

FACULTY OF LIFE SCIENCES

SYLLABUS

for

MASTER OF PHARMACY

(UNDER CREDIT BASED CONTINUOUS EVALUATION GRADING SYSTEM)

(SEMESTER: I-IV)

Examinations: 2015-16



GURU NANAK DEV UNIVERSITY AMRITSAR

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MASTER OF PHARMACY (SEMESTER SYSTEM)
(Under Credit Based Continuous Evaluation Grading System)

M. Pharm. (Pharmaceutical Chemistry)

Semester-I:

Sr. No.	Course Code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL501	Advanced Pharmaceutical Analysis –I	03	0	0	03
2	PHL502	Advanced Pharmaceutical Chemistry –I; Advanced Organic Chemistry.	03	0	0	03
3	PHL503	Advanced Pharmaceutical Chemistry –II : Advanced Organic and Drug Synthesis	03	0	0	03
4	PHS504	Seminar	0	0	0	02
5	PHP505	Advanced Pharmaceutical Analysis – II.	0	0	04	04
6	PHP506	Advanced Pharmaceutical Chemistry –III	0	0	04	04
Total Credits						19

M. Pharm. (Pharmaceutics)

Semester-I:

Sr. No.	Course Code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL501	Advanced Pharmaceutical Analysis –I	03	0	0	03
2	PHL507	Advanced Pharmaceutics –I.: Dosage form Design, Development and Validation	03	0	0	03
3	PHL508	Advanced Pharmaceutics –II: Advances in Drug Delivery	03	0	0	03
4	PHS509	Seminar	0	0	0	02
5	PHP505	Advanced Pharmaceutical Analysis – II.	0	0	04	04
6	PHP510	Advanced Pharmaceutics-III	0	0	04	04
Total Credits						19

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M. Pharm. (Pharmacology)

Semester-I:

Sr. No.	Course Code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL501	Advanced Pharmaceutical Analysis –I	03	0	0	03
2	PHL511	Advanced Pharmacology –I : Clinical Pharmacology and Drug Therapy – I	03	0	0	03
3	PHL512	Advanced Pharmacology –II : Drug Evaluation and Advanced Pharmacological Techniques	03	0	0	03
4	PHS513	Seminar	0	0	0	02
5	PHP505	Advanced Pharmaceutical Analysis – II	0	0	04	04
6	PHP514	Advanced Pharmacology –III	0	0	04	04
Total Credits						19

M. Pharm. (Pharmacognosy)

Semester-I:

Sr. No.	Course Code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL501	Advanced Pharmaceutical Analysis –I	03	0	0	03
2	PHL515	Advanced Pharmacognosy –I : Phamacognosy and Phytochemistry	03	0	0	03
3	PHL516	Advanced Pharmacognosy –II : Plant Drug Cultivation	03	0	0	03
4	PHS517	Seminar	0	0	0	02
5	PHP505	Advanced Pharmaceutical Analysis – II	0	0	04	04
6	PHP518	Advanced Pharmacognosy –III	0	0	04	04
Total Credits						19

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M. Pharm. (Pharmaceutical Chemistry)

Semester-II:

Sr. No.	Course code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL519	Modern Pharmaceutical Techniques-I	03	0	0	03
2	PHL520	Advanced Pharmaceutical Chemistry-IV: Drug Designing	03	0	0	03
3	PHL521	Advanced Pharmaceutical Chemistry -V: Current Pharmaceutical Chemistry	03	0	0	03
4	PHS522	Seminar	0	0	0	02
5	PHP523	Modern Pharmaceutical Techniques -II	0	0	04	04
6	PHP524	Advanced Pharmaceutical Chemistry -VI	0	0	04	04
Total Credits						19

M. Pharm. (Pharmaceutics)

Semester-II:

Sr. No.	Course code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL519	Modern Pharmaceutical Techniques-I	03	0	0	03
2	PHL525	Advanced Pharmaceutics-IV: Biopharmaceutics and Advanced Pharmacokinetics	03	0	0	03
3	PHL526	Advanced Pharmaceutics-V: Pharmaceutical Technology and IPR Management	03	0	0	03
4	PHS527	Seminar	0	0	0	02
5	PHP523	Modern Pharmaceutical Techniques -II	0	0	04	04
6	PHP528	Advanced Pharmaceutics -VI	0	0	04	04
Total Credits						19

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M. Pharm. (Pharmacology)**Semester-II:**

Sr. No.	Course code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL519	Modern Pharmaceutical Techniques-I	03	0	0	03
2	PHL529	Advanced Pharmacology-IV : Clinical Pharmacology and Drug Therapy-II	03	0	0	03
3	PHL530	Advanced Pharmacology-V: Current Trends in Pharmacology	03	0	0	03
4	PHS531	Seminar	0	0	0	02
5	PHP523	Modern Pharmaceutical Techniques –II	0	0	04	04
6	PHP532	Advanced Pharmacology-VI	0	0	04	04
Total Credits						19

M. Pharm. (Pharmacognosy)**Semester-II:**

Sr. No.	Course code	Subject	Lecture (L)	Tutorial (T)	Practical (P)	Credits
1	PHL519	Modern Pharmaceutical Techniques-I	03	0	0	03
2	PHL533	Advanced Pharmacognosy –IV: Drug Development From Natural Sources	03	0	0	03
3	PHL534	Advanced Pharmacognosy –V: Plant Drug Standardization	03	0	0	03
4	PHS535	Seminar	0	0	0	02
5	PHP523	Modern Pharmaceutical Techniques –II	0	0	04	04
6	PHP536	Advanced Pharmacognosy –VI	0	0	04	04
Total Credits						19

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M. Pharm. (Pharmaceutical Chemistry)

Semester-III:

Course No.	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHS 537	C	Seminar	0	0	02	02
PHP 538	C	Dissertation (Part-I)	0	0	08	08

Elective/Optional Course (Opt any one course)

Course No:	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHL 539	E	Advanced Pharmaceutics	3	0	0	03
PHL 540	E	Fundamentals of Experimental and Clinical Pharmacology and Toxicology	3	0	0	03
PHL 541	E	Biomedicinals	3	0	0	03

***Interdisciplinary Course**

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Total credits for Semester –III: 16

M. Pharm. (Pharmaceutics)

Semester-III:

Course No.	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHS 542	C	Seminar	0	0	02	02
PHP 543	C	Dissertation (Part-I)	0	0	08	08

Elective/Optional Course (Opt any one course)

Course No:	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHL 539	E	Advanced Pharmaceutics	3	0	0	03
PHL 540	E	Fundamentals of Experimental and Clinical Pharmacology and Toxicology	3	0	0	03
PHL 541	E	Biomedicinals	3	0	0	03

***Interdisciplinary Course**

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Total credits for Semester –III: 16

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M. Pharm. (Pharmacology)

Semester-III:

Course No.	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHS 544	C	Seminar	0	0	02	02
PHP 545	C	Dissertation (Part-I)	0	0	08	08

Elective/Optional Course (Opt any one course)

Course No:	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHL 539	E	Advanced Pharmaceutics	3	0	0	03
PHL 540	E	Fundamentals of Experimental and Clinical Pharmacology and Toxicology	3	0	0	03
PHL 541	E	Biomedicinals	3	0	0	03

Total credits for Semester –III: 16

M. Pharm. (Pharmacognosy)

Semester-III:

Course No.	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHS 546	C	Seminar	0	0	02	02
PHP 547	C	Dissertation (Part-I)	0	0	08	08

Elective/Optional Course (Opt any one course)

Course No:	C/E/I	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHL 539	E	Advanced Pharmaceutics	3	0	0	03
PHL 540	E	Fundamentals of Experimental and Clinical Pharmacology and Toxicology	3	0	0	03
PHL 541	E	Biomedicinals	3	0	0	03

***Interdisciplinary Course**

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Total credits for Semester –III: 16

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M. Pharm. (Pharmaceutical Chemistry)

Semester-IV

Course No.	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHP 548	Dissertation (Part-II)	0	0	12	12
PHP 549	Viva Voce	0	0	04	04
Total Credits					16

Total M Pharmacy Credits: 19+19+16+16=70

M. Pharm. (Pharmaceutics)

Semester-IV

Course No.	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHP 550	Dissertation (Part-II)	0	0	12	12
PHP 551	Viva Voce	0	0	04	04
Total Credits					16

Total M Pharmacy Credits: 19+19+16+16=70

M. Pharm. (Pharmacology)

Semester-IV

Course No.	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHP 552	Dissertation (Part-II)	0	0	12	12
PHP 553	Viva Voce	0	0	04	04
Total Credits					16

Total M Pharmacy Credits: 19+19+16+16=70

M. Pharm. (Pharmacognosy)

Semester-IV

Course No.	Course Title	Lecture (L)	Tutorial (T)	Practical (P)	Credits
PHP 554	Dissertation (Part-II)	0	0	12	12
PHP 555	Viva Voce	0	0	04	04
Total Credits					16

Total M Pharmacy Credits: 19+19+16+16=70

PHL501: Advanced Pharmaceutical Analysis-I

3 Credits (3-0-0)

1. **UV-Visible Spectroscopy:** Electromagnetic spectrum: UV-visible range. Energy, wavelength and color relationship. Interaction of electromagnetic radiation (UV visible) with matter and its effects. Chromophores and their interaction with UV-visible radiation. Absorption spectra of organic compounds and complexes, and their utilization for structural, qualitative, and quantitative analysis of drug molecules. Shifts in spectra including solvent induced shifts and their interpretation. Empirical correlation of structure with spectra, Woodward-Fieser rules. Derivative spectra. Quantitative estimations. Modern instrumentation.
2. **Infrared Spectroscopy:** Nature of infrared radiation and its interaction with organic molecules. Vibrational excitations. Classical instrumentation and particle details for obtaining spectra, including sample preparation. Qualitative interpretation of I.R. spectroscopy. FTIR & ATR
3. **Nuclear Magnetic Resonance Spectroscopy:** Fundamental principles of NMR (Magnetic properties of nuclei, applied field and precession), Chemical shifts concept: isotopic nuclei, reference standards. Proton Magnetic resonance spectra, their characteristics, presentation terms used in describing spectra and their interpretation. Brief outline of instrumental arrangements and some practical details. Spin-spin coupling. Application of signal shift and coupling constant data for interpretation of spectra. Decoupling- double resonance and shift reagent methods. Brief outline of principles of FT-NMR with reference to ^{13}C NMR, Free induction decay (FID). Average time domain and frequency domain signals. Spin - spin and spin-lattice relaxation phenomenon. Proton noise decoupled spectra. Nuclear Overhauser enhanced ^{13}C NMR spectra. APT and DEPT techniques. Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments. Introduction to 2-D NMR techniques: COSY, HETCORE, NOESY with applications
4. **Mass Spectrometry:** Basic principles and brief outline of instrumentation. Ion formation and types: molecular ion, meta-stable ions. Fragmentation processes. Fragmentation pattern and fragmentation characteristics in relation to molecular structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks. Chemical ionization. FAB and ESI mass spectrometry . GC-MS and other recent advances in mass spectrometry.
5. **X-ray Diffraction Methods:** Introduction, Generation of X-rays. Elementary crystallography. Miller indices, X-ray diffraction - Bragg's law, X-ray powder diffraction, obtaining and interpretation of X-ray powder diffraction data.
6. **Chromatographic Techniques:** Classification of chromatographic methods based on mechanisms of separation. Paper chromatographic techniques and applications. Thin Layer chromatography and comparison with paper chromatography and HPLC, adsorbents for TLC. Preparative techniques, mobile phase selection, reversed phase

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- TLC. High performance TLC (HPTLC) detection methods. Quantitative methods in TLC. Programmed multiple development techniques.
7. **Gas Chromatography:** Instrumentation. Packed and open tubular columns. Column efficiency parameters - the Vandemeter equation. Resolution. Liquid stationary phase. Derivatization methods for GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; **FID, ECD, TCD, NPDA** - critical comparison of sensitivity, selectivity and field of applications of these detectors, Examples of GC applications in pharmaceutical analysis.
 8. **HPLC :** Comparison of GC and HPLC. Instrumentation in HPLC. Analytical, preparative and micro bore columns. Normal and reversed phase packing materials. Reverse phase HPLC column selection. Mobile phase selection. Efficiency parameters. Resolution. Detectors in HPLC - Refractive index, Photometric and electrochemical Comparison of sensitivity selectivity and field of applications of these detectors. HPLC-instrumentation and applications.

Recommended Books (Latest editions unless specified):

1. Skoog: Principles of Instrumental Analysis (Saunders College Publishing Philadelphia).
2. M. Orchin and H.H-Jaffe- Theory and applications of ultra violet spectroscopy (John Wiley and Sons, N.Y).
3. Silverstein. Basseler, Moiril-Spectrometric identification of organic compounds (John Wiley and Sons, N.Y).
4. Willard, Merritt, Dean-instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi).
5. J.R. Dyer- Applications of Absorption Spectroscopy of Organic Compounds (Prentice Hall, London).
6. Higuchi: Instrumental Methods of Analysis (CBS Publishers).
7. Analytical Chemistry by open learning series.
8. Wim kok: Capillary Electrophoresis: Instrumentation and Operation
9. R. J. Hamilton - Introduction to High Performance Liquid Chromatography, (Chapman and Hall, London).
10. Ewing-Instrumental Methods of Chemical Analysis (McGraw Hill Book Co., New York).

**PHL502: Advanced Pharmaceutical Chemistry – I:
Advanced Organic Chemistry**

3 Credits (3-0-0)

1. Reactive intermediates in organic synthesis.

- a) **Carbocations:** Formation, structure, stability and reactions of carbocations. Rearrangement reactions like, Wagner-Meerwein, pinacol-pinacolone and trans-annular rearrangements.
- b) **Carbanions:** Formation, structure, stability and reactions of carbanions. Perkin, Claisen, Benzoin Aldol condensations, Cannizaro reaction and Favorskii rearrangement.
- c) **Free radicals:** Formation, structure, stability, detection, reactions involving free radicals, addition to carbon-carbon multiple bonds.
- d) **Carbenes:** Formation, structure, stability and reactions of carbenes. Reimer-Tiemen reaction, Wolff rearrangement. Ring expansion reactions - conversion of pyrrole to pyridine.
- e) **Nitrenes:** Formation, structure, stability and reactions of nitrenes. Hofman, Curtius, Schmidt, Lossen rearrangements.

2. (a) Stereochemistry : Stereoisomerism. Optical Isomerism. Molecular dissymmetry. Configuration. Correlation of configurations. Diastereomers. Meso-compounds. Formation and resolution of racemic mixtures. Axially dissymmetric molecules. Stereochemistry of some elements other than carbon: stereochemistry of Nitrogen Sulfur and Phosphorous compounds.

(a) Conformational analysis: Conformations of acyclic molecules. Conformation of cyclic molecules - study of carbocyclic rings with 3, 5 and 6 carbon atoms and decalins. Conformations of large rings. Introduction to conformations of heterocycles such as dioxanes piperidines morpholines and tetrahydro-pyrans. Conformation and reactivity: Stereocontrol in acyclic system. Stereocontrol in cyclic systems. Neighbouring group and chelation effects. Acyclic stereocontrol via cyclic precursors. Ring forming reactions and stereochemical influences.

3. Asymmetric synthesis: Cram's rule and its variations. Chiral auxiliaries - Chiral diols, carbohydrates, terpenes, and other natural products as chiral auxiliaries. Chiral Lewis acid catalysis. Diastereoselective rearrangements. Sharpless asymmetric epoxidation. Asymmetric Reductions. Chiral reagents (Grignards reagent, Organocuprates, Organoirons). Catalytic asymmetric hydrogenation, Enolate alkylation and oxidation of sulfides. Microbial transformations.

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4. Organic Photochemistry: Light absorption. Electronic transitions, Jablonski diagram. Intersystem crossing. Photosensitization. Excited states of ketones. α Cleavage, γ - hydrogen abstraction, Paterno-Buchii reaction and Photoreduction. Photochemistry of conjugated dienes and enones.

Reading Material Recommended (Latest editions unless specified):

- 1) Jerry March's Advanced Organic Chemistry, Reactions, Mechanisms and Structure, 5th edition, M.B. Smith and Jerry March, John Wiley and Sons, New York, U.S.A., 2001.
- 2) Stereochemistry of Carbon Compounds, reprint 14th edition, Ernest L. Eliel McGraw-Hill Book Company Inc., New York, U.S.A., 1990.
- 3) Organic Photochemistry by William Horsepool.
- 4) Reactive Intermediates by C.W. Rees.
- 5) S.P. Singh and S.M. Mukherji, Reaction Mechanism in Organic Chemistry, The Macmillian Company of India Limited, New Delhi, India.
- 6) Organic Chemistry Vol-II, by I.L. Finar, Chapter II and IV.

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**PHL503: Advanced Pharmaceutical Chemistry – II:
Advanced Organic & Drug Synthesis**

3 Credits (3-0-0)

1. **Combinatorial Chemistry:** Introduction. Creating molecular libraries. Split synthesis and parallel synthesis. Introduction to solution phase and liquid phase combinatorial organic synthesis. Deconvulsion method of identification.
2. **Oxidation and Reduction in Organic Chemistry:** Oxidation of alcohols to carbonyl. Phenols to quinines. Conversion of alkenes to epoxides and diols. Oxidative bond cleavages. Oxidation of sulfur, selenium & nitrogen. Reduction with metal hydrides, Alkoxyamines, alkoxy- and alkyl-borohydrides. Stereoselectivity in hydride reduction. Catalytic hydrogenation and dissolving metal reductions.
3. **Some Classics in organic Synthesis:** Corey's synthesis of Prostaglandins (PGF and PGE). Woodward's synthesis of Strychnine. Synthesis of Progesterone by W.S. Johnson, Synthesis of Reserpine by Woodward, Synthesis of Indolizomycin by Danishefsky. Synthesis of Taxol by K.C. Nicolau, Vitamin B₁₂, Menthol
4. **Reltegravir (Isentress):** Background, Pharmacology, Structure Activity relationship (SAR), Pharmacokinetics and Drug Metabolism, efficacy and safety, Synthesis.
5. **Sitagliptin (Januvia):** Background, Pharmacology, Structure Activity relationship (SAR), Pharmacokinetics and Drug Metabolism, efficacy and safety, Synthesis.
6. **Raloxifene (Evista):** Background, Pharmacology, Structure Activity relationship (SAR), Pharmacokinetics and Drug Metabolism, efficacy and safety, Synthesis.
7. **Rivaroxaban (Xarelto):** Background, Pharmacology, Structure Activity relationship (SAR), Pharmacokinetics and Drug Metabolism, efficacy and safety, Synthesis

Reading Material Recommended:

1. Some Modern Methods of Organic Synthesis, IIIrd edition, by W. Carruthers, 1993. Chapter-1, 3 and 6.
2. Organic Synthesis by M.B. Smith, McGraw International edition, 1994 Chapter 1,3,4 & 5.
3. The Logic of Organic Synthesis by E.J. Corey and X.M. Cheng, John Wiley and Sons, 1989, Chapter 1 & 2.
4. Principles of Organic Synthesis, R.O.C. Norman and J.M. Coxon, Chapman and Hall, 1998.
5. Cycloadditions in Organic Synthesis by W.R Carruthers, Pergamon Press, London, 1990.
6. Classics in Total Synthesis by K.C. Nicolau and E.J. Sorensen, John Wiley, 1996.

MASTER OF PHARMACY (SEMESTER-I)
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PHP505: Advanced Pharmaceutical Analysis - II

4 Credits (0-0-4)

1. Simultaneous estimation of Paracetamol and Ibuprofen: Aspirin and Caffeine; Rifampicin and Isoniazid or other combination formulation (4 expts).
2. U.V. Visible spectrum scanning of certain organic compounds - absorption and correlation of structures and comparison e.g.,
 - a) Chloramphenicol
 - b) Analgin
 - c) Sulphadiazine
 - d) Ibuprofen
3. Comparison of three different analytical methods for Salbutamol or other drugs.
4. Workshop on spectroscopy structural elucidation of at least 5 unknown compounds
5. IR, NMR & Mass spectroscopy (1 compound each)
6. Case studies on quality control lab planning & analytical reporting of raw materials, In Process and finished goods, minor Experiments.
7. Effect of pH and solvent on U.V. Spectrum of certain drugs.
8. Two dimensional paper chromatography and TLC (Minor expts)
9. Any other relevant exercise based on Theory

Books Recommended (Latest editions unless specified):

1. Instrumental Methods of Analysis by Skoog and West.
2. Spectrometric Identification of Organic Compounds by Silverstein Recent Edition.
3. Instrumental Methods of Analysis by Willard Dean & Merrit.
4. Drugs & Pharma, Sciences Series, Marcel Deicker Inc.

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PHP506: Advanced Pharmaceutical Chemistry –III

4 Credits (0-0-4)

1. Preparation of organic compounds through multi-step synthetic schemes and their characterization by spectroscopic techniques.
2. Chromatographic techniques for qualitative and quantitative estimation.
3. Identification of organic compounds in a mixture through physical chemical and spectral studies and their confirmation through the preparation of derivatives.
4. Stereomodel Workshop : Exercises involving preparation of stereomodels with a view to assess the importance of stereochemistry in drug action. Examples of pharmacopoeial substances of stereochemical importance should be taken for illustration.

Books Recommended (Latest editions unless specified):

1. F.C. Mann and B.C. Saunders, Practical Organic Chemistry, Orient Longman, 4th Edition, New Delhi, India 1960.
2. A.i. Vogel, A Text Book of Practical Organic Chemistry, 5th Edition, The English Language Book Society and Longman Group Limited London, U.K. 1991.
3. R.M. Silverstein, G.C. Bassler and T.C. Morrill, Spectrometric Identification of Organic Compounds, 5th Edition, John Wiley and Sons, Inc., New York, U.S.A., 1991
4. E.L. Eliel, Stereochemistry of Carbon Compounds, Reprint 14th Edition, McGraw Hill Book Company, Inc., New York, U.S.A. 1990.

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**PHL507: Advanced Pharmaceutics I:
Dosage form Design, Development and Validation**

3 Credits (3-0-0)

1. **Preformulation Studies** – Introduction, goals of preformulation, physicochemical properties, criteria for selection of drug and excipients, compatibility tests.
2. **Solubility and Solubilization** – Development of theoretical relationships of prognostic relevance, techniques of solubilization of drugs.
3. **Partition Coefficient** – Pharmaceutical significance of partition co-efficient, choice of solvent systems, correlation with in-vivo performance, theoretical computation using Hanch & Leo / Rekker principle, effect of various variants like temp., pH etc. on partition coefficient.
4. **Rheology** – Modern concepts of rheology, viscoelastic analysis of semisolids, application and practice of rheology, selection of most suitable viscometer for a given sample.
5. **Complexation** – Metal and organic molecular complexes, Inclusion complexes with reference to cyclodextrins, types of cyclodextrins, and their pharmaceutical applications.
6. **Packaging Development** – Packaging materials, unit dose packaging, blister packing, strip packing and FDA regulations, packs for tablets, capsules, ointments and aerosols, child resistant packaging, evaluation of packaging materials.
7. **Pharmaceutical Process Validation** –
 - a) Definition, scope, importance and various terms used in process validation, design and techniques of process validation.
 - b) Validation of solid dosage forms: Introduction, validation of raw materials, analytical methods validation, definition and control of process validation, definition and control of process variables guidelines for process validation of solid dosage forms.
 - c) Process validation and quality assurance - Introduction, quality assurance and organization, process validation as a quality assurance tool.
 - d) Validation of sterilization processes and sterile products –
Validation of steam, dry heat, gaseous and radiation sterilization processes validation of sterilizing filters, validation of equipment, container and closures, sterilization processes and environmental conditions employed in manufacturer of sterile products.

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Reading Material Recommended (Latest editions unless specified):

1. J.I.Wells, Pharmaceutical Preformulation : The Physico-chemical Properties of Drug Substances, Ellis Horwood, Chichester (UK), 1998
2. S.H. Yalkowsky, Techniques of Solubilization of Drugs, Marcel Dekker, Inc., New York, USA.
3. C. Doornbos, and P. Hann, Optimization Techniques in Formulation and Processing, in Encyclopedia of Pharmaceutical Technology, Vol. II, J. Swarbrick and J.C. Boylan, Eds., PP. 77-160. Marcel Dekker, N.Y., 1995.
4. J. Swarbrick and J.C. Boylan, Eds., Encyclopedia of Pharmaceutical Technology Vol. 12, Marcell Dekker, N.Y., 1995, PP.1.
5. I.R. Berry and R.H. Nash, Pharmaceutical Process Validation, Marcel Dekker, N.Y., 1993.

MASTER OF PHARMACY (SEMESTER-I)
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**PHL508: Advanced Pharmaceutics II:
Advances in Drug Delivery**

3 Credits (3-0-0)

1. Controlled Drug Delivery :

- a) Fundamentals of Controlled Release (CR) Drug Delivery: Rationale of sustained / controlled drug delivery, Physicochemical and biological factors influencing design and performance of CR products, therapeutic status of CDDS.
- b) Theory of mass transfer, Fick's first and second laws and their applications in drug release and permeation.
- c) Pharmacokinetic/ pharmacodynamic basis of controlled drug delivery, bioavailability assessment of CR systems.
- d) Regulatory requirements.

2. Design and Fabrication of Technology Based CR Systems:

- a) Polymers in drug delivery: Polymer classifications, biodegradable and non-biodegradable polymers and their applications in controlled release, biocompatibility testing.
- b) Strategies and design of oral controlled release delivery systems, oral systems based on dissolution, diffusion and dissolution, ion-exchange resins, pH-independent formulations, altered density formulations. Buccoadhesive/ mucoadhesive system. Osmotic controlled oral drug delivery.
- c) Parenteral systems, biopharmaceutical considerations, design and development, polymeric microspheres, dispersed drug delivery.
- d) Implantable therapeutic system, biocompatibility of polymers and carriers, Intrauterine devices and intervaginal devices.
- e) Transdermal Therapeutic Systems (TTS): Drug absorption through skin, permeation enhancers, basic components of TTS, approaches to development and kinetic evaluation, testing of transdermal patches, pressure sensitive adhesive, iontophoresis, sonophoresis and electroporation.
- f) Novel Ocular Drug Delivery Systems: Ocular therapeutics and constraints to effective delivery formulation, consideration to improve the ocular bioavailability, ocular inserts including insoluble and soluble inserts, non-corneal routes and their use for systemic drug delivery.
- g) Nasal drug / pulmonary drug delivery systems.

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3. Colloidal and Supramolecular Delivery systems:

- a) Closed Bilayered system : Historical background. Structural aspects, preparation, characterization, evaluation and applications, specialized liposomes in drug targeting, niosomes, erythrosmes, pharmacosomes, aquasomes and solid lipid nanoparticles,
- b) Nanoparticles, Microspheres : Method of preparation, characterization, evaluation and pharmaceutical applications.
- c) Multiple w/o/w emulsions as drug vehicles: Introduction, composition of the multiple emulsion and stability, influence of the nature of oily phase, methods for stabilizing w/o/w multiple emulsions, mechanisms of transport of solutes, in vivo studies.
- d) Microemulsions : Introduction, structure of mircoemulsions, solubilization and formulation of microemulsions, transport properties and pharmaceutical applications of emulsions.

4. Protein and Peptide Drug Delivery:

Considerations in the physiological delivery of therapeutic proteins, carrier mediated transport of peptides and peptide analogues. Problems associated with the delivery of protein and peptides (stability and membrane barriers, delivery systems for protein and peptide drugs, toxicity aspects. Enzyme and enzyme immobilization, recent trends in vaccine and vaccine delivery systems.

5. Triggered Pulsed and Programmed Drug Delivery System :

Targeted Drug Delivery : History, concept, types and key elements, ideal carrier system and approach with special reference to organ targeting (e.g brain, tumor, lung, liver and lymphatics). Basics of temperature, pH and magnetically induced targeting tactics.

Reading Material Recommended:

1. J.R. Robinson & V.H.L. Lee (Eds.) Controlled Drug Delivery, Fundamentals and Applications. Vol. 29 & Vol. 31, 2nd Edition, Marcel Dekker, N.Y. 1987
2. Y.W. Chien (Ed), Transdermal Controlled Systemic Medication, Marcel Dekker, N.Y., 1987.
3. S.D. Bruck, Controlled Drug Delivery, Vol-I9 (Basic Concepts) CRC Press, Florida, 1983
4. S.D. Bruck, Controlled Drug Delivery, Vol II (Clinical Applications), CRC Press, Florida, 1983.

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5. P. Tyle and B. Ram. Targetted Therapeutic Systems, Marcel Dekker, N.Y., 1990.
6. L.F. Prescott and W.S. Nimmo, Novel Drug and its Therapeutics Applications, John Wiley and Sons. Chichester (1990).
7. S.P. Vyas and R.K. Khar, Targetted and Controlled Drug Delivery, 2001.
8. N.K. Jain, Controlled and Novel Drug Delivery, 1997, CBS, New Delhi
9. N.K. Jain, Advances in Controlled and Novel Drug Delivery, 2001, CBS, New Delhi.
10. G.S. Banker & C.T. Rhoden (Eds.), Modern Pharmaceutics, 2nd Edition, Marcel Dekker, N.Y., 1990
11. Sanjay Kumar Jain , Vandana Soni Bentley's Textbook of Pharmaceutics. Elsevier India 2012.
12. Jain N.K. Pharmaceutical Product Development. CBS Publisher & Distributors P Ltd. 2011.
13. Linda Felton Remington: Essentials of Pharmaceutics. Pharmaceutical Press; 1 edition. 2013

PHP510: Advanced Pharmaceutics-III

4 Credits (0-0-4)

Experiments based on following concepts:

1. Powder Characterization: Microscopy, compression and compaction.
2. Solubilization: Effect of dielectric constant on solubility, complexation, solid dispersions.
3. Stability studies: Degradation kinetic study of a drug in solution. Accelerated stability studies of a formulation.
4. Dissolution studies of various dosage forms.
5. Formulation and evaluation of following drug delivery systems: Transdermal, microencapsulation, controlled release formulations, gels, and fast dissolving tablets.

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PHL511: Advanced Pharmacology –I
Clinical Pharmacology and Drug Therapy – I

3 Credits (3-0-0)

1. **Basic Principles of Clinical Pharmacology:** Four processes of drug therapy, monitoring of drug therapy, adverse drug reactions, patient compliance, pharmacogenetics, principles of pediatric and geriatric, drug therapy in pregnant and lactating patients, drug interactions.
2. **Drugs Affecting the Autonomic Nervous System:** Neurotransmission Muscarinic receptor agonists and antagonists, anticholinestrase agents Agents acting at the neuromuscular junction and autonomic ganglia Catecholamines, sympathomimetic drugs and adrenergic receptor antagonists Skeletal muscle relaxants
3. **General considerations of the CNS and Drug Therapy of Neurological disorders:** Neurotransmission, pharmacology of general anesthetics, local anesthetics, alcohol, opioid analgesics
 - Biochemical basis and drug therapy of anxiety
 - Biochemical basis and drug therapy of schizophrenia
 - Biochemical basis and drug therapy of depression
 - Biochemical basis and drug therapy of sleep disorders
 - Biochemical basis and drug therapy of seizures
 - Biochemical basis and drug therapy of neurodegenerative disorders (Parkinsonism, Huntington's chorea, ALS, Alzheimer's disease)
4. **Drug therapy of Inflammatory disorders :**
 - Molecular and biochemical basis of inflammation
 - Pharmacology of histamine
 - Pharmacology of bradykinin
 - Pharmacology of lipid derived autocooids
 - Treatment of gout and rheumatoid arthritis.
5. **Drug therapy of Respiratory disorders :**
 - Pathophysiology and drug therapy of asthma.
6. **Drug therapy of Gastrointestinal disorders :**
 - Pathophysiology and drug therapy of peptic ulcers
 - Drug therapy of emesis, diarrhea and constipation.

Books Recommended: (Latest Edition)

1. D.G Grahame-Smith and J.K. Aronson, Oxford Textbook of Clinical Pharmacology and Drug Therapy, Oxford University Press, New York, U.S.A.
2. J.G. Hardman and L.E. Limbird (eds.), Goodman and Gilman's: The Pharmacological Basis of Therapeutics, 10th Edition, Pergamon Press, New York, U.S.A.
3. E.T. Herfindal and D.R. Gourley, Textbook of Therapeutics, 6th Edition, Williams and Wlikins, London, U.K.
4. J.T. Dipiro, R.I. Talbert, P.E. Hayers, G.C. Yee and L.M. Possy (eds.), Pharmacotherapy: A Pathophysiologic Approach, Appleton Lange, U.S.A.
5. T.M. Speight (Ed.), Avery's Drug Treatment Principles and Practice of Clinical
6. Pharmacology and Therapeutics, 3rd Edition, ADIS Press, Sydney, Australia.

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PHL512: Advanced Pharmacology –II
Drug Evaluation and Advanced Pharmacological Techniques

3 Credits (3-0-0)

1. Principles of Experimental Pharmacology:

Common laboratory animals in pharmacological research, some standard techniques and anesthetics used in laboratory animals, euthanasia of experimental animals, limitations of animal tests, regulations for the care of animals and ethical requirements. Alternatives to animals.

2. Strategies in Drug Discovery and Evaluation:

New approaches in drug discovery, preclinical, safety and clinical evaluation of new chemical entity, basic concepts of combinatorial chemistry, high throughput screening, ultraHTS, HCS, pharmacogenomics, proteomics, errors in screening procedures, methods of statistical analysis.

3. Pharmacological Techniques to Preclinical Evaluation of the following Classes of Drugs :

- a) Antihypertensive agents
- b) Antianginal agents
- c) Antiarrhythmic agents and drugs used in sudden cardiac death
- d) Drugs used in congestive cardiac failure and cardiomyopathies
- e) Drugs used in hyperlipoproteinemias and atherosclerosis
- f) Anti-infarct agents
- g) Antiplatelets and thrombolytics agents
- h) Antipsychotics
- i) Antiepileptics
- j) Antiparkinsonian agents
- k) Drugs affecting memory
- l) Analgesics
- m) Anti-inflammatory agents
- n) Local anesthetics
- o) Skeletal muscle relaxants and neuromuscular blockers
- p) Antidiabetic agents
- q) Antimalarial agents
- r) Antiviral agents
- s) Dermatological agents
- t) Anti-ulcer agents
- u) Antihistaminic agents
- v) Genetically modified animals.

4. Pharmacological in-vitro techniques: Bioassays, Animal and Human cell lines, Advantages and limitations of these techniques

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Reading Material Recommended (Latest editions unless specified):

1. H.G . Vogel and W.H. Vogel Drug Discovery and Drug Evaluation.Pharmacological Assays, 2nd Edition Springer Verlag, Berlin, Germany.
2. M.N. Ghosh, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Kolkota, India.
3. D.R. Laurence and A.L. Bacharach (eds.), Evaluation of Drug Activities : Pharmacometrics Vol.I and I I, Academic Press London, U.K.
4. P. Mantegazza and F. Piccinini (eds.), Methods in Evaluation, North Holland Publishing Company, Amsterdam, The Netherlands.
5. A.A. Rubin (ed.) New Drugs Discovery and Development, Marcel Dekker Inc., New York, U.S.A.
6. David R. Gross, Animal Models in Cardiovascular Research, Kluwer Academic Publishers, London, U.K.
7. Journal of Pharmacological and Toxicological Methods, Elsevier Science Inc., New York, U.S.A.
8. Kulkarni, S. K. Handbook of Experimental Pharmacology, (Vallabh Prakashan, Delhi).
9. Relevant Review Articles from Recent Journals.

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PHP 514: Advanced Pharmacology – III

4 Credits (0-0-4)

1. Introduction to isolated tissue experiments.
2. Basic experiments using isolated tissues: pD₂ value, pA₂ value.
3. Experiments in intact animals to study the drugs affecting the central nervous system, muscle:
 - i) Evaluation of antianxiety activity
 - ii) Evaluation of antidepressant activity
 - iii) Evaluation of drug induced catatonia
 - iv) Evaluation of effects on memory
 - v) Evaluation of sedative- hypnotic activity
 - vi) Evaluation of muscle relaxant activity
 - vii) Evaluation of anticonvulsant activity
4. Screening of anti-inflammatory drugs and analgesics.
5. Use of physiograph (students' and biopac).
6. Introduction to pharmacoepidemiological studies.
7. Prescription studies.

Books Recommended (Latest editions unless specified):

1. H.G. Vogel and W.H. Vogel, Drug Discovery and Drug Evaluation. Pharmacological Essays, 2nd Edition, Springer Verlag, Berlin, Germany.
2. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd Edition, Scientific Bookagency, Kolkata, India.
3. D.R. Laurence and A.L. Bacharach (Eds.), Evaluation of Drug Activities Pharmacometrics Vol. I and II, Academic Press London, U.K.
4. P. Mantegazza and F. Piccinini (Eds.), Methods in Evaluation, North Holland Publishing Company, Amsterdam, The Netherlands.
5. A.A. Rubin (Ed.) New Drugs Discovery and Development, Marcel Dekker Inc., New York, U.S.A.
6. Journal of Pharmacological and Toxicological Methods, Elsevier Science Inc., New York, U.S.A.
8. Kulkarni, S. K. Handbook of Experimental Pharmacology, (Vallabh Prakashan, New Delhi).

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**PHL515 Advanced Pharmacognosy-I :
Pharmacognosy and Phytochemistry**

3 Credits (3-0-0)

1. Study of plants and plant products having following types of biological activity :

- 1.1 Anti-inflammatory
- 1.2 Antihyperlipidemic
- 1.3 Anticancer
- 1.4 Antidiabetic
- 1.5 Hepatoprotective
- 1.6 Adaptogenic and immunomodulating
- 1.7 Antimalarial

2. Biological active compounds from marine sources

3. Toxic/ Poisonous plants

4. Plant allergens

5. Isolation and Estimation of

Clove oil	Atropine
Curcumin	Vinca alkaloids
Podophyllotoxin	Taxol
Quinine	Sennosides
Glycyrrhizin	Starch

Recommended Reading Material (Latest editions unless specified):

1. Trease and Evans, Pharmacognosy, Ed., W.C. Evans, Gopsons Papers Ltd., Noida, India.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia.
3. Various Journals like Journal of Ethnopharmacology, Phytotherapy Research, Journal of Natural Products, Pharmaceutical Biology, Journal of Medicinal and Aromatic Plants, Fitoterapia, etc.
4. Phytochemical Methods: J. B. Harborne.
5. Herbal Drug Industry: R. D. Chudhary, Eastern Publishers, New Delhi.

PHL516: Advanced Pharmacognosy – II: Plant Drug Cultivation

3 Credits (3-0-0)

1. **Scope of plant drug cultivation.** Problems of cultivation and processing medicinal and aromatic plants
2. **Introduction to important properties of soils.** General constitution of soils, Texture and soil structure, Characteristics and behavior of soil water, Practical significance of organic and inorganic soil colloids, importance of organic matter of soil, Essential elements for plant growth; Fertilizers and their management.
3. **Problems and recent trends in pest management:** Scope of biological control and use of Environment friendly pesticides especially plant derived products. Discussion on synthetic and natural pyrethroids, pheromones and juvenile hormones.
4. **Plant growth regulators:** Understanding of biochemical and physiological aspects of different classes of plant growth regulators. Effect of growth hormones on production of secondary plant metabolites.
5. **Cultivation Management :** Steroid yielding plants especially Dioscorea, Tropane alkaloid producing plants, Cinchona, Opium, Digitalis, Senna, Plantago, Mentha, lemon grass and Vetiver grass.
6. **Plant tissue culture**
 - 6.1 Callus cultures, suspension cultures, protoplast cultures and immobilization.
 - 6.2 Regeneration of plants from tissue cultures.
 - 6.3 Biosynthetic potential of tissue cultures and factors affecting production of secondary metabolites by tissue culture technique.

Recommended Reading Material (Latest editions unless specified):

1. Cultivation and utilization of Medicinal Plants, Eds., C.K. Atal and B.M. Kapur, R.R.L., Jammu.
2. Cultivation and Utilization of Aromatic Plants, Eds., C.K. Atal and B.M. Kapur, R.R.L., Jammu.
3. Psyllium Production and Marketing in India, D.P. Mathur, B. Rangarajan and V.K. Gupta, Oxford and IBH Publishing Co., New Delhi.
4. Markets for selected Medicinal Plants and Their Derivatives, International Trade Centre, UNCTAD / GATT, Geneva.
5. Natural Products for Innovative Pest Management, Eds, David L., Whitehead and William S., Bowers, Pergamon Press, Oxford.
6. The Nature and Properties of Soils, Hyle C. Brady, Macmillian Publishing Co., N.Y.
7. H.E. Street, Botanical Monographs, Vol. II, Plant Tissue and Cell Culture, Blackwell Scientific Publication, London.
8. J. Reinert and Y.P.S. Bajaj, Applied and Fundamental Aspects of Plant Cell, Tissue and Organ Culture, Narosa Publishing House, New Delhi.
9. Journal of Medicinal and Aromatic Plant Sciences.

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PHP518: Advanced Pharmacognosy - III

4 Credits (0-0-4)

Extraction, isolation and purification of bioactive phytoconstituents such as:

- 1.1 Curcumin
- 1.2 Piperine
- 1.3 Glycyrrhizin
- 1.4 Caffeine
- 1.5 Hesperidin
- 1.6 Berberine
- 1.7 Vasicine
- 1.8 Sennosides
2. Exercises on standarization and quality control of plant drugs.
3. Plant tissue culture.

PHL 519: Modern Pharmaceutical Techniques-I

3 Credits (3-0-0)

1. Electrophoresis: Moving boundary electrophoresis, zone electrophoresis, isotachopheresis, isoelectric focusing and immunoelectrophoresis, 2D Gel electrophoresis, Continuous electrophoresis (preparative) applications.
2. Statistical Analysis:- Introduction, significance of statistical methods. Normal distribution. Degrees of freedom. Measures of variation - standard deviation, Non linear regression, iteration methods. Analysis of variance. Standard error. Test for statistical two ways ANOVA and multiple comparison procedures. Study of various software's used in statistical analysis
3. Thermal Analysis:- Theory, Instrumentation and Application of Thermogravimetric Analysis, Differential Thermal Analysis. Differential Scanning Calorimetry.
4. Extraction, isolation, identification (By chemical tests, TLC, HPTLC, HPLC) and characterization of bioactive compounds of following classes
 - i. Alkaloid
 - ii. Flavonoids
 - iii. Glycosides
 - iv. Steroids
 - v. Triterpenoids
5. Role of plant tissue culture in production of secondary metabolites.
6. Immunochemical Techniques – Immunoelectrophoresis, Immunoprecipitation, ELISA, Radio-immuno assays. Southern blot and northern blot assays.
7. Bioassays: in- vitro and in-vivo techniques. Bioavailability and bioequivalence testing: Definitions, in-vitro and in-vivo bioavailability testing
8. Basic Biotechnological and Molecular Biology Techniques: for Diagnosis and Treatment: Isolation of DNA & RNA. Amplification of Genes by PCR. Recombinant DNA technologies. Various cloning vectors including plasmids and bacteriophages. Hosts for cloning vectors. Monoclonal antibody production and other practical applications.
9. Lyophilization: Principles and Practice of freeze-drying. Freeze drying equipment.
10. Spheronization: Introduction, extrusion - spheronization methods, Formulation, Process variables, evaluation of pellets, Equipment.
11. Stability Testing: Stability testing of drug substances, stability testing protocols, shelf life determination. Photo-stability testing. Post approval changes. Packaging influence on stability, ICH guidelines.

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Books Recommended (Latest editions unless specified):

1. Silverstein. Basseler, Moiril–Spectrometric identification of organic compounds (John Wiley and Sons, N.Y)
2. Willard, Merit, Dean–Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi).
3. Higuchi: Instrumental Methods of Analysis (CBS Publishers).
4. Analytical Chemistry by open learning series.
5. Wim kok: Capillary Electrophoresis: Instrumentation and Operation
6. R. J. Hamilton–Introduction to High Performance Liquid chromatography, (Chapman and Hall, London).
7. Pharmaceutical dosage forms, Lachman et. al., Tablets, Volumees I, II, III.
8. Pharmaceutical dosage forms, Lachman et. al., Parenterals, Volumes I and II,
9. Ewing-Instrumental Methods of Chemical Analysis (McGraw Hill Book Co., New York).
10. Various pharmacopoeias
11. Practical Pharmacognosy: Kokate C. K., Vallabh prokashan, New Delhi.
12. Practical Pharmacognosy: Khndelwal K.R.. Nirali Prakashan Pune.
13. Phytochemical methods: J. B. Harborne
14. Thin layer chromatography: Stahl.
15. J.T. Carstensen, Drug Stability: Principles and Practices, Marcel Dekker, N.Y.

PHL 520: Advanced Pharmaceutical Chemistry – IV: Drug Designing

3 Credits (3-0-0)

1. Drug designing: Introduction, Trends in Lead Identification. Structure based and Ligand based drug designing.
 - 1.1 Three dimensional structure aided drug design, Methods to obtain three-dimensional structures: Crystallography, Nuclear Magnetic Resonance and Homologous Modeling.
 - 1.2 Peptides, nucleotides, lipids and carbohydrates as lead sources
 - 1.3 Examples of Structure Aided Drug Design: Design of inhibitors for angiotensin converting enzyme (ACE), Renin & HIV Protease.
- 2. Drug Receptors**
 - 2.1 Concept of receptors and receptor theories.
 - 2.2 Molecular biology of receptors: Important structural features in G- protein coupled receptors and ion channel linked receptors.
 - 2.3 Receptors binding assays: Membrane receptor assay.
- 3. Drug Target Binding Forces**
 - 3.1 Energy components for intermolecular non-covalent interactions in gas phase.
 - 3.2 Thermodynamics of association in gas phase and solvation effects.
 - 3.3 Examples of drug receptor interactions: Biotin- avidin. Dihydrofolate reductase-trimethoprim. DNA-intercalators.
- 4. Analog Design**
 - 4.1 Strategies of Analog Design: Bioisosteric replacement, rigid analogs, homologation of alkyl chains, alteration in chain branching, ring size and ring position isomers,
 - 4.2 Alteration in stereochemistry fragments of lead molecules, variation in inter-atomic distances.
- 5. Computer Aided Molecular Modeling in Drug Design.**
 - 5.1 Basics of Molecular mechanics. Applications of quantum mechanics to molecular mechanics. Energy minimization, geometry optimization, conformational analysis
 - 5.2 Molecular Graphics. Scope and Limitations of molecular modeling, Design of ligands for known receptors: Characterization of site, design of ligands and calculation of affinity.
 - 5.3 Design of Ligands for unknown Receptors: Pharmacophore versus binding site models. Searching for similarity. Molecular comparisons and finding common patterns
- 6 Quantative Structure Activity Relationships:**
 - 6.1 Parameters of describe intermolecular forces of drug receptors interaction
 - 6.2 Topological and topographical descriptors
 - 6.3 Quantitative Models: Hansch analysis. Free Wilson analysis. Other QSAR approaches and their applications.
 - 6.4 Statistical Methods: Regression analysis. Partial least squares (PLS) analysis.
 - 6.5 3D- QSAR Approaches: Comparative Molecular Field Analysis (COMFA) and COMSIA

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7. Rational Design of Enzyme inhibitors

- 7.1 Enzyme inhibitors in medicine and basic research.
- 7.2 Rational Design of non-covalently binding enzyme inhibitors: Forces in formation of enzyme-inhibitor complexes. Rapid reversible inhibitors. Transition state analogs. Multi-substrate inhibitors.
- 7.3 Rational design of covalently binding enzyme inhibitors: Mechanism based inhibitors. Affinity labels. Pseudo- irreversible inhibitors.

8. Peptidomimetic Drug Designing

- 8.1 Introduction. Non-peptide ligands for peptidic receptors, .Constrained amino acids : α -Methylated amino acids. α , α - dialkylglycine and aminocycloalkane carboxy acids. N^{α} - C^{α} Cyclized amino- acids. N-Methylated-aminoacids, and aminocycloalkane carboxylic acids. Unsaturated amino acids. Dimethyl and β - methylamino acids. Substituted 2,3 methanamino acids. Cyclization of peptides.
- 8.2 Amide bond isosters: Retro-inverse modifications. Reduced amide bonds. Methylene, thioether and methylene sulfoxide. Methylene ether. Ethylene thioamide. trans-olefin, Ketomethylene. 1, 5- Disubstituted tetrazole ring.

9 Oligonucleotide Therapeutics

- 9.1 Introduction, Antisense oligonucleotides..
- 9.2 Mechanism of oligonucleotides interactions with nucleic acids, oligo- nucleotide stability.
- 9.3 Medicinal Chemistry of oligonucleotides: Heterocyclic modifications, enhanced cellular uptake, cleavage reagents, sugar and backbone modifications

Books Recommended:

1. Manfred E Wolff, (ed), Burger's Medicinal Chemistry and Drug Discovery, Vol.-I Principles and Practice, 5th Ed., John Wiley and Sons, 1995.
2. J. G Vinter and Mark Gardner, (Eds.) Molecular Modelling and Drug Design, The Macmillan Press Ltd., London, U.K., 1994.
3. C. Hansch, A. Leo and D. Heokman, Exploring QSAR: Applications in Chemistry and Biology, ACS Professional Reference Book, American Chemical Society, Washington U.S.A., 1995.
4. Comprehensive Medicinal Chemistry, Pergamon Press, 1990, Vol. 4.
5. Medicinal Chemistry for the 21st Century, Edited by C.G. Wermuth, Blackwell Scientific Publications, Oxford, 1992.
6. Pseudopeptides in Drug Discovery, Edited by P.E. Nielson, Wiley-VCH, 2004.
7. Introduction to the Principles of Drug Design and Drug Action, Edited by H.J. Smith, Taylor and Francis, 2006.
8. The Organic Chemistry of Drug Design and Drug Action, 2nd edition, R.B. Silverman, Academic Press, 2006.
9. Molecular Modeling in Drug Design, Edited by N.C. Cohen, Elsevier, 2006.

PHL521: Advanced Pharmaceutical Chemistry –V: Current Pharmaceutical Chemistry

3 Credits (3-0-0)

Structure, Physicochemical properties, Structure activity relationships, Mode of action and Applications (**Synthesis Excluded**) of the following classes of drugs:

1. Antibacterial

Introduction, Development of resistance to known antibacterials and search for new drugs. Bacterial DNA-gyrase inhibitors - Mode of action of fluoro-quinolones and development of newer analogues: Trovafloxacin, Levofloxacin, Gratifloxacin, Moxifloxacin. Angucyclines: Urdamycinone, Aquayamycin. Redesigned Vancomycins. Carbapenams, Carbacephams. Oxazolidinones: Linezolid, eperzolid. Inhibitors of DNA Synthesis: Quinupristin, Rifampicin, Dalforpistin. Glycopeptides. Macrolides.

2. Anti-cancer

Topoisomerase inhibitors: Doxorubicins, Camptothecins. , Telomerase Inhibitors. Antimitotic agents. Tubulin interacting agents: Taxol, Paclitaxel, Vinca alkaloids, Bleomycin .Anti-cancer enediyne antibiotics: Neo-carzinostatin and analogues. DNA-intercalators: Acridines, bis-acridines and other tethered polycyclic aromatics. DNA-threading agents: indenoisoquinolines. Tumor necrosis factor converting enzyme (TACE) inhibitors. Targetting apoptosis inhibitors to make chemotherapy more effective. Anti cancer drugs for crossing BBB. Photodynamic therapy. Hormonal therapy

3. Cardiovascular drugs:

Anti-hypertensives: Designing of ACE & AT1 inhibitors – Captopril, Enalapril, Enalaprilat, Lisinpril, Losartan; -blockers, -blockers and , -blockers – Atenolol, Metprolol and analogues, Carvedilol, Prazosin, Trazocin, Labetelol; Calcium Channel blockers: 1,4-dihydropyridines (Nifedipine, Nimodipine, Nicardipine), Verapamil, Diltiazem. Lipid lowering and anti-clotting agents – Statins eg., Atorvastatin, Zucor, Rosuvastatin; Aspirin, Lipitor, Gemfibriogel, abciximab, Probucol, , clopidgrel. Clot busters: Urokinase, Streptokinase, Alfineprase. Anti – arrhythmic agents: Amidorane, Digoxin, Flecainide, Mexiletine, Tocainide, Lidocaine.

4. Antiviral :

Anti-HIV agents: HIV-protease inhibitors, SAR, Amprenavir, Fosamprenavir, Atazanavir. Anti-HIV- Nucleosides: Lamivudine, Retrovir, Videx, Hivid, Zerit, Viread, HEPT, TIBO, Delaviridine, Ziduvudine, Efavirenz, Mixed type- Integrase and Protease inhibitors. Calanolide, Capravine, Nevirapine, Neuramidase inhibitors: Oseltamivir phosphate (Tamiflu), Zanamvir (Relenzes), Rilipvine, Valganciclovir. Aminodiols. Capsid binders: Disoxaril, Pieconaril, Pirodavidir. DNA-polymerase inhibitors: Acylcovir, Ganciclovir, Penciclovir, Famciclovir, Valaciclovir, Valomaciclovir, Cidofvir.

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5. Anti-malarials

Mechanism of action of Antimalarials, Resistance to Anti-malarials. Targets for antimalarials, Endoperoxide anti-malarials: Artemisinin and analogues – artemether, arteether, artesunate, artelinic acid. Glutathione inhibitors as Anti-malarials. Lumifantrine. Biguanides: Proguanil, Chlorproguanil, Pyrimethamine. New antimalarial alkaloids: Febrifugine. Quinoline base antimalarials – recent advancements. Naphthoquinones: Atovaquone. Iron Chelating agents: Desferrioxamine. Antimalarial antibiotics. Antimalarial vaccine development program.

6. NSAIDs

Selective COX-2 inhibitors-Computer aided designing, Molecular docking and 3D QSAR, design of selective inhibitors using pharmacophore models. Nimesulide and methanesulfonamides, 1,5- Diarylpyrazoles: Celecoxib, Rofecoxib, Valdecoxib, Atoricoxib, Celebrex. 1,2-Diarylpyrroles. 1,2- Diarylimidazoles, Diarylspiro[2.4]heptenes, Indomethacin and analogues. Terphenyls, Aryl-/hetero-arylpropionic acid derivatives. (S)-Etorolac, (S)-Ketorolac.

7. Antifungal:

Introduction, Mechanism of action of anti-fungal agents. Problems of anti fungal therapy and resistance, and recent advancements: Azoles: Clotrimazole, Miconazole, Ketoconazole, Fluconazole, Itraconazole, Voriconazole, Ravuconazole, Posaconazole. Echinocandins: Echinocandin B, Cilofungin, Anidulafungin, Caspofungin, Micafungin. Polyenes: Amphotericin B, Nystatin, Pimiracin. Allylamines, Thiocarbamates. Butenafine, Amorolfine, Soradins; Sordaricin Griesofulvin. Flucytosine. Chromone derivatives.

Reading Material Recommended: (Latest editions unless specified):

- 1) L.A. Mischer, Chem. Rev. 2005, 105, 559-592.
- 2) Y. Pommier, A.A. Johnson, C. Marchand, Nat. Rev. Drug Discovery, 2005, 4, 236-248.
- 3) C. H. Wermuth, "The Practice of Medicinal Chemistry", Academic Press, London, 1969, 264.
- 4) The Quinolones, 2nd Edition, Edited by V.T. Andriole. Academic Press, 1998
- 5) Cancer Chemotherapeutic Agents. Edited by W.O. Foye, American Chemical Society, 1995.
- 6) E. Hamel. Med. Res. Rev., 1996, 16, 207-231.
- 7) Introduction to the Principles of Drug Design and Drug Action, Edited by H.J. Smith, Taylor and Francis, 2006.
- 8) A. Brik and C.H. Wong, Org. Biomol. Chem. 2003, 1, 5-14.
- 9) J. Med. Chem., 2002, 45, 4847-4857.
- 10) J. Med. Chem., 1995, 38, 404-424
- 11) J. Med. Chem., 1995, 38, 395-407

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- 12) Anticancer Drug Design, 1999, 14, 1-9, 19- 36, 265-274, 275-88, 327-339, 341-347, 349-354.
- 13) J. Med. Chem., 1997, 50, 1347-1365, 1619-1633; 2000, 43, 775-77, 3168-3185; 2001, 44, 3932-3936; 2002, 45, 4816-482, 841-852, 5430-5439; 2003, 46, 1372-1382
- 14) Chem. Rev. 2005, 105, 3235-3277,
- 15) Angew. Chem. Int. Edn., 2002, 41, 3767; 2005, 44, 7469-7473.
- 16) Current reviews on selected topics.

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PHP523: Modern Pharmaceutical Techniques - II

4 Credits (0-0-4)

1. Experiments based on HPLC
2. Isolation of DNA & RNA. Separation by electrophoresis.
3. Evaluation of Analgesic, Anticonvulsant, Anti-inflammatory, Anti-anxiety, anti-depressants, anti-ulcer activities and Effects on HR and ECG.
4. Extraction, isolation, identification (By chemical tests, TLC, HPTLC, HPLC) and characterization of bioactive compounds of following classes
 - i. Alkaloid
 - ii. Flavonoids
 - iii. Glycosides
 - iv. Steroids
 - v. Triterpenoids
5. Chemical kinetics and stability testing of different drug formulations to determine shelf life and any other experiments involving pharmaceutical techniques.

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PHP524: Advanced Pharmaceutical Chemistry –VI

4 Credits (0-0-4)

Multi-step Synthesis of Organic Medicinal Compounds and Intermediates Their chromatographic (Preparative layer, Column, Flash, Chromatotron and HPLC-semi-reparative) purification and spectroscopic characterization.

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**PHL525: Advanced Pharmaceutics IV:
Biopharmaceutics and Advanced Pharmacokinetics**

3 Credits (3-0-0)

1. **Biopharmaceutics and Pharmaceutical Bioequivalence :**
 - 1.1 Bioequivalence and its determination, Bioequivalence and therapeutic equivalence, study design for the assessment of bioavailability & Bioequivalence, factors influencing bioavailability & bioequivalence, intestinal metabolism & bioavailability, bioavailability of transdermal & topical dosage forms, in-vitro and in-vivo correlation to determine bioavailability, statistical concepts used in estimation of bioavailability and evaluation of bioequivalence.
 - 1.2 Pharmacodynamic models in bioequivalence.
 - 1.3 Regulatory agencies and bioequivalence testing
2. **Concept of Chronopharmacokinetics and its evaluation**
3. **Toxicokinetics :**
 - 3.1 Role of toxicokinetics in drug safety evaluation
 - 3.2 Importance of toxicokinetics in pre-clinical evaluation of drug safety.
 - 3.3 Interspecies scaling in toxicokinetics and risk assessment.
 - 3.4 Pharmacodynamic aspects of toxicokinetics
 - 3.5 Gastrointestinal toxicity
 - 3.6 Renal toxicity
4. **Non-Linear Pharmacokinetics:**

Introduction, Recognition of non-linearity and the tests employed. Computation of non-linear pharmacokinetic parameters (V_m , K_m , AUC etc) from time course and AUC of drug being eliminated by single Michaelis-Menten kinetics. One compartment and two compartments open models with Michaelis-Menten kinetics.
5. **Pharmacokinetics of Drugs and pharmacological response:**
 - 5.1 Introduction to relationship between pharmacodynamics and pharmacokinetics.
 - 5.2 Relationship between duration of response and dose, elimination half life and drug distribution.
 - 5.3 Pharmacodynamic models used in the study of relationship between kinetics and response of drugs, analysis of clinical relevance of kinetic studies.
6. **Protein Binding:**

Theory of plasma protein binding and implications, elements of scatchard, klotz and Rosenthal analysis for computation of binding parameters, experimental techniques to determine protein binding with their merits and limitations, factors influencing protein binding, effect of binding on drug pharmacokinetics.
7. **Computer use in Pharmacokinetics :**
 - 7.1 Introduction
 - 7.2 Strategy for the building of Pharmacokinetic models
 - 7.3 Digital computers
 - 7.4 ADME

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- 7.5 Critical evaluation of computer fits
- 7.6 Study of some computer software's such as AUTOANI, AUTOAN2, CSTRIP, NONLIN, NONMEM, MACDOPE , TOPFIT etc.
- 7.7 Advanced mathematical techniques to determine area under curve.
- 8. Statistical Modeling

Reading Material Recommended:

- 1. J.G. Wagner, Fundamentals of Clinical Pharmacokinetics, Drug Intelligence Publications, Hamilton, USA., 1971.
- 2. J.G Welling, F. L. S Tse and S. V Dighe (eds.), Pharmaceutical Bioequivalence, Marcel Dekker Inc. New York, USA, 1991.
- 3. M. Gibaldi and D. Perrier, Pharmacokinetics, Second Edition, Marcel Dekker Inc. New York USA, 1982.
- 4. L. Shargel and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT, 1993.
- 5. M. Rowland & T. N. Tozer, Clinical Pharmacokinetics: Concepts and Applications, Henry, UK 1995.
- 6. yacobi, J. P Skelly and V. K Batra (ed) Toxicokinetics and New Drug Development, Pergamon Press, New York, USA, 1989.
- 7. Veng Pedersen, Linear and Nonlinear System Approaches in Pharmacokinetics: How much do they offer? (General Consideration), J. Pharm. Biopharm 16 (4), 413-472, 1988.
- 8. Veng Pedersen, Linear and Nonlinear system approaches in pharmacokinetics: How much do they offer ? II (The RMO Approach), J. Pharm. Biopharm. 16(5). 543-571, 1988.
- 9. R.E. Notari, Biopharmaceutics and Clinical Pharmacokinetics – An Introduction, 4th Edition, Marcel Dekker, N.Y., 1987

MASTER OF PHARMACY (SEMESTER-II)
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**PHL526: Advanced Pharmaceutics V:
Pharmaceutical Technology and IPR Management**

3 Credits (3-0-0)

1. Pharmaceutical Technology:

Improved tablet production systems: Benefits, production, process design considerations, materials handling, processing step combination and elimination, unit operation improvement, tablet production equipments.

Tablet Production: Layout of facilities, materials flow, design of facilities, construction consideration, equipment consideration, material management

Coating Techniques : Advances in coating process, coating equipments. Fluid bed coating, particle coating, techniques and problems.

Spray Drying: Introduction, advantages, equipment, process variables, applications

Processing of small volume parenterals and related sterile products: Planning and scheduling , material and personnel management, documentation control, Facilities-AHU's, humidity and temp controls, air filtration systems, dust collectors etc. manufacturing, SVP solutions, suspensions, powders/freeze dried powders for reconstruction, filling sealing, inspection and labelling.

Manufacture of LVPS: Raw materials, stability , storage and inventory control, batch mixing, clarification by membrane filters and support systems.

Environmental factors in the Design of Parenteral production facilities: Site selection, facility area use planning including type of production line environmental control needs and product characteristics, environmental control zone groupings and functional groupings, design concepts

2. IPRs (Intellectual Property Rights) Management: Introduction to Intellectual Property concepts. : Types, importance for pharma industry, global treaties of relevance to pharma industry.

Practical aspects of IPRs: Patenting in India - some practical aspects. e.g.conducting a prior art search , drafting of a patent application, claims-key aspects etc., components of a patent application in India, regional routes, Patent infringement and Litigation in pharma-case studies, Integration of IPRs in to research, for enhancing efficiency and productivity.Commercialization of Research- some practical aspects. eg drafting of a technology offer, networking with specialized agencies, MOUs, do's and don'ts etc.

Transfer of Technology (TOT): Its significance in Pharma sciences and industry; IPR and technology management as key components of strategic R &D and business planning; Funding sources for IPR / TOT related activities – incentives for pharma industry, IPR, TOT new career opportunities for pharma professionals, global demand and supply in the respect to human resources in IPR / TOT.

Ethics in IPRs- Positive and negative aspects of patenting, conflicts in IPR, drug related controversies-case studies, traditional knowledge, life forms and crops, current global strategies and solutions.

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Reading Material Recommended (Latest editions unless specified):

1. Pharmaceutical Dosage forms. Lachman et al., Tablets, Volume I, II, III, 1982.
2. Pharmaceutical Dosage forms. Lachman et al., Parenterals, Volume I, II, 1984
3. Technology Transfer –making the most of your intellectual property by Neil F. Sullivan
4. Intellectual Property: Patents, trademarks, and Copyright (Nutshell Series) by Arthur R. Miller and Michael H. Davis.
5. Technology Transfer – Dependence and Self Reliant Development in the third world: The Pharmaceutical and Machine tool industries in India by Sunil K. Sahu.
6. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad, 2008
7. Sanjay Kumar Jain , Vandana Soni Bentley's Textbook of Pharmaceutics. Elsevier India 2012.
8. Jain N.K. Pharmaceutical Product Development. CBS Publisher & Distributors P Ltd. 2011.
9. Linda Felton Remington: Essentials of Pharmaceutics. Pharmaceutical Press; 1 edition. 2013

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PHP528: Advanced Pharmaceutics VI

4 Credits (0-0-4)

1. Experiments for determination of Pharmacokinetics and Bioavailability based on salivary secretion, urinary excretion and blood levels of drugs in man and animals following peroral, i.v., buccal routes etc.
2. Computation of Pharmacokinetic Parameters using computer programs based on W-N/residual methods, Effect of adjuvants on drug absorption, exercises on Simulation of Pharmacokinetics and establishing in-vitro & in-vivo correlations.

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PHL529: Advanced Pharmacology IV
Clinical Pharmacology and Drug Therapy-II

3 Credits (3-0-0)

- 1. General considerations and drug therapy of renal disorders :**
 - Pharmacology of diuretics
 - Pharmacology of antidiuretics
 - Pharmacology of agents acting on renin angiotensin system
 - Pathophysiology and drug therapy of oedema
 - Pathophysiology and drug therapy of diabetes insipidus
- 2. Drug Therapy of Cardiovascular Disorders:**
 - Pathophysiology and drug therapy of hypertension
 - Pathophysiology and drug therapy of ischemic heart disease
 - Pathophysiology and drug therapy of congestive heart failure
 - Pathophysiology and drug therapy of cardiac arrhythmias
 - Pathophysiology and drug therapy of hypercholesterolemia and dyslipidemia
- 3. Drug therapy of Endocrine disorders :**
 - Pharmacology of corticosteroids
 - Drug therapy of diabetes mellitus
 - Drug therapy of thyroid and parathyroid disorders
 - Drug therapy of infertility and contraception
 - Drugs affecting uterine motility.
- 4. Drug therapy of blood disorders :**
 - Pharmacology of haematopoietic agents, coagulants and anticoagulants, clot busters
 - Pathophysiology and drug therapy of anaemias
 - Pathophysiology and drug therapy of thrombosis
- 5. Drug therapy of infectious diseases:**
 - General principles, sulphonamides, penicillins, cephalosporins, tetracyclins, chloramphenicol, macrolides, fluoroquinolones, aminoglycosides
 - Drug therapy of tuberculosis, leprosy
 - Drug therapy of mycotic infections
 - Drug therapy of viral infections
 - Drug therapy of acquired immuno deficiency syndromeDrug therapy of protozoal infections : malaria
 - Drug therapy of protozoal infections: trypanosomiasis, leishmaniasis, amoebiasis, etc.
 - Drug therapy of helminthiasis
- 6. Drug therapy of neoplastic disorders :**
 - Pharmacology of anticancer drugs

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7. Immunopharmacology :

Elements of immune system

Immunosuppressive agents and their clinical implications

Immunomodulators and their clinical implications

8. Pathobiology and management of following diseases:

Anorexia nervosa and bulimia nervosa

Ischaemia-reperfusion injury

Cystic fibrosis

HIV-related opportunistic infections

Inflammatory bowel disease.

Recommended Reading Material: (Latest editions unless specified):

1. D.G Grahame-Smith and J.K. Aronson, Oxford Textbook of Clinical Pharmacology and Drug therapy, Oxford University Press, New York, U.S.A.,1984.
2. J.G. Hardman and L.E. Limbird (eds.), Goodman and Gilman's : The Pharmacological Basis of Therapeutics, 10th edition, Pergamon Press, New York, U.S.A., 2001.
3. E.T. Herfindal and D.R. Gourley, Textbook of Therapeutics, 6th edition, Williams and Wilkins, London, U.K.,1996.
4. J.T. Dipiro, R.I. Talbert, P.E. Hayers, G.C. Yee and L.M. Possy (eds.), Pharmacotherapy : A Pathophysiologic Approach, Appleton Lange, U.S.A.,1997.
5. T.M. Speight (ed.), Avery's Drug Treatment Principles and Practice of Clinical Pharmacology and Therapeutics, 3rd edition, ADIS Press, Sydney, Australia.

MASTER OF PHARMACY (SEMESTER-II)
(Under Credit Based Continuous Evaluation Grading System)

PHL530: Advanced Pharmacology – V
Current Trends in Pharmacology

3 Credits (3-0-0)

- 1. Molecular Pharmacology:** Receptor occupancy and Basic of cell signaling & cellular signaling systems. Second messengers: cyclic nucleotides, calcium and phosphatidyl inositol, phospholipases and their modulators.
- 2. Pharmacology of receptors:** Classification, cellular signaling systems, pharmacology of agonists and antagonists of the following receptor types:
 - Adrenergic receptors
 - Cholinergic receptors
 - Dopamine receptors
 - Excitatory amino acid receptors (EAA)
 - Serotonin receptors
 - GABA and Benzodiazepine receptors
 - Opioid receptors
 - Purinergic receptors
 - Glutamate receptors
 - Cannabinoid receptors
 - Neurosteroids
- 3. Neuropeptides:** Neuropeptide Y, calcitonin gene related peptide, cholecystokinin, endogenous opioids, substance P, ATP binding cassette proteins family.
- 4. Apoptosis:** Pharmacological implications and therapeutic opportunities.
- 5. Biology of vascular endothelium :** EDRF, EDCF, EDHF, endothelins and nitric oxide
- 6. Chiral pharmacology:** Basic concepts of chirality and chronopharmacology.
- 7. Pharmacogenomics:** Introduction and implications of pharmacogenomic variations in therapeutics.
- 8. Cytokines and chemokines:** Pharmacological, pathological and clinical implications.
- 9. Growth factors and cell adhesion molecules:** Biology and therapeutic implications.
- 10. Gene Therapy:** Basic concept and clinical potentials of gene therapy, nucleic acid therapy, aptamer technology and ribozyme therapy.

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Reading Material Recommended: (Latest editions unless specified):

1. D.G. Grahmae-Smith and J.K. Aronson, Oxford Textbook of Clinical Pharmacology and Drug Therapy, Oxford University Press, New York, U.S.A.
2. J.G. Hardman and L.E. Limited (eds), Goodman and Gilman's : The pharmacological Basis of Therapeutics, 10th Edition, Pergamon Press, New York, U.S.A.
3. E.T. Herfindal and D.R. Gourley, Textbook of Therapeutics, 6th Edition, Wiliams and Wilkins, London, U.K.
4. J.T. Dipiro, R.I. Talbert, P.E. Hayers, G.C. Yee and L.M. Possy (eds) Pharmacotherapy : A Pathophysiologic Approach, Appleton Lange, U.S.A.
5. T.M. Speight (ed), Avery's Drug Treatment Principles and Practice of Clinical Pharmacology and Therapeutics, 3rd Edition, ADIS Press, Sydney, Australia.

Recommended latest edition of the books.

MASTER OF PHARMACY (SEMESTER-II)
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PHP532 Advanced Pharmacology VI

4 Credits (0-0-4)

1. Surgical techniques such as ovariectomy, adrenalectomy and Goldblatt's technique.
2. Experiments to study acute toxicity.
3. Assay of drugs on the blood pressure of anaesthetized animals.
4. Four point bioassay of oxytocin using rat uterus.
5. Enzyme linked immunosorbent assay.
6. Clinical pharmacology experiments using data collected from hospitals, clinics, university health centre etc., ADR monitoring, therapeutic drug monitoring of drugs in biological fluids.
7. Bioequivalence studies of commonly used drugs.
8. Prescription evaluation for rational drug use.
9. Preparation of informed consent forms for clinical studies.
10. Pharmacoepidemiological studies and techniques of statistical analysis.

Books Recommended: (Latest editions unless specified):

1. H.G. Vogel and W.H. Vogel, Drug Discovery and Drug Evaluation. Pharmacological Assays, 2nd Edition Springer Verlag, Berlin, Germany, 1997.
2. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd Edition, Scientific Book Agency, Kolkata, India, 1984.
3. D.R. Laurence and A.L. Bacharach (eds.), Evaluation of Drug Activities: Pharmacometrics Vol.I and II, Academic Press London, U.K., 1964.
4. P. Mantegazza and F. Piccinini (eds.), Methods in Evaluation, North Holland Publishing Company, Amsterdam, The Netherlands, 1966.
5. A.A. Rubin (ed.) New Drugs Discovery and Development, Marcel Dekker Inc., New York, U.S.A., 1978.
6. David R. Gross, Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, U.K., 1994.
7. Journal of Pharmacological and Toxicological Methods, Elsevier Science Inc., New York, U.S.A.
8. Turner R.A., Screening Methods in Pharmacology, Academic Press, London.

MASTER OF PHARMACY (SEMESTER-II)
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PHL533: Advanced Pharmacognosy –IV: Drug Development from Natural Sources

3 Credits (3-0-0)

1. **Natural Products as Drugs:** Historical background, present status and future scope of natural products in drug discovery.
2. **Model Approaches of Drug Discovery from Natural Sources**
 - 2.1. Lipinski's rule and role of natural products in drug discovery.
 - 2.2. Different approaches to drug discovery: Rational (sense), irrational (non-sense) and antisense approach.
 - 2.3. Selection of natural sources for drug development based on random approach, phytoconstituents and ethnopharmacological records.
 - 2.4. Advanced screening technology for natural products: Introduction to high throughput screens and natural product libraries.
 - 2.5. Synergy principle in herbal drugs.
 - 2.6. Preparation of plant material for biological evaluation (preliminary treatment of material, preparation of extracts and enrichment of constituents, dose and mode of administration for pharmacological screening).
 - 2.7. Bioactivity directed fractionation
 - 2.8. Applications, advantages and limitations of various separation techniques (column chromatography, centrifugally accelerated chromatography, HPLC and MPLC) for isolation of lead molecules.
 - 2.9. Recent developments in natural products.
3. **Discovery of Lead Molecules from Natural Sources and their Contribution to Modern Therapeutics with Reference to following:**
Aspirin, morphine, vinca alkaloids, podophyllum lignans, silymarin, quinine, artemisinin, -lactam, statins, calanolides, digitalis glycosides and cannabinoids.

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4. Ensuring identity, quality, purity and uniformity in therapeutic efficacy of crude drugs, extracts, fractions, pure isolates and formulations.
5. Intellectual property rights governing discovery and development of drugs from natural sources.

Reading Material Recommended: (Latest editions unless specified):

1. Harvey AL. Ed. *Advances in Drug Discovery Techniques*. John Wiley and Sons, New York. Latest Edition.
2. *Journal of Ethnopharmacology* (1996). Vol. 51 (1-3 special issue).
3. Grabley S. and Thiericke R. Eds. *Drug Discovery from Nature*. Springer-Verlag, Berlin Heidelberg. Latest Edition.
4. Vogel HG and Vogel WH. *Drug Discovery and Evaluation*. Springer-Verlag, Berlin. Latest Edition.
5. Kaufman PB, Warber CS, Duke JA and Brielmann HL. Eds. *Natural Products from Plants*. CRC Press, Florida. Latest Edition.
6. Williamson EM, Okpako DT and Evans FJ. Eds. *Selection, Preparation and Pharmacological Evaluation of Plant Material*. John Wiley and Sons, New York. Latest Edition.
7. Hostettmann K, Hostettmann M and Marston A. *Preparative Chromatography Techniques: Applications in Natural Product Isolation*. Springer-Verlag, Berlin. Latest Edition.
8. WHO guidelines on relevant topics.

MASTER OF PHARMACY (SEMESTER-II)
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**PHL534: Advanced Pharmacognosy –V:
Plant Drug Standardization**

3 Credits (3-0-0)

1. **Factors Affecting Quality of Plant Drugs:** Moisture, temperature, light, oxygen, living organisms. Storage of drugs.
2. **Crude drug adulteration**
 - 2.1 Microbial contamination, toxic residues and radioactive contamination
3. **Methods of standardization and quality control of plant drugs**
 - 3.1 Organoleptic methods including gross morphology, sampling, preliminary examination and foreign matter.
 - 3.2 Physical methods.
 - 3.2.1 Solubility, Specific gravity, Optical rotation, Specific rotation, Refractive index, Melting point, Swelling index, Foaming index and Bitterness value.
 - 3.2.2 Moisture content : Different methods of moisture determination
 - 3.2.3 Ash Values : Methods of determination of ash values.
 - 3.2.4 Extractive values and determination of volatile oil
 - 3.2.5 Fluorescence analysis.
 - 3.2.6 Chromatographic analysis
 - 3.3 Chemical methods
 - 3.3.1 Qualitative chemical tests.
 - 3.3.2 Microchemical tests.
 - 3.3.3 Quantitative chemical tests : Acid value, Iodine value, Saponification value, Ester value, Unsaponifiable matter, Acetyl value, Volatile acidity and chemical assay.
 - 3.4 Microscopic methods.
 - 3.4.1 General microscopy
 - 3.4.2 Histochemistry
 - 3.4.3 Quantitative microscopy : lycopodium spore methods, Palisade ratio, stomatal number, stomatal index, veinlet number of veinlet termination number.
 - 3.5 Biological evaluation
 - 3.6 Microbial Evaluation
 - 4.6.1 Determination of microorganisms in medicinal plant materials.
 - 4.7 Miscellaneous methods
 - 4.7.1 Spectroscopic methods
 - 4.7.2 Radioimmunoassays.
5. **Determination of toxic residues.**
 - 4.1 Pesticide residues.
 - 4.2 Arsenic and heavy metals.

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RECOMMENDED READING MATERIAL: (Latest editions unless specified):

1. Guidelines for the Assessment of Herbal Medicines – WHO Report, Geneva, 1991, Fitoterapia LXIII, 105-110.
2. Quality Control Methods for Medicinal Plant Material WHO/PHARM/92, 559/rev, pp 1-84.
3. Trease and Evans, Pharmacognosy, Ed., W.C. Evans, 14th Edn., Gopson Paper Ltd., Noida, India 1997.
4. Pharmacopoeia of India, Govt. of India Ministry of Health and Family Welfare, Delhi 1996.
5. British Pharmacopoeia, Her Majesty's Stationary Office, London, 1993.

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PHP 536: Advanced Pharmacognosy – VI

4 Credits (0-0-4)

1. Exercises on standardization and quality control of plant drugs using microscopic, spectroscopic and chromatographic techniques.
2. Preparation of detailed monograph of at least one medicinal plant covering taxonomy, phytochemical and pharmacological investigation and its use in traditional system of medicine.

Books Recommended:

1. Guidelines for the Assessment of Herbal Medicines – WHO Report, Geneva, 1991,
2. Quality Control Methods for Medicinal Plant Material WHO/PHARM/92, 559/rev, pp 1-84.
3. Trease and Evans, Pharmacognosy, Ed., W.C. Evans, 14th Edn., Gopson Paper Ltd., Noida, India 1997.
4. Pharmacopoeia of India, Govt. of India Ministry of Health and Family Welfare, Delhi 1996.
5. British Pharmacopoeia, Her Majesty's Stationary Office, London, 1993.
6. Williamson EM, Okpako DT and Evans FJ. Eds. Selection, Preparation and Pharmacological Evaluation of Plant Material. John Wiley and Sons, New York. Latest Edition.
7. Hostettmann K, Hostettmann M and Marston A. Preparative Chromatography Techniques: Applications in Natural Product Isolation. Springer-Verlag, Berlin. Latest Edition.
8. WHO guidelines on relevant topics.

MASTER OF PHARMACY (SEMESTER-III)
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PHL 539: ADVANCED PHARMACEUTICS (Elective)

3 Credits (3-0-0)

1. **Dissolution and IVIVC:** Dissolution: Factors influencing Drug Dissolution from Dosage Forms, Dissolution Testing of pharmaceutical dosage forms, Types of dissolution apparatus, *In Vitro-In Vivo* correlation, varied IVIVC approaches with applications and limitations, BCS classification and its importance,
2. **Polymers in drug delivery:** Applications of carbopol, PVP, PVA, PLGA, chitosan, ethylvinyl acetate copolymer, ethylcellulose, alginates and HPMC in dosage form design
3. **Controlled Drug delivery:** Introduction of sustained and controlled drug delivery systems, Rationale of CR delivery, physicochemical and biological factors influencing design and performance of CR products, evaluation of controlled release products, study of marketed controlled release formulations.
4. **Carrier Approach in Drug Delivery:** An introduction to delivery systems including liposomes, transfersomes, niosomes, micro- and nanoparticulate systems, microemulsions, self emulsifying drug delivery systems (SEDDS).
5. **Regulatory Considerations:**
Intellectual property rights, various mechanisms and emerging importance of IPRs
Different phases of India's evolving patent regime, Indian Patent Act 1970 and recent amendments in the Indian Patent Act, Indian patent filing and International patent filing through PCT.
Trade Related Aspects of Intellectual Property Rights (TRIPs) and public health issues
Registration applications for marketing approval (IND, NDA, ANDA).
6. **Pharmaceutical Additives :**Recent advances in pharmaceutical additives (surfactants, co-surfactants, stabilizers, superdisintegrant, Emulsifier)

Books Recommended:

1. Handbook of Pharmaceutical Excipients. Second Edition. Aniley Wade and Paul Weller Eds. The Pharmaceutical Press, London. 1994.
2. Excipients and Delivery Systems for Pharmaceutical Formulations. D.R. Karsa and R.A. Stepensan Eds. The Royal Society of Chemistry, Cambridge. 1995.
3. Pharmaceutical Dissolution Testing. Jennifer Dressman and Johannes Kramer Eds. Taylor and Francis group, Boca Raton. 2005
4. Intellectual Property: Patents, trademarks, and Copyright (Nutshell Series) by Arthur R. Miller and Michael H. Davis.
5. Technology Transfer – Dependence and Self Reliant Development in the third world: The Pharmaceutical and Machine tool industries in India by Sunil K. Sahu.
6. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad, 2008

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**PHL 540: Fundamentals of Experimental and Clinical Pharmacology and Toxicology
(Elective)**

3 Credits (3-0-0)

1. Care, handling and breeding techniques of laboratory animals: Regulations for laboratory animal care and ethical requirements. Knowledge of CPCSEA guidelines. GLP norms. Performa for experiments on animals. Alternatives to animal studies. Normal biochemical reference values in various animal species

2. Genetically Modified Animals as Tools of Experimental Pharmacology: Transgenic animals and their applications in drug discovery, techniques involved in transgenic technology and gene knockout animals.

3. Toxicology: Concept, development and scope of toxicology, behavioral and neurotoxicity, teratology, pesticides, principles and management of different types of poisoning, toxicity reactions.

4. Introduction to clinical Trials: History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments.

5. Ethical issues in clinical trials: Principal, responsible conduct, supervision of ethics, Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, the Nuremberg Code, the Declaration of Helsinki, The Belmont Report.

Suggested Readings: (Latest editions unless specified):

1. Recent Journals in Experimental Pharmacology.
2. Vogel H.G. and Vogel, W.H. Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
3. Ballantyne B, Marrs T and Turner P. General and Applied Toxicology. Grove's Dictionaries .
4. Niesink R. J. M. de Vries J and Hollingers M.A. toxicology, Principles and Applications, CRC Press .
5. Gupta P.K. and Salunkhe D.K. Modern Toxicology, Vol – I, II, and III.
6. Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG and Posey LM, Eds. Pharmacotherapy: A Pathophysiologic Approach. McGraw-Hill, New York.
7. Harrison's Principle and Practice of Medicine, 18th Edition, Churchill, Livingston, London.
8. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London, 4th Edition.
9. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics. Williams and Wilkins, 5th Edition.
10. R J Green, N D Harris. Pathology and Therapeutics for Pharmacists: A Basis for Clinical Practice, Pharmaceutical Press.

PHL 541: Biomedicinals (Elective)

3 Credits (3-0-0)

1. Natural sources of drugs and their contribution to modern therapeutics

1.1 Plants

1.2 Animals

1.3 Minerals

1.4 Marine

1.5 Plant Tissue culture as a source of biomedicinals

1.6 Natural Products as leads for new pharmaceuticals

2. Cultivation, collection, processing and storage of crude drugs: Factors influencing cultivation of medicinal plants. Types of soils and fertilizers of common use. Pest management and natural pest control agents. Plant hormones and their applications.

3. Plant tissue culture

Callus cultures, suspension cultures, protoplast cultures and immobilization. non classical techniques in the production of secondary metabolites, production of endogeneous compounds, antimicrobial agents, anti-tumor compounds, flavouring compounds, secondary metabolite with fungal elicitors, immobilization of cell system for the production of plant metabolites & production of edible vaccines from genetically engineered.

4. General methods of extraction, isolation and characterization of bioactive constituents.

4.1 Solvent extraction

4.2 Isolation : Role of fractionation, various chromatographic techniques including column chromatography. TLC. Preparative TLC, HPLC

4.3 Bioactivity directed fractionation

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5. Ensuring identity, quality and purity of Crude drugs, Extracts, Fraction, pure isolates and Formulations.

5.1 Model approach to ensure uniformity in therapeutic efficacy

5.2 Application of various organoleptic, Microscopic and Chromatographic techniques

5.3 Fingerprinting Herbal extracts and Formulations using TLC densitometry and HPLC

6. Determination of toxic residues.

6.1 Pesticide residues.

6.2 Arsenic and heavy metals.

Books Recommended:

1. Biotechnology and Pharmacy, John M, Pazzute, Michael E. Johnson, and Hanri R. Manasse, Jr (1994).
2. An Introduction to plant Tissue culture by M. K. Razdan, 1994, Oxford & IEH.
3. Plant cell tissue and organ culture fundamental methods by O. L. Gambarg and G. C. Phillips, 1996, Narosa Publishing House.
4. Secondary metabolism in plant cell cultures by Phillip Marris, Alan H. Scragg, Angle Staff and Michael W. Fowler 1986, Cambridge University Press.
5. Biotechnology in Agriculture and Forestry Vol. IV, Medicinal and aromatic plants I by Y. P. S. Bajaj 1988, Springer Verlag.
6. Biotechnological applications of plant cultures by Peter D. Shargoel and That T. Ngo, 1994. CRC Press Inc.
7. Cultivation and utilization of Medicinal Plants, Eds., C.K. Atul and B.M. Kapur, R.R.L., Jammu, 1982.
8. H.E. Street, Botanical Monographs, Vol. II, Plant Tissue and Cell Culture, Blackwell Scientific Publication, London, 1977.
9. J. Reinert and Y.P.S. Bajaj, Applied and Fundamental Aspects of Plant Cell, Tissue and Organ Culture, Narosa Publishing House, New Delhi, 1988.
10. Journal of Medicinal and Aromatic Plant Sciences.

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