BANASTHALI VIDYAPITH

Master of Pharmacy (Pharmaceutics)

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.

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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 (Pharmaceutics)

First Year

Semester - I

Course	Code	Course Name	L	T	P	C*
PHAR	514	Drug Delivery Systems	4	0	0	4
PHAR	516	Modern Pharmaceutical Analytical Techniques	4	0	0	4
PHAR	517	Modern Pharmaceutics	4	0	0	4
PHAR	529	Regulatory Affairs	4	0	0	4
PHAR	522L	Pharmaceutics 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	502	Advanced Biopharmaceutics and Pharmacokinetics	4	0	0	4
PHAR	512	Computer Aided Drug Development	4	0	0	4
PHAR	513	Cosmetics and Cosmeceuticals	4	0	0	4
PHAR	518	Molecular Pharmaceutics	4	0	0	4
PHAR	523L	Pharmaceutics 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	533	Pharmacological and Toxicological Screening Methods-I	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	Nutraceuticals	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 514 Drug Delivery Systems

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 criteria for selection of drugs and polymers for the development of novel dosage forms
- Need of different approaches for preparation of novel drug delivery systems.
- Formulation and evaluation of novel drug delivery systems.

SECTION-A

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, mechanism of drug delivery from SR/CR formulation.

Polymers: Introduction, definition, classification, properties and application.

Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, categories of patients for personalized medicines, customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, telepharmacy.

SECTION-B

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

SECTION-C

Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Books recommended:

1. Chien, Y.W. (1992). Novel drug delivery systems. 2nd Ed., New York: Marcel Dekker, Inc.
2. Robinson, J.R., Lee, V.H.L. (1992). Controlled drug delivery systems. New York: Marcel Dekker, Inc.
3. Mathiowitz, E. (1999). Encyclopedia of controlled delivery. New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
4. Jain, N.K. (1997). Controlled and novel drug delivery. 1st Ed., New Delhi: CBS Publishers & Distributers.
5. Vyas, S.P., Khar, R.K. (2002). Controlled drug delivery-concepts and advances. 1st Ed., New Delhi: VallabhPrakashan.

Suggested e materials:

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

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:

1. Silverstein, R.M. (2004). Spectrometric Identification of Organic compounds. 6th Ed., New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
2. Skoog, D.A., Holler, F.J., Nieman, T.A. (1998). Principles of Instrumental Analysis. 5th Ed., Bangalore: Eastern press.
3. Beckett, A.H., Stenlake, J.B. (1987). Practical Pharmaceutical Chemistry. 4th Ed., vol 2. New Delhi: CBS Publishers & Distributers.
4. Kemp, W. (1991). Organic Spectroscopy, 3rd Ed., London: Red Globe Press.
5. Sethi, P.D. (1987). Quantitative Analysis of Drugs in Pharmaceutical formulation. 3rd Ed., New Delhi: CBS Publishers & Distributers.
6. Munson, J.W. (2008). Pharmaceutical Analysis- Modern methods – Part B. vol 11. New York: Marcel Dekker, Inc.

Suggested e-material:

1. http://www.sciencedirect.com/science/book/9780123869845 (Infrared and Raman spectroscopy)
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 517 Modern Pharmaceutics

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 concept of pre-formulation and its effect on formulation, efficacy and stability of pharmaceutical products at industry.

- Formulation, evaluation and stability aspect of emulsion, suspension, SMEDDS, and parenteral at large scale production.
- Aspects related to compression and compaction of tablets.
- Better way of application of pharmaceutical and statistical tools.

SECTION-A

Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.

Dissolution parameter: Similarity factors – f2 and f1, Higuchi and Peppas plot.

Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability

Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

SECTION-B

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, Heckel plots.

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & PQ of facilities.

cGMP& Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance.

SECTION-C

Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation

Linearity, Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

Books Recommended:

1. Lachmann, L., Libermann, H.A., Kanig, J.L. (2013). Theory and practice of industrial pharmacy. 4th Ed., Bombay: Varghese Publishing House.

2. Lachmann, L., Libermann, H.A., Joseph, B. (1989). Pharmaceutical dosage forms: Tablets. 2nd Ed.,vol. I-III. New York: Marcel Dekker.

3. Lachmann, L., Libermann, H.A., Martin, M.R., Banker, G.S. (1996). Pharmaceutical dosage forms: disperse systems. vol. I-II, CRC press.

4. Avis, K.E., Lachmann, L., Libermann, H.A. (1984). Pharmaceutical dosage forms: parentral medications. vol.1. New York: Marcel Dekker.

5. Gillbert, S.B., Christopher, T.R. (1996). Modern Pharmaceutics.4th Ed., CRC press.

6. Remington, J.P. (2005). Remington: The science and practice of pharmacy. 21st Ed., Lippincott Williams and Wilkins.

7. Bean, H.S., Beckett, A.H., Carless, J.E. (1964). Advances in pharmaceutical sciences.vol. I-V, London, Berkeley: Academic press.

8. Sinko, P.J. (2011). Martin's physical pharmacy and pharmaceutical sciences.6th Ed., Lippincott Williams and Wilkins.

9. Rawlins, E.A. (2012). Bentley's textbook of pharmaceutics. 8th Ed., Elsevier.

10. Willing, S.H. (2001). Good manufacturing practices for pharmaceuticals: a plan for total quality control. 5th Ed., New York: Marcel Dekker, Inc.

11. Quality Assurance Guide, By Organization of Pharmaceutical producers of India.

12. Kohli, D.P.S., Shah, D.H. (2008). Drug formulation manual. New Delhi: Eastern publishers.

13. Sharma, P.P. (2015). How to practice GMPs. 7 th Ed., Agra: Vandhana publications.

14. Nash, R.A., Watcher, A.H. (2003). Pharmaceutical process validation.3rd Ed., vol. 129. New York: Marcel Dekker Inc.

15. Wells, J.I. (1990). Pharmaceutical preformulation: The physiochemical properties of drug substances. vol. 79.Chichester: Ellis Horwood.

16. Evans, J.R., Anderson, D.R., Sweeny, D.J., Williams, T.A. (1990). Applied production and operations management. 3rd Ed

17. Swarbrick, J. (2006). Encyclopaedia of pharmaceutical technology.3rd Ed., CRC press.

Suggested e-material:

1. https://pharmaclub.in/free-pharmacy-ebooks-pharmaceutics/
2. https://www.pdfdrive.com/pharmaceutical-books.html
3. http://www.statsoft.com/Textbook
4. http://202.74.245.22:8080/xmlui/handle/123456789/39/browse?type=subject
5. https://accesspharmacy.mhmedical.com/books.aspx?view=library
6. https://www.managementstudyguide.com/elements-of-total-quality-management.htm

PHAR 529 Regulatory affairs

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:

- concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's for filing and approval process
- preparation of dossiers and their submission to regulatory agencies in different countries
- post approval regulatory requirements for actives and drug product
- clinical trials requirements for approvals for conducting clinical trials

SECTION-A

Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

SECTION-B

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

CMC, post approval regulatory affairs.Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.

SECTION-C

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

Books recommended:

1. Shargel, L, Kaufer, I. (2005). Generic Drug Product Development, Solid Oral Dosage forms. Vol.143. New York: Marcel Dekker Inc.
2. Berry, I.R., Martin, R.P. (2008). The Pharmaceutical Regulatory Process.2nd Ed., vol. 185.Drugs and the Pharmaceutical Sciences. New York: CRC press.
3. Guarino, R.A. (2004). New Drug Approval Process: Accelerating Global Registrations. 5th Ed., vol. 190, New York: Marcel Dekker Inc.
4. Weinberg, S. (2009). Guidebook for drug regulatory submissions.1st Ed., John Wiley & Sons Inc.
5. Pisano, D.J., Mantus, D. (2005). FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. 2nd Ed., New York: CRC press.
6. Rozovsky, F.A., Adams, R.K. (2003). Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance. 1st Ed., Washington: John Wiley and Sons.

Suggested e-material:

1. www.ich.org/
2. www.fda.gov/
3. europa.eu/index_en.htm
4. https://www.tga.gov.au/tga-basics

PHAR 522L Pharmaceutics Lab – I

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

Learning outcomes

Upon completion of this course the student will develop skills of:

- Developing new analytical method
- Designing pre-formulation study for new drug
- Formulation and characterization of dosage forms

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
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.

16. To study the effect of particle size on dissolution of a tablet.

17. To study the effect of binders on dissolution of a tablet.

18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

Books Recommended:

1. Remington, J.P. (2005). Remington: The science and practice of pharmacy. 21st Ed., Lippincott Williams and Wilkins.

2. Lachmann, L., Libermann, H.A., Kanig, J.L. (2013). Theory and practice of industrial pharmacy. 4th Ed., Bombay: Varghese Publishing House.

3. Jain, N.K. (1997). Controlled and novel drug delivery. 1st Ed., New Delhi: CBS Publishers & Distributers.

4. Vyas, S.P., Khar, R.K. (2002). Controlled drug delivery-concepts and advances. 1st Ed., New Delhi: VallabhPrakashan.

5. Beckett, A.H., Stenlake, J.B. (1987). Practical Pharmaceutical Chemistry. 4th Ed., vol 2. New Delhi: CBS Publishers & Distributers.

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

Second Semester

PHAR 502 Advanced Biopharmaceutics and Pharmacokinetics

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 concepts in biopharmaceutics and pharmacokinetics.
- The critical evaluation of biopharmaceutical studies involving drug product performance.
- compartment modelling and nonlinear

- Bioavailability – bioequivalence (BA-BE) study.
- PK-PD.

SECTION-A

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors. Physiological factors related to drug absorption.

SECTION-B

Biopharmaceutic considerations in drug product design and in vitro drug product performance: Introduction, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and Vmax.

Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

SECTION–C

Bioavailability and Bioequivalence: Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of

bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example. Biopharmaceutics classification systems.In-vitro, in-situ and In-vivo permeability methods. Clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies.

Introduction to Pharmacokinetics and pharmacodynamic (PK-PD)

Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

Books recommended:

1. Gibaldi, M. (1991). Biopharmaceutics and Clinical Pharmacokinetics. 4th Ed. Philadelphia: Lea and Febiger.
2. Treatise, A., Brahmankar, D.M., Jaiswal, S.B. (2015). Biopharmaceutics and Pharmacokinetics. Delhi: VallabhPrakashan.
3. Shargel, L., Yu, A., Pong, S.W. (2012). Applied Biopharmaceutics and Pharmacokinetics.6th Ed. New York: Mcgraw Hill Publication.
4. Rani, S., Hiremath R. (2012). Textbook of Biopharmaceutics and Pharmacokinetics. 2nd Ed. Delhi: Prism Publications.
5. Gibaldi, M., Perrier, D. (1982). Pharmacokinetics.2nd Ed. Revised and expanded. New York: CRC press.
6. Swarbrick, J. (1970). Current Concepts in Pharmaceutical Sciences: Biopharmaceutics. Philadelphia: Lea and Febiger.
7. Rowland, M. Tozer, T.N.(1995). Clinical Pharmacokinetics, Concepts and Application, 3rd edition, Philadelphia: Lippincott Williams and Wilkins.
8. Mack, H.M. (1989). Dissolution, Bioavailability and Bioequivalence, Pennsylvania: Mack Publishing Company.
9. Notari, R.E. (1987). Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded, New York: Marcel Dekker.
10. Wagner, J.G. Pemarowski, M.(1971). Biopharmaceutics and Relevant Pharmacokinetics, 1st edition, Illinois: Drug Intelligence Publications.

11. Swarbrick, J. Boylan, J.G. (1996). Encyclopedia of Pharmaceutical Technology, New York: Marcel Dekker.

12. Jambhekar, S.S. Breen, P.J. (2009). Basic Pharmacokinetics, 1st edition, Pharmaceutical press.

13. Avdeef, A. (2003).Absorption and Drug Development- Solubility, Permeability, and Charge State, New York: John Wiley & Sons Inc.

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 512 Computer Aided Drug Development

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:

- Computational modeling of drug for its pharmacokinetic evaluation.
- Usage of software in designing and optimizing pharmaceutical formulations.
- Application of artificial intelligence and robotics in pharmaceutical automation.
- implementation of computational fluid dynamics (cfd) to overcome challenges in pharmaceutical product development.

SECTION-A

Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

Quality-by-Design in Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

SECTION–B

Computational Modeling of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

Computer-aided Formulation Development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro-emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

Computer-aided Biopharmaceutical Characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations

SECTION–C

Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

Books recommended:

1. Ekins, S. (2006). Computer Applications in Pharmaceutical Research and Development, John Wiley & Sons.

2. Djuris, J. (2013). Computer-Aided Applications in Pharmaceutical Technology, 1st Ed. Cambridge: Woodhead Publishing.

3. Swarbrick, J., Boylan, J.G. (1996). Encyclopedia of Pharmaceutical Technology.vol 13. New York: Marcel Dekker Inc.

4. Bolton, S., Bon, C. (2010). Pharmaceutical Statistics.5th Ed.,vol 203. New York: Informa

Suggested e-material:

1. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.710.2898&rep=rep1&type=pdf

2. http://file.zums.ac.ir/ebook/235-Drug%20Design%20and%20Discovery%20-%20Methods%20and%20Protocols%20(Methods%20in%20Molecular%20Biology)-Seetharama%20D.pdf

PHAR 513 Cosmetics and Cosmeceuticals

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 key ingredients and basic science involve to develop cosmetics and Cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability and efficacy with compliance to Indian Regulatory Authority.

SECTION–A

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with

oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

SECTION–B

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste.Soaps and syndetbars.

Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

SECTION–C

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

Herbal Cosmetics: Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

Books recommended:

1. Harry, R.G., Reiger, M.M. (2000). Harry's Cosmeticology.8th Ed. New York: Chemical publishing company.
2. Butler, H. (2000). Poucher's perfume cosmetics and Soaps, 10th Ed. London: Kluwar academic publishers.
3. Sharma, P.P. (2008). Cosmetics - Formulation, Manufacture and quality control. 4th Ed. New Delhi: Vardhan publishing pvt ltd.
4. Barel, A.O., Paye M, Maibach H.I. (2001). Handbook of cosmetic science and Technology.3rd Ed. NewYork: Marcel Decker Inc.

5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

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 518 Molecular Pharmaceutics

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 criteria for selection of drugs and polymers for the development of Targeted drug delivery.
- The various approaches for development of novel drug delivery systems.
- The formulation and evaluation of novel drug delivery systems.

SECTION-A

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting.Tumor targeting and Brain specific delivery.

Targeting Methods: Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

SECTION-B

Micro Capsules / Micro Spheres:Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

SECTION-C

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer).Liposomal gene delivery systems.

Biodistribution and Pharmacokinetics: Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

Books recommended:

1. Chien, Y.W. (1992). Novel Drug Delivery Systems. 2nd Ed. revised and expanded. New York: Marcel Dekker.
2. Vyas, S.P., Khar R.K. (2002). Controlled Drug Delivery - concepts and advances. New Delhi: VallabhPrakashan.
3. Jain, N.K. (2001). Controlled and Novel Drug Delivery.1st Ed. New Delhi: CBS Publishers & Distributors.

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 523L Pharmaceutics 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:

- Formulation and characterization of NDDS.

- Various pharmacokinetic and statistical softwares.
- Clinical and nonclinical data collection.

1. To study the effect of temperature change,non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products

22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

Books Recommended:

1. Remington, J.P. (2005). Remington: The science and practice of pharmacy. 21st Ed., Lippincott Williams and Wilkins.

2. Lachmann, L., Libermann, H.A., Kanig, J.L. (2013). Theory and practice of industrial pharmacy. 4th Ed., Bombay: Varghese Publishing House.

3. Jain, N.K. (1997). Controlled and novel drug delivery. 1st Ed., New Delhi: CBS Publishers & Distributers.

4. Vyas, S.P., Khar, R.K. (2002). Controlled drug delivery-concepts and advances. 1st Ed., New Delhi: VallabhPrakashan.

5. Butler, H. (2000). Poucher's perfume cosmetics and Soaps, 10th Ed. London: Kluwar academic publishers.

6. Sharma, P.P. (2008). Cosmetics - Formulation, Manufacture and quality control. 4th Ed. New Delhi: Vardhan publishing pvt ltd.

(Discipline Elective)

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.
- the 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 thepharmacological 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 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.

Recommended books:

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.

Recommended books:

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:

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.Nutrition labelling.European Regulation on Novel Foods and Novel Food Ingredients.Recommended Dietary Allowances(RDA) in Europe.

Books recommended:

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 DeviceNomenclature (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:

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 PharmacoviGilance 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

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.

5. The International Pharmacopoeia (2005)– Vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd Ed., WHO, Geneva.

6. Hirsch, A. F. (1989). Good Laboratory Practice Regulations. Vol 38, New York: Marcel Dekker Inc.

7. Deshpande, S. W., Gandhi, N. The Drugs and Cosmetics Act 1940 and Rules 1945. 8th Ed., Mumbai:Susmit Publishers.

8. Shah, D. H. (2000). QA Manual. 1st Ed., Business Horizons, Elsevier.

9. Willig, S. H., Stoker J. (1991). Good Manufacturing Practices for Pharmaceuticals A Plan For Total Quality Control. Vol. 52, 3rd Ed., New York: Marcel Dekker Inc.

10. Steinborn L. (2003). GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis.

11. Sarker, D.K. (2008). Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons.

Suggested e-material:

1. www.ich.org
2. www.iso.org
3. www.fda.gov