VEER NARMAD SOUTH GUJARAT UNIVERSITY, SURAT.

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.

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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.

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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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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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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.

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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

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Part - II

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

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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

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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.

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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.

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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

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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