



Swami Ramanand Teerth Marathwada University, Nanded

School of Technology

M.Pharm (Pharmaceutics) Syllabus

Credit-grade based performance and assessment system (CGPA))

Features of the Credit System

With effect from September 2008

FEATURES OF THE CREDIT SYSTEM

- Master's degree would be of 75 credits each.
- One credit course of theory will be of one clock hour per week running for 12 weeks.
- Two credit course of theory will be of two clock hours per week running for 12 weeks.
- Four-credit course of theory will be of four clock hours per week running for 12 weeks.
- One credit course of practicals will consist of 4 hours of laboratory exercise for 6 weeks.
- Two credit course of practicals will consist of 4 hours of laboratory exercise for 12 weeks.
- Four credit course of practical will consist of 8 hours of laboratory exercise for 12 weeks.

ACADEMIC CALENDAR AND TERMS

The terms and academic activities of the School of Technology under CGPA shall be as per the dates given below, only the years shall be changed i.e. the dates shall remain same as given below irrespective of the year.

Beginning of First Term (Semester I and III)	: September 05
Teaching begins (Semester III)	: September 15
Teaching begins (Semester I)	: September 22
Teaching ends (Semester III)	: February 05
Teaching ends (Semester I)	: February 10
Semester End Examination	: February 20
End of First Term	: March 09
Vacation	: October 07 to Nov. 06
Beginning of Second Term (Semester II and IV)	: March 10
Teaching begins	: March 16
Teaching ends	: August 05
Semester End Examination	: August 17
End of Second Term	: August 31
Vacation	: May 09 to June 05



Swami Ramanand Teerth Marathwada University, Vishnupuri, Nanded
M.Pharm. Syllabus Credit System
Effective from September 2008

M. Pharm. Pharmaceutics

Semester-I

Subject code	Subject	Marks	Credits
MPY -101	Research Methodology & Biostatistics	100	04
MPY -102	Advance Analytical Techniques	100	04
MPY -103	Quality Assurance of Pharmaceutical Products	100	04
MPY -104	Drug Regulatory Affairs	100	04
MPY -105	Laboratory course -1	100	04
MPY -106	Laboratory course -2	100	04
MPY -107	Seminar	025	01
Total		625	25

Semester-II

Subject code	Subject	Marks	Credits
MPY -211	Novel Drug Delivery Systems	100	04
MPY -212	Biopharmaceutics & Pharmacokinetics	100	04
MPY -213	Industrial Pharmacy	100	04
MPY -214	Advanced Pharmaceutics & Cosmatics	100	04
MPY -215	Laboratory Course -3	100	04
MPY -216	Laboratory Course -4	100	04
MPY -217	Seminar	025	01
Total		625	25

Semester-III

Subject code	Subject	Marks	Credits
MPY -311	Seminar on Research envisaged for dissertation	100	04
MPY -312	Seminar on recent trends in pharmaceutical sciences	150	06
Total		250	10

Semester-IV

Subject code	Subject	Marks	Credits
MPY-411	Dissertation	200	08
MPY-412	Seminar (on dissertation)	075	03
MPY-413	Viva-voce	100	04
Total		375	15



Swami Ramanand Teerth Marathwada University, Nanded

School of Technology

M.Pharm. Syllabus (Credit System)

Effective from September 2008

M. Pharm. (Semester – I) Pharmaceutics

Subject code : MPY-101

Subject : RESEARCH METHODOLOGY & BIOSTATISTICS

THEORY

60 Hours (4 hrs. /week)

I. Research:

1. Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research) objects of research (4 hrs).
2. Literature survey:
 - Using library, book and journals, MEDLINE- internet getting patents and reprints of articles as sources for literature survey. (2 hrs)
3. Selecting a problem and preparing a research proposal for different types of research sources of procurements of grants. (2 hr)
4. Documentation: (4 hrs)
 - Importance of documentation in case of research record and GMP/GLC
 - Techniques of documentation in case of research record and GMP and GLC
 - Uses of computer packages in clinical trials
 - Documentation in clinical trails
5. Research report/paper writing/thesis writing / poster presentation: (10 hrs)
 - Different parts of research report or paper
 - Title-title of project with authors name
 - Abstract-statement of the problem, background list in brief, purpose and scope
 - Key words
 - Methodology-subject, apparatus/instrumentation and procedure
 - Results-tables, graphs, figures and statistical presentation
 - Discussion-support or non-support to hypothesis. Practical and theoretical implications
 - Acknowledgements
 - References
 - Errata
 - Importance of spell check
 - Use of foot notes

II. Methods and tools used in research: (5 hrs)

- Research design (features of good design, types of research designs, basic principles of experimental design).
- Qualitative studies, quantitative studies.
- Simple data organization, descriptive data organization.
- Limitations and sources of errors.
- Enquiries in forms of questionnaire, opinionnaire and interviews

III. Presentation: (5 hrs)

- Importance, types, different skills
- Content of presentation format of model, introduction and endings.
- Posture, gesture, eye contact, facial expression, stage fright.
- Volume, pitch, speed, pauses and languages
- Visual aids and seating arrangements
- Question and answer session

IV. Cost Analysis of Projects and Clinical Trials (3 hrs)

V. Biostatistics (10 hrs)

- Statistical analysis of data including variance, standard deviation, students 't' test and ANOVA, co relation of data and its interpretation, computer data analysis, bio statistics for clinical trials.
- Scientific method in medicine
- Scientific equations of therapy

VI. Home Assignment

1. Industrial institute interaction
2. Industrial projects their feasibility reports.
3. Funds in research
4. GATT trips

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 Mofarlane
- (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 Furness
- (13) Preparation for publications – King Edwards hospital foundation for London
- (14) Information technology – The hindu speaks
- (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

Subject code : MPY -102

Subject : ADVANCED ANALYTICAL TECHNIQUES

THEORY

60 Hours (4 hrs. /week)

- 1 Spectroscopic methods:** Theory, Instrumentation, chemical applications and structural elucidation by UV, IR, FTIR, NMR, C¹³ NMR, Mass Spectrometry, ESR and Emission spectroscopy. (25 hrs)
- 2. Separation Techniques:** Fundamental principles, theory, instrumentation and applications of Gas-liquid chromatography, HPLC, Gel chromatography, GC-MS, HPTLC, and Ion Pair Chromatography. (15 hrs)
- 3. Thermal Analysis:** Theory, Instrumentation and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA). (5 hrs)
- 4. Home Assignment**
Immunochemical Techniques: Immuno-electrophoresis, Immunoprecipitation, ELISA, Radioimmunoassay.

References:

- (1) Theory and applications of ultraviolet spectroscopy – M. Orchin and H. H. Jaffe, John Wiley and Sons, N. Y.
- (2) Spectrometric identification of organic compounds – Silverstein, Basseler, Morrill, John Wiley and Sons, N. Y.
- (3) Instrumental Methods of Analysis– Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
- (4) Applications of Absorption Spectroscopy of Organic Compounds – J. R. Dyer, Prentice Hall, London
- (5) Chemical Applications of Infra-red spectroscopy – C. N. R. Rao., Academic Press, N. Y.
- (6) Applications of NMR spectroscopy in organic chemistry – L. M. Jackmann and B. D. Sternhell, Pergamon Press, London
- (7) Interpretation of Mass Spectra. – F. W. McLafferty
- (8) Introduction to High Performance Liquid Chromatography – R. J. Hamilton, Chapman and Hall, London
- (9) Pharmaceutical Analysis Modern Methods-Part A and Part B – J. W. Munson, Marcel and Dekker
- (10) Indian Pharmacopoeia-2007
- (11) Martindale: The complete Drug Reference – 2007
- (12) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
- (13) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) - Satinder Ahuja , Neil Jespersen
- (14) Practical HPLC Method Development, 2nd Edition- Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch

Subject code: MPY -103

**Subject : QUALITY ASSURANCE OF PHARMACEUTICAL PRODUCTS
THEORY**

60 Hours (4 hrs. /week)

1. **Good manufacturing practices:** GMP in manufacturing processing and quality control of drugs, control of facility, personal, production and process controls, packaging and labeling controls, documents, WHO GMP guidelines. GMP for ayurvedic products, Good clinical practice (GCP), Good laboratory practice (GLP), Good Pharmacy practice (GPP) (10 hrs)
2. **Validation:** Pharmaceutical process validation, equipment validation and sterile products validation. (10 hrs)
3. **Quality control of pharmaceutical dosage forms:** Solid and semi-solid dosage forms, disperse systems and parenteral dosage forms. (8 hrs)
4. **ICH Stability Guidelines** (3 hrs)
5. **Schedule M and Schedule Y** (14 hrs)
6. **Home Assignment**
 1. Preparation of Validation Protocol for different dosage form and preparation of SOP for Laboratory Instruments / Equipments.
 2. The Indian Patent Act 1970 and Amendments.

References:

- (1) Automation and Validation of information in Pharmaceutical Processing – J. F. Despautz, Marcel and Dekker
- (2) Validation of aseptic pharmaceutical processing – F. J. Carleton and J. P. Agalloco, Marcel and Dekker
- (3) Pharmaceutical process validation – J. R. Berry and R. A. Nash, Marcel and Dekker
- (4) Good Manufacturing Practices for pharmaceuticals – S. H. Will and J. R. Stoker, Marcel and Dekker
- (5) Design of Experiments for process improvement and quality Assurance – R. F. Brewer
- (6) Law and drug –S. N. Katju, Law of publication (I) Pvt Ltd
- (7) Encyclopedia of pharmaceutical technology, Marcel and Dekker
- (8) Achieving sterility in medical and pharmaceutical products – N.A.Halls, Marcel and Dekker

Subject code : MPY -104

**Subject : DRUG REGULATORY AFFAIRS
THEORY**

60 Hours (4 hrs. /week)

- 1. Aims, objects and salient features of following legislations affecting pharmaceutical industry. (5 hrs)**
 - Industrial Development and Regulation Act 1951.
 - Consumer Protection Act.
- 2. Australian TGA guidelines (2 hrs)**
- 3. US-FDA, CDER guidelines (5 hrs)**
- 4. New Drug Application (4 hrs)**
- 5. Pollution and Environmental Control Act (3 hrs)**
- 6. Drug Master File (3 hrs)**
- 7. Intellectual Property Rights: (10 hrs)**
 - Protection of patents and trademarks and design and copy rights and patent system in India.
 - Present status of IPR future changes expected in Indian patents.
 - What may be patented
 - Who may apply for patent
 - Preparation of patent proposal
 - Registration of patent in India and foreign countries and vice versa
 - ICH guidelines for clinical trials, therapeutic drugs monitoring drugs and bioequivalence.
 - Exclusive marketing rights
 - Black box
 - IPR and IDMA views on patents
 - Human health and patent laws latent lethality
 - Indian patent act and copyright (Indian act)
- 8. Drug and Cosmetics Act 1940 (8 hrs)**
- 9. Prevention of Food Adulteration Act 1954 (5 hrs)**
- 10. Home Assignment**
 1. Preparation of DMF, Site Master File, Master Formula Record.
 2. Procedure for filing of Patent.

Reference:

- (1) Guidelines of various countries like MCA, TGA, ICH.
- (2) Drug and cosmetic act 1940 and rules their under
- (3) IPR Lecture notes
- (4) GLP regulation by Alen Hirsch Vol 38 Marcel Decker series
- (5) GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.

- (6) I.P., B.P., U.S.P. International Pharmacopoeia
- (7) Pharmacokinetics, Regulatory, Industrial, academic prospective by P. G. Willing and F.T.S. Tse.

Subject code : MPY-105

Subject : Laboratory course -1

Practical 8 hrs. /week (Minimum 12 practicals should be conducted)

1. Combination Drug Analysis (any two)
Vitamins, Sulphas, Analysis of Antipyretics and Analgesics, Steroidal anti-inflammatory drugs, Antihistamins.
2. Illustrations of theoretical principles using assay of drugs form in various pharmacopoeias (any five).
This should cover titrimetric, gravimetric, spectro-photometric (including flame photometric) methods. HPLC etc. The titrimetric methods should include argentometric, conductometric, potentiometric end point determination. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.
3. Interpretation of UV, IR, NMR, C^{13} NMR spectra and Mass Spectroscopy of some chemicals and drugs. (minimum three combined spectra).
4. Preparation of research proposal for a specific problem and assessment (any two).

References:

- (1) Pharmaceutical Analysis – Modern methods – Part A and Part B – J. W. Munson, Marcel – Dekker
- (2) Quantitative Analysis of Drugs in Pharmaceutical formulations – P. D. Sethi, VBS Publishers, Delhi
- (3) Pharmacopoeia of India.
- (4) Practical Pharmaceutical Chemistry, Part I and Part II – A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
- (5) Colorimetric Methods of Analysis – F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.
- (6) Chemical Applications of Infrared spectroscopy – C. N. R. Rao, Academic Press N. Y.
- (7) Applications of Absorption Spectroscopy of Organic Compound – J. R. Dyer, Prentice Hall Englewood

Subject code : MPY-106

Subject : Laboratory course -2

Practical 8 hrs. /week (Minimum 12 practicals should be conducted)

Experiments based on following concepts:

1. Validation of equipments: Autoclave, hot air oven, membrane filter
(Minimum two practical).
2. Validation of an analytical method: Calibration of instruments as per official procedure (UV, FTIR, Conductivity meter, fluorimeter, Digital pH meter, Digital balance, Potentiometer, HPLC, Gas chromatography)
(Minimum two practical).
3. Quality control of pharmaceutical dosage forms: Tablets, Capsules, Liquid oral, Parenteral, External preparation (minimum eight practical).

References:

- (1) Pharmaceutical Analysis – Modern methods – Part A and Part B – J. W. Munson, Marcel – Dekker
- (2) Quantitative Analysis of Drugs in Pharmaceutical formulations – P. D. Sethi, VBS Publishers, Delhi
- (3) Pharmacopoeia of India.
- (4) Practical Pharmaceutical Chemistry, Part I and Part II – A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
- (5) Colorimetric Methods of Analysis – F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.
- (6) Chemical Applications of Infrared spectroscopy – C. N. R. Rao, Academic Press N. Y.
- (7) Applications of Absorption Spectroscopy of Organic Compound – J. R. Dyer, Prentice Hall Englewood



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School of Technology

M.Pharm. Syllabus (Credit System)

Effective from September 2008

**M. Pharm. (Semester – II)
Pharmaceutics**

Subject code : MPY-211

Subject : NOVEL DRUG DELIVERY SYSTEM

THEORY

60 Hours (4 hrs. /week)

1. SUSTAINED AND CONTROLLED RELEASE DRUG DELIVERY

SYSTEMS

14 hours

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.

Introduction, Design and Development of oral controlled release drug administration: Dissolution controlled, Diffusion controlled (Reservoir devices, Matrix devices), Membrane permeation controlled, Osmotic pressure controlled, Gel diffusion controlled, pH controlled, Ion - exchange controlled delivery systems.

2. POLYMERS SCIENCE

5 Hours.

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.

3. TRANSDERMAL DRUG DELIVERY SYSTEMS

6 Hours

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

5. MUCOADHESIVE DRUG DELIVERY SYSTEMS

7 Hours

Introduction, 1) Buccal drug delivery system: Concepts, Advantages and Disadvantages, Structure of oral mucosa, Trans-mucosal permeability, Permeability enhancers, *in vitro* and *in vivo* methods for Buccal absorption; 2) 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.

6. OCCULAR DRUG DELIVERY SYSTEMS

3 Hours

Formulation and evaluation of ocular controlled drug delivery systems, ophthalmic inserts and *in situ* gels.

7. TARGETED DRUG DELIVERY SYSTEMS

10 Hours

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.

HOME ASSIGNMENT:

Protein & Peptide Drug Delivery System

Physical aspects, biochemistry of protein drug (structure, properties & stability), barrier to transport & pharmacokinetics, different routes of delivery.

Intrauterine Drug Delivery Systems

Development of intrauterine devices (IUDs), copper IUDs, hormone-releasing IUDs.

REFERENCE BOOKS:

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.

Subject code: MPY-212

**Subject : BIOPHARMACEUTICS AND PHARMACOKINETICS
THEORY 60 Hours (4 hrs. /week)**

1. ABSORPTION OF DRUGS 7 Hours

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.

2. DISTRIBUTION OF DRUGS 7 Hours

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,

3. PROTEIN BINDING 3 Hours

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

4. METABOLISM OF DRUGS 5 Hours

Definition, brief overview of Phase I (Oxidative, reductive and hydrolytic reactions) and Phase II reactions (Conjugation) of Biotransformation. Factors affecting biotransformation.

5. EXCRETION OF DRUGS

5 Hours

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

6. BASIC CONCEPTS OF PHARMACOKINETICS

14 Hours

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.

7. NON-LINEAR PHARMACOKINETICS

4 Hours

Cause of non-linearity, Michaelis-Menten equation, Estimation of K_m and V_{max} .

HOME ASSIGNMENT.

- Application of Pharmacokinetics in Novel drug delivery systems.
- Dosage Regimen
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.
- BCS Classification of drugs.

REFERENCE BOOKS:

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. Biopharmaceutics 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.

Subject code : MPY-213

Subject : INDUSTRIAL PHARMACY

THEORY

60 Hours (4 hrs. /week)

1. PREFORMULATION

10 Hours

Introduction, organoleptic properties, purity, particle size, shape, and surface area. Solubilisation, surfactants and its importance, temperature, pH, co-solvency; Techniques for the study of crystal properties and polymorphism. Physicochemical characteristics of new drug molecules with respect to different dosage forms.

2. COMPACTION AND COMPRESSION

6 Hours

Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; Effect of particle size, moisture content, lubrication etc on strength of tablets.

3. OPTIMIZATION TECHNIQUES IN PHARMACEUTICAL

FORMULATION AND PROCESSING

5 Hours

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

4. PILOT PLANT SCALE UP TECHNIQUES

10 Hours

Significance of pilot plant scale up study and large scale manufacturing techniques (formula, equipment, process, stability and quality control) of some important dosage

forms such as tablets, capsules, injections, liquid orals, semisolids, ophthalmic products, emulsions including multiple emulsions.

5. METHODS OF ENHANCING BIOAVAILABILITY 7 Hours

Solubilization, Prodrugs, and enhancement of dissolution characteristics, cyclodextrin, permeation enhancer, solid dispersion, surfactant, bioavailability enhancers.

6. SURFACTANT SYSTEM 7 Hours

Introduction, micellization, thermodynamics and kinetics of micelle formation, classification,. Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Surfactants in emulsions and suspensions. drug absorption, antibacterial activity.

HOME ASSIGNMENT:

- Optimization & Pilot plant scale up techniques for Tablets & Capsules- an overview.
- Automation & Effluent testing and Treatment in Pharmaceutical industries.
- Industrial hazards- Monitoring and preventive systems (Safety measures)

REFERENCE BOOKS:

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.

Subject code : MPY-214

**Subject : ADVANCED PHARMACEUTICS AND COSMETICOLOGY
THEORY 60 Hours (4 hrs./week)**

1. STERILIZATION PROCESS 8 Hours

Principle, Advantages, Disadvantages, Applications of different sterilization methods, equipments. Sterility testing: Principle, general procedure, control tests, sterility testing of some preparations like parenterals and ophthalmic preparation, ampoules, vials, syringes and needles.

2. STABILITY TESTING 5 Hours

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

3. BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES 9 Hours

Definition, Objective of bioavailability, Parameters of bioavailability, Determination of AUC. Estimating absorption rate of drugs; Measurement of bioavailability- Pharmacokinetic methods and Pharmacodynamic methods. Drug dissolution rate & bioavailability. *In vitro* drug dissolution testing models. In-vitro in-vivo correlation. Definitions: Bio equivalence, Chemical equivalence, Therapeutic equivalence, Pharmaceutical equivalence; Testing of bioequivalence of dosage forms.

4. MICROMERITICS AND RHEOLOGY 6 Hours

A detailed account of micromeritics and rheology including apparatus involved in this area and their application in pharmacy.

5. PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS

7 Hours

Approaches for injectable controlled release formulations, Development of Injectable controlled - Release formulations; Approaches and applications of Implantable Drug Delivery Systems.

6. MANUFACTURING TECHNIQUES AND EVALUATION OF COSMETICS

10 Hours

Manufacturing of Cosmetics like creams, powders, compacts, shampoo, lipstick liquids, foam, aerosol cosmetics and their Performance, physicochemical and microbiological evaluation. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives.

HOME ASSIGNMENT:

- Packaging Of Pharmaceuticals
Desirable features and a detailed study of different types of Pharmaceutical containers and closures (Glass, Plastics and Rubber), including their merits and demerits; selection and evaluation of Pharmaceutical packaging materials.
- Importance and status of herbal medicines and cosmetics.

REFERENCE BOOKS:

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.

Subject code : MPY - 215

Subject : LABORATORY COURSE-3

Practical 8 hrs. /week

(Minimum 12 practical should be conducted)

1. Preparation and evaluation of microcapsules/micro spheres by different techniques.
2. Study on diffusion of drugs through various polymer membranes.
3. Study on In-vitro dissolution of various sustained release formulations of marketed products.
4. Preparation of matrix tablets using various polymers, like polyvinyl alcohol, polyvinyl pyrrolidone etc., and studying their release patterns.
5. Preparation of various polymer films, loading of drugs and studying the release Pattern.
6. Film coating of drug pellets for granules with sodium CMC and the study on In Vitro dissolution.
7. Preparation and evaluation of following drug delivery systems:
 - a. Fast dissolving tablets
 - b. Gels
8. Preparation of various drug formulations by solid dispersion technique and their evaluation. (Minimum Two Practical)
9. Formulations based on the cosmetics like vanishing cream, talcum powder, tooth paste, coconut oil shampoo, paste depilatory, nail polish, lipstick etc. (Minimum Three Practical)
10. Other formulations based on the theory topics.

RECOMMENDED BOOKS:

All books mentioned as reference books for theory should be used.

Subject code : MPY - 216

Subject : LABORATORY COURSE-3

Practical 8 hrs. /week

(Minimum 12 practical should be conducted)

1. Pre-formulation study of tablets.
2. Studying the stability of suspensions using the data on sedimentation volume and degree of flocculation.
3. Determinations of flow properties of powders by Angle of repose and flow through an orifice with, and without glidants. (Minimum Two Practical)
4. Comparison of dissolution studies of two different marketed products.
5. Calculation k_a , k_e , $t_{1/2}$, C_{max} , T_{max} .
6. Calculation of AUC and bioequivalence from the given data for two drugs.
7. In vitro absorption studies.
8. To study the pharmacokinetics of suitable drug after oral administration. (Minimum Two Practical)
9. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug)at different concentrations.
10. Accelerated stability study
11. Experiment based on the theory topics.

RECOMMENDED BOOKS:

All books mentioned as reference books for theory should be used.



Swami Ramanand Teerth Marathwada University, Nanded

School of Technology

M.Pharm (Pharmaceutical Chemistry) Syllabus

Credit-grade based performance and assessment system (CGPA)

Features of the Credit System

With effect from September 2008

FEATURES OF THE CREDIT SYSTEM

- Master's degree would be of 75 credits each.
- One credit course of theory will be of one clock hour per week running for 12 weeks.
- Two credit course of theory will be of two clock hours per week running for 12 weeks.
- Four-credit course of theory will be of four clock hours per week running for 12 weeks.
- One credit course of practicals will consist of 4 hours of laboratory exercise for 6 weeks.
- Two credit course of practicals will consist of 4 hours of laboratory exercise for 12 weeks.
- Four credit course of practical will consist of 8 hours of laboratory exercise for 12 weeks.

ACADEMIC CALENDAR AND TERMS

The terms and academic activities of the School of Technology under CGPA shall be as per the dates given below, only the years shall be changed i.e. the dates shall remain same as given below irrespective of the year.

Beginning of First Term (Semester I and III)	: September 05
Teaching begins (Semester III)	: September 15
Teaching begins (Semester I)	: September 22
Teaching ends (Semester III)	: February 05
Teaching ends (Semester I)	: February 10
Semester End Examination	: February 20
End of First Term	: March 09
Vacation	: October 07 to Nov. 06
Beginning of Second Term (Semester II and IV)	: March 10
Teaching begins	: March 16
Teaching ends	: August 05
Semester End Examination	: August 17
End of Second Term	: August 31
Vacation	: May 09 to June 05



Swami Ramanand Teerth Marathwada University, Vishnupuri, Nanded
M.Pharm. Syllabus (Credit System)
Effective from September 2008

M. Pharm. Pharmaceutical Chemistry

Semester-I

Subject code	Subject	Marks	Credits
MPY -101	Research Methodology and Biostatistics	100	04
MPY -102	Advance Analytical Techniques	100	04
MPY -103	Quality Assurance of Pharmaceutical Products	100	04
MPY -104	Drug Regulatory Affairs	100	04
MPY -105	Laboratory Course -1	100	04
MPY -106	Laboratory Course -2	100	04
MPY -107	Seminar	025	01
Total		625	25

Semester-II

Subject code	Subject	Marks	Credits
MPY -221	Advanced Organic Chemistry	100	04
MPY -222	Advanced Medicinal Chemistry	100	04
MPY -223	Drug Design	100	04
MPY -224	Natural Product	100	04
MPY -225	Laboratory Course -3	100	04
MPY -226	Laboratory Course -4	100	04
MPY -227	Seminar	025	01
Total		625	25

Semester-III

Subject code	Subject	Marks	Credits
MPY -321	Seminar on Research envisaged for dissertation	100	04
MPY -322	Seminar on recent trends in pharmaceutical sciences	150	06
Total		250	10

Semester-IV

Subject code	Subject	Marks	Credits
MPY-421	Dissertation	200	08
MPY-422	Seminar (on dissertation)	075	03
MPY-423	Viva-voce	100	04
Total		375	15



Swami Ramanand Teerth Marathwada University, Nanded

School of Technology

M.Pharm. Syllabus (Credit System)

Effective from September 2008

M. Pharm. (Semester – I) Pharmaceutical Chemistry

Subject code : MPY-101

Subject : RESEARCH METHODOLOGY & BIOSTATISTICS

THEORY

60 Hours (4 hrs. /week)

I. Research:

1. Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research) objects of research (4 hrs).
2. Literature survey:
 - Using library, book and journals, MEDLINE- internet getting patents and reprints of articles as sources for literature survey. (2 hrs)
3. Selecting a problem and preparing a research proposal for different types of research sources of procurements of grants. (2 hr)
4. Documentation: (4 hrs)
 - Importance of documentation in case of research record and GMP/GLC
 - Techniques of documentation in case of research record and GMP and GLC
 - Uses of computer packages in clinical trials
 - Documentation in clinical trails
5. Research report/paper writing/thesis writing / poster presentation: (10 hrs)
 - Different parts of research report or paper
 - Title-title of project with authors name
 - Abstract-statement of the problem, background list in brief, purpose and scope
 - Key words
 - Methodology-subject, apparatus/instrumentation and procedure
 - Results-tables, graphs, figures and statistical presentation
 - Discussion-support or non-support to hypothesis. Practical and theoretical implications
 - Acknowledgements
 - References
 - Errata
 - Importance of spell check
 - Use of foot notes

II. Methods and tools used in research (5 hrs)

- Research design (features of good design, types of research designs, basic principles of experimental design).
- Qualitative studies, quantitative studies.
- Simple data organization, descriptive data organization.
- Limitations and sources of errors.
- Enquiries in forms of questionnaire, opinionnaire and interviews

IV. Presentation (5 hrs)

- Importance, types, different skills
- Content of presentation format of model, introduction and endings.
- Posture, gesture, eye contact, facial expression, stage fright.
- Volume, pitch, speed, pauses and languages
- Visual aids and seating arrangements
- Question and answer session

IV. Cost Analysis of Projects and Clinical Trials (3 hrs)

VI. Biostatistics (10 hrs)

- Statistical analysis of data including variance, standard deviation, students 't' test and ANOVA, co relation of data and its interpretation, computer data analysis, bio statistics for clinical trials.
- Scientific method in medicine
- Scientific equations of therapy

VI. Home Assignment

1. Industrial institute interaction
2. Industrial projects their feasibility reports.
3. Funds in research
4. GATT trips

References:

- (22) Research in education – John W. Best Jems V. Kahn
- (23) Research methodology – C. R. Kothari
- (24) Methodology and techniques of social research – Wilkinson and Bhandarkar
- (25) Presentation skills – Michel Halton – Indian society for institute education
- (26) Practical introduction to copyrights – Gavin Mofariane
- (27) Thesis projects in sciences and engineering – Richard M. Devis
- (28) Scientist in legal system – Ann Labor Science
- (29) Thesis and assessment writing – Janolthon Anderson
- (30) Writing a technical paper – Donald Manzel
- (31) Effective business report writing – Lel and Brown
- (32) Protection of industrial property rights – Purshottam Das and Gokul Das
- (33) Spelling for millions – Edna Furness
- (34) Preparation for publications – King Edwards hospital foundation for London
- (35) Information technology – The hindu speaks
- (36) Documentation – genesis and development – 3792.
- (37) Ayurveda and modern medicine – R. D. Lele

- (38) How to write and publish a scientific paper – Robert A. Day Cambridge University Press 4th edition 1994
- (39) Lecture notes on patent TIFAC: DOC: 022, TIFAC July 2002.
- (40) Introduction to Statistical Methods- C. B. Gupta
- (41) A first course in Mathematical Statistics- C. E. Weatherborn
- (42) Introduction to Biostatistics-Mahajan

Subject code : MPY -102

Subject : ADVANCED ANALYTICAL TECHNIQUES

THEORY

60 Hours (4 hrs. /week)

- 1 Spectroscopic methods:** Theory, Instrumentation, chemical applications and structural elucidation by UV, IR, FTIR, NMR, C¹³ NMR, Mass Spectrometry, ESR and Emission spectroscopy. (25 hrs)
- 2. Separation Techniques:** Fundamental principles, theory, instrumentation and applications of Gas-liquid chromatography, HPLC, Gel chromatography, GC-MS, HPTLC, and Ion Pair Chromatography. (15 hrs)
- 3. Thermal Analysis:** Theory, Instrumentation and applications of Thermogravimetric Analysis (TGA) and Differential Thermal Analysis (DTA). (5 hrs)
- 4. Home Assignment**
Immunochemical Techniques: Immuno-electrophoresis, Immunoprecipitation, ELISA, Radioimmunoassay.

References:

- (1) Theory and applications of ultraviolet spectroscopy – M. Orchin and H. H. Jaffe, John Wiley and Sons, N. Y.
- (2) Spectrometric identification of organic compounds – Silverstein, Basseler, Morrill, John Wiley and Sons, N. Y.
- (3) Instrumental Methods of Analysis– Willard, Merritt, Dean, CBS-Publishers and Distributors, Delhi
- (4) Applications of Absorption Spectroscopy of Organic Compounds – J. R. Dyer, Prentice Hall, London
- (5) Chemical Applications of Infra-red spectroscopy – C. N. R. Rao., Academic Press, N. Y.
- (6) Applications of NMR spectroscopy in organic chemistry – L. M. Jackmann and B. D. Sternhell, Pergamon Press, London
- (7) Interpretation of Mass Spectra. – F. W. McLafferty
- (8) Introduction to High Performance Liquid Chromatography – R. J. Hamilton, Chapman and Hall, London
- (9) Pharmaceutical Analysis Modern Methods-Part A and Part B – J. W. Munson, Marcel and Dekker
- (10) Indian Pharmacopoeia-2007
- (11) Martindale: The complete Drug Reference – 2007
- (12) Impurities Evaluation of Pharmaceuticals- Satinder Ahuja
- (13) Modern Instrumental Analysis, Vol 47(Comprehensive Analytical Chemistry) - Satinder Ahuja , Neil Jespersen
- (14) Practical HPLC Method Development, 2nd Edition- Lloyd R. Snyder, Joseph J. Kirkland, Joseph L. Glajch

Subject code: MPY -103

**Subject : QUALITY ASSURANCE OF PHARMACEUTICAL PRODUCTS
THEORY**

60 Hours (4 hrs. /week)

1. **Good manufacturing practices:** GMP in manufacturing processing and quality control of drugs, control of facility, personal, production and process controls, packaging and labeling controls, documents, WHO GMP guidelines. GMP for ayurvedic products, Good clinical practice (GCP), Good laboratory practice (GLP), Good Pharmacy practice (GPP) (10 hrs)
2. **Validation:** Pharmaceutical process validation, equipment validation and sterile products validation. (10 hrs)
3. **Quality control of pharmaceutical dosage forms:** Solid and semi-solid dosage forms, disperse systems and parenteral dosage forms. (8 hrs)
4. **ICH Stability Guidelines** (3 hrs)
5. **Schedule M and Schedule Y** (14 hrs)
6. **Home Assignment**
 1. Preparation of Validation Protocol for different dosage form and preparation of SOP for Laboratory Instruments / Equipments.
 2. The Indian Patent Act 1970 and Amendments.

References:

- (9) Automation and Validation of information in Pharmaceutical Processing – J. F. Despautz, Marcel and Dekker
- (10) Validation of aseptic pharmaceutical processing – F. J. Carleton and J. P. Agalloco, Marcel and Dekker
- (11) Pharmaceutical process validation – J. R. Berry and R. A. Nash, Marcel and Dekker
- (12) Good Manufacturing Practices for pharmaceuticals – S. H. Will and J. R. Stoker, Marcel and Dekker
- (13) Design of Experiments for process improvement and quality Assurance – R. F. Brewer
- (14) Law and drug –S. N. Katju, Law of publication (I) Pvt Ltd
- (15) Encyclopedia of pharmaceutical technology, Marcel and Dekker
- (16) Achieving sterility in medical and pharmaceutical products – N.A.Halls, Marcel and Dekker

Subject code : MPY -104

Subject : DRUG REGULATORY AFFAIRS

THEORY

60 Hours (4 hrs. /week)

- 1. Aims, objects and salient features of following legislations affecting pharmaceutical industry. (5 hrs)**
 - Industrial Development and Regulation Act 1951.
 - Consumer Protection Act.
- 2. Australian TGA guidelines (2 hrs)**
- 3. US-FDA, CDER guidelines (5 hrs)**
- 4. New Drug Application (4 hrs)**
- 5. Pollution and Environmental Control Act (3 hrs)**
- 6. Drug Master File (3 hrs)**
- 7. Intellectual Property Rights: (10 hrs)**
 - Protection of patents and trademarks and design and copy rights and patent system in India.
 - Present status of IPR future changes expected in Indian patents.
 - What may be patented
 - Who may apply for patent
 - Preparation of patent proposal
 - Registration of patent in India and foreign countries and vice versa
 - ICH guidelines for clinical trials, therapeutic drugs monitoring drugs and bioequivalence.
 - Exclusive marketing rights
 - Black box
 - IPR and IDMA views on patents
 - Human health and patent laws latent lethality
 - Indian patent act and copyright (Indian act)
- 8. Drug and Cosmetics Act 1940 (8 hrs)**
- 9. Prevention of Food Adulteration Act 1954 (5 hrs)**
- 10. Home Assignment**
 1. Preparation of DMF, Site Master File, Master Formula Record.
 2. Procedure for filing of Patent.

Reference:

- (1) Guidelines of various countries like MCA, TGA, ICH.
- (2) Drug and cosmetic act 1940 and rules their under
- (3) IPR Lecture notes
- (4) GLP regulation by Alen Hirsch Vol 38 Marcel Decker series
- (5) GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.

- (6) I.P., B.P., U.S.P. International Pharmacopoeia
- (7) Pharmacokinetics, Regulatory, Industrial, academic prospective by P. G. Willing and F.T.S. Tse.

Subject code : MPY-105

Subject : Laboratory course -1

Practical 8 hrs. /week (Minimum 12 practicals should be conducted)

1. Combination Drug Analysis (any two)
Vitamins, Sulphas, Analysis of Antipyretics and Analgesics, Steroidal anti-inflammatory drugs, Antihistamins.
2. Illustrations of theoretical principles using assay of drugs form in various pharmacopoeias (any five).
This should cover titrimetric, gravimetric, spectro-photometric (including flame photometric) methods. HPLC etc. The titrimetric methods should include argentometric, conductometric, potentiometric end point determination. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.
3. Interpretation of UV, IR, NMR, C¹³ NMR spectra and Mass Spectroscopy of some chemicals and drugs. (minimum three combined spectra).
4. Preparation of research proposal for a specific problem and assessment (any two).

References:

- (1) Pharmaceutical Analysis – Modern methods – Part A and Part B – J. W. Munson, Marcel – Dekker
- (2) Quantitative Analysis of Drugs in Pharmaceutical formulations – P. D. Sethi, VBS Publishers, Delhi
- (3) Pharmacopoeia of India.
- (4) Practical Pharmaceutical Chemistry, Part I and Part II – A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
- (5) Colorimetric Methods of Analysis – F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.
- (6) Chemical Applications of Infrared spectroscopy – C. N. R. Rao, Academic Press N. Y.
- (7) Applications of Absorption Spectroscopy of Organic Compound – J. R. Dyer, Prentice Hall Englewood

Subject code : MPY-106

Subject : Laboratory course -2

Practical 8 hrs. /week (Minimum 12 practicals should be conducted)

Experiments based on following concepts:

1. Validation of equipments: Autoclave, hot air oven, membrane filter
(Minimum two practical).
2. Validation of an analytical method: Calibration of instruments as per official procedure (UV, FTIR, Conductivity meter, fluorimeter, Digital pH meter, Digital balance, Potentiometer, HPLC, Gas chromatography)
(Minimum two practical).
3. Quality control of pharmaceutical dosage forms: Tablets, Capsules, Liquid oral, Parenteral, External preparation (minimum eight practical).

References:

- (1) Pharmaceutical Analysis – Modern methods – Part A and Part B – J. W. Munson, Marcel – Dekker
- (2) Quantitative Analysis of Drugs in Pharmaceutical formulations – P. D. Sethi, VBS Publishers, Delhi
- (3) Pharmacopoeia of India.
- (4) Practical Pharmaceutical Chemistry, Part I and Part II – A. H. Beckett, J. B. Stenlake, CBS Publishers, Delhi
- (5) Colorimetric Methods of Analysis – F. D. Snell and C. T. Snell, Van Nostrand Reinhold Company, N. Y.
- (6) Chemical Applications of Infrared spectroscopy – C. N. R. Rao, Academic Press N. Y.
- (7) Applications of Absorption Spectroscopy of Organic Compound – J. R. Dyer, Prentice Hall Englewood



Swami Ramanand Teerth Marathwada University, Nanded

School of Technology

M.Pharm. Syllabus (Credit System)

Effective from September 2008

**M. Pharm. (Semester – II)
Pharmaceutical Chemistry**

Subject code : MPY - 221

Subject : ADVANCED ORGANIC CHEMISTRY

THEORY

60 Hours (4 hrs. /week)

1. STEREOCHEMISTRY

12 hrs

Molecular dissymmetry, compounds with one, two or more unequal asymmetric carbon atoms and racemic modifications, configuration absolute and relative, synthesis of optically active compounds, conformations in cyclic compounds, optical isomerism, shapes of cyclohexanes and six-membered heterocyclic rings, shapes of rings other than six membered. Stereoselective synthesis, role of inductive, resonance and steric effects in structure and reactivity.

2. MECHANISM STEREOCHEMISTRY AND APPLICATIONS OF

12 hrs

Birch reduction, Clemensen reduction, Meerwein-Ponndorf reduction, Oppenauer oxidation, Wolf Kishner reduction, Wittig Reaction, Pinacol and related rearrangements, Beckmann rearrangement, Hoffman rearrangement, Claisen rearrangement, Schmidt, Lossen and Curtius rearrangement.

3. PERICYCLIC REACTIONS

8 hrs

Basic theory, orbital symmetry rules and their applications, mechanism, types of pericyclic reactions-cycloaddition, electrocyclic reaction, and sigmatropic rearrangement

4. PHOTOCHEMICAL REACTIONS

7 hrs

Introductions and basic principles, photochemistry of carbonyl compounds, photo rearrangements, photochemistry of alkenes and dienes.

5. SYNTHON APPROACH

6 hrs

- a. Definition of terms- disconnection, synthon, functional group interconversions.
- b. Basic rules in disconnection.
- c. Use of synthon approach in synthesis of following components:
Trimethoprim, Ibuprofen, Propranolol, Piroxicam.

HOME ASSIGNMENT

- ❖ Green Chemistry
- ❖ Allylic bromination, ozonolysis, free radical reactions, use of diazomethane and peracids in synthesis
- ❖ Study of some reduction of synthetic importance:
Reduction with metallic hydroxides, hydrogenation..

REFERENCES

1. Advanced Organic chemistry, Reaction mechanisms and structure, J. March, John Wiley and Sons, N.Y.
2. Mechanism and structures in Organic chemistry, E.S Gold, Hold Richard and Winstone, New York.
3. The Organic chemistry of Drug Design and Action, R.B. Silverman, Academic press In., San Diego, 1992.
4. Asymmetrical Synthesis, R.A Aitkin and S.M. Kilengi, Ed., Blackie Academic and professional London, 1995.
5. Organic chemistry, Clayden, Greeves, Warren and Wothers., Oxford University press 2001.
6. Organic chemistry, Vol I and II. I. L. Finar. ELBUS, Sixth ed., 1995.
7. A guide to mechanisms in Organic chemistry- Peterskyes Orient Longman, New Delhi.
8. Reactive intermediates in Organic chemistry- Tandom and Gowel.
9. Molecular reaction and photochemistry- C.H. Deupuy and O.L. Chapman
10. Drug stereochemistry Wainer Stering 1st Edn. 1996 Marcel Decker.
11. Photochemistry and Pericyclic reactions, Jagdamba Singh, Jaya Singh, 2nd edition, New edge International Publishers.
12. Reaction Mechanism In Organic Chemistry, S. M. Mukherji, S.P.Singh, 3rd edition, Macmillan India Ltd.
13. Comprehensive book of stereochemistry- by Eliel
14. Text Book of Organic chemistry – by Morrison and Boyd
15. Text Book of Organic chemistry – by S. K. Ghosh

Subject code : MPY - 222

Subject : ADVANCED MEDICINAL CHEMISTRY

THEORY

60 Hours (4 hrs. /week)

1. MEDICINAL CHEMISTRY OF

12 hrs

- a. Antiviral Agents and agents under development of HIV infection.
- b. Immunosuppressant and Immunostimulants.
- c. Agents used in Neurodegenerative disease Like Alzheimer's and Parkinsonism.
- d. GABAnergic Agonists.

2. GASTRIC PROTON PUMP INHIBITORS

5 hrs

Introduction, Gastric acid secretion and its inhibitors, test assay for studying gastric acid inhibitors, irreversible gastric proton pump inhibitors

3. PROTEINS AND PEPTIDE DRUGS

6 hrs

Chemistry, structure and stability, Reactivity of proteins and peptides. Different ways to synthesize these Drugs- Study of insulin, Relaxin, Somatostatin, DNase interferon.

4. COMBINATORIAL CHEMISTRY

8 hrs

- a. Introduction
- b. Combinatorial approaches
- c. Chemical peptide and small molecule libraries
- d. Applications, methodology
- e. Combinatorial Organic Synthesis
- f. Assays and screening of combinatorial libraries
- g. Introduction to high Throughputs Screening (HTS)

5. CHIRAL TECHNOLOGY

8 hrs

Introduction to chirality and Techniques used in asymmetric synthesis of Vitamin C, Ampicillin, dextra-propoxyphen, Citrenalol, propanolol

6. PRODRUG DESIGN

6 hrs

Introduction, chemical bond, gastrointestinal absorption, parenteral administration, distribution, transdermal absorption, pharmacokinetics and biopharmaceutical aspects, rational of prodrug design and practical considerations

HOME ASSIGNMENT

- ❖ Recent advances and trends in the above mentioned categories of drugs.

REFERENCES

1. Burger: Medicinal Chemistry series, John Wiley & Sons N.Y.
2. Foye: Principals of Medicinal Chemistry (Varghese & Co.)
3. Lednicer: Organic drug synthesis Vol.1,2,3,4; John Wiley & Sons N.Y.
4. Ariens: Medicinal Chemistry series.
5. Elies & West: Progress in Medicinal Chemistry series.
6. Wilson & Gisvold: Text book of Medicinal Chemistry, J. B. Lippin
7. Comprehensive Medicinal Chemistry series I-IV, Academic Press.
8. Combinational Chemistry-synthesis and applications- Stephen R. Wilson
9. Recent advances in chiral separations, Ed. Stevenson & Wi, Latest 1990, Plenum Press.
10. Chiral Technology, R. A. Steldon, Marcell Dekker Inc. New York.
11. Combinatorial Chemistry Ed. Fennirl Hicham 2000 Oxford University

Subject code : MPY - 223
Subject : DRUG DESIGN
THEORY

60 Hours (4 hrs. /week)

1. DRUG DISCOVERY 5 hrs

- 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

8 hrs

- 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.

4. QUANTITATIVE STRUCTURE ACTIVITY RELATIONSHIP 12 hrs

- 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

5. MOLECULAR MODELING

20 hrs

- 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, descent, 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

HOME ASSIGNMENT

- ❖ Study of software for QSAR, Docking, Molecular modeling and protein sequencing.

REFERENCES

1. QSAR & Strategies in the design of Bioactive Compound J. K. Seydel Latest after 1984 Deutsche 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

Subject code : MPY - 224

Subject : NATURAL PRODUCTS

THEORY

60 Hours (4 hrs. /week)

1. NATURAL PRODUCTS AS LEADS FOR NEW PHARMACEUTICALS

5 hrs

- a. Introduction
- b. Primary and secondary metabolites in plants
- c. Study of natural products as leads like cannabinoids, etoposide, teniposide, khellin, artemisin etc.

2. ALKALOIDS

8 hrs

- a. Detailed chemistry and properties of alkaloids
- b. Isolation, purification and structural elucidation of morphine, vincristine, reserpine, ephedrine and atropine.

3. STEROIDS

8 hrs

- a. General introduction
- b. Stereochemistry, nomenclature and structural elucidation of sterols (cholesterol), sapogenin (diosgenin), and solasodine.

4. FLAVONOIDS

4 hrs

Detailed chemistry and properties of Flavonoids and chemical account of rutin & quercetin

5. ANTIBIOTICS

12 hrs

a. β -Lactum Antibiotics

Mechanism of action, penicillins, cephalosporins, nocardicilins and monobactams, carbopenams and penams, β -Lactamaseinhibitors and other β -Lactum agents

b. Non β -Lactum Antibiotics

Aminoglycosides, macrolides, linomycins & polypeptide antibiotics

6. ROLE OF RECOMBINANT DNA TECHNOLOGY AND DRUG

DISCOVERY

8 hrs

Cloning DNA, expression of clonal DNA, manipulation of DNA sequence information new biological targets for drug developments, novel biotechnology derived pharmaceutical products. Antibody, antisense oligonucleotide therapy and gene therapy.

HOME ASSIGNMENT

Advances of the active constituents of some drugs used in the following indigenous system of medicines.

- ❖ Diabetic Therapy- *Gymnes sylvestre*, *salacia reticulate*, *pterocarpus marsupiam*, *swertia*, *chirata*, *trigonella*, *foenum-graccum*
- ❖ Liver Disfunction- *phyllanthus niruri*
- ❖ Antitumor- *curcuma longa linn*, *taxol*, *teniposide*, *etoposide*.

REFERENCES

1. Natural product chemistry by Nakanishi Goggolo
2. Modern methods of plant analysis – Peech and M. V. Tracey
3. Phytochemistry Vol I & II by Miller, Jan, Nostrant, Rein Hid
4. Recent advances in Phytochemistry Vol. I & IV – Scilicet, Runeckles
5. Natural Product Chemistry “A laboratory guide” by Rapheal Ikan.
6. The alkaloid chemistry and physiology by THF Manske

7. Introduction to molecular Phytochemistry – CH Wells, Chapman&Hall
8. Organic chemistry of natural products Vol I & II by Gurudeep Chatwal
9. Organic chemistry of natural products Vol I & II by O. P. Agarwal
10. Organic chemistry Vol I & II by I. L. Finar
11. Elements of Biotechnology by P. K. Gupta
12. Pharmaceutical Biotechnology by S. P. Vyas and V. K. Dixit
13. Biotechnology by Purohit and Mathoor
14. Phytochemical methods by Harborne

Subject code : MPY-225

Subject : LABORATORY COURSE-3

Practical 8 hrs. /week

(Minimum 12 practical should be conducted)

1. Mixture analysis of 2/3 organic compounds (At least 6)
2. Synthesis of drugs using 3/4 steps, and/ OR Synthon approach and their structure confirmation. (At least 3)
3. To perform the following reaction of synthetic importance (Any 3)
 - a. Birch reaction
 - b. Clemmenson's reduction
 - c. Meerwin-Ponndorf, s reduction
 - d. Grignard reaction
 - e. Oppenauer oxidation
 - f. Benzylic acid rearrangement
 - g. Beckmann rearrangement

REFERENCES

1. Organic synthesis: Fisher and William Son (CBA Publisher)
2. Mann and Saunders, 'Practical Organic chemistry' (Orient Longman)
3. A.I.Vogel, 'Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)
4. Systematic Identification of Org. Compounds Shriner & Herman 1998 John Wiley & sons
5. Reaction Synthesis in Organic Chemistry Laboratory Tiezel/ Ether 1989 University Science.

Subject code : MPY - 226

Subject : LABORATORY COURSE-4

Practical 8 hrs. /week

(Minimum 12 practical should be conducted)

1. Synthesis of drugs mentioned in the theory using basic operations like molecular distillation, fractional crystallization and purification by column chromatography, preparative TLC and structural confirmation by spectroscopic methods. (At least 4)
2. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis co chromatographic techniques for identification of isolated compounds and interpretation of UV&IR data of following (Any 8)
 - a. Eugenol from Clove
 - b. Curcumin from Turmeric
 - c. Sennosides from Senna
 - d. Hesperidine from Orange peel
 - e. Embelin from embela Ribes
 - f. Glycyrrhizin from glycyrrhiza glabra
 - g. Plumbigin from Plumbago Rosea
 - h. Solarin from potato
 - i. Naringen from grape fruit peel
 - j. Trimystin and Myristin from Nutmeg
 - k. Azylic acid from Castor oil
 - l. Pectin from Orange peel
 - m. Lycopene from Tomato peel
 - n. Epicatechin from Cashew kernel, outer kernel
 - o. Piperin from Black pepper

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