SWAMI RAMANAND TEERTH MARATHWADA UNIVERSITY, NANDED

Post Graduate Course in Pharmacy (M. Pharmacy)

Credit System (Semester Pattern)
Choice Based Credit System (CBCS)
to
Affiliated Colleges

Teaching Scheme & Course Content

w.e.f.: 2014-2015

Swami Ramanand Teerth Marathwada University, Vishnupuri, Nanded

Post Graduate Course in Pharmacy (M. Pharmacy)

Credit System (Semester Pattern) (Choice Based Credit System)

Effective from October 2014

Teaching Scheme

Specialization: Pharmacology

Semester-I

Course Code	Subject Title	Contact Hours/Week				Credits
		L	T	P	Total	
PHC-101	Advanced Analytical Techniques	03	01	-	04	04
PCY-101	Molecular Pharmacology	03	01	-	04	04
PHE	Elective-1	03	01	-	04	04
PHE	Elective-2	03	01	-	04	04
PHC-102	Lab-I: Analytical Techniques	-	-	06	06	03
PHC-103	Seminar	One seminar/student				03
	Total	**12**	**04**	**06**	**20**	**22**

Semester-II

Course Code	Subject Title	Contact Hours/Week				Credits
		L	T	P	Total	
PCY-102	Clinical Pharmacology and Toxicology	03	01	-	04	04
PCY-103	Pharmacological Screening Methods	03	01	-	04	04
PHE	Elective-1	03	01	-	04	04
PHE	Elective-2	03	01	-	04	04
PCY-104	Lab-II : Pharmacology (General Laboratory in an area of specialization)	-	-	06	06	03
PHC-104	Seminar	One seminar/student				03
	Total	**12**	**04**	**06**	**20**	**22**

Semester-III

PCY-105	Synopsis and Presentation:	06 Credits
PCY-106	Experimental /Research Work	20 Credits
PCY-107	End term progress and Presentation of Work:	04 Credits
	Total:	**30 Credits**

Semester-IV

PCY-108	Experimental /Research Work & Midterm presentation	18 Credits
PCY-109	Dissertation & Defense (Viva-Voce)	08 Credits
	Total:	**26 Credits**

Swami Ramanand Teerth Marathwada University, Vishnupuri, Nanded

Post Graduate Course in Pharmacy (M. Pharmacy)

Credit System (Semester Pattern) (Choice Based Credit System)

Effective from October 2014

Teaching Scheme

Specialization: Quality Assurance

Semester-I

Course Code	Subject Title	Contact Hours/Week				Credits
		L	T	P	Total	
PHC-101	Advanced Analytical Techniques	03	01	-	04	04
PQA-101	Quality and its Concepts	03	01	-	04	04
PHE	Elective-1	03	01	-	04	04
PHE	Elective-2	03	01	-	04	04
PHC-102	Lab-I: Analytical Techniques	-	-	06	06	03
PHC-103	Seminar	One seminar/student				03
	Total	**12**	**04**	**06**	**20**	**22**

Semester-II

Course Code	Subject Title	Contact Hours/Week				Credits
		L	T	P	Total	
PQA-102	Pharmaceutical Process Validation	03	01	-	04	04
PQA-103	Method Development and Validation	03	01	-	04	04
PHE	Elective-1	03	01	-	04	04
PHE	Elective-2	03	01	-	04	04
PQA-104	Lab-II : Quality Assurance (General Laboratory in an area of specialization)	-	-	06	06	03
PHC-104	Seminar	One seminar/student				03
	Total	**12**	**04**	**06**	**06**	**22**

Semester-III

PQA-105	Synopsis and Presentation:	06 Credits
PQA-106	Experimental /Research Work	20 Credits
PQA-107	End term progress and Presentation of Work:	04 Credits
	Total:	**30 Credits**

Semester-IV

PQA-108	Experimental /Research Work & Midterm presentation	18 Credits
PQA-109	Dissertation & Defense (Viva-Voce)	08 Credits
	Total:	**26 Credits**

Swami Ramanand Teerth Marathwada University, Vishnupuri, Nanded

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Effective from October 2014

Teaching Scheme

Specialization: Pharmaceutics

Semester-I

Course Code	Subject Title	Contact Hours/Week				Credits
		L	T	P	Total	
PHC-101	Advanced Analytical Techniques	03	01	-	04	04
PPH-101	Advances in Dosage Form Design	03	01	-	04	04
PHE	Elective-1	03	01	-	04	04
PHE	Elective-2	03	01	-	04	04
PHC-102	Lab-I: Analytical Techniques	-	-	06	06	03
PHC-103	Seminar	One seminar/student				03
	Total	**12**	**04**	**06**	**20**	**22**

Semester-II

Course Code	Subject Title	Contact Hours/Week				Credits
		L	T	P	Total	
PPH-102	Pharmaceutical Production Technology	03	01	-	04	04
PPH-103	Advances in Drug Delivery System	03	01	-	04	04
PHE	Elective-1	03	01	-	04	04
PHE	Elective-2	03	01	-	04	04
PPH-104	Lab-II : Pharmaceutics (General Laboratory in an area of specialization)	-	-	06	06	03
PHC-104	Seminar	One seminar/student				03
	Total	**12**	**04**	**06**	**06**	**22**

Semester-III

PPH-105	Synopsis and Presentation:	06 Credits
PPH-106	Experimental /Research Work	20 Credits
PPH-107	End term progress and Presentation of Work:	04 Credits
	Total:	**30 Credits**

Semester-IV

PPH-108	Experimental /Research Work & Midterm presentation	18 Credits
PPH-109	Dissertation & Defense (Viva-Voce)	08 Credits
	Total:	**26 Credits**

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Post Graduate Course in Pharmacy (M. Pharmacy)

Credit System (Semester Pattern) (Choice Based Credit System)

Effective from October 2014

List of Elective Courses/Subjects

Semester-I

PHE-101: Research Methodology & Biostatistics
PHE-102: Regulatory Affairs & IPR
PHE-103: Pharmacovigilance & Pharmacoepidemiology
PHE-104: Drug Metabolites
PHE-105: Pharmacoinformatics

Semester-II

PHE-106: Applied Biopharmaceutics and Pharmacokinetics
PHE-107: Pharmaceutical Biotechnology
PHE-108: Pharmaceuticals Stability Studies
PHE-109: Quality Assurance Approach and Improvement
PHE-110: Clinical Pharmacokinetics
PHE-111: Pharmacological Aspects of Natural Products
PHE-112: Drug Design
PHE-113: Sterile Products Formulation & Technology
PHE-114: Biomaterials for Drug Delivery
PHE-115: Nano Drug Delivery Systems
PHE-116: Polymers in Pharmaceutics
PHE-117: Phytochemistry

I & II Semester:

Full marks for each Theory Course:	100 (50 ESE + 50 CA)
Full marks for each Lab Course:	100 (50 ESE + 50 CA)
Full marks for each Seminar:	50 (50 Internal)

IIIrd Semester:

Full marks for Synopsis and Presentation:	50 (100 Internal)
Full marks for Experimental /Research Work	100 (100 Internal)
Full marks for End term progress and Presentation of Work:	50 (100 Internal)

IVth Semester:

Full marks for Experimental /Research Work & Midterm presentation	100 (100 Internal)
Full marks for Dissertation & Defense (Viva-Voce)	300 (300 ESE)

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Compulsory & Common Subject)

Subject code: PHC-101

Subject : Advanced Analytical Techniques (TH) (4 Credits)

I. Spectroscopic Methods:

1. **UV- Visible spectroscopy:** Introduction, Basic principles, applications; Absorption spectra of organic compounds & complexes illustrating the phenomenon & its utilization in qualitative & quantitative studies of drugs; calculation of absorption maximum of unsaturated hydrocarbons.
2. **IR Spectroscopy:** Interaction of infrared radiation with organic molecules & its effect on bonds; Instrumentation- dispersive IR spectrophotometer, FTIR; sample handling, interpretation of spectra.
3. **NMR Spectroscopy:** Fundamental principles of NMR, Instrumentation; Chemical shifts concept, spin-spin coupling, s[in-spin decoupling, shielding & deshielding, solvents; interpretation of spectra; introduction & application of ^{13}C-NMR and 2D NMR.
4. **Mass Spectroscopy:** Basic principles & instrumentation; Ionization techniques, mass spectrum & its characteristics, molecular ion, metastable ion, fragment ions; fragmentation process & patterns, fragment characteristics in relation to parent structure & functional groups; relative abundance of isotopes & their contribution to characteristic peaks.

II. Chromatographic Techniques:

1. Classification of chromatographic methods based on mechanism of separation & their basic principles.
2. **Gas Chromatography:** Instrumentation, column efficiency parameters, derivatisation methods, application in pharmaceutical analysis.
3. **Liquid Chromatography:** Comparison of GC & HPLC, instrumentation in HPLC, phase packing materials, column selection, mobile phase selection, efficiency parameters, application in pharmaceutical analysis.
4. Instrumentation & pharmaceutical applications of HPTLC, Ion exchange chromatography, Gel permeation chromatography, Chiral chromatography, Flash chromatography, Supercritical Fluid chromatography.

III. Other Analytical Techniques:

1. **Thermal Analysis:** Theory, instrumentation & applications of Thermo-gravimetric analysis, differential thermal analysis, differential scanning calorimeter.
2. **Immunochemical Techniques:** Immuno-electrophoresis, immuno-precipitation, ELISA, radio-immuno assay.
3. **Powder X-ray Diffraction:** Instrumentation and pharmaceutical applications.

References:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath printers, Haryana, 2007
2. Silverstein, RM, Webstar, FX. Spectrometric identification of organic compounds. 6th ed., John Wiley & Sons (Asia) Pvt. Ltd., Singapore, 2005
3. William Kemp. Organic spectroscopy, 3rd ed., Palgrave, New York, 2006
4. Jag Mohan, Organic spectroscopy: Principles and Applications, 2nd ed., Narosa publishing house Pvt Ltd., New Delhi, 2005
5. Conners KA. A Text book of pharmaceutical analysis, 3rd ed., John Wiley & Sons, Singapore, 2004
6. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986
7. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to spectroscopy. 4th ed., Brookescole publishers, California, 2008
8. Sharma BK. Instrumental methods of chemical analysis, 25th Ed., Goel Publishing house, Meerut, 2006
9. Beckett, AH, Stenlake, JB. Practical pharmaceutical chemistry, Part I & II, 4th ed., CBS Publishers & distributors, New Delhi, 2004
10. Ewing, GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985
11. Schirmer, RE. Modem methods of pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000
12. Moffat, AC, Osselton, MC, Widdop, B. Clarke's analysis of drugs and poisons, Vol. I & II, 3rd ed., K.M. Varghese Company, Mumbai, 2004

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus
M. Pharm. (Semester – I)
PHARMACOLOGY
(Compulsory Subject)

Subject code: PCY-101

Subject : Molecular Pharmacology (TH) **(4 Credits)**

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1. Introduction to Molecular Pharmacology, Techniques to study molecular pharmacology such as Western Blotting, Immunostaining, RT-PCR, Cloning, Cell Culture etc. Recombinant DNA technology and its applications.
2. **Molecular Mechanism of drug action:** Receptor occupancy and cellular signaling system such as G-Protein, cyclic nucleotides, calcium and phosphatidyl inositol, Ionic channels and their modulators.
3. Endogenous bioactive molecules as TNF-α, Interleukins, process of apoptosis, arachidonic acid metabolites, COX-2 regulators and their role in inflammation. Endothelium derived vascular substances such as NO, endothelins etc; and their modulators.
4. **Molecular Toxicology:** Receptor mediated toxicity, Mechanism of cell death, calcium mediated toxicity, excitatory amino acid toxicity, NO toxicity and steroid hormone induced toxicity. Mechanism of chemical toxicity, Oxidative stress, Necrosis and significance of toxicity evaluation.
5. **Molecular Oncobiology:** Causes and genetics of cancer, oncogenes, tumor suppression genes
6. **Molecular Neurobiology:** Molecular genetics of Alzheimer's disease, Myasthenia gravis, Parkinsonism and regulation of behavior.
7. Recent trends on different classes of receptor and drugs acting on them.

References:

1. Goodman and Gilman, Pharmacological Basis of Therapeutics, Mc Graw Hill
2. Craig C R and Stitzel B E, Modern Pharmacology with Clinical Application, Lippincott Williams & Wilkins.

3. Katzung B G, Basic and Clinical Pharmacology, Lange Medical Publisher, USA

4. Melmon K L and Morelli, Clinical Pharmacology: Basic Principles of Therapeutics, Mc Millan, New York

5. Bacq Z M, Fundamentals of Biochemical Pharmacology.

6. Grollman Pharmacology and Therapeutics, Lea & Tebiger, Philadelphia.

7. Harrisons Principles of Internal Medicine, McGraw Hill.

8. Davidson's Principles and Practice of Medicine, Churchill Livingston.

9. Lawrnce D R and Bennette, Clinical Pharmacology.

10. Goldstein, Aranow & Kolman, Principles of Drug Action.

11. Rang H P, Dale M N, Pharmacology, Churchill Livingston, UK

12. Drill V A, Pharmacology in Medicine, McGraw Hill, New York.

13. Review articles and Research articles from Medical and Pharmacological Journals

Subject code : PQA-101

Subject : Quality and Its Concepts **(4 Credits)**

- Quality: Concept of quality, nature of product quality, study of various approaches for quality like Deming', Juran, Crosby, Feigenbaum, Shikaw.
- Quality income and cost. TQM awards and prizes.
- Quality benchmarking, details of international standards (ISO, GMP, GLP, TGM, VAN and ISI), its need and fact sheet evaluation (should include review or statistics of industries implemented these standards with those which have not implemented these)
- Role of quality audit and quality circle in quality assurance.
- Quality assurance and GLP, implementing of GLP in non GLP analytical laboratory.
- Process management, project management, strategic development and product development.
- Measurement of quality, information and decision making or utilization of data.
- Quality operations, its inspection and test used for it.
- Human resource and training for quality.
- Market survey, customer demand and marketing in addition to supplier and customer relationships.
- Quality, society and national culture.
- Computerized system- software development, computer applications and quality system.
- Requirements of product registration, in India and other countries (USA, UK, Japan and Europe etc).

REFERENCES:

1. Juran's Quality Handbook, 5th Ed, by J M Juran, A B Godfrey, McGrawHill International Edition
2. Total Quality Management- Guiding Principle for Application, J. P. Peker, ASTM manual series, Philadelphia.
3. Total Quality Management – The Key to Business Improvement, Champman and Hall, Londan.
4. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
5. ISO 9000 and Total Quality Management – Sadhank. G. Ghosh.
6. Project Management, Clifford F. Gray and Erik W., Larson Publisher: McGraw Hill Company.
7. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO.
8. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu

9. ISO 9000 Quality Systems Handbook - updated for the ISO 9001:2008 standard, Sixth Edition: Using the standards as a framework for business improvement by David Hoyle (Paperback - July 10, 2009).
10. Total quality management: strategies and techniques proven at today's most successful companies (Portable Mba Series) by Stephen George and Arnold Weimerskirch (Hardcover - Feb. 1998).

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M.Pharm. Syllabus

M. Pharm. (Semester –I)

Pharmaceutics

(Compulsory Subject)

Subject code : PPH-101

Subject : Advances In Dosage Form Design (4 Credits)

1. Dosage form design aspects Physiochemical aspect:

pKa, Partition coefficient,Hygroscopicity, Polymorphism & crystal habbits, solubility etc. **Biological aspects**: Role of physicochemical parameters on drug absorption and their implications, routes of administrations and implication on bioavailability

2. Preformulation:-

Techniques for physico-chemical characterization of Drug and excipient significance and methods for evaluation of drug-excipient, excipient-excipient and drug containers/closures interactions and incompatibilities

3. Solid :-

Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression. Recent techniques for particle size enlargement and micronization significance and recent advancement, Compatibility and compressibility, different methods of evaluation of lubricant efficiency.

4. Dissolution & Dissolution Testing :-

Theories of drug dissolution, dissolution test apparatus, selection of dissolution medium, dissolution of different dosage form solids, suspensions, topical, suppositories and controlled release systems. Enhancement of dissolution rate. Biopharmaceutical classification system, In-vivo dissolution techniques, in vitro models for evaluation.

5. Surfactant & polyphasic system :-

Phase behavior of surfactant in binary and ternary Systems. Factors affecting phase behavior. Micellization, micelle structure, shape, size factor affecting CMC and micellar size, thermodynamics and kinetics of micelle formation; Pharmaceutical aspects of solubilization in non-aqueous systems, interaction with polymers and oppositely charged species; SEDDS & SMEDDS, Multiple emulsions, Ternary & Pseudoternary phase diagrams, Zeta potential.

6. Solubility enhancement by solid dispersions, complexation, salt formation, micronization and cosolvency.

7. **Optimization techniques and Factorial design** :

Concept of optimization, Optimization parameters, Classical optimization, Optimization methods and Statistical design

References:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
12. Pharmaceutical Preformulations; By J.J. Wells.

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M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-101

Subject : Research Methodology and Biostatistics (TH) (4 Credits)

I) Research Methodology

1. **Introduction:** Meaning & Objectives of research, types of research, approaches to research; Research methods, research process; Criteria for good research, common problems, qualitative & quantitative research methods.
2. **Research Topic:** Selection of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work.
3. **Data Collection:** Primary & secondary data collection method, design of questionnaires for data collection, identification of sources of information, searching and classifying information; compilation, processing & analyzing of data & information.
4. **Interpretation of Results and Presentation:** Meaning of interpretation, techniques of interpretation; scientific writing & report preparation, fundamentals of scientific writing, report preparation, types & layout of report, precautions in writing research report; statistical aspects of research output.
5. Principles of validity & reliability of research work, ethical aspects of research methodology.
6. **Developing research proposals:** Format of research proposals, Individual & Institutional research proposals.

II) Biostatistics

1. Introduction, its role and uses. Collection, organization, graphic & pictorial representation of data, measurement of central tendencies & dispersion; degree of freedom, standard deviation, standard error, Coefficient of variation, Probability, Sample and Sampling method

2. **Estimation and Hypothesis testing:** Null Hypothesis, confidence level, Point & interval estimation, concept of hypothesis testing & types of error, Student 't' test, Chi-Square test.

3. **Linear regression and Correlation:** Analysis of variance (one way & two way), Factorial design

4. Brief review of non parametric tests, experimental design in clinical trials, statistical test for bioequivalence, Dose-Response study, statistical quality control; validation, optimization techniques & screening design, significance of coefficient of correlation, non-linear regression, application of software for statistical calculations.

References:

(1) Research in education – John W. Best Jems V. Kahn
(2) Research methodology – C. R. Kothari
(3) Methodology and techniques of social research – Willkinson and Bhandarkar
(4) Presentation skills – Michel Halton – Indian society for institute education
(5) Practical introduction to copyrights – Gavin Mofariane
(6) Thesis projects in sciences and engineering – Richard M. Devis
(7) Scientist in legal system – Ann Labor Science
(8) Thesis and assessment writing – Janolthon Anderson
(9) Writing a technical paper – Donald Manzel
(10) Effective business report writing – Lel and Brown
(11) Protection of industrial property rights – Purshottam Das and Gokul Das
(12) Spelling for millions – Edna Furmess
(13) Preparation for publications – King Edwards hospital foundation for London
(14) Information technology – The hindu speeks
(15) Documentation – genesis and development – 3792.
(16) Ayurveda and modern medicine – R. D. Lele
(17) How to write and publish a scientific paper – Robert A. Day Cambridge University Press 4th edition 1994
(18) Lecture notes on patent TIFAC: DOC: 022, TIFAC July 2002.
(19) Introduction to Statistical Methods- C. B. Gupta
(20) A first course in Mathematical Statistics- C. E. Weatherborn
(21) Introduction to Biostatistics-Mahajan
(22) Experimental Pharmacology by S K Kulkarni.

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M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-102

Subject : Regulatory Affairs and IPR (TH) (4 Credits)

II. Regulatory Affairs:

1. Historical perspectives, organization structure, activities and responsibilities of drug regulatory agencies in India, US, EU, etc.
2. Concepts of total quality management, Good laboratory practices and ISO; Quality assurance & quality control for APIs and other intermediates in process & finished products. GMP for bulk drugs & formulations, Good clinical practice guidelines. US regulatory practices, ICH guidelines.
3. Validation of process, equipments, procedures, validation master plan. Documentation like master records, batch records, regulatory compliance records, distribution records, drug recall registers, management review records.
4. **Regulatory Acts:** Drugs & Cosmetic act-1940 & rules 1945 with special relevance to schedule M, Y, U; latest drug price control order & latest drug policy; Pollution & environmental control act.

III. Intellectual Property Rights:

1. **Introduction:** Scope, Objectives & IPR in pharmacy, Indian legal system & its role in IPR; importance for pharma industry.
2. Concept of property with respect to intellectual creativity; Tangible & Intangible property, concept of IPR, scope & nature of patents, copyrights, trade mark, geographical limitations.
3. **Patent and its Practical aspects:** Indian Patent Act 1970, Patenting in India & abroad, role of international organization WTO, WIPO, EPO in patent act; practical aspects of patent filing, components of a patent application in India, PCT filing, patent infringement & litigation therein, commercialization & licensing
4. **Ethics in IPR:** Positive & negative aspects, drug related controversies, traditional knowledge, crops & life forms, current strategies & solutions.

References:

1. Drugs & Cosmetics Act 1940 and rules there under.
2. Drugs Laws by Hussain.
3. Indian Patent Act.
4. Quality assurance & GLP by Y. Anjaneyulu.
5. Quality control & Application by Bentrand L. Hanser.
6. Quality assurance in Analytical chemistry by Werner Funk..
7. Guidelines of various countries like MCA, TGA, ICH.
8. GLP regulation by Alen Hirsch Vol 38 Marcel Decker series
9. GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
10. I.P., B.P., U.S.P. International Pharmacopoeia

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M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-103

Subject: Pharmacovigilance & Pharmacoepidemiology (TH) (4 Credits)

1: Introduction to Pharmacovigilance:
Introduction, Definition, requirement of Pharmacovigilance needed, Objectives of Pharmacovigilance, Agencies concerned with Pharmacovigilance, Reporting ADRs, and changes to recommendations for use, Methods involved in Pharmacovigilance, Pharmacovigilance plans, Scope of Pharmacovigilance, Indian scenario, Pharmacovigilance and pharmacogenomics

2: **Safety monitoring process & good Pharmacovigilance Practices (GPP)**:
The Monitoring Process, The Role of Institutional Review Boards and Data Safety Monitoring Boards, Quality Assurance Monitoring, Ending Trials Early: Protecting the Interests of Participants and the Public.GPP, Overview of Risk Management Goals and Guidance, Adverse events, serious adverse events, Reporting of AE & SAE, Pharmacovigilance

3: Good reporting practices and safety signals:
Risk management process, Signals, Case report, Case series, Causality, Data mining, reporting rates Vs incidence rates, Pharmacovigilance plans, Pharmaco-epidemiologic safety studies

4: **Pharmacoepidemiology, Registers, Surveys**:
Pharmacoepidemiology, Guidelines for Good Pharmacoepidemiology Practices (GPP), Pharmacovigilance Methods, Use of health care databases in pharmacoepidemiology, Registries, Surveys, Pharmacoeconomics and pharmacoepidemiology, Pharmacoepidemiology and pharmacokinetics, International drug monitoring, Using eHealth information for comprehensive Pharmacovigilance surveillance, Pharmacoepidemiology in India, Pharmacovigilance and India

References:

1. Textbook of therapeutics Drug and Disease Management: Eric T Herfindel, Dick R. Gourley, 6th ed.
2. Assuring Data Quality And Validity In Clinical Trials For Regulatory Decision Making: Janet Woodcock, Frederick Ognibene, John Overbeke.2003; Welly Publication.
3. Medical Transcription Guide: Do's and Don'ts (Medical Transcription Guide): Marilyn Takahashi Fordney, Marcy Otis Diehl.

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M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-104

Subject : Drug Metabolites (TH) (4 Credits)

1. Review of drugs metabolism & metabolites. Importance in drug design and discovery, use of software/ study of current available software
2. Chemical changes / biochemical changes takes place while drugs metabolism along with chemistry of metabolites.
3. Introduction to metabolite identification in body (urine, serum, organs etc)
    a. Various analytical techniques to identify metabolites
    b. Chromatography (HPLC, GC), spectroscopic (NMR, MS)
    c. Hyphenated (LC-MS, GC-MS) Tandem (MS-MS)
    d. Emerging- proteomics, Metabolomic etc
4. Metabolites in disease conditions
   Overview of occurrence of drugs / endogenous metabolite during following disease/disorder conditions along with their physiological/pathological role-
    a. Diabetes mellitus
    b. Cancer
    c. Epilepsy
    d. Infectious conditions like bacterial, fungal & viral
    e. Cardiovascular disorders
    f. Pregnancy, lactation like special conditions
    g. Endogenous metabolites and diseased condition
        I. Vitamins (Vit D –cancer, bone health; Vit E-atherosclerosis, etc)
        II. Enzymes
        III. Hormones
5. Metabolites of imp category of drugs related to above mentioned conditions
6. Metabolites of important phytochemicals like papavarine, nicotine, taxol, isoflavones, omega 3 fatty acids etc
7. Guidelines for Safety Testing of Drug Metabolites
8. Effect of modification of drugs formulation on occurrence/formation of metabolites
9. Age and genetic related variation in formation of drugs metabolites and its clinical significance.

References:

1. Metabolomic in Practice: Successful Strategies to Generate and Analyze ... edited by Michael Lämmerhofer, Wolfram Weckwerth
2. Guidance for Industry Safety Testing of Drug Metabolites U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) February 2008 Pharmacology and Toxicology
3. Guidance for Industry Safety Testing of Drug Metabolites U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) February 2008 Pharmacology and Toxicology
4. Identification and Quantification of Drugs, Metabolites and Metabolizing Enzymes by LC-MS Edited by Swapan Choudhary Hardbound, 354 Pages Published: November 2005 ISBN 13: 978-0-444-51710-4
5. High Throughput Bioanalytical Sample Preparation By David Wells Hardbound, 640 Pages Published: January 2003 ISBN 13: 978-0-444-51029-7
6. Biotransformation and Metabolite Elucidation of Xenobiotics: Characterization and Identification Ala F. Nassar (Editor) ISBN: 978-0-470-50478-9 328 pages November 2010 Copyright © 2000-2014 by John Wiley & Sons, Inc., or related companies. All rights reserved.
7. Reactive Drug Metabolites, Volume 55, Amit Kalgutkar, Deepak Dalvie, R. Scott Obach, Douglas A. Smith, Raimund Mannhold (Series Editor), Hugo Kubinyi (Series Editor), Gerd Folkers (Series Editor) ISBN: 978-3-527-33085-0, 402 pages, October 2012, Copyright © 2000-2014 by John Wiley & Sons, Inc., or related companies. All rights reserved.
8. Mass Spectral and GC Data of Drugs, Poisons, Pesticides, Pollutants and Their Metabolites, 4th Edition Hans H. Maurer, Karl Pfleger, Armin A. Weber ISBN: 978-3-527-32992-2 1642 pages August 2011 Copyright © 2000-2014 by John Wiley & Sons, Inc., or related companies. All rights reserved.
9. Metabolome Analysis: An Introduction Silas G. Villas-Boas, Jens Nielsen, Jorn Smedsgaard, Michael A. E. Hansen, Ute Roessner-Tunali ISBN: 978-0-471-74344-6 319 pages February 2007 Copyright © 2000-2014 by John Wiley & Sons, Inc., or related companies. All rights reserved.
10. All related reference books/ journal articles under Pharmacology, Medicinal Chemistry, Pharmaceutical Analysis, Pharmacognosy & Phytochemistry etc.

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code : PHE-105

Subject : Pharmacoinformatics (TH) (4 Credits)

1. Chemoinformatics: Introduction, molecular structures, representation and manipulation of 2D and 3D structures, generation of 3D structures visualization techniques, molecular databases, virtual screening, chemical libraries, molecular descriptors, calculation of descriptors reflecting physical and chemical properties of molecules, molecular similarities and complementarities, selection of structurally diverse and representative sets, molecular properties, solubility partition coefficient, drug like properties, data analysis, quantitative and qualitative structure activity relationship, prediction of ADME properties, application of Chemoinformatics in drug research.
2. Programming in C, C++, character manipulation, programming techniques for data base management and developing database oracle.
3. Programming in database environment, development of databases, relational databases, information retrieval systems, general search methods, Means-ends analysis, depth first search, breath first search, optimal search, branch and bound etc. Oracle database environment.
4. Web based search engines and the details of their search algorithms especially pertaining to bio-computing.
5. Molecular modeling : Energy minimization, geometry optimization, conformational analysis, global conformational minima determination, approaches and problems, bioactive vs. global minimum conformations, automated methods of conformational search, advantages and limitations of available software, molecular graphics, computer methodologies behind molecular modeling including artificial intelligence methods.
6. Structure activity relationships in drug design: qualitative vs. quantitative approaches, advantages and disadvantages, random screening, nonrandom screening, drug metabolism studies, clinical observations, rational approaches to lead discovery, homologation, chain branching, ring chain transformations, bio-isosterism, insights into molecular recognition phenomenon, structure based drug design, ligand based drug design.
7. QSAR: Electronic effects, Hammett equations, lipophilicity effects, Hansch equation, steric effects, Taft equation, experimental and theoretical approaches for determination of physicochemical parameters, parameter inter-dependence, case studies, regression analysis, extrapolation vs. interpolation, linearity vs. non linearity, importance of biological data in the correct form, 3D-QSAR –example CoMFA and CoMSIA.

References:

Westhead, D.R, Parish, J.H. and Twyman, R. M., Instant notes in bio informatics, BIOS scientific publishers, 2002. (ISBN. 1859962726)

Attwood, T.K. and parry-smith, D.J., Introduction to bioinformatics, Addison-Wesney-Longman Ltd. 1999 (ISBN 0582327881)

Baxevanis, A.D. and Ouellette, B.F.F., Bioinformatics; A practical guide to the analysis of genes and proteins, John Wiley, 1998 (ISBN 047119196)

Mount, D.W, Bioinformatics: Sequence and genome analysis, cold spring harbor laboratory press. (ISBN 0879695978)

Lesk, A.M., Introduction to bioinformatics, Oxford University press (ISBN 0199251967)

Durbin, R., Eddy, S., Krogh and Mitchison, G., Biological sequence analysis: Probabilistic models of proteins and nucleic acid, Cambridge university press, 1998. (ISBN 0521629713)

Baldi, P. and Brunak, S., Bioinformatics: The machine learning approach, MIT, 1998 (ISBN 026202442X.)

Brandon, C.I. and Tooze J., Introduction to protein structure, Garland pub., 1991. (ISBN 0815302703)

Lesk, A.M., Introduction to protein architecture: The structural biology of proteins, Oxford University press 2001. (ISBN 0198504748)

Creighton, T.E., Protein Structure: A practical approach. Irl. Pr., 1997. (ISBN 0199636184)

Schultz, G.E., Principles of protein structure, Springer Verlag, 1978 (ISBN: 0387903348)

Sternberg, M (Ed), Protein structure prediction- A practical approach, Oxford university press, London 1996.

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus
M. Pharm. (Semester – I)
Pharmacology/Pharmaceutics/Quality Assurance
(Compulsory & Common Subject)

Subject code: PHC-102

Subject : Analytical Techniques Lab. (3 Credits)

*A minimum of 13 Practicals shall be conducted from the given modules.

Module-1

UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures and isosbestic point in case of mixtures.

Module-2

Effect of solvents and pH on UV spectrum of drugs

Module-3

Estimation of multicomponent formulation by UV- Spectrophotometer in formulations

Module-4

Experiments based on the application of derivative spectroscopy.

Module-5

Experiments based on HPLC (Isocratic and Gradient elution) techniques.

Module-6

Interpretation of drugs by IR spectra

Module-7

Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of few compounds

Module-8

Separation of protein drug substances by electrophoresis.

Module-9

Any other relevant experiments based on theory.

SEMESTER-II

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus
M. Pharm. (Semester – II)
PHARMACOLOGY
(Compulsory Subject)

Subject code: PCY-102

Subject : Clinical Pharmacology And Toxicology (TH) (4 Credits)

1. Introduction to clinical pharmacology, importance of clinical pharmacokinetics, therapeutic-Monitoring of drugs,

2. Organization, types of clinical research; design and organization of phase-I to IV of clinical studies, ethics of clinical trials

3. Drug-drug, drug-food, drug-pollutants interactions

4. Principles of pediatric, geriatric pharmacology; drug therapy in pregnancy and lactation.

5. **Neuropharmacology:** Clinical aspects of drug therapy of Epilepsy, Parkinson's disease, migraine, myasthenia gravis and Alzheimer's disease

6. **Endocrinology:** Concept of Homeostasis, molecular mechanism of hormone action, calcium homeostasis, neurohypophysial hormones, endocrine role of pineal gland. Clinical aspects of drug therapy of diabetes, goiter, Infertility, Erectile dysfunction

7. **Immunopharmacology:** Current concept in theory and research of vaccines, sera, tissue transplantation; Immunostimulants, immunomodulators, immunosuppressants, drug therapy for immune disorder and immunological investigations

8. Current concept and research in drug therapy in cardiovascular, gastric, renal, respiratory and hepatic disorders.

9. **Infectious Pharmacology:** General guidelines and **c**linical aspects of drug therapy of infectious disorders.

10. **Gene Therapy:** Current concept in theory and research of gene therapy; its application and limitations.

11. **Toxicology:** General principles of toxicology, toxicological evidence, common household poisons, qualitative & quantitative aspects of toxic effects, detoxification & disposition

Single dose and repeat dose toxicity studies; factors influencing such studies like species, sex, size, route and dose level; regulatory requirements, determination of effective dose & LD 50 as per international guidelines, invitro methods of toxicology; basic concepts of toxicokinetics. Brife review of Organ and system toxicology, Reproductive toxicology assessment, Mutagenicity and Carcinogenicity

References:

1. Goodman and Gilman, Pharmacological Basis of Therapeutics, Mc Graw Hill

2. Craig C R and Stitzel B E, Modern Pharmacology with Clinical Application, Lippincott Williams & Wilkins.

3. Katzung B G, Basic and Clinical Pharmacology, Lange Medical Publisher, USA

4. Melmon K L and Morelli, Clinical Pharmacology: Basic Principles of Therapeutics, Mc Millan, New York

5. Bacq Z M, and Capek R, Fundamentals of Biochemical Pharmacology, Pregmon Press, Oxford.

6. Grollman Pharmacology and Therapeutics, Lea & Tebiger, Philadelphia.

7. Harrisons Principles of Internal Medicine, McGraw Hill.

8. Davidson's Principles and Practice of Medicine, Vol I and II, Churchill Livingston.

9. Lawrnce D R and Bennette, Clinical Pharmacology.

10. Goldstein, Aranow & Kolman, Principles of Drug Action.

11. Rang H P, Dale M N, Pharmacology, Churchill Livingston, UK

12. Crossland Lewis's Pharmacology, Churchill Livingstone, Edinburgh, London.

13. Drill V A, Pharmacology in Medicine, McGraw Hill, New York.

14. Roger and Walkar, Clinical Pharmacy and Therapeutics, Churchill Livingstone, London.

15. Patten J, Neurological Differential Diagnosis.

16. Koda-Kimble, Applied Therapeutics: The clinical uses of Drugs.

17. Herfidal E T and Hirschman J L, Clinical Pharmacy and Therapeutics.

18. Review articles and Research articles from Medical and Pharmacological Journals

19. Niesink R J M, De Vries L and Hollinger M A, Toxicology: Principles and Applications, CRC Press.

20. Gupta P K and Salunke DK, Modern Toxicology, Vol. I, II, and III, Metropolitan, New Delhi.

21. Gad SC, Safety assessment for Pharmaceuticals, Van Nostrand Reinhold, New York.

22. Benichou C, Adverse Drug Reaction: A practical guide to diagnosis and management, Chichester, West Sussex, England.

23. Cobert B L, Manual of drug safety and Pharmacovigilance, Sudbury, Jones and Bartlett Publisher.

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus
M. Pharm. (Semester – II)
PHARMACOLOGY
(Compulsory Subject)

Subject code: PCY-103

Subject : Pharmacological Screening Method (TH) (4 Credits)

1. **Drug Discovery Process:** Principles, techniques and strategies used in new drug discovery, basic concepts of combinatorial chemistry, high through screening, cell lines, and their applications; Standard techniques used in laboratory animals, euthanasia of experimental animals, Regulations for laboratory animal care and ethical requirements.
2. **Bioassays:** Basic principles of bioassays, official bioassays, experimental models, design of bioassays and statistical methods used in biological standardization.
3. Principles of toxicity evaluations, ED_{50}, LD_{50} and TD value estimation. International guidelines and regulatory agencies for toxicity studies like ICH, OECD, FDA, WHO etc.
4. **Preclinical Evaluation:** Preclinical models employed and organization of screening of new drugs. Preclinical evaluation of following categories of drugs-
   - i) Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotic, analgesics, antipyretics, antimigraines, anticonvulsants, CNS stimulants
   - ii) Antiinflammatory agents, Local anesthetics
   - iii) Cardiac glycosides, antiarrythmics, antihypertensives, antianginals, anti-atherosclerotic
   - iv) Bronchodilators, Diuretics, Antitussives, Laxatives & antidiarrhoeals; Antiulcers, Antiemetics, Hepatoprotective
   - v) Antidiabetics, Antithyroids, Antifertility agents
   - vi) Anticholinergics, Sympatholytics, Muscle relaxants
   - vii) Antimalarials, Antivirals, Antitumor agents, Anthelmintics
   - viii) Dermatologicals and experimental models in skin pharmacology
5. Alternatives to animal screening procedures, cell line handling, maintenance and propagation of cell lines, their uses and limitations, in-vitro testing of drugs

References:

1. Laurence D R and Bacharach A L, Evaluation of Drug Activities: Pharmacometrics, Academic Press, London & New York.
2. Nodine J H and Siegler P E, Animal and Clinical Pharmacological Techniques in Drug Evaluation, Year Book Medical Publishers.
3. Turner R A and Hebbron P, Screening Methods in Pharmacology, Vol I & II, Academic Press, New York.
4. Vogal H G, Drug Discovery and Evaluation, Pharmacological Assays, Springer_verlog Berlin Heidelberg.
5. Goldstein A, Aronow L and Kalman S M, Principles of Drug Actions: The basis of Pharmacology, John Wiley and sons, New York.
6. Kulkarni S K, Handbook of Experimental Pharmacology, Vallabh Prakashan, Delhi.
7. Ghosh M N, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Kolkatta.
8. Sheth U K, Dadkar N K and Kamat U G, Selected topics in Experimental Pharmacology, Kotari Book Depot, Mumbai.
9. Jann Hau, Handbook of Laboratory Animal Science, Animal Models, Vol I and II.
10. Perry W L M, Pharmacological Experiments on Isolated preparations, E & S Livingstone, London.
11. Burn J H, Practical Pharmacology, Blachwell Scientific Co., Oxford.
12. Jaju B P, Pharmacology: A Practice Excersise Book, Jaypee Brothers, New Delhi.
13. Parmar N S and Shivkumar, Pharmacological Screening Methods.
14. Review articles published in various medical and pharmaceutical journals and CPCSEA, OECD, FDA, WHO, ICH guidelines from respective website.

Subject code : PPH-102
Subject : Pharmaceutical Production Technology (4 Credits)

Size reduction: Objectives and mechanisms of size reduction, factors affecting size reduction, laws governing energy and power requirements of a mill, colloid mill, high pressure homogenization, microfluidizers, and ultrasonicators.

Mixing: Theory of mixing and types of mixers including high speed mixers, ultrasonic mixers, industrial mixer-Nauta mixer and RMG, Diosna.

Filtration and centrifugation: Theory of filtration, filter media, factors affecting filtration, industrial filters, optimum-cleaning cycle in batch filters, Principles of centrifugation, industrial centrifugal filters and centrifugal sedimeters, ultracentrifugation.

Drying: Mechanisms of heat transfer, internal mechanism of moisture flow, psychrometry, drying mechanism, Moisture content and mechanism of drying, rate of drying and time of drying, Dryers used in pharmaceutical industries and special drying methods, e.g., tray, fluidized bed, spray, freeze, tunnel, microwave, granulators-cum-driers, IR dryers.

Tableting technology:
Introduction, benefits of improved tablet production system, material, processing step, processing problems, unit operation improvements, Role of computer process control and tablet tooling.

Pelletization technology: Introduction, Pelletization process and formulation, equipments for Pelletization Spheronizer**.**

Capsulation technology: Advances in capsulation technology: Hard and soft gelatin capsules.

Parenteral technology: Environmental control and design considerations for Parenteral production facility, processing and manufacturing of small and large volume parenterals,

Packaging Material Science: Packing design and specification, packaging validation trials, materials of construction, regulatory requirements, quality control testing and standards, GMP requirements and its deficiencies. In process control during component manufacture, Sterlisation of packing component, packging and filling equipment

Stability Testing: Physicochemical and biological factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Overages.

REFERENCES

1. Evans, Anderson, Sweeney and Williams Applied production and operations management 3rd edition, West publishing company Ltd. St.paul.

2. Peter F. Drucker. Management (task, responsibility and practices) Allied publication. Bangalore

3. HWTomski A Text of Pharmacy management Kogan Page ltd. London

4. Harold Koonz, Cyril a Donnell, Heinz, Weihrich Essentials of Management McGraw Hill Book Company. New Delhi.

5. Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition

6. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.

7. ISO 9000 and 14000 Series

8. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt Ltd.

9. Pharmaceutical Production and management by C.V.S. Subrahmanyam, Vallabh Prakashan.

10. Alderban, ed., Pharmaceutical powder compaction technology, Marcel Dekker Inc, New York.

11. Carlton and Agallaco, Aseptic process. Avis, Lachman, and Libermann, Pharmaceutical dosage forms: Tablets, vol. II, Marcel Dekker Inc, New York.

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus

M. Pharm. (Semester – II)

Pharmaceutics

(Compulsory Subject)

Subject code : PPH-103

Subject : Advances In Drug Delivery System **(4 Credits)**

Sustained Release Drug Delivery Systems: Introduction; Rationale of SRDDS; Advantages and Disadvantages of SRDDS; Factors influencing the design and performances of SRDDS: A) Physicochemical properties of a drug influencing design and performance; B) Biological factors influencing design and performance of SRDDS. Different Micro- encapsulation processes.

Controlled release drug delivery system: Introduction, Design and Development of oral controlled release drug administration: Dissolution controlled, Diffusion controlled Membrane permeation controlled, Osmotic pressure controlled, Gel diffusion controlled, pH controlled, Ion - exchange controlled delivery systems.

Polymers Science: Introduction, Polymer-classification, Applications of Polymers in formulation of controlled drug delivery systems, Biodegradable and Nonbiodegradable polymers, Properties of following commonly used polymers- Starch, Gelatin, Chitosan, Albumin, Cellulose derivatives and Poloxamers.

Transdermal drug delivery systems: Permeation through skin, Factors affecting permeation, Basic components of TDDS, Formulation approaches used in development of TDDS and their evaluation, Permeation enhancers.

Mucoadhesive Drug Delivery Systems: Introduction, Transmucosal drug delivery system: Concepts, Advantages and Disadvantages, Structure of oral mucosa, Trans-mucosal permeability, Nasal Drug Delivery Systems: Introduction, Physiology of nose, Fundamentals of nasal absorption, Distribution of drug in the nasal cavity, Enhancement in absorption, *in vitro* and *in vivo* methods for determination of nasal absorption.

Occular Drug Delivery Systems: Formulation and evaluation of occular controlled drug delivery systems, ophthalmic inserts and *in situ* gels.

Targeted Drug Delivery Systems: Concepts, Advantages and Disadvantages, Targeting of drugs through nanoparticles, liposomes, resealed erythrocytes, microspheres, magnetic microspheres, monoclonal antibodies, pulsatile drug delivery. Study on colon targeting. Biosome.

Intrauterine Drug Delivery Systems: Development of intrauterine devices (IUDs), copper IUDs, hormone-releasing IUDs.

Reference:

1. Encyclopedia of controlled delivery; By Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester /Weinheim.
2. Controlled and Novel Drug Delivery; By N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
3. Controlled Drug Delivery - Concepts and Advances; By S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002.
4. Remington's Pharmaceutical Sciences.
5. Novel drug delivery system; By Y.M.Chien, Marcel Dekker, Inc.
6. Controlled Drug Delivery - Fundamentals and Applications, 2nd edition; By Joseph R.Robinson and Vincent H.L.Lee.
7. Pharmaceutical Dosage forms, disperse system: Volume 1, By Herbert A.Libermann et.al, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.
9. Bentley's Textbook of Pharmaceutics; By E.A.Rawline, ELBS Publications.
10. Microencapsulation and Related Drug Process; By Patric B.Deasy.

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus

M. Pharm. (Semester – II)

Quality Assurance/Quality Assurance Techniques

(Compulsory Subject)

Subject code : PQA-102

Subject : Pharmaceutical Process validation (4 Credits)

- Introduction to pharmaceutical validation: definition, manufacturing process model, scope of validation, advantage of validation, organization for validation, validation of master plan, types of process validation, design qualification, installation qualification, operational qualification and performance qualification of facilities.
- Process validation: prospective, concurrent, retrospective and revalidation,
- Process validation of formulations like tablets, capsules, ointment/creams, liquid orals, sterile dosage form which should include following aspects-
    - Personnel and organization
    - Raw materials
    - Equipments (e.g. Dry powder mixers, fluid bed and tray dryers, tablet compression machine, capsule filling machines etc)
    - Area, premises and environment including storage of raw materials to finished products
    - Water (validation of pharmaceutical water system and pure steam),
    - Packaging and labeling controls and its validation
    - Cleaning validation: cleaning of equipment, cleaning of facilities
    - Validation of Integrated lines by media fill test.
    - Validation of HVAC system
- Vendor Certification.
- Validation of compressed air, validation of water and air handling systems
- Validation of existing equipment and utilities validation
- Computer system validation including installed softwares
- Pharmaceutical development of drug substance and drug product, formulations, manufacture and supply of materials, labeling and presentation, stability and storage, purity, compatibility, disposal.

REFERENCES:

1. Pharmaceutical Process Validation, B. T. Loftus and R. A. Nash, Drugs and Pharm Sci. Series, Vol. 129, Marcel Dekker Inc., New York.
2. Pharmaceutical Packaging Technology, Dean, D. A. Evans, E. R. and Hall, J. H., Taylor and Francis, London.
3. Validation of Aseptic Pharmaceutical Processes, Carleton and Agalloco, Marcel Dekker Inc., New York.
4. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries by Syed Imtiaz Haider and Erfan Syed Asif
5. Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance, Second Edition by Guy Wingate

6. Pharmaceutical Process Scale-Up", Michael Levin, Drugs and Pharm. Sci. Series, Vol. 157, Marcel Dekker Inc., New York.
7. Pharmaceutical Packaging Technology, Dean, D. A. Evans, E. R. and Hall, J. H., Taylor and Francis, London.

Subject code : PQA-103
Subject : Method Development and Validation (4 Credits)

- Application of process analytical technology (PAT) in quality assurance
- Qualification validation and calibration of equipment. Analytical and bioanalytical method validation
- Calibration and validation of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR spectrophotometer, spectrofluorimeter, HPLC, HPTLC and GC.
- Regulatory requirement in pharmaceutical analysis – US-FDA, ICH, PAC-ALTS: Post approval changes – analytical testing laboratory site etc.
- Analysis of drug from biological fluids
- Application of analytical methods to product obtained through genetic engineering, Amino acid sequence analysis, tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc.
- Application of analytical methods to product obtained from natural sources (extracts, herbal formulations, isolated compounds, modern herbal formulations) (Compendial methods for evaluation of crude drug and herbal formulation)
- Dosage form impurity profile and its validation
- Organization & personnel, responsibilities, training and records. Equipment selection purchase specifications, maintenance, clean in place for analytical department
- Premises - location, design, plant layout, construction maintenance and utilities and services like gas, water for analytical department

REFERENCES:

1. Pharmaceutical Analysis – Modern Methods – Part A, Part B, J. W. Munson, Marcel Dekker, NY.
2. Spectroscopic identification of organic compounds. John Dyer, Willy, NY.
3. Organic Spectroscopy W. Kemp, NY.
4. NMR spectroscopy (Basic Principles, concepts and application in Chemistry) Herald Gunther, (John Wiley and Sons), NY.
5. Spectroscopic identification of organic compounds. R.M. Silverstein, G.C. Bassler, T.C. Morrill, Pub: John Wiley and Sons, NY.
6. Quality control of herbal drugs: an approach to evaluation of botanicals, Pulok K. Mukherjee, 2002, Business horizons.
7. Encyclopedia of Pharmaceutical Technology Vol.1-3, Swarbric, J and Bolyln, J. C., Marcel Dekker, Inc., New York.
8. United States Pharmacopoeia-27(NF-22), 2004, United State of Pharmacoppeal convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
9. The International Pharmacopoeia Vol. 1,2,3,4, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.

10. Phytochemical Methods, J.B.Harborne, Chapman and Hall, London and New York.
11. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine and Homeopathy).

Subject code : PHE-106
Subject : Applied Biopharmaceutics & Pharmacokinetics (4 Credits)

Absorption Of Drugs: Definition, Structure of cell membrane and composition, Gastrointestinal absorption – Mechanism, Factors affecting drug absorption: Biological, Physiological, Physico-Chemical and Pharmaceutical dosage form factors; Methods of determining absorption*: In Vitro* and *In Vivo* methods.

Distribution Of Drugs: Definition, Distribution in blood and other fluids: cellular distribution, drug penetration to CNS, placental transfer of drugs and blood flow, Factors affecting drug distribution, Volume of distribution,

Protein Binding: Plasma protein binding: factors affecting, significance and kinetics of protein binding.

Metabolism of drugs: Definition, brief overview of Phase I and Phase II reactions. Factors affecting biotransformation.

Excretion of drugs: Definition, Renal and non-renal excretion, Concept of clearance - Renal clearance, Organ clearance & Hepatic clearance.

Basic concepts of pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: one compartment model - IV bolus, IV infusion, Extra-vascular; Multi Compartment models; Two compartment model - IV bolus, IV infusion, Extra-vascular, Three Compartment model in brief.

Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis-Menten equation, Estimation of Km and Vmax.

Application of Pharmacokinetics in Novel drug delivery systems. Concept of loading dose & maintenance dose, Multiple dosing with respect to I.V. and oral route, Adjustment of dosage in renal and hepatic impairment, Individualization of therapy, Therapeutic Drug Monitoring.

References:

1. Biopharmaceutics and clinical Pharmacokinetics By Milo Gibaldi.
2. Remington's Pharmaceutical Sciences; By Mack publishing company, Pennsylvania.
3. Pharmacokinetics; By Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics; By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics; By Robert E. Notari.

6. Biopharmaceutics; By Swarbrick.
7. Biopharmaceuties and Pharmacokinetics- A Treatise; By D.M.Brahmankar and Sunil B.Jaiswal., Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications; By Malcolm Rowland and Thomas N.Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence; By Abdou.H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C.Boylan. Marcel Dekker Inc, New York, 1996.

Swami Ramanand Teerth Marathwada University, Nanded

M.Pharm. Syllabus

M. Pharm. (Semester – II)

Pharmacology/Pharmaceutics/Quality Assurance

(Elective)

Subject code : PHE-107

Subject : Pharmaceutical Biotechnology (4 Credits)

Introduction to genetic organization in prokaryotes, protein biosynthesis and its regulation, gene transcription, RNA splicing Protein immobilization; different methods like adsorption, entrapment, microencapsulation and bioreactors used in protein immobilization.

Introduction to R-DNA technology, their application in synthesis of insulin, growth hormone etc Genetic mechanism of drug resistance with reference to antibiotics.

Pharmaceutical products: Human protein replacement, Human therapeutics, and vaccines.

Human diagnostics: Methods of linkage analysis and mutation detection, Diagnostics for infectious agents: methods with examples

Gene therapy: types, vectors, methods, safety and advances.

Fermentation technology – Introduction to fermentation technology, Fermentors, general design of fermentor, fermentation techniques and processes, production of alcohols, antibiotics, steroids and enzymes; biotransformation, biomass & production of single cell protein.

Enzyme Technology - Large scale production of enzymes, enzyme reactors, immobilization of enzymes by chemical and physical methods. Effect of partition on kinetics and on changes in pH and hydrophobicity. Applications: synthetic organic chemistry, industry, food technology, medicines. Synzymes, enzyme electrodes and biosensors. Enzyme Engineering.

Hybridoma technology – Monoclonal antibodies, selection of hybrids, hybridomas, purification and application of monoclonal antibodies.

Xenobiotic metabolism – Biodegradation, detoxification of xenobiotics by micro-organisms, biodegradation of hydrocarbons, pesticides, surfactants, polyaromatic hydrocarbons, dyes; role of cytochrome P450 in detoxification.

Tissue culture – Plant tissue culture, anther and pollen culture, protoplast culture, protoplast fusion, embryo rescue, animal cell lines and organ culture.

References:

1. J. Rehm and G. Reed, Enzyme Technology, Vol. 7a, VCH-Verlag.

2. Michael L. Shuler and Fikret Kargi, Bioprocess Engineering: Basic Concepts, 2nd Edition, Prentice Hall, 2001.
3. Pauline M. Doran, Bioprocess Engineering Principles, 1st Edition, Academic Press, 1995.
4. Pelczar MJ Jr., Chan ECS and Kreig NR., Microbiology, 5th Edition, Tata McGraw Hill, 1993.
5. Crueger and A Crueger, Biotechnology: A Textbook of Industrial Microbiology, Sinaeur Associates, 1990.

6. G Reed, Prescott and Dunn's, Industrial Microbiology, 4th Edition, CBS Publishers, 1987.

7. M.T. Madigan and J.M. Martinko, Biology of Microorganisms, 11th Edition, Pearson Prentice Hall, USA, 2006
8. Whitaker et al, Principles of Fermentation Technology, Indian Edition, Hall Books, 2007.
9. S. J. Pirt, Principles of microbe and cell cultivation, 3rd Edition, Wiley, 1975.

10. S N Mukhopadhay, Process biotechnology fundamentals, Viva Books, 2001.

Subject code : PHE-108

Subject : Pharmaceutical Stability Studies (4 Credits)

- **Stability aspects: Basic concept and objectives of stability study**.
    - Regulatory requirement for stability studies: A very brief introduction to FDA and WHO guidelines. Detail study of ICH guidelines [Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C].
    - Kinetic principles applied for stability evaluation and their applications in predicting shelf life and half life of pharmaceutical formulations. Importance of accelerated stability study.
    - Degradation pathways (Degradation by hydrolytic, oxidative, reductive, photolytic, etc) and stabilization methods for formulation.
    - Stability indicating assays and its importance
- **Stability testing and dating of solid and liquid dosage forms:**
    - Different approaches for stability testing of solid and liquids, kinetic principles, physical and chemical stability testing of pharmaceutical dosage forms and packages.
- Product life-cycle management
- Product liability and compensation
- Stability issues related to proteins and insulin type formulations
- Stability issues related to herbal formulations, extracts, fractions and natural products/isolated compounds.
- Stability issues for vaccines and biological products

REFERENCES:

1. Drug Stability, J.T. Carstensen, Marcel Dekker, New York.
2. Chemical Stability of Pharmaceuticals-A Handbook for Pharmacists, Kenneth Connors, John Wiley and Sons, Inc.
3. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumit
4. United States Pharmacopoeia-27(NF-22), United State of Pharmacoppeal convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
5. The International Pharmacopoeia Vol. 1,2,3,4, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
6. Phytochemical Methods, J.B.Harborne, Chapman and Hall, London and New York.
7. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine and Homeopathy).

Subject code : PHE-109
Subject : Quality Assurance Approach and Improvement (4 Credits)

- Quality improvement process
- Quality in research and development
- Complaints and recalls: evaluation of complaints, recall procedure, related records and documents.
- Quality control laboratory – responsibilities and laboratory practices. Routine controls on instruments, reagents, sampling plans, standard test procedures and protocols, control on animal house, data generation and storage, quality control documentation and audits of QC facilities.
- Finished product release, quality review, quality audits and batch release documents.
- Validation and security measures for electronic data and computer assisted process.
- Calibration and validation of master plan
- Cosmetics, biotechnological, microbiological products & regulations, medical device regulations; fraud and professional misconduct

REFERENCES:

1. Encyclopedia of Pharmaceutical Technology Vol.1-3, Swarbric, J and Bolyln, J. C., Marcel Dekker, Inc., New York.
2. United States Pharmacopoeia-27(NF-22), 2004, United State of Pharmacoppeal convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
3. The International Pharmacopoeia Vol. 1,2,3,4, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
4. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine and Homeopathy).
5. Juran's Quality Handbook, 5th Ed, by J M Juran, A B Godfrey, McGrawHill International Edition
6. Official books like IP, BP, USP, etc of recent editions

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M.Pharm. Syllabus
M. Pharm. (Semester – II)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-110

Subject : Clinical Pharmacokinetics (TH) (4 Credits)

1. **Introduction:** Basic concepts of ADME profile of drugs, absorption rate constant, volume of distribution, elimination rate constant, clearance, extraction ratio, area under curve (AUC), protein and tissue binding. Calculation of parameters from plasma and urine data.
2. **Bioavailability and Bioequivalence:** Principles, objectives, protocols and variation of bioavailability & bioequivalence, measurement, designing of bioavailability studies & interpretation of results, Physiological, physico-chemical & formulation factors affecting bioavailability, enhancing bioavailability of drug products.
3. **Integration with Kinetics:** Interrelation between kinetic parameters and physiological variables, drug disposition, induction and inhibition of metabolism
4. Basic concepts of compartment modeling with reference to some therapeutic agents.
5. Pharmacokinetics of multiple dosing & its determination, Chronopharmacokinetics, individualization of drug therapy. Non-linear pharmacokinetics like saturable enzymatic process, examples of drugs that follow non-linear pharmacokinetics and its clinical implications.
6. Altered kinetics in pregnancy, child birth, infant and geriatrics; Kinetics of drugs & its clinical implications in GI diseases, malabsorption syndrome, liver, cardiac, renal and pulmonary diseases; genetic based altered drug kinetics, kinetics clinically harmful drug interaction; some case studies of altered kinetics in above conditions

References:

1. Malcolm Rowland and Thomas Tozer, Clinical Pharmacokinetics: Concept and Application, Lea and Febiger, Philadelphia.
2. Abdou H M, Dissolution, Bioavailabilty & Bioequivalance, Mack Publishing Company, Pennsylvania.

3. Shargel L and Yu ABC, Applied Biopharmaceutics & Pharmacokinetics, Connecticut, Appleton Century Crofts.

4. Milo Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, Lea and Febiger, Philadelphia.

5. Milo Gibaldi and Laurie Prescott, Hand Book of Clinical Pharmacokinetics, Adis Health Science Press, New York.

6. John Wagner and M Pernarowski, Biopharmaceutics and Relavant Pharmacokinetics, Drug Intelligence Publication, Hamilton.

7. Robert E Notari, Biopharmaceutics and Clinical Pharmacokinetics, Marcel Dekker Inc., New York.

8. Swarbick J, Current concept in Pharmaceutical Sciences: Biopharmaceutics, Lea and Febiger, Philadelphia.

9. Niazi, Biopharmaceutics and Clinical Pharmacokinetics, Prentice Hall, London.

10. Gennaro A R, Remington: The Science & Practice of Pharmacy, Lippincott (Recent edition).

11. Larry Bauer and P B Bauer, Clinical Pharmacokinetics, McGraw Hill.

12. Michael E Winter, Basic Clinical Pharmacokinetics, Lippincott Willams and Wilkins.

13. Brahmankar D M and Jaiswal S B, Biopharmaceutics and Pharmacokinetics: A Treatise, Vallabh Prakashan, Delhi.

14. Larry Bauer, Applied Clinical Pharmacokinetics, McGraw Hill Medical

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M.Pharm. Syllabus
M. Pharm. (Semester – II)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-111

Subject : Pharmacological aspects of Natural Products (TH) (4 Credits)

1. **Introduction to Natural Products:** Role of natural products in drug development, plant-derived drugs, novel drug templates, bioactive compounds from microorganism, microbial phytotoxins
2. **General methods of processing and extraction of herbs:** Sources, identification, authentification, collection, storage and drying methods of herbs. Different methods of extraction of herbs, selection of extraction method, isolation & purification of biomolecules from natural sources
3. Use of natural products in diseases, adaptogens, memory enhancers, anti-inflammatory agents, antiparasitics
4. **Herb-drugs Interaction:** Basic concept, types and mechanism of clinically important Herbs-Drug Interactions.
5. **Standardization of Natural Products:** Standardization requirements for herbal medicines, factors affecting quality of herbal drugs & products, safety and efficacy assessment, guidelines of WHO for herbal standardization, principles & methods of qualitative and quantitative estimation of active principles from natural products; stability testing of natural products, testing methods & its limitations for natural products
6. **Biological standardization:** Bioavailability and pharmacokinetic aspects of herbal drugs, phytoequivalence, Pharmacological screening of herbal extracts, herbal formulations and constituents obtained from natural sources, potency assays for some commonly used natural products, in-vitro biochemical testing for steroids estimation
7. Global regulatory status of herbal medicines.

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M.Pharm. Syllabus
M. Pharm. (Semester – II)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-112

Subject : Drug Design (TH) (4 Credits)

1. DRUG DISCOVERY

a. Historical Perspective
b. Drug Discovery studies in Direct Drug Design (Structure based) ND Indirect Drug Design
c. Target Selection and Lead Identification
   i) Natural Product Sources
   ii) Fermentation/ microbial sources
   iii) Synthetic
d. Introduction to Pharmacogenomics.

2. APPROACHES TO THE RATIONAL DESIGN OF ENZYME INHIBITORS

a. Introduction
   i) Enzyme inhibitors in Medicine
   ii) Enzyme inhibitors in basic Research
   iii) Drug Design based on Antagonism and Enzyme Inhibition
b. Rational design of non-covalently & covalently binding enzyme inhibitors, rapid reversible inhibitors, slow & tight binding inhibitors, Transition state analogs, multisubstrate inhibitors.

3. QUANTITATIVE STRUCTURE ACTIVITY RELATIONSHIP

a. History and development of QSAR
b. Drug-Receptor Interactions
c. Quantitative model parameters: lipophilicity, electronic and steric factors
d. Hansch Analysis, Free Wilson analysis, relationship between them and their application.
e. Statistical methods-regression analysis, partial-least square analysis (PLS) and other multivariate statistical methods
f. 2D and 3D QSAR approaches

4. MOLECULAR MODELING

a. introduction to Molecular Modeling- concepts and methods
b. Molecular mechanics-Force field (potential energy function)
c. Quantum Mechanics- Calculation of affinity, unknown receptors, Pharmacophore models
d. Known receptor sites
e. Searching for similarity, molecular comparison and finding common pattern
f. Energy Minimization methods-Steepest, desent, conjugate gradients, Newton

methods (Non mathematical)

g. Conformational Analysis
    i) Systematic search
    ii) Monte Carlo Simulations
    iii) Molecular Dynamics Simulations

h. Ligand design based on 3D structure

REFERENCES

1. QSAR & Strategies in the design of Bioactive Compound J. K. Seydel Latest after 1984 Deuts che Bibliofech.
2. Nucleic acid targeted Drug Design Propst & Thomas 1997 Marcel Decker.
3. Structure based Drug Design Pandi veera Pandian 1997 Merck Decker
4. A Guide to chemical Basis of Drug Design Burger Alfred 1997 Wiley interscience.
5. Computer aided Drug Design Perun 1st 1989 / Latest Marcel Decker
6. Computational Medicinal Chemistry for Drug Design Patrick Bultinck 1st 2004 Marcel Decker.
7. Nucleic acid targeted Drug Design Propst & Thomas 1997 Marcel Decker 8. Principles of Drug Design by Smith
9. Strategy of Drug Design by Brucell
10. The organic chemistry of the Drug Design and Drug action by Richard B. Silverman
11. Introduction to Quantitative Drug Design by Y.C.Martin
12. Drug Design volumes by Ariens
13. QSAR: Hansch Analysis and Related Approaches by Hugo Kubinyi
14. Textbook of Drug Design and Discovery, Third Edition, Larsen, Liljeors and Madsen

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M.Pharm. Syllabus
M. Pharm. (Semester – II)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-113

Subject : Sterile Products Formulation and Technology (TH) (4 Credits)

1. Biopharmaceutical Factors Influencing Bioavailability: Physicochemical influences on bioavailability, Physiologic factors influencing drug absorption, Dosage form considerations, Drug absorption and bioavailability from intramuscular injection. Drug absorption from subcutaneous injection, Biopharmaceutics of intrathecal injections, parenteral administration of peptides and proteins, Parenteral drug delivery systems.

2. Preformulation Research: Introduction, Drug substance physicochemical properties, General modes of drug degradation, Preformulation studies for proteins and peptides, Preformulation screening of parenterals packaging components.

3. SVP and LVP: Introduction to SVP, Formulation principle, Special types of Parenteral (Suspension, Emulsion, Dried Forms), Container effect on formulation, Stability evaluation. Introduction to LVP, Concept of formulation, Formulation development, Solution Quality.

4. Sustained/Controlled Release Parenterals Drug products: Biopharmaceutics, Biocompability of polymeric materials, Sustained/controlled release dosage forms: - Aqueous solutions, Aqueous suspensions, O il solutions, Oil suspensions, Biocompatible carrier, Liposomes, Nanoparticles, Infusion devices, Prodrug.

5. Design Consideration For Parenteral Production Facility: Introduction, Site selection, Facility area use planning, Design concepts.

6. Environmental control: Introduction, Control of contamination, Environmental contamination control system design, Clean rooms, Personnel contamination control.

7. Quality Control: Sterility testing, FDA guidelines on sterility testing, Pyrogen testing, Particulate matter testing, and Package integrity testing.

References:

1. K. E. Avis, H. A. Liebermann and Lachman; Pharmaceutical dosage forms: Parenteral Medications: Vol.1, 2, 3, Marcel Dekker.
2. S. J. Turco Sterile Dosage Forms: their preparation and clinical application; 4th Edition. Lee and Febiger.
3. N. K. Jain; Controlled and Novel drug delivery: CBS Publication.
4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.

5. S.P. Vyas and R. K. Khar, Controlled drug delivery: concepts and advances; Vallabh Prakashan.
6. M. J. Akers, Parenteral Quality Control. Third Edition. Marcel Dekkers.

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M.Pharm. Syllabus
M. Pharm. (Semester – II)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-114

Subject : Biomaterials for Drug Delivery (TH) (4 Credits)

1. **Biomaterials:** Introduction, classification, mechanical, surface, electrochemical, & physiochemical properties of biomaterials: metallic, ceramic, polymeric, composite, biodegradable hydrogels, and biologic biomaterials.

2. **Biodegradable polymers:** Mechanisms of polymer degradation, factors affecting biodegradability, various methods to study biodegradability: enzyme assays, plate tests, respiration tests, gas (CO2 or CH4) evolution tests, radioactively labeled polymers. Study of segmented co-polyesters with prolonged strength retention profiles, polyaxial crystalline fiber forming co-polyester, polyethylene glycol-based co-polyesters, cyanoacrylate-based systems as tissue adhesives, chitosan-based systems.

3. **Development and applications of new systems:** Fabrication of crystalline fiber-forming aliphatic copolyesters, medical absorbable devices, tissue engineering systems, synthetic vascular constructs, implantable insulin controlled release systems, absorbable delivery systems, tumor immunotherapeutic systems.

4. **Testing of biomaterials:** Biocompatibility, blood compatibility and tissue compatibility of biomaterials. In-vitro and in-vivo testing of toxicity, sensitization, carcinogenicity, mutagenicity testing of biomaterials.

5. **Regulatory aspects of biomaterials:** Regulatory aspects of biomaterials and their approval status in various countries. Toxicity and interaction of biomaterials with body components.

References:

1. Sujata V. Bhatt, Biomaterials, Springer, 2002.
2. Buddy D. Ratner, Fredrick J. Schoen, Allan S. Hoffman, and Jack E. Lemons "Biomaterials Science: An introduction to Materials in medicine, Academic Press, 2004.
3. Jonathan Black, Biological Performance of materials, Taylor & Francis,2006
4. C.P.Sharma & M.Szycher, Blood compatible materials and devices, Technomic Publishing Co. Ltd., 1991.
5. Piskin & A.S Hoffmann, Polymeric Biomaterials (Eds), Martinus Nijhoff Publishers, 1986
6. J. B. Park, Biomaterials - Science and Engineering, Plenum Press, 1984.

M.Pharm. Syllabus

M. Pharm. (Semester – II)

Pharmacology/Pharmaceutics/Quality Assurance (Elective)

Subject code: PHE-115

Subject : Nano Drug Delivery Systems (TH) (4 Credits)

1. Manufacturing of nanocarriers: Procedures involved in design and development of various nanosized drug delivery systems: nanocrystals, nanoparticles, nanocapsules, nanofibers, dendrimers, solid lipid nanoparticles, liposomes, fullerenes, i.e., carbon nanotubes, nanorods, and self-assembling nanostructures.

2. Target oriented nanocarrier based drug delivery systems: Rational for targeted drug delivery, biological processes involved, cellular uptake and processing transport across epithelium, extravasation, lymphatic uptake. Pharmacokinetic and pharmacodynamic considerations.

3. Long-circulating polymeric nanoparticles: Rational of long circulation and mechanism of clearance of nanoparticles from body. Chemistry involved in PEGylation of nanocarriers. Stealth nanoparticles. Bioconjugation, antibodies based mechanism.

4. Nanoparticles and targeted systems for cancer diagnosis and therapy: Targeted delivery through enhanced permeability and retention. Folate receptors, Targeting through angiogenesis

5. Targeting to specific organs or tumor types, Tumor-specific targeting: Breast cancer, Liver, Targeting tumor vasculature for Imaging.

6. Nanosized materials used in diagnosis: Nanosized materials used in diagnosis of cancer and other critical diseases, MRI contrast enhancement, and in diagnostic kits.

References:

1. Gilbert S. Banker, Christopher T. Rhodes, Modern Pharmaceutics, Marcel Dekker.

2. R. B. Gupta, U. B. Kompella, Nanoparticle technology for drug delivery, Tayler & Francis.
3. Deepak Thassu, Michel Deleers, Yashwant Pathak, Nanoparticulate drug delivery systems, Informa healthcare.
4. Mansoor M. Amiji, Nanotechnology for cancer therapy, CRC Press.

M.Pharm. Syllabus

M. Pharm. (Semester – II)

Pharmacology/Pharmaceutics/Quality Assurance (Elective)

Subject code: PHE-116

Subject : Polymers in Pharmaceutics (TH) (4 Credits)

1. Classification of polymers**,** synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsion polymerizations. Properties of following commonly used polymers such as Starch, cyclodextrins, chitosan, gelatin, albumin, Cellulose derivatives, acrylates and poloxamers.
2. Characterization of polymers**:** Molecular weight and Molecular weight distribution of polymers, flow characteristics, crystallinity, solubility and thermodynamics of polymers solutions, biodegradability and biocompatibility testing of polymers.
3. Factors affecting selection of polymers, Effect of additives on polymer properties, Effect of environmental conditions on polymer properties, Polymer properties influencing drug permeation, Factors influencing kinetics of solute release.
4. Natural & Synthetic Acrylates and their applications
5. Biodegradable polymers and their application in pharmaceuticals
6. Application of polymers in sustained & controlled release drug delivery system (Oral, Mucosal, Transdermal)
7. Applications of polymers in new drug delivery systems.

References:

1. J. Brandrup, E.H. Immergur; Polymer Handbook; John Wiley and Sons.
2. Charles G. Gebelein, T.C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
3. D.S. Soane; Polymer Applications of Biotechnology; Prentice Hall Inc.
4. J. R. Robison and V. H. Lee; Controlled Drug delivery- Fundamentals and Applications; Marcel Dekker.
5. N.K. Jain; Controlled and Novel Drug Delivery; CBS publication.
6. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press
7. A. F. Kydonieus: Controlled Release Technologies: Methods, Theory and Applications, Vol. I & II CRC press Inc.

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M.Pharm. Syllabus
M. Pharm. (Semester – II)
Pharmacology/Pharmaceutics/Quality Assurance
(Elective)

Subject code: PHE-117

Subject : Phytochemistry (TH) **(4 Credits)**

Developments in Phytochemistry: **(03)**

General and specific techniques, procedure and methods in phytochemical analysis, General biosynthetic relationship between primary metabolites with interlink precursors and secondary metabolites, Importance of phytochemical to human being/ Man, Aspects of biotechnology in biochemical and molecular regulations in the industrial development of plant phytochemical with the syntheses of metabolites.

Bioassay-guided Isolation of active principals from following categories: **(13)**

1) Glycosides: Steroidal, flavonoids, Coumarins and saponins.
2) Alkaloids: Indole , Phenantherene, Quinoline and imidazole.
3) Terpenes: Monoterpenes, Diterpenes, Triterpenes and Tetraterpenes.
4) Natural colours

Elucidation of Pharmacologically active Plant substances: **(10)**

1) Nicotine
2) Phytol
3) Androsterone
4) Testosterone
5) Apigenine
6) Anthocyanins
7) Aureusin
8) Conine
9) Hemoglobin/ Haemin
10) Menthol

Diets and Medicines as Modulator of energy metabolism **(10)**

Emphasis shall be given on prospection of medicinal plants with respect to photochemistry, various bioactivities in relation to human health.

1) Piper nigrum
2) Ferula asafetida
3) Corcus sativus
4) Tamarindus indicus
5) Trachyspermum ammi
6) Murraya koenigii

7) Punica granatum
8) Capsicum annum
9) Allium cepa
10) Trigonella foenumgraaecum

Reference books:

1) Phytochemical Methods of analysis -J B Harborne
2) Modern Methods of Plant analysis – Peech and Tracey
3) Natural product chemistry " A Laboratory Guide " – Rapheal Ikan
4) Organic Chemistry of Natural Products – Vol-I and II – Chatwal and Anand
5) Organic Chemistry of Natural Products – Vol-I and II – O P Agrawal
6) Organic Chemistry Vol-I and II – I L Finar
7) Herbal Drugs, A Twenty first century perspective – Rakesh Sharma and Rajesh Arora
8) Natural product chemistry – Jagdamba Singh and Jaya Singh

M.Pharm. Syllabus
M. Pharm. (Semester – I)
PHARMACOLOGY
(Compulsory Subject)

Subject code: PCY-104

Subject : Pharmacology Lab. (3 Credits)

*A minimum of 15 Practicals shall be conducted from at least 06 modules. Module 1 and 2 are compulsory. A right side figure indicates maximum practical conducted from single module.

Module-1 Prerequisite for Pharmacology Practicals: (01)

In this module it is expected student should know general principles, techniques and strategies for pharmacological screening of drugs; animal care, handling, ethical requirements and regulations therein.

Module-2 Basic Experimental Techniques: (02)

1. Standard techniques collection of blood samples and feeding of animals
2. Administration of drugs by different routes in mice
3. Use of anaesthetics and cannulation of veins, arteries, trachea

Module-3 Practicals using software's such as BioPac: (04)

In this module it is expected student should know working of Biopac and setting of physiologic and animal experimentation and perform at least four experiments from following or others-

1. To record temperature using thermal transducer
2. To measure blood pressure using Blood pressure transducer
3. To measure drug response curve using isotonic transducer
4. Measurement of isometric contraction using force displacement transducer.
5. To measure a change in volume using volume transducer
6. To measure a respiration using a respiratory transducer
7. To study various transducers and couplers
8. To study ECG using ECG coupler with BioPac
9. To measure vital capacity, forced expiratory volume etc., using isotonic transducer and spirometer

Module-4 Experiments on intact animals: (04)

1. To study locomotor activity by using Actophotometer.
2. To evaluate analgesic activity of drug using tail flick latency test.
3. To determine the effect of carrageen induced edema in rats by using digital Plethysmometer.
4. To study the anticonvulsant effect of Phenobarbitone against MES induced convulsions in rats.
5. To determine the analgesic effect by using Eddy's hot plate.
6. To study effect of pentabarbitone sodium on righting reflex (hypnosis) in mice.

7. To study Anti-anxiety effect of diazepam in mice using elevated plus maze apparatus.
8. To study the Apomorphine induced compulsive behaviour (Stereotype) in mice.
9. To study the muscle relaxant property of Diazepam in mice using ratarod.
10. To study amnesic (loss of memory) effect of drug using passive avoidance step-down task paradigm in mice.

Module-5 Bioassays: (04)

1. Drug /concentration response curve of test drugs
2. Estimation of potency of test substance by bioassay methods
3. Bioassays of agonist such as Ach, Histamine, Adrenaline, Oxytocin and their antagonist

Module-6 In-vivo experiments: (02)

1. To study antisecretory and ulcer protective effect of Cimetidine in pylorus ligated rats.
2. To study the local anaesthetic property of procaine hydrochloride using foot withdrawal reflex of frog.
3. To study Diuretic effect of any one marketed preparation

Module-7 Toxicity Studies: (02)

1. Regulations and guidelines of toxicity studies
2. Method of calculation of ED_{50} and LD_{50}
3. Observation of behavioral changes in animals during acute and sub acute toxicity study of test drug

Module-8 Biochemical: (02)

In this module it is expected a student should perform some of following experiments by chemical assay method or by using Autoanalyser.

1. To determine cholesterol, triglycerides, LDL, HDL.
2. To determine liver enzyme in order to evaluate Hepatoprotective drugs.
3. Determination of ALT, AST, Serum bilirubin and alkaline phosphatase.
4. To evaluate renal function by measuring blood urea nitrogen, creatinine clearance.
5. To evaluate blood sugar by GOD-POD method.

Module-8 Clinical: (02)

In this module, it is expected a student should collect data from field targeted as disease oriented, drug use oriented, adverse events oriented, biochemical oriented etc and compile it with conclusive output.

Module-9 Statistical: (02)

1. Statistical evaluation of data and finding level of significance
2. Hand on experience on online, offline, open source statistical software's

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M.Pharm. Syllabus

M. Pharm. (Semester – II)

Quality Assurance/Quality Assurance Techniques

(Compulsory Subject)

Subject code : PQA-104

Subject : Quality Assurance Lab.

(General Laboratory in an area of Specialization) (3 Credits)

*A minimum of 15 Practical's shall be conducted from at least 08 modules. Module 1 is compulsory. A right side figure indicates maximum practical conducted from single module.

Module 1: Prerequisite **(01)**

Basics of instrumentation, validation documentation

Module 2: **(03)**

1) Quantitative estimation by UV, HPLC
2) Acquaintance with working or principles of major spectroscopic and chromatographic techniques (IR, NMR, MS, AAS, GC, HPTLC and HPLC etc

Module 3: **(02)**

1. Method development and validation using UV, HPLC and HPTLC

Module 4: **(03)**

1. Quantization of different phytoconstituents from extracts and herbal formulation by Spectroscopic, HPLC and HPTLC method

Module 5: **(02)**

1. Stability indicating assay methods

Module 6: **(02)**

1. Impurity profile (AIP, formulations)
2. Quantitative estimation of drugs in biological fluids

Module 7: **(04)**

1. Validation of following equipment:
   Autoclave, hot air oven, powder mixer (dry), tablet compression machine and equipments required for formulations
2. Validation of a processing area.
3. Cleaning validation of equipment.
4. Validation of tablet, capsule, liquid (oral, topical etc) manufacturing facilities
5. Evaluation equipments validation

Module 8: **(01)**

1. Preparation of calibration master plan

Module 9: **(02)**

1. Evaluation and validation of packaging materials & facilities.
2. Test of packaging materials, cartons, aluminum foils, strip packing, blister packing, ampoules, vials, etc.

Module 10: **(01)**

1. Software, computer system validation.

Module 11: **(01)**

Documentation involved in above process

REFERENCES:

1. Practical Pharmaceutical Chemistry (part II) by Beckett and Stenlake
2. Interpretation of Mass Spectra of organic compounds-B. Kienicz, C. Djerassi
3. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and
4. Biotechnology Industries by Syed Imtiaz Haider and Erfan Syed Asif
5. Pharmaceutical Process Validation – Robert A. Nash, Alfred H. Wachter.
6. Pharmaceutical Analysis – Modern Methods – Part A, Part B, J. W. Munson, Marcel Dekker, NY.
7. United States Pharmacopoeia-27(NF-22), 2004, United State of Pharmacopeial convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
8. British Pharmacopoeia, 2004, The British Pharmacopoeia commission office, Market Tower, Nine Elms Lane, London.
9. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission, Sector-23, Raj Nagar, Ghaziabad.
10. Chromatographic Analysis of Pharmaceuticals, A. John, Adamovics, Cytogan Corporation, Princeton, NJ.
11. Clinical Pharmacotherapecutics, edited by Kamalesh Kohli, Elsevier Publication.
12. Biological standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.
13. Pharmaceutics of Solids and Solid dosage form by Cartensens.
14. Advance in Pharm. Sciences by Bean and Beckett.
15. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials (v. 1) by WHO.
16. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
17. Pharmaceutical Computer Systems Validation: Quality Assurance, Risk Management and Regulatory Compliance, Second Edition by Guy Wingate.
18. Relevant articles from journals.
19. Quality control of herbal drugs: an approach to evaluation of botanicals, Pulok K. Mukherjee, 2002, Business horizons.
20. Pharmaceutical Packaging Technology, Dean, D. A. Evans, E. R. and Hall, j. H., Taylor and Francis, London.
21. Packaging of Pharmaceutical and Healthcare products, H. Lockhart, F. A. Paine, Champman and Hall, London.
22. Packaging of Pharmaceuticals, C.F. Ross.
23. Drug Stability, J.T. Carstensen, Marcel Dekker, New York.
24. Chemical Stability of Pharmaceuticals-A Handbook for Pharmacists, Kenneth Connors, John Wiley and Sons, Inc.

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M.Pharm. Syllabus

M. Pharm. (Semester – II)

Pharmaceutics

(Compulsory Subject)

Subject code : PPH-104

Subject : Pharmaceutics Lab.

(General Laboratory in an area of Specialization) (3 Credits)

Module 1

Pre-formulation study of pharmaceutical products.

Module 2

Determinations of flow properties of powders

Module 3

Quality control of pharmaceutical dosage forms: Tablets, Capsules, Liquid oral, Parenteral, External preparation

Module 4

Comparison of dissolution studies of two different marketed products.

Module 5

Stability/Accelerated stability study of Pharmaceutical products

Module 6

Preparation and evaluation of Matrix tablets, fast dissolving tablets, microcapsules, gels, solid dispersion, coating (tablets, pellets), polymer films etc.

Module 7

Formulations based on the cosmetics like vanishing cream, talcum powder, tooth paste, shampoo, paste, depilatory, nail polish, lipstick etc.

References:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
2. Modern Pharmaceutics; By Gillbert and S. Banker. 3. Remington's Pharmaceutical Sciences.
4. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
5. Physical Pharmacy; By Alfred martin
6. Bentley's Textbook of Pharmaceutics – Rawbins.
7. Pharmaceutical Preformulations; By J.J. Wells.
8. Harry's Cosmeticology.
9. Textbook of Cosmeticology by B.M.Mittial.
10. Textbook of Cosmeticology by P.P.Sharma