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शिवाजी विद्यापीठ, कोल्हापूर ४१६ ००४, महाराष्ट्र
दूरध्वनी - इपीबीएक्स - २०६०९०००, अभ्यासमंडळे विभाग : ०२३१- २६०९०९४. २६०९४८७
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Estd. 1962
"A++" Accredited by NAAC (2021)
With CGPA 3.52

SU/BOS/Sci & Tech/ 180 **Date: 10/06/2026**

The Principal/ Director,
All affiliated Engineering Colleges/ Institute,
Shivaji University, Kolhapur.

Subject: Regarding revised syllabus of Ph. D. Pharmacy Coursework under the Faculty of Science and Technology as per NEP - 2020.

Sir/Madam,

With reference to the subject mentioned above, I am directed to inform you that the university authorities have accepted and granted approval to the revised syllabi, Nature of Question paper and equivalence of Ph. D. Pharmacy Coursework under the Faculty of Science & Technology as per National Education Policy 2020.

This Syllabus, shall be implemented from the academic year 2025-26 onwards. A soft copy containing the syllabus is attached herewith and it is available on university website **www.unishivaji.ac.in.>Syllabus>Syllabus as per NEP2020.**

You are therefore, requested to bring this to the notice of all students and teachers concerned.

Thanking you,

Yours faithfully,

Dy. Registrar

Encl. : As above.

Copy to: For Information and necessary action.

1	The I/c Dean, Faculty of Science & Technology	7	P.G.Admission Section
2	Director, Board of Examination and Evaluation	8	Affiliation T. 1 & T. 2 Section
3	The Chairman, Respective Board of Studies	9	Appointment A & B Section
4	PGBUTR Section	10	P.G.Seminar Section
5	B.Sc. / M.Sc. Exam Section	11	I.T. Cell / Computer Centre
6	Eligibility Section	12	Internal Quality Assurance Cell (IQAC)

SHIVAJI UNIVERSITY,

KOLHAPUR

Faculty of Science and Technology

Syllabi of Ph.D. Course Work

PHARMACY

(To be Implemented from Academic Year 2025-26)

SHIVAJI UNIVERSITY, KOLHAPUR

Pre Ph.D. Coursework for

PHARMACY

Paper I RESEARCH METHODOLOGY

Objectives:

- Provide comprehensive knowledge of research concepts, design, and methodology.
- To be able to formulate the problem statement and research plan for the problem under investigation
- To be able to apply various numerical/ quantitative techniques for data collection & data analysis.
- Enable preparation of research proposals, theses, and scientific publications

Course Outcomes (COs)

After successful completion of the course, the scholar will be able to:

- CO1: Understand fundamentals and types of research
- CO2: Formulate research problems and hypotheses
- CO3: Design appropriate research methodologies
- CO4: Apply statistical tools for data analysis
- CO5: Prepare research proposals, reports, and publications ethically

Unit I: Introduction: [25 mks]

- Concepts of Research, Meanings, characteristics, and Objectives of Research, Research process & scientific method, Motivation of research, Types of research (e.g., experimental, descriptive, qualitative, quantitative).
- **Components of research work:** Problem identification, Necessity of defining the problem, drafting a problem statement, framing proper objectives of research, hypothesis development, research design, and report writing.
- **Literature Review:** Importance, process, and use of various sections of a research paper.
- **Research Proposals, Thesis & Publications:** Types, contents, Sponsoring agency's requirements, Ethical aspects, Structure of thesis/dissertation, Referencing styles (APA, Vancouver, Harvard), Plagiarism, Societal responsibility, IPR issues like patenting, copyrights etc.
- **Critical Appraisal of Literature:** Assessing the quality, biases, and authenticity of primary literature.
- **Evidence Synthesis:** Steps for conducting systematic reviews and meta-analysis, use of relevant guidelines (e.g., PRISMA, MOOSE), and software.

Unit II: Research design and methods: [25 mks]

Research design: Meaning, Need and Types of research design with reference to the identified problem – basic principles, features of good design, important concepts relating to research design, Research Design Process (Exploratory, Descriptive, Experimental), Measurement and scaling techniques,

observation and facts, laws and theories, prediction and explanation, research databases, development of models, developing a research plan – exploration, description, diagnosis, and experimentation.

Experimental Design and Analysis of Variance: Completely randomized, randomized blocks, Latin square, and factorial designs etc.

Unit III: Execution of the research, data collection and analysis: [25 mks]

Data Collection: concepts, types and methods, Aspects of method validation, observation and collection of data, Sampling fundamentals and methods, data processing and analysis strategies and tools, hypothesis testing, data analysis with statistical packages (GraphPad Prism, SPSS for Student t-test, ANOVA, etc), Chi square test, Multivariate analysis (Correlation and regression) and applications of various statistical software's and interpretation.

Non-parametric Tests: Sign test, Mann-Whitney U, Wilcoxon, Kruskal-wallis tests.

Unit IV: Computer Applications [25 mks]

Pre-writing considerations, Principles of Thesis Writing, Formats of Report Writing and Publication in Research Journals, Documentation and presentation tools- LATEX, Microsoft Office with basic presentations skills, Use of Internet and advanced search techniques.

- **Information Retrieval Systems:** Use of computers and online databases for information retrieval.
- **Specialized Software:** Use of specific pharmaceutical software systems and potentially computer-aided design/manufacturing (CAD/CAM) tools depending on the specialization.

References:

1. Management Research Methodology' by K.N. Krishnaswamy, Appa Iyer Sivakumar & M. Mathirajan, Person Education.
2. Research Methodology. G.C. Ramamurthy, Dream Tech Press, New Delhi
3. Research Methodology: A Step by Step Guide for Beginners' by Ranjit Kumar, 2nd Edition
4. Research Methodology: An Introduction for Science and Engineering Students', by Stuart Melville and Wayne Goddard
5. Research Methodology: An Introduction' by Wayne Goddard and Stuart Melville
6. Research Methodology: Methods and Techniques', by Dr. C.R. Kothari
7. Research Methodology by Garg, B.L.

SHIVAJI UNIVERSITY, KOLHAPUR

Pre Ph.D. Coursework for

PHARMACY

Paper-II PHARMACEUTICAL SCIENCES

UNIT-I **[20 mks]**

UV-Visible Absorption Spectroscopy: Spectra of isolated chromophores, Auxochromes, Batho-chromic shift, Hypsochromic shift, Hyperchromic and hypochromic effect.

Choice of solvents and solvent effect, Woodword's Fieser, Fieser Kuhn and Nelson rule, Spectral correlation with structures of compounds and Qualitative and quantitative analysis applications of UV-Visible spectrophotometry.

Infrared Spectroscopy: Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies, Interpretation of spectra of compounds and Applications of IR spectroscopy to drug product and excipient analysis.

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, fluorescent Quenchers, fluorescent tags, Applications of fluorescence spectrophotometer.

UNIT-II **[20 mks]**

1H and 13C NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent Requirement in NMR, Chemical shift, Factors influencing chemical shift, Spin- Spin coupling, coupling constant, Nuclear magnetic double resonance, Brief outline of principle of FT-NMR, Interpretation of spectra of compounds for structure elucidation.

UNIT-III **[20 mks]**

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, Applications of mass spectroscopy to structural elucidation of compounds.

UNIT-IV **[20 mks]**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

Paper chromatography, Thin Layer chromatography, Ion exchange chromatography, Column chromatography, Gas chromatography, High Performance Liquid chromatography, HPTLC.

Hyphenated techniques: Principle, instrumentation and applications of LC-MS/MS, GC-MS/MS, HPTLC-MS, strategies and techniques employed for the qualitative and quantitative evaluation of impurities, degradation products, drug-drug and drug-excipient interaction products, metabolites, phytochemicals and trace components.

UNIT-V **[20 mks]**

Validation using ICH Guidelines: For Analytical and Bioanalytical methods.

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 including Solid State Characterization of Pharmaceuticals.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, derivative differential thermal analysis (DDTA), pharmaceutical applications including Solid State Characterization of Pharmaceuticals.

TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications including Solid State Characterization of Pharmaceuticals.

References:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

8. Handbook of Pharmaceutical Analysis by Lena Ohannesian, Antony J. Streeter

9. HPLC for Pharmaceutical Scientists, Edited by Yuri Kazakevich and Rosario LoBrutto

10. Vogel HG, Drug Discovery and Evaluation, Springer, Germany.2008.

11. Wu G Assay development: fundamentals and practices. Wiley, New York (2010).

SHIVAJI UNIVERSITY, KOLHAPUR
Pre Ph.D. Coursework for
PHARMACY
PAPER-III
E-01: ADVANCED PHARMACEUTICAL PRODUCT DEVELOPMENT AND DRUG DELIVERY SYSTEMS

UNIT-I **[15 MKS]**

Recent trends in formulation development: Importance of formulation development in pharmaceutical industry, advancements in formulation approaches and their impact on drug delivery, bioavailability and therapeutic outcomes. Translational aspects in formulation development and role of digital tools including artificial intelligence in formulation development and optimization.

Polymers and excipients: Classification and pharmaceutical applications of polymers including biodegradable systems, role of excipients in formulation design, safety and regulatory considerations. Case studies highlighting applications of advanced drug delivery systems in therapeutic areas.

Preformulation studies: Scope and significance in drug development, bulk characterization, solubility, stability and polymorphism. Drug–excipient compatibility and key challenges in preformulation development. Case study-based understanding of formulation success or failure.

UNIT-II **[15 MKS]**

Novel drug delivery systems: Overview of liposomes, nanoparticles, micelles and dendrimers, formulation approaches and applications in targeted and controlled drug delivery with improved bioavailability.

Principles of drug targeting and molecular basis of targeted drug delivery: Receptor med iated endocytosis; Different levels of targeting-
first order, second order and third order targeting; Different types of targeting-
active and passive targeting.

Disease based targeting approaches: Novel approaches to target diseases and disorders suc h as cancer and infectious diseases, exploitation of disease environment for the targeted deliv ery of therapeutics.

UNIT-III **[15 MKS]**

Solid-state pharmaceutics: Importance of solid-state characterization, polymorphism,

amorphous systems and co-crystals, and their influence on drug performance. Characterization techniques including X-ray diffraction, DSC, FTIR and microscopy. Stability and degradation pathways of solid dosage forms.

Physicochemical approaches of targeting: Stimuli responsive: Magnetically, thermal an d pH assisted drug delivery systems, Chemical drug delivery (prodrugs), Lipiddrug/Polymer-drug conjugates.

Advanced dosage forms: Modified-release systems, oral films, implants, inhalation systems and nanosuspensions. Biopharmaceutical approaches for improving solubility and stability including amorphous solid dispersions and cyclodextrin complexes. Case studies on formulation of poorly soluble drugs.

UNIT-IV **[15 MKS]**

Nutraceuticals and cosmeceuticals: Overview of nutraceuticals, bioactive compounds and their role in health and disease management. Development of nutraceutical dosage forms and evaluation of efficacy. Cosmeceuticals and advanced skin and hair care formulations, including sustainable and green formulation approaches.

Personalized medicine and precision formulation: Concept of customized therapies and integration of biomarkers in formulation design. Case studies on personalized formulations and functional products.

UNIT-V **[20 MKS]**

Quality by Design (QbD) and regulatory aspects: Principles of QbD in formulation development, application of design of experiments for optimization and control of product quality. Overview of regulatory requirements including ICH guidelines, intellectual property considerations and ethical aspects in pharmaceutical development. Optimization techniques: Factorial design and response surface methodology for formulation optimization.

Application-oriented and problem-solving approaches: Systematic approach for formulation design based on physicochemical properties of drug candidates, selection of suitable dosage form and excipients, identification and resolution of formulation challenges, and evaluation of scale-up considerations. Application of theoretical knowledge to solve formulation-related problems with emphasis on analytical thinking and decision-making.

References:

1. Novel Drug Delivery Systems: Fundamentals, Developmental Concepts, Biomedical Assessments" by Yie W. Chien
2. Controlled Drug Delivery: Fundamentals and Applications" edited by Joseph R. Robinson and Vincent H. Lee.
3. Nanotechnology-Based Approaches for Targeting and Delivery of Drugs and Genes" edited by Vijay Mishra and Rahul Dev Jayant.
4. Pharmaceutical Quality by Design: Principles and Applications" edited by Walkiria S. Schlindwein and José C. Menezes.
5. J.I. Wells, Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances, Ellis Horwood, Chiechester (UK).
6. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, N.Y.
7. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann. Third edition, Varghese Publishing House.
8. Modern Pharmaceutics; By Gillbert and S. Banker.
9. Pharmaceutical Preformulation and Formulation: The Science and Practice of Dosage Form Design" by Mark Gibson.
10. Pharmaceutical Excipients: Properties, Functionality, and Applications in Research and Industry" edited by Linda A. Felton.
11. Solid State Characterization of Pharmaceuticals" edited by Bruno C. Hancock and Gary L. Amidon.
12. Pharmaceutical Solids: Characterization and Drug Delivery" edited by Harry G. Brittain.
13. Polymorphism in Pharmaceutical Solids" edited by Harry G. Brittain.
14. Solid State Properties of Pharmaceutical Materials" edited by Jens T. Carstensen and Christopher L. Forster.
15. Pharmaceutical Regulatory Affairs: Basics, Challenges, and Strategies" by Stephen C. Denyer, Norman A. Hodges, and Anthony J. Rawlins.

SHIVAJI UNIVERSITY, KOLHAPUR

Pre Ph.D. Coursework for

PHARMACY

PAPER-III

E-02 MEDICINAL CHEMISTRY RESEARCH

UNIT-I **[15 MKS]**

Molecular modeling and Bioactive conformation: Wave function of drug molecules. Hamiltonian of Drugs. Absolute and relative energies of drug conformers. Energy minimization, comparison between global minimum conformation and bioactive conformation. Manual and automated conformational search methods, their advantages and disadvantages. Implicit and explicit solvent effects on the structures of drugs. Conformational interconversion, transition-state determination and their role in designing rigid analogs

UNIT-II **[15 MKS]**

Molecular Docking: Rigid docking, flexible docking, manual docking, induced fit docking. Algorithms for molecular docking. Advantages and disadvantages of Glid, GOLD, Autodock and Dock software, with successful examples.

Virtual Screening: Protocol development in virtual screening. Qualitative versus quantitative approaches- advantages and disadvantages. Random screening, Non-random screening, drug metabolism studies, clinical observations, rational approaches to lead discovery.

Pharmacophore Perception: Unity in diversity; common minimum feature identification. Pharmacophore mapping techniques, methods of conformational search used in pharmacophore mapping. Comparison between the popular pharmacophore methods like Catalyst/HipHop, DiscoTech, and GASP with practical examples.

UNIT-III **[20 MKS]**

Retrosynthetic analysis, disconnections and reliability of reactions, synthons: Donor and acceptor, functional group interconversions, one group carbonheteroatom and carbon-carbon disconnections, two group carbon- heteroatom and carbon-carbon disconnections, chemo-, regio-and stereoselectivity considerations, natural reactivity and umpolung, 1,3 and 1,5-difunctional compounds.

Chemistry of protecting groups: Protection for alcohols, carbonyl groups, carboxylic group and amino groups.

QSAR: Steric and electronic effects: Hammett equation, lipophilicity effects. Hansch equation. Experimental and theoretical approaches for the determination of physico-chemical parameters, descriptors from Graph theory. Regression analysis, extrapolation versus interpolation, linearity versus nonlinearity. Descriptor calculation. The importance of biological data in the correct form; 2D QSAR; 3D-QSAR examples of CoMFA and CoMSIA.

UNIT-IV **[15 MKS]**

De novo Bioactive Design : Active sites, allosteric sites, subpockets. receptor/enzyme cavity size prediction. Predicting the functional components of cavities, designing drugs fitting into cavity. Trypanothione inhibitor Design using De novo design strategies.

Molecular Dynamics :Trajectories – structural, energy, interaction. Dynamics of drugs, dynamics of biomolecules, dynamics of drug-receptor complexes. Molecular dynamics in estimation of free energy from dynamical methods. Entropy and van der Waals vs. electrostatic component. Residuewise interaction energy estimation using MD simulations. Human vs. PfDHFR interaction energy difference with P218.

UNIT-V **[15 MKS]**

Case studies including SAR and ADMET: Anti-malarial agent design using CADD methods (PfDHFR), Anti-diabetic agent design (GSK3), anti-cancer agent design (TopoisomeraseII), Anti-leishmanial agent design (TR inhibitors), antihypertensive agent design (ACE inhibitors), antitubercular drug design by inhibiting IdeR (iron-dependent regulator protein) or siderophore synthesis disrupts iron uptake which is a crucial mechanism for survival of MTB.

Recommended books and links:

1. Molecular Modelling, byA. R. Leach
2. Organic Chemistry of Drug Design and Drug Action, by R.B. Silverman
3. Practical applications of computer aided drug design, by P.S. Charifson
4. Molecular modeling in Drug Design, by C. Cohen
5. Chemical applications of Molecular modeling, by J. Goodman
6. Pharmacophore perception, by O.F. Guner
7. https://www.drugdesign.org/chapters/success-stories-in-drug-discovery/#success-story-1-captopril
8. doi: 10.2147/DDDT.S96315
   https://pmc.ncbi.nlm.nih.gov/articles/PMC4708961/#:~:text=Abstract,was%20determined%20in%20experimental%20mice.
9. https://pmc.ncbi.nlm.nih.gov/articles/PMC10140854/
10. https://pmc.ncbi.nlm.nih.gov/articles/PMC10140854/
11. https://ijnrd.org/papers/IJNRD2509124.pdf
12. Protective Groups in Organic Synthesis, Theodora W. Greene, Peter G. M. Wuts, Wiley, 4th Edition, 2006. ISBN: 978-0-471-69754-1.
13. https://www.organic-chemistry.org/protectivegroups/

SHIVAJI UNIVERSITY, KOLHAPUR

Pre Ph.D. Coursework for

PHARMACY PAPER-III

E-03 RECENT TRENDS IN PHARMACOLOGY AND TOXICOLOGY

UNIT-I **[10 MKS]**

Toxicological Screening of drugs-

Acute, subacute, chronic - Oral and Dermal as per OECD guidelines.

Human equivalent dose calculations, animal equivalent dose calculation.

UNIT-II **[20 MKS]**

Preclinical screening of new substances for evaluation of following:

a. Analgesics, Anti-inflammatory agents and Anti-Pyretic.
b. Antiulcer drugs, Hepato-protective, Nephroprotective
c. Anti-anxiety, Anti-depressants, Anti-epileptics, Anti-Parkinsonism, anti-Alzheimer

UNIT-III **[20 MKS]**

Pharmacotherapy and preclinical screening-

a. Pharmacotherapy of Cancer, Tuberculosis, diabetes, peptic ulcer, Depression
b. preclinical Evaluation Techniques for Anticancer, Antiviral, Antidiabetic, Anti-tubercular, Antioxidants and Antimicrobials.

UNIT-IV **[15 MKS]**

Alternatives to animal testing:

a. Cell based assays, Enzymatic assays, Patch clamp technique
b. High throughput screening, Hybridoma based target protein biosynthesis, target protein based bioassay development, Tissue Bioprinting
c. In- silico methods (Molecular docking, virtual screening, ADMET prediction, Molecular dynamic simulations, toxicity prediction, etc.)

UNIT-V **[15 MKS]**

Introduction to pharmacogenomics:

a. Recent advances in Transgenic and Knockout animals.
b. Gene therapy: Concept of Gene therapy and recent development in treatment of hereditary diseases.
c. Techniques for the study of molecular pharmacology, ELISA, Western Blot, PCR etc.

References:

1) *Turner*, *R.A. Screening Methods* of *Pharmacology*. Vol. *1*, *Academic Press*,1967, New York, *London*, 111-112.
2) Goodman and Gilman: Pharmacological Basis of Therapeutics, 14th Edition, Mc Graw Hill Publication Press, New York.
3) Drill V. A. Pharmacology in medicine. (McGraw Hill Co. New York).
4) Lawrence DR and Bacharach AL, Evaluation of Drug Activities: Pharmacometrics, Academy Press, London.
5) Vogel HG, Drug Discovery and Evaluation, Springer, Germany.
6) Ghosh MN, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta.
7) Kulkarni SK, Handbook of Experimental Pharmacology, Vallabh Prakashan, Delhi.
8) Seth UK, Dadkar NK, and Kamat UG: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Bombay.
9) LaFollette H, Shanks N: *Brute Science: Dilemmas of animal experimentation*. London and Neww York: Routledge; 1996.
10) Hau J: Animal Models. In *Handbook of Laboratory Animal Science Animal Models*. *VolumeII*. 2nd edition.
11) Overmier JB, Carroll ME: Basic Issues in the Use of Animals in Health Research. In *Animal Research and Human Health*. Edited by Carroll ME, Overmier JB. American Psychological Association; 2001:5.
12) Houdebine LM: Transgenic animal models in biomedical research, willy online library, 2003.
13) Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor Basic and Clinical Pharmacology, The McGraw-Hill Companies inc., 2004.
14) H.P. Rang and M.M. Dale, Pharmacology, 10th edition , Elsevier, 2023.
15) OECD test guidelines: https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/test-guidelines.html#
16) Dr. U. Satyanarayana & Dr. U. Chakrapani,.Textbook of Biotechnology , 2005.
17) KD.Tripathi. Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, 2004.
18) B. Parekh, "Bioassay Development for Complex Molecules," presentation at CASSS Bioassays (Silver Spring, MD, 2016).

SHIVAJI UNIVERSITY, KOLHAPUR

Pre Ph.D. Coursework for

PHARMACY

PAPER-III

E-04 NATURAL PRODUCT DRUG DEVELOPMENT

UNIT-I **[20 MKS]**

Phytochemical classification of plants, relationship between phytochemistry and taxonomy. Significance of classification of medicinal plants.

Different approaches for the discovery of new drugs from natural sources. Plant selection criteria along with the issue related to biodiversity and IPR. Detailed phytochemical investigation of plant material.

Novel herbal formulations and its evaluation: Phytosomes, Liposomes, Niosomes, Nanosphere, Microspheres, Proniosomes, Cubosomes, Plantibodies (immunoglobins) from plants,etc.

Use of excipients in herbal medicines. Stability studies of herbal medicinal products.

UNIT-II **[15 MKS]**

Flavopiridol: A novel flavonoid analogue designed on a natural product rohitukine. Chemistr y, SAR study and clinical status.

Triterpenoid compounds viz. lupeol, oleanolic-, ursolic- and betulinic acid derived plants as leads for drug development: Chemistry, SAR study, clinical trial status of leads derived from oleanolic, ursolic-and betulinic acid.

Artemisinin: A novel anti-malarial drug discovered from traditional Chinese medicine (TCM). Chemistry, SAR study, Artemisinin as a scaffold for the development of novel trioxa ne and tetraoxane anti-malarials agents.

UNIT-III **[15 MKS]**

Epothilones as novel microtubule inhibitors for anti-cancer drug development: Mechanism of action, and SAR study, epothilone leads under clinical development.

Vancomycin and other glycopetpide antibiotics: Classification of glycopeptide antibiotics, mechanism of action, structural modifications and SAR study.

Discodermolide, a potent microtubule inhibitor obtained from a marine sponge: Chemis try, SAR study and clinical status of analogues.

UNIT-IV **[15 MKS]**

Huperzine A: A drug for the treatment of Alzheimer's disease:Pharmacological activity, SA R study, clinical trial status of HA and analogues.

Curcumin: an exciting Natural product lead molecule for development of anti-

cancer drug: Chemistry, biological activity, SAR study, and clinical Status of curcumin an d lead molecules derived from curcumin.

Forskolin: A labdane diterpenoid isolated from Indian herb Coleus forskohlii is a potent ade nylate cyclase activator developed for the treatment of cardiomyopathy, glaucoma and asthm a. Chemistry and SAR study.

UNIT-V **[20 MKS]**

Quality control of herbal drugs/formulations- Overview of various Pharmacopeial monographs, general monographs on quality and other issue related publications. Conventional methods, Modern techniques (Role of genetic markers, RAPD, DNA fingerprinting technique etc). Determination of contaminants (Microbial load, aflatoxins, pesticide residues and heavy metals).

Phytochemical Reference Standards (PRS), Source and preparation of PRS, Fingerprint techniques, Analytical method development for the markers and validation assays.

Herbal Drug Regulatory affairs (D and C Act 1940 legal aspects related to Herbal / ASU drugs). WHO guidelines on good manufacturing practices (GMP) for herbal medicines. Role of AYUSH department in quality control of herbs and herbal formulations. Phytopharmaceutical Drugs and General Guidance for Development

References-

1. FDA Regulatory Affairs by Donglas J Pisano & David Mantus.
2. FDA Guidelines.
3. Yoganasimhan, S.N., Medicinal Plants of India, 1 st Edition, Interlive Publishing Pvt. Ltd.
4. Medicinal and Aromatic Plant abstracts (MAPA) CSIR, New Delhi.
5. Evans, W.C., Trease and Evans Pharmacognosy, W.B. Saunder& co., London.
6. Wallis, T.E., Text Book of Pharmacognosy.
7. Indian Herbal Pharmacopoeia.
8. Indian Pharmacopoeia.
9. Novel Drug Delivery Systems for Phytoconstituents Edited by Madhu Gupta, CRC
10. Kalia, A.N., Textbook of Industrial Pharmacognosy.
11. Mohammad Ali, Pharmacognosy and Phytochemistry.
12. Bruneton Jean, Pharmacognosy and Phytochemistry of Medicinal Plants.
13. Kaufmann, Natural Products from Plants, CRC Press, New York.
14. PhytotherapyA quick reference to herbal medicine, F Capasso, TS Gaginella, G Gradolini, AA Izzo, Springer Berlin, Heidelberg.

15.https://ayushnext.ayush.gov.in/detail/writeUps/ayurvedic-formulary-of-india-and-ayurvedicdrug-industry.
16. http://archiv.ayurveda.hu/doc/Protocol_For_Testing.pdf
17. https://apps.who.int/iris/bitstream/handle/10665/43510/?sequence=1
18. https://www.who.int/publications/i/item/9789241547161
19. Natural Products: Drug Discovery and Therapeutic Medicine by L Zhang, A L Demain
20. https://ipc.gov.in/images/29.08.2025_Phytopharmaceutical-Drugs-General-Guidance-for-Development.pdf
21. Phytoceuticals in Food for Health and Wellness, Harnessing Plant Therapeutics, Chapter 32 - Phytochemicals in drug discovery: potential as lead compounds and therapeutic agents, 2026, Pages 653-671.
22. Int J Mol Sci. 2024 Aug 13;25(16):8792. doi: 10.3390/ijms25168792