BANASTHALI VIDYAPITH

Master of Pharmacy (Pharmacology)

Curriculum Structure

First Semester Examination, December-2020
Second Semester Examination, April/May-2021
Third Semester Examination, December-2021
Fourth Semester Examination, April/May-2022

BANASTHALI VIDYAPITH
P.O. BANASTHALI VIDYAPITH
(Rajasthan)-304022

July, 2020

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No. F. 9-6/81-U.3

Government of India
Ministry of Education and Culture
(Department of Education)

New Delhi, the 25th October, 1983

N O T I F I C A T I O N

In exercise of the powers conferred by Section 3 of the University Grants Commission Act, 1956 (3 of 1956) the Central Government, on the advice of the Commission, hereby declare that BanasthaliVidyapith, P. O. BanasthaliVidyapith, (Rajasthan) shall be deemed to be a University for the purpose of the aforesaid Act.

Sd/-
(M. R. Kolhatkar)
Joint Secretary of the Government of India

N O T I C E

Changes in Bye-laws/Syllabi and Books may from time to time be made by amendment or remaking, and a Candidate shall, except in so far as the Vidyapith determines otherwise, comply with any change that applies to years she has not completed at the time of change.

Programme Educational Objectives

Pharmacy programme deals with various aspects of modern drug design, drug development, production and quality assurance that are the basis for expertise in all domains of medicine. Pharmacy professionals being a member of healthcare team are unique in their detailed and comprehensive understanding of physical, chemical and biological interactions on the outcomes of drug therapy. They require an understanding of drug entities chemistry, delivery characteristics of dosage formulations, physiological and pharmacological outcomes of drug interactions.Pharmacy curriculum incorporate components of problem solving, case study and project work in the areas of specialization.The main objectives of the Pharmacy programme are:

- To provide exemplary education in a stimulating environment where delivery of pharmaceutical knowledge is integrated with nationally and internationally recognized research to conduct and publish cutting-edge multidisciplinary research in the discovery, utilization and evaluation of therapeutic agents.
- To prepare competent pharmacists at various levels for India.
- To raise sensitivity to professional ethical codes of conduct and social values.
- To prepare globally recognized pharmacy professionals.
- To demonstrate standards of digital literacy that would support professional needs in manufacture, patient care, hospital administration etc.
- To create awareness in society for rationale usage of medicines.
- To create awareness about environmental hazards in relation to GMP & GLP.
- To develop gender-neutral attitudes and practices; respect for all races, nations, religions, cultures, languages and traditions.
- To nurture a temperament that would enable individuals to set and work towards self-driven performance-goals, entrepreneurial ventures and overall leadership.

Programme Outcomes

PO1: Pharmacy Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical science and technology; behavioral, social, and administrative pharmaceutical sciences; and manufacturing practices.

PO2: Planning abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

PO3: Problem analysis: Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decision during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.

PO4: Modern tool usage: Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.

PO5: Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizen or leadership roles when appropriate to facilitate improvement in health and well-being.

PO6: Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

PO7: Pharmaceutical Ethics: Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.

PO8: Communication: Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective, make effective presentations and documentation, and give and receive clear instructions.

PO9: The Pharmacist and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.

PO10: Environment and sustainability: Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.

PO11: Life- long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-access and use feedback effectively from others to identify learning needs and to satisfy theses needs on an ongoing basis.

Curriculum Structure

Master of Pharmacy (Pharmacology)

First Year

Semester - I

Course Code	Course Name	L	T	P	C*
PHAR 505	Advanced Pharmacology - I	4	0	0	4
PHAR 508	Cellular and Molecular Pharmacology	4	0	0	4
PHAR 516	Modern Pharmaceutical Analytical Techniques	4	0	0	4
PHAR 533	Pharmacological and Toxicological Screening Methods - I	4	0	0	4
PHAR 526L	Pharmacology Lab - I	0	0	12	6
	Discipline Elective	4	0	0	4
	Semester Total:	**20**	**0**	**12**	**26**

Semester - II

Course Code	Course Name	L	T	P	C*
PHAR 506	Advanced Pharmacology - II	4	0	0	4
PHAR 510	Clinical Research and Pharmacovigilance	4	0	0	4
PHAR 534	Principles of Drug Discovery	4	0	0	4
PHAR 525	Pharmacological and Toxicological Screening Methods - II	4	0	0	4
PHAR 527L	Pharmacology Lab - II	0	0	12	6
	Open Elective	4	0	0	4
	Semester Total:	**20**	**0**	**12**	**26**

Second Year

Semester - III

Course	Code	Course Name	L	T	P	C*
PHAR	610P	Project (Part - I)	0	0	48	24
		Reading Elective - I	0	0	4	2
		Semester Total:	**0**	**0**	**52**	**26**

Semester - IV

Course	Code	Course Name	L	T	P	C*
PHAR	611P	Project (Part - II)	0	0	48	24
		Reading Elective - II	0	0	4	2
		Semester Total:	**0**	**0**	**52**	**26**

List of Discipline Elective

Course	Code	Course Name	L	T	P	C*
PHAR	535	Principles of Medicinal Chemistry	4	0	0	4
PHAR	531	Herbal Cosmetics	4	0	0	4
PHAR	530	Advanced Pharmaceutical Biotechnology	4	0	0	4
PHAR	515	Intellectual Property Rights	4	0	0	4
PHAR	536	Regulatory Aspects Food and Neutraceuticals	4	0	0	4
PHAR	537	Regulatory Aspects of Medical Devices	4	0	0	4

List of Reading Elective

Course	Code	Course Name	L	T	P	C*
PHAR	607R	Pharmacovigilance	0	0	4	2
PHAR	604R	Nutraceutials	0	0	4	2
PHAR	609R	Toxicology	0	0	4	2
PHAR	605R	Pharmaceutical Industrial Management	0	0	4	2
PHAR	608R	Product Development	0	0	4	2
PHAR	603R	Molecular Basis of Drug Discovery	0	0	4	2
PHAR	606R	Pharmaceutical Quality Assurance	0	0	4	2

*** L - Lecture hrs/week; T - Tutorial hrs/week; P-Project/Practical/Lab/All other non-classroom academic activities, etc. hrs/week; C - Credit Points of the Course**

Student can opt open (Generic) elective from any discipline of the Vidyapith with prior permission of respective heads and time table permitting.

Every Student shall also opt for:
Five Fold Education: Physical Education I, Physical Education II, Five Fold Education: Aesthetic Education I, Aesthetic Education II, Five Fold Education: Practical Education I, Practical Education II one each semester

Project Evaluation Scheme

Duration	Course Code	Course Name	L	T	P	C
2 Semesters (10 months) 1 July - 30 April	PHAR 610P	Project (Part - I)	0	0	48	24
	PHAR 611P	Project (Part - II)	0	0	48	24

Continuous Assessment (40 Marks)

1. Joining report, brief project outlay	- 10 Marks
2. Synopsis	- 10 Marks
3. Mid-term evaluation by Supervisor	- 10 Marks
4. Further evaluation by Supervisor	- 10 Marks
Total	**- 40 Marks**

End Semester Assessment (60 Marks)

1. Project Report	- 20 marks
2. Presentation	- 20 Marks
3. Viva-voce	- 20 Marks
Total	**- 60 Marks**

Five Fold Activities

Aesthetic Education I/II		Physical Education I/II	
BVFF 101	Classical Dance (Bharatnatyam)	BVFF 201	Aerobics
BVFF 102	Classical Dance (Kathak)	BVFF 202	Archery
BVFF 103	Classical Dance (Manipuri)	BVFF 203	Athletics
BVFF 104	Creative Art	BVFF 204	Badminton
BVFF 105	Folk Dance	BVFF 205	Basketball
BVFF 106	Music-Instrumental (Guitar)	BVFF 206	Cricket
BVFF 107	Music-Instrumental (Orchestra)	BVFF 207	Equestrian
BVFF 108	Music-Instrumental (Sarod)	BVFF 208	Flying - Flight Radio Telephone Operator's Licence (Restricted)
BVFF 109	Music-Instrumental (Sitar)	BVFF 209	Flying - Student Pilot's Licence
BVFF 110	Music-Instrumental (Tabla)	BVFF 229	Aeromodelling
BVFF 111	Music-Instrumental (Violin)	BVFF 210	Football
BVFF 112	Music-Vocal	BVFF 211	Gymnastics
BVFF 113	Theatre	BVFF 212	Handball
Practical Education I/II		BVFF 213	Hockey
BVFF 301	Banasthali Sewa Dal	BVFF 214	Judo
BVFF 302	Extension Programs for Women Empowerment	BVFF 215	Kabaddi
BVFF 303	FM Radio	BVFF 216	Karate - Do
BVFF 304	Informal Education	BVFF 217	Kho-Kho
BVFF 305	National Service Scheme	BVFF 218	Net Ball
BVFF 306	National Cadet Corps	BVFF 219	Rope Mallakhamb
		BVFF 220	Shooting
		BVFF 221	Soft Ball
		BVFF 222	Swimming
		BVFF 223	Table Tennis
		BVFF 224	Tennis
		BVFF 225	Throwball
		BVFF 226	Volleyball
		BVFF 227	Weight Training
		BVFF 228	Yoga

Every Student shall also opt for:
Five Fold Education: Physical Education I, Physical Education II,
Five Fold Education: Aesthetic Education I, Aesthetic Education II,
Five Fold Education: Practical Education I, Practical Education II
one each semester

Evaluation Scheme and Grading System

Continuous Assessment (CA) (Max. Marks)					End-Semester Assessment (ESA) (Max. Marks)	Grand Total (Max. Marks)
Assignment		Periodical Test		Total (CA)		
I	II	I	II			
10	10	10	10	40	60	100

In all theory, laboratory and other non classroom activities (project, dissertation, seminar, etc.), the Continuous and End-semester assessment will be of 40 and 60 marks respectively. However, for Reading Elective, only End semester exam of 100 marks will be held. Wherever desired, the detailed breakup of continuous assessment marks (40), for project, practical, dissertation, seminar, etc shall be announced by respective departments in respective student handouts.

Based on the cumulative performance in the continuous and end-semester assessments, the grade obtained by the student in each course shall be awarded. The classification of grades is as under:

Letter Grade	Grade Point	Narration
O	10	Outstanding
A+	9	Excellent
A	8	Very Good
B+	7	Good
B	6	Above Average
C+	5	Average
C	4	Below Average
D	3	Marginal
E	2	Exposed
NC	0	Not Cleared

Based on the obtained grades, the Semester Grade Point Average shall be computed as under

$$SGPA = \frac{CC_1 * GP_1 + CC_2 * GP_2 + CC_3 * GP_3 + ---- + CC_n * GP_n}{CC_1 + CC_2 + CC_3 + ---- + CC_n} = \frac{\sum_{i=1}^{n} CC_i * GP_i}{\sum_{i=1}^{n} CC_i}$$

Where n is the number of courses (with letter grading) registered in the semester, CC_i are the course credits attached to the i^{th} course with letter grading and GP_i is the letter grade point obtained in the i^{th} course. The courses which are given Non-Letter Grades are not considered in the calculation of SGPA.

The Cumulative Grade Point Average (CGPA) at the end of each semester shall be computed as under:

$$CGPA = \frac{CC_1 * GP_1 + CC_2 * GP_2 + CC_3 * GP_3 + ----+ CC_n * GP_n}{CC_1 + CC_2 + CC_3 + ----+ CC_n} = \frac{\sum_{i=1}^{n} CC_i * GP_i}{\sum_{i=1}^{n} CC_i}$$

Where n is the number of all the courses (with letter grading) that a student has taken up to the previous semester.

Student shall be required to maintain a minimum of 4.00 CGPA at the end of each semester. If a student's CGPA remains below 4.00 in two consecutive semesters, then the student will be placed under probation and the case will be referred to Academic Performance Review Committee (APRC) which will decide the course load of the student for successive semester till the student comes out of the probationary clause.

To clear a course of a degree program, a student should obtain letter grade C and above. However, D/E grade in two/one of the courses throughout the UG/PG degree program respectively shall be deemed to have cleared the respective course(s). The excess of two/one D/E course(s) in UG/PG degree program shall become the backlog course(s) and the student will be required to repeat and clear them in successive semester(s) by obtaining grade C or above.

After successfully clearing all the courses of the degree program, the student shall be awarded division as per following table.

Division	CGPA
Distinction	7.50 and above
First Division	6.00 to 7.49
Second Division	5.00 to 5.99
Pass	4.00 to 4.99

CGPA to % Conversion Formula: % of Marks Obtained = CGPA * 10

First Semester

PHAR 505 Advanced Pharmacology - I

	L	T	P	C
Max. Marks : 100				
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- The basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications
- Recent advances in the drugs used for the treatment of various diseases.
- Concepts of drug action and mechanisms involved.
- Pathophysiology and pharmacotherapy of certain diseases
- Underlying mechanism of drug actions at cellular and molecular level.
- Adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

SECTION-A

Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models.Significance of Protein binding.

Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.

Neurotransmission: General aspects and steps involved in neurotransmission.

Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters: Adrenaline and Acetylcholine).

Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters: histamine, serotonin, dopamine, GABA, glutamate and glycine).Non adrenergic non cholinergic transmission (NANC). Cotransmission.

SECTION-B

Systemic Pharmacology: A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems.

Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

Central nervous system Pharmacology: General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases.Narcotic and non-narcotic analgesics.

SECTION-C

Cardiovascular Pharmacology: Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolyticsand antiplatelet drugs.

Autocoid Pharmacology: The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines,5HT antagonists.

Books recommended(Latest edition):

1. Brunton, L., Chabner, A.B., Knollman, B. (2011). *Goodman & Gillman's The Pharmacological Basis of Therapeutics*, 3rd Ed. Mc Graw-Hill Education.

2. Golan, D.E., Tashjian, A.H., Armstrong, E.J., Armstrong, A.W., Kluwer, L.W. (2011). *Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy*, 3rd Ed., Kluwer-Lippincott Williams & Wilkins Publishers.

3. Katzung, B.G. (2017). *Basic and Clinical Pharmacology*, 14th Ed., McGraw-Hill Education Publishers.

4. Gibaldi, M., Prescott, L. (1983). *Hand book of Clinical Pharmacokinetics*, New York: ADIS Health Science Press.

5. Yu, A., Shargel, L. (2016). *Applied Biopharmaceutics and Pharmacokinetics*, 8th Ed., New York: McGraw-Hill Education Publishers.

6. Smith, G., Aronson, J. (2002). *Oxford Textbook of Clinical Pharmacology and Drug Therapy*, 3rd Ed., OUP Oxford Publishers.

7. Speight, M.T. (2011). *Holford HGN Avery's Drug Treatment*, 4th Ed., Wiley India Pvt Ltd.

8. Dipiro, T.J., Talbert, L.R., Yee, C.G., Matzke, R.G., Wells, G.B., Posey, M. (2011). *Pharmacotherapy: A Pathophysiologic Approach*, 10th Ed., New York: Mc Graw-Hill Education Publishers.

9. Zdanowicz, M.M. (2002). *Essentials of Pathophysiology for Pharmacy*, 3rd Ed., Routledge Publishers.

10. Kumar, V., Abbas, K.A., Aster, C.J. (2014). *Robbins &Cortan Pathologic Basis of Disease*, 9th Ed., Amsterdam: Elsevier.

11. Srivastava, S.K. (2017). *A Complete Textbook of Medical Pharmacology*, New Delhi: Avichal Publishing Company.

12. Tripathi, K.D. (2018). *Essentials of Medical Pharmacology*, 8th, New Delhi: Jaypee Brothers Medical Publishers.

13. Craig, R.C., Stitzel, R.E (2004). *Modern Pharmacology with Clinical Applications,* Lippincott Publishers.

14. Rowland, M., Tozer, N.T. (2010). *Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications*, 4th Ed., Philadelphia: Lippincott Williams & Wilkins Publishers.

15. Yu, A., Shargel, L. (1999). *Applied Biopharmaceutics and Pharmacokinetics*, 4th Ed., New York: Appleton & Lange Publishers.

16. Craig, C.R., Stitzel, R.E. (1990). *Modern Pharmacology*, 3rd Ed., Boston: Little Brown and Company.

Suggested e-material:

1. Pharmacology (Miles Hacker, William S. Messer) http://www.sciencedirect.com/science/book/9780123695215
2. Therapeutic drug monitoring Dasgupta, Amitava http://www.sciencedirect.com/science/book/9780123854674
3. A comprehensive guide to toxicology in preclinical drug development Faqi, Ali S.http://www.sciencedirect.com/science/book/9780123878151
4. Biomarkers in toxicology Gupta, Ramesh C. http://www.science-direct.com/science/book/9780124046306
5. Biased signaling in physiology, pharmacology and therapeutics Arey, Brian http://www.sciencedirect.com/science/book/9780124114609
6. Drug-induced liver disease Kaplowitz, Neil http://www.science-direct.com/science/book/9780123878175

PHAR 508 Cellular and Molecular Pharmacology

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Fundamental knowledge on the structure and functions of cellular components
- Interaction of these components with drugs.
- Drug discovery and receptor signal transduction processes.
- Molecular pathways affected by drugs.
- Applicability of molecular pharmacology and biomarkers in drug discovery process.
- Molecular biology techniques as applicable for pharmacology.

SECTION-A

Cell biology: Structure and functions of cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing, Cell cycles and its regulation.

Cell death: events, regulators, intrinsic and extrinsic pathways of apoptosis.Necrosis and autophagy.

Cell signaling: Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

SECTION-B

Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.Gene therapy-Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

Immunotherapeutics: Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

SECTION-C

Cell culture techniques: Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability

assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry. Biosimilars

Pharmacogenomics: Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism. Genetic variation in drug transporters. Genetic variation in G protein coupled receptors. Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics.

Books recommended(Latest edition):

1. Cooper, M.G., Hausman, E.R. (2013). *The Cell: A Molecular Approach,* 6th Ed., Sinauer Associates.
2. Licinio, J., Wong, Li. (2002). *Pharmacogenomics: The Search for Individualized Therapies*, 1st Ed., Weinheim: Wiley VCH Publishers.
3. Bradshaw, A.R., Dennis, A.E. (2003). *Handbook of Cell Signaling,* 2nd Ed., Cambridge: Academic Press.
4. Dickenson, J., Freeman, F., Mills, L.C, Thode, C (2012). *Molecular Pharmacology: From DNA to Drug Discovery*, 1st Ed., Wiley-Blackwell Publishers.
5. Helgason, D.C., Miller, L.C. (2005). *Basic Cell Culture protocols*, 3rd Ed., New York: Humana Press.
6. Davis, M.J. (1995). *Basic Cell Culture: A Practical Approach,* OUP Oxford Press.
7. Masters, J. (2000). *Animal Cell Culture: A Practical Approach*, 3rd Ed., OUP Oxford Publishers.
8. Ausubel, M.F. (1987). *Current Protocols in Molecular Biology*, Hoboken: John Wiley & Sons Inc Publishers.

Suggested e-material:

1. Pharmacology (Miles Hacker, William S. Messer) http://www.sciencedirect.com/science/book/9780123695215
2. Therapeutic drug monitoring Dasgupta, Amitava http://www.sciencedirect.com/science/book/9780123854674

3. A comprehensive guide to toxicology in preclinical drug development Faqi, Ali S. http://www.sciencedirect.com/science/book/9780123878151

4. Biomarkers in toxicology Gupta, Ramesh C. http://www.science-direct.com/science/book/9780124046306

5. Biased signaling in physiology, pharmacology and therapeutics Arey, Brian http://www.sciencedirect.com/science/book/9780124114609

6. Drug-induced liver disease Kaplowitz, Neil http://www.science-direct.com/science/book/9780123878175

PHAR 516 Modern Pharmaceutical Analytical Techniques

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Significance of Pharmaceutical Analysis in the profession.
- Various tools and techniques available for the analysis of drugs.
- Principles of various conventional analytical techniques.
- Application of Pharmacopoeial purity and identity tests for samples.
- Interpretation of spectra and correlation with sample.

SECTION-A

UV-visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

Infra-red spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier-Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

SECTION-B

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography**.**

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing.

SECTION-C

X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-ray diffraction.

Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

Potentiometry: Principle, working, Ion selective electrodes and application of potentiometry.

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). **TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Books recommended(Latest edition):

1. Silverstein, R.M. (2004). *Spectrometric Identification of Organic compounds*, 6th Ed., John Wiley & Sons.

2. Skoog, D.A, Holler, F.J., Nieman, T.A. (1998). *Principles of Instrumental Analysis*, 5th Ed., Bangalore: Eastern press, Bangalore.

3. Beckett, A.H., Stenlake, J.B. (1987). *Practical Pharmaceutical Chemistry,* 4th Ed., New Delhi: CBS publishers.

4. Kemp, W. (1991). *Organic Spectroscopy*, 3rd Ed., ELBS.

5. Sethi, P.D. (1987). *Quantitative Analysis of Drugs in Pharmaceutical formulation*, 3rd Ed., New Delhi: CBS Publishers.

6. Munson, J.W. (2012). *Pharmaceutical Analysis- Modern methods* – Part B, Informa Health care Publishers.

Suggested e-material:

1. http://www.sciencedirect.com/science/book/9780123869845 Infrared and Raman spectroscopy Larkin, Peter
2. http://www.sciencedirect.com/science/book/9780124115897 Solving problems with NMR spectroscopy Atta-ur-Rahman, Muhammad Iqbal
3. http://lib.myilibrary.com/?id=543351 Quantum Chemistry and Spectroscopy: Pearson New International Edition Engel, Thomas

PHAR 533 Pharmacological and Toxicological Screening Methods – I

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development.
- Maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes
- Regulations and ethical requirement for the usage of experimental animals.
- various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Various screening methods involved in the drug discovery process.

SECTION-A

Laboratory Animals: Common laboratory animals: Description, handling andapplications of different species and strains of animals.Transgenic animals: Production, maintenance and applications.Anaesthesia and euthanasia of experimental animals.Maintenance and breeding of laboratory animals.CPCSEA guidelines to conduct experiments on animals

Good laboratory practice.

Bioassay: Principle, scope and limitations and methods.

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and otherpossible animal alternative models.

General principles of preclinical screening. CNS Pharmacology:behavioral and muscle co ordination, CNS stimulants anddepressants, anxiolytics, anti-psychotics, anti epileptics andnootropics. Drugs for neurodegenerative diseases likeParkinsonism, Alzheimers and multiple sclerosis. Drugs acting onAutonomic Nervous System.

SECTION-B

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible animal alternative models.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, anti-inflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti-emetic, antidiarrheal and laxatives.

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.

SECTION-C

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro and other possible animal alternative models.

Immunomodulators, Immunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation.

Immunoassay for digoxin and insulin.

Anti cancer agents.Hepatoprotective screening methods.

Limitations of animal experimentation and alternate animalexperiments.

Extrapolation of in vitro data to preclinical and preclinical to humans

Books recommended(Latest edition):

1. Kulkarni, S.K. (2013). *Handbook of Experimental Pharmacology*, VallabhPrakashan.
2. Ghosh, M.N. (2008). *Fundamentals of Experimental Pharmacology*, 5th Ed., Kolkata: Hilton & Company Publishers.
3. *Handbook on GLP, Quality Practices for Regulated Non-Clinical Research and Development*, World Health Organization, 2nd Ed., 2008.
4. *Schedule Y, Guideline: Drugs and cosmetics (second amendment) Rules*, CDSCO, 1945.
5. *Annual Report to the People on Health*, Ministry of Health and Family Welfare, New Delhi, 2005
6. Rick, N.G. (2015). *Drugs from Discovery to Approval*, 3rd Ed., United States: Wiley-Blackwell Publishers.
7. Gad, C.S. (2015). *Animal Models in Toxicology*, 3rd Ed., NewYork: CRC Press.

8. *OECD (452) guidelines for the Testing of Chemicals*, 2018

9. Stine, E.R., Brown, M.T. (2015). *Principles of toxicology*, 3rd Ed., New York: CRC Press.

10. *Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals*, U.S. Department of Health and Human Services, ICH, 2010.

11. *Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims*, U.S. Department of Health and Human Services Food and Drug Administration, 2009.

Suggested e-material:

1. (http://www.fda.gov/downloads/drugs/guidancecompliance regulatoryinformation /guidances/ucm073246.pdf)

2. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook. pdf).

PHAR 526L Pharmacology Lab - I

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**0**	**0**	**12**	**6**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Estimation of drug from the biological samples using various instruments.
- Evaluation and study of various animal models for biological response.
- Statistical analysis of the results

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.

15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).

16. Cell viability assays (MTT/Trypan blue/SRB).

17. DNA fragmentation assay by agarose gel electrophoresis.

18. DNA damage study by Comet assay.

19. Apoptosis determination by fluorescent imaging studies.

20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares Enzyme inhibition and induction activity

22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)

23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

Books Recommended:

1. Ghosh, M.N. (2012). *Fundamentals of Experimental Pharmacology*, 6th Ed., Kolkata: Hilton & Company.

2. Kulkarni, S.K. (2005). *Handbook of experimental pharmacology*. 3rd Ed., New Delhi: Vallabh Prakshan.

3. Brunton, L.L., Knollmann, B., Dandan, R.H. (2017). *Goodman and Gilman's, The Pharmacological Basis of Therapeutics,* 13th Ed., New York: McGraw-Hill Education.

4. Marry, A.K.K., Lloyd, Y.Y., Brian, K. A., Robbin, L.C., Joseph, G.B., Wayne, A.K., Bradley, R.W. (2008). *Applied Therapeutics, The Clinical use of Drugs*, 9th Ed., Philadelphia: Lippincott Williams &Wilkins.

5. Grover, J.K., (1990). *Experiments in Pharmacy & Pharmacology,* New Delhi: CBS Publishers.

Second Semester

PHAR 506 Advanced Pharmacology - II

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- The basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications
- Recent advances in the drugs used for the treatment of various diseases.
- Concepts of drug action and mechanisms involved.
- The pathophysiology and pharmacotherapy of certain diseases
- Underlying mechanism of drug actions at cellular and molecular level.
- Adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

SECTION-A

GIT Pharmacology: Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Endocrine Pharmacology: Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation

SECTION-B

Chemotherapy: Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral and anti-TB drugs.

Chemotherapy: Drugs used in Protozoal Infections, Drugs used in the treatment of Helminthiasis. Chemotherapy of cancer, **Immunopharmacology:** Cellular and biochemical mediators of inflammation and immune response.

Allergic or hypersensitivity reactions: Pharmacotherapy of asthma and COPD.

Immunomodulator: Immunosuppressants and Immunostimulants

SECTION-C

Chronopharmacology: Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

Free radicals Pharmacology: Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

Books recommended (Latest edition):

1. Brunton, L., Chabner, A.B, Knollman, B. (2017). *Goodman & Gilman's: The Pharmacological Basis of Therapeutics*, 3rd Ed., McGraw-Hill Education.
2. Golan, D.E., Tshjian, A.H., Armstrong, E.J., Armstron, A.W. (2016). *Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy*, 3rd Ed., Wolters Kluwer Health/Lippincott Williams & Wilkins: 2016.
3. Katzung, B.G. (2017), *Basic and Clinical Pharmacology*, 14th Ed., McGraw-Hill Companies.
4. Ritter, J., Flower, R., Henderson, R., Rang, H. (2015). *Rang & Dale's Pharmacology*, 8th Ed., Churchill Livingstone.

5. Gibaldi, M., Prescott, L. (1983). *Handbook of Clinical Pharamacokinetics*, New York: ADIS Health Science.

6. Herfindal, E.T., Hirschman, J.L., Gourley, D.R. (2000), *Textbook of therapeutics: drug and disease management,* 7th Ed.,Philadelphia: Lippincott Williams & Wilkins.

7. Shargel, L., Yu, A. (2016). *Applied Biopharmaceutics & Pharmacokinetics*, 8th Ed., New York: McGraw-Hill Companies.

8. Younggil K. (2002). *Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists*, New York: Springer.

9. Kumar, V., Abbas, A., Aster, J. (2014). *Robbins &Cotran Pathologic Basis of Disease*, 9th Ed., Amsterdam: Elsevier.

10. Srivastava, S.K. (2017). *A Complete Textbook of Medical Pharmacology*, New Delhi: Avichal Publishing Company.

11. Tripathi, K.D. (2018). *Essentials of Medical Pharmacology*, 8th Ed., New Delhi: Jaypee Brothers Medical Publishers.

Suggested e-material:

1. Pharmacology (Miles Hacker, William S. Messer) http://www.sciencedirect.com/science/book/9780123695215

2. Therapeutic drug monitoring Dasgupta, Amitavahttp://www.sciencedirect.com/science/book/9780123854674

3. A comprehensive guide to toxicology in preclinical drug development Faqi, Ali S.http://www.sciencedirect.com/science/book/9780123878151

4. Biomarkers in toxicology Gupta, Ramesh C. http://www.sciencedirect.com/science/book/9780124046306

5. Biased signaling in physiology, pharmacology and therapeutics Arey, Brian http://www.sciencedirect.com/science/book/9780124114609

6. Drug-induced liver disease Kaplowitz, Neil http://www.sciencedirect.com/science/book/9780123878175

PHAR 510 Clinical Research and Pharmacovigilance

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- The clinical research.
- Regulatory requirements for conducting clinical trial.
- Responsibilities of key players involved in clinical trials
- Safety monitoring, reporting and close-out activities.
- Principles of pharmacovigilance

SECTION-A

Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines.

Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR.

Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process.

Clinical Trials: Types and Design, Experimental Study- RCT and Non RCT. Observation Study: Cohort, Case Control, Cross sectional.

Clinical Trial Study Team: Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

SECTION-B

Clinical Trial Documentation: Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT.

Adverse Drug Reactions: Definition and types. Detection andreporting methods, Severity and seriousnessassessment,Predictability and preventability assessment,Management of adverse drug reactions, Terminologies of ADR.Pharmacoepidemiology, pharmacoeconomics, safety pharmacology.

SECTION-C

Basic aspects, terminologies and establishment of pharmacovigilance: History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

Methods, ADR reporting and tools used in Pharmacovigilance: International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

Books recommended (Latest edition):

1. Central Drugs Standard Control Organization- *Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India*. New Delhi: Ministry of Health: 2001.

2. *International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline.* Guideline for Good Clinical Practice.E6; May 1996.

3. *Ethical Guidelines for Biomedical Research on Human Subjects*, Indian Council of Medical Research, New Delhi: 2006.

4. Machin, D., Day, S., Green, S. (2006). *Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons*, 6th Ed., England: John Wiley & Sons Ltd.

5. Rondels, R.K., Varley, S.A., Webbs, C.F. (2000). *Clinical Data Management*, 2nd Ed., England: Wiley Publications.

6. Lloyd, J., Raven, A. (1994). *Handbook of clinical Research*, 2nd Ed., New York: Churchill Livingstone.

7. Giovanna, D.L., Haynes, G. (2001). *Principles of Clinical Research*, 1st Ed., Routledge publisher.

Suggested e-material:

1. https://www.who-umc.org/ (Global Pharmacovigilance)

2. https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en (WHO Pharmacovigilance)

PHAR 534 Principles of Drug Discovery

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Different CADD techniques and their applications in drug discovery.
- The use of software in identifying drug receptor interactions and pharmacophore mapping.
- The applicability of *in silico* virtual screening protocols in drug research.

SECTION-A

Introduction to Computer Aided Drug Design (CADD); historical aspect, different CADD techniques and applications.

Quantitative Structure Activity Relationships:

History and development of QSAR. Physicochemical parameters; experimental and theoretical approaches for the determination of the following physicochemical parameters Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters).

Statistical methods used in QSAR analysis and importance of statistical parameters. Applications and validation of Hansch analysis, Free Wilson analysis, advantages and disadvantages of 2D-QSAR modeling.

Section B

3D-QSAR: 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.

Pharmacophore mapping and virtual screening: Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping. In silico drug design and virtual screening techniques, similarity based methods and pharmacophore based screening, structure based In-silico virtual screening protocols.

Molecular docking: Molecular and Quantum Mechanics in drug design. Energy Minimization Methods, comparison between global minimum conformation and bioactive conformation. Molecular docking and drug receptor interactions, Rigid docking, flexible docking and extra-precision docking.

Section C

Molecular properties and drug design: Prediction and analysis of ADMET properties of new molecules and its importance in drug design.

De novo drug design, Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.

Computational prediction of protein structure: Threading and homology modeling methods and generation of 3D-structure of protein.. Application of NMR and X-ray crystallography in protein structure prediction

Books recommended (Latest edition):

1. Robert, M. (2007). *Computational and structural approaches to drug discovery*, 1st Ed., RCS Publishers.
2. Martin, Y.C. (2010). *Introduction to Quantitative Drug Design*, 2nd Ed., New York: CRC Press.
3. Ariens (1975). *Drug Design*, Academic Press, Elsevier Publishers.
4. Smith, H.J., Williams, H. (2005). Smith *Principles of Drug Design*. CRC Press.
5. Silverman, R.B. (2010). *The Organic Chemistry of the Drug Design and Drug action*, Elsevier Publishers.
6. Abraham, D.J., Rotella, D.P (2010). Burger's *Medicinal Chemistry*, 7th Ed., Wiley Publishing Co.
7. Patrick, G.L. (1995). *An Introduction to Medicinal Chemistry,* Oxford University Press.
8. Gisvold's, W. (2004). *Text book of Organic Medicinal andPharmaceutical Chemistry,* 11th Ed., Lippincott Williams & Wilkins.

Suggested e-material:

1. https://www.pdfdrive.com/computational-methods-in-drug- discover e24068030.html
2. https://www.pdfdrive.com/textbook-of-drug-design-and-discovery-d33454550.html
3. https://www.pdfdrive.com/drug-design-and-discovery-methods and-protocols-methods-in-e36557495.html

PHAR 525 Pharmacological and Toxicological Screening Methods-II

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Preclinical safety and toxicological evaluation of drug & new chemical entity.
- Regulatory aspects for the toxicological evaluation of drugs and chemicals.
- Types of toxicity studies and their procedure.
- Alternative methods to animal toxicity testing.

SECTION-A

Basic definition and types of toxicology (general, mechanistic,regulatory and descriptive)Regulatory guidelines for conducting toxicity studies OECD, ICH,EPA and Schedule Y

OECD principles of Good laboratory practice (GLP)History, concept and its importance in drug development

Acute, sub-acute and chronic- oral, dermal and inhalationalstudies as per OECD guidelines.Acute eye irritation, skin sensitization, dermal irritation & dermaltoxicity studies.Test item characterization- importance and methods in regulatorytoxicology studies.

SECTION-B

Reproductive toxicology studies, Male reproductive toxicitystudies, female reproductive studies (segment I and segment III),teratogenecity studies (segment II).

Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleusand Chromosomal aberrations studies)

In vivo carcinogenicity studies.

IND enabling studies (IND studies) - Definition of IND, importanceof IND, industry perspective, list of studies needed for INDsubmission.

SECTION-C

Safety pharmacology studies- origin, concepts and importance ofsafety pharmacology.

Tier1- CVS, CNS and respiratory safety pharmacology, HERGassay. Tier2- GI, renal and other studies

Toxicokinetics- Toxicokinetic evaluation in preclinical studies,saturation kinetics Importance and applications of toxicokineticstudies.

Alternative methods to animal toxicity testing.

Books recommended:

1. WHO (2009), *Handbook: Good Laboratory Practice (GLP). Quality practices for regulated non-clinical research and development*, 2nd Ed.
2. Ng, R. (2015). *Drugs: From Discovery to Approval*, 3rd Ed., New Jersey: Wiley-Blackwell.
3. Gad, S.C. (2015). *Animal Models in Toxicology*, 3rd Ed., Florida: CRC Press.
4. Stine, K.E., Brown, T.M. (2015). *Principles of Toxicology*, 3rd Ed., Florida: CRC Press.
5. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi.
6. OECD test guidelines, 2018.

   (http://www.oecd.org/env/ehs/testing/2018%20TG%20List%20EN%20Aug%202018.pdf).
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals.

   (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinform ation/guidances/ucm073246.pdf)

Suggested e-material:

1. http://www.fda.gov/downloads/drugs/guidancecompliance regulatoryinformation /guidances/ucm073246.pdf

2. https://www.who.int/tdr/publications/documents/glp-handbook.pdf?ua=1

PHAR 527L Pharmacology Lab – II

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**0**	**0**	**12**	**6**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Evaluation and study of various animal models for biological response.
- Bioassays & toxicity studies
- Statistical analysis of the results

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.

10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial. (3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

Books Recommended:

1. Ghosh, M.N. (2012). *Fundamentals of Experimental Pharmacology*, 6th Ed., Kolkata: Hilton & Company.
2. Kulkarni, S.K. (2005). *Handbook of experimental pharmacology*. 3rd Ed., New Delhi: Vallabh Prakshan.
3. Brunton, L.L., Knollmann, B., Dandan, R.H. (2017). *Goodman and Gilman's, The Pharmacological Basis of Therapeutics,* 13th Ed., New York: McGraw-Hill Education.
4. Marry, A.K.K., Lloyd, Y.Y., Brian, K. A., Robbin, L.C., Joseph, G.B., Wayne, A.K., Bradley, R.W. (2008). *Applied Therapeutics, The Clinical use of Drugs*, 9th Ed., Philadelphia: Lippincott Williams &Wilkins.
5. Grover, J.K., (1990). *Experiments in Pharmacy & Pharmacology,* New Delhi: CBS Publishers.

(Discipline Elective)

PHAR 535 Principles of Medicinal Chemistry

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Various aspects of drug designing and methods for their analysis.
- Factor to design new drug against particular biochemical.
- Medicinal and stereochemistry of various class of drugs

SECTION-A

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists.

Stereochemistry and drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug absorption, metabolism, distribution and elimination.

Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

SECTION-B

Drug biotransformation: Drug biotransformation and its role in development of new drug molecules.

Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability,

Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

Soft drug design, its advantages and applications.

SECTION-C

Enzyme Inhibitors: Rational Design of Enzyme Inhibitors Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AChE & BChE)

An overview of target discovery and validation.

Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.

Books recommended(Latest edition):

1. Abraham, D.J., Rotella, D.P. (2010). *Burger's Medicinal Chemistry, Drug Discovery and Development*, 7th Ed., New Delhi: Willey Publishers.
2. Beale, J.M. (2010). *Wilson and Gisvold's: Text book of Organic Medicinal and Pharmaceutical Chemistry*, 12th Ed., New Delhi: Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd.
3. Chackalamannil, S., Rotella D., Ward, S. (2017). *Comprehensive Medicinal Chemistry III*, 3rd Ed., Elsevier.
4. Martin, Y.C. (2010). *Quantitative Drug Design: A critical Introduction*, 3rd Ed., New York: CRC Press.

5. Lemke, T.S., Williams, D.A., Roche, V.F., Zito S.W., Foye, S. (2013). *Principles of Medicinal Chemistry*, 7th Ed., New Delhi: Lippincott Williams & Wilkins, Wolters Kluwer (India) Pvt. Ltd.
6. Arienes, E.J. (1975). *Drug Design,* 1st Ed., Academic Press, Elsevier.
7. Smith, W. (2005). *Introduction to the Principles of Drug Design and Action*, 4th Ed., New York: CRC Press.
8. Silverman, R.B. (2012). *The Organic Chemistry of the Drug Design and Drug Action*, 2nd Ed., Elsevier Publishers.
9. Patrick, G.L. (1995). *An Introduction to Medicinal Chemistry,* 1st Ed., Oxford University Press.
10. Brahmankar, D.M., Jaiswal, S.B. (2014). *Biopharmaceutics and Pharmacokinetics*, 2nd Ed., New Delhi: VallabhPrakashan.
11. Guarna, A., Trabocchi, A. (2014), *Peptidomimetics in Organic and Medicinal Chemistry,* 1st Ed., New Delhi: Wiley publishers.

Suggested e-material:

1. https://books.google.co.in/books/about/Foye_s_Principles_of_Medicinal_Chemistry.html?id=R0W1ErpsQpkC
2. https://www.wiley.com/enus/Burger%27s+Medicinal+Chemistry%2C Drug+Discovery%2C+and+Development%2C+7th+Edition-p 9780470278154

PHAR 531 Herbal Cosmetics

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

After completion of the course, student shall be able to

- Understand the basic principles of various herbal/natural cosmetic preparations
- Current Good Manufacturing Practices of herbal/natural cosmetics as per the regulatory authorities

SECTION-A

Introduction: Herbal/natural cosmetics, Classification & Economic aspects.

Regulatory Provisions relation to manufacture of cosmetics: License, GMP, offences & Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production of Herbal/natural cosmetics, commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs.

Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants, oils, colors, and some functional herbs, preformulation studies, compatibility studies, possible interactions between chemicals and herbs, design of herbal cosmetic formulation.

SECTION-B

Herbal Cosmetics: Physiology and chemistry of skin and pigmentation, hairs, scalp, lips and nail.

Preparation and standardisation of Cleansing cream, Lotions, Face powders, Face packs, Lipsticks, Bath products, soaps and baby product, Tonic, Bleaches, Dentifrices and Mouth washes & Tooth Pastes, Cosmetics for Nails.

SECTION-C

Cosmeceuticals of herbal and natural origin: Hair growth formulations, Shampoos, Conditioners, Colorants & hair oils, Fairness formulations, vanishing & foundation creams, anti-sun burn preparations, moisturizing creams, deodorants.

Analysis of Cosmetics, Toxicity screening and test methods: Quality control and toxicity studies as per Drug and Cosmetics Act.

Books recommended (Latest edition):

1. Panda, H. (2000). Herbal Cosmetics: Hand book, New Delhi: Asia Pacific Business Press Inc.
2. Thomson, E.G. (2015). Modern Cosmetics, vol 1, Mumbai: Universal Publishing Corporation.

3. Sharma, P.P. (2014). Cosmetics - Formulation, Manufacturing & Quality Control, Ed.5th, New Delhi: Vandana Publications.

4. Supriya, B. (2000). Handbook of Aromatic Plants, Jaipur: Pointer Publishers.

5. Skaria, B.P. (2007). Aromatic Plants: Horticulture Science Series, New Delhi: New India Publishing Agency.

6. Keville, K., Green, M., (2008). Aromatheraphy: A Complete Guide to the Healing Art, New Delhi: Sri Satguru Publications.

7. Balsam, M.S., Edward S. (1974). Cosmetics Science and Technology, vol 3, New York: Wiley Interscience.

Suggested e-material:

https://www.pdfdrive.com/cosmetics-books.html

PHAR 530 Advanced Pharmaceutical Biotechnology

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Enzyme technology, genetic Engineering, Peptides and its applications.
- Transgenic animal, human genome and signal transduction.
- Microbial transformation, biodegradation and biosensors.

SECTION-A

Enzyme Technology: Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase,amylase and trypsin.

Genetic Engineering: Techniques of gene manipulation, cloning strategies,procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast.

Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences.

Gene library and cDNA

Applications of the above technique in the production of,

- Regulatory proteins - Interferon, Interleukins
- Blood products - Erythropoietin
- Vaccines - Hepatitis-B
- Hormones – Insulin

Therapeutic peptides: Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration.

SECTION-B

Transgenic animals: Production of useful proteins in transgenic animals and gene therapy.

Human Genome: The human genome project-a brief study, Human chromosome – Structure and classification, chromosomal abnormalities – Syndromes

Signal transduction: Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle andproliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases.

SECTION-C

Oncogenes: Introduction, definition, various oncogenes and their proteins.

Microbial Biotransformation: Biotransformation for the synthesis of chiral drugs and steroids.

Microbial Biodegradation: Biodegradation of xenobiotics, chemical and industrial wastes, Production of single-cell protein, Applications of microbes in environmental monitoring.

Biosensors: Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.

Books recommended (Latest edition):

1. Trevan, M.D., Boffey, S., Goulding, K.H., Stanbury, P.F. (1987). Biotechnology-The biological principles. Ed. 1, Stony Stratford: Open University Press.
2. Bickerstaff, G.F. (1997). Immobilization of cells and enzymes. Totowa: Humana Press Inc.
3. Old, R.W., Primrose, S.B. (1981). Principles of Gene Manipulating. University of California Press
4. Lodish, H., Berk, A., Zipursky, L., Matsudaira, P., Baltimore, D. Darnell, J. (1999). Molecular Cell Biology. 4th ed. W. H. Freeman Publishers.
5. Primrose, S.B. (1991). Modern Biotechnology. 2nd Ed. London: Blackwell Scientific Publications Ltd.
6. Murray E.T. (1991). Gene transfer and expression protocols-methods in Molecular Biology, vol. VII, Totowa: Humana Press Inc.
7. Asubel, F.M. (2003). Current protocols in Molecular Biology, Vo1.I & II, John Wiley Publishers.

Suggested e-material

1. http://202.74.245.22:8080/xmlui/handle/123456789/39/browse?type=subject
2. https://pharmaclub.in/free-pharmacy-ebooks-pharmaceutics/
3. https://www.pdfdrive.com/pharmaceutical-books.html

PHAR 515 Intellectual Property Rights

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Patent and copyright for innovative works.
- Selected IP issues that might arise in practice.
- Federal and state IP protection.
- Tools and activities of IP practitioners such as the Copyright, Patent, and Trademark websites, searching, reading patents, and more.

SECTION-A

Intellectual property rights (IPR): Definition, scope, objectives, Concepts and fundamentals: intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property.

Patents: Criteria for patentability, Indian patent act. 1970, filing of a patent application, precautions before patenting-disclosures/non-disclosures, publication-article/ thesis, prior art search – published patents search, internet search patent sites, specialized service search requests, costs, patent application forms and guidelines, fee structure, time frames, jurisdiction aspects, types of patent application- provisional, non-provisional, PCT and convention patent applications, international patenting requirement procedures and costs.

Patent infringement: Meaning, scope, litigation, drug related patents infringements, case studies and examples, patenting by research students.

SECTION-B

Copyright, **Trademarks:** (Introduction, meaning of trademark, criteria for eligibility, filling application for trademark registration).

Trade secrets: Scope modalities and protection case studies. Role of IP in pharmaceutical industry.

Trade related aspects of intellectual property rights: Intellectual property and international trade, concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trades in Services).

WTO-objectives, scope, functions, structure, status, membership and withdrawal, dispute settlement, impact on globalization

SECTION-C

Technology development/transfercommercialization related aspects: Meaning, drug related technology development, bioequivalence (BE), scale-up, semi-commercialization and commercialization– practical aspects and problems, significance of transfer of technology (TOT), bottlenecks, managing technology transfer, guidelines for research students, scientists and related personnel, TOT agencies in India APCTD, NRDC, TIFAC, IBCIL, TBSE/SIDBI.

TOT related documentation: Confidentiality agreements, licensing, MOUs, legal issues, compulsory licensing and issuing of access to medicines, DOHA declaration.

Related quality systems: Objectives and brief review of US-FDA, UK-MCA, and TGA guidelines.

Standard institutes and certification agencieslike: ISI, BSS, ASTM.

Books recommended(Latest edition):

1. Treece, D.J. (2003). Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. London: Oxford University Press.

2. Wadedhra, B.L. (2004). Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. New Delhi: Universal Law Publishing.

3. Bansal, P. (2008). IPR Handbook for Pharma Students and Researchers. Hyderabad: Pharma Book Syndicate.

4. Trivedi, P.R. (2008). Encylcopedia of Intellectual Property Rights. New Delhi: JnanadaPrakashan.

5. Willig, S.H. (1982). Good Manufacturing Practices for Pharmaceuticals. vol 78, New York: Marcel Dekker,.

6. Das, P., Das, G. (2008). Protection of Industrial Property Rights Kolkata: Kamal Law House.

7. Katju, S.N. (2002). Law and Drugs. Delhi: Delhi Law House.

Suggested e-material

1. Copyright Protection in India [http:copyright.gov.in].
2. Information on orange book [www.fda.gov/cder/ob/default.htm].
3. World Trade Organization [www.wto.org].

PHAR 536 Regulatory Aspects of Food and Nutraceuticals

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of the course, the student shall be able to

- Know the regulatory Requirements for nutraceuticals
- Understand the regulation for registration and labeling of nutraceuticals
- Know food supplements in India, USA and Europe.

SECTION-A

Nutraceuticals: Introduction, History of Food and Nutraceutical, Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.

Global Aspects: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements and Nutraceuticals Industries, NSF Certification, NSF Standards for Food And Dietary Supplements. Good Manufacturing Practices for Nutraceuticals

SECTION-B

India: Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.

USA: US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S.

SECTION-C

European Union: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements.Nutritionlabelling.European Regulation on Novel Foods and Novel Food Ingredients.Recommended Dietary Allowances(RDA) in Europe.

Books recommended (Latest edition):

1. Hasler,Clare M. (2005).Regulation of Functional Foods and Nutraceuticals: A Global Perspective. Vol.1, Delhi: Blackwell Publishing.
2. Bagchi, D. (2014). Nutraceutical and Functional Food Regulations in the United States and Around the World. Elsevier.
3. Pathak, Y. (2009). *Handbook of Nutraceuticals*. Vol 1.CRC Press.
4. Fortin, N.D. (2007).*Food Regulation: Law, Science, Policy and Practice.* Vol 1. Wiley Publishers.

Suggested e-material

1. http://www.who.int/publications/guidelines/nutrition/en/
2. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_STU(2015)536324_EN.pdf

PHAR 537 Regulatory Aspects of Medical Devices

Max. Marks : 100	**L**	**T**	**P**	**C**
(CA: 40 + ESA: 60)	**4**	**0**	**0**	**4**

Learning outcomes

Upon completion of the course, the student shall be able to know

- Basics of medical devices and IVDs, process of development, ethical and quality considerations
- Harmonization initiatives for approval and marketing of medical devices and IVDs
- Regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- Clinical evaluation and investigation of medical devices and IVDs

SECTION A

Medical Devices: Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals.

History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices.

IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).

SECTION B

Ethics: Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011).

Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device

USA: Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI). Basics of In vitro diagnostics, classification and approval process.

SECTION C

European Union: Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.

ASEAN, China & Japan: Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.

Books recommended (Latest edition):

1. Pisano, D. J., Mantus, D. (2008). *FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics*. 2nd Ed., CRC Press.
2. Kahan, J. S. (2000). *Medical Device Development: A Regulatory Overview*. PAREXEL International Corporation.
3. Tobin, J. J., Walsh, G. (2008). *Medical Product Regulatory Affairs: Pharmaceuticals, DiagnosticsMedical, Devices.*Wiley-Blackwell
4. Medina, C. (2003). *Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics*. CRC Press.

Suggested e-material

1. Country Specific Guidelines from official websites.
2. Code of Federal regulations (Annual Edition) from official websites, US government.
3. www.fda.gov

(Reading Elective)

PHAR 607R Pharmacovigilance

Max. Marks : 100	**L**	**T**	**P**	**C**
(ESA: 100)	**0**	**0**	**4**	**2**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Types of clinical trial designs.
- Responsibilities of key players involved in clinical trials
- Safety monitoring, reporting and close-out activities.
- Principles of pharmacovigilance

Introduction to Pharmacovigilance, Basic terminologies used in pharmacovigilance, Regulatory terminologies, History and development of Pharmacovigilance

Importance of safety monitoring of Medicine, WHO international drug monitoring programme , Pharmacovigilance Program of India(PvPI), WHO adverse reaction terminologies, WHO drug dictionary,

Introduction to adverse drug reactions, Terminologies of adverse medication related events, Specialised resources for ADRs, Definitions and classification of ADRs, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment Management of adverse drug reactions.

Drug and disease classification, Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses

International Nonproprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

Information resources in pharmacovigilance, Basic drug information resources,

Establishing pharmacovigilance programme in hospital & industry

Pharmacovigilance methods

Passive surveillance – Spontaneous reports and case series

Active surveillance – Sentinel sites, drug event monitoring and registries

Comparative observational studies – Cross sectional study, case control study and cohort study

Communication in pharmacovigilance, Drug Safety Crisis management, Contract Research Organisations (CROs)

Establishing a national programme, Vaccine Pharmacovigilance

Regulatory Agencies, Business Partners, Healthcare facilities & Media

Safety data generation, Pre-clinical phase & Clinical phase

Post approval phase, ICH Guidelines for Pharmacovigilance

Pharmacovigilance planning, good clinical practice in pharmacovigilance studies

Drug safety evaluation in special population Paediatrics, Pregnancy and lactation,Geriatrics

CIOMS, D&C Act and Schedule Y Differences in Indian and global pharmacovigilance requirements

Pharmacogenomics of adverse drug reactions

Books recommended:

1. Waller, P. and Harrison-Woolrych, Mira. (2017). *An Introduction to Pharmacovigilance*. Second edition, New Jersy: John Wiley & Sons Ltd

2. Cobert, B.L. (2015).*Manual of Drug Safety and Pharmacovigilance*. Burlington: Jones and Bartlett Publishers.

3. Gupta, S.K. (2018). *Textbook of Pharmacovigilance Icri Institute of Clinical Research (India)*, New Delhi: Jaypee Brothers Medical Publishers.

Suggested e-material:

1. http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf; 200 (World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: WHO)

2. http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/docs/acs_consultation_final.pdf; 2006. (Assessment of the European Community System of Pharmacovigilance)

3. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/ Investigational New Drug IND Application/ucm226358.html

4. (Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans,)

5. Common Terminology Criteria for Adverse Events(The Importance of Pharmacovigilance and Common Terminology Criteria for Adverse Events)

6. www.cdsco.nic.in/writereaddata/pharmacovigilanceGuidance.pdf (Guidance for industry on Pharma coviGilance requirements)

PHAR 604R Nutraceuticals

Max. Marks : 100	**L**	**T**	**P**	**C**
(ESA: 100)	**0**	**0**	**4**	**2**

Learning outcomes

Upon completion of the course, the student will be able to understand

- Concept of nutraceuticals and their use in various aspect of health.
- Chemical aspects of Nutraceuticals and their anti-nutritional factors.
- Nutraceuticals regulations.

Nutraceuticals as Science: Introduction, historical perspective, classification, current trends and future scope. Sources of nutraceuticals.

Applied aspects of Nutraceutical in Medicine, Human physiology, genetics, food technology, chemistry and nutrition.

Nutraceutical Supplements: Inorganic mineral supplements, Vitamin supplements, Digestive enzymes, Dietary fibers, Cereals and grains, Health drinks of natural origin, Antioxidants, Polyunsaturated fatty acids, Herbs as functional foods.

Properties, structure and functions of: Glucosamine, Octacosanol, Lycopene, Carnitine, Melatonin and Ornithine alpha ketoglutarate. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals.

Anti-nutritional Factors present in Foods: Types of inhibitors present in various foods and how they can be inactivated. Role of Probiotics and Prebiotics as nutraceuticals. Recent advances in techniques & feeding of substrates. Assessment of nutritional status and Recommended Daily allowances.

Food as remedies: Nutraceuticals bridging the gap between food and drug, Nutraceuticals in treatment for cognitive decline, Nutraceutical remedies for common disorders like Arthritis, Bronchitis, circulatory problems, hypoglycemia, Nephrological disorders,

Brief idea about some Nutraceutical rich supplements e.g. Bee pollen, Caffeine, Green tea, Lecithin, Mushroom extract, Chlorophyll, Kelp and Spirulina etc.

Formulation and standardization of Nutraceuticals, Regulatory aspects, FSSAI guidelines.

Books recommended:

1. Pathak, Y., Selvamuthukumaran, M. (2019). *Flavors for Nutraceuticals and functional foods*, Taylor & Francis Ltd.
2. Matthews, K.R. (2014). *Practical Food Safety: Contemporary Issues and Future Directions,* John Wiley & Sons, Ltd.
3. Hasler, C.M., (2005).*Regulation of Functional Foods and Nutraceuticals: A Global Perspective,* Blackwell publishing.
4. Gupta, R.C. (2016). *Nutraceuticals, Efficacy, safety and toxicity*, Mica Haley publisher.
5. Aluko, R.E. (2012). *Functional foods and Nutraceuticals*, Springer.

Suggested e-material

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3257668/

PHAR 609R Toxicology

Max. Marks : 100	**L**	**T**	**P**	**C**
(ESA: 100)	**0**	**0**	**4**	**2**

Learning outcomes

Upon completion of course student will have understanding of:

- Principles of toxicology &clinical toxicology
- Management of poison individual
- Role of antidotes in various poisoning
- Clinical management of various types of drug poisoning

Introduction to toxicology,definitions, sub disciplines, types and scope of toxicology, Principles of toxicology &clinical toxicology, mechanisms of toxicities, Pharmacological factors, physiological factors, pathophysiological factors principles of toxicokinetics, clearance, volume of distribution and half-life, Drug-Induced Diseases, adverse drug reactions.

General principles involved in the management of poisoning, Antidotes and the clinical applications, Supportive care in clinical Toxicology, Gut Decontamination, Elimination Enhancement. Diagnostic test and their interpretation. Clinical symptoms and management of acute poisoning with the following agents : Heavy metals poisoning, Pesticide poisoning, Opiates overdose, antidepressants, barbiturates and benzodiazepines, Alcohol poisoning.

Clinical symptoms and management of acute poisoning with the following agents Paracetamol and salicylates poisoning, Food poisoning, Hydrocarbons: Petroleum products and PEG, Caustics: inorganic acids and alkali poisoning, CNS stimulants:amphetamine, Radiation poisoning, tobacco, venomous snake bites, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries, plants poisoning. Mushrooms, Mycotoxins

Books recommended:

1. Ellenhorn, M.J. (1997), Medical *toxicology – Diagnosis and Treatment of Poisoning*. Second edition. London: Williams and Willkins publication.

2. Hodgson, A. (2010). *Textbook of Modern Toxicology*. New York: J Wiley & Sons.

3. Smart, RC. (2008). *Molecular and Biochemical Toxicology*. 4th ed, New York: J Wiley & Sons.

4. Gilbert, S.G. (2004). *A Small Dose of Toxicology: The health effects of common chemicals*. Boca Raton: CRC Press.

PHAR 605R Pharmaceutical Industrial Management

Max. Marks : 100	**L**	**T**	**P**	**C**
(ESA: 100)	**0**	**0**	**4**	**2**

Learning outcomes

Upon completion of this course student will have an understanding of:

- Principles of management
- techniques used in marketing
- application of the marketing in the pharmaceutical industrysales promotion

Marketing: Definition, general concepts, and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market: Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation&targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Product decision: Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Promotion: Meaning and methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Pharmaceutical marketing channels: Designing channel, channel members, selecting the appropriatechannel, conflict in channels, physical distribution management: Strategic importance, tasks in physicaldistribution management.

Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issuesin price management in pharmaceutical industry.An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Books recommended:

1. Kotler, P. Keller, K.L. (2011). *Marketing Management*, New Delhi: Prentice Hall of India.

2. Walker, O.C., Boyd, H.W. and Larreche, J.C. (2006). *Marketing Strategy- Planning and Implementation*, New Delhi: Tata MC GrawHill.

3. Grewal, D. Levy, M. *Marketing*. (2012). 6th edition, New Delhi: Tata MC GrawHill.

4. Kumar, A. Menakshi, N. (2011). *Marketing Management*, New Delhi: Vikas Publishing.

5. Saxena, R. (2009). *Marketing Management*. New Delhi: Tata MC GrawHill.

PHAR 608R Product Development

Max. Marks : 100	L	T	P	C
(ESA: 100)	0	0	4	2

Learning outcomes

Upon completion of this course student will be able:

- To understand the concept of pre-formulation and their influence on formulation and stability of products.
- To develop understanding of BCS Classification, rheology and solubilization in context to dosage form development.
- To develop understanding of students about in vitro dissolution study of solids and interpretation of dissolution data.

Preformulation studies: Introduction, goals of preformulation, physicochemical properties, criteria for selection of drug and excipients, compatibility tests.

Solubility and solubilization: Development of theoretical relationships of prognostic relevance, techniques of solubilization of drugs including surfactant systems, co-solvents, solid state manipulations, complexation and chemical modifications.

BCS classification: Introduction, classification and its applications.

Partition coefficient: Pharmaceutical significance of partition coefficient, correlation with in-vivo performance, techniques to estimate log P values, shake flask method, choice of solvent systems, chromatographic determination, effect of various variants like temperature, pH, etc. on partition coefficient.

Rheology: Concepts of rheology, viscoelastic analysis of semisolids, applications and practice of rheology, viscometers.

Performance evaluation, in vitro: Dissolution: Introduction, Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products, methods of interpretation of dissolution data: model dependent and model independent methods, dissolution profile comparison.

Books recommended:

1. Wells, J.I. (1990). Pharmaceutical Prefomulation: The Physicochemical Properties of Drug Substances. London: Ellis Horwood, Chiechester.
2. Yalkowsky, S.H. (1981). Techniques of Solubilization of Drugs. New York: Marcel Dekker.
3. Lewis, G.A. (2007). Optimization Methods. In Encyclopedia of Pharmaceutical Technology. New York: Informa Healthcare.
4. Banker, G.S. Rhode, C.T. (1979). Modern Pharmaceutics. New York: Marcel DekkarInc.
5. Bean, H.S. Beckett, A.H., Careless, A.H. (1982). Advances in pharmaceutical sciences, Vol. I, II, III & IV, London: Academic Press.

Suggested e-material:

1. https://pharmaclub.in/free-pharmacy-ebooks-pharmaceutics/
2. https://www.pdfdrive.com/pharmaceutical-books.html
3. http://202.74.245.22:8080/xmlui/handle/123456789/39/browse?type=subject
4. http://swepub.kb.se/
5. https://ethos.bl.uk/Home.do

PHAR 603R Molecular Basis of Drug Discovery

Max. Marks : 100	**L**	**T**	**P**	**C**
(ESA: 100)	**0**	**0**	**4**	**2**

Learning outcomes

Upon completion of the course, the student will be able to:-

- Understand receptors and enzymes, the body's molecules most often targeted by drugs.
- Learn pharmacokinetics (drug adsorption, elimination, and half-life) and metabolism

Drug Target Identification: Direct biochemical and genetic methods as well as computational inferences can be used to identify and validate small molecule drug targets. To fully delineate “on-target” and “off-target” effects, a blend of these approaches is merited.

Assay development/HTS: Development and validation of assays for hit identification and confirmation.

Protein Structure determination: Protein mechanistic and functional studies, as well as rational inhibitor design are often facilitated by the protein structure determination. Basic techniques and procedures for structural biology are described.

Rational Small-Molecule Inhibitor Design: Introduction of ligand-, structure-, as well as computer-aided drug design targeting a protein. Interested students may have hands-on training in computational drug design using the Schrödinger drug design software after class.

Concepts toward Developing Screening Collections for Drug Discovery: Natural products and their analogs account for over 50% of the pharmacopeia. Fragmentbased drug discovery relies on the identification of smaller ligands to disease targets and their optimization toward more potent lead compounds. Diversity-oriented synthesis aims to produce compound libraries with expanded diversity in molecular architecture. Each of these areas is vitally represented in modern day drug discovery. The lecture will focus on general merits and challenges within each of these drug discovery paradigms.

Lead optimization/Medicinal Chemistry: Upon identification of lead compounds, medicinal chemistry optimization is required to find compounds with improved biological potency as well as drug properties (e.g., pharmacokinetics, Lipinski’s rule of 5).

Pharmacokinetics, Toxicology and Formulation: Many small molecule drug leads showing excellent in vitro activity have failed in vivo mainly due to their poor pharmacokinetics and biodistribution. Drug delivery techniques can improve the pharmacokinetics and enhance the drug

accumulation at the pathological site. An overview of drug delivery techniques will be introduced. In addition, some basics in pharmacokinetics and toxicology will also be discussed.

Books recommended:

1. Beale, J.M., Block, J., Wilson, G. (2010). Organic medicinal and Pharmaceutical Chemistry, 12th Ed., Philadelphia: Lippincott Williams and Wilkins.
2. Lemke, T.L., Williams, D.A., Rocho, V.F., Zito, S.W. (2012). Foye's Principles of Medicinal Chemistry, 7th Ed., Philadelphia: Lippincott Williams and Wilkins.
3. Abraham, D.J., Rotella, R.J. (2010). Burger's Medicinal Chemistry, Drug Discovery and Development, 7th Ed., New York: John Wiley and Sons.
4. Smith, J.H., Williams, H. (2010). Introduction to principles of drug design, 3rd Ed., Harwood Academic Publishers.
5. Remington, P.J., Beringer, P. (2006). Remington's Pharmaceutical Sciences, 21st Ed., Philadelphia: Lippincott Williams and Wilkins.
6. Buckley, G. (1988). Martindale's extra pharmacopoeia, 29th Ed., British journal of general practice.
7. Finar, I.L. (2002). Organic Chemistry: 5th Ed. Volume 2. , London:Pearson.
8. Lednicer, D. (1997). The Organic Chemistry of Drug Synthesis, 5th Edition, New York: John Wiley and Sons Ltd.
9. Indian Pharmacopoeia.
10. Furniss, B.S., Hannaford, A.J., Smith, P.W.G. (2009). Vogel's Tatchell-Text book of practical organic chemistry, 5th Ed., London: Pearson.

Suggested e-material:

1. https://www.wiley.com/enus/Burger%27s+Medicinal+Chemistry%2C+Drug+Discovery%2C+and+Development%2C+7th+Edition-p-9780470278154 (Burger's Medicinal Chemistry)

PHAR 606R Pharmaceutical Quality Assurance

Max. Marks : 100	**L**	**T**	**P**	**C**
(ESA: 100)	**0**	**0**	**4**	**2**

Learning outcomes

On the completion of this course student shall be able to know

- The cGMP aspects in a pharmaceutical industry
- The importance of documentation
- Scope of quality certifications applicable to Pharmaceutical industries
- Responsibilities of QA & QC departments

Introduction: An understanding of the concepts of Quality Assurance, Current Good Manufacturing Practice (cGMP), TQM and Quality Control as applied to the pharmaceutical industry.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation.

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities andmaintenance of sterile areas, control of contamination and Good Warehousing Practice.

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention andretrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports, Protocols and reports, Distribution records.

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.

Books recommended:

1. Quality Assurance Guide (1996) by Organization of Pharmaceutical Procedures of India, 3rd revised Ed., Volume I & II.
2. Weinberg, S. (1995). Good Laboratory Practice Regulations. 2nd Ed., Vol. 69, New York: Marcel Dekker, Inc.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. Sharma, P. P. (1991). How to Practice GMP's. Agra:Vandana Publications.
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Suggested e-material:

1. www.ich.org

2. www.iso.org

3. www.fda.gov