**MODEL CURRICULUM** 

FOR

# **POSTGRADUATE PROGRAMME**

IN

# MASTERS OF PHARMACY

# (PHARMACEUTICAL CHEMISTRY) - 2011



ALL INDIA COUNCIL FOR TECHNICAL EDUCATION

7<sup>TH</sup> FLOOR, CHANDRALOK BUILDING, JANPATH

NEW DELHI - 110 001

## FOREWORD

It is with great pleasure and honour that I write a forward for the Model scheme of instruction and syllabi for the Undergraduate Pharmaceutical Education Programme prepared by the All India Board of Pharmaceutical Education with Dr. S.Y. Ghabe as its Chairman and other members. All India Council for Technical Education has the onerous responsibility for uniform development and qualitative growth of the Technical Education system and preparation of syllabi to maintain uniform standards throughout the county. In pursuance to clause 10 (2) of the AICTE Act 1987 AICTE has the objective of bringing about uniformity in the curriculum of Pharmaceutical Education. In that direction, the efforts of the All India Board of Pharmaceutical Education has been quite commendable and praiseworthy. A painstaking effort was made by the Chairman, members of the Board and various working groups composed of experts from leading institutions in framing of the Instruction and Syllabi. The Board was ably assisted by the official of the Academics Bureau in successfully organizing the meetings making available necessary documents and follow up action on the minutes of the meetings.

Chairman

All India Council for Technical Education

## SCHEME: PHARMACEUTICAL CHEMISTRY TERMINOLOGY: S MEANS SEMESTER, MPC MEANS MASTER OF PHARMACEUTICAL CHEMISTRY, T & TH MEANS THEORY, P & PR MEANS PRACTICAL.

### Subject Hours/week CREDITS MARKS Code Sem Subject ΤН PR ΤН TH PR PR S1-MPC-1 Research Methodology First S1-MPC-2 Modern Analytical Techniques **Computers & Statistics** S1-MPC-3 S1-MPC-4 Nanotechnology & Biotechnology Total: Second S2-MPC-1 **Research Project** S2-MPC-2 Advanced Pharmaceutical Chemistry - 1 Advanced Organic Chemistry S2-MPC-3 Elective - 1 S2-MPC-4 Total: Drug Regulatory aspects & IPR Third S3-MPC-1 Research work Seminar S3-MPC-2 S3-MPC-3 **Research Project** Advanced Pharmaceutical Chemistry – 2 S3-MPC-4 S3-MPC-5 Elective – 2 Total: Research Project & Colloquium S4-MPC-1 Fourth Total: **GRAND TOTAL:**

## **CREDIT SYSTEM: 1CREDIT = 25 MARKS**

Name of	the Course : Research and Teaching Method	dology	
Course	code: S1-MPC-1[T]	Semester :	
Duratio	n : 60 Hrs	Maximum Marks : 100	
Teachin	g Scheme	Examination Scheme	
Theory :	Theory : 04Hrs/week Mid Semester Exam: 20 Marks		
Tutorial	Hrs/week [ If required ]	Assignment &Quiz: 10 Marks	
Practica	: Hrs/week [ N A ]	End Semester Exam: 70 Marks	
Credits :	04		
Aim :-			
Objectiv	<u>/e :-</u>		
S. No			
1	To familiarize students regarding teaching	g methodology & research project	s.
2	To teach students preparation of a researc with it.	h projects & different aspects ass	ociated
3	To acquaint students with experimental data	ata analysis.	
4	To impress upon students the importance of ethical issues in the profession & plagiarism.		ı &
Pre-Req	uisite:-		
S. No			
1	A B. Pharm. degree from any AICTE approv	ed institution or its equivalent.	
	Contents		Hrs
Unit -1	Learning and instruction Principles of Instructional design and learnin and Gagne's condition of learning. Act collaborative learning, problem-based le Experiential learning model of Kolb.	tive learning, group learning,	08
Unit -2	<b>Curriculum development</b> A six step approach- Problem identification targeted needs assessment, goals and ob implementation, evaluation and feedback. Bl of educational objectives.	jectives, educational strategies,	06
Unit -3	<b>Funding &amp; Scholarship</b> Agencies funding research in pharmaceutica scholarships in education.	al sciences, Scholarship, types of	03
Unit -4	Assessment Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.		03
Unit -5	Basics of Research Definition, objectives, motivation, types of research and approaches: descriptive research, conceptual, theoretical, applied and experimental.		03
Unit -6	<ul> <li>Formation of Research Problem</li> <li>A. Research Process: To determine what type research work.</li> <li>B. Selection of research area, prioritization of C. Literature review: importance and method D. Objectives and scope of work, developi</li> </ul>	be of research to be done, plan of f research. ds, sources,	04

	Scheduling constraints, steps, problems in scheduling, limitations.	
Unit -7	Mathematical Modeling and Simulation Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative, experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	05
Unit -8	<ul> <li>Experimental Modeling</li> <li>a) Definition of experimental design, examples, single factor experiments blocking and Nuisance factors, guidelines for designing experiments.</li> <li>b) General model of process: Input factors/ variables, Output parameters / variables controllable / uncontrollable variables, dependent / independent variables, experimental validity.</li> <li>c) Introduction to Risk assessment, reliability, sustainability, and uncertainty.</li> </ul>	04
Unit -9	<ul> <li>Analysis of data</li> <li>a) Types of data: parametric and nonparametric, descriptive and inferential data,</li> <li>b) Collection of data: normal distribution, calculation of co-relation coefficient</li> <li>c) Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions,testing linearity/nonlinearity of model, testing adequacy of model.</li> <li>d) Test to be used in data exploration and their choice</li> <li>e) Introduction of software used in data analysis.</li> </ul>	08
Jnit-10	<ul> <li>Research Deliverables</li> <li>a) Various Forms of Publication: Thesis, paper, research proposal.</li> <li>b) Thesis Writing: Introduction, literature review or state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices.</li> <li>c) Presentation: Poster, thesis, proposal, and paper.</li> </ul>	04
Uni-11	<b>Ethical issues in research</b> Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
Unit-12	<b>Plagiarism</b> Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.	02
	Total	60
Text Boo	oks:	
	ce books :	
<ul> <li>B.D. J school</li> <li>J.R. F</li> </ul>	John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experient of". Washington, DC: National Academy Press. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education: McGraw-Hill.	

- K.E. David, 2009. Curriculum Development for Medical Education: *A Six-Step Approach*, 2<sup>nd</sup> Ed. The John Hopkins University Press. ISBN 0-8018-9367-4.
- N. Peter, 2009. "Leadership: Theory and Practice." 3<sup>rd</sup> Ed. Thousand Oaks: Sage Publications.
- G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28

questions. *Medical Education*, 37(4): 376-385.

- B.J. Avolio, F.O. Walumbwa, T.J. Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology*, *60*: 421-449.
- C.R. Kothari, 2004. "Research Methodology". 2<sup>nd</sup> Ed. New Age International (p) Limited, Publishers.
- D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3<sup>rd</sup> ed. Himalaya publishing, Mumbai.
- Schank Fr, 2008. "Theories of Engineering Experiments". 2<sup>nd</sup> Ed. Tata McGraw Hill.
- D.C. Montgomery, 2009. "Introduction to SQC" 6th Ed. John Willy & sons.
- Cochran & Cocks, 1957. 2<sup>nd</sup> Ed. "Experimental Design" New York, John Willy & sons.
- J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.
- S.S. Rao, 1983. "Optimization Theory & Applications". 2<sup>nd</sup> Ed. Wiley Eastern Ltd. ND.
- P.D. Kulkarni, 1986. "Independent Study Techniques", TTTI Chandigarh.

## Suggested List of Laboratory Experiments : NA

Suggested List of Assignments/Tutorial : NA

Course	code: \$1-MPC-2 [ T & P ] \$6	emester:	
Duration : 60 Hrs [ T ], 120 Hrs [ P ]		aximum Marks : 100	
Teachir	ig Scheme Ex	kamination Scheme	
		id Semester Exam: 20 Marks	
Tutorial	: Hrs/week [ If required ]	ssignment &Quiz: 10 Marks	
Practica	I:08 Hrs/week Er	nd Semester Exam: 70 Marks	
Credits :	04 Each [ T & P ]		
Aim :-			
Objectiv	/e:-		
S. No			
1	To familiarize students in use of modern te areas / fields of pharmacy.	. ,	
2	To give training in use of the technique & it		
3	To build on the basics learned at UG level &	give latest advances in the area	a
4	To give more stress on application based ki one.	nowledge than instrumentation	based
5	To give hands on training on use of as many possible.	y different sophisticated instrur	nents as
Pre-Rec	uisite:-		
S. No			
1	Minimum two UG level courses in Pharmaceut	tical analysis.	
2	A B. Pharm. Degree from any AICTE approved	institution or its equivalent.	
	Contents		Hrs
Jnit -1	Ultraviolet – Visible spectrometry: Woodward – λmax. Derivative spectroscopy.	Fisher rules for calculation of	05
	Introduction to Optical rotatory Dispersion and C	ircular Dichroism.	
Unit -2	Introduction to Optical rotatory Dispersion and C Fourier Transformed Infrared Spectrometry. spectrum.		03
Jnit -2 Jnit -3	Fourier Transformed Infrared Spectrometry. spectrum. High Resolution <sup>1</sup> H & <sup>13</sup> C NMR Spectrometry chemical shifts of various carbon atoms. Technic carbon like attached proton test (APT), distor transfer (DEPT). Homonuclear & heteronucle Different 1D & 2D NMR correlation spectromet NOESY, HETCOR, INADEQUATE, HSBC, HMQC	Interpretation of Infrared /. Theoretical calculation of ques used for finding types of tion less energy polarization ar correlation spectrometry. tric techniques such as COSY,	
	Fourier Transformed Infrared Spectrometry. spectrum. High Resolution <sup>1</sup> H & <sup>13</sup> C NMR Spectrometry chemical shifts of various carbon atoms. Technic carbon like attached proton test (APT), distor transfer (DEPT). Homonuclear & heteronucle Different 1D & 2D NMR correlation spectromet NOESY, HETCOR, INADEQUATE, HSBC, HMQC determination of absolute configuration. Mass spectrometry: use of isotopic abunda calculation. Different ionization techniques like Fragmentation of molecule using these technique	Interpretation of Infrared /. Theoretical calculation of ques used for finding types of tion less energy polarization ar correlation spectrometry. tric techniques such as COSY, etc. Use of this technique in ance in molecular formula EI, CI, FD, FI, MALDI, API, ESI.	03
Jnit -3	Fourier Transformed Infrared Spectrometry. spectrum. High Resolution <sup>1</sup> H & <sup>13</sup> C NMR Spectrometry chemical shifts of various carbon atoms. Technic carbon like attached proton test (APT), distor transfer (DEPT). Homonuclear & heteronucle Different 1D & 2D NMR correlation spectromet NOESY, HETCOR, INADEQUATE, HSBC, HMQC determination of absolute configuration. Mass spectrometry: use of isotopic abunda calculation. Different ionization techniques like	Interpretation of Infrared A. Theoretical calculation of ques used for finding types of tion less energy polarization ar correlation spectrometry. tric techniques such as COSY, etc. Use of this technique in ance in molecular formula EI, CI, FD, FI, MALDI, API, ESI. es. Tandem mass spectrometry ibration. Analytical method	03

	development, validation as per ICH guidelines and troubleshooting. Quantification methods used in HPLC. Ultra pressure liquid chromatography.	
Unit -7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC),	05
Jiiit - 7	Thermogravimetry (TG), Thermo mechanical analysis (TMA): Principles	05
	instrumentation and applications (including interpretation of data) in	
	pharmacy.	
Unit -8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc.	06
Jnit -9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocal microscopy.	05
	Total	60
Text Bo	oks:	
Referer	ice books :	
orga • Pavi • Mur	ert M. Silverstein, Francis X. Webster, David J. Kiemle, 2009. "Spectrometric identifi nic compounds". 7 <sup>th</sup> Ed. John Wiley & Sons a D. L., 2009. "Introduction to spectroscopy". 4 <sup>th</sup> , Belmont CA ison & Munson, "Pharmaceutical analysis: modern methods". edited by James W. Mi < : M. Dekker	
	neth A. Connors, 2007. "A Textbook Of Pharmaceutical Analysis" 3rd Ed. Wiley India	-wse
	Thuro Carstensen, 2001. "Advanced pharmaceutical solids" Marcel Dekker, New Ye	
	ph B. Lambert, Scott Gronert, Herbert F. Shurvell, David Lightner, Robert Graham C	
	anic structural spectroscopy", 2 <sup>nd</sup> Ed. Pearson Education, Limited.	00110, 20101
	strongly recommended that some standard book/s be used for practicals. Th	e choice of
	k/s is left to the concerned teachers.	
Suggest	ed List of Laboratory Experiments :	
S.No		
1	Estimation of two drugs by simultaneous equation method and absorbance ratio	method.
2	Calibration of UV spectrometer for wavelength and stray light.	
3	Analysis of drugs by second derivative UV spectrometry.	
4	Determination of pK value by UV visible spectrometry.	
5	Calculation of λmax values using Woodward Fisher rules.	
6	Study of hydrogen bonding using IR spectrometer.	
7	Interpretation of IR spectra.	
8	Calibration of IR spectrometer using standard polystyrene film.	
9	Interpretation of 1D proton NMR spectrum of simple compounds (10-12 carbons	5).
10	Interpretation of 1D 13C NMR spectrum of simple compounds (10-12 carbons).	
11	Calculation of carbon chemical shifts for various carbons such as sp3, sp2, sp carl	DON ELC.
12	Assignment of m/z values to various fragments in the mass spectrum.	
13	Qualitative and quantitative analysis using HPTLC.	
14	Analytical method development for three component mixture using HPTLC.	
15	Calibration of HPLC instrument for flow rate & wavelength.	nont
16	Determination of theoretical plate, HETP, resolution, tailing factor for two compo mixture	ment

17	Determination of caffeine content in tea/ coffee/ other beverages.		
18	Quantitation using different methods such as area normalization, one point, two point method with the help of internal standard.		
19	Determination of melting point & heat of fusion using DSC.		
20	Determination of glass transition temperature using DSC.		
21	Interpretation of ORD and CD spectrum.		
Suggest	Suggested List of Assignments/Tutorial : NA		

Name of	f the Course :Computer and Statistics		
Course	code: S1-MPC-3 [ T ] Sen	nester : I	
Duration : 60 Hrs[ T ], 60 Hrs [ P ]		<b>kimum Marks</b> : 100	
Teachin	ig Scheme Exa	mination Scheme	
		Semester Exam: 20 Marks	
Tutorial	: Hrs/week [ If required ] Ass	ignment &Quiz: 10 Marks	
Practica	I: 04 Hrs/week End	Semester Exam: 70 Marks	
Credits:	04 Each [ T & P ]		
Aim :-	<b>i</b>		
Objectiv	/e :-		
S. No			
1	To train students in basics of computer	hardware.	
2	To train them on hands on experience i	n use of different software.	
3	To teach them applications of computer	rs in different areas of Pharmacy.	
4	To train the students for applications o analysis of data.	f various statistical methods availa	ble for
Pre-Req			
S. No			
1	A 10 + 2 level mathematics & rudimentary	v knowledge of computers.	
2	A B, Pharm. Degree from any institution a	oproved by AICTE or its equivalent.	
	Contents		Hrs
Compute	ers		
Jnit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.		03
Jnit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).		15
Jnit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).		06
Jnit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).		05
Jnit -5	Web page design: Need, concept and use of H		08
	Databases: Meaning, Need and creating table, record creating and maintenance.		05
Jnit -6	Databases: Meaning, Need and Creating table,		

Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
Statisti		
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	60
	C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Win Chi Publishers Inc. A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", C Francis. G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CR W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley. http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf www.Pubmed.com www.Pubchem.com www.mdl.com http://www.vlifesciences.com http://spdbv.vital-it.ch http://www.winstat.com www.uspto.gov Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Mueller AG & Co. Kg. http://www.vlifesciences.com http://spdbv.vital-it.ch	CRC/Taylor & C Press.
•	Scholarships, Fellowships & Loans, Chrystal Rozs, Gale, 2002. It is strongly recommended that some standard book/s be used for practica choice of book/s is left to the concerned teachers.	ls. The
Sugges	ted List of Laboratory Experiments :	

S. No	
1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.
Suggest	ed List of Assignments/Tutorial: NA

Name of	f the Course : Nanotechnology and Bio	otechnology	
Course	code: \$1-MPC-4 [ T & P ]	Semester : 1	
Duratio	n : 60 Hrs [ T ], 120 Hrs [ P ]	Maximum Marks : 100	
Teachin	eaching Scheme Examination Scheme		
Theory :	04 Hrs/week	Mid Semester Exam: 20 Marks	
Tutorial	: Hrs/week [ If required ]	Assignment & Quiz: 10 Marks	
Practica	I:08 Hrs/week	End Semester Exam: 70 Marks	
Credits :	04 Each [ T & P ]		
Aim :-			
Objectiv	/e :-		
S. No			
1	To give basics of nanotechnology.		
2	To impart advanced level training use in Pharmacy. To make use of this advanced level k	in bio & nanotechnology with emphasi	is on their
4		he sophisticated experiments in these a	
-		ne sophisticated experiments in these a	eas.
Pre-Rec	uisite:-		
S. No			
1	A B. Pharm. Degree from any institu	tion approved by AICTE or its equivalen	t.
	Content	S S	Hrs
Unit -1		opportunities and challenges of I of bionanotechnology, significance of ne.	04
Unit -2	<b>NANO-DRUG DELIVERY:</b> Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nanosize in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals,		10
Unit -3	nano-drug delivery chip.11 <b>BIONANOCARRIERS:</b> Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.		11
Unit -4	NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY: Synthesis10and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications10		10
Unit -5	applications. BIONANOIMAGING: Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and		08

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	imaging-AFM, molecules, cells, materials and systems design based on	
Unit -6	nanobiotechnology for use in bioanalytical technology.	02
JIII -0	<b>DRUG DISCOVERY:</b> Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine	03
JIII(-7	sources, cell based therapies, encapsulated cells for disease treatment.	03
Jnit -8	<b>INSTRUMENTATION AND PRINCIPLES:</b> Electrophoresis techniques, laser	08
Jint -0	confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme	00
	purification and assay techniques. Techniques in cytogenetics: DNA	
	sequencing, DNA microarray.Spectral analysis techniques: Introduction,	
	estimation of proteins, DNA and RNA.	
Jnit -9	SAFETY CONCERN OF BIONANOTECHNOLICALS: Inhalation, contact/dermal	04
	delivery, environmental impact, explosion hazards.	
	Total	60
Text Boo	oks:	
Referen	ce books :	
• E.S. F	apazoglou and A. Parthasarathy, "Bionanotechnology". 1 <sup>st</sup> Ed. Morgan and Claypoc	ol.
• N.H. I	Valsch. 2005. "Biomedical nanotechnology" CRC Press.	
• D.S. C	Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.	
• T. Vo	p-Dinh, "Nanotechnology in biology and medicine: methods, devices, and application	ations" CRC
Press		
	bhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnol	ogy".Wiley
Inter	science: Hoboken.	
	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and	controlled
drug	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors.	
drug <ul> <li>It is s</li> </ul>	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. Th	
drug <ul> <li>It is s</li> </ul>	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The concerned teachers.	
drug <ul> <li>It is s         <ul> <li>book</li> <li>Suggester</li> </ul> </li> </ul>	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. Th c/s is left to the concerned teachers. ed List of Laboratory Experiments :	
drug tit is s book Suggeste Deve	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. Th c/s is left to the concerned teachers. ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method.	
drug drug book <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u> <u>book</u>	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The c/s is left to the concerned teachers. ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method. gn of nanospheres by emulsification method.	
drug It is s book Suggeste Deve Desig Prep	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The c/s is left to the concerned teachers. ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method. yn of nanospheres by emulsification method. aration of polymeric nanocapsules by solvent-diffusion method.	e choice of
drug drug book Suggeste Deve Desig Prep Evalu	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The t/s is left to the concerned teachers. ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method. gn of nanospheres by emulsification method. aration of polymeric nanocapsules by solvent-diffusion method. Jation of nanoparticles for particle size, zeta potential, drug entrapment efficien	e choice of
drug drug book Suggeste Deve Desig Prep Evalu and c	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The c/s is left to the concerned teachers. ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method. gn of nanospheres by emulsification method. aration of polymeric nanocapsules by solvent-diffusion method. Juation of nanoparticles for particle size, zeta potential, drug entrapment efficien other parameters.	e choice o
drug • It is s book Suggeste • Deve • Desig • Prep • Evalu and c • Deve	/yas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The c/s is left to the concerned teachers. ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method. gn of nanospheres by emulsification method. aration of polymeric nanocapsules by solvent-diffusion method. uation of nanoparticles for particle size, zeta potential, drug entrapment efficien other parameters. lopment of solid lipid nano particles using various lipids.	e choice o
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drug drug drug book Suggeste Deve Deve Prep Deve Prep Deve Prep Deve Prep Locor Prep Deve Prep Deve Prep Synth Synth Synth	Ayas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. <b>Strongly recommended that some standard book/s be used for practicals. Th</b> <b>Extremation of concerned teachers.</b> <b>Exactles of Laboratory Experiments :</b> Topment of nanoparticles by solvent-evaporation method. aration of polymeric nanocapsules by solvent-diffusion method. aration of nanoparticles for particle size, zeta potential, drug entrapment efficien other parameters. Topment of solid lipid nano particles using various lipids. aration of nanoemulsions by solvent dispersion/film hydration method. Iopment and evaluation of nano-niosomes. Iopment and evaluation of nano-suspensions. aration of nanoemulsions by using ternaray phase diagrams. "poration of nanoemulsions in topical gels. Juation of dermal retention, penetration, skin irritation and toxicity potential of r ulations. Iopment of solubility enhancement by nano formulations. Iation of nanoparticles using sol.gel method. hesis of Al <sub>2</sub> O <sub>3</sub> nanoparticles using sol.gel method. hesis of Fe <sub>2</sub> O <sub>3</sub> nanoparticles using sol.gel method. hesis of nanoparticles using biological process (2-3 methods).	cy, stability
drug lt is s book Suggeste Deve Deve Prep Deve Prep Deve Prep Deve Prep Locor Prep Deve Prep Syntl Syntl Syntl Func	Ayas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and delivery" CBS Publishers and Distributors. strongly recommended that some standard book/s be used for practicals. The <i>Lys</i> is left to the concerned teachers. Ed List of Laboratory Experiments : lopment of nanoparticles by solvent-evaporation method. aration of polymeric nanocapsules by solvent-diffusion method. aration of nanoparticles for particle size, zeta potential, drug entrapment efficien other parameters. lopment of nano-liposomes by solvent dispersion/film hydration method. lopment and evaluation of nano-niosomes. lopment and evaluation of nano-suspensions. aration of nanoemulsions by using ternaray phase diagrams. poration of dermal retention, penetration, skin irritation and toxicity potential of rulations. lopment of solubility enhancement by nano formulations. lation of nanoparticles. ssment of solubility enhancement by nano formulations. lation of nanoparticles using sol.gel method. hesis of Al <sub>2</sub> O <sub>3</sub> nanoparticles using sol.gel method. hesis of Fe <sub>2</sub> O <sub>3</sub> nanoparticles by chemical method.	e choice o

- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO<sub>2</sub>, CdS, ZnO, SnO<sub>2</sub>, Cu<sub>2</sub>S, CuCNS, Cu<sub>2</sub>O, BaTiO<sub>3</sub>, SrTiO<sub>3</sub> by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Suggested List of Assignments/Tutorial : NA

Name of the Course : Research Project				
Course code: S2-MPC-1 [ P ]	Semester : 11 Maximum Marks : 50			
Duration : 120 Hrs				
Teaching Scheme	Examination Scheme			
Theory : Hrs/week [ N A ]	Mid Semester Exam: 20 Marks			
Tutorial: Hrs/week [ N A ]	Assignment & Quiz: Marks [NA]			
Practical : 08 Hrs/week	End Semester Exam: 30 Marks			
Credits : 02				
Aim :-	1			
Objective :-				
S. No				
1 To give exposure on how	v to do literature survey for the project work.			
2 To develop technical wr	iting skills in the form of a research report.			
3 To develop report prese	ntation ability, orally.			
4 To develop question ans	To develop question answer capability confidently.			
Pre-Requisite:-				
S. No				
1 A B. Pharm. Degree from	any institution approved by AICTE or its equivalent.			
Text Books: N A				
	s & other literature shall depend on the topic of research &			
the choice is left with the individu				
Suggested List of Laboratory Expe				
Suggested List of Assignments/Tu	itorial : N A			

Name o	f the Course : Advanced Pharmaceutical Cher	nistry – 1	
Course	code: S2-MPC-2 [ T & P ] Ser	nester: II	
Duratio	on : 60 Hrs [ T ], 120 Hrs [ P ] Ma	ximum Marks : 100	
Teachi	ng Scheme Exa	amination Scheme	
Theory	: 04 Hrs/week Mid	d Semester Exam: 20 Marks	
Tutoria	I: Hrs/week [ If required ] Ass	signment & Quiz: 10 Marks	
Practica	II:08 Hrs/week End	d Semester Exam: 70 Marks	
Credits	: 04 Each [ T & P ]		
Aim :-			
Objecti	ve :-		
S. No			
1	To teach students the basics & applications	s of drug design using computer soft	ware.
2	To impart training in handling these drug of experiments.	design software by means of laborat	ory
3	To give latest developments in some of the	therapeutically useful classes of dr	ugs.
4	To develop the laboratory skills by giving a	dvanced level reactions.	
Pre-Re	quisite:-		
S. No			
1	At least two UG level courses in Pharm. / Me	ed. Chem.	
2	A B. Pharm. Degree from any institution ap	proved by AICTE or its equivalent.	
	Contents		Hrs
Unit -1	Drug design & various rational approache biopharmaceutical consideration in drug desig		04
Unit -2	OSAR, CADD, molecular modeling, & docking. Use of these methods in the development of fluoroquinolones, dihydropyridines& other drugs. Study of software like ISIS, Chemsketch, RASMOL, Protein Explorer etc for structure drawing & visualization.		10
Unit -3	Prodrugs.		11
Unit -4	Recent advances in enzyme inhibitors.		10
Unit -5	Recent advances in drugs used in the treatment of:         a] cancer,         b] AIDS,         c] cardiovascular disorders,         d] diabetes,         e] hepatitis, and         f] immunosuppression.		08
	Recent advances in the area of lipid / cholester	rol lowering agents.	02
Unit -6	Recent devences in the died of lipid / choicster		

	Total 60
e	xt Books:
<b>le</b>	ference books :
•	J. H. Block & J. M. Beale, "Wilson & Giswold's Text Book of Organic Medicinal & Pharmaceutical
	Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A
	T. L. Lemke & D. A. Williams, "Foye's Principles of Medicinal Chemistry", Lippincott Williams &
	Wilkins, Baltimore, U. S. A.
	R. B. Silverman, "The Organic Chemistry of Drug design & Drug Action". Academic Press,
	Massachusetts, U.S. A.
	Corwin Hansch, Peter George Sammes, John Bodenhan Taylor, 1990. "Comprehensive Medicinal
	Chemistry". Pergamon Press,
	Corwin Hansch, Albert Leo, D. H. Hoekman, 1995. "Exploring QSAR: Fundamentals and applications
	in chemistry and biology". American Chemical Society.
	Alfred Burger, Manfred E. Wolff, "Burger's Medicinal Chemistry and Drug Discovery: Therapeutic
	agents". Wiley.
	http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
	www.Pubmed.com
	www.Pubchem.com
	www.mdl.com
	http://www.vlifesciences.com
	http://spdbv.vital-it.ch
	http://www.winstat.com
	http://www.organic-chemistry.org/prog/peo/cLogP.html
	http://intro.bio.umb.edu/111-112/OLLM/111F98/newclogp.html
	http://pdbbeta.rcsb.org/pdb/home/home.do
	It is strongly recommended that some standard book/s be used for practicals. The choice of
	book/s is left to the concerned teachers.
ju	ggested List of Laboratory Experiments :
	Drawing, editing and cleaning structure
	Structure optimization using molecular mechanical & semiempirical method
	Creating function library
	Visualization
	Changing display style
	2D & 3D rotation of structure
	Quarrying geometry
	Calculating structural parameters
	Calculating descriptors
	Creating worksheet
	Calculating correlation
	Building regression model
	Predicting activity
	Protein file downloading
	Protein molecule visualization & querying
	Performing simple Docking
	Birch reduction
	Wolff-Kishner reduction
	Grignard reaction
	Synthesis of appropriate prodrug of aspirin/ salicylic acid

Course	code: S2-MPC-3[ T ],120 Hrs [ P ]	Semester : 11	
	n : 60 Hrs	Maximum Marks : 100	
Teachin	g Scheme	Examination Scheme	
	04 Hrs/week	Mid Semester Exam : 20 Marks	
Tutorial	Hrs/week [ If required ]	Assignment & Quiz: 10 Marks	
	I:08 Hrs/week	End Semester Exam: 70 Marks	
Credits :	04 Each [ T & P ]		
Aim :-			
Objectiv	/e :-		
S. No			
1	To teach different protecting group	s used in synthesis & their applications.	
2		lge in the area of stereochemistry, novel re	agents,
3	anions formation & their applicatio		
4	To give hands on training on the use precautions.	e of various reactive reagents & the necess	ary safet
Pre-Rec	uisite:-		
S. No			
1	At least two UG level courses in Orga	anic Chemistry & practicals of the same.	
	Conten	ts	Hrs
Jnit -1	Protective groups for –OH, -NH <sub>2</sub> , -COOH. Special protective groups for aldehydes / ketones such as oxazolines[ A. I. Meyer's reagent ] & 1,3- dithianes. Methods for the deprotection of the above groups. Concept of "Umplong". Reactions of 1,3- dithiane.		06
Init -2		spiro- compounds. Stereochemistry of	03
Init -3	Oxidations using Cr, Mn, Os, Ru, period	late, & Se reagents.	05
Init -4	Homogeneous & heterogeneous reductions / hydrogenations. Metal - ammonia / 04 amines reductions.		04
Init -5	Preparation & reactions of P, S, & N ylides. 02		
	Fluorinating agents & their use in drug synthesis.		02
Init -6		Preparation & use of boron reagents in asymmetric drug synthesis. 04	
	Preparation & use of boron reagents in	asymmetric drug synthesis.	04
Init -7	Regio- & stereoselective & stereosp	ecific formation of enolate anions, their e of Li, Na, K, Mg, & B metal ions in the	04 06
Init -7 Init -8	Regio- & stereoselective & stereosp nucleoplillic& addition reactions. Role	ecific formation of enolate anions, their e of Li, Na, K, Mg, & B metal ions in the formation of enolate anions.	
Jnit -6 Jnit -7 Jnit -8 Jnit -9 Jnit -10	Regio- & stereoselective & stereosp nucleoplillic& addition reactions. Rol regio- & stereoselective & reospecific f	ecific formation of enolate anions, their e of Li, Na, K, Mg, & B metal ions in the ormation of enolate anions. of carbonyl derivatives.	06

Unit -12 General approaches towards peptide synthesis & solid phase synthesis.	02				
Unit -13 Connection & disconnection approaches in drug synthesis.	Connection & disconnection approaches in drug synthesis. 02				
Unit -14 Stereochemistry &its importance in medicinal chemistry. Methods for resolution of racemic mixtures.					
Unit -15 Dynamic stereochemistry, conformations & reactivity in open chain & cyclic systems. Weinstein, Curtin – Hammet principle. Cram's rule & Prelog modification. Topicity & its significance in dynamic stereochemistry.	systems. Weinstein, Curtin – Hammet principle. Cram's rule & Prelog				
Unit -16 Pericyclic reactions. HOMO & LUMO. Conservation of orbital symmetry. Woodward rules for allowed & disallowed motions. Stereo specificity of these reactions.	06				
Total	60				
Text Books:					
Name of AuthorsTitles of the BookEditionName of the Publis	her				
Reference books :					
<ul> <li>D. Nassipuri, "Stereochemistry of Organic Compounds". Wiley Eastern Limited, New Delf</li> <li>M. B. Smith, "Organic Synthesis", McGraw-Hill, Inc., New York, U. S. A.</li> <li>I. L. Finar, "Organic Chemistry", ELBS Series. Longman Publishers, London.</li> <li>It is strongly recommended that some standard book/s be used for practicals. The book/s is left to the concerned teachers.</li> </ul>					
Suggested List of Laboratory Experiments :					
Birch reduction.					
Lithium aluminum hydride reduction.					
	ium borohydride reduction.				
	xidation of conjugated and non-conjugated double bonds . dation of sulphide to sulfevides and sulfenes with hydrogen perovide & perceid				
dation of sulphide to sulfoxides and sulfones with hydrogen peroxide & peracid.					
<ul> <li>Preparation of Wittig reagent &amp; reaction with aldenyde and ketone.</li> <li>Resolution of a acidic and basic racemic mixture by diasteriomer formation.</li> </ul>	paration of Wittig reagent & reaction with aldehyde and ketone.				
<ul> <li>Kinetic resolution of racemic mixture by biochemical transformation.</li> </ul>	5				
<ul> <li>Synthesis of thiazide &amp; hydrothiazide derivative in a multistep process.</li> </ul>					
<ul> <li>Diel's Alder reaction for preparing bicyclo [2.2.1] system.</li> </ul>	5				
<ul> <li>Synthesis of any tripeptide from amino acids.</li> </ul>					
Suggested List of Assignments/Tutorial : N A					
· · · · · · · · · · · · · · · · · · ·					

Name of the Course : Elective - 1	
Course code: S2-MPC-4 [ T ]	Semester : II
Duration : 60 Hrs [ T ]	Maximum Marks: 100
Teaching Scheme	Examination Scheme
Theory: 04 Hrs/week	Mid Semester Exam: 20 Marks

Tutoria	: Hrs/week [ N A ]	Assignment & Quiz: 10 Marks	
Practical : Hrs/week [ N A ]		End Semester Exam: 70 Markss	
Credits : 04			
Aim :-		1	
Objecti	ve :-		
S. No.			
1	To give additional knowledge to stude	nts based on their choice of topics.	
Pre-Ree	uisite:-		
S. No.			
1	A B. Pharm. Degree from any institution	n approved by AICTE or its equivalent.	
	Contents		Hrs
Unit -1	Chemo informatics.		
Unit -2	Analysis of recombinant proteins.		
Jnit -3	Bioinformatics.		
Jnit -4	Microwave assisted synthesis.		
Jnit -5	Green chemistry.		
Unit -6	Supramolecular chemistry & its importan	ce in pharmacy.	
		Total	60
Text Bo	oks: N A		
	ce books: The choice of literature is I	eft to the concerned teacher dependi	ng on th
selecte	а торіс.		

Name of	the Course :Drug Regulatory Aspect and IP	R	
Course code: S3-MPC-1 [ T ]		Semester : III	
Duratio	n: 60 Hrs Ma	aximum Marks : 100	
Teachin	g Scheme Ex	amination Scheme	
		d Semester Exam: 20 Marks	
Tutorial:	Hrs/week [ N A ] As	signment & Quiz: 10 Marks	
Practical	Practical : Hrs/week [ N A ] End Semester Exam: 70 Marks		
Credits:	04		
Aim :-			
Objectiv	/e:-		
S. No			
1	To impart information on various drug reg	gulatory aspects involved in the prof	ession.
2	To teach the import / export related regul	ations with respect to some countrie	es.
3	To make the students understand the imp matters.	ortance & implications of IPR & rela	ted
4	To train the students in GMP & the latest d	evelopments there.	
Pre-Req	uisite:-		
S. No			
1	A course at UG level regarding regulatory aspects, law governing Pharmacy profession.		
2	A B. Pharm. Degree from any institution approved by AICTE or its equivalent.		
	Contents		Hrs
Unit -1	DRUG REGULATORY ASPESTS		40
(a)	Drug Regulatory Aspects (India) –		10
	<ol> <li>Indian drug regulatory authorities, C (FDA).</li> </ol>	entral and State regulatory bodies	
	2. Drugs and Cosmetics Act and Rules with latest Amendments (selective).		
	3. Special emphasis – Schedule M and Y.		
		on development clinical trials PE	
	4. New Drugs – Importation, Registration	on, development, clinical trials, BE	
	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> </ol>		
	4. New Drugs – Importation, Registration	for testing of drugs and API's, Mfg.,	
(b)	<ol> <li>New Drugs – Importation, Registrati NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic.</li> </ol>	for testing of drugs and API's, Mfg.,	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification.</li> </ol>	for testing of drugs and API's, Mfg., ing.	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification, WHO GMP certification and complexity testing and complex</li></ol>	for testing of drugs and API's, Mfg., ing. ertification. other relevant ones (Q1 – Q10).	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacture</li> <li>Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification, WHO GMP certification and a license and a structure</li> <li>ICH guidelines for stability testing and a Export permissions and manufacturing</li> </ol>	for testing of drugs and API's, Mfg., ing. ertification. I other relevant ones (Q1 – Q10). g for semi-regulated countries.	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification, WHO GMP certification and manufacturing and a stability testing and a stability testility testing and a stability testing and a stability testing and</li></ol>	for testing of drugs and API's, Mfg., ing. ertification. other relevant ones (Q1 – Q10). g for semi-regulated countries. s with special emphasis on the	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification, WHO GMP certification and the statement of the</li></ol>	for testing of drugs and API's, Mfg., ing. ertification. other relevant ones (Q1 – Q10). g for semi-regulated countries. s with special emphasis on the	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification, which were according to the plant lay-out environment &amp; safety. (HVAC, ware effluent etc.).</li> </ol>	for testing of drugs and API's, Mfg., ing. ertification. I other relevant ones (Q1 – Q10). g for semi-regulated countries. is with special emphasis on the ter systems, stores management,	12
(b)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –         <ol> <li>Indian GMP certification, WHO GMP certification, WHO GMP certification, WHO GMP certification, WHO GMP certification and manufacturing and the stability testing and testing and testing and testing and testing and testing and tes</li></ol></li></ol>	for testing of drugs and API's, Mfg., ing. ertification. I other relevant ones (Q1 – Q10). g for semi-regulated countries. is with special emphasis on the ter systems, stores management,	12
(b) (c)	<ol> <li>New Drugs – Importation, Registration NOC &amp; B.E. studies.</li> <li>Various licenses – Test lic., Import lic. Contract and Loan license manufacturing Good Manufacturing Practices (GMP) –</li> <li>Indian GMP certification, WHO GMP certification, which were according to the plant lay-out environment &amp; safety. (HVAC, ware effluent etc.).</li> </ol>	for testing of drugs and API's, Mfg., ing. ertification. other relevant ones (Q1 – Q10). g for semi-regulated countries. s with special emphasis on the ter systems, stores management, I – Basic understanding for in-built	12

2. CDER, INDA, NDA, ANDA's (types), CTD. Formats of dossiers, E- submission, US DMF (various types), IIG Limits, Orphan Drugs, vanilla ANDA's, exhibit/pivotal batches, validation batches, various guidance issued by CDER, OGD, Orange Book (and patents), RLD (reference listed drug) for BE studies and the norms for US submission, bioequivalence and dissolution recommendations, packaging, stability studies and the product information leaflet, US FDA inspection (audits), pre-approval inspections and approvals.     3. European Union Requirements -     4. All the aspects for European registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1).     5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries.     6. GMP audits, role of quality assurance, product approvals and supplies. Unit -2     INTELLECTUAL PROPERTY RIGHTS (IPR)     20     (a) Introduction to IPR & Patents – Development of IP law in India. IPR regime, introduction to IPR & Patents, patent infingement proceedings, IPAB – role and functions (IP Appellate Board). Indian IP case laws.     (c) American & European patent system - Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system in Europe.     (d) International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO.     (e) Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003.     (f) Introduction to geographical indication / trademark/ copyright; filling procedures.     (g) Patent search, patent analysis & patent drafting.     (h) Allied Patents Related Issues: Exploitation of patent, abuse of patents, compulsory licensing, infringement analysis, drug-patent linkage.     Text Books: Reference books :     CDSO pu			
Unit -2       INTELLECTUAL PROPERTY RIGHTS (IPR)       20         (a)       Introduction to IPR & Patents – Development of IP law in India, IPR regime, introduction to IP laws in India, role of IP in pharma industry growth.       20         (b)       Patenting in India – Introduction, patent legislation, Indian Patents Act 1970 and amendments, procedure for patent application, grant and opposition proceedings, patent licensing, patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP case laws.         (c)       American & European patent system – Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system in Europe.         (d)       International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO.         (e)       Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003.         (f)       Introduction to geographical indication / trademark/ copyright; filing procedures.         (g)       Patent search, patent analysis & patent drafting.         (h)       Allied Patents Related Issues: Exploitation of patent, abuse of patents, compulsory licensing, infringement analysis, drug-patent linkage.         Text Books:       Efference books :         • CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).         • CDER Publications and Guidance         • EMEA Publications and Guidance		<ul> <li>submission, US DMF (various types), IIG Limits, Orphan Drugs, vanilla ANDA's, exhibit/pivotal batches, validation batches, various guidance issued by CDER, OGD, Orange Book (and patents), RLD (reference listed drug) for BE studies and the norms for US submission, bioequivalence and dissolution recommendations, packaging, stability studies and the product information leaflet, US FDA inspection (audits), pre-approval inspections and approvals.</li> <li>European Union Requirements –</li> <li>All the aspects for European registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1).</li> <li>A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South &amp; Latin American countries.</li> </ul>	
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R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.	<ul> <li>Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.</li> <li>J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.</li> <li>I. Kanfer&amp; L. Shargel, "Generic Product Development BE issued" Informa Healthcare.</li> </ul>		
<ul> <li>R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.</li> <li>Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.</li> <li>Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David</li> <li>USPTO and WIPO Guidelines, Indian Patents Act</li> </ul>	<ul><li>Watc</li><li>Phare</li><li>USPT</li></ul>	cher and Nash, "Pharmaceutical Process Validation". Marcel Dekker. maceutical Product Dev. IVIVC by Murthy, Sunkara and David TO and WIPO Guidelines, Indian Patents Act	

### • USPTO and WIPO Guidelines, Indian Patents Ac Suggested List of Laboratory Experiments : N A

Suggested List of Assignments/Tutorial: NA

Course co					
	ode: \$3-MPC-2 [ P ]	Semester : 111			
Duration	: 120 Hrs	Maximum Marks : 100			
Teaching	Scheme	Examination Scheme			
Theory : H	Hrs/week [ N A ]	Mid Semester Exam: 30 Marks			
Tutorial:	Hrs/week [ NA ]	Assignment & Quiz: Marks [ N A ]			
Practical	: 08 Hrs/week	End Semester Exam: 70 Marks			
Credits : (	)4				
Aim :-					
Objective	9:-				
S. No					
1	To effectively present the rese	earch work carried out by the student.			
Pre-Requ	Pre-Requisite:-				
S. No					
1	A B. Pharm. Degree from any institution approved by AICTE or its equivalent.				
Text Books: N A					
Reference books: The choice of books & other literature material depends on the topic selected					
& is left v	with the concerned faculty men	nber.			
Suggested List of Laboratory Experiments : NA					
Suggested List of Assignments/Tutorial : N A					

Name of the Course : Research Project				
Course code: S3-MPC-3 [ P ]		Semester : III		
Duratio	n : 240 Hrs	Maximum Marks : 150		
Teachin	g Scheme	Examination Scheme		
Theory :	Hrs/week [ N A ]	Mid Semester Exam: Marks [ N A ]		
Tutorial:	Hrs/week [ N A ]	Assignment & Quiz: Marks [NA]		
Practical	: 16 Hrs/week	End Semester Exam: 150 Marks		
Credits :	06			
Aim :-				
Objectiv	e:-			
S. No				
1	To manage the research work in tim	e bound manner.		
Pre-Req	Pre-Requisite:-			
S. No				
1	A B. Pharm. degree from any institution approved by AICTE or its equivalent.			
Text Books: NA				
Reference books : N A				
Suggested List of Laboratory Experiments : N A				
Suggested List of Assignments/Tutorial : NA				

Name of the Course : Advanced Pharmaceutical Chemistry – 2				
Course	code: \$3-MPC-4 [ T ]	Semester : III		
Duratio	n: 60 Hrs	Maximum Marks : 100		
Teachin	g Scheme	Examination Scheme		
Theory :	04 Hrs/week	Mid Semester Exam: 20 Marks		
Tutorial	: Hrs/week [If required]	Assignment & Quiz: 10 Marks		
Practical	Practical : Hrs/week [NA] End Semester Exam: 70 Marks			
Credits :	04			
Aim :-				
Objectiv	/e :-			
S. No				
1	To give detailed coverage of the follow pharmacology involved should be give	ing topics, including chemistry, biochen n.	nistry &	
2	To provide latest knowledge on the top	pics mentioned in the units.		
3	To train the students in basic & newer approaches in synthesis of drug molecules / chemical entities.		iles /	
4				
Pre-Req	uisite:-			
S. No				
1	1 At least two courses at UG level & an advanced level course in organic chemistry at PG level.			
2	2 A B. Pharm. Degree from any institution approved by AICTE or its equivalent.			
	Contents		Hrs	
Unit-1	Antibiotics & drug resistance. Monobacta their preparation. Asymmetric synthesis of		06	
Unit-2	Endogenous opioids.		05	
Unit-3	Methods used in the synthesis of glycoside	es, nucleosides, & nucleotides.	06	
Unit-4	Synthetic methodology / approaches to t [2.2.2], & [2.2.1] systems. This should appropriate drug molecules like mecamyla	I be illustrated by the synthesis of	05	
Unit-5				
Unit-6	Biosynthesis of cholesterol, estrogen & progesterone from acetate. Biomimetic 05 synthesis of steroids, illustration of Prof. W. S. Johnson's synthesis			
Unit-7				
Unit-8			16	
	<u> </u>	Total	60	
Text Bo	aks			

### Reference books :

- J. H. Block & J. M. Beale, "Wilson & Giswold's Text Book of Organic Medicinal & Pharmaceutical Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A
- T. L. Lemke & D. A. Williams, "Foye's Principles of Medicinal Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A.
- R. B. Silverman, "The Organic Chemistry of Drug design & Drug Action" Academic Press, Massachusetts, U.S. A.
- Triger and Taylor, "Comprehensive Medicinal Chemistry". All Volumes. Ist Ed. Elsevier Science.
- C. Hansch,
- Burger. "Medicinal Chemistry". All volumes. Interscience Publishers, Inc., New York-London.
- H. O. House, W. A. Benjamin, "Modern synthetic Reactions". Menlo Park, California, U. S. A.
- J. D. Morrison, "Asymmetric Synthesis" vols. 1 5. Academic Press, Orlando,
- U. S. A.
- R. A. Aitken & S. N. Kilenyi, "Asymmetric Synthesis" Edited by, Blackie Academic & Professional, An imprint of Chapman & Hall, London, U. K.
- R. A. Sheldon, "Chirotechnology, Industrial Synthesis of Optically Active Compounds". Marcel Dekker, Inc., New York, U. S. A.
- R. Porter, & S. Clark, "Enzymes in Organic Synthesis" Pitman, London, U. K.

G. W. Moody, P. B. Baker, "Bioreactors & Biotransformations". Elsevier, Amsterdam

Suggested List of Laboratory Experiments : NA Suggested List of Assignments/Tutorial : NA

Name o	f the Course : Elective – 2		
Course code: S3-MPC-5 [T] Semester : III			
Duration : 60 Hrs		Maximum Marks : 100	
	5	mination Scheme	
5		Semester Exam: 20 Marks	
Tutorial	: Hrs/week [ N A ] Assi	gnment & Quiz: 10 Marks	
Practica	I:Hrs/week[NA] End	Semester Exam: 70 Marks	
Credits	04		
Aim :-			
Objectiv	/e :-		
S. No			
1	To enrich the knowledge of a student desire	ous of studying special topic / s of ir	nterest.
Pre-Rec	uisite:-		
S. No			
1	A B. Pharm. Degree from any institution approved by AICTE or its equivalent.		
	Contents		Hrs
Unit-1	Chiral synthons.		
Unit-2	Screening models for anticancer drugs.		
Unit-3	Ultra pressure liquid chromatography & Overp	ressure liquid chromatography.	
Unit-4	Receptor isolation.		
Unit-5	Special reagents in organic chemistry.		
Unit-6	Combinatorial chemistry.		
		Total	60
	oks: N A		
	ce books: The choice is discretionary depend	ing on the selected topic.	
	ed List of Laboratory Experiments : NA		
Suggest	ed List of Assignments/Tutorial : NA		

Name of the Course :Research Project and Colloquium				
Course code: S4-MPC-1 [ P ]		Semester : IV		
Duratio	n : 540 Hrs	Maximum Marks : 400		
Teachin	g Scheme	Examination Scheme		
Theory :	Hrs/week [NA]	Mid Semester Exam: Marks [ N A ]		
Tutorial	Hrs/week [NA]	Assignment & Quiz: Marks [NA]		
Practica	: 36 Hrs/week	End Semester Exam: 400 Marks		
Credits :	16			
Aim :-				
Objectiv	re :-			
S. No				
1	To complete the given research	project.		
2	To effectively defend the work b	efore a group of qualified evaluators.		
Pre-Req	Pre-Requisite:-			
S. No	·			
1	A B. Pharm. degree from any institution approved by AICTE or its equivalent.			
Text Books: NA				
Reference books: It is left at the discretion of the teacher depending on the topic selected.				
Suggested List of Laboratory Experiments : NA				
Suggested List of Assignments/Tutorial: NA				