Osmania University

Syllabus for M. Pharmacy (Pharmaceutical Chemistry)

(w.e.f. academic year 2009-10)

G.Pulla Reddylyderabad

G.Pulla

Faculty of Technology, Hyderabad

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutical Chemistry)

I-Semester

Subject Code	Subject / Paper	Theory / Practic	Instruction Hours per week		Evaluation	Duration of External Examination		
		al			Theory	Practic al	Intern al	Extern al
M PCH.T.1.1 01	Pharmaceutica l Analytical Techniques	Theory	4	_	30	70		3
M PCH.T.1.1 02	Advanced Pharmaceutica 1 Organic Chemistry – I	Theory	4	_	30	70	arn	3
M PCH.T.1.1 03	Advanced Medicinal Chemistry – I	Theory	4	_	30	70		3
M PCH.T.1.1 04	Advanced Chemistry of Natural Products	Theory	4	S	30-5	70		3
M PCH.P.1.1 05	Pharmaceutica 1 Analytical Techniques	Practica 1		6	30	70		6
M PCH.P.1.1 06	Advanced Chemistry of Natural Products	Practica 1	76/10	6	30	70		6
M PCH.T.1.1 07	Entrepreneurs hip Management (SAIL)	Tutorial s	2	_	A/B/C/D	_		_
M PCH.1.108	Seminar	_	_	8	50			
			18	20	230	420		

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutical Chemistry) II– Semester

Subject Code	Subject / Paper	Theory / Practic	Instruction Hours per week		Evaluation	Duration of External Examination		
		al			Theory	Practic al	Interna	Extern al
M PCH.T.1.2	Intellectual Property	Theory	4	<u> </u>	30	70		3
01	Rights & Regulatory Affairs							
M PCH.T.1.2 02	Advanced Pharmaceutic al Organic	Theory	4	_	30	70		3

	Chemistry – II						
M PCH.T.1.2 03	Advanced Medicinal Chemistry – II	Theory	4	_	30	70	3
M PCH.T.1.2 04	Drug Screening Methods & Biostatistics	Theory	4	_	30	70	3
M PCH.P.1.2 05	Advanced Pharmaceutic al Organic Chemistry – II	Practica 1	1	6	30	70	6
M PCH.P.1.2 06	Advanced Medicinal Chemistry – II	Practica 1	1	6	30	70	6
M PCH.T.1.2 07	Scientific and Technical Writing (SAIL)	Tutorial s	2	-	A/B/C/D	71-1	-
M PCH.T.1.2 08	Seminars	-	1160	8	50	-	-
			18	20	230	420	

SAIL: Self assess Instrumentation Learning

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutical Chemistry)

Semester III and IV

DISSERTATION – Original research work carried out by the candidate under the guidance of regular teaching faculty/visiting faculty of the department should be submitted in a bound form.

Evaluation of the dissertation shall be done by external and internal examiners appointed by the university.

Dissertation viva-voce Grade A/B/C/D/F
Dissertation report Grade A/B/C/D/F

A: Excellent B. Very good C. Good D: Fair F. Fail

PHARMACEUTICAL ANALYTICAL TECHNIQUES

M PCH.T.1.101 Period/Week: 4

Sessional: 30 Duration of Exam: 3 hrs Examination: 70 Nature of Exam: Theory

UNIT – I

- a) UV-Visible Spectroscopy: Basic principles, interaction of electromagnetic radiation with matter and its effects (electronic transitions). Concept of chromophore and auxochrome, effect of conjugation, solvent and pH. Instrumentation (components and their significance). Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs including multicomponent analysis. Woodward-Fieser rules for caculating absortion maximum for unsaturated hydrocarbons. Difference and derivative spectra.
- **b) Infra-Red Spectroscopy**: Interaction of infrared radiation with organic molecules and it's effects on bonds. Instrumentation- Dispersive IR spectrophotometers and Fourier transform spectrophotometers. Sample handling for IR spectroscopy. Interpretation of IR spectra. Brief note on ATR. (Attenuated Total Reflectance).

UNIT – II

Nuclear Magnetic Resonance Spectroscopy: Fundamental principles of NMR, instrumentation (components and their significance). Chemical shifts concept, spin-spin coupling, spin-spin decoupling, shielding and deshielding, solvents, signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra.

Brief introduction about Carbon-13 NMR and 2D NMR Spectroscopy.

UNIT – III

Mass Spectrometry: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT - IV

Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation and their basic principles. **Gas chromatography**: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis. **Liquid chromatography**: Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

UNIT – V

- a) **Electrophoresis:** Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.
- b) Radio immunoassay and ELISA: Principle, instrumentation, applications and limitations.

- 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. 6 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, 7 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, 25 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, 2 ed., CRC Press, Florida, 2000.

ADVANCED PHARMACEUTICAL ORGANIC CHEMISTRY - I

M PCH.T.1.102 Period/Week: 4
Sessional: 30 Duration of Exam: 3 hrs
Examination: 70 Nature of Exam: Theory

UNIT – I

Stereochemistry: Elements of symmetry-plane of symmetry, center of symmetry, alternating axis of symmetry and simple axis of symmetry. Nomenclature – D, L and R, S- nomenclature, sequence rules, kinds of molecules displaying optical activity. Stereochemistry of biphenyls, allenes and spiranes. Cis/Trans, E-Z isomerism resulting from double bonds, monocyclic compounds, fused ring systems. Racemic modifications and methods of resolution of racemic mixtures. Asymmetric Synthesis and stereoselective synthesis.

UNIT - II

Reactive Intermediates: Definition, generation, stability, structure and reactivity of free radicals, carbocations, carbanions, carbenes, nitrenes/ nitrenium ions.

UNIT - III

Mechanisms of Organic Reactions: Electrophilic (addition and substitution), Nucleophilic (addition and substitution), elimination and free radical (addition and substitution) reactions.

UNIT -IV

Pericyclic Reactions: Electrocyclic, cycloaddition and sigmatropic reactions-introduction, terminology and mechanism with suitable examples.

UNIT - V

Molecular Rearrangements:

- 1. Carbon to carbon migration: Wagner- Meerwin rearrangement, Claisen rearrangement, Pinacol-pinacolone rearrangement and Benzil- benzilic acid rearrangement.
- 2. Carbon to nitrogen migration: Hoffmann rearrangement, Curtius rearrangement, Beckmann rearrangement and Lossen rearrangement.
- 3. Carbon to oxygen migration: Bayer- Villager rearrangement and rearrangement of hydroperoxides.

- 1. Carey FA, Sundberg RJ. Advanced organic chemistry. Part- B: Reactions and synthesis. 5th ed. New York: Springer; 2007.
- 2. Eliel EL, Wilen SH. Stereochemistry of organic compounds. Delhi: John Wiley & Sons; 2008
- 3. March J. Advanced organic chemistry: reactions, mechanisms and structures. 4 ed. Singapore: John Wiley & Sons; 2003.
- 4. Finar IL. Organic Chemistry. 5th ed. vol 1. Delhi: Dorling Kindersley (India) Pvt. Ltd; 2006.
- 5. Finar IL. Organic Chemistry-stereochemistry and the chemistry of natural products. 5th ed. vol 2. Delhi: Dorling Kindersley (India) Pvt. Ltd; 2006.
- 6. Clayden J, Greeves N, Warren S, Wothers P. Organic chemistry. Delhi: Oxford University Press; 2001.

- 7. Carrruthers W. Modern methods of organic synthesis. 4th ed. Delhi: Cambridge University Press; 2007.
- 8. Ege S. Organic chemistry. 3 rd ed. Delhi: A.I.T.B.S. Publishers & Distributors; 1999.
- 9. Morrison RT, Boyd RN. Organic chemistry. 6th ed. New Delhi: Pearson Education; 2007.
- 10. Skyes P. A guided book to mechanism in organic chemistry. 6 ded. Delhi: Pearson Education; 2006.
- 11. Loudon GM. Organic chemistry, 4th_{th} ed. India: Delhi: Oxford University Press; 2006.
- 12. Mc Murry J. Organic chemistry, 5th ed. Singapore: Thomson Asia Pte Ltd; 2001.
- 13. Gallego MG, Sierra M.A. Organic reaction mechanisms. Delhi: Rajkamal Electric Press; 2007.
- 14. Fergusson LN. Textbook of organic chemistry. 2 ed. New Delhi: East-West Press Private Limited; 2008.
- 15. Patrick G. Organic chemistry. New Delhi: Viva Books Private Limited; 2000.
- 16. Macomber R. Organic chemistry, 1st ed. Vol I. New Delhi: Viva Books private Limited; 2002.
- 17. Roland EL, Alan PM. Orbital symmetry: a problem solving approach, New York: Academic Press.
- 18. Ahluwalia VK. Organic reaction mechanisms, 3rd ed. Kolkata: Narosa Publishing house; 2007.
- 19. Nasipuri. Stereochemistry. New Delhi: New Age International (P) Ltd Publishers.

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ADVANCED MEDICINAL CHEMISTRY - I

M PCH.T.1.103 Period/Week: 4
Sessional: 30 Duration of Exam: 3 hrs
Examination: 70 Nature of Exam: Theory

UNIT - I

Theoretical aspects of drug action: Introduction, brief account on various forces involved in drug-receptor complex, types of receptors. Theories of drug-receptor interactions: 1) occupancy theory, 2) rate theory, 3) induced fit theory, 4) macro molecular perturbation theory, 5) topographical and stereo chemical considerations, 6) Ion channel blockers. Case history of drug development cimetidine.

UNIT - II

Design and application of prodrugs: Prodrug concept, choice and function of pro-moiety, bioreversible derivatives for various functional groups, applications of the pro-drug approach.

UNIT – III

Targets for the development of following chemotherapeutic agents: antiulcer, analgesic, antiinflammatory, antifungal, antiangiogenesis and antihypertensive agents.

UNIT - IV

Biotransformation of drugs: Enzymes responsible for biotransformation, microsomal and non-microsomal mechanisms. Phase-I and phase-II transformations with suitable examples. Factors influencing enzyme induction and inhibition.

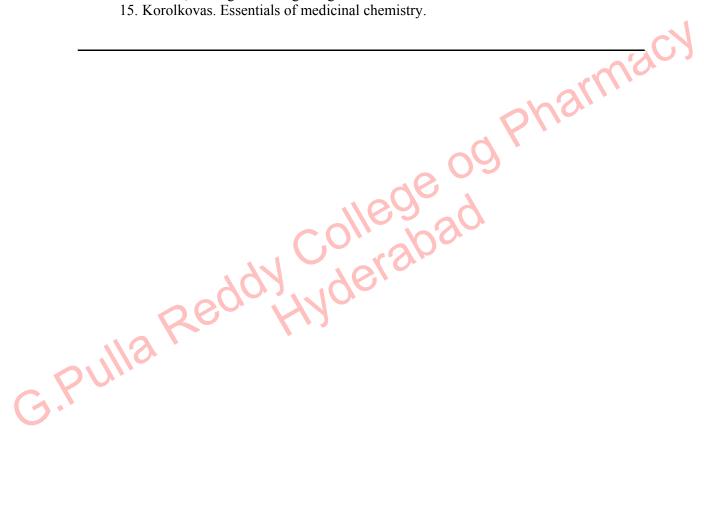
UNIT - V

Genesis of new drugs: Serendipity, random screening, extraction of active principles from natural sources, molecular modification of known drugs, selection or synthesis of soft and hard drugs, and rational drug design.

- 1. Abraham DJ, editor. Burger's Medicinal Chemistry and Drug Discovery, 6th ed. Vol 1-6. New Jersey: John Wiley & Sons; 2007.
- 2. Hansch C, editor. Hansch's comprehensive medicinal chemistry, Delhi: Rajkamal Electronic Press; 2005.
- 3. Silvermann RB. The organic chemistry of drug design and drug action. 2nd ed. London: Academic press (Elsevier); 2004.
- 4. Ariens EJ, editor. Drug design vol. I-X. Noida: Academic Press; 2009.
- 5. Lednicer D, Mitscher LA, The organic chemistry of drug synthesis, Volume-1-6. New York: A wiley-interscience publication; 2005.
- 6. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.
- 7. Lemke TL, Williams DA, editor. Foye's principles of medicinal chemistry. 6th ed. New Delhi: Wolters Kluwer and Lippincott Williams & Wilkins; 2008.
- 8. Gyorgy K, Istvan T. Molecular pathomechanisms and new trends in drug research. New York: Taylor & Franscis; 2003.
- 9. Andrejus K. Essentials of Medicinal Chemistry. 2nd ed. New Delhi: John Wiley & Sons;

1988.

- 10. Testa B, Jenner P. Drug metabolism: chemical and biochemical aspects, New York: Marcel Dekker; 1976.
- 11. William AP. Strategies of Drug design: A guide to biological activity, John Wiley & Sons, 1973.
- 12. Block JH, Beale JM, editor. Wilson and gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Baltimore: Lippincott Williams & Wilkins; 2004.
- 13. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincatt Willams & Wilkings, New Delhi, 2005.
- 14. Purcell, Strategies of drug design.
- 15. Korolkovas. Essentials of medicinal chemistry.



ADVANCED CHEMISTRY OF NATURAL PRODUCTS

M PCH.T.1.104 Period/Week: 4
Sessional: 30 Duration of Exam: 3 hrs
Examination: 70 Nature of Exam: Theory

UNIT – I

Natural products as leads for new drugs: Introduction/history, approaches to discovery and development of natural products as potential new drugs selection and optimization of lead compounds for further development with suitable examples from antibiotics, CNS, and cardiovascular agents.

UNIT - II

Alkaloids: Introduction and general methods of structure elucidation.

From opium: morphine-structural elucidation, development of morphine analogues and morphine antagonists.

From Rauwolfia: Reserpine-structural eludication, structural modifications and uses.

From vinca rosea: vincristine and vinblastine - structural modification, semi synthetic derivatives, and uses.

UNIT – III

Steroids: Introduction, nomenclature, stereochemistry of steroids. Source and structure elucidation of cholesterol and diosgenin.

Structures, structural modifications and therapeutic uses of steroidal anti-inflammatory agents and antifertility agents.

UNIT - IV

Polypeptides and proteins: introduction and general methods of separation, general methods of degradation and end group analysis, general methods of synthesis of peptides. Primary, secondary, tertiary and quaternary structure of proteins; chemistry of insulin.

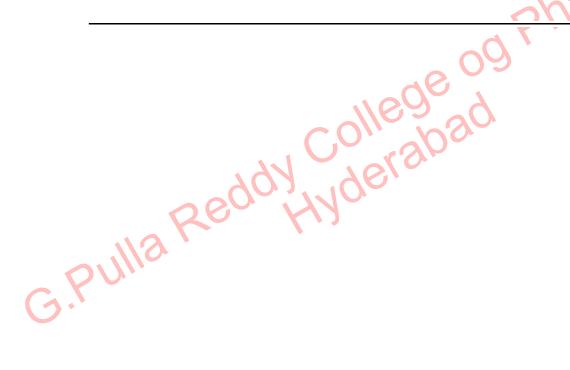
UNIT – V

Miscellaneous compounds: Structure, structural modifications, mechanism of action and therapeutic uses of a) taxanes b) camptothecin c) artemisicin e) ginkolides and f) gymnemic acids.

- 1. Finar IL. Organic Chemistry-stereochemistry and the chemistry of natural products. 5th ed. vol 2. Delhi: Dorling Kindersley (India) Pvt. Ltd., 2006.
- 2. Morrison RT, Boyd RN. Organic Chemistry. 6th ed. Delhi: Pearson education Pvt. Ltd., 2003.
- 3. Pelletier SW. Alkaloids-chemical & biological perspectives. vol 1-15. London: Pergamon; 2001.
- 4. Steroids by Fischer & Fischer.
- 5. Evans WC. Trease and evans pharmacognosy. 15th ed. Edinburgh: Saunders. 2004.
- 6. Ataur Rahman. Chemistry of natural products
- 7. Bhat SV, Nagasampagi BA, Sivakumar M. Chemistry of natural products. New Delhi: Narosa Publishing House; 2005.
- 8. Agrawal OP. Organic chemistry-natural products. 30th ed. vol 1-2. Meerut: Goel Publishing House; 2006.
- 9. Wallis TE. Textbook of pharmacognosy. 5th ed. New Delhi: CBS Publishers &

Distributors; 2002.

- 10. Abraham DJ, editor. Burger's medicinal chemistry and drug discovery. 6th ed. vol 1-6, Singapore: John Wiley & Sons, 2007.
- 11. Lemke TL, Williams DA, Roche VF, Zito SW. Foye's principles of medicinal chemistry. 6 ed. New Delhi: Wolters Kluwer/ Lippincott Williams & Wilkins. 2008.
- 12. Block JH, Beale JM, editor. Wilson and gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Baltimore: Lippincott Williams & Wilkins; 2004.
- 13. Jerry M. Advanced organic chemistry-reactions, mechanisms, and structure. 4th ed. Kundli: Replika Press Pvt. Ltd; 2003.
- 14. Murray RK, Granner DK, Mayes PA, Rodwell VW. Harper's Illustrated biochemistry. 26th ed. New Delhi: Mc Graw Hill, 2003.
- 15. Rama Rao AVSS. A text book of biochemistry. 9th ed. Delhi: Rajkamal electric press, 2004
- 16. Remington: The science and practice of pharmacy. 21st ed., vol. I & II, Lippincatt Willams & Wilkings, New Delhi, 2005.



PHARMACEUTICAL ANALYTICAL TECHNIQUES

M PCH.P.1.105 Period/Week: 6

Sessional: 30 Duration of Exam: 6 hrs
Examination: 70 Nature of Exam: Practical

List of Experiments: (Minimum of 8 experiments shall be conducted)

- 1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
- 2. Effect of solvents and pH on UV spectrum of drugs. (2 experiments)
- 3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments)
- 4. Experiments based on the application of derivative spectroscopy. (2 experiments)
- 5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments)
- 6. Interpretation of drugs by IR spectra.
- 7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds. (4 experiments)
- 8. Any other relevant experiments based on theory.

ADVANCED CHEMISTRY OF NATURAL PRODUCTS

M PCH.P.1.106 Period/Week: 6 Sessional: 30 Duration of Exam: 6 hrs

Examination: 70 Nature of Exam: Practical

List of Experiments: (Minimum of 8 experiments shall be conducted)

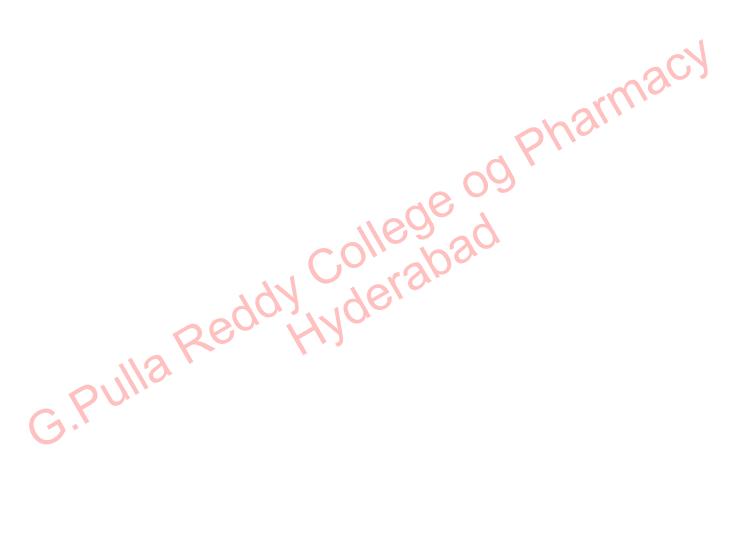
- 1. Isolation and characterization of the following natural products:
 - a. Piperine from black pepper
 - b. Hesperidin from orange peel.
 - c. Strychnine from Nux vomica seeds.
 - d. Curcumin from turmeric powder.
 - e. Lycopene from tomatoes.
 - f. Myristicin and trimyristicin from nutmeg.
 - g. Tannic acid from myrobalan.
 - h. Isolation of casein from milk.
 - i. Lysozyme from albumen.
- 2. Extraction and estimation of carvone from caraway seeds.
- 3. Separation of natural products through column chromatography.
- 4. Degradation and characterization of degradation products of a) Piperine b) Atropine and
- c) Caffeine.
- 5. Any other relevant experiments based on theory.

References:

- 1. Raphel I. Natural products: a laboratory guide. 2nd ed. New Delhi: Elsevier, 2005.
- 2. Kokate CK. Practical pharmacognosy. New Delhi: Vallabh Prakashan.
- 3. Khandelwal KR. Practical pharmacognosy. Pune: Nirali Prakashan.
- 4. Rangari VD. Pharmacognosy & phytochemistry. Part II. Nashik: Career Publications:

2004.

5. Qadry JS. Shah and Qadry's pharmacognosy. 12th ed. Ahmedabad: B. S. Shah Prakashan; 2005



ENTREPRENEURSHIP MANAGEMENT

Subject Code: M PCH.T.1.107 Grade: A/B/C/D

Periods/week: 2 **Examination: --**

Nature of Exam: Tutorials Exam Duration: --

Course Objectives:

• To provide conceptual inputs regarding entrepreneurship management.

- To Sensitise and motivate the students towards entrepreneurship management.
 - To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities. harmac'
- To develop management skills for entrepreneurship management.

UNIT - I: CONCEPTUAL FRAME WORK:

- Concept need and process in entrepreneurship development.
- Role of enterprise in national and global economy
- Types of enterprise Merits and Demerits
- Government policies and schemes for enterprise development
- Institutional support in enterprise development and management

UNIT – II: THE ENTREPRENEUR

- Entrepreneurial motivation dynamics of motivation.
- Entrepreneurial competency Concepts.
- Developing Entrepreneurial competencies requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur' role.

UNIT - III: LAUNCHING AND ORGANISING AN ENTERPRISE

- Environment scanning Information, sources, schemes of assistance, problems.
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis.
- Resource mobilisation finance, technology, raw material, site and manpower.
- Costing and marketing management and quality control.
- Feedback, monitoring and evaluation.

UNIT - IV: GROWTH STRATEGIES AND NETWORKING

- Performance appraisal and assessment
- Profitability and control measures, demands and challenges
- Need for diversification
- Future Growth Techniques of expansion and diversification, vision strategies
- Concept and dynamics
- Methods, Joint venture, co-ordination and feasibility study

UNIT -V: PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE

- Project work – Feasibility report; Planning, resource mobilisation and implementation.

- 1. Akhauri MMP. Entrepreneurship for women in India. New Delhi: NIESBUD; 1990.
- 2. Hisrich RD, Brush CG. The women entrepreneurs. Toranto: D.C. Health & Company; 1996.
- 3. Hisrich RD, Peters MP. Entrepreneurship-starting, developing and managing a new enterprise. USA: Inwin, INC; 1995.
- 4. Meredith GG. et.al., Practice of Entrepreneurship. Geneva: ILO; 1982.
- 5. Patel VC. Women entrepreneurship-developing new entrepreneurs. Ahmedabad: EDII; 1987.

G.Pulla Reddy College og Pharmacy

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS

M PCH.T.1.201 Period/Week: 4
Sessional: 30 Duration of Exam: 3 hrs
Examination: 70 Nature of Exam: Theory

UNIT - I

Patents and Intellectual Property Rights (IPR): definition, scope, objectives, source of patient information, patent processing and application. Patents, copyrights, trademarks, silent features, trade related aspects (TRIPS), international and regional agreements.

UNIT - II

GATT and WTO: GATT – historical, prospectives, objectives, fundamental principles, impact on developing countries. WTO-objectives, scope, functions, structure, status, membership and withdrawal, dispute settlement, impact on globalization, India-tasks & challenges.

UNIT - III

Regulatory Affairs: Indian context – requirements and guidelines of GMP, understanding of drugs and cosmetics act 1940 and rules 1945 with reference to schedule M, U and Y.

UNIT - IV

Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.

UNIT - V

Documentation: Documentation types related to pharmaceutical industry, protocols, harmonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

- 1. Guarino RA. New drug approval process, 4 ed., vol 139, Marcel Dekker Inc., New York, 2004.
- 2. Willing SH. Good manufacturing practices for pharmaceuticals. 5th ed., vol 109, Marcel Dekker Inc., New York, 2001.
- 3. Das P, Das G. Protection of industrial property rights.
- 4. Katju SN. Laws and drugs. Law Publishers.
- 5. Original Laws published by Government of India.
- 6. Hussain. Law of drugs in India.
- 7. Websites: www.fda.org; www.wipo.int, www.ich.org, www.cder.org.

ADVANCED PHARMACEUTICAL ORGANIC CHEMISTRY – II

M PCH.T.1.202 Period/Week: 4 Sessional: 30 **Duration of Exam: 3 hrs Examination: 70 Nature of Exam: Theory**

UNIT – I

Synthetic Reagents and Applications: Lead tetra acetate (LTA), n-bromo succinamide (NBS), osmonium tetraoxide, lithium aluminium hydride (LAH), sodium borohydride, DCC (Dicyclohexyl carbodimide), and 2,3-dichlro-5,6-dicyano-1,4-benzoquinone (DDQ). varwac,

UNIT - II

Mechanism and applications of reactions and reagents:

- a. Claisen ester condensation,
- b. Mannich reaction,
- c. Micheal addition,
- d. Witting reaction,
- e. Synthetic applications of ethyl aceto acetate, diethyl malonate, ethylcyano acetate.

UNIT - III

Development & scale up of process for the manufacture of new pharmaceuticals:

- 1. Introduction, synthetic route selection, development and scale up, optimization of synthetic routes-yield improvement, investigative approach, streamlining the process.
- 2. A brief account on Green Chemistry: principles, and applications.

UNIT - IV

Synthetic Strategies: Introduction to disconnection approach, consecutive vs convergent synthesis, various strategic approaches in retro synthesis, strategic bond approach-preliminary scan, criteria in disconnection of strategic bonds, identifying strategic bonds in rings.

UNIT - V

Combinatorial Chemistry: Introduction, solid phase techniques, parallel synthesis, mixed combinatorial chemistry, deconvulution techniques, tagging, photolithography, limitations of combinatorial chemistry, planning and designing of combinatorial synthesis.

- 1. Carrruthers W, Coldham I. Modern methods of organic synthesis. 4 ed. Delhi: Cambridge University Press; 2007.
- 2. Clayden J, Greeves N, Warren S, Wothers P. Organic chemistry. Delhi: Oxford University Press; 2001.
- 3. Carey FA, Sundberg RJ. Advanced organic chemistry. Part- B: Reactions and synthesis. 5th ed. New York: Springer; 2007.
- 4. Mackie RK. A guide book to organic synthesis. New Jersy: Prentice Hall Private Limited; 1977.
- 5. Wuts PGM, Greene TW. Greene's protective groups in organic synthesis. 4 ed. New Jersy: John Wiley & Sons; 2007.

- 6. Smith MB. Organic synthesis. 2 ed. New Delhi: Tata McGraw Hill Publishing Comapany Limited; 2002.
- 7. Patrick G. Organic chemistry. New Delhi: Viva Books Private Limited; 2000.
- 8. Gyorgy K, Istvan T. Molecular pathomechanisms and new trends in drug research. New York: Taylor & Franscis; 2003.
- 9. Hansals VAS. Green Chemistry.

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- 10. March J. Advanced organic chemistry: reactions, mechanisms and structures. 4th ed. Singapore: John Wiley & Sons; 2003.
- 11. Finar IL. Organic Chemistry. 5th ed. vol 1. Delhi: Dorling Kindersley (India) Pvt. Ltd; 2006.
- 12. Morrison RT, Boyd RN. Organic chemistry. 6th ed. New Delhi: Pearson Education; 2007.
- 13. Skyes P. A guided book to mechanism in organic chemistry. 6th ed. Delhi: Pearson Education; 2006.
- 14. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.
- 15. Groggins PH. Unit process in organic synthesis. 5 ded. New Delhi: Tata McGraw Hill Publishing Comapany Limited; 2004.
- 16. Hillish A, Hilgenfeld R, editor. Modern methods of drug discovery. Berlin: Berkhauser Verlag; 2003.

ADVANCED MEDICINAL CHEMISTRY – II

M PCH.T.1.203 Period/Week: 4
Sessional: 30 Duration of Exam: 3 hrs
Examination: 70 Nature of Exam: Theory

UNIT – I

Computer aided drug design (CADD):

- 1. Virtual screening: concept, drug likeness screening, focused screening libraries for lead identification, pharmacophore screening, structure based virtual screening and applications.
- 2. Molecular modeling: Molecular mechanics, quantam mechanics, modeling ligands for known receptors and unknown receptors.

UNIT – II

Rational Drug design: Quantitative structure activity relationship (QSAR): Physico chemical properties: hydrophobicity, electronic effects, steric factors-Taft's steric factor (Es), molar refractivity, verloop steric parameter, other physico chemical parameters.

Methods used to correlate physico chemical parameters with biological activity: Hansch analysis, Free and Wilson approach, Topliss scheme, bioisosteres, planning a QSAR study. 3D QSAR, molecular graphics based drug design and mathematical methods.

UNIT – III

Enzyme Inhibitors: A detailed study of the following types of enzyme inhibitors, related drugs and their pharmaceutical significance.

- P.G. Synthease (Cyclooxygenase and Lipoxygenase) inhibitors,
- Phosphodiesterase (PDE) inhibitors,
- HMG Co A reductase inhibitors,
- Xanthine oxidase inhibitors,
- Angiotensin convertin enzyme (ACE) inhibitors.

UNIT – IV

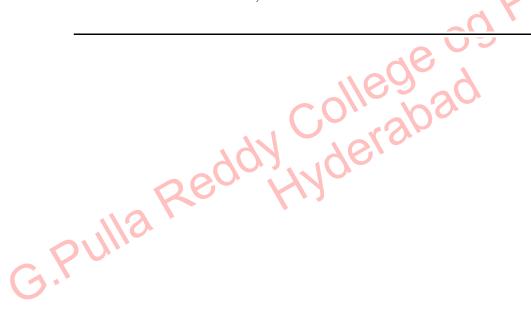
Anti Viral Agents: Viruses, viral diseases, structure and life cycle of viruses; antiviral agents used against DNA viruses- herpes, chicken pox; and RNA viruses – HIV, influenza.

UNIT - V

Chemotherapy of Cancer: Molecular biology of caner: introduction, biochemical basis of cancer, types of cancer, SAR and mechanism of action of anticancer agents, alkylating agents, antimetabolites, antitumor antibiotics. A brief account on cancer chemotherapy and drug resistance.

- 1. Abraham DJ, editor. Burger's Medicinal Chemistry and Drug Discovery, 6th ed. Vol 1-6. New Jersey: John Wiley & Sons; 2007.
- 2. Lemke TL, Williams DA, editor. Foye's principles of medicinal chemistry. 6 ed. New Delhi: Wolters Kluwer and Lippincott Williams & Wilkins; 2008.
- 3. Ariens EJ, editor. Drug design vol. I-X. Noida: Academic Press; 2009.
- 4. Purcell, Strategy of drug design.
- 5. Hansch C, editor. Hansch's comprehensive medicinal chemistry, Delhi: Rajkamal Electronic Press; 2005.

- 6. Silvermann RB. The organic chemistry of drug design and drug action. 2nd ed. London: Academic press (Elsevier); 2004.
- 7. Smith & Williams. Introduction to principles of drug design-Harwood academic press.
- 8. Gyorgy K, Istvan T. Molecular pathomechanisms and new trends in drug research. New York: Taylor & Franscis; 2003.
- 9. Thomas Nogardy. Medicinal chemistry. A biochemical approach. Oxford University Press.
- 10. Patrick GL. An introduction to medicinal chemistry. 3^{rd} ed. New Delhi: Oxford University Press; 2006.
- 11. Andrejus K. Essentials of Medicinal Chemistry. 2nd ed. New Delhi: John Wiley & Sons; 1988.
- 12. William AP. Strategies of Drug design: A guide to biological activity, John Wiley & Sons, 1973.
- 13. Block JH, Beale JM, editor. Wilson and gisvold's textbook of organic medicinal and pharmaceutical chemistry. 11th ed. Baltimore: Lippincott Williams & Wilkins; 2004.
- 14. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.



DRUG SCREENING METHODS AND BIOSTATISTICS

M PCH.T.1.204 Period/Week: 4
Sessional: 30 Duration of Exam: 3 hrs
Examination: 70 Nature of Exam: Theory

UNIT - I

Bio-statistics: Regression and correlation: Linear regressions, Method of least squares; correlation coefficients, rank correlation, multiple regression tests of significance: testing hypotheses, tests of significance based on normal distribution. T-test; significance of correlation coefficient. F-test, Analysis of variance: 1-way, 2-way and 3-way classification, Chi-square test of (i) Variance of a normal population (ii) Goodness of fit, (iii) Independence in contingency tables.

UNIT - II

Design of experiment: Principles of randomization, replication and local control, completely randomized block of the above designs in pharmaceutical research, Statistical quality control, process control, control charts, acceptance sampling – sampling plans.

UNIT - III

High throughput screening: introduction, bioassay design, and screen construction-assay design, assay construction, homogeneous and non homogeneous biochemical assays and cellular assays.

UNIT – IV

- 1. **Bioassay:** Different types: dose effect relationships, calculation of LD₅₀, ED₅₀ Probit analysis.
- 2. *In vivo* screening methods: Antihypertensive, antiarrythmic, cardiotonic, and anticancer and diuretic drugs.

UNIT - V

In vivo screening methods: Analgesic, anti-inflammatory, antiepileptic, antidiabetic, and antifertility drugs.

- 1. Abraham DJ, editor. Burger's Medicinal Chemistry and Drug Discovery, 6th ed. vol 1-6. New Jersey: John Wiley & Sons; 2007.
- 2. Vogel H and Volgel WH. Drug discovery and evaluations-pharmacological assays. 2 nd ed. Germany: Springer; 2002.
- 3. Seethala R, Fernandes PB. Hand book of drug screening. New York: CBS Publishers & Distributors; 2008.
- 4. Lewis AE. Biostatistics, 2 ed. New York: Reinhold Publishers Corporation; 1984.
- 5. Alder HL, Roesseler EB. Introduction to probability and statistics. 12th ed. San Francisco: WH. Freemann and company; 2006.
- 6. Gupta SC, Kapoor VK. Fundamentals of applied statistics. 4th ed. New Delhi: Sulttaan Chand and sons; 2007.
- 7. Saunders and Fleming. Mathematics and statistics for use in pharmacy, biology and chemistry.
- 8. Gupta SK. Drug screening methods. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2004.
- 9. Arora PN, Malhan PK. Biostatistics. Mumbai: Himalaya Publishing House; 2008.

10. Bolton S, Bon C, Pharmaceutical statistics, 4 ed. New York: Marcel Dekker Inc; 2004

.ADVANCED PHARMACEUTICAL ORGANIC CHEMISTRY - II

M PCH.P.1.205 Period/Week: 6 Sessional: 30 Duration of Exam: 3 hrs

Examination: 70 Nature of Exam: Practical

List of Experiments: (Minimum of 8 experiments shall be conducted)

- 1. Synthesis and characterization of the following drugs:
 - a. Benzanilide by bechmann rearrangement
 - b. 4-benzylidene-2-methyloxazol-5-one (or) azalactone
 - c. N-(m-nitrobenzyl)aniline from m-nitrobenzaldehyde
 - d. 2,3-diphenyl quinoxaline
 - e. 1H-indole-3-carbaldehyde
 - f. 3,4-dihydropyrimidin-2(1H)-one from benzaldehyde, ethyl acetoacetate and urea in presnce of CaCl₂ catalyst.

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- g. Schiff base by microwave irradation
- h. Cinnamic acid by perkin reaction
- i. β-dimethylamino propiophenone hydrochloride (mannich base)
- i. 2-phenyl indole
- k. Dimedone (5,5-dimethyl cyclohexane-1,3-dione)
- 1. 3-bromo cyclohexene from cyclohexene using NBS.
- m. p-amino benzyl alcohol from p-amino benzaldehyde using sodium borohydride.
- n. Cyclohexane-2,5-dicarboxylic acid from benzoic acid (hydrogenation).
- 2. Any other relevant experiments based on theory.

References:

- 1. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.
- 2. Mann FG, Saunders BC. Practical organic chemistry. 4th ed. New Delhi: Orient Longman: 2005.
- 3. Furniss BS, Hanaford AJ, Smith PWG, Tatchell AR. Vogel's textbook of practical organic chemistry. 5th ed. Singapore: Longman Singapore Publishers P Ltd; 1989.
- 4. Vogel A. Elementary practical organic chemistry. Part 1: Small scale preparations. 2nd ed. New Delhi: CBS publishers and distributors; 2004.
- 5. Bansal RK. Laboratory manual of organic chemistry. 4th ed. New Delhi: New Age International (P) limited; 2005.
- 6. Kar A. Advanced Practical Medicinal Chemistry. New Delhi: New Age International (P) limited; 2006.

ADVANCED MEDICINAL CHEMISTRY – II

M PCH.P.1.206 Period/Week: 6 Sessional: 30 Duration of Exam: 3 hrs

Examination: 70 Nature of Exam: Practical

List of Experiments: (Minimum of 8 experiments shall be conducted)

- 1. Synthesis and characterization of the following drugs:
 - a. Phenacetin
 - b. Antipyrin
 - c. Benzocaine
 - d. Uramil
 - e. Tolbutamide
 - f. Phenothiazine
 - g. Isoniazid
 - h. Sulphasalazine
 - i. aspirin from salicylic acid
 - j. paracetamol from p-aminophenol
- 2. Determination of partition coefficient of any medicinal compound by shake flask method.

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3. Any other relevant experiments based on theory.

References:

- 1. Lednicer D, Mitscher LA, The organic chemistry of drug synthesis, Volume-1-6. New York: A wiley-interscience publication; 2005.
- 2. Mann FG, Saunders BC. Practical organic chemistry. 4th ed. New Delhi: Orient Longman; 2005.
- 3. Furniss BS, Hanaford AJ, Smith PWG, Tatchell AR. Vogel's textbook of practical organic chemistry. 5th ed. Singapore: Longman Singapore Publishers P Ltd; 1989.
- 4. Vogel A. Elementary practical organic chemistry. Part 1: Small scale preparations. 2nd ed. New Delhi: CBS publishers and distributors; 2004.
- 5. Bansal RK. Laboratory manual of organic chemistry. 4 ed. New Delhi: New Age International (P) limited; 2005.
- 6. Kar A. Advanced Practical Medicinal Chemistry. New Delhi: New Age International (P) limited; 2006.
- 7. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
- 8. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
- 9. United States Pharmacopoeia. United States Pharmacoepial Convention, Inc, USA, 2003.

SCIENTIFIC AND TECHNICAL WRITING

Subject Code: M PCH.T.1.207 Grade: A/B/C/D

Periods/week: 2 Examination: --

Nature of Exam: Tutorials Exam Duration: --

Course Objectives:

• To be able to appreciate and understand importance of writing scientifically.

- To develop competence in writing and abstracting skills.
- To write either a draft research proposal or a chapter of dissertation.

UNIT - I: COLLECTION AND EVALUATION OF INFORMATION

Identification, sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

UNIT - II: WRITING AS A MEANS OF COMMUNICATION

- Different forms of scientific and technical writing.
- Articles in journals, research notes and reports, review articles, monographs, dissertations, bibliographies.

How to formulate outlines: The reasons for preparing outlines

- as a guide for plan of writing
- as skeleton for the manuscript

Kinds of outline: topic outlines, conceptual outline, sentence outlines and combination of topic and sentence outlines

UNIT – III: DRAFTING TITLES, SUB TITLES, TABLES, ILLUSTRATIONS

Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.

Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head Appendices: use and guidelines.

The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Rereading. Checking: Organization, Headings, Content, Clarity and Grammar.

Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

UNIT - IV: PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE

Introduction, Review of Literature, Methodology, Results and Discussion. Ask questions related to: content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

UNIT - V: WRITING FOR GRANTS

- Clearly state the question to be addressed
- Rationale and importance of the question being address
- Emperial and theoretical conceptualization
- Presenting pilot study/data
- Research proposal, clarity, specificity of method
- Clear organization
- Outcome of study and its implications
- Budgeting, available infra-structure and recourses
- Executive summary

- 1. APA: Publication Manual of Americal Psychological Association, 3th ed. Washington: APA; 1984.
- 2. Cooper HM. Integrating research: a guide for literature reviews, 2nd ed. California: Sage; 1990.
- 3. Dunn FV, et al., Disserninating research: changing Practice. New York: Sage; 1984.

