VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part I

O. Pharm II – A

A candidate for the degree of Master of Pharmacy must have taken the degree of B.Pharm. of this University or any other University recognized by this University and have passed the M.Pharm. Part-I and M. Pharm. Part-II Examinations after keeping terms as laid down, that is one year for each, and have completed the courses as laid down in the relevant regulations.

Registration as post graduate student is essential, within one month of his /her admission to this course. In the registration, candidate must specify the subjects and papers of study for M.Pharm.

O. Pharm II – B

A candidate who has failed in any head of passing at M.Pharm. Part-I Examination (theory & Practical are considered as separate heads) will not be allowed to pursue courses for M.Pharm. Part-II.

O. Pharm II – C

M.Pharm. Part-I and M.Pharm. Part-II examinations will be held twice a year.

O. Pharm II – D

Candidates for the M.Pharm. Part-I Examination shall be examined after they have satisfactorily completed the prescribed courses of study and have kept one year in the institution recognized for the purpose under the recognized post graduate teachers in the following subjects:

SCHEME FOR EXAMINATION OF M.PHARM PART-I

SUB. CODE	SUBJECT	TOTAL MARKS FOR THEORY			TOTAL MARKS FOR PRACTICAL		
		INTER-NAL	EXTERNAL	TOTAL	INTERNAL	EXTER-NAL	TOTAL
100	MODERN ANALYTICAL TECHNIQUE (COMPULSORY)	30	70	100	40	60	100
200	ADVANCES IN PHARMACEUTICAL SCIENCES PAPER-I (COMPULSORY)	30	70	100	-	-	-

AND SUBJECT OF SPECIALIZATION							
400	PHARMACEUTICS & PHARMACEUTICAL TECHNOLOGY SPECIALIZATION						
411	PHARMACEUTICAL FORMULATION DEVELOPMENT & BIOPHARMACEUTICS	30	70	100	40	60	100
412	INDUSTRIAL PHARMACY	30	70	100	-	-	-
OR							
500	PHARMACEUTICAL CHEMISTRY SPECIALIZATION						
511	ADVANCED ORGANIC CHEMISTRY	30	70	100	40	60	100
512	CHEMISTRY OF NATURAL PRODUCTS	30	70	100	-	-	-
OR							
600	PHARMACOLOGY SPECIALIZATION						
611	ADVANCED SYSTEMIC PHARMACOLOGY	30	70	100	40	60	100
612	CELLULAR AND MOLECULAR PHARMACOLOGY	30	70	100	-	-	-
OR							
700	PHARMACOGNOSY SPECIALIZATION						
711	CHEMISTRY OF MEDICINAL NATURAL PRODUCTS	30	70	100	40	60	100
712	BIOTECHNOLOGY AND CULTIVATION OF MEDICINAL PLANTS	30	70	100	-	-	-
OR							
800	QUALITY ASSURANCE SPECIALIZATION						
811	BIOLOGICAL ECALUATION, CLINIC RESEARCH AND NDA	30	70	100	40	60	100
812	GOOD MANUFACTURING AND GOOD LABORATORY PRACTICE AND QUALITY AUDIT	30	70	100	-	-	-

N.B. Written examination in each paper shall be three hours duration while each practical examination shall be of six hours duration.

O. Pharm II – E

Every candidate for the M.Pharm. Part-II Examination shall be required to have passed the M.Pharm. Part-I Examination of this University and have completed the courses as laid down in the relevant regulations.

O. Pharm II – F

Every candidate presenting himself/herself for the M.Pharm. Part-II Examination for the first time is required to submit three type /computer written copies of a dissertation, forwarded by the Principal of the recognized institution to the University Office, containing the results of his/her own study of the investigation, carried out at the recognized institution, under the supervision and guidance of a recognized University Post-Graduate teacher in the subject.

The dissertation is to be submitted after completion of M.Pharm. Part-II and after the presentation of Seminar on Dissertation (423, 523, 623, 723 or 823)

The Dissertation Examination (423, 523, 623, 723 or 823) is to be conducted by the examiners appointed for the purpose by the University, during University Examinations.

O. Pharm II – G

A candidate who has registered for the M.Pharm. Degree Examination shall be allowed to change the subject of specialization. Such a change must be done only in the beginning of the study for the M.Pharm. Part-I course. Fresh registration and keeping of fresh terms are required.

O. Pharm II – H

Once a new application being forwarded and fresh fee paid a candidate who has already passed the M.Pharm. Degree Examination, may present himself again for the examination in the Subject of Specialization, not offered by him. Fresh registration and keeping of fresh terms are required.

R. Pharm XI

90 hours of teaching (including seminars) for each theory paper and 180 hours of laboratory works for each practical is essential. Regular records of both theory and practical class work, conducted at a recognized institution, imparting training for this course, shall be maintained for each student and must be submitted to the University before the commencement of M.Pharm. Part-I Examination.

R. Pharm XII

The syllabus laid down for various papers and practical of M.Pharm. Part-I Examination is as under.

R. Pharm XII

To pass an examination, candidate must obtain at least 40% of the marks in theory and in practical separately and in addition, must obtain at least 50% of the total marks assigned to the whole M.Pharm. Part-I Examination.

No class shall be awarded to the successful candidate at the M.Pharm. Part-I Examination.

R. Pharm XIV

Candidates for the M.Pharm. Part-II Examination shall be examined after they have satisfactorily completed the prescribed courses of study and have kept one year in an institution recognized for the purpose under the recognized post graduate teachers, in the following subjects:

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part I

100 MODERN ANALYTICAL TECHNIQUES (Compulsory Subject)
THEORY

1. Basic principle, applications and recent trends in chromatography.
    a. GC
    b. HPLC
    c. HPTLC
    d. Ion exchange chromatography
    e. Ion pair chromatography
    f. Size exclusion chromatography
    g. Affinity chromatography
    h. Electro kinetic chromatography
2. Theory of UV, IR, Derivative spectroscopy. FTIR, NIR, ATR and their applications in structural elucidation.
3. Theory and instrumentation of NMR, Pulse NMR and CM,. their application in structural elucidation
4. Basic principle and application of mass spectrometry.
5. Radio and Enzyme immunoassay, Quality control of radio pharmaceuticals.
6. Atomic Spectrometry.
7. Thermal method of analysis.
8. Basic principles, classification, instrumentation and application of LASER.
9. Reference standards-source, preparation, characterization, usage, storage and records.
10. Electrophoresis.
11. Water determination.
12. General principle, instrumentation and application of optical rotatory dispersion (ORD) and circular dichroism.

100 MODERN ANALYTICAL TECHNIQUE (Compulsory Subject)
PRACTICAL

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

REFERENCES

1. Munson Janues W. “Pharmaceutical Analysis” Marcel Dekker.
2. Willard “Instrumental Method of Analysis” CBS publication
3. Skoog “Principles of Instrumental Analysis”- Thomson.
4. Kenneth A. Conors “A textbook of Pharmaceutical Analysis, - John Wiley & sons.
5. Robert M. Silverstein, “Spectrometric identification of organic compound”
6. B.K.Sharma Instrumental methods of chemical analysis, Goel Publication, 23rd edition.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part I

200 ADVANCES IN PHARMACEUTICAL SCIENCES (Compulsory Subject) THEORY

1. Pharmacokinetic approach to New Drug Discovery.
2. Basic concepts and Definition, Importance of ADME parameters in disposition therapeutics and development - their implications in drug discovery.
3. Overview on Computer Aided Drug Design (CADD) including QSAR, QSPR, Combinatorial Chemistry, High Throughput Screening (HTS)
4. Molecular Basis of Drug Action
5. Drug Latentiation
6. Basic concept, Prodrugs- functional groups, Bioprecurssor prodrugs Chemical Delivery System.
7. Biotechnology in Drug Discovery:
8. Cloning of DNA, Expression of cloned DNA, Manipulation of DNA sequence information, New Biological Targets for Drug Development, Novel Drug Screening Strategies, Novel Biological Agents, Antibodies, Antisense oligonucleotide Therapy, Gene Therapy
9. Herbal Neutraceutical as a new source for medicines
10. Study of Advanced Drugs From Natural Sources of following groups:
11. Anticancer, AntiAIDS, Hepatoprotectives, Antidiabetics, Antiarthritic, Adoptogenic, Cardiotonics, Antipyretics, Antimalarials, diuretics, Hypnotics, Braintonics, Urolithiatics, Antifilarial, Antihyperlipidamics,
12. Recent trends in the study of authentic and controversial drugs of above mentioned groups
13. Modern Photochemical Screening Techniques and Evaluation of Herbal drugs, their extracts and formulations- Concept of reverse Pharmacognosy
14. Natural Insecticides and Pesticides.
15. General animal models for screening of drugs. Ethics and techniques in animal handling & sampling protocols.

References

1. Wilson and Giswold's -Textbook of Organic Medicinal and Pharmaceutical Chemistry , Ed.Jaime N Delgado and W.A. Remers, Lippincott-Raven Inc NewYork.
2. Burger's Medicinal Chemistry and Drug Discovery, Ed.Manfred E. Wolff, John Wiley Sons Inc. New York.
3. Comprehensive Medicinal Chemistry, Vol-4, Ed. C. Hansch, Pergamon press. New York
4. Comprehensive Biotechnology, Ed. Murray Moo-Young, Pergamon press, New York.

5. National Center for Biotechnology information publications (www.ncbi.nlm.nih.gov)
6. Dewick Paul M. “Medicinal Natural Products-A Biosynthetic Approach”
7. Chakravarty T. K. "Herbal Options".
8. Progress in Controlled & Novel Drug Delivery Systems by N.K.Jain, CBS Publisher, New Delhi.
9. Drug Discovery & Evaluation by H.Gerhard Vogel.
10. Pharmacokinetics by Milo Gibaldi, Marcel Dekker Inc.
11. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
12. The practical evaluation of Phytopharmaceuticals by Brain and Turner.
13. Computer added drug design by T.J.Perun & C.L.Propst, Maarcel Dekker Inc.
14. Novel Drug Delivery Systems by Y.W.Chien, Marcel Dekker Inc.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part-I

400 PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY
Specialization Paper – I

411 Pharmaceutical Formulation Development & Biopharmaceutics (Theory)

1. **Preformulation Studies**
   a. Physical, chemical and Pharmaceutical factors influencing formulation.
   b. Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties and etc.,
   c. Crystalline and polymorphism and its evaluation. Rational for selecting the preferred polymorph/crystalline form.
   d. General Principal and applications of Differential thermal analysis, Differential scanning colorimetery, X- Ray Diffraction, FT-IR in preformulation study.
   e. Drug-expient compatibility study.
   f. Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents)
2. **Solubilization and solubilized system**
   a. Theoretical aspects and applications.
   b. Techniques for improvement in drug solubilization for development of various dosage forms.
3. **Dissolution study**
   a. Importance, objectives, equipments,
   b. Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
   c. Selection of dissolution medium and conditions,
   d. Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent method.
4. **Stability study**
   a. Basic concept and objectives of stability study,
   b. Order of reaction and their application in predicting shelf life and half-life of pharmaceutical formulations,
   c. Importance of accelerated stability study,
   d. Effect of various environmental/processing factors (i.e. light, pH, metal etc.,) on stability of the formulation and techniques for stabilization of products against the same,
   e. Regulatory requirement related to stability testing with emphasis on matrixing/bracketing technique, climatic zone, impurities in stability study, photo stability testing etc.,
   f. Application of micricalorimetry in stability study

5. **Drug Absorption**
   Factor affecting drug absorption; i.e. physicochemical, physiological and pharmaceutical.
   Method of studying bioavailability and bioequivalence.
   Transport across CACO 2 monolayers-Biological, Pharmaceutical and Analytical considerations.

6. **Pharmacokinetic parameters**
   a. Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.
   b. Analysis of blood and urine data. Compartment models, kinetics of one and two compartment model.

7. **In-vitro In vivo Correlation (IVIVC)**
   c. Method of establishing IVIVC
   d. Factor effecting IVIVC

8. **Cosmetic and dental products**
   Formulation and evaluation of various cosmetic and dental products.

Reference:

1. Pharmaceutics "The Science of Dosage form design" **by Aulton.**
2. Encyclopedia of Pharmaceutical technology-volume: 1 to 19.
3. **Remingtons** "Pharmaceutical Sciences"
4. **Lachman** "The theory and Practice of industrial Pharmacy"
5. Pharmaceutical dispensing **by Husa.**
6. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
7. Stability of drug and dosage forms **by Yoskioka.**
8. Pharmaceutical dissolution testing **by Banaker.**
9. United States Pharmacopoeia.
10. Applied Biopharmaceutics and pharmacokinetics, **by Leon Shargel**,
11. Pharmacokinetic **by Welling and Tse.**
12. Pharmacokinetics **by Gibaldi and Perrier.**
13. Modern pharmaceutics **by G.S.Banker.**
14. Clinical pharmacokinetics, concepts and application **by Rowland and Tozer.**
15. Biopharmaceutics and pharmacokinetics-An introduction **by Notari.**
16. Pharmacokinetics for pharmaceutical scientist **by John Wagner.**
17. Techniques of Solubilization of Drug **by Yalkowsky.**
18. Novel Cosmetic Drug Delivery System **by Magdassi and Touitou.**
19. Cosmetics **by Sagarin.**
20. Perfumes, Cosmetics and Soaps **by Poucher.**
21. Dissolution, Bioavailability and Bioequivalence **by Abdul.**

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part I

PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY Specialization
Paper-I
Practicals

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part I

400 PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY
Specialization Paper-II

412 Industrial Pharmacy
(Theory only)

1. Preparation of Qualitative and quantitative departmental lay out with equipments required for different dosage forms-solids, liquids, semi solids, sterile.
2. Detailed study of the equipments required in the manufacture of different dosage forms as per schedule-M.
3. Pharmaceutical factory location: Selection, layout and planning, utility service-service facilities and personnel facilities.
4. Pilot plants, scale up techniques.
5. GMP and its application.
6. Production planning and controls.
7. Preparation of documents like batch manufacturing record, batch packing record, validation protocols,
8. Preparation of standard operative procedure (SOPs) for equipments, manufacturing or processing steps.

Reference:

1. **Lachman** "The theory and Practice of industrial Pharmacy" 3rd edition.
2. **Remingtons** "Pharmaceutical Sciences".
3. **Bentley's** Pharmaceutics.
4. Pilot plants model and scale-up methods, by **Johnstone and Thring.**
5. GMP practices for pharmaceutical-**James Swarbrick**.
6. How to practice GMPs **by P.P.Sharma**.
7. Chemical engineering plant design **by Vibrant**.
8. Pharmaceutical process validation **by Loftus and Nash.**
9. Drug and cosmetic act 1940.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M Pharm Part I

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION
Paper-I

511 Advanced Organic Chemistry-theory

1. Chemical Bonding and Structure.
2. Chemical bonding, Bond energies, Orbital theory, Orbital Hybridization, Resonance, Electronegetivity, Polarity, Hyperconjugation.
3. Chemical Reactivity and Molecular Structure.
4. Kinetics, Resonance, Steric, inductive and electrostatic effect on reactivity, acids and bases.
5. Various Reaction mechanisms
    a. Substitution Reaction: Nucleophilic substitution reaction in aliphatic systems-S_N1, S_N2. S, Hydride transfer reaction, Cram's rule, Participation of neighboring group in nucleophilic substitution-reactions and rearrangements. Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, Reactivity and orientation in electrophilic substitution.
    b. Elimination Reaction: Beta elimination reactions, E1,E2, & E1cb,Mechanisms, Hoffman and Saytzeff's elimination.
    c. Addition Reactions: Nucleophilic additions, Markonikov's rule.
    d. Rearrangement reactions: Transannular rearrangements, Pinacol and related rearrangements, Beckman rearrangements, Hoffman rearrangements.
    e. Free radical reactions: Formation – Detection – Reactions, Homolysis and free radical displacements – additions and rearrangements of free radicals.
6. Reactions of carboxylic acids and esters,BAC2, AAc2, BAL2, BAL1, AAL1. Claisen condensation , decarboxylation, carbanions, enolisation, keto-enol equilibria.
7. Stereochemistry, Molecular asymmetry, compounds with one, two or more unequal asymmetric carbon atoms, racemic modifications, Configurations-absolute, relative, synthesis of optically active compounds-cyclohexane, six membered heterocyclic rings-stereoisomerism of compounds with asymmetric plane – allenes and related compounds – stereoselective synthesis.
8. Study of individual reactions-allylic rearrangement-Amdt Eister synthesis, Baeyer-Villiger reaction-Baker-venkatraman reaction-benzidine rearrangement-benzilic acid rearrangement-Buchner method of ring enlargement-Carrol reaction

-Curtius rearrangement-Dimorth rearrangement-Fries rearrangement- Lossen Schmidt rearrangement-Pinner reaction-Reformatsky reaction-Robinson-Annelation reaction-Witting reaction-Diels-Alder reaction.

9. Use of diazonium salt-diazomethane and peracids in sysnthesis.
10. Y-lides of phosphorus-sulphur-nitrogen
11. Photochemistry: Theory-energy transfer-characteristics of photoreactios- typical photo reactions.
12. Concerted pericyclic reactions – electrocyclic reactions – sigmatropic rearrangements-cycloaddition reaction

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. Pharm Part I

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION Paper-I
(Practical)
(Advanced Organic Chemistry)

Laboratory examination including oral and practical examination in general course illustrative of theoretical section in the syllabus.

REFERENCES:

1. Gould-Mechanism and structure in Organic Chemistry.
2. Sykes- A Guidebook to Mechanism in Organic Chemistry.
3. March- Advanced Organic Chemistry Reaction Mechanism and Structure.
4. Eliel- Stereochemistry of Carbon Compounds.
5. Alexander- Principles of Ionic Organic Reactions.
6. Surrey- Reactions in Organic Chemistry
7. Hendrickson- Organic Chemistry
8. Carey F.A.- Advanced Organic Chemistry Part-A.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. Pharm Part I

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION Paper-II
(Theory only)

512 Chemistry of Natural Products

1. Carbohydrates: Disaccharides – determination of structures – sucrose-maltose-lactode-polysachharides-cellulose-starch-introduction to lignin-pectin-peptic substances.
2. Amino acids & polypeptides: Introduction-classification-synthesis of amino acids-poly peptides synthesis.
3. Synthesis of naturally occurring proteins-structure of polypeptides –amino and Carboxyl end degradation-protein classification-composition-structure-chemistry of oxytocin-insulin-andiotensin-peptides of medicinal importance.
4. Alkaloids: General methods of degradation and structure determination-study of constituents of atropine-Introduction-general nature-synthesis-structure of anthocyanidin-flavones-isoflavons-depsides.
5. Purines and nucleic acids.
6. Heterocyclic chemistry ; Introduction-nomenclature-properties-synthesis and reactions involved in five member and six member heterocyclic. Heterocyclic with one,two of more hetero atoms, biological importance of heterocyclics.

REFERENCES:

1. Finar – Organic Chemistry Vol 1 & 2.
2. Fieser and Fieser – Steroids
3. Gilman – Organic chemistry.
4. Fleming – Selected Organic synthesis.
5. Nakanishi – Natural Product Chemistry – Vol 1 and 2.
6. Palmer – Structure and Reaction of Heterocyclic Compounds.
7. Acheson – Introduction to Chemistry of Heterocyclic Compounds.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm Part-I

600 Pharmacology Specialization Paper-I Theory

611 Advanced Systemic Pharmacology

Pharmacology of the following

1. Parasympathomimetics
2. Parasympathetic blocking agents
3. Sympathomimetics
4. Sympathetic blocking agents
5. Ganglion stimulants & blockers
6. Neuromuscular stimulants & blockers
7. General & local Anaesthetics
8. Sedatives & Hypnotics
9. Antiepileptic
10. Psychopharmacological agents
11. Analgesics
12. Anti-inflammatory agents
13. Drugs used in Alzeimer's disease
14. Drugs used in Migraine
15. Antiparkinson's drugs
16. CNS stimulants
17. Cardiotonics
18. Antihypertensive drugs
19. Antiarrhythmic drugs
20. Drugs used in Ischaemic heart disease
21. Drugs used in Atherosclerosis
22. Diuretics
23. Drugs used in Gastro intestinal disorders
24. Drugs used in Respiratory disorder
25. Drugs used in Urino-Genital disorders
26. Drugs used in Endocrine disorders

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm Part-I

600 Pharmacology Specialization Paper-I Practical

(611 Advanced Systemic Pharmacology)

1. Calculation of PA_2, PD_2, PD'_2, values using isolated tissue.
2. Preparations – Rat Fundus strip, Rat Uterus, Guinea pig Tracheal chain, Rabbit Aortic strip, Ileum preparations, Mammalian heart etc.
3. Simple Bioavailability studies
4. Bioassays of Autonomic drugs & Autacoids
5. Exercises in Molecular Pharmacology

References:

1. Pharmacokinetics by: Milo Gibaldi & Donald Perrier
2. Biopharmaceutics & Pharmacokinetics, An introduction by E. Notary
3. Drug metabolism by Berhard Testa & Peter Jenner
4. Principles of drug action by Goldstein, Aranow & Kalman
5. International & National Journal

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm Part-I

600 Pharmacology Specialization Paper-II (Theory)

612 Cellular & Molecular Pharmacology

1. Molecular structure of Biological membrane & transport mechanism across cell membrane
2. Factors influencing drug absorption
3. Drug distribution- Protein binding, Tissue binding- Blood Brain Barrier, Placental barrier, Volume of distribution
4. Biotransformation of drugs- Microsomal, Non microsomal metabolism, Factors influencing, Enzyme induction & inhibition, Pharmacogenetics
5. Drug excretion- Renal & Non renal, Factors influencing Renal clearance, Biological half life
6. Pharmacokinetics- Single & multiple dose therapy, Single & multiple compartment models, Bioavalibility
7. Theories of drug receptors & drug receptor interactions
8. Drug antagonism
9. Cellular molecular basis of drug action
10. Neurotransmitters & Neuropeptides in CNS disorders
11. Electro physiology of heart- Pathophysiology of cardiac disorders
12. Molecular structure & Functions of ion channels
13. Physiology of renal functions- Electrolyte metabolism, Acid base equilibrium, Renin Angiotensin system
14. Vitamins
15. Haematinics
16. Gene expression & Regulation, Gene Cloning & Pharmacogenetics.
17. Autacoids
18. Immnopharmacology

References :

1. Clinical Pharmacology By D.R Lawrence & P.N Bennett
2. Pharmacology & Pharmacotherapeutics By R.S Satoskar & S.D Bhandarkar
3. The Pharmacology Basis Of Therapeutics, 10th Edition By Louis S Goodman & Alfred Gillman
4. Pharmacology By H.P. Rang & M.M.Dale

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. PHARM Part-1

700 PHARMACOGNOSY SPECIALIZATION PAPER-I (Theory)

711 Chemistry of Medicinal Natural Products

1. Classification of medicinally active constitutes general methods of isolation, purification and production of natural products: Alkaloids, Glycosides, Tannins, Volatile oils. Fixed oils, Steroids.
2. General chemical tests to identify them and their quantitative determination.
3. Study of different biogenetic pathways of therapeutically important active constitutes.
4. Study of sources, isolation, estimation, biosynthesis, structure elucidation, stereochemistry, therapeutic and economic importance of following pharmaceuticals:
   a. Atropine, colchicines, Ergometrine, Vincristrine, Camptothecin.
   b. Diosgenin, Sennosides, Glycyrhetinic acid, Guggul lipid, Rutin, Psoralen, Xanthotoxin, Digoxin
   c. Menthol, Thymol, Citral, Taxol
   d. Podophyllotoxin
   e. Penicillin, Streptomycin, Griseofulvin
   f. Echimic acid, Ginkolide, Silymarin, Picroside, Artemisin, Gymnemic acid

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. PHARM Part-1

700 PHARMACOGNOSY SPECIALIZATION PAPER-I (Practical)

711 Chemistry of Medicinal Natural Products

Laboratory examination including oral and practical examination in general course illustrative of theory section in syllabus

References:

1. Manske- The Alkaloid-Chemistry and physiology
2. Sim- Medicinal plant Glycosides.
3. Sim- Medicinal plant Alkaloids
4. IUPAC- Chemistry of Natural products-International symposium
5. Zechmeister-Progress in the chemistry of Organic natural products
6. Reinhold- Liwschitz- Progress in phytochemistry
7. Wagner-Wolf- New natural products and plant Drugs with Pharmacological, Biological or Therapeutic activity
8. Finar- Organic chemistry
9. Peach-tracey- Modern methods of Plant Analysis
10. Geissman- Modern methods of Plant Analysis
11. Garatt- The Quantitative Analysis of Drugs
12. Backett-Stenlake- Practical Pharmaceutical chemistry
13. Arthur- Symposium on Phytochemistry
14. Pridham- Swain- Biosynthetic pathways in higher Plants
15. Greenbury- Metabolic pathways
16. Margaret-Brain- Secondary Plant Metabolism
17. Wagner-Horhammer- Pharmacognosy and phytochemistry
18. Harborne- Comparative Biochemistry of Flavonoids
19. Lehninger- Principles of Biochemistry
20. Bonner- Plant Biochemistry
21. Harborne- Phytochemical methods
22. Rosenthaler- The chemical investigation of the plants
23. Cheronis- Organic function group analysis
24. Nakanishi- Natural product chemistry, Vol.I & Vol.II

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M.Pharm.

M. PHARM Part-1

700 PHARMACOGNOSY SPECIALIZATION PAPER-II (Theory only)

712 Biotechnology and cultivation of medicinal plants

1. Medicinal plants biotechnology
2. Principles of plant genetics, genetic factors affecting plants and their constituents.
3. Plant growth regulators and factors affecting cultivation of the medicinal plants
4. Production of medicinal plants as raw materials and importance of Ergot, Ispaghula, Senna, Digitalis, Glycyrrhiza, Dioscorea, Mentha, Cardamom, Cinnamon, Aloe, Sandalwood, Pinus, Ginger, Shatavari, Musli, Taxus Baccata, Ginseng, Majith, Guggul, Artemisia

References:

1. Ramstad- Modern Pharmacognosy
2. Herskowitz- Principles of genetics
3. Stricknerger- Genetics
4. Hess- Plant physiology
5. William- Genetical principles and plant breeding
6. Kruse- Patterson- Tissue culture- Methods and applications
7. Bartz- Reinhard- Zenk- Plant tissue culture and its biotechnical applications
8. John- Dodds- Lorin- Experiments in plant tissue culture
9. Handa S.S and Kaul, K.L.- Suppliment to cultivation and utilization of medicinal plants
10. Gamborg, O.L. an Wetter, L.R.- Plant tissue culture methods, National research council of Canada, Saskatchewan
11. H.E.Street- Plant tissue and cell culture, Blackwell Scientific publication
12. P.Prave, U. Faust, W. sttig and D.A. Sukatsch, Fundamentals of Biotechnology, V.C.H. Publishers
13. Alan T. Bull, Howarb Dalton, and Murray Mao- Young – Comprehensive biotechnology, " The principles, application and regulation of biotechnology in industry, agriculture and medicine" Vol. 1 to 4
14. Pruthi J.S.- Major species of India
15. CSIR – Cultivation and utilization of medicinal plants
16. CSIR- Wealth of India, raw materials

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. Pharma Part-I

800 Quality Assurance Specialization Paper I
Theory

811 Pharmaceutical Quality Assurance- Biological Evaluations, Clinical Research and NDA

1. Calibration of Equipment & Instruments
2. Analytical Method Development & its Validation
3. Development of Monograph
4. Biological Standardization: General Principles, Scope & limitations of Bioassays. Bio- assays of some Official Drugs
5. Sterility Tests: Methodology & Interpretation
6. Pyrogens: Production, Chemistry Properties of Bacterial Pyrogens & endotoxins, official Pyrogen tests
7. Preclinical Drug Evaluation, acute, sub acute & Chronic toxicity studies, LD_{50} & ED_{50} determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity & mutagenicity.
8. Drug Stability: Solution stability, solid stability, parameters for physical stability testing programme, accelerated stability studies shelf assignment.
9. Approval of New drugs: Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.
10. Clinical Research—Clinical Research Protocols, objective & protocol design, Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs & dosage forms, reviews & approval of Clinical Study, Good Clinical Practices.
11. Pharmacokinetic & Bioequivalence study. Requirement criteria for Bioequivalence study.

Quality Assurance Specialization Paper I

Practical

811 Pharmaceutical Quality Assurance- Biological Evaluation, Clinical Research and NDA

Laboratory Examination including oral & practical examination in general course illustrative of theory section in syllabus.

BOOKS RECOMENDED

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry
5. Michael E. Swartz, Analytical method development & validation.
6. S.Suzanne Nielsen, “Introduction to the Chemical analysis of foods”.
7. D.C.Garratt “The quantitative analysis of drugs” 2nd edition.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. Pharma Part-I

800 Quality Assurance Specialization Paper II (Theory only)

812 Pharmaceutical Quality Assurances- QA, GMP, GLP

1. Concepts of Philosophy of QA, GMP, GLP
2. Good Manufacturing Practices:
   a. Organization & Personnel, responsibilities, training, hygiene.
   b. Premises: Location, design, Plant Layout, Construction, Maintenance & Sanitation, Environmental control, utilities & services like gas, water, maintenance of sterile areas, and control of contamination.
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP)
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials & finished dosage forms.
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes & facilities.
   f. In Process quality controls on various dosage forms: Sterile & non sterile , standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc
   g. Packaging & labeling control, Line clearance, reconciliation of labels, cartons & other packaging materials.
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation & storage, quality control documents, retention samples, records, audits of quality control facilities.
   i. Finished product release, quality review, quality audits and batch release documents.
   j. Warehousing, design, construction, maintenance & sanitation; good warehousing practice, materials & management.
   k. Distribution & distribution records, handling of returned goods, recovered materials & reprocessing.
   l. Complaints & recalls, evaluation of complaints, recall procedures, related records & documents.
   m. Waste disposal, scrap disposal procedures & records.
3. Good Laboratory Practices.
4. Quality Assurance Standards.
5. WHO certification.
6. Testing of Packaging materials.
7. Quality Audit.
8. Specifications for materials, intermediates & finished product.

References:

1. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
5. P.P.Sharma “How to practice GMPs”, 3rd edition Vandana Publi.
6. P.P.Sharma “How to practice GLP” Vandana Publi.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part II

R. Pharm XII

To pass an examination, candidate must obtain at least 40% of the marks in theory and in practical separately and in addition, must obtain at least 50% of the total marks assigned to the whole M.Pharm. Part-I Examination.

No class shall be awarded to the successful candidate at the M.Pharm. Part-I Examination.

R. Pharm XIV

Candidates for the M.Pharm. Part-II Examination shall be examined after they have satisfactorily completed the prescribed courses of study and have kept one year in an institution recognized for the purpose under the recognized post graduate teachers, in the following subjects:

SCHEME FOR EXAMINATION OF M.PHARM. PART-II

SUB. CODE	SUBJECT	TOTAL MARKS FOR THEORY			TOTAL MARKS FOR PRACTICAL		
		INTER-NAL	EXTER NAL	TOTAL	INTE RNAL	EXTER NAL	TOTAL
300	ADVANCES IN PHARMACEUTICAL SCIENCES PAPER-II (PHARMAINFORMATICS, PATENTS & EXPERIMENTAL DESIGN) (COMPULSORY)	30	70	100	40	60	100
AND SUBJECT OF SPECIALIZATION							
400	PHARMACEUTICS & PHARMACEUTICAL TECHNOLOGY SPECIALIZATION						
421	NOVEL DRUG DELIVERY SYSTEMS	30	70	100	40	60	100
422	PHARMACEUTICAL TECHNOLOGY – GLOBAL REGULATORYREQUIREMENTS	30	70	100	-	-	-
423	DISSERTATION	40	160	200	-	-	-
OR							
500	PHARMACEUTICAL CHEMISTRY SPECIALIZATION						
521	MEDICAL CHEMISTRY	30	70	100	40	60	100
522	DRUG DESIGN AND DISCOVERY	30	70	100	-	-	-
523	DISSERTATION	40	160	200	-	-	-
OR							
600	PHARMACOLOGY SPECIALIZATION						
621	PHARMACOMETRICES AND EVALUATION OF DRUGS	30	70	100	40	60	100
622	CLINICAL PHARMACOTHERAPEUTICS AND TOXICOLOGY	30	70	100	-	-	-
623	DISSERTATION	40	160	200	-	-	-
OR							

700	**PHARMACOGNOSY SPECIALIZATION**						
721	**ADVANCED ANALYTICAL PHARMACOGNOSY**	**30**	**70**	**100**	**40**	**60**	**100**
722	**TRADITIONAL HERBAL DRUGS**	**30**	**70**	**100**	**-**	**-**	**-**
723	**DISSERTATION**	**40**	**160**	**200**	**-**	**-**	**-**
OR							
800	**QUALITY ASSURANCE SPECIALIZATION**						
821	**MODERN PHARMACEUTICAL ANALYSIS**	**30**	**70**	**100**	**40**	**60**	**100**
822	**VALIDATION, REGULATORY AFFAIRS AND PRODUCT DEVELOPMENT**	**30**	**70**	**100**	**-**	**-**	**-**
823	**DISSERTATION**	**80**	**120**	**200**	**-**	**-**	**-**

R. Pharm XV

To pass an examination, candidate must obtain at least 40% of the marks in theory and in practical separately and in addition, must obtain at least 50% of the total marks assigned to the whole M.Pharm. Part-II Examination.

Distinction:

70% or more marks at M.Pharm. Part-I & Part-II (Aggregate) Examinations including Dissertation Examination.

First Class:

60% or more marks at M.Pharm. Part-I & Part-II (Aggregate) Examinations including Dissertation Examination.

Second Class:

50% or more marks at M.Pharm. Part-I & Part-II (Aggregate) Examinations including Dissertation Examination.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part II

300 ADVANCES IN PHARMACEUTICAL SCIENCES
PAPER-II

300 Bio-statistics, Pharmainformatics, Experimental Design and Patents
(COMPULSORY-THEORY ONLY)

1. **Bio-statistics:** The applications of the following topics in pharmacy shall be covered
   Mean Median and Mode, Standard Deviation and Coefficient of variation, Students t-test, one way ANOVA, Chi-square test, Probability, Frequency Distribution, Regression Analysis, Bioavailability Cross over study, Wilcoxon signed rank test and Introduction to control chart

2. **Pharmainformatics :** Introduction to information resources available on internet for various subjects in pharmacy (Pharmaceutical Technology, Pharmaceutical Chemistry, Quality Assurance, Pharmacology and Pharmacognosy)

3. **Experimental Design :** Introduction to Full & Fractional Factorial Designs, Central composite designs, Evolution of full and reduced mathematical models in experimental design, Application of the experimental designs for the subjects mentioned under Pharmainformatics, Introduction to Contour plots

4. **Patents:** Definition, Need for Patenting, Type of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search.

   The essential elements of patent, Guideline for preparation of laboratory note book, Non-obviousness in patent, Drafting of Patent claims, Important Patent related websites Brief introduction to intellectual property rights.

   Introduction to “The Patent Act 1970” and “The Patent Rules 2003”, with special emphasis on the form to be submitted along with a patent application

References:

1. Web Resources in Pharmacy, InPharma Publication, Bangalore
2. Basic Statistics and Pharmaceutical Statistical Applications by James E. De Muth, Marcel Dekker Inc.
3. Method in Biostatistics by B.K.Mahajan, JayPee Brothers, New Delhi.
4. Statistical Methods in Biological & Health Sciences by J.Susan Milton, Tata Mc GrawHill Int. Edition.
5. Pharmaceutical Statistics by Standards Bolton, Marcel Dekker Inc.
6. Pharmaceutical Experimental Design by G.A.Lewis, D.Mathiea, Roger Phan-Tan-Luu, Marcel Dekker Inc.
7. Pharmaceutical Experimental Design and Interpretation by N.A.Armstrong L.K.C. James, Taylor & Francis.
8. Current Patent Acts of Various countries.
9. Sanford Bolton, "Pharmaceutical Statistics" 3rd edition, Drug & Pharmaceutical Sciences series Vol:80, Marcel Dekker Inc.
10. James E. Demath " Basic Statistics and Pharmaceutical Statistical Application Marcel Dekker Inc.
11. Mueen Ahmed K.K. "Web Resources in Pharmacy"
12. Gareth A. Lewis, Didier Mathieu, Roger Phan – Tan-Luu, "Pharmaceutical Experimental Design", Vol-92, Marcel Dekker Inc.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part II

400: PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY Specialization

421: NOVEL DRUGDELIVERY SYSTEMS
Paper-III
Theory

1. Recent innovation in convectional dosage form like tablets, capsules, sterile dosage forms, pellets and etc.
2. Theory, manufacturing methods/techniques, evaluation methods, excipients and application of following new drug delivery systems:
   a. Microcapsules/Micro spheres.
   b. Transdermal drug delivery system,
   c. Ionotophoresis and Sonophoresis,
   d. Bioadhesive drug delivery system,
   e. Osmotic drug delivery system,
   f. Ocular drug delivery system,
   g. Gastro-retentive drug delivery system,
   h. Colon targeted drug delivery system,
   i. Metered dose inhaler,
   j. Liposomes, niosomes, nanoparticles etc.,
   k. Techniques modulation of drug release from dosage form
3. Introduction of formulation of protein and peptides, supercritical fluid technique, PEGylation, Biotechnology based pharmaceutical, taste masking, particle coating.
4. Formulation of herbal products- factors, methods and application.

PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY Specialization
Paper III
Practicals

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm. Part II

400: PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY Specialization

422: PHARMACEUTICAL TECHNOLOGY-GLOBAL REGULATORY REQUIREMENTS Paper-IV
(Theory only)

1. Packaging components and its evaluation: selection, factor effecting selection of components, primary and secondary component, and regulatory aspects of packing.
2. Brief introduction to general requirements of health regulatory agencies such as US FDA, MCA, TGA, WHO, ANVISA etc.,
3. Decision trees for the various steps in the regulatory guide lines like ICH, SUPAC etc.,
4. Basics in drug approval process with special reference to some of the following:
    a. History and various phases of drug development and drug approval
    b. Investigational New drug (IND),
    c. New drug application (NDA) (Phase-I-IV): content and format
    d. Abbreviated new drug application (ANDA);
    e. Content, development flow sheet and format, exclusivity, concept of paragraph I to IV.
    f. Clinical study and basic concept of Good clinical practice
5. Introduction to orange book, freedom of information (FOI), inactive ingredients guide (IIG), Drug master file (DMF), open part of DMP, codes of therapeutic equivalency, CDER, CBER.
6. Validation of process like blending, granulation, cleaning validation, equipments like sterilizer, filters, dissolution apparatus, etc., Computer system validation (21 CFR 11), basic concept in analytical method validation.
7. Introduction to Scale up and post approval changes (SUPAC) for immediate release and modified release formulation.
8. Quality assurance and its importance- concept of process deviation, change controls, sampling protocols etc.,

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M.Pharm.

M. Pharm Part II

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION Paper – III

521 Medicinal Chemistry

Survey of recent development in following areas – brief chemistry – synthetic approach to marketed drugs – Mode of action – SAR of following classes : Cardiovascular – CNS – Immunosuppressant – antibacterial – antiviral – antineoplastics – drugs for tropical diseases and malaria – tuberculosis -leprosy – filarial – antiamoebic – leichmania – radio protective – drugs against aging.

PRACTICALS

Laboratory examination including oral and practical examination in general course illustrative of theoretical section in the syllabus.

REFERENCES:

1. Burger – Medicinal Chemistry vol 1-6
2. Foye – Principles of Medicinal Chemistry.
3. Lednicer – Organic Drug Synthesis – 1 & 2.
4. Hans – Jurgen Hess – Annual Reports in Medicinal Chemistry.]
5. Ariens – Medicinal Chemistry Series.
6. Ellis and West – Progress in Medicinal Chemistry Series.

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M.Pharm.

M. Pharm. Part II

500 : PHARMACEUTICAL CHEMISTRY SPECIALIZATION
Paper – IV
(Theory only)

522 : Drug Design and Discovery

1. General Introduction
2. Physicochemical approach for rational drug discovery
3. Metabolism of the drugs.
4. Relation of metabolism to drug design.
5. Drug receptor – an overview
6. Various approaches for drug discovery
7. Rational approaches for drug discovery
8. QSAR – Methods of QSAR – physicochemical parameters – lipophilic electronic and steric. Practical application Hansch LFER model and Free Wilson analysis.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm Part-II

600 Pharmacology Specialization-Paper-III

621 Pharmacometrics & evaluation of Drugs

Screening & Evaluation (Including Modern Method like Molecular Pharmacology) Techniques of The Following

1. Parasympathomimetics
2. Parasympathetic blocking agents
3. Sympathomimetics
4. Sympathetic blocking agents
5. Ganglion stimulants & blockers
6. Neuromuscular stimulants & blockers
7. General & local Anaesthetics
8. Sedatives & Hypnotics
9. Antiepileptic
10. Psychopharmacological agents
11. Analgesics
12. Anti-inflammatory agents
13. Drugs used in Alzeimer's disease
14. Drugs used in Migraine
15. Antiparkinson's drugs
16. CNS stimulants
17. Cardiotonics
18. Antihypertensive drugs
19. Antiarrhythmic drugs
20. Drugs used in Ischaemic heart disease
21. Drugs used in Atherosclerosis
22. Diuretics
23. Drugs used in Gastro intestinal disorders
24. Drugs used in Respiratory disorder
25. Drugs used in Urino-Genital disorders
26. Drugs used in Diabetes
27. Hormone & Endocrine disorders
28. Concepts of high throughput screening, cell line & stem cell research

600 Pharmacology Specialization-Paper-III

621Pharmacometrics & evaluation of Drugs (Practical)

Practical related to above mentioned syllabus for paper-III

REFERENCES

1. Evaluation of drug activities: Pharmacometrics; Lawrence
2. DR, Bucharach AL, 964,Academic press, London & New York
3. Screening methods in Pharmacology, Turner
4. Toxicology Text Handbook. Principles, Applications & data interpretations by David Jacobson-Kram Kit A Keller, 2001,Marcel Dekker
5. New Concepts & developments in Toxicology by P L
6. Chambers, P Gehring, F Sakar, 1986, Oxford, New York
7. Experimental toxicology. The basic issues by Diana Anderson & D.M.Conning, 1990, The Royal society of chemistry
8. Evaluation methods in laboratory medicine by Rainer Haecker, 1993, VCH
9. Drug Discovery & Evaluation: Pharmacological assays, H.gerahd Vogel .
10. Drug Bioscreening: Drug discovery & evaluation, M.Emuenl

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M.Pharm Part-II

600: Pharmacology Specialization-Paper-IV

622: Clinical Pharmacotherapeutics & Toxicology

1. General principles of toxicology & various preclinical toxicity tests as per schedule Y & ICH guidelines
2. Clinical trials, GCP, ICH & WHO guidelines
3. General principles of Chemotherapy
4. Sulphonamides- Trimethoprim- Nitrofurans
5. Antibiotics
6. Chemotherapy of Tuberculosis- Leprosy- Malaria- Amoebiasis- Helminthiasis- Viral disease- Fungal disease- Neoplastic disease
7. Introduction to diseases- Pathophysiology, symptoms & general principles of treatments of the following:
8. Cardio Vascular System
9. Central Nervous System
10. Respiratory system-Excretory system
11. Gastro intestinal system
12. Endocrine system
13. Infectious disease
14. Immunological disorders
15. Clinical Pharmacy Practice, Clinical Pharmacology & Therapeutics of above mentioned disease
16. Clinical Pharmacokinetics
17. Drug allergies- Drug dependence- Drug tolerance & Drug interactions
18. Management in acute care medicine- Role in intensive Care
19. Unit, Emergencies, Total parenteral nutrition
20. Heavy metals poisoning & chelating agent
21. Adverse drug reactions, Latrogenic disease & their importance in clinical pharmacy
22. A Radio active isotopes- Handling of cytotoxic drugs &
23. Radiopharmaceuticals
24. Drug & poison information. Pharmacy administration
25. Social Pharmacy, Development of inter personal skills, Pharmacy practice & prescription analysis

REFERENCES

1. Clinical pharmacy & Therapeutics: Roger Walker, Churchil Living stone publication
2. Clinical Pharmacy & Therapeutics: H.Herfindal
3. Clinical Pharmacology: Katzung
4. Clinical Pharmacy & Therapeutics: Dipiro

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. PHARM Part-II

700: PHARMACOGNOSY SPECIALIZATION PAPER-III

721 Advanced Analytical Pharmacognosy

WHO guidelines for manufacturing and standardization of Herbal drugs and their formulations

1. Identification, Anthentification and Evaluation of herbal drugs and their products using modern techniques, Analysis of a few Selected indigenous herbal formulations including Physicochemical properties

2. Importance and standardization as per different pharmacopoeias

3. Regulatory and safety measures with herbal, ayurvedic and other drugs of traditional origin

Practicals

Practical exercises based on the relevant topics mentioned in theory syllabus. (Paper III)

References:

1. Randerath- Thin Layer Chromatography
2. Stahl- Thin Layer Chromatography
3. Wilson- Gisvold- Text book of Organic Medicinal and Pharmaceutical Chemistry
4. Garatt- The Quantitative Analysis of drugs
5. Backett-Stenlake- Practical Pharmaceutical chemistry
6. Stahl- Drug analysis- Chromatography and microscopy
7. Wallis- Practical Pharmacognosy
8. Munson- Pharmaceutical analysis
9. Wilard- Instrumental methods of analysis
10. Handa S.S and Kaul, K.L.- Suppliment to cultivation and utilization of medicinal plants, 1996
11. R.D. Chaudhary, Herbal drugs industry, Eastern Publishers, New Delhi.
12. Stahl, E., Thin layer chromatography- A Laboratory Hand Book, Springer-Verlag Berlin
13. Wallis, T.E., Analytical Microscopy, J&A Churchill Ltd.
14. Wagner, H. Bladt S. & Zgainski, Plant drug analysis Springer, Verlag, New York
15. Clark, E.C.G., Isolation and Identification of drugs, The Pharmaceutics Press, London.
16. Brain, K.R. and Turner, R.D., The practical evaluation of Phytopharmaceutics, Wright- Scientechnics Bristol.

17. Peach K. & Tracey, M. V., Modern Methods of plant analysis, 1-4, Narosa publisher house, N.D.
18. WHO Publication
19. The Ayurvedic Pharmacopoeia of India, Part I, Vol. I,II & III, First edition, Govt. of India, Ministry of Health family welfare, Dept. of Indian Systems of medicine Homeopathy, New Delhi
20. Indian Herbal Pharmacopoeia Vol. II, Published by RRL, Jammu & IDMA, Mumbai-1998 &1999.
21. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association, 1996.
22. Ayurvedic Formulary of India, Vol.I & II, Ministry of Health, New Delhi.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. PHARM Part-II

700 : PHARMACOGNOSY SPECIALIZATION PAPER-IV (Theory only)

722 Traditional Herbal Drugs

1. Export & Import potential of herbal &traditional drugs, their medicinally important constituents & formulations
2. Biodiversity conservation, economic development &drug discovery from traditional , medicinal plants of India.
3. Distribution & Chemotaxonomy of essential oils in plants.Role of Volatile oils in medicine, their industry & industrial importance in India.
4. Basic principles in Ayurvedic systems of medicine & various types of the formulations available.
   Studies on different aspects of Ayurvedic formulations:
   Collection and processing of crude drugs, Methods of production, Their inprocess quality control Standardization
5. Herbal medicine information sources:
   1. Books
   2. Journals
   3. On-line databases

References:

1. Guenther- Essential oils

2. Jean Bruneton, Pharmacognosy: Photochemistry medicinal plants. Londres, Paris, New York

3. Paul M. Dewick; Medicinal natural products, A biosynthetic approach, John-Wiley & Sons, Inc; New York, USA

4. R.D. Chaudhary, Herbal Drugs industry, Eastern Publishers, New Delhi

5. Pulok K. Mukharjee, Quality control of Herbal drugs, Business Horizons pharmaceutical publishers

6. Trease and Evan's, Pharmacognosy, 15th edition, 2002, English language books society/ Bailliere Tindall

7. Edward P. Claus, Varro E. Tyler, Lynn R. Brady, Pharmacognosy, eighth edition, K.M. Varghese company Bombay.

8. James E. Robbers, Varro E. Tyler, Herbs of choice- The therapeutic uses of phytomedicinals

9. CSIR – Cultivation and utilization of medicinal aromatic plants

10. Ayurvedic formulatory of India, Ministry of Health, New Delhi

11. WHO Monographs

12. British herbal compendium, Vol. 1, Edited by Peter R. Bradley, British Herbal medicine association and its scientific committee, Dorset BH7 6JZ, 1992

13. Indian herbal pharmacopoeia Vol.I & II, Jointly published by RRL, Jammu and IDMA, Mumbai-1998 & 1999.

14. The Ayurvedic Pharmacopoiea of India, Part I, vol.I, II and III, First edition, Govt. of India, Ministry of Health and family welfare, Dept. of Indian systems of Medicine and Homeopathy, New Delhi.

VEER NARMAD SOUTH GUJARAT UNIVERSITY
M.Pharm.

M. Pharm. Part II

800 QUALITY ASSURANCE SPECIALIZATION
Pharmaceutical Quality Assurance- Paper III

821 Modern Pharmaceutical Analysis

1. Application of analytical methods to product obtained through genetic engineering ,Amino acid sequence analysis, Tryptic maping, ion exchange amino acid analysis, isoelectric focusing etc.
2. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH
3. Solid state analysis of drug substance including degradation and impurity analysis
4. Preformulation analysis
5. Analysis of solid oral dosage form
6. Analysis of injectable dosage form
7. Compendial testing
8. Automated analysis
9. Compendial methods for evaluation of crude drug and herbal formulation
10. Analysis of drugs in biological fluids
11. Analysis of cosmetics
12. X- ray analysis

Practical:

Practical exercises based on theory syllabus

VEER NARMAD SOUTH GUJARAT UNIVERSITY
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M. Pharm. Part II

QUALITY ASSURANCE SPECIALIZATION
Pharmaceutical Quality Assurance- Paper IV

822 Validation, Regulatory affairs and Product development

Elements of validation, benefits, types of process validation, validation prototcol, process characterization and optimization.

1. Qualification of equipments
2. Validation of processes
   a. Non- sterile: Mixing, granulation, drying, compression, filtration, filling
   b. Sterile: Dry heat sterilization, autoclaving, membrane filtration, gaseous sterilization and sterilization by radiation.
3. Validation of Personnel.
4. Validation of air handling equipment and facilities
5. Validation of water supply system
6. Cleaning Validation
7. Validation of electronic data processing
8. Product development
   a. Preformulation study
   b. Manufacturing process design and development in process controls of:
      - Tablets, Capsule
      - Liquid orals
      - Opthalmic applications
      - Aerosols
      - Sterile parenterals
   c. Scale up operations
9. Regulatory affairs
      - Drug regulatory and accrediting agencies of world and their guidelines (USFDA, TGA, MCA, ICH, WHO etc.)
      - Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
      - Contract manufacturing
      - Recent amendments to Drug & Cosmetic Act and other relevant rules.

- Relevant provisions of Consumer Protection Act, Environment Protection Act, Factory Act
- Certification and Licensing Procedures
- Quality safety and legislation for cosmetic and herbal products.

References

1. Food additive- R. J. Taylor
2. Antimicrobial in food- Alfred larry branen. P Michael division publishing corporation
3. Method of protein analysis by istran kerese.
4. Cosmetic analysis- selective methods and techniques by P. Borc
5. Henry,s cosmeticology- Martin M. Rieger.
6. Cosmaceuticals Drug vs Cosmetics
7. Herbal cosmetics. Beuty through Herbs- Dr. Urjita jain.
8. Morris B. Jacobs. The chemical analysis of foods and food products.
9. S. Suzanne Neilson. “Introduction to chemical analysis of foods.’
10. Jemns T Cartenson. Drug stability- Principles and Practices, Marsel Deckker.
11. Applied Microbiology. Vinitakale Kishor Bhusari.
12. Michael J. Pelezar/ Chan/ Kricg. “Microbiology.
13. Tortora, Funke, Case.” Microbiology”- An introduction.
14. P.P.Sharma - Cosmetics Formulation, Manufacturing and Quality control.
15. WHO Guide line for the quality control of herbal plant material.
16. The practical evaluation of phytopharmaceutical by brain & turner
17. Indian herbal pharmacopoea- Vol-I & II