5.1 Microbiological assay

6.0 Statistics

6.1 Methods of collection of data, classification of data, mean, median, mode dispersion and standard deviation.

6.2 Confidence level, null hypothesis, calculation of statistical significance between two means, analysis of variance.

6.3 Association of attributes & contingency, classification of attributes, coefficient of association, Chi Square test.

6.4 Theory of probability, simple probability, laws of probability.

6.5 Correlation and regression, least square method & its application, significance of coefficient of correlation.

6.6 Non-parametric statistics, rank order correlation.

6.7 Calculation of LD_{50}, ED_{50}, probit analysis.

6.8 Application of statistics in pharmaceutical technology, statistical quality control and control of analytical methods.

Practicals: Based on the theory

.....100 Marks

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M.Pharm: CLINICAL RESEARCH
COURSE MODULES

M.Pharm First Year

PAPER I.MODERN ANALYTICAL TECHNIQUES (Theory & Practical)

200 marks

PAPER II. INTRODUCTION TO CLINICAL RESEARCH

100 marks

PAPER III. PRINCIPLES OF CLINICAL RESEARCH

100 marks

PAPER IV. CLINICAL RESEARCH METHODOLOGY-I

100 marks

PAPER V. BIOETHICS IN CLINICAL RESEARCH & DRUG SAFETY IN CLINICAL TRIALS; PHARMACOVIGILANCE

100 marks

PAPER VI. PRACTICALS &WORK SHOPS

200marks

M.Pharm Second Year

Computer (Theory & Practical)	**200 marks**
Thesis	**400 marks**
Viva –voce	**200 marks**

Computers

M.Pharm Part-II A

Computer In Pharmacy
(Common to all branches of M.Pharm.) 100 Marks

Application of computers in pharmaceutical sciences: Stores management & inventory control, production planning, quality control, and product development.

Data processing: System analysis, development & creation of a basis useful in pharmacy practice.

Writing programme in basic for pharmaceutical calculation

Information acquisition & retrieval systems, abstracting devices, drug information systems

Statistics in computing, statistical data analysis, quality control charts using computers

Use of application software like Harward graphics, Nonlin, Windows etc.

Introduction to expert system, medical diagnosis aid systems

Computer modeling & simulation: Application in drug design

Quantitative structure activity relationship (QSAR)

Practicals: Based on theory

100 Marks

5.1 Microbiological assay

6.0 Statistics

6.1 Methods of collection of data, classification of data, mean, median, mode dispersion and standard deviation.

6.2 Confidence level, null hypothesis, calculation of statistical significance between two means, analysis of variance.

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6.8 Application of statistics in pharmaceutical technology, statistical quality control and control of analytical methods.

Practicals: Based on the theory

.....100 Marks

M. Pharm. Part –I, A

Paper -I

Modern Pharmaceutical Analytical Techniques And Statistics

(Common to all branches of M.Pharm.) ....100 Marks

1.1 Principles of separation process, application of such techniques viz. adsorption, partition, paper, gas, thin layer & ion exchange chromatography, counter current distribution & electrophoresis.

2.1 Theoretical basis of working, instrumentation and its applications in pharmaceutical analysis for the following instrumental methods

2.2 (1) Potentiometry
(2) Conductometry
(3) Polarography
(4) Colorimetry
(5) Fluorimetry

3.1 Principles, techniques and applications including interpretation of data of the following;

(1) U.V & IR spectrophotometry
(2) X- Ray diffraction analysis
(3) Thermal analysis
(4) Optical rotation, optical rotatory dispersion and circular dichroism.
(5) Water determination by Karl Fischer.
(6) Gas chromatography
(7) HPLC & HPTLC
(8) NMR
(9) Mass spectrometry

5.1 Microbiological assay

6.0 Statistics

6.1 Methods of collection of data, classification of data, mean, median, mode dispersion and standard deviation.

6.2 Confidence level, null hypothesis, calculation of statistical significance between two means, analysis of variance.

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6.6 Non-parametric statistics, rank order correlation.

6.7 Calculation of LD_{50}, ED_{50}, probit analysis.

6.8 Application of statistics in pharmaceutical technology, statistical quality control and control of analytical methods.

Practicals: Based on the theory

.....

Paper -I

Modern Pharmaceutical Analytical Techniques And Statistics

(Common to all branches of M.Pharm.)

Theory & Practicals.... 200 Marks

1.1 Principles of separation process, application of such techniques viz. adsorption, partition, paper, gas, thin layer & ion exchange chromatography, counter current distribution & electrophoresis.

2.1 Theoretical basis of working, instrumentation and its applications in pharmaceutical analysis for the following instrumental methods

2.2 (1) Potentiometry

(2) Conductometry

(3) Polarography

(4) Colorimetry

(5) Fluorimetry

3.1 Principles, techniques and applications including interpretation of data of the following;

(1) U.V & IR spectrophotometry

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(3) Thermal analysis

(4) Optical rotation, optical rotatory dispersion and circular dichroism.

(5) Water determination by Karl Fischer.

(6) Gas chromatography

(7) HPLC & HPTLC

(8) NMR

(9) Mass spectrometry

4.1 Principles of bioassay

M.Pharm. Part-II A

Computer In Pharmacy

(Common to all branches of M.Pharm.) 100 Marks

Application of computers in pharmaceutical sciences: Stores management & inventory control, production planning, quality control, and product development.

Data processing: System analysis, development & creation of a basis useful in pharmacy practice.

Writing programme in basic for pharmaceutical calculation

Information acquisition & retrieval systems, abstracting devices, drug information systems

Statistics in computing, statistical data analysis, quality control charts using computers

Use of application software like Harward graphics, Nonlin, Windows etc.

Introduction to expert system, medical diagnosis aid systems

Computer modeling & simulation: Application in drug design

Quantitative structure activity relationship (QSAR)

Practicals: Based on theory 100 Marks

(4)

PAPER – II
INTRODUCTION TO CLINICAL RESEARCH

Max. Marks Theory: 100
Theory: 4 hrs / week

1. KEY STAGES IN DRUG DEVOLPMENT

- Introduction to pharmaceutical Industry
- Inventing New Drugs
- Patents
- How Drugs are made
- Chemistry of pharmacy and manufacturing

2. INTRODUCTION TO CLINICAL RESEARCH

- Definition of Clinical Research and Development.
- History of Randomized Trial
- Literature: Finding and Evaluating Databases of Scientific Literature.
- Critiquing of a Research Project.
- Time Management and resource Implications
- Epidemiology
- Experimental Procedures: Controlled Experiments, Sampling techniques.
- Questionnaire Design, Validity and Reliability of Observations, Primary variables, Acquisition and use of secondary data
- Randomization and Blinding: Theory and practice.
- Statistical Planning: Types of data binary categorical continuous.
- Normal distribution; Sampling size and Power

PAPER III. PRINCIPLES OF CLINICAL RESEARCH

Max. Marks Theory: 100
Theory: 4 hrs / week

- Clinical trial process phase I to IV.
- Post-Marketing Surveillance.
- ICH and GCP Guidelines.
- Protocol Designing.
- Case Report Forms.(X-ray, ECG)
- Investigator's Brochure.
- Statistical Designing
- Monitoring
- Data Management
- Report Writing
- Clinical Research Methods.

PAPER IV. CLINICAL RESEARCH METHODOLOGY-I

Max. Marks Theory: 100

Theory: 4 hrs / week

1. **Designing of Clinical Trials**
   - The Elements of trail design sources and bias.
   - Designing a multicenter trial
   - Clinical trial Protocol
   - Elements of Protocol.
   - The main design to be made: Protocol review and sign off.
   - Amendments
2. **Investigator selections**
   - Identifying proper investigators.
   - Site management.
   - Selection criteria.
   - Ste Visits.
   - Meeting with Investigators
   - Review of the Site.
3. **Regulatory requirements for new drugs**
   - Rules and regulations for new drugs
   - Legal basis for the central medicinal products.
   - By regulatory authorities.
   - Regulatory aspects of clinical researches.
   - Regulatory system in India, USA and Europe.

4. **Pharmacovigilance**

- Adverse events
- Laboratory safety data.
- Vital signs and physical findings
- Investigator's brochure.
- Causality assessment
- Breaking the treatment Lind.
- Data safety.
- Monitoring boards.
- Spontaneous reporting.
- Case control studies.
- Cohort studies.
- Prescription event monitoring
- Industry sponsored PMS.

5. **Management of Clinical Research Project**

- Basics of Project management.
- Create a structure and tack network.
- Defining the project objectives.
- Feasibility studies.
- Risk assessment.
- Steps involved in the Project development.
- Developing a breakdown structure.
- Managing the project team.
- Tracking the project and dealing with variance.
- Tracking the management of the project.

6. **Project management in drug development**

- History of project management.
- Project management tools.

- Use of management tools in clinical research.

7. **Project close out**
   - Key stakeholders.
   - How does business strategy influence projects success criteria?
   - Problem solving and decision-making.
   - Managing and controlling change during clinical project.

8. **Audits and Inspections**
   - Elements of a GCP quality system.
   - Clinical quality assurance audit.
   - Types of inspections.
   - Types of audit.
   - Inspections by regulatory authorities.
   - Preparation for audit and inspection.
   - Regulatory requirements.

9. **Clinical trial project outsourcing.**
   - Strategic concepts of outsourcing.
   - Contract out
   - Geographical attractions for outsourcing.
   - Choosing the optional CRO
   - Evaluating time and cost involved.
   - Assessing partnership between managing and CRO
   - The way ahead of outsourcing.

10. **Regulations for biotechnology products and medicinal devices.**
    - Orientation for biotechnology products and requirements.

11. **Communication skills.**
    - Written and spoken English. Presentation in meetings.
    - Designing poster presentation and organizing meetings.

PAPER V. BIOETHICS IN CLINICAL RESEARCH & DRUG SAFETY IN CLINICAL TRIALS; PHARMACOVIGILANCE

Max. Marks Theory: 100

Theory: 4 hrs / week

1. **Bio ethics**
    - Helsinki Declaration.
    - Ethics Committee function.
    - Consent Forms.
    - Investigator's responsibilities.
    - Information sheet.
    - Constitution of the committees.

2. **Role laboratory Investigations in Clinical Research**
    - Need for clinical investigations
    - Hematological data
    - Pathology
    - Urine analysis
    - Collection and preservation of samples
    - Clinical significance
    - Common diseases
    - Masking of samples and drugs
    - Interpretation of results
    -

3. **Pharmacokinetics and drug interactions**
    - Early phase studies
    - Selections of volunteers
    - Design of study
    - Linear and non linear pharmacokinetic
    - Population pharmacokinetics early phase
    - Drug interaction studies

(10)

PAPER –VI
PRACTICALS &WORK SHOPS

Max. Marks : 200

Practicals 8 hrs / week

M. Pharm. Part –I, A

Paper -I

Modern Pharmaceutical Analytical Techniques And Statistics

(Common to all branches of M.Pharm.) ....100 Marks

1.1 Principles of separation process, application of such techniques viz. adsorption, partition, paper, gas, thin layer & ion exchange chromatography, counter current distribution & electrophoresis.

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(5) Water determination by Karl Fischer.
(6) Gas chromatography
(7) HPLC & HPTLC
(8) NMR
(9) Mass spectrometry

M.Pharm. Part-II, B

1. Dissertation of research work to be submitted. 300 Marks

2. Viva-voce [illegible]arks