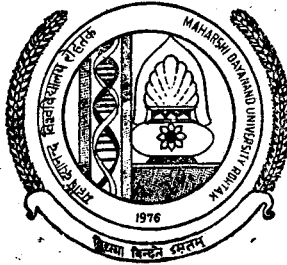


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Maharshi Dayanand University
Rohtak



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Syllabus and Courses of Reading for
B.Pharmacy Part-IV
Examination

Session—1999-2000

Available from :

Deputy Registrar (Publication)
Maharshi Dayanand University
Rohtak-124 001 (Haryana)

Price :

At the Counter : Rs. 50/-
By Regd. Parcel : Rs. 75/-
By Ordinary Post : Rs. 60/-

ORDINANCE : BACHELOR OF PHARMACY

1. The duration of the course of instruction for the degree of Bachelor of Pharmacy shall be four years.
2. A person who shall attain the age of 17 years or more on December 31 of the year of admission and must have passed the following examination shall be eligible to join the first year of Bachelor of Pharmacy Course.

Senior Secondary Examination (10+2) of the Board of School Education Haryana, Bhiwani OR an examination recognised as equivalent thereto by Maharshi Dayanand University, Rohtak with atleast 33% marks in each subject i.e. English, Physics, Chemistry and Biology (Botany and Zoology) in theory and practical separately and 50 % marks in aggregate of these subjects.

3. The examination shall be held in four parts, viz. Part-I at the end of the course of Ist year, Part-II at the end of second year, Part-III at the end of third year and Part-IV at the end of the fourth year.
4. The examination in each part shall ordinarily be held in the month of April or on such other dates as may be fixed by the Vice-Chancellor.
5. A supplementary examination shall be held ordinarily in the month of August/September or on such dates as may be fixed by the Vice-Chancellor for the students who have failed in one or more subject(s) or having been eligible failed to appear in the annual examination.
6. A candidate who has secured atleast 50% marks in the aggregate but has secured less than 50% marks in not more than two subjects (separtely in theory & practical) may be promoted to the next higher class and be permitted to appear at the examination in that subject of the previous year alongwith the examination of the year to which thus promoted. However, for promotion from Part-II to Part-III and Part-III to Part-IV a student shall be required to clear all the subjects of Part-I and Part-II of the course respectively.

(ii)

7. A candidate who fails to pass or fails to qualify for promotion to the next higher class on the result of the supplementary examination shall become ex-student till such period he/she becomes eligible (in subsequent annual/supplementary examination) for admission/promotion to next higher class. However, the number of attempts for appearing in any single subject (theory and practical separately) will not exceed four. If he/she secures pass marks in the higher examination, his/her result for the same shall be declared provisionally subject to his/her passing the lower examination. While re-appearing in the examination, the candidate shall be exempted from re-appearing in paper(s) and or practical(s) in which he has obtained atleast 50% marks. He/she will also retain the sessional marks of the previous examination.
8. 20% marks in each subject (theory and practical separately) will be reserved for internal assessment. In theory, these marks will be based upon the average of marks obtained during two sessional examination conducted during academic year. In case of practical, these marks will be based upon day to day assessment of practical work, viva, attendance and laboratory records etc. However, there will be no sessional practical examination. The conduct of practical sessional examination of B.Pharmacy (old scheme) will henceforth be discontinued w.e.f. B.Pharm-II following promulgation of new ordinance.
9. The candidates must pass the final year examination within seven years of their admission to the 1st year of the course. A candidate who fails to pass the Bachelor Pharmacy Course within a period of seven years of his/her admission to the course shall be deemed to be unfit for the course.
10. The examination shall be open to a person :-
 - (A) Who has passed not less than one academic year previously the requisite examination; and

(iii)

- (B)(i) Who has been on the rolls of the department admitted to the privileges of this University throughout the academic year preceding the examination; and
- (ii) whose name is submitted to the Registrar/ Controller of Examinations by the Head of the Department has most recently attended and produced the following certificate signed by him :-
- (a) of possessing good character;
 - (b) of having remained on the rolls of the Department during the year preceding the examination and of having attended not less than 75% of the full course of lectures delivered in each subject and 75% of the periods assigned to practical work in each subject (the course to be counted upto the last day when the classes break up for the preparatory holidays). However, the Head of the Deptt. may in bonafide cases, condone deficiency in lectures as per University rules.

11. Every candidate shall be examined according to the scheme of examinations and syllabus as approved by the Academic Council from time to time.

12. The amount of examination fee to be paid by a candidate for each part shall be as prescribed by the University :

A candidate who re-appears in one or more paper(s)/ practical(s) for the purpose of passing the theory examination shall pay fee as for the whole examination.

13. The medium of instruction and examination shall be English.

14. The minimum number of marks required to pass the examination shall be as under :-

- i) 50% in theory paper; (including sessional)
- ii) 50% in practicals (including sessional)
- iii) 50% in aggregate.

(iv)

15. The successful candidates shall be classified into three divisions and the division obtained by the candidates will be
 - i) candidates who pass all the four parts of examination obtaining 75% or more marks of the total aggregate shall be declared to have passed with distinction.
 - ii) those who obtain 60% or more of the aggregate number of marks in all the subjects in Part-I, Part-II, Part-III & Part-IV examination taken together shall be placed in the first division.
 - iii) those who obtain 50% or more but less than 60% marks in all subjects in Part-I, Part-II, Part-III & Part-IV examination taken together shall be placed in second division.
16. There will no improvement facilities to Bachelor of Pharmacy students. However, the grace marks will be allowed as per University rules.
17. The students admitted to B. Pharmacy Part-I during Academic Session 1995-96 will be following old syllabus-termed as B.Pharmacy (old scheme) whereas the students admitted during academic Session 1996-97 and afterwards will be following a revised syllabus - termed as B.Pharmacy (New Scheme). The students (admitted to B.Pharmacy-I during 1995-96), if any, detailed during 1995-96 owing to shortage of attendance will also be required to follow syllabi of B.Pharm. (New Scheme).
18. This ordinance also supercedes the earlier ordinance of 'Bachelor of Pharmacy' passed during 130th meeting of Executive Council. Accordingly various classes of new ordinance will henceforth be applicable to all the students admitted during 1995-96 except in case of syllabi.
19. Notwithstanding the integrated nature of the Bachelor of Pharmacy course which is spread over more than one academic year, the Ordinance in force at the time a student joins course shall hold good only for the examination(s) held during or at the end of the academic year and nothing in these Ordinances shall be deemed to debar the University from amending the Ordinances subsequently and the amended Ordinance, if any, shall apply to all students whether old or new.

**B. PHARMACY IV YEAR (New Scheme)
1999-2000**

SCHEME OF EXAMINATION

Paper No.	Course Contents
24.	Pharmaceutics-X (Biopharmaceutics & Pharmacokinetics)
25.	Pharmaceutics-XI (Pharmaceutical Technology)
26.	Pharmacognosy-IV
27.	Pharmacology-III
28.	Pharmaceutics-XII (Pharmaceutical Management)
29.	Pharmaceutics-XIII (Packaging Technology)
30.	Pharmaceutical Chemistry-VIII (Medicinal Chemistry-II)
31.	Pharmaceutical Chemistry-IX (Pharmaceutical Analysis-II)

Courses of Study of B. Pharmacy-IV (N.S).

Subject to be taught	Teaching-load	
	Lectures (Hours/ Week)	Practical (Hours/ Week)
24. Pharmaceutics-X (Biopharmaceutics & Pharmacokinetics)	2	4
25. Pharmaceutics-XI (Pharmaceutical Technology)	3	3
26. Pharmacognosy-IV	2	3
27. Pharmacology-III	2	3
28. Pharmaceutics-XII (Pharmaceutical Management)	2	—
29. Pharmaceutics-XIII (Packaging Technology)	2	—
30. Pharmaceutical Chemistry-VIII (Medicinal Chemistry-II)	2	3
31. Pharmaceutical Chemistry IX (Pharmaceutical Analysis-II)	2	3
	17	19

B. Pharmacy IV (New Scheme)

Subject of Examination	Total Marks for Theory including sessional	Total Marks for Practical including sessional
24. Pharmaceutics-X (Biopharmaceutics & Pharmacokinetics)	100	100
25. Pharmaceutics-XI (Pharmaceutical Technology)	100	100
26. Pharmacognosy-IV	100	100
27. Pharmacology-III	100	100
28. Pharmaceutics-XII (Pharmaceutical Management)	100	—
29. Pharmaceutics-XIII (Packaging Technology)	100	—
30. Pharmaceutical Chemistry-VIII	100	100
31. Pharmaceutical Chemistry-IX (Pharmaceutical Analysis-II)	100	100
	800	600

Scheme of Examination for B. Pharmacy-IV (New Scheme)

Paper No.	Subject	Theory		Practical	
		Duration of Exam. (Hours)	Max. Marks Annual Sessional	Duration of Exam. (Hours)	Max. Marks Annual Sessional
24.	Pharmaceutics-X (Biopharmaceutics & Pharmacokinetics)	3	80 20	6	80 20
25.	Pharmaceutics-XI (Pharmaceutical Technology)	3	80 20	6	80 20
26.	Pharmacognosy-IV	3	80 20	4	80 20
27.	Pharmacology-III	3	80 20	6	80 20
28.	Pharmaceutics-XII (Pharmaceutical Management)	3	80 20	—	—
29.	Pharmaceutics-XIII (Packaging Technology)	3	80 20	—	—
30.	Pharmaceutical Chemistry-VIII (Medicinal Chemistry-II)	3	80 20	6	80 20
31.	Pharmaceutical Chemistry-IX (Pharmaceutical Analysis-II)	3	80 20	6	80 20

**B. PHARMACY IV (NS)
PHARMACEUTICS-X
(Biopharmaceutics and Pharmacokinetics)**

Theory

1. Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting.
2. Biopharmaceutics :
 - 2.1 Passage of drug across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis).
 - 2.2 Factors influencing absorption-Physiochemical physiological and pharmaceutical.
 - 2.3 Drug distribution in the body, plasma protein binding.
3. Pharmacokinetics.
 - 3.1 Significance of plasma drug concentration measurement.
 - 3.2 Compartmental model : Definition and scope.
 - 3.3 Pharmacokinetics of drugs absorption-zero order and first order absorption rate constant using Wagner Nelson and Loo-Riegelman method.
 - 3.4 Volume of distribution and distribution co-efficient.
 - 3.5 Compartment kinetics-one compartment and two compartment models. Determination of Pharmacokinetics parameters from plasma and urine data after drug administration by intravascular and oral route.
 - 3.6 Curve fitting (method of Residuals), regression procedures.
 - 3.7 Clearance concept, Mechanism of renal clearance, clearance ratio, determination of renal clearance.
 - 3.8 Hepatic elimination of drugs, first pass effect, Extraction ratio. hepatic clearance, biliary excretion, Enterohepatic circulation.
 - 3.9 Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration, Michaelis Menten Equation, detection of non-linearity (Saturation mechanism).
4. Clinical pharmacokinetics :
 - 4.1 Definition and Scope.
 - 4.2 Dosage adjustment in patients with and without renal and hepatic failure.

- 4.3 Dosage regimen adjustment for repeated therapy.
- 4.4 Introduction to Pharmacokinetics drug interactions and its significance in combination therapy.
- 5 Bioavailability and bioequivalence :
 - 5.1 Measures of bioavailability : C_{max} , t_{max} and Area Under Curve (AUC).
 - 5.2 Design of single dose, bio-equivalence study and relevant statistics.
 - 5.3 Overview of regulatory equipments for conduction of bio-equivalence study.

Practicals

A sufficient number of experiments based on aforementioned theory topics should be conducted.

PHARMACEUTICS-XI **(Pharmaceutical Technology)**

THEORY

1. **Tablets** : types of tablets, formulation of tablets, various granulation techniques including slugging, chilsonator, extractor, Day-Nauta granulator, double cone granulator, spray granulator. Tableting machinery for production of single layer, multilayer and compression coated tablets.
Physics of tablet making strain gauze, measurement of applied and transmitted pressure, distribution of forces during compression, effect of applied pressure on relative volume and factors affecting strength of tablet.
Tablet coating—sugar coating, film coating and compression coating, coating processes i.e. air suspension coating and pan coating (using conventional, rear, vented and perforated pans). Quality control of tablets.
2. **Capsules**—advantages, applications, formulation, large scale production and quality control of hard and soft capsules.
3. **Microencapsulation**—terminology, advantages and applications. Various processes for microencapsulation i.e. coacervation phase separation, multiorifide centrifuge, electrostatic deposition, vacuum deposition, spray-drying spray congealing, polymerization, complex emulsion and pan coating.

4. **Aerosols** definitions, advantages and applications, liquified-gas systems, compressed gas systems, propellants, containers, valves, cold-filling process, pressure filling process and quality control of aerosols.
5. **Parenterals**—types of parenteral products, formulation, containers, pyrogens, production facilities, production procedures for small volume and large volume parenterals, large scale production of injectable grade water and quality control of parenterals.
6. **Radiopharmaceuticals**--Fundamentals of Radiopharmacy, therapeutic applications of isotopes, diagnostic applications of isotopes, Use of radioisotopes in basic reasearch, product development, product production, process control and quality control.

Practicals : Number of experiments based on aforementioned theory and including the following : —

1. Microencapsulation by coacervation phase separation brought about by change of temperature.
2. Microencapsulation by coacervation phase separation brought about by addition of nonsolvent.
3. Formulation, preparation and evaluation of Paediatric tablets.
4. Preparation and evaluation of aspirin tablets.
5. Coating of tablets.
6. Evaluation of coatings.
7. Granulation by slugging.
8. Determination of BA and M/G factor.
9. Formulation of hard capsules.
10. Quality control of soft and hard capsules.
11. Preparation of small volume parenterals.
12. Test for pyrogen.
13. Preparation and evaluation of large volume parenteral.
14. Formulation, preparation and evaluation of aerosol.
15. Microencapsulation by complex emulsion method.

PHARMACOGNOSY—IV**Theory**

1. Role of medicinal and aromatic plants in national economy.
2. World-wide trade in medicinal plants and derived products with special reference to diosgenin (dioscorea) taxol(taxus sps), digitals, tropance, alkaloid containing plants, papain, cinchona, ipecac, liquorice, ginseng, Aloe vera, valerian, rauwolfia and plants containing laxatives.
3. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India, Utilization and production of phytoconstituents of poppy, ergot, cinchona, ipecac, tropance alkaloids, vinca, aloes, senna, ispaghula, digitalis, dioscorea and Solanum Khasianum.
4. Utilization of aromatic plants and derived products with special reference to menthol, citral, sandalwood oil, vetiver oil, geronium oil, eucalyptus oil, and vetiver oil.
5. Historical development of plant tissue culture, types of cultures, nutritional requirements, growth and their maintenance Applications of plant tissue culture in pharmacognosy.
6. Chemotaxonomy of medicinal plants.
7. Marine pharmacognosy, novel medicinal agents from marine sources.
8. Natural allergens and photosensitizing agents.

Practicals : Number of experiments based on aforementioned theory portion and including the following :—

- i) Isolation of some selected phytoconstituents studied in theory.
- ii) Extraction of volatile oils and their chromatographic profiles.
- iii) Some experiments in plant tissue culture.

PHARMACOLOGY—III**Theory**

1. Drugs Acting on the Gastrointestinal Tract ;
 - a) Antacids, Antisecretory and Anti-ulcer Drugs.
 - b) Laxatives and antidiarrhoeal drugs.

- c) Appetite Stimulants and Supressants.
 - d) Emetics and anti-emetics.
 - e) Miscellaneous : Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.
2. **Pharmacology of Endocrine System :**
- a) Hypothalamic and pituitary hormones.
 - b) Thyroid hormones and antithyroid drugs, parathormone calcitonin and Vitamin-D.
 - c) Insulin, Oral hypoglycemic agents & glucagon.
 - d) ACTH and corticosteroids.
 - e) Androgens and anabolic steroids.
 - f) Drugs acting on the uterus.
3. **Chemotherapy**
- a) General principles of chemotherapy.
 - b) Sulphonamides and co-trimoxazole.
 - c) Antibiotics, Pancilines, Cehalosporins.
Batalactams, Tetracyclines, Aminoglycosides, Chloramphenical, Erythormycin, Quinolones and Miscellaneous Anti-biotics.
 - d) Chemotherapy of tuberculosis, Laprosy, fungal Diseases, Virul diseases, urinary tract infections and sexually transmitted diseases.
 - e) Chemathery of malignancy and Immunosuppressive Agents.
4. **Principles of Toxicology :**
- a) Definition of Posion, general principles of treatment of poisoning with particular reference to barbiturates opids, organophosphorus and atropine poisoning.
 - b) Heavy metals and heavy metal antagonisirs.
5. Introduction to Clinical Pharmacy.
6. **Basic concepts of Pharmacotherapy.**
- a) **Clinical Pharmacokinetics and individualisation of Drug Therapy.**

- b) Drug Delivery systems and their Biopharmaceutic and Therapeutic considerations.
 - c) Drug use during Infancy and in the Elderly (Paediatrics & Geriatrics).
 - d) Drug use during Pregnancy.
 - e) Drug induced Diseases.
 - f) The Basics of Drug Interactions.
 - g) General Principles of Clinical Toxicology.
 - h) Interpretation of Clinical Laboratory Tests.
7. Important Disorders of Organ Systems and Their Management : —
- a) Cardiovascular Disorders : Hypertension, congestive Heart Failure, Angina, Acute Myocardial Infarction, Cardiac Arrhythmias.
 - b) CNS Disorders ; Epilepsy, Parkinsonism, Schizophrenia, Depressions.
 - c) Respiratory Diseases ; Asthma.
 - d) Gastrointestinal Disorders : Peptic Ulcer Disease, Ulcerative colities, Hepatitis, Cirrhosis.
 - e) Endocrine Disorders : Diabetes Mellitus and Thyroid Disorders.
 - f) Infections Diseases : Tuberculosis, Urinary Tract Infection, Enteric Infections, Upper Respiratory Infections
 - g) Hematopoietic Disorders : Anemias.
 - h) Joint and Connective Tissue Disorders : Rheumatic Diseases gout and Hyperurricemia.
 - i) Neoplastic Diseases : Acute Leukaemias, Hodgkin's Diseases and Carcinoma of Breast.
8. Therapeutic Drug Monitoring.
9. Concept of Essential drugs and Rational Drug Use.

Practicals :

- 1. Experiments on Isolated Preparations :
 - a) To calculate the PA_2 value of atropine using acetylcholine as an agonist on rat ileum preparation.
 - b) To calculate the PA_3 value of mepyramine or chlorpheniramine using histamine as agonist on guinea pig ileum.

- c) To find out the strength of the given sample on agonist (e.g. Acetylcholine, Histamine, 5-HT, Oxytocin etc.) using a suitable isolated muscle preparation by—
 - Matching Assay
 - Two point Assay
 - Three point Assay
2. Pharmacology of the Gastrointestinal Tract :
 - a) To study the Anti-Secretory and anti-ulcer activity using pylorus ligated rats.
3. Clinical Pharmacology :

To demonstrate the effects of certain clinically useful drugs on human volunteers like:—

 - a) Anti-histaminics.
 - b) Anti-anxiety and sedative drugs.
 - c) Analgesics.
 - d) Betablockers.

PHARMACEUTICS-XII

(Pharmaceutical Management)

Theory :

1. Pre-requisites : (Basic Information Services)

Concept of Management

Administrative Management (Planning, Organising, Staffing, Directing and Controlling).

Operative Management (Personnel, Material, Production, Financial, Marketing, Time/Space, Margin/Morale.

Principles of Management (Co-ordination, Communication, Motivation, Decision-making, leadership, Innovation, Creativity, Delegation of Authority/Responsibility, Record keeping).

Identification of key points to give maximum thrust for development and perfection.

2. Accountancy :

Principles of Accountancy, ledger posting and book entries, preparation of trial balance, columns of a cash book, Bank reconciliation statement, rectification of errors, profits and loss account, balance sheet, purchase, keeping and pricing of stocks, treatment of cheques, bills of exchange, promissory notes and hundies, documentary bills.

3. Economics :

Principles of Economics with special reference to the laws of demand and supply, demand schedule, demand curves, labour welfare, general principles of insurance and inland & foreign trade, procedure of exporting and importing goods.

4. Pharmaceutical Marketing :

Functions buying, selling, transportation, storage, finance, feedback, information. channels of distribution, wholesale, retail, departmental store, multiple shop and mail order business.

5. Salesmanship :

Principles of sales promotion, advertising, ethics of sales, merchandising, literature, detailing,

6. Market Research :

Recruitment, training, evaluation, compensation to the pharmacist.

7. Material Management :

A brief exposure of the basic principles of material management, purchase, store and inventory management,

8. Production Management :

A brief exposure of the different aspects of production management (Visible and Invisible inputs, Methodology of Activities, performance evaluation, Technique, Process-Flow, Process know-how.)

9. Personnel Management :

Eligibility, Efficiency, Evaluation, Recruitment Methodology Service conditions, Termination, Performance Evaluation etc.

**PHARMACEUTICS-XIII
(Packaging Technology)**

Theory

- 1. Introduction :** Definition, Life history of a package, qualities of the package, purpose of packaging, choosing the form of package, hazards encountered by the package, various types of inner and outer packages, selection of a suitable package and child resistant packages.

2. **Packaging Materials** : Detailed study with regard to composition, packaging characteristics, advantages, economics and limitations of various packaging materials with special emphasis on glass, plastics, metals and rubber. Evaluation of packaging materials.
3. **Strip packing** : Significance of Strip packing, advantages, economics and limitations of strip packing, strip packing machinery, films employed in strips packing (including composites and laminates) and evaluation of films and strips packs.
4. **Blister Packaging** : Blister packaging materials, significance of Blister packing, advantages, economics and limitations of blister packing, blister packing machinery, various types of blister packages, evaluation of blister package.
5. **Pouch Packaging** : Materials used, advantages, economics and limitations of pouch packing, pouch packing machinery, spectrum of applications, evaluation of pouch packing.
6. **Liquid Formulation packaging** : Various containers/closures employed for liquid formulations terminology involved, machinery employed for liquid filling, bottle washing, bottle drying & sealing, evaluation of liquid formulation packages.
7. **Semi-Solid Packaging** : Various types of containers/packages used for semi-solid products, filling & sealing machinery (including collapsible tube filling & sealing machine) merits and limitations of various packages, evaluation of semi-solid product package.
8. **Sterile Product Packaging** : Various types of containers used for sterile products like ampoule, vials, bottles for I.V. fluid etc. Types of closures used for the sterile products, sterile products filling & sealing machinery i.e. ampoule filling & sealing machine. Limitations and merits of various packages, evaluation of the sterile product packages.
9. **Packaging of Surgicals** : Types of packages for sterile and non-sterile surgical dressings and allied products, machinery & technology involved, evaluation of packages.
10. **Labelling** : Labelling requirements, packaging inserts and machinery employed for labelling.

PHARMACEUTICAL CHEMISTRY-VIII
(Medicinal Chemistry-II)

Theory

Synthetic procedures of selected drugs, mode of action, uses structure activity relationship including physio-chemical properties of the following classes of drugs :

1. Drugs acting on the Central Nervous System
General Anesthetics, Local anesthetics, Hypnotics and sedative opioid analgesics, antitussives, Anticonvulsants, Antiparkinsonian drugs, CNS stimulants, psychopharmacological agents (neuroleptics, antidepressants, anxiolytics).
2. Drugs Metabolism and concepts in prodrug.
3. Synthetic procedures of selected drugs, mode of action, uses, structure activity relationship including physiochemical aspects of the following classes of drugs should be covered. (Biochemical approaches in drugs designing wherever applicable should be discussed.)

Antimetabolites (including sulphonamides):

Chemotherapeutic agents used in protozoal, parasitic and other infections ;

Antiviral agents including anti HIV; and Immunosuppressive agents.

4. Amino Acids, proteins and peptide hormones;
 - a. Thyroid and Antithyroid drugs.
 - b. Insulin and oral hypoglycemic agents.
5. Diagnostic agents.
6. Pharmaceutical Aids.

Practical

Note of enforcement based in the aforementioned theory portion and including the following :—

1. Experiments designed on drug metabolism.
 - a. Preparation of S-9 and microsomes from tissue homogenates and standardisation of protein.

- b. Effects of phenobarbital pretreatment on microsomal cytochrome P-450, cytochrome b5, and NADPH-cytochrome C-reductase and comparison of microsomes from Control.
 - c. Determination of microsomal aminopyrine demethylase and p-nitroanisole o-demethylase activity.
 - d. Determination of microsomal azo and nitroreductase activities.
2. Submission of pilot project (Work-up on all pilot scale) alongwith the economics of one drug.
 3. Synthetics of selected drugs.
 4. Establishment of the pharmacopeial standard and spectral studies.

PHARMACEUTICAL CHEMISTRY-IX

(Pharmaceutical Analysis-II)

Theory

A. Quality Assurance :

- i) Philosophy of GLP, ISO-9000, TQM, quality Review and Quality Documentation.
- ii) Regulatory Aspects :
Legislation & Regulatory Control, Regulatory Drug Analysis, Interpretation of Analytical Data.
- iii) Validation/Quality Audit
Quality of equipment,
Validation of equipment,
Validation of Analytical procedures.

B. The theoretical aspects, basic instrumentation, elements of interpretation of spectra and applications of the following analytical techniques should be discussed :

1. Ultraviolet and visible spectrophotometry.
2. Fluorimetry.
3. Infrared spectrophotometry.
4. Nuclear magnetic Resonance Spectroscopy including ^{13}C NMR.

5. Mass Spectroscopy.
6. Flame Photometry
7. Emission Spectroscopy.
8. Atomic Absorption Spectroscopy.
9. X-ray Diffraction.
10. Radioimmunoassay.

Practicals—Number of experiments based on aforementioned theory portion and including the following :

1. Using official procedure involving instrumental techniques, carry out the quantitative estimation of atleast ten formulations containing single drug or more than one drug.
2. Using flame photometry, carry out the estimation of Na^+ , K^+ , Ca^{2+} ions.
3. Carry out the IR of samples having different functional groups ($-\text{COOH}$; $-\text{COOR}$, $\text{CONHR}-1^\circ$, 2° , 3° ; $-\text{NH}_2$, $-\text{NHR}$, $-\text{OH}$, etc.
4. Workshop to interpret the structure of sample organic compounds using UV, IR, NMR and MS.