SYLLABUS

For

Master of Pharmacy

Faculty of Pharmacy,
Integral University,
Dasauli, Kursi Road,
Lucknow-226026

w.e.f. session 2015-2016

INDEX

M. Pharm. (Pharmaceutical Chemistry)

TERMINOLOGY:
L MEANS LECTURE.
T MEANS TUTORIAL.
P MEANS PRACTICAL.

Year	Subject code	Subject	Hours/week			Marks			
			L	T	P	Sessional Exam./ Synopsis	T.A. / Seminar	Annual Exam.	Total
First	PRY501	Modern Analytical Techniques	03	02	00	30	20	100	150
	PRY502	Modern Analytical Techniques(P)	00	00	06	30	20	100	150
	PRY503	Drug Regulatory Aspects & IPR	03	02	00	30	20	100	150
	PRY504	Advanced Pharmaceutical Chemistry – I	03	02	00	30	20	100	150
	PRY505	Advanced Pharmaceutical Chemistry – I (P)	00	00	06	30	20	100	150
	PRY506	Advanced Pharmaceutical Chemistry – II	03	02	00	30	20	100	150
	TOTAL		**12**	**08**	**12**	**180**	**120**	**600**	**900**
Second	PRY601	Pharmaceutical Chemistry Research Project & Colloquium (P)	00	00	33	200	200	700	1100
	TOTAL		**00**	**00**	**33**	**200**	**200**	**700**	**1100**
GRAND TOTAL			**12**	**08**	**45**	**380**	**320**	**1300**	**2000**

Name of the Course : Modern Analytical Techniques		
Course code: PRY501	**Year :1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
	SECTION - A	
Unit 1	Ultraviolet – Visible spectroscopy: Woodward – Fisher rules for calculation of λ_{max}. Infrared Spectroscopy : Molecular vibrations, Factors influencing Vibrational Frequencies , Instrumentation , Fourier Transform Infrared Spectroscopy, Sampling Techniques, Applications of Infrared Spectroscopy- Identification of Functional groups.	**07**
Unit 2	High Resolution ^{1}H & ^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Techniques used for finding types of carbon like attached proton test (APT), distortion less energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY	**10**
Unit 3	Mass spectrometry: Use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI, CI, FD, FI, MALDI, API, ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc.	**10**
Unit 4	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and troubleshooting. Quantification methods used in HPLC. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc. Microscopy: SEM, TEM, size exclusion chromatography.	**08**

Unit 5	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG), Thermo mechanical analysis (TMA): Principles instrumentations and applications (including interpretation of data) in pharmacy. HPTLC: Basic instrumentation and its calibration. Analytical method development and its validation as per ICH guidelines. Quantification using HPTLC	**08**
	SECTION B	
Unit 6	Definition of Computer, Input & Output devices, Storage devices. Definition & functions of an operating system, Single user and Multi-user operating system, Introduction & Type of softwares Introduction of MS – DOS, internal and external commands of MS-DOS, Basic idea of computer networking [LAN, MAN, WAN, Internet, Intranet, network topology(Ring, Star, Fully Connected and Bus)].	**07**
Unit 7	Introduction and Need of Language, Low level and high level languages,Compiler and Interpreter, Meaning & Need of database. Introduction & Uses of Internet, Browsers, common problems of internet,. Introduction of Web page, some basic commands of HTML	**07**
	SECTION C	
Unit 8	**Data & Graphs :** Collection of data: Primary and Secondary data, Preparation of data: Frequency distribution table, Bar diagram, Histogram, Frequency curve and Pie chart..	**04**
Unit 9	**Hypothesis testing**: Statistical hypothesis, null and alternative hypothesis, critical region, type I and II error, power of a test, Test of significance based on t distribution, F distribution and Chi – square test, Analysis of variance: One – way and two way classification (with equal size).	**06**
Unit 10	**Clinical data management**: Definitions, Importance in Statistical analysis and its various tools. **Statistical Quality control:** Causes and variations, Process control and Product control, Control charts, controls charts for variables: X – Charts and R – Charts, Control charts for attributes: p – chart and c – chart. **Introduction to common statistical software:** SPSS software.	**08**

Reference books :

- Robert M. Silverstein, Francis X. Webster, David J. Kiemle, 2009. "Spectrometric identification of organic compounds". 7th Ed. John Wiley & Sons.
- Pavia D. L., 2009. "Introduction to spectroscopy". 4th, Belmont CA
- Munson & Munson, "Pharmaceutical analysis: modern methods". edited by James
- W. Munson, New York : M. Dekker.
- Kenneth A. Connors, 2007. "A Textbook Of Pharmaceutical Analysis" 3rd Ed. Wiley India-wse
- Jens Thuro Carstensen, 2001. "Advanced pharmaceutical solids" Marcel Dekker, New York
- Joseph B. Lambert, Scott Gronert, Herbert F. Shurvell, David Lightner, Robert Graham Cooks, 2010. "Organic structural spectroscopy", 2nd Ed. Pearson Education, Limited.
- Bioassay by Prof. H. H. Siddiqui

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**
- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC
- Press.
- 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
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM
- Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- Scholarships, Fellowships & Loans, Chrystal Rozs, Gale, 2002.

Name of the Course : Modern Analytical Techniques (P)	
Course code: PRY502	**Year : 1st**
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	**Maximum Marks :** 150
	Sessional Exam: 30 Marks
	T. A. / Lab.Work (Record) : 20 marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

S. No	List of Laboratory Experiments
1	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2	Calibration of UV spectrometer for wavelength and stray light.
3	Calculation of λ_{max} values using Woodward Fisher rules.
4	Interpretation of IR spectra
5	Determination of pK value by UV visible spectrometry.
6	Calibration of HPLC instrument for flow rate & wavelength.
7	Determination of caffeine content in tea/ coffee/ other beverages.
8	Qualitative and quantitative analysis using HPTLC from published material
9	Drug Content determination using HPLC.
10	Practicals related to basic statistics (mean, median, mode, S. D., % RSD)
11.	Practicals realted to t test.
12.	Practicals related to ANOVA.
13.	To create, editing & formatting worksheet using MS - Excel.
14.	To make use of formula, create graphs for representing data in MS - Excel.
15	To understand various menu options of MS - word.
16	To make PowerPoint presentations with Animation effects.
17	To design simple web page using HTML editor

Name of the Course : Drug Regulatory Aspect and IPR	
Course code: PRY503	**Year : 1st**
Duration : 75 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Theory : 03 Hrs/week	Sessional Exam: 30 Marks
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks
	Annual Exam: 100 Marks

Contents		Hrs
Unit 1	Drug Regulatory Aspects (India) – • Indian drug regulatory authorities, Central and State regulatory bodies (FDA) • Drugs and Cosmetics Act and Rules with latest Amendments (Selective) • Special emphasis – Schedule M and Y • New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies • Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	**10**
Unit 2	Good Manufacturing Practices (GMP) – • Indian GMP certification, WHO GMP certification • ICH guidelines for stability testing and other relevant ones (Q1 – Q10) • Export permissions and manufacturing for semi-regulated countries • Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) • Quality Assurance and Quality Control – Basic understanding for in-built Quality • GMP audits, role of Quality Assurance, product approvals and supplies.	**10**
Unit 3	Drug Regulatory Aspects (International & highly regulated markets) – • US Requirements – (for Generic Drugs especially formulations) • 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. • European Union Requirements – • 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) • A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries.	**20**

Unit 4	**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. **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	**8**
Unit 5	**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	**6**
Unit 6	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	**5**
Unit 7	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	**04**
Unit 8	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	**04**
Unit 9	**Patent search, Patent analysis & Patent drafting**	**04**
Unit 10	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	**04**
	Total	**75**

Text Books: N A

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.
11. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
12. USPTO and WIPO Guidelines

Name of the Course : Advanced Pharmaceutical Chemistry - I		
Course code: PRY504	**Year :** 1st	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial : 0 2 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	
Content		**Hours**
Unit -1	Drug design- Various rational approaches to drug design. Introduction to biopharmaceutical consideration in drug design. Concepts of Prodrugs	10
Unit -2	QSAR, CADD, molecular modeling and docking. Use of these methods in the development of drugs like fluoroquinolones, dihydropyridines and others. Study of software like ISIS, Chemsketch, RASMOL, Protein Explorer etc for structure drawing and visualization.	10
Unit -3	Recent advances in drugs used in the treatment of: a] cancer, b] AIDS, c] cardiovascular disorders, d] diabetes, e] hepatitis, and f] immunosuppression.	10
Unit -4	Recent advances in the area of lipid / cholesterol lowering agents and enzyme inhibitors.	07
Unit -5	Antisense drugs and gene therapy.	03
Unit -6	Methods used in the synthesis of glycosides, nucleosides and nucleotides.	05
Unit -7	Synthetic methodology or approaches to the synthesis of bicyclo [4.3.2], [3.2.1], [2.2.2] and [2.2.1] systems, illustrated by the synthesis of appropriate drug molecules like mecamylamine, atropine, scopolamine.	05
Unit -8	Biosynthesis of cholesterol, estrogen and progesterone from acetate. Biomimetic synthesis of steroids. Illustration of Prof. W. S. Johnson's synthesis.	06
Unit -9	Chiral technology in drug synthesis. Asymmetric synthesis of drugs like propranolol, metoprolol, naproxen, vitamin C using asymmetric epoxidations, asymmetric reductions or hydrogenations, asymmetric enzymatic or bacterial biotransformations. Illustration of 1st, 2nd, 3rd and 4th generation methods of asymmetric synthesis with one example each.	09
Unit -10	Total synthesis of the following drug molecules: A] Reserpine [Prof. Woodword's synthesis], B] Progesterone from diosgenin, C] Emetine, D] Quinine, and E] Prostaglandins F and E [Profs. Corey, Stork & Sih's methods].	10
Total		**75**

Name of the Course : Advanced Pharmaceutical Chemistry–I (P)	
Course code: PRY505	**Year : 1st**
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	Sessional Exam: 30 Marks
	Seminar / T. A.: 20 Marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

- Drawing, editing and cleaning of chemical structure
- Structure optimization using molecular, mechanical and semi-empirical methods
- Creating function library
- Visualization
- Changing display style
- 2D and 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 and querying
- Performing simple docking
- Birch reduction
- Wolff-Kishner reduction
- Grignard reaction
- Synthesis of appropriate prodrug of aspirin/ salicylic acid.

Name of the Course : Advanced Pharmaceutical Chemistry - II		
Course code: PRY506	**Year : 1st**	
Duration : 75 Hrs	**Maximum Marks : 150**	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial : 0 2 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	
Content		**Hours**
Unit -1	Protective groups for -OH, -NH_2 and -COOH. Special protective groups for aldehydes or ketones such as oxazolines [A. I. Meyer's reagent] and 1,3-dithianes. Methods for the deprotection of the above groups. Concept of "Umplong". Reactions of 1,3-dithiane.	06
Unit -2	Nomenclature and stereochemistry of spiro-compounds. Stereochemistry of allenes and biphenyls. Stereochemistry and its importance in medicinal chemistry. Methods for resolution of racemic mixtures.	05
Unit -3	Preparation and reactions of P, S and N -ylides.	03
Unit -4	Fluorinating agents and their use in drug synthesis. Chemistry of active methylene compounds.	10
Unit -5	Regio- and stereo- selective and stereospecific formation of enolate anions. Their nucleoplillic and addition reactions. Role of Li, Na, K, Mg and B metal ions in the regio- and stereo -selective and stereospecific formation of enolate anions. Different methods for the preparation o f α-methylene lactones and similar functionalities. General approaches towards solid phase synthesis.	07
Unit -6	Pericyclic reactions. HOMO and LUMO. Conservation of orbital symmetry. Woodward rules for allowed and disallowed motions. Stereo specificity of them.	04
Unit -7	Introduction to the concepts of Green Chemistry- History, need, goals, limitations, obstacles and opportunities.	06
Unit -8	Introduction to the principles of Green Chemistry- Basic principles of green chemistry illustrated with examples to discuss issues of prevention of waste or minimize by products, atom economy, prevent and minimize formation of hazardous or toxic products, design of safer chemical equivalents, selection of appropriate solvents, media, separation agents, improve economy and efficiency of reactions by use of microwaves, ultrasound etc, and use of renewable starting materials.	10
Unit -9	Microwave assisted organic synthesis- Introduction, microwave reactions in water (Hofmann elimination, hydrolysis and oxidation), microwave reactions in organic solvents, solid state reactions. Advantages of microwave technique.	08
Unit -10	Application of green synthetic reactions- Green starting materials, green reagents, green solvents and reaction conditions, green catalysis and examples of green synthesis, green analytical methods. Future trends in green chemistry.	16
Total		**75**

Name of the Course : Pharmaceutical Chemistry Research Project and Colloquium (P)	
Course code: PRY601	**Year : 2nd**
Duration : 540 Hrs	**Maximum Marks :** 1100
Teaching Scheme	**Examination Scheme**
Practical : 33 Hrs/week	Synopsis: 200 Marks
	T. A. / Seminar: 200 Marks
	Annual Exam: 700 Marks

M. Pharm. (Pharmacognosy & Phytochemistry)

TERMINOLOGY:-
L MEANS LECTURE.
T MEANS TUTORIAL.
P MEANS PRACTICAL.

Year	Subject code	Subject	Hours/week			Marks			
			L	T	P	Sessional Exam./ Synopsis	T.A. / Seminar	Annual Exam.	Total
First	PRY501	Modern Analytical Techniques	03	02	00	30	20	100	150
	PRY502	Modern Analytical Techniques(P)	00	00	06	30	20	100	150
	PRY503	Drug Regulatory Aspects & IPR	03	02	00	30	20	100	150
	PRY507	Advanced Pharmacognosy & Phytochemistry -I	03	02	00	30	20	100	150
	PRY508	Advanced Pharmacognosy & Phytochemistry – I (P)	00	00	06	30	20	100	150
	PRY509	Advanced Pharmacognosy & Phytochemistry - II	03	02	00	30	20	100	150
	TOTAL		**12**	**08**	**12**	**180**	**120**	**600**	**900**
Second	PRY602	Pharmacognosy Research Project & Colloquium (P)	00	00	33	200	200	700	1100
	TOTAL		**00**	**00**	**33**	**200**	**200**	**700**	**1100**
GRAND TOTAL			**12**	**08**	**45**	**380**	**320**	**320**	**2000**

Name of the Course : Modern Analytical Techniques		
Course code: PRY501	**Year :1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
	SECTION - A	
Unit 1	Ultraviolet – Visible spectroscopy: Woodward – Fisher rules for calculation of λ_{max}. Infrared Spectroscopy : Molecular vibrations, Factors influencing Vibrational Frequencies , Instrumentation , Fourier Transform Infrared Spectroscopy, Sampling Techniques, Applications of Infrared Spectroscopy- Identification of Functional groups.	**07**
Unit 2	High Resolution ^{1}H & ^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Techniques used for finding types of carbon like attached proton test (APT), distortion less energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY	**10**
Unit 3	Mass spectrometry: Use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI, CI, FD, FI, MALDI, API, ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc.	**10**
Unit 4	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and troubleshooting. Quantification methods used in HPLC. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc. Microscopy: SEM, TEM, size exclusion chromatography.	**08**

Unit 5	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG), Thermo mechanical analysis (TMA): Principles instrumentations and applications (including interpretation of data) in pharmacy. HPTLC: Basic instrumentation and its calibration. Analytical method development and its validation as per ICH guidelines. Quantification using HPTLC	**08**
	SECTION B	
Unit 6	Definition of Computer, Input & Output devices, Storage devices. Definition & functions of an operating system, Single user and Multi-user operating system, Introduction & Type of softwares Introduction of MS – DOS, internal and external commands of MS-DOS, Basic idea of computer networking [LAN, MAN, WAN, Internet, Intranet, network topology(Ring, Star, Fully Connected and Bus)].	**07**
Unit 7	Introduction and Need of Language, Low level and high level languages,Compiler and Interpreter, Meaning & Need of database. Introduction & Uses of Internet, Browsers, common problems of internet,. Introduction of Web page, some basic commands of HTML	**07**
	SECTION C	
Unit 8	**Data & Graphs :** Collection of data: Primary and Secondary data, Preparation of data: Frequency distribution table, Bar diagram, Histogram, Frequency curve and Pie chart..	**04**
Unit 9	**Hypothesis testing**: Statistical hypothesis, null and alternative hypothesis, critical region, type I and II error, power of a test, Test of significance based on t distribution, F distribution and Chi – square test, Analysis of variance: One – way and two way classification (with equal size).	**06**
Unit 10	**Clinical data management**: Definitions, Importance in Statistical analysis and its various tools. **Statistical Quality control:** Causes and variations, Process control and Product control, Control charts, controls charts for variables: X – Charts and R – Charts, Control charts for attributes: p – chart and c – chart. **Introduction to common statistical software:** SPSS software.	**08**

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- Press.
- 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
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM
- Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- Scholarships, Fellowships & Loans, Chrystal Rozs, Gale, 2002.

Name of the Course : Modern Analytical Techniques (P)	
Course code: PRY502	**Year : 1st**
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	**Maximum Marks :** 150
	Sessional Exam: 30 Marks
	T. A. / Lab.Work (Record) : 20 marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

S. No	List of Laboratory Experiments
1	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2	Calibration of UV spectrometer for wavelength and stray light.
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4	Interpretation of IR spectra
5	Determination of pK value by UV visible spectrometry.
6	Calibration of HPLC instrument for flow rate & wavelength.
7	Determination of caffeine content in tea/ coffee/ other beverages.
8	Qualitative and quantitative analysis using HPTLC from published material
9	Drug Content determination using HPLC.
10	Practicals related to basic statistics (mean, median, mode, S. D., % RSD)
11.	Practicals realted to t test.
12.	Practicals related to ANOVA.
13.	To create, editing & formatting worksheet using MS - Excel.
14.	To make use of formula, create graphs for representing data in MS - Excel.
15	To understand various menu options of MS - word.
16	To make PowerPoint presentations with Animation effects.
17	To design simple web page using HTML editor

Name of the Course : Drug Regulatory Aspect and IPR		
Course code: PRY503	**Year : 1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
Unit 1	Drug Regulatory Aspects (India) – • Indian drug regulatory authorities, Central and State regulatory bodies (FDA) • Drugs and Cosmetics Act and Rules with latest Amendments (Selective) • Special emphasis – Schedule M and Y • New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies • Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	**10**
Unit 2	Good Manufacturing Practices (GMP) – • Indian GMP certification, WHO GMP certification • ICH guidelines for stability testing and other relevant ones (Q1 – Q10) • Export permissions and manufacturing for semi-regulated countries • Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) • Quality Assurance and Quality Control – Basic understanding for in-built Quality • GMP audits, role of Quality Assurance, product approvals and supplies.	**10**
Unit 3	Drug Regulatory Aspects (International & highly regulated markets) – • US Requirements – (for Generic Drugs especially formulations) • 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. • European Union Requirements – • 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) • A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries.	**20**

Unit 4	**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. **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	**8**
Unit 5	**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	**6**
Unit 6	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	**5**
Unit 7	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	**04**
Unit 8	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	**04**
Unit 9	**Patent search, Patent analysis & Patent drafting**	**04**
Unit 10	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	**04**
	Total	**75**

Text Books: N A

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.
11. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
12. USPTO and WIPO Guidelines

Name of the Course : Advanced Pharmacognosy & Phytochemistry - I	
Course code: PRY507	**Year : 1st**
Duration : 75 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Theory : 03 Hrs/week	Sessional Exam: 30 Marks
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks
	Annual Exam: 100 Marks

Unite-1	**Standardization of medicinal plants:** Preparation of herbarium specifications, use of flora and keys of plant identification, Microtomy and advanced histological techniques as applied to pharmacognostical specimen, pharmacognostical drawings and macro and micro photography, tests for extraneous material, physico-chemical analysis (moisture content, loss on drying, ash value determinations, crude fibre content).	10
Unite-2	**Biosynthesis & biogenesis** Biogenetic pathways for the production of phytopharmaceuticals, such as cardiac glycosides,coumarins, flavones, menthol, nicotinic acid, quinidine, papaverine and ergocryptine.	8
Unite-3	**Extraction and isolation techniques** Methods of extraction, isolation, separation and purifications of plant constituents. General methods used for the isolation of alkaloids, glycosides, volatile oils, bioflavonoids, steroids, terpenoids and resins. Solvent extraction method and application of column and thin layer chromatographic techniques for the isolation of phytopharmaceuticals.	8
Unite-4	**Structural elucidation of phytoconstituents belonging to different groups:**Application of UV, IR, NMR, ^{1}HNMR, ^{13}CNMR and Mass spectroscopy for structural elucidation of phytosterols, flavonoids and terpenoids, Nicotine, Atropine, Morphine, Caffeine.	10
Unite-5	**Biological evaluation:** Methods of biological evaluation of plant drugs. (a) Anti-diabetic (b) Hepatoprotective (c) Antioxidant (d) Anti-bacterial (e) Anti-tussive (f) Psychopharmacology (g) Anti-inflammatory (h) Analgesic	8
Unite-6	**Toxic Drugs:** Study of Allergens, hallucinogens, narcotics, mycotoxins, toxic mushrooms and Indian toxic plants.	6
Unite-7	**Nutraceuticals:** Global market prospects and study of five important plants and their products in the international market.	6
Unite-8	**Marine Pharmacognosy:** Definition, present status, classification of important bioactive agents, general methods of isolation and purification, study of important bioactive agents, chemistry and uses. a) Hepatoprotective b) Antioxidant c) Anti-microbial d) Anti-inflammatory e) Anti-viral	6

Unite-9	**Industrial trading of aromatic oils:** Natural occurrence, their chemistry and trade of volatile oils.	5
Unite-10	**Tissue culture:** History, media, requirements for growth of culture, isolation of organ, tissue and cells; transfer and maintenance of culture, growth measurement and application of tissue culture with reference to medicinal plants, its scope and limitations.	8
	References: • Herbal Drug Industry by R. D. Choudhary. 1st Edition, Eastern Publisher, New Delhi, 1996. • GMP for Botanicals – Regulatory and Quality issues on Phytomedicine Business horizons, New Delhi, 1st Edition, 2003, Robert Verpoorte, Pulok K Mukharjee. • Herbal Cosmetics – H. Pande, Asia Pacific Business press, New Delhi. • H. Pande, "The complete technology book on herbal perfumes and cosmetics", National Institute of Industrial Research, Delhi. • Quality control of herbal drugs by Pulok K Mukarjee, 1st edition, Business horizons pharmaceuticals publisher, New Delhi, 2002. • PDR for herbal medicines, 2nd Edition, Medicinal economic company, New Jersey, 2000. • Indian Herbal Pharmacopoeia, Volume 1st & 2nd, RRL,LDMA. • Text book of Pharmacognosy by C. K. Kokate, Purohit, Gokhlae, 4th Edition, Nirali Prakashan, 1996. • Text book of Pharmacognosy and Phytochemistry by Rangare. • Plant drug Analysis, 2nd edition by Wagner, Bladt. • Biological standardization by J. N. Barn, D. J. finley and L. G. Good win.	

Name of the Course : Advanced Pharmacognosy & Phytochemistry – I (P)	
Course code: PRY508	**Year : 1st**
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	Sessional Exam: 30 Marks
	Seminar / T. A.: 20 Marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

1. Isolation of Rutin from Rutagraveolens
2. Hesperidin from Orange peel
3. Aloin from Aloes
4. Rhein from rhizome of Rheum species
5. Piperine from Black pepper
6. Quinine from Cinchona bark
7. Estimation antimicrobial activity of some volatile oils.
8. Caffeine from Tea leaves
9. Menthol from Mentha species
10. Determination of Phenolic content in methanolic extract.
11. Reserpine in Rauwolfia by photometric method
12. Carvone content of Umbelliferous fruits
13. Citral content in Lemon grass oil
14. Bitter principles of Chirata
15. Solanin from Solanaceous drugs
16. Determination of flavonoids content in methanolic extract.
17. Quantitative estimation of Saponin as per W.H.O. protocol in suitable plant material
18. Resin content in sample of podophyllum by B.P.C. method
19. Optical rotation of oil of Lemon
20. Acid value of Colophony resin by B.P. method.

Name of the Course : Advanced Pharmacognosy & Phytochemistry – II	
Course code: PRY509	**Year : 1st**
Duration : 75 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Theory : 03 Hrs/week	Sessional Exam: 30 Marks
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks
	Annual Exam: 100 Marks

Unite-1	**Cultivation and collection:** Scope of plant cultivation, factors affecting quality of plant and animal drugs. Problems and recent trends in pest management, scope of biological control and use of environment friendly pesticides especially plant derived products.	8
Unite-2	**Qualitative chemical analysis:** Chemical test of phytoconstituents, fluorescence analysis of the extractives, TLC fingerprint analysis of the extractives.	8
Unite-3	**Quality control:** GMP for the production of quality botanicals. Substitution and adulteration of crude drugs, type of adulteration, physical & chemical methods of drug evaluations. Determination of sugar, alcohol content, reducing power, shelf life of extracts and finished products.	8
Unite-4	**Chromatography technique :** Application of chromatographic techniques in separation and identification of natural products with special references to alkaloids, steroids, sugars, glycosides, terpenoids, lipids.	7
Unite-5	**Natural products:** Recent advances in the field of Pharmacognosy and Phytochemistry with special reference to anticancer, antidiabetic, anti-inflammatory, hepatoprotective, adaptogenic and immunomodulators, memory enhancers, antiviral agents and antihyperlipidemics.	10
Unite-6	**Traditional system of medicine:** Ayurvedic system of medicines, unani system of medicines, homeopathy system of medicines, folklore medicine. Importance of monographs of medicinal plants, their comparative study as per IP, API, Unani, Pharmacopoeia, Homoeopathic Pharmacopoeia, Siddha Pharmacopoeia, BHP, Japanese Pharmacopoeia, Chinese Pharmacopoeia.	8
Unite-7	**Plant growth regulators, their use in pharmacognosy:** Auxin, Cytokine, Absisic acids, Ethylene, 2,4-D.	6
Unite-8	**Natural pesticides and Insecticides** Study of pesticides and weedicides with special importance to natural pesticides & weedicides. Disease management of medicinal and aromatic plants. Tobacco, Pyrethrum, Cevadilla, Neem, Ryania. Introduction to herbicides, fungicides, fumigants and rodenticides.	7

Unite-9	**Chemotaxonomic significance in medicinal plants :** History of Chemotaxonomic developments. Chemotaxonomy of higher and lower plants and distribution of certain chemotaxonomical group of constituents in plant kingdom like alkaloids, glycosides and terpenoids.	6
Unite-10	**Herbal formulations** Principles involved in Ayurveda, Sidha, Unani, Chinese and Homeopathic systems of medicines, preparation of Ayurvedic formulations like Aristas, Asava, Ghutika, Tailia, Churna, Avaleha, Ghrita and Bhasms; Unani formulations like Majooms, Safoofs.	7
	References: • Herbal Drug Industry by R. D. Choudhary. 1st Edition, Eastern Publisher, New Delhi, 1996. • GMP for Botanicals – Regulatory and Quality issues on Phytomedicine Business horizons, New Delhi, 1st Edition, 2003, Robert Verpoorte, Pulok K Mukharjee. • Herbal Cosmetics – H. Pande, Asia Pacific Business press, New Delhi. • H. Pande, "The complete technology book on herbal perfumes and cosmetics", National Institute of Industrial Research, Delhi. • Quality control of herbal drugs by Pulok K Mukarjee, 1st edition, Business horizons pharmaceuticals publisher, New Delhi, 2002. • PDR for herbal medicines, 2nd Edition, Medicinal economic company, New Jersey, 2000. • Indian Herbal Pharmacopoeia, Volume 1st & 2nd, RRL,LDMA. • Text book of Pharmacognosy by C. K. Kokate, Purohit, Gokhlae, 4th Edition, Nirali Prakashan, 1996. • Text book of Pharmacognosy and Phytochemistry by Rangare. • Plant drug Analysis, 2nd edition by Wagner, Bladt. • Biological standardization by J. N. Barn, D. J. finley and L. G. Good win.	

Name of the Course : Pharmacognosy Research Project and Colloquium (P)	
Course code: PRY602	**Year : 2nd**
Duration : 540 Hrs	**Maximum Marks :** 1100
Teaching Scheme	**Examination Scheme**
Practical : 33 Hrs/week	Synopsis: 200 Marks
	T. A. / Seminar: 200 Marks
	Annual Exam: 700 Marks

M. Pharm. (Pharmacology)

TERMINOLOGY:-
L MEANS LECTURE.
T MEANS TUTORIAL.
P MEANS PRACTICAL.

Year	Subject code	Subject	Hours/week			Marks			
			L	T	P	Sessional Exam./ Synopsis	T.A. / Seminar	Annual Exam.	Total
First	PRY501	Modern Analytical Techniques	03	02	00	30	20	100	150
	PRY502	Modern Analytical Techniques(P)	00	00	06	30	20	100	150
	PRY503	Drug Regulatory Aspects & IPR	03	02	00	30	20	100	150
	PRY510	Advanced Pharmacology-I	03	02	00	30	20	100	150
	PRY511	Advanced Pharmacology-I (P)	00	00	06	30	20	100	150
	PRY512	Advanced Pharmacology-II	03	02	00	30	20	100	150
	TOTAL		**12**	**08**	**12**	**180**	**120**	**600**	**900**
Second	PRY603	Pharmacology Research Project & Colloquium (P)	00	00	33	200	200	700	1100
	TOTAL		**00**	**00**	**33**	**200**	**200**	**700**	**1100**
GRAND TOTAL			**12**	**08**	**45**	**380**	**320**	**1300**	**2000**

Name of the Course : Modern Analytical Techniques		
Course code: PRY501	**Year :1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
	SECTION - A	
Unit 1	Ultraviolet – Visible spectroscopy: Woodward – Fisher rules for calculation of λ_{max}. Infrared Spectroscopy : Molecular vibrations, Factors influencing Vibrational Frequencies , Instrumentation , Fourier Transform Infrared Spectroscopy, Sampling Techniques, Applications of Infrared Spectroscopy- Identification of Functional groups.	**07**
Unit 2	High Resolution ^{1}H & ^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Techniques used for finding types of carbon like attached proton test (APT), distortion less energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY	**10**
Unit 3	Mass spectrometry: Use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI, CI, FD, FI, MALDI, API, ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc.	**10**
Unit 4	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and troubleshooting. Quantification methods used in HPLC. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc. Microscopy: SEM, TEM, size exclusion chromatography.	**08**

Unit 5	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG), Thermo mechanical analysis (TMA): Principles instrumentations and applications (including interpretation of data) in pharmacy. HPTLC: Basic instrumentation and its calibration. Analytical method development and its validation as per ICH guidelines. Quantification using HPTLC	**08**
	SECTION B	
Unit 6	Definition of Computer, Input & Output devices, Storage devices. Definition & functions of an operating system, Single user and Multi-user operating system, Introduction & Type of softwares Introduction of MS – DOS, internal and external commands of MS-DOS, Basic idea of computer networking [LAN, MAN, WAN, Internet, Intranet, network topology(Ring, Star, Fully Connected and Bus)].	**07**
Unit 7	Introduction and Need of Language, Low level and high level languages,Compiler and Interpreter, Meaning & Need of database. Introduction & Uses of Internet, Browsers, common problems of internet,. Introduction of Web page, some basic commands of HTML	**07**
	SECTION C	
Unit 8	**Data & Graphs :** Collection of data: Primary and Secondary data, Preparation of data: Frequency distribution table, Bar diagram, Histogram, Frequency curve and Pie chart..	**04**
Unit 9	**Hypothesis testing**: Statistical hypothesis, null and alternative hypothesis, critical region, type I and II error, power of a test, Test of significance based on t distribution, F distribution and Chi – square test, Analysis of variance: One – way and two way classification (with equal size).	**06**
Unit 10	**Clinical data management**: Definitions, Importance in Statistical analysis and its various tools. **Statistical Quality control:** Causes and variations, Process control and Product control, Control charts, controls charts for variables: X – Charts and R – Charts, Control charts for attributes: p – chart and c – chart. **Introduction to common statistical software:** SPSS software.	**08**

Reference books :

- Robert M. Silverstein, Francis X. Webster, David J. Kiemle, 2009. "Spectrometric identification of organic compounds". 7th Ed. John Wiley & Sons.
- Pavia D. L., 2009. "Introduction to spectroscopy". 4th, Belmont CA
- Munson & Munson, "Pharmaceutical analysis: modern methods". edited by James
- W. Munson, New York : M. Dekker.
- Kenneth A. Connors, 2007. "A Textbook Of Pharmaceutical Analysis" 3rd Ed. Wiley India-wse
- Jens Thuro Carstensen, 2001. "Advanced pharmaceutical solids" Marcel Dekker, New York
- Joseph B. Lambert, Scott Gronert, Herbert F. Shurvell, David Lightner, Robert Graham Cooks, 2010. "Organic structural spectroscopy", 2nd Ed. Pearson Education, Limited.
- Bioassay by Prof. H. H. Siddiqui

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**
- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC
- Press.
- 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
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM
- Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- Scholarships, Fellowships & Loans, Chrystal Rozs, Gale, 2002.

Name of the Course : Modern Analytical Techniques (P)	
Course code: PRY502	**Year : 1st**
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	**Maximum Marks :** 150
	Sessional Exam: 30 Marks
	T. A. / Lab.Work (Record) : 20 marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

S. No	List of Laboratory Experiments
1	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2	Calibration of UV spectrometer for wavelength and stray light.
3	Calculation of λ_{max} values using Woodward Fisher rules.
4	Interpretation of IR spectra
5	Determination of pK value by UV visible spectrometry.
6	Calibration of HPLC instrument for flow rate & wavelength.
7	Determination of caffeine content in tea/ coffee/ other beverages.
8	Qualitative and quantitative analysis using HPTLC from published material
9	Drug Content determination using HPLC.
10	Practicals related to basic statistics (mean, median, mode, S. D., % RSD)
11.	Practicals realted to t test.
12.	Practicals related to ANOVA.
13.	To create, editing & formatting worksheet using MS - Excel.
14.	To make use of formula, create graphs for representing data in MS - Excel.
15	To understand various menu options of MS - word.
16	To make PowerPoint presentations with Animation effects.
17	To design simple web page using HTML editor

Name of the Course : Drug Regulatory Aspect and IPR		
Course code: PRY503	**Year : 1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
Unit 1	Drug Regulatory Aspects (India) – • Indian drug regulatory authorities, Central and State regulatory bodies (FDA) • Drugs and Cosmetics Act and Rules with latest Amendments (Selective) • Special emphasis – Schedule M and Y • New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies • Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	**10**
Unit 2	Good Manufacturing Practices (GMP) – • Indian GMP certification, WHO GMP certification • ICH guidelines for stability testing and other relevant ones (Q1 – Q10) • Export permissions and manufacturing for semi-regulated countries • Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) • Quality Assurance and Quality Control – Basic understanding for in-built Quality • GMP audits, role of Quality Assurance, product approvals and supplies.	**10**
Unit 3	Drug Regulatory Aspects (International & highly regulated markets) – • US Requirements – (for Generic Drugs especially formulations) • 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. • European Union Requirements – • 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) • A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries.	**20**

Unit 4	**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. **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	**8**
Unit 5	**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	**6**
Unit 6	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	**5**
Unit 7	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	**04**
Unit 8	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	**04**
Unit 9	**Patent search, Patent analysis & Patent drafting**	**04**
Unit 10	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	**04**
	Total	**75**

Text Books: N A

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.
11. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
12. USPTO and WIPO Guidelines

Name of the Course : Advanced Pharmacology-I	
Course code: PRY510	**Year :** 1st
Duration : 75 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Theory : 03 Hrs/week	Sessional Exam: 30 Marks
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks
	Annual Exam: 100 Marks

	Contents	Hrs
Unit -1	**Molecular mechanism of drug action** • Drug receptor interactions and second messenger systems. • Signal transduction and termination of receptor activity. • G - proteins and receptor structures, CAMP pathway, Phospholipase C, IP3, DAQ pathway.	05
Unit -2	**Pharmacology of receptors** Classification, cellular signaling systems, associated diseases and advances in pharmacology of the following receptor types • Excitatory Amino Acid receptors,GABA and Benzodiazepine receptors • Dopamine receptors,Serotonin receptors,Purinergic receptors, Opioid receptors	12
Unit -3	**Neuro peptides** Biological functions, pharmacological implications, their receptors systems and therapeutic potentials of the following neuropeptides: • Neuropeptide Y • Cholecystokinin • Tachykinins (Substance P/ Neurokinin) • Cortcotrophin releasing factor • Arginine vasopressin	10
Unit -4	**Cytokines & Chemokines** Classification, physiology, pharmacology, pathological, and therapeutic implications of various cytokines and chemokines.	03

Unit -5	**Endogenous bioactive molecules** • Physiology, pharmacology, and therapeutic potential of Neurosteroids and its modulators • Endothelium derived vascular substances (Nitric oxide) and their modulators • Phosphodiestrase enzyme and protein kinase C • Arachidonic acid metabolites, COX-2 regulators and their role in inflammation. • Endorphins	06
Unit-6	**Recent trends and advances in the following classes of drugs acting on CNS:** Sedatives, hypnotics and psychopharmacological agent.	06
Unit-7	**Cardiovascular and Renal drugs** Cardiotonics, antiarrhythemics, antihypertensives, antianginals and hypolipedemics, Diuretics and anti-diuretics.	14
Unit-8	**Drugs acting on Gastrointestinal Disorders** Emetics and antiemetic, Antiulcer, antidiahorreal, Drug used in constipation.	04
Unit-9	**Endocrine drugs** Thyroid, antithyroid, antidiabetic, oral contraceptives and corticosteroids.	05
Unit-10	**Chemotherapy & immunomodulators** Cellular and molecular mechanism of action and resistance of antimicrobial and anticancer drugs, Molecular and cellular mechanism of immunomodulators.	10
	Total	**75**

Reference books :

1. Hardman J. G., Limbird L. E. 2001. "Goodman and Gilman's The Pharmacological Basis of Therapeutics" 1oth Ed.McGraw-Hill Professional.
2. H. P. Rang and M. M. Dale, "Pharmacology" 5th Ed. Churchill Livingstone.
3. B. G. Katzung, "Basic and Clinical Pharmacology" 9th Ed. McGraw-Hill Medical.
4. Annual Reviews of Pharmacology series.
5. Harvey R. A, Champe P. C., "Pharmacology-Lippincott's illustrated Reviews" 4th Ed. Lippincott Williams & Wilkins.
6. Journal Trends in Pharmacological sciences.
7. H.G. Vogel, 2003. "Drug Discovery and Evaluation-Pharmacological Assays" 3rd Ed. Springer Verlag, Berlin, Germany.

Name of the Course : Advanced Pharmacology I (P)	
Course code: PRY511	**Semester :** 1st
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	Sessional Exam: 30 Marks
	T. A./ Seminar: 20 Marks
	Annual Practical Exam: 100 Marks

List of Laboratory Experiments :

1. To study about the different Laboratory animals used for Pharmacological Screening Methods.
2. To study different routes of drug administration Techniques.
3. To study the different Equipments/Instruments used in Pharmacology Practical.
4. To prepare and study different types of Physiological salt solutions.
5. Simulated experiments on agonists.
6. Simulated experiments on effect of antagonists on agonists DRC.
7. Simulated experiments on rabbit eye .
8. Simulated experiments on isolated frog heart
9. Simulated experiments on DRC of Acetylcholine on Guinea pig Ileum.
10. Simulated experiments on DRC of Histamine on Guinea pig Ileum.
11. Effect of Epinephrine on blood pressure and heart rate in anaesthetized dogs (Simulated).
12. Effect of Nor-epinephrine on blood pressure and heart rate in anaesthetized dogs (Simulated).
13. Effect of Isoprenaline on blood pressure and heart rate in anaesthetized dogs (Simulated).
14. Demonstration of muscarinic activity of a drug using suitable isolated tissue (Chicken Ileum) collected from local Meat supplier.
15. Demonstration of, nicotinic activity of a drug using suitable isolated tissue (Chicken Ileum) collected from local Meat supplier.
16. Demonstration of 5HT activity of a drug using suitable isolated tissue (Chicken Ileum) collected from local Meat supplier.

Reference books :

1. Pillai, KK, Experimental Pharmacology, CBS Publishers, Delhi.
2. Ghosh, MN; Fundamentals of Experimental Pharmacology, Scientific Book Agency,Calcutta.
3. Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, Delhi.

Name of the Course : Advanced Pharmacology - II	
Course code: PRY512	**Year :** 1st
Duration : 75 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Theory : 03 Hrs/week	Sessional Exam:30 Marks
Tutorial: 02 Hrs/week	T. A./ Seminar: 20 Marks
	Annual Exam: 100 Marks

Contents		Hrs
Unit -1	Regulations for Laboratory animal use and care. Limitations and alternatives to animal use. Principles involved in preclinical evaluation of new drugs. Blind screening programme, Preclinical Safety Assessment tests including carcinogenicity and reproductive studies, OECD Guidelines.	12
Unit -2	Critical assessment, limitations, and validation criteria of animal models, employed to evaluate the drugs belonging to following categories: Hypertension, Angina, Arrhythmia, Cardiac failure, Atherosclerosis.	08
Unit -3	CNS stimulants and Depressants: Stress Cognitive disorders and Alzheimer's disease, Epilepsy, Parkinsonism, Anxiety, Depression, Psychosis.	10
Unit -4	Analgesics and drugs used in Neuropathic pain, Inflammation and Arthritis.	06
Unit -5	Antihistaminics, Antidiabetics, Antifertility, Hepatoprotective and Anti-obesity and Anticancer drugs.	09
Unit -6	Principles of bioassay, Types of Bioassay, Methods, Bioassay of D-Tubocurarine, Digitalis, Oxytocin	06
Unit- 7	Drug therapy in pregnancy and Neonates	06
Unit-8	Drug-drug interactions, Drug-food interactions. Herb-Drug Interactions	08
Unit-9	Drug therapy in Geriatrics	05
Unit-10	Adverse drug Reactions and Heavy metal Poisoning.	05
	Total	75

Reference books :

. H.G. Vogel, 2002. "Drug Discovery and Evaluation-Pharmacological Assays", 2nd Ed. Springer Verlag, Berlin, Germany.

2. D.R. Laurence and A.L. Bacharach, 1964. "Evaluation of Drug Activities: Pharmacometerics" Vol. 1 and 2, Academic Press, London, U.K.

3. R.A. Turner, 1965. "Screening methods in pharmacology", Academic press, New York.

4. A. Schwartz, "Methods in Pharmacology".Plenum Publishing Corporation.

5. H.H.Siddiqui , 2009, "Bioassay of drugs", Globalmedic, New Delhi

Name of the Course : Pharmacology Research Project and Colloquium (P)	
Course code: PRY603	**Year :** 2nd
Duration : 540 Hrs	**Maximum Marks :** 1100
Teaching Scheme	**Examination Scheme**
Practical : 33 Hrs/week	Synopsis: 200 Marks
	T. A. / Seminar: 200 Marks
	Annual Exam: 700 Marks

M. Pharm. (Pharmaceutics)

TERMINOLOGY:-
L MEANS LECTURE.
T MEANS TUTORIAL.
P MEANS PRACTICAL.

Year	Subject code	Subject	Hours/week			Marks			
			L	T	P	Sessional Exam./ Synopsis	T.A. / Seminar	Annual Exam.	Total
First	PRY501	Modern Analytical Techniques	03	02	00	30	20	100	150
	PRY502	Modern Analytical Techniques(P)	00	00	06	30	20	100	150
	PRY503	Drug Regulatory Aspects & IPR	03	02	00	30	20	100	150
	PRY513	Advanced Pharmaceutics-I	03	02	00	30	20	100	150
	PRY514	Advanced Pharmaceutics (P)	00	00	06	30	20	100	150
	PRY515	Advanced Pharmaceutics -II	03	02	00	30	20	100	150
	TOTAL		**12**	**08**	**12**	**180**	**120**	**600**	**900**
Second	PRY604	Pharmaceutics Research Project & Colloquium (P)	00	00	33	200	200	700	1100
	TOTAL		**00**	**00**	**33**	**200**	**200**	**700**	**1100**
GRAND TOTAL			**12**	**08**	**45**	**380**	**320**	**1300**	**2000**

Name of the Course : Modern Analytical Techniques		
Course code: PRY501	**Year :1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
	SECTION - A	
Unit 1	Ultraviolet – Visible spectroscopy: Woodward – Fisher rules for calculation of λ_{max}. Infrared Spectroscopy : Molecular vibrations, Factors influencing Vibrational Frequencies , Instrumentation , Fourier Transform Infrared Spectroscopy, Sampling Techniques, Applications of Infrared Spectroscopy- Identification of Functional groups.	**07**
Unit 2	High Resolution ^{1}H & ^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Techniques used for finding types of carbon like attached proton test (APT), distortion less energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY	**10**
Unit 3	Mass spectrometry: Use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI, CI, FD, FI, MALDI, API, ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc.	**10**
Unit 4	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and troubleshooting. Quantification methods used in HPLC. Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmunoassay, ELISA etc. Microscopy: SEM, TEM, size exclusion chromatography.	**08**

Unit 5	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG), Thermo mechanical analysis (TMA): Principles instrumentations and applications (including interpretation of data) in pharmacy. HPTLC: Basic instrumentation and its calibration. Analytical method development and its validation as per ICH guidelines. Quantification using HPTLC	**08**
	SECTION B	
Unit 6	Definition of Computer, Input & Output devices, Storage devices. Definition & functions of an operating system, Single user and Multi-user operating system, Introduction & Type of softwares Introduction of MS – DOS, internal and external commands of MS-DOS, Basic idea of computer networking [LAN, MAN, WAN, Internet, Intranet, network topology(Ring, Star, Fully Connected and Bus)].	**07**
Unit 7	Introduction and Need of Language, Low level and high level languages,Compiler and Interpreter, Meaning & Need of database. Introduction & Uses of Internet, Browsers, common problems of internet,. Introduction of Web page, some basic commands of HTML	**07**
	SECTION C	
Unit 8	**Data & Graphs :** Collection of data: Primary and Secondary data, Preparation of data: Frequency distribution table, Bar diagram, Histogram, Frequency curve and Pie chart..	**04**
Unit 9	**Hypothesis testing**: Statistical hypothesis, null and alternative hypothesis, critical region, type I and II error, power of a test, Test of significance based on t distribution, F distribution and Chi – square test, Analysis of variance: One – way and two way classification (with equal size).	**06**
Unit 10	**Clinical data management**: Definitions, Importance in Statistical analysis and its various tools. **Statistical Quality control:** Causes and variations, Process control and Product control, Control charts, controls charts for variables: X – Charts and R – Charts, Control charts for attributes: p – chart and c – chart. **Introduction to common statistical software:** SPSS software.	**08**

Reference books :

- Robert M. Silverstein, Francis X. Webster, David J. Kiemle, 2009. "Spectrometric identification of organic compounds". 7th Ed. John Wiley & Sons.
- Pavia D. L., 2009. "Introduction to spectroscopy". 4th, Belmont CA
- Munson & Munson, "Pharmaceutical analysis: modern methods". edited by James
- W. Munson, New York : M. Dekker.
- Kenneth A. Connors, 2007. "A Textbook Of Pharmaceutical Analysis" 3rd Ed. Wiley India-wse
- Jens Thuro Carstensen, 2001. "Advanced pharmaceutical solids" Marcel Dekker, New York
- Joseph B. Lambert, Scott Gronert, Herbert F. Shurvell, David Lightner, Robert Graham Cooks, 2010. "Organic structural spectroscopy", 2nd Ed. Pearson Education, Limited.
- Bioassay by Prof. H. H. Siddiqui

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**
- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC
- Press.
- 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
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM
- Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- Scholarships, Fellowships & Loans, Chrystal Rozs, Gale, 2002.

Name of the Course : Modern Analytical Techniques (P)	
Course code: PRY502	**Year : 1st**
Duration : 90 Hrs	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	**Maximum Marks :** 150
	Sessional Exam: 30 Marks
	T. A. / Lab.Work (Record) : 20 marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

S. No	List of Laboratory Experiments
1	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2	Calibration of UV spectrometer for wavelength and stray light.
3	Calculation of λ_{max} values using Woodward Fisher rules.
4	Interpretation of IR spectra
5	Determination of pK value by UV visible spectrometry.
6	Calibration of HPLC instrument for flow rate & wavelength.
7	Determination of caffeine content in tea/ coffee/ other beverages.
8	Qualitative and quantitative analysis using HPTLC from published material
9	Drug Content determination using HPLC.
10	Practicals related to basic statistics (mean, median, mode, S. D., % RSD)
11.	Practicals realted to t test.
12.	Practicals related to ANOVA.
13.	To create, editing & formatting worksheet using MS - Excel.
14.	To make use of formula, create graphs for representing data in MS - Excel.
15	To understand various menu options of MS - word.
16	To make PowerPoint presentations with Animation effects.
17	To design simple web page using HTML editor

Name of the Course : Drug Regulatory Aspect and IPR		
Course code: PRY503	**Year : 1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	Seminar / T. A.: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
Unit 1	Drug Regulatory Aspects (India) – • Indian drug regulatory authorities, Central and State regulatory bodies (FDA) • Drugs and Cosmetics Act and Rules with latest Amendments (Selective) • Special emphasis – Schedule M and Y • New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies • Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	**10**
Unit 2	Good Manufacturing Practices (GMP) – • Indian GMP certification, WHO GMP certification • ICH guidelines for stability testing and other relevant ones (Q1 – Q10) • Export permissions and manufacturing for semi-regulated countries • Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) • Quality Assurance and Quality Control – Basic understanding for in-built Quality • GMP audits, role of Quality Assurance, product approvals and supplies.	**10**
Unit 3	Drug Regulatory Aspects (International & highly regulated markets) – • US Requirements – (for Generic Drugs especially formulations) • 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. • European Union Requirements – • 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) • A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries.	**20**

Unit 4	**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. **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	**8**
Unit 5	**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	**6**
Unit 6	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	**5**
Unit 7	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	**04**
Unit 8	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	**04**
Unit 9	**Patent search, Patent analysis & Patent drafting**	**04**
Unit 10	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	**04**
	Total	**75**

Text Books: N A

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.
11. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David
12. USPTO and WIPO Guidelines

Name of the Course : Advanced Pharmaceutics I		
Course code: PRY513	**Year : 1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	T. A. / Seminar: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
Unit 1	**Preformulation** **Physical characteristics:** Particle Size, Shape, Surface Area, Solubilization, Surfactants and its importance, Temperature, pH, Co-Solvency; Techniques for the study of crystal properties and Polymorphism. **Chemical characteristics:** Degradation**,** Hydrolytic, Oxidative, Reductive, Photolytic degradations; **Biopharmaceutics characteristics:** Solubility, Dissociation, Dissolution rate, Diffusibility, and Drug stability in GI tract. Physicochemical characteristics of new drug molecules with respect to different dosage forms.	**7**
Unit 2	**Drug Stability** Drug stability, Solution stability, Solid state stability, Parameters for physical stability, Protocol for physical stability testing, Accelerated stability studies and shelf assignment, ICH guideline. Strategy and tactics of stability testing: (1) Regulatory requirements (2) Stability protocols (3) Experimental design (4) Interpretation of Data	7
Unit 3	**Scale-up Techniques & Product development** Pilot plant scale up techniques, importance and technique involved, Packaging material science, Novel packaging techniques, cGMP Stages in product development and evaluation, Product developments functions, Data required for product development, Formulation factors	**6**

Unit 4	**Pharmaceutical Packaging Technology** Selection and evaluation of pharmaceutical packaging materials, Containers and closures, Problems of container-product interactions, Pharmacopoeial specifications, Test and standards for packaging materials. Recent advances in packaging techniques for various types of sterile and non sterile dosage forms.	**7**
Unit 5	**Advances in Industrial Process:** **Granulation:** Roller Compaction Technology, High-Shear Granulation, Low-Shear Granulation, Rapid Release Granulation, Lyophilization: LYOGUARD **Coating:** Coating, Coating machines, Coating techniques in tablet technology for product development, Film-coating materials and their properties	**8**
Unit 6	**Compartmental modeling** **One compartment open model:** I.V and oral route of administration, Volume of distribution, elimination half-life, first order elimination, fraction of drug remaining, renal clearance, total clearance, calculation of elimination rate constant from urinary excretion data. **Multi compartment modeling:** Two compartment and three compartment open I.V and oral administration model. **Non compartment analysis:** Statistical moment analysis, Mean residence time and Bioavailability, Clearance, half-life, Absorption kinetics, Apparent volume of distribution etc, Steady state concentration.	**10**
Unit 7	**Non-linear Pharmacokinetics** Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, Mixed drug elimination, Time dependent pharmacokinetics, Bioavailability of drug that follow non-linear pharmacokinetics due to protein binding (e.g. phenytoin)	**08**
Unit 8	**Multiple dosage regimen** Drug level-time relationship, steady state plateau value, mean residence tie, time to reach plateau, bolus and infusion, practical issues, drug accumulation, average amount and concentration at plateau, accumulation index, maintenance dose, loading dose, maintenance of dose in therapeutic range.	**08**

Unit 9	**Drug distribution and protein binding** Physiological factors, Calculations of apparent volume of distribution, Protein binding of drugs, Kinetics of protein binding, determination of binding constant and binding sites, Graphic method, Clinical significance of drug – protein binding **Clinical Pharmacokinetics** Drug elimination, Drug clearance, Physiological approach to clearance, Renal clearance, Renal drug excretion, Determination of renal clearance, Relationship of clearance elimination half-life and Volume of distribution, Hepatic elimination of drugs. Fraction of drug excretion unchanged (fe) and fraction of drug metabolized, clinical focus	**08**
Unit 10	**Bioavilability and bioequivalence** Biopharmaceutical classification of drugs, Absorption of permeability and solubility limited drugs. Bioequivalence and its determination, Study design for the assessment of bioavailability and bioequivalence, Factors influencing bioavailability and bioequivalence. Statistical concepts in estimation of bioavailability and bioequivalence. Biowavers for bioequivalence studies, Strategies to enhance bioavailability In-vivo, in-vitro correlation: Concept of correlation, types and establishment If correlation. Regulatory aspects.	**06**
	Total	75

Text Books: N A

Reference books :

1. M. Gibson, 2001. "Pharmaceutical preformulation and formulation"1st Ed. Informa Healthcare.
2. A. Hickey, 2009. "Pharmaceutical process engineering" 2nd Ed. Marcel Dekker, Inc
3. J. Swarbrick, 2006. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-3, Informa Healthcare.
7. D. A.Dean, E.R.Evans, I.H.Hall, "Pharmaceutical Packaging Technology", Taylor & Francis group
8. H. R. Brittain, "Physical Characterization Of Pharmaceutical Solids", Marcel Dekker.
9. L. Rey, J.C. May, "Freeze-Drying/ lyophilization of Pharmaceutical and Biological Products" Marcel Dekker, Inc.
10. D. M. Parikh, "Handbook of Pharmaceutical Granulation Technology". Taylor & Francis Group
11. G. Cole, "Pharmaceutical Coating Technology". Taylor & Francis Group
12. M. Rowland, T. N. Tozer, 1989. "Clinical Pharmacokinetics: Concept and Applications", 3rd Ed. B. I. Lea & Febiger.
13. L. Shargel, S. Wu-Pong, B. C Andrew, 2005. "Applied Biopharmaceutics and pharmacokinetics", 3rd Ed. McGraw-Hill Medical Pub. Division.
14. M. Gibaldi and D. Perrier, 1982. "Pharmacokinetics", M. Dekker.

Name of the Course : Advanced Pharmaceutics – I (P)	
Course code: PRY514	**Year:** 1st
Duration : 90 hrs.	**Maximum Marks :** 150
Teaching Scheme	**Examination Scheme**
Practical : 06 Hrs/week	Sessional Exam: 30 Marks
	T. A. / Lab.Work (Record) : 20 marks
	Annual Exam: 100 Marks

Suggested List of Laboratory Experiments :

1. To study the effect of pH on stability of aspirin
2. To prepare and evaluate microemulsion by aqueous titration method.
3. To prepare and evaluate the fast dissolving films of given drug sample
4. To determine molecular weight of polymer using Ostwalds viscometer
5 To study the effect of super disintegrates on release of drugs.
6. To perform various quality control tests for different packaging material
7. To prepare and evaluate microspheres by different techniques.
8. To prepare and evaluate different types of suspensions, emulsions and gels.
9. To study the comparative release profile of conventional and sustained release dosage formulations.
10. To study plasma protein binding of drug using egg albumin
11. To study erythrocytic binding of drug using blood
12. To study urinary excretion of aspirin after oral administration
13. To study effect of pH on urinary excretion of aspirin
14. To study effect of tablet hardness on dissolution of aspirin
15. To calculate pharmacokinetic parameters using supplied data after oral administration in one compartment open model
16. To perform statistical analysis of given data for bioequivalence.

Name of the Course : Advanced Pharmaceutics II		
Course code: PRY515	**Year :1st**	
Duration : 75 Hrs	**Maximum Marks :** 150	
Teaching Scheme	**Examination Scheme**	
Theory : 03 Hrs/week	Sessional Exam: 30 Marks	
Tutorial: 02 Hrs/week	T. A. / Seminar: 20 Marks	
	Annual Exam: 100 Marks	

Contents		Hrs
Unit 1	**Oral delivery:** Introduction of new technologies as TIMERx, MASSRx & COSRx, Procise technology, RingCap technology, Accudep Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technology, Buccal Mucoadhesives. **Solid dispersion technology:** Overview of Solid dispersion technology, MELTREX technology, Controlled Release with Meltrex Technology, Solid Dispersions with Meltrex Technology.	**08**
Unit 2	**Drug targeting:** Concepts and drug carrier systems. Approaches to active drug targeting: Monoclonal antibodies, Targeting to particular organs such as brain, lungs, liver and targeting to neoplastic diseases **Brain delivery:** Enhancing Drug Influx in the Blood–Brain Barrier: Drug Modification, Drug Solubilization in Nano- or Microcontainers, Disrupting of the Blood–Brain Barrier Restricting Drug Efflux in the Blood–Brain Barrier.	**08**
Unit 3	**Transdermal delivery:** Transdermal/skin drug delivery system Principles of skin permeation, factors affecting percutaneous absorption of drugs, sorption promoters, absorption enhancement by energy input - iontophoresis, sonophoresis and electroporation, pharmacokinetics of skin permeation, development and evaluation of transdermal devices.	**06**
Unit 4	**Overview of different carrier systems for drug delivery**: Microparticles, liposomes, niosomes, polymeric nanoparticles, solid lipid nanoparticles, carbon nanotubes. **Carrier & vector mediated delivery:** Carrier-Mediated Delivery Systems: Barriers to oral delivery of macromolecular drugs, Design of macromolecular drugs through chemical modification, Design of colloidal drug carriers. Design of Vector-Mediated Delivery Systems for Genetic Materials: Barriers to vector-mediated gene delivery, Viral vector, Nonviral vector.	**10**

Unit 5	**Rectal delivery:** Advantages, Limitation, Drug delivery development, Solid suppositories, Solutions Gels/ foams/ ointments, Controlled-release formulations, Marketed drugs and therapeutic classes. **Intrauterine Drug Delivery Systems:** Introduction, Development of intra uterine devices (IUDs), advantages and disadvantages, types, copper IUDs, hormone releasing IUDs.	**08**
Unit 6	**Parenteral Drug Delivery Systems:** Definition, advantages and disadvantages, Approaches for injectable controlled release formulations with examples, formulation and evaluation of Implantable drug delivery systems. **Ocular Drug Delivery Systems:** Introduction, controlled ocular drug delivery requisites & approaches for ocular drug delivery devices-matrix type, capsular type & implantable types.	**08**
Unit 7	**Mucosal Drug Delivery:** Introduction, Principles of mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability, formulation and evaluation of buccal, nasal and pulmonary drug delivery systems. **Protein and Peptide Drug Delivery:** Manifestation of protein instability and stability. Drug delivery systems for proteins and peptides with special reference to oral & nasal routes.	**08**
Unit 8	**Biopolymers:** Definition & types of biopolymers, Biopolymers Vs Synthetic polymers, nomenclature as polypeptides, nucleic acids and sugars, structural characterization, safety concern of biopolymers. Types of bioplastics, such as starch based, cellulose based plastics and aliphatic polesters (PLA, PHB), polyamides, bio – derived polyethylene and genetically modified bioplastics.	**06**
Unit 9	**Excipients:** General considerations of excipients used in formulations and factors governing selection. **Compatibility issues regarding excipients:** drug- excipients and excipient-excipient, excipients-package interactions. **Safety and regulatory issues of excipients Study of novel excipients:** Superdisintegrants, directly compressible and spray dried diluents, film coating materials, solubilizing agents like surfactants, Cyclic Glucose Polymers, polymeric excipients for controlled release applications, Improved excipients functionality by co processing, methods of preparation and evaluation	**07**

Unit 10	**BIONANOCARRIERS:** 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. **SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	**06**
	Total	75

Text Books: N A

Reference books :

1. R. Williams, D. Taft and J. McConville, "Advanced formulation design to optimize therapeutic outcomes" Marcel Dekker, Inc.
2. L. Xiaoling, B.R. Jasti, "Design of Controlled Release Drug Delivery Systems" McGraw-Hill.
3. B. O. Mashkevich, "Drug delivery research advances" Nova Science Publishers, Inc.
4. W. M. Saltzman, 2001 "Drug Delivery_Engineering Principles for Drug Thera". Oxford University Press.
5. E. Touitou, W.B. Boca "Enhancement in Drug Delivery" CRC Press Britain.
6. M. J. Rathbone, J. Hadgraft, M. S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc.
7. J. Swarbrick, "Encyclopedia of pharmaceutical Technology". Informa healthcare.
8. D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
9. T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
10. V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology". Wiley- Interscience: Hoboken.

Name of the Course : Pharmaceutics Research Project and Colloquium (P)	
Course code: PRY604	**Year :** 2nd
Duration : 540 Hrs	**Maximum Marks :** 1100
Teaching Scheme	**Examination Scheme**
Practical : 33 Hrs/week	Synopsis: 200 Marks
	T. A. / Seminar: 200 Marks
	Annual Exam: 700 Marks