antibiotics Producing Micro-organisms: GSermonti
2. Principles of Gene Manipulation: RW Old and S B Primrose
3. Genes V and VI: Lewin Benjamin
4. Biochemical Engineering: F CWebb.
5. Biochemical Engineering: R Steel
6. Immunoassays - Daniel W Chan and Marie T Perlstein
7. Pharmaceutical Biotechnology, S. P. Vyas and V. K. Dixit
8. Gene Transfer and Expression Protocols - Methods in molecular biology, Vol VII, E T Murray
9. Current Protocols in Molecular Biology, Vol. I and II: F M Asubel, JohnWiley Publishers
10. Current Protocols in Cellular Biology, Vol. I and II, JohnWiley Publishers
11. Biological Reaction Engineering: I J Dunn, E Heinzle, J Ingham, J E Prenosil
12. The Pharmacological basis of therapeutics – Goodman and Gilman's.
13. Pharmacotherapy – DiPiro.
14. Pharmacology – Katzung.
15. Fundamentals of experimental pharmacology by M.N.Ghosh.
16. Handbook of experimental pharmacology by S.K.Kulkarni.
17. Text book of In vitro practical pharmacology by IanKitchen.
18. Pharmacological experiments on intact preparations by Churchill Livingstone.
19. Hand book of clinical pharmacokinetics- Gibaldi and Prescott.
20. Principles of drug action by Goldstein, Amaow and Kalman.
21. Clinical pharmacology by Molmon and Morrelli.
22. Clinical trials and tribulations by Allen E. Cato.

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23. Drug interactions by Ivan H. Stockley.
24. Text book of therapeutics- drug, disease and management by Herfindal and Gourley
25. Biological standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.
26. Indian Pharmacopoeia and other pharmacopoeias.
27. Screening methods in Pharmacology by Robert Turner, A.
28. Evaluation of drugs activities by Laurence and Bachrach.
29. Methods in Pharmacology by Arnold Schwartz.
30. Selected topics on the Experimental Pharmacology by Usha G. Kamat, Dadkar, N.K and Seth, U.K.
31. Fundamentals of experimental Pharmacology Ghosh, M.N.
32. Pharmacological experiment on intact preparations by Churchill Livingstone.
33. Drug Discovery and Evaluation by Vogel HG.
34. Animal models in toxicology by Shayne Cox Gad and Christopher P. Chengelis.
35. The UFAW Handbook on the care and management of laboratory animals by UFAW.
36. Principles and methods of toxicology by Hayes.
37. CRC Handbook of toxicology by Derelanko and Hollinger
38. Current protocols in molecular biology by Frederick. M. Ausubel.
39. Human molecular genetics by Tomstracham & Andrew P. Read.
40. Bioinformatics: Genes, proteins & Computers by Christine Orengo.
41. The Cell – A molecular approach, Geoffrey M. Cooper.
42. Genetherapy, Therapeutic mechanism and strategies by NancySmyth, Templeton Danilo D. Lasic.

2.19 Reference books

1. 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.
2. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: LittleBrown.Co.
3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
4. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.
5. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.
6. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition,Publisher: Churchill livingstone.

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7. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher:Scientific book agency, Kolkata.
8. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher:Black well Scientific.

2.20. Journals

All Pharmacy and related medical Journals

2.21. Logbook

Registers to be maintained

3. EXAMINATIONS

3.1. Eligibility to appear for exams

a. Attendance, conduct and condonation option:

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M. Pharm Part I examination.

No condonation of attendance is permitted.

b. Internal assessment

Candidates obtaining minimum of 50% marks separately in both theory and practical shall be eligible for appearing in University examination

3.2. Schedule of Regular/Supplementary exams

There will be two examinations one regular and one supplementary in an academic year. The supplementary examinations shall be conducted within 6 months after declaration of results.

3.3. Scheme of examination showing maximum marks and minimum marks

University Examination:

M. Pharm Part I Examination:-

I. Theory:

There shall be 4 theory papers (including compulsory paper) each of 3 hours duration each carrying 100marks.

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II. Practical:

There shall be practical examination for the compulsory subject (MCS-II) of 6 hours duration including viva voce. The marks for the practical examination are out of 100, which are distributed as follows:

Distribution of marks for Compulsory subject (MCS-II) practical examination

Synopsis	20
One Major Experiment	40
One Minor Experiment	25
Basic Spectral Analysis	15
Total	100
Viva Voce	25

The practical examination of the 3 different papers in the specialization subject are to be conducted separately. Duration of the practical examination for the three different papers together is 3×6 hrs = 18hrs, including Viva-voce. Viva voce is also conducted separately for the three papers in specialization subject. The marks distribution is as follows in each paper.

Distribution of marks for specialization subject practical examination

Synopsis	20
Experiment/s	80
Total	100
Viva-voce	25

Distribution of marks and hours for theory and practical examination

Subject	**Theory**				**Practical**					**Total**
	Duration	**Exam**	**Sessional**	**Total**	**Duration**	**Exam**	**Sessional**	**Viva-voce**	**Total**	
Compulsory subject										
Modern Analytical and Research Methods	3hrs	100	50	150	6hrs*	100	25	25	150	300

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Specialization subjects										
Paper I	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper II	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper III	3hrs	100	50	150	6hrs*	100	25	25	150	300
Total										**1200**

*** including viva voce**

Scheme of evaluation

Evaluation system for M. Pharm Part I is Centralized Double valuation by examiners from outside University and within University. The averages of marks of the two examinations are taken as the mark of the theory paper. If the variation in total marks obtained in two valuations is more than 15%, the paper should undergo a third valuation, and the average of aggregate of the nearest two will be counted. M. Pharm Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

No re-evaluation is permitted, only re-totaling can be allowed on request by the candidate.

Criteria for pass & Re- appearance in case of failure

I. M. Pharm Part I Examination:-

i. For passing the university examination, a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination individually and overall aggregate of 50% marks, including Sessional marks in each theory paper and in the case of practical examination including viva-voce and Sessional marks.

ii. If a candidate fails in any of the theory papers or practical papers in the examination of compulsory subject or in the specialization subject, he/she has to appear again in the compulsory subject or in that paper/s of the specialization subjects including the theory and practical as the case may be.

II. M. Pharm Part II Examination:-

(A) Submission of thesis and Distribution of marks:

a. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M. Pharm Part -2

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course. The candidate shall be eligible to submit their thesis only after passing M. Pharm Part-1 examination.

b. Any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year, after discussion in Institutional research committee.

c. The dissertation should be submitted one month in advance to the II year M. Pharm examinations duly signed by the respective guide and the same has to be forwarded to the Controller of Examinations through the Principal of the College.

M. Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Four copies of the thesis duly certified by the supervising teacher shall be submitted to the University one month before by the candidate either in printed or typewritten form through the Head of the institution before the last date prescribed by the University.

The distributions of marks for evaluation of M. Pharm part II dissertation work is as follows:

M. Pharm part II examination is of total marks 500, which has been divided into as shown in the table

Distribution of marks for M. Pharm part II examination

Thesis	300
Oral	100
Seminar	100
Total	500

(B) Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University within an examination center. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with duration of about 30 minutes, which is followed by a viva voce.

(C) Evaluation of thesis and criteria for pass

Any candidate who secures less than 50% of the total marks, he/she has to reappear based on the evaluation report of the examiners, before maximum duration of course (four years)

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3.4 Papers in each year:

S.No.	Code. No	Title
Compulsory Subject		
1.	MCS-I	Modern Analytical and Research Methods
BRANCH E : Pharmacology		
2.	MPH.E-I	Pharmacological Screening methods and Drug Development
3.	MPH.E-II	Biochemical and Molecular Pharmacology
4.	MPH.E-III	Recent Advances in Pharmacology

3.5 Details of theory exams

There shall be 4 theory papers (including compulsory paper) each of three hours duration each carrying 100 marks

3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– September 2014(2011 Scheme)

Modern Analytical and Research Methods (Common for all branches)

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. What are the principles of spin-spin decoupling and describe any three methods. Discuss the factors affecting chemical shift with suitable examples.

2. Explain the principle and instrumentation of gas chromatography. Derive the Beer-Lamberts law and explain its deviations.

Short Essays: **(6 X 10 = 60)**

3. Explain the principle, instrumentation and sample handling techniques in infrared spectroscopy.

4. Discuss the principle and Instrumentation of atomic absorption spectroscopy.

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5. Explain the principle involved in assay of riboflavin, thiamine and quinine by fluorimetry. Mention the transitions involved in fluorescence.

6. Explain briefly about resolution in mass spectrophotometer and MC-Lafferty rearrangement.

7. Compare TLC & HPTLC on the basis of its principle and mention its pharmaceutical applications.

8. Explain briefly about Miller's indices. How will you calculate mean, median, mode and students T-test.

****

QP Code: **Reg No:**

First Year M. Pharm Degree Examinations– September 2014 (2011 Scheme)

(Pharmacology)

Paper I – Pharmacological Screening Methods & clinical evaluation

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1. Explain the general principles of bioassay. Explain the specific basic principle and procedure involved in interpolation and four point bioassays with relevant examples.

2.Discuss in detail the following: Transgenic animal models in the development of new drugs Screening models for drugs used in lzheimer's disease

Short Essays: **(6x10=60)**

3.Explain the basic principle, methods and application of ELISA test

4.Elaborate the acute, sub acute and chronic toxicity evaluation as per OECD guidelines.

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5.Explain the propagation and preservation of cell lines

6.Explain the following: Applications of two way ANOVA in biomedical research Procedure of intra-cerebro-ventricular administration in rats

7.Discuss about CPCSEA guidelines for laboratory animal facility and animal welfare requirements

8.Explain the concepts of high throughput screening, leed identification and leed optimization

QP Code: 106328 **Reg No:**

First Year M. Pharm Degree Examinations– September 2014 (2011 Scheme)

(Pharmacology)

Paper II – Biochemical and Molecular Pharmacology

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1 .Explain in detail the recent methods and treatment modes of genetic disorders

2. Explain the pharmacological and therapeutic applications of cytokines and chemokines

Short Essays: **(6x10=60)**

3.Discuss about arachidonic acid metabolites and their role in inflammation Therapeutic

4.Describe Applications of recombinant DNA technology strength of immune toxins

5.Explain: ATP binding cassette Pathophysiology, manifestations and symptoms of Diabetes mellitus

6.Explain on chronopharmacology and discuss about the influence of genetic factors on drug action

7.Discuss about the transcription of DNA and RNA

8.Explain briefly : Southern blotting EDRF

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QP Code: 107328 **Reg No**

First Year M. Pharm Degree Examinations– September 2014 (2011 Scheme)

(Pharmacology)

Paper III – Recent Advances in Pharmacology

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2x20 =40)**

1.State the physiological functions, pathways and pharmacological activity of protein kinase protein.

2.Which receptors are activated by adrenaline. Explain the signal transduction response of adrenergic receptors. State the pharmacological actions of adrenaline

Short Essays: **(6x10=60)**

3.Explain various force involved in drug receptor interactions with suitable example.

4.Explain the stem cells therapeutic potentials in Parkinson's disease and thalassemia.

5.How free radicals are generated. Name the drugs used as antioxidants and mention its therapeutic uses.

6.What are anti sense agents and mention its therapeutic uses with example

7.Explain the regulatory requirement to market nutraceuticals

8.Describe the various reasons for irrational drug use

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3.7 Internal assessment component

Sessional Examination:

I. Theory:

The Sessional marks for the compulsory subjects and for each specialization subjects are 50; out of which 40 marks are awarded for Sessional examination.10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, confidence in the topic and defense performances.

There shall be minimum 3 Sessional examinations in each of the three papers of specialization M. Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be two evaluation seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

Marks distribution for compulsory and specialization subjects in Theory

Theory	Marks
Written examination	40
Seminar	10
Total	50

II. Practical:

Compulsory subject:

The Sessional marks for the compulsory subject are 25, of which 20 are awarded for daily assessment and 5 marks for practical Sessional examination.

Specialization subjects:

The marks for practical in each paper of the specialization subject are 25. 20 marks are awarded for daily assessment in each paper and 5 marks are awarded for the Sessional practical examination conducted towards the end of the academic year.

Marks distribution for compulsory and specialization subjects in Practical

Practical	Marks
Practical Examination	05
Daily assessment	20
Total	25

The daily assessment is done on the basis of followingcriteria. -Assembly of equipments

- Use of instruments -Manipulative skills -Precision and Accuracy -Cleanliness

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- Interpretation of data and results
- Preparation of protocols, case presentation, case study analysis
- Record maintenance
  (Whichever applies)

3.8 Details of practical/clinical practical exams

Each practical paper shall be of 6 hours duration carrying 100 marks each.

Practical examination shall be conducted to test the knowledge and competence of the candidates for making valid and relevant observations based on the experimental/Laboratory studies and his ability to perform such studies as are relevant to his subject.

3.9 Number of examiners needed (Internal & External) and their qualifications

A post graduate (PG) degree in M. Pharm shall be eligible as teacher.

A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.

A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.

A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

3.10 Details of Viva: Division of marks

M. Pharm Part I Examination

The Oral examination shall be thorough and shall aim at assessing the candidates knowledge and competence about the subject, investigative procedures, technique and other aspects of the speciality, which form a part of the examination.

The Oral examination marks: 25 marks

M. Pharm Part II Examination

Thesis:

The Oral examination marks: 100 marks

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4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.

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REGULATIONS 2016

SYLLABUS

for Courses affiliated to the

Kerala University of Health Sciences

Thrissur 680596

POST GRADUATE COURSE IN

PHARMACY PRACTICE

Course Code:281

(2016-17 Academic year onwards)

2016

2. COURSE CONTENT

2.1 Title of course:

Master of Pharmacy in Pharmacy Practice

2.2 Objectives of course

To generate Pharmacy Post Graduates with profound knowledge in various branches of Pharmaceutical Sciences to meet with the rapidly increasing demands put forward by-

- Pharmaceutical Manufacturing
- Pharmaceutical Research & Development
- Pharmacological research including preclinical & clinical studies.
- Herbal Drug Research
- Pharmaceutical & Herbal Drug Analysis
- Clinical Toxicology & Toxicological Analysis

To discover the potential to become faculty in Pharmaceutical Sciences with unmatched quality and excellence, so as to educate the future pharmacy generation (Undergraduate, Postgraduate, and Doctoral).

2.3 Medium of instruction:

Medium of instruction shall be in English

2.4 Course outline

a) M.Pharm Part – I course of study consists of two subjects namely *one compulsory* and *one optional*

course of study for each branch have been divided into *one compulsory* subject and *three specialization* subjects. The *compulsory subject* consist of two subjects papers – a theory paper and a practical paper.

The *specialization subject* consists of three theory paper (Paper I, Paper II, Paper III) with one practical paper for each respective theory paper.

b) M.Pharm Part – II course of study consists of a thesis written on the basis of regular research work durig the second year by the candidate. A certificate by the supervising teacher (guide) stating that the candidate has worked under him/her during the M.Pharm Part – II course and has satisfactorily conducted the two seminars during the period shall be attached along with the thesis. Certificate from the co-guide, if any, is also necessary.

The candidate shall be eligible to submit their thesis only after passing M.Pharm Part – I examination. Students of Pharmacy Practice have to undergo clerkship programme in various clinical departments during the first 3 months of M.Pharm Part – II.

All M.Pharm Part –II students have to present two seminars relevant to their subject specialization including recent advances before submission of thesis.

2.5 Duration

Duration of the course:

a) The duration of the M.Pharm course shall be of two academic years full time with each academic year spread over a period of not less than 365 working days.
b) The study of M. Pharm course shall be of annual system, which includes M.Pharm (Part-I) extending for 12 months from the commencement of the academic term and M.Pharm (Part-II) of another 12 months duration.
c) At the end of M.Pharm (Part-I) there shall be a university examination of M.Pharm (Part-I). At the end of M.Pharm (Part-II) the candidate shall submit a dissertation on the topic approved by the university.

2.6 Syllabus

As given under "Content of each subject in each year"(clause 2.10)

The concept of health care counselling shall be incorporated in all relevant areas.

2.7 Total number of hours

As in "Content of each subject in each year"(clause 2.10)

2.8 Branches if any, with definition:

As in "Content of each subject in each year"(clause 2.10)

2.9 Teaching-Learning method:

As in "Content of each subject in each year"(clause 2.10)

2.10 Content of each subject in each year

MCS I -MODERN ANALYTICAL AND RESEARCH METHODS

(Compulsory to all branches of M. Pharm course)

THEORY 75hrs [3hrs/week]

1. UV-VISIBLE SPECTROSCOPY 5hrs

Brief review of electromagnetic spectrum, UV-Visible range, energy, wavelength and colour relationship. The chromophore concept, absorption laws and limitations.

Woodward –Fischer rules for calculating absorption maxima. Modern instrumentation - design and working principle. Instrumentation, choice of solvents, application of UV absorption spectroscopy in pharmacy.

2. INFRA RED SPECTROSCOPY **5hrs**

Theory, brief outline of classical IR and FTIR, instrumentation and interpretation of spectra. Sample preparation for spectroscopy. Qualitative interpretation of IR spectra and application in pharmacy. Recent advances in IR spectroscopy, including FT-IR, ATR etc., their instrumentation and application.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY **10hrs**

Fundamental principles of NMR, Chemical shift concept, isotopic nuclei, reference standards, Proton Magnetic spectra and their interpretation. Brief outline of instrumentation. Application of signal splitting and coupling constant data to the interpretation of spectra. Decoupling and shift reagent method. Brief outline of principles of FT-NMR with reference to C^{13} NMR. Nuclear overhauser effect, C^{13} NMR spectra, their presentation, characteristics, interpretation examples and applications.

4. MASS SPECTROSCOPY **12hrs**

Basic principles and brief outline of instrumentation, Ionisation types: Ion formation and types; molecular ion, Meta stable ions, fragmentation processes. Fragmentation patterns and fragmentation characteristics in relation to parent structure and functional groups. Relative abundance of isotopes and their contribution to characteristic peaks. Mass spectrum, its characteristics, presentation and interpretation. Hyphenation of MS with other analytical instruments (LC-MS, GC-MS) and applications in Pharmacy.

5. CHROMATOGRAPHIC TECHNIQUES **9hrs**

Classification of chromatographic methods based on the mechanism of separation; Paper chromatography, techniques and application. Thin layer chromatography, comparison to paper chromatography and HPLC, adsorbents for TLC, preparation techniques, mobile phase selection, reversed phase TLC, High performance TLC, detection methods, quantitative methods in TLC.

6. GAS CHROMATOGRAPHY **4hrs**

Instrumentation, packed open tubular columns, Column efficiency parameters, resolution, liquid stationary phases. Derivatisation methods of GC including acylation, perflouroacylation, alkylation and esterification. Detectors -FID, ECD, TCD, NPD. Examples of GC application in pharmaceutical analysis. Hyphenation of GC with other instruments.

7. LIQUID CHROMATOGRAPHY **4hrs**

Comparison of GC and HPLC. Instrumentation in HPLC; analytical, preparative and microbore columns, normal and reversed phase packing material. Reversed phase HPLC, column selection, and mobile phase selection, efficiency parameters, resolution; detectors in HPLC - refractive index, photometric, electrometric and other detectors. HPLC instrumentation and applications.

8. FLUORIMETRY **3hrs**

Theory; fluorescence and chemical structure, factors affecting fluorescence intensity, Fluorescent immunoassay, Fluorescence polarization immunoassay; Instrumentation and application in pharmacy.

9. X-RAY DIFFRACTION METHODS **3hrs**

Introduction; generation of X-Ray, elementary crystallography, Miller's Indices, X-Ray diffraction, Bragg's law, X-Ray powder diffraction, X-Ray powder diffractometer.

10. ATOMIC ABSORPTION SPECTROPHOTOMETER **2hrs**

Theory and instrumentation, elementary analysis and its application in pharmacy.

11. STATISTICAL ANALYSIS **10hrs**

Introduction, significance of statistical methods, normal distribution, probability, Degree of freedom, standard deviation, correlation, variance, accuracy, precision, Classification of errors, reliability of results, confidence interval, Test for statistical Significance; students T-TEST, F-test, Chi-square test, correlation and regression.

MCS-II – MODERN ANALYTICAL AND RESEARCH METHODS

PRACTICALS [4hrs/week]

1. Use of UV-Visible Spectrometer in the analysis of Pharmacopoeial compounds and their formulation
2. Use of spectroflourimeter in the analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for the analysis of sodium, potassium, calcium and lithium in body fluids.
4. Experiments in chromatography; TLC, Paper chromatography (ascending, descending and circular techniques).
5. Identification of drugs using UV-Visible scanning spectrophotometry.
6. Quantitative analysis using HPLC.

7. Qualitative analysis of drugs using IR Spectrophotometry.
8. Clinical toxicological analysis.

BRANCH F - PHARMACY PRACTICE

MPH- F-I (PAPER – I)

CLINICAL PHARMACY PRACTICE AND HOSPITAL PHARMACY

THEORY (3 hrs/wk) (75 hrs) **Hrs**

1. Definition, development and scope of clinical pharmacy **01**

Role of clinical Pharmacist in the health care system

2. Introduction to daily activities of a clinical pharmacist **06**

Pharmaceutical care: concepts and its implementation.
Ward round participation
Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
Medication history
Drug information and poison information
Adverse drug reaction management
Drug utilization evaluation (DUE) and review (DUR)
Quality assurance of clinical pharmacy services
Therapeutic drug Monitoring (TDM)

3. Patient data analysis **05**

The patient's case history, its structure and use in evaluation of drug therapy. Understanding common medical abbreviations and terminologies used in clinical practices.
Patient Counselling, Compliance, non – compliance, Factors affecting compliance.
Communication: Introduction, Importance of communication skills, Model of communication, Barriers to communication, verbal communication skills, nonverbal communication, patient interviewing and written communication including patient counselling techniques, medication history interview, presentation of cases.

4. Clinical laboratory tests used in the evaluation of disease states and interpretation of Test results **09**

Haematological tests, Liver function, Renal function, Thyroid function tests
Tests associated with cardiac disorders, Fluid and electrolyte balance
Pulmonary Function Tests
Common tests in Urine, sputum, faeces & CSF.
Sensitivity screening for common pathogenic microorganisms: - Its significance, resistance in disease states, and selection of appropriate anti-microbial regimens.

5. Drug & Poison information **06**

Introduction to drug information and Drug Information resources. Poisons information-organization & information resources
Systematic approach in answering DI queries
Critical evaluation of drug information and biomedical literature
Preparation of written and verbal reports Establishing a Drug
Information Centre Drug information bulletin

6. Medication error and medication adherence **03**

Categories and causes of medication error, tools to measure the performance of the medication use process, categories of medication non-adherence.

7. Pharmacoepidemiology **08**

Definitions and scope
Prevalence, incidence, and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.
Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.
Drug utilization review, surveys of drug use, case reports, case series, cross-sectional studies, cohort studies, case control studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system

8. Pharmacoeconomics: **04**

Definition and scope, types of economic evaluation, cost models and cost effectiveness Analysis

9. Concept of essential drugs & rational use of Drugs: **02**

Importance of rational drug use, Drug use indicators, Guidelines for rational prescribing.

10. Pharmacovigilance **05**

Scope, definition and aims of pharmacovigilance

Adverse drug reactions – Classification, mechanism, predisposing factors and causality assessment (different scales used).
Role of clinical pharmacist in Reporting, evaluation, monitoring, prevention and management of ADRs

11. Public health policy: WHO, national & state level **01**

12. Evidence Based Medicine: **02**

Formulating clinical questions, searching for the evidence, Critical appraisal of the evidence. Applying evidence to patients & Evaluation

B. HOSPITAL PHARMACY

1. Drug distribution: **04**

Purchasing, Warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking, drug recalls), Drug distribution methods, Ward Pharmacy, Satellite Pharmacy and Bed side Pharmacy, Specific requirements for inpatients, outpatients, Casualty/Emergency, Operation Theatres, ICU/CCU, Drugs of dependence, Hospital waste management.

2. Hospital drug policy: **05**

Drug Committees, Pharmacy & Therapeutics committee, Pharmacy and Therapeutics Committee: Selection of drugs, Hospital formulary development and management, Assessing drug efficacy, Assessing and managing drug safety, Adverse drug reaction monitoring and management, evaluating the cost of pharmaceuticals, identifying and addressing drug use problems including standard treatment guidelines (STG's). Other hospital committees such as infection control committee, antibiotic policy committee and research & ethics committee.

3. Central Sterile Supply Department: **02**

Central sterile supply unit and their management: Types of materials used for sterilization, Sterilization equipment and techniques, procedures, application of surgical dressings used in OT and other equipments used in Hospital (Cotton, Bandage, Adhesive taps, IV sets, B.G sets, Ryles tube, Catheters, and syringes).

4. Surgical Supplies **01**

An account of surgical dressing like primary would dressings, adsorbents bandages, adhesive tapes, protective, sutures and suture materials (method of preparation are to be avoided).

5. Drug Procurement and Warehousing **01**

Introduction, Procurement procedures for various materials used in Hospitals.

6. Inventory control **02**

Introduction, Objectives & Principles, methods of inventory control, ABC, VED, EOQ, Lead time and safety stock

Organisation of drug store, types of materials stocked, levels of inventory and categorization of stores. Storage conditions & store management.

7. Hospital Manufacturing **05**

Sterile and non-sterile production of pharmaceuticals

8. The Budget – Preparation and implementation **01**

9. Hospital pharmacy management **02**

Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centers, sources of revenue, revenue collection), Policy and planning, Infrastructure requirements (building, furniture and fittings, specialized equipment, maintenance and repairs), Workload statistics

MPH -F-II (PAPER – II)

CLINICAL RESEARCH & COMMUNITY PHARMACY

(THEORY) 3hrs/wk (75 hrs)

A. CLINICAL RESEARCH

1. Introduction to Drug Discovery and drug Development **01**

Drug development process

2.Clinical development of drugs:

Introduction and designing of clinical trials **02**

Various phases of clinical trials **02**

Post Marketing surveillance – methods **02**

Principles of sampling	**01**
Inclusion and exclusion criteria	**01**
Methods of allocation and randomization	**01**
Informed consent process	**01**
Monitoring treatment outcome	**02**
Termination of trial	**01**
Safety monitoring in clinical trials	**02**

3. Documents in clinical study

Investigator Brochure (IB),	**01**
Protocol & Amendment in Protocol,	**01**
Case Report Form (CRF),	**01**
Informed Consent Form (ICF),	**01**
Content of Clinical Trial Report	**01**
Essential Documents in Clinical Trial	**01**

4. Data Management in clinical Research **02**

5. Ethical guidelines in clinical research **07**

History
ICH-GCP & its Principles
Indian GCP (CDSCO Guidelines)
ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects
Schedule Y

6. Roles & Responsibilities of various clinical trial personnel as per ICH GCP **02**

Sponsor
Investigator
Clinical research associate
Clinical research coordinators
Monitor
Auditors
Regulatory authority

7. Institution Ethics Committee / Independent Ethics Committee **01**

8. BA/BE studies: Introduction, Regulatory requirements and methodology **02**

9. Clinical Trial Application in India **03**

10. Investigational New Drug application (IND) **01**

11. Abbreviated New Drug Application (ANDA) **02**

12. New Drug Application (NDA) **01**

B. CLINICAL PHARMACOKINETICS **10**

Normograms and tabulations in designing dosage regimen, conversion from intravenous to oral dosing, determination of dose and dosing interval, drug dosing in the elderly and paediatrics and obese patients.

Pharmacokinetic drug interactions, Inhibition and induction of drug metabolism,
Inhibition of biliary excretion

Therapeutic drug monitoring

Introduction

Individualization of drug dosage regimen (variability – genetic, age and weight, disease, interacting drugs).

Indications for TDM, Protocol for TDM

Pharmacokinetic/Pharmacodynamics correlation in drug therapy

TDM of drugs use in disease conditions like: cardiovascular disease, CNS conditions etc

Dosage adjustment in renal and hepatic disease

Renal impairment

Pharmacokinetic considerations

General approach for dosage adjustment in renal disease

Measurement of glomerular filtration rate and creatinine clearance

Effect of hepatic disease of pharmacokinetics

C. CLINICAL TOXICOLOGY **05**

General principles involved in the management of poisoning

Antidotes and their clinical applications

Supportive care in clinical toxicology

Gut decontamination

Elimination enhancement

Toxicokinetics.

D. COMMUNITY PHARMACY

1. Definition and scope of community pharmacy
   Roles and responsibilities of community pharmacist **01**

2. Prescribed medication order - interpretation and legal requirements. **01**

3. OTC medication-definition, OTC medication list and counselling **04**
   Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrheal preparations)

4. Health education and community pharmacy: Family planning- methods,
   Commonly occurring communicable diseases, causative agents, clinical presentation, and prevention of communicable diseases: Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,syphilis, Gonorrhea and AIDS. **06**

   Smoking cessation, Health screening programs: methods for screening blood pressure/blood sugar/lung function and cholesterol. **02**

5. Community Pharmacy management: Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy. **03**

6. Code of ethics for community pharmacists. **01**

MPH –F-III (PAPER III)

PHARMACOTHERAPEUTICS

THEORY (3 hrs./wk.) (75 hrs)

Pathophysiology and applied therapeutics of diseases associated with following System/diseases with special reference to the drugs of choice.

1. Cardiovascular system **09**
Hypertension, Congestive cardiac failure, Ischaemic heart disease (Angina, Myocardial infarction), Arrhythmias, Hyperlipidaemias, Thromboembolic disorders, Cardiac arrest – resuscitation.

2. Respiratory system **05**
Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases.

3. Renal system **06**
Diuretic therapy, Potassium depletion, Hyperkalemia, Alkalosis, Acute renal failure, Chronic renal failure, Dialysis, Renal replacement therapy, End-stage renal disease, Drug induced renal diseases.

4. Haematological diseases **05**

Blood and body fluids, Complications of blood transfusion and blood substitutes, Anaemia, Deep vein thrombosis Drug induced haematological disorders

5. Endocrine system **05**

Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

6. Nervous system **04**

Epilepsy, Parkinson's disease, Stroke and transient ischaemic attacks, Headache, Migraine.

7. Psychiatric disorders **04**

Schizophrenia, Depression, Anxiety disorders, Sleep disorders.

8. Gastrointestinal system **04**

Peptic Ulcer diseases, inflammatory bowel diseases, Hepatitis, Jaundice, Cirrhosis. Diarrhoea and Constipation.

9. Bone and joint Disorders **04**

Rheumatoid arthritis, osteoarthritis, Systemic lupus erythematosus , gout.

10. Infectious diseases **10**

Guidelines for the rational use of antibiotics and surgical prohylaxis .Meningitis, Respiratory tract infections, Gastroenteritis, Bacterial endocarditis, Septicaemia, Urinary tract infections, Leprosy, Protozoal infections and helmenthiasis, HIV and opportunistic infections, Fungal infections.

11. Skin and sexually transmitted diseases **02**

Psoriasis, Acne, Eczema and scabies, Syphilis, Chancroid, Gonorrhoea. Drug related skin reactions

12. Oncology **05**

Cell cycle, General principles of cancer chemotherapy, commonly used cytotoxic drugs,

Chemotherapy of lung cancer, breast cancer, head and neck cancer, prostate cancer, Cervical cancer, colorectal cancer, haematological malignancies.

Management of chemotherapy associated complications

13. Ophthalmology **01**

Glaucoma, Conjunctivitis-viral and bacterial

14. Pain management **04**

Pathophysiology of inflammation and repair, Pain pathways, Analgesics and NSAIDs, Opiates, Local anaesthetics, Muscle relaxants. Neuralgia(post herpetic, trigeminal and glossopharyngeal neuralgia),.Palliative care,.

15. General Prescribing Guidelines for: - **02**

Paediatric patients.

Geriatric patients.

Pregnancy & Breast feeding.

Antibiotics & parenterals.

MPH –F-IV

PHARMACY PRACTICE PRACTICAL

CLINICAL PHARMACY PRACTICE AND HOSPITAL PHARMACY (Practicals)

(12 hrs/wk)

A. Clinical Pharmacy practice clinical

Patient medication history interview, answering drug information questions, patient medication counseling, participation in ward rounds. Case studies related to laboratory investigations covering the topics dealt in theory class.

1. Answering drug information questions (Any four)
   (Queries related to Dosage, administration, Contraindications, Adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety)
2. Patient medication counseling (Any three) Common diseases like Diabetes, Asthma, Hypertension, TB, and COPD
3. Case studies related to laboratory investigations (Any four) LFT, Hematology, Thyroid, Renal, Cardiac enzymes
4. Patient medication history interview (Any two)
5. Medication order Review (Any five)
6. Detection and assessment of adverse drug reactions and their documentation (Any five)

ASSIGNMENTS

Drug information, Patient medication history interview, Patient medication counseling, Problem solving in Clinical Pharmacokinetics, Literature evaluation pertaining to therapeutic range used in therapeutic monitoring of any two drugs frequently subjected for TDM.

Critical appraisal of two recently published articles in biomedical literatures that deals with drugs or therapeutic issue.

B. Hospital Pharmacy Practicals

Preparation of assignments are required for the below mentioned topics and practical need to be designed based on the assignments as per the availability of pharmaceutical services in hospital

Assignments for Hospital Pharmacy

1. **Drug information services:**

   -You have been asked to establish a drug information center in a 1200 bed teaching hospital. Prepare a written report for the hospital's administration summarizing the resources you will need to do this, including a budget for both initial and ongoing expenditure.

   Provision and Evaluation of Drug Information Services to General Practitioners of your City

   Preparation and familiarization with:

   -list of common allied medical-surgical and laboratory supplies

   -emergency drug list,

   -sound alike and look alike drug list

   -high-risk potential drug list

2. Hospital formulary system:

Select a new drug, which has recently been marketed in India for the first time. Prepare a report for a hospital's Drug and Therapeutics Committee, and make a case either for or against the addition of this new drug on to the hospital's formulary. Issues, which you may need to cover, include the drug's pharmacology, its clinical use, the opinions of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.

3. Hospital pharmacy layout, workflow and range of pharmaceutical services as per the need of hospital:

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- Describe and evaluate the layout and workflow patterns in the dispensary of a local hospital. Include in your report any improvements, which you would recommend to achieve more efficient work practices.
- Drug distribution system:
- Examine and report on the drug distribution methods used in a local hospital.
- Preparation and maintenance of Inventory -Prepare one Inventory for the following

  Drugs and Surgicals, based on ABC and VED Analysis.

  a) Injection ASV
  b) Injection Adrenaline
  c) Injection Deriphylline
  d) Injection Garamycin
  e) Bandage cloth, Vasofix
  f) Disposable Syringes
  g) Antacid tablets
  h) Tablet Erythromycin
  i) Vitamin tablets

4. Store Management practices in Teaching/ District/ local hospitals for the following aspects.

a) Indent preparation.

b) Receipt of Stores

c) Storage

d) Issue

e) Documentation

5. Requisition of biological preparations

- Procurements and storage of vaccine, sera and biological preparations in District Health Office.

6. Drug evaluation services:

- Evaluation of Efficacy of different bronchodilators used in Chronic Obstructive Pulmonary disease (COPD).

7. Educational services to patient:

- Patient Counseling to in-patients suffering from Asthma, hypertension, diabetes, Tuberculosis, peptic ulcer disease, anemia and AIDS

- Development of patient drug information leaflets using readability and layout and design scores.

8. Manufacturing of sterile and non-sterile preparations:

- Preparation and evaluation of any two commonly used transfusions fluids in a Hospital

- Preparation of extemporaneous medication (any two)

9. Quality evaluation of surgical supplies:

- a) Polyglactin 910 (b) Poliglecaprone 25 (c) Polydioxanone (d) Surgical cat gut chromic

- Evaluation of surgical dressings

10. CSSD services:

Sterilization of surgical instruments

CLINICAL RESEARCH AND COMMUNITY PHARMACY (Practicals)

Preparation of assignments are required for the below mentioned topics and practical need to be designed based on the assignments as per the availability of pharmaceutical services in the hospital or community setting.

A. Assignment for Clinical research and clinical pharmacokinetics

1. Toxicological analysis and management
2. Preparation of protocol for different clinical studies.
3. Correspondence procedures for constitution of IRB
4. Designing of informed consent process
5. Clinical data monitoring
6. Designing of CRF
7. Dosage adjustment in geriatrics, pediatrics, hepatic failure, renal failure & heart failure cases

B. Assignments for Community Pharmacy

1. Critical study of two community pharmacies in the neighborhood for schedule M compliance.
2. Comparison of prescription handling in two community pharmacies.

3. Audit of OTC sales over a 24 hour period in a local community pharmacy
4. Role of community pharmacists in health education, family planning, first aid, smoking cessation screening programmes, immunization, etc. Finance and material management in community pharmacies.
5. Critical study of two community pharmacies in large hospitals.
6. Code of ethics for community pharmacies.
7. Summary of the advice and recommendations which should be provided to the following customers at a community pharmacy
    - A 57 year old woman who requests a cough mixture. She has no other associated symptoms, and is being treated for diabetes and hypertension.
    - A young mother requesting an anti-diarrhoeal medication for her 18 month old son
    - A patient with confirmed anaemia who has been advised by their Doctor to take GlobacTM
    - A 25 year old man who wishes to purchase medication for temporary relief of myalgia and fever

9. Prescription analysis in community pharmacy setup
10. Preparation of patient leaf lets for commonly used drugs in community Pharmacy

PHARMACOTHERAPEUTICS (Practical)

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of the cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 15 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in their practical records following SOAP [Subjective, Objective, Assessment, Plan] technique

1. **Cardiology**

a) Arrhythmias, b) Ischaemic heart disease, c) Congestive heart failure, d) Myocardial Infarction, e) Hypertension, f) Thrombo-embolic disease, g) Endocarditis.

2. **Gastroenterology**

a) Diarrhoea, Constipation, b) Acid peptic disease, c) Hepatic diseases - Hepatitis, Cirrhosis & Drug induced hepatic disorders, d) Oesophageal reflux, e) Helicobacter pylori induced gastric disorders.

3. **Rheumatology**

a) Rheumatoid arthritis, b) Gout, c) Systemic lupus erythmatosis.

4. **Respiratory medicine**

a) Asthma, b) Congestive obstructive airways disease (c) respiratory tract infections

5. **Surgery**

a) Prophylactic Antibiotics, b) Anticoagulants - Heparin, Warfarin, c) Thrombolytics, d) Adjunctive therapy, e) Pre-operative medications, f)Analgesia.

6. **Geriatric Medicine**

a) Postural hypotension, b) Dementia & delirium, c) Compliance assessment.

7. **Paediatrics**

a) Acute otitis media, b) Tonsillitis, c) Paediatric asthma, d) Paediatric gastroenteritis, e) Colic, f) Immunisation, g) Attention deficit disorder

8. **Oncology**

a) Breast Cancer, b) Lung cancer - Small cell, Non-small cell, c) Gastric cancer, d) Colon cancer, e) Genitourinary tract cancer - Bladder, Prostate, Testicular, f) Skin cancer, g) Radiation therapy h) Adjunctive therapy - Anti-emetics, Mouth care, Nutrition, Extravasations, Pain control, Blood products, i) Colony stimulating factors, j)Infectious disease in immuno-compromised patients, k) Hypercalcemia l) Cerebral oedema m) Malignant effusions.

9. **Renal**

a) Acute renal failure, b) Chronic renal failure, c) Drug induced renal disease.

10. **Haematology**

a) Leukaemias, b) Lymphomas - Hodgkin's, Non-Hodgkin's, c) Multiple myeloma, d) Anaemia, e) Bleeding disorders.

11. **Infectious Disease**

a) Respiratory tract infections b) Tuberculosis c) Urinary tract infections, d) Joint and borne infections, e) Skin and Soft tissue infections.

12. **Critical Care**

a) Haemodynamic monitoring, b) Parenteral & enteral nutrition, c) Pharmacotherapy of ventilated patients, d) Shock - Septic, Cardiogenic.

13. **Endocrinology**

a) Diabetes, b) Osteoporosis, c) Thyroid disorders, d) Adrenal disorders.

14. **Dermatology**

a) Psoriasis, b) Dermatitis, c) Drug induced skin disorders.

15. a) Convulsive disorder b) Parkinson 's disease, c) Neuro-degenerative disorders, d) Stroke, e) TIAs.

16. **Psychiatry**

a) Uni-polar and bipolar disorders, b) Anxiety, c) Psychosis, d) Alcohol abuse, e) Drug abuse.

17. Ophthalmology

a) Ocular infections, b) Conjunctivitis, c) Glaucoma d) Post-operativemanagement.

ASSIGNMENTS

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of six assignments [1500 – 2000 words] should be submitted in each year for evaluation.

Model Assignments

1. Management of Idiopathic thrombocytic purpura
2. Therapy of Helicobacter pylori infection.
3. Role of oral corticosteroids in Chronic Obstructive Pulmonary Disease
4. Management of Multidrug resistant tuberculosis
5. Use of antiplatelet in the secondary prevention of stroke
6. Secondary failure to oral hypoglycemic agents and its management

2.11. No: of hours per subject

As given under "Content of each subject in each year "(clause 2.10)

2.12. Practical training

As given under "Content of each subject in each year " (clause 2.10)

2.13. Records

To be maintained for all Practical Work

2.14. Dissertation:

Standard format of dissertation

a) Every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized guide. The results of such a work shall be submitted in the form of a dissertation.

b) Synopsis shall be forwarded to University, for information within 3 months from the starting of 2nd year.

c) The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, collection of data, critical analysis, and comparison of results and drawing conclusions

The dissertation should be written under the following headings

1. Introduction
2. Aims or Objectives of study
3. Review of literature
4. Material and Methods
5. Results
6. Discussion
7. Conclusion
8. Summary
9. References
10. Tables
11. Annexure

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed conventional (Times New Roman) font, size 12-point, 10 to 12characters per inch must be used with 1.5 line spacing on one side of the bond paper (A4size, 8.27" x 11.69") All margins should be consistently 25mm in width and bound properly. Spiral binding should be avoided. The dissertation shall be certified by the guide and co-guide if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of M. Pharm Part II term.

Change of dissertation topic / guide – rules

The decision regarding change of title/guide shall be taken as per the Institute research committee recommendations and the same can be intimated to the University.

2.15. Speciality training, if any

As per "Teaching, learning methods " and "Content of each subject in each year " above.

2.16. Project work to be done if any

Thesis

1. Every candidate shall carry out work on an assigned research project under the guidance of a recognised Postgraduate Teacher, the result of which shall be written up and submitted in the form of a Thesis.

2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature. Thesis shall be submitted at least one month before the examination.

3. The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

2.17. Any other requirements [CME, Paper Publishing etc.]

As per the instruction of HoD of concerned Department

2.18. Prescribed/recommended textbooks for each subject

Compulsory subject

1. Spectrophotometry Identification of Organic Compounds by R.M.Silverstein et al.
2. Organic Spectroscopy by William Kemp.
3. Pharmaceutical Analysis Modern methods [Part A, Part B] by James W. Munson.
4. Instrumental Methods of Analysis by Donglas A. Skoog, James J. Leary.
5. Instrumental Methods of Analysis by Willard et al.
6. Application of Absorption Spectroscopy of Organic Compounds by John Dyer.
7. Vogel's Textbook of Quantitative Chemical Analysis.
8. Chromatographic Analysis of Pharmaceuticals by John A. Admovics.
9. Practical Pharmaceutical Chemistry by A.H.Beckett, J.B.Stenlake.
10. Techniques and Practice of Chromatography Raymound P.W.Scott.
11. Quantitative Analysis of Drugs by D.C.Garetth.
12. Quantitative Analysis by Jenkins.
13. Isolation and Identification of Drugs by Clark.
14. Fundamentals of Mathematical Statistics by S.C.Gupta, V.K.Kapoor.

Specialized subjects

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Remington Pharmaceutical Sciences.
5. WHO Guidelines for the procurement of various materials.
6. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002

7. Clinical Pharmacokinetics – concepts and applications Malcom Rowland & Thomas N tozer
8. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel , Prentice Hall Publication
9. Text book of Pharmacy Practice By G. Parthasarathi.
10. Biopharmaceutics and Clinical Pharmacokinetics: - Milo Gibaldi.
11. WHO Guidelines for ICH – GCP.
12. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
13. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia, 1997
14. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone Publication.
15. Pharmacotherapy: A Patho-physiological approach- Joseph T. Dipiro et al. Appleton and Lange.
16. Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
17 Pathologic basis of diseases-Robins SL, W.B.Saunders publication..
18. Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
19. Manual of basis techniques for a health laboratory, 2nd edition, World Health Organization, Geneva
20. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.Green and Harris, Chapman and Hall Publication.
21.Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications
22.Basic principles of clinical research and methodology ,S.K Gupta, Jaypee brothers publications
23.Davidson's Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D. Boucher ELBS with Chu0rchill Living stone. Edinburgh. Latest Edition
24. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
25. Relevant review articles from recent medical and pharmaceutical literature.
26. British Medical Journal.
27. New England Journal of Medicine.
28. Annals of Pharmacotherapy.

29. Lancet.
30. Relevant review articles from recent medical and Pharmaceutical literature.
31. Pharmaceutical Journal. Royal Pharmaceutical Society, London
32. Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia. International Journal of Pharmacy Practice, United Kingdom
33. Indian Journal of Hospital Pharmacy

2.19 Reference books

1. Relevant review articles from recent medical and pharmaceutical literature.
2. Charaka Samhita, Sushrut Samhita, Sharangardhar Samhita, Ayurvedic formulary of India.
3. Pharmacopocial standards for Ayurvedic drugs C.C.A.R.A., New delhi
4. Hospital Pharmacist, U.K.
5. Clinical Pharmacy and therapeutics- Eric Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].
7. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
8. Relevant review articles from recent medical and pharmaceutical literature.
9. British Medical Journal.
10. New England Journal of Medicine.
11. Annals of Pharmacotherapy.
12. Lancet.

2.20. Journals

All Pharmacy and related medical Journals

2.21. Logbook

Registers to be maintained

3. EXAMINATIONS

3.1. Eligibility to appear for exams

a. Attendance, conduct and condonation option:

Candidates who have attended a minimum of 80% of the theory and practical classes separately in each prescribed subject shall be permitted to appear for the M. Pharm Part I examination.

No condonation of attendance is permitted.

b. Internal assessment

Candidates obtaining minimum of 50% marks separately in both theory and practical shall be eligible for appearing in University examination

3.2. Schedule of Regular/Supplementary exams

There will be two examinations one regular and one supplementary in an academic year. The supplementary examinations shall be conducted within 6 months after declaration of results.

3.3. Scheme of examination showing maximum marks and minimum marks

University Examination:

M. Pharm Part I Examination:-

I. Theory:

There shall be 4 theory papers (including compulsory paper) each of 3 hours duration each carrying 100marks.

II. Practical:

There shall be practical examination for the compulsory subject (MCS-II) of 6 hours duration including viva voce. The marks for the practical examination are out of 100, which are distributed as follows:

Distribution of marks for Compulsory subject (MCS-II) practical examination

Synopsis	20
One Major Experiment	40
One Minor Experiment	25
Basic Spectral Analysis	15
Total	100
Viva Voce	25

The practical examination of the 3 different papers in the specialization subject are to be conducted separately. Duration of the practical examination for the three different papers together is 3×6 hrs = 18hrs, including Viva-voce. Viva voce is also conducted separately for the three papers in specialization subject. The marks distribution is as follows in each paper.

Distribution of marks for specialization subject practical examination

Synopsis	20
Experiment/s	80
Total	100
Viva-voce	25

Distribution of marks and hours for theory and practical examination

Subject	Theory				Practical					Total
	Duration	Exam	Sessional	Total	Duration	Exam	Sessional	Viva-voce	Total	
Compulsory subject										
Modern Analytical and Research Methods	3hrs	100	50	150	6hrs*	100	25	25	150	300
Specialization subjects										
Paper I	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper II	3hrs	100	50	150	6hrs*	100	25	25	150	300
Paper III	3hrs	100	50	150	6hrs*	100	25	25	150	300
Total										**1200**

*** including viva voce**

Scheme of evaluation

Evaluation system for M. Pharm Part I is Centralized Double valuation by examiners from outside University and within University. The averages of marks of the two examinations are taken as the mark of the theory paper. If the variation in total marks obtained in two valuations is more than 15%, the paper should undergo a third valuation, and the average of aggregate of the nearest two will be counted. M.

Pharm Part I practical and Oral examination shall be evaluated jointly by the examiners appointed by the University.

No re-evaluation is permitted, only re-totaling can be allowed on request by the candidate.

Criteria for pass & Re- appearance in case of failure

I. M. Pharm Part I Examination:-

i. For passing the university examination, a candidate shall be required to obtain 50% marks in each theory paper and in each practical examination individually and overall aggregate of 50% marks, including Sessional marks in each theory paper and in the case of practical examination including viva-voce and Sessional marks.
ii. If a candidate fails in any of the theory papers or practical papers in the examination of compulsory subject or in the specialization subject, he/she has to appear again in the compulsory subject or in that paper/s of the specialization subjects including the theory and practical as the case may be.

II. M. Pharm Part II Examination:-

(A) Submission of thesis and Distribution of marks:

a. Head of the institution shall forward the list of candidates, names of supervising teachers and the title of the thesis work to the university within three months from the commencement of the M. Pharm Part -2 course. The candidate shall be eligible to submit their thesis only after passing M. Pharm Part-1 examination.
b. Any changes in the dissertation topic, the same has to be informed within 6 months after commencement of 2nd year, after discussion in Institutional research committee.
c. The dissertation should be submitted one month in advance to the II year M. Pharm examinations duly signed by the respective guide and the same has to be forwarded to the Controller of Examinations through the Principal of the College.

M. Pharm Part II Examination consists of evaluation of thesis, seminar on the thesis topic and oral examination. Four copies of the thesis duly certified by the supervising teacher shall be submitted to the University one month before by the candidate either in printed or typewritten form through the Head of the institution before the last date prescribed by the University.

The distributions of marks for evaluation of M. Pharm part II dissertation work is as follows:

M. Pharm part II examination is of total marks 500, which has been divided into as shown in the table

Distribution of marks for M. Pharm part II examination

Thesis	300
Oral	100
Seminar	100
Total	500

(B) Evaluation system:

The thesis, seminar and viva-voce shall be evaluated jointly by one external examiner and one internal examiner appointed by the University within an examination center. The internal examiner shall be the supervising teacher of the candidate. The candidates have to present the dissertation work using audio-visual aids with duration of about 30 minutes, which is followed by a viva voce.

(C) Evaluation of thesis and criteria for pass

Any candidate who secures less than 50% of the total marks, he/she has to reappear based on the evaluation report of the examiners, before maximum duration of course (four years)

3.4 Papers in each year:

S.No.	Code. No	Title
Compulsory Subject		
1.	MCS-I	Modern Analytical and Research Methods
BRANCH F : Pharmacy Practice		
2.	MPH.B-I	Clinical Pharmacy Practice And Hospital Pharmacy
3.	MPH.B-II	Clinical Research & Community Pharmacy
4.	MPH.B-III	Pharmacotherapeutics

3.5 Details of theory exams

There shall be 4 theory papers (including compulsory paper) each of three hours duration each carrying 100 marks

3.6 Model question paper for each subject with question paper pattern

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– September 2014 (2011 Scheme)

Modern Analytical and Research Methods (Common for all branches)

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. What are the principles of spin-spin decoupling and describe any three methods. Discuss the factors affecting chemical shift with suitable examples.

2. Explain the principle and instrumentation of gas chromatography. Derive the Beer-Lamberts law and explain its deviations.

Short Essays: **(6 X 10 = 60)**

3. Explain the principle, instrumentation and sample handling techniques in infrared spectroscopy.

4. Discuss the principle and Instrumentation of atomic absorption spectroscopy.

5. Explain the principle involved in assay of riboflavin, thiamine and quinine by fluorimetry. Mention the transitions involved in fluorescence.

6. Explain briefly about resolution in mass spectrophotometer and MC-Lafferty rearrangement.

7. Compare TLC & HPTLC on the basis of its principle and mention its pharmaceutical applications.

8. Explain briefly about Miller's indices. How will you calculate mean, median, mode and students T-test.

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QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– July 2015 (2011 Scheme)

Paper I – Clinical Pharmacy Practice and Hospital Pharmacy

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. Discuss the clinical laboratory tests used in the evaluation of liver renal disease states and its interpretation of test results.
2. Discuss the various drugs distribution system in the hospital with its advantages and disadvantages

Short Essays: **(6 X 10 = 60)**

3. Discuss the steps in systematic approach in answering DI queries
4. Explain the various categories of medication error with suitable example
5. Discuss the responsibilities of pharmacy and therapeutic committee
6. Classify adverse drug reactions. Discuss the predisposing factors and causality assessment scales used
7. Discuss the various types and barriers in communication
8. Discuss the various types of economic evaluation with suitable examples.

****

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– July 2015 (2011 Scheme)

Paper II – Clinical Research and Community Pharmacy

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. Define the term investigational new drug application. Describe the component and categories of investigational new drug application.
2. Describe the ethical guidelines for biomedical research on human subjects

Short Essays: **(6 X 10 = 60)**

3. Discuss the role of pharmacist in family planning
4. Explain the essential documents for conducting clinical trial and its purpose
5. Describe the role and responsibilities of sponsor in clinical trial as per ICH GCP
6. Discuss in detail on drug dosing in elderly and pediatrics
7. Describe code of ethics for community pharmacist
8. Explain the pharmacokinetic drug interations

****

QP Code: **Reg No:……**

First Year M. Pharm Degree Examinations– July 2015 (2011 Scheme)

Paper III - Pharmacotherapeutics

Time: 3 hrs **Maximum Marks: 100**

Answer all questions

Draw diagrams wherever necessary

Essays: **(2 X 20 = 40)**

1. Explain the pathophysiology, symptoms and pharmacotherapy of diabetes mellitus
2. Discuss the etiology, clinical manifestations and management of chronic renal failure

Short Essays: **(6 X 10 = 60)**

3. Discuss the types and management of epilepsy
4. Explain the clinical manifestation and pharmacotherapy of rheumatoid arthritis
5. Explain the pathogenesis and management of hepatitis
6. Discuss the general prescribing guidelines for pediatric patients
7. Discuss the pharmacotherapy of hyperlipidemia
8. Discuss the pathogenesis of tuberculosis. Add a note on the treatment of tuberculosis.

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3.7 Internal assessment component

Sessional Examination:

I. Theory:

The Sessional marks for the compulsory subjects and for each specialization subjects are 50; out of which 40 marks are awarded for Sessional examination.10 marks are assigned for seminars conducted for each subject. Seminars are evaluated on the basis of coverage of topic, use of audio visual aids, confidence in the topic and defense performances.

There shall be minimum 3 Sessional examinations in each of the three papers of specialization M. Pharm part I during an academic year and aggregate of best two is computed out of 40. There shall be two evaluation seminars in each paper and aggregate of best two performances in seminar is computed out of 10.

Marks distribution for compulsory and specialization subjects in Theory

Theory	Marks
Written examination	40
Seminar	10
Total	50

II. Practical:

Compulsory subject:

The Sessional marks for the compulsory subject are 25, of which 20 are awarded for daily assessment and 5 marks for practical Sessional examination.

Specialization subjects:

The marks for practical in each paper of the specialization subject are 25. 20 marks are awarded for daily assessment in each paper and 5 marks are awarded for the Sessional practical examination conducted towards the end of the academic year.

Marks distribution for compulsory and specialization subjects in Practical

Practical	Marks
Practical Examination	05
Daily assessment	20
Total	25

The daily assessment is done on the basis of followingcriteria. -Assembly of equipments

- Use of instruments -Manipulative skills -Precision and Accuracy -Cleanliness

- Interpretation of data and results
- Preparation of protocols, case presentation, case study analysis
- Record maintenance
  (Whichever applies)

3.8 Details of practical/clinical practical exams

Each practical paper shall be of 6 hours duration carrying 100 marks each.

Practical examination shall be conducted to test the knowledge and competence of the candidates for making valid and relevant observations based on the experimental/Laboratory studies and his ability to perform such studies as are relevant to his subject.

3.9 Number of examiners needed (Internal & External) and their qualifications

A post graduate (PG) degree in M. Pharm shall be eligible as teacher.

A post graduate degree in M. Pharm with 5 years Post PG experience is eligible as internal examiner.

A post graduate degree in M. Pharm with 10 years Post PG is eligible as external examiner.

A post graduate degree in M. Pharm with 5 years Post PG is eligible to guide maximum of 5 candidates for M. Pharm dissertation.

The Thesis shall be examined by a minimum of two examiners; one internal and one external examiner.

3.10 Details of Viva: Division of marks

M. Pharm Part I Examination

The Oral examination shall be thorough and shall aim at assessing the candidates knowledge and competence about the subject, investigative procedures, technique and other aspects of the speciality, which form a part of the examination.

The Oral examination marks: 25 marks

M. Pharm Part II Examination

Thesis:

The Oral examination marks: 100 marks

4. INTERNSHIP

Not applicable

5. ANNEXURES

5.1 Check Lists for Monitoring:

Log Book, Seminar Assessment etc. to be formulated by the curriculum committee of the concerned Institution.