Savitribai Phule Pune University
M. Pharm Phytopharmacy and Phytomedicine

SYLLABUS DRAFT

Table – 1: Course of study for M. Pharm. (Phytopharmacy & Phytomedicine)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPM102T	Experimental Phytopharmaceuticals	4	4	4	100
MPM103T	Traditional medicines and allied Plant Based therapies	4	4	4	100
MPM104T	TQM, Patent regulation and validation	4	4	4	100
MPM105P	Phytopharmacy and phytomedicine Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPM201T	Phytopharmaceutical product development	4	4	4	100
MPM102T	Nutraceuticals and Herbal health supplements	4	4	4	100
MPM203T	Standardization and validation of phytopharmaceuticals	4	4	4	100
MPM204T	Plant Biotechnology and Bioassay of phytomedicines	4	4	4	100
MPM205P	Phytopharmacy and phytomedicine Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 2: Course of study for M. Pharm. III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
-	Journal club	1	1
-	Discussion / Presentation (Proposal Presentation)	2	2
-	Research Work	28	14
	Total	**35**	**21**

* *Non University Exam*

Table - 4: Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/Final Presentation	3	3
	Total	**35**	**20**

Table - 5: Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

**Credit Points for Co–curricular Activities*

THEORY

SEMESTER I

MPAT101T - MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Sr. No.	Chapters & Content	Hours
1.	**UV-Visible Spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of **UV Visible Spectroscopy IR 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.	12
2.	**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	10
3.	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analysers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	10
4.	**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	10

5.	**Electrophoresis and X-ray Crystallography:** **a. 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 b. 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 Xray diffraction.	10
6.	**Potentiometry:** Principle, thermal transitions and instrumentation (heat flux and power compensation anddesigns) working, Ion selective Electrodes and Application of potentiometry. Thermal Analysis: Polymer behavior, factors affecting and instrumentation, and working, application of TGA	8

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, 4 th edition, CBSPublishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3 rd Edition, CBSPublishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, MarcelDekker Series

MPM102T - EXPERIMENTAL PHYTOPHARMACEUTICALS

Sr. No.	Chapters & Content	Hours
1.	**Phytochemical extraction techniques:** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction e.g. microwave assisted extraction, Supercritical Fluid Extraction, Accelerated Solvent Extraction etc. and their industrial applicability, Extraction methods and chemical identification tests for the alkaloids, saponins, phenolics, oligosaccharides, polysaccharides, peptides, proteins etc.	12
2.	**Characterization & structure elucidation of certain classes of secondary metabolites:** **A] Terpenoids**: i) General chromatographic characteristics ii) General means of structure elucidation by chemical & physical methods **B] Alkaloids**: i) General means of structure elucidation by chemical methods. **C] Flavonoids**: i) General means of structure elucidation by spectral methods.	12
3.	**Drug Discovery and Development:** Approaches for Drug discovery and development, Lead Identification, structure development, product development and registration process. Role of natural products in new drug development with case studies. Plant-derived drugs, novel drug templates, chemical diversity, and structure-based drug design.	10
4.	**Phytopharmaceuticals:** A] **Occurrence, classification, stereochemistry, isolation and characteristic features of following.** a) Carbohydrates: Mono, di, oligo- and polysaccharides b) Glycoproteins, lipoproteins and glycopeptidolipids c) saponins d) Alkaloids e) Steroids and triterpenoids f) Flavonoids, coumarins and lignans B] **Marine natural products chemistry in drug development:** Chemistry and biology of marine natural products. Marine medicinal toxins from bacteria, microalgae, rhodophyta, chlorophyta, porifera, ascidians, corals, nudibranchs. General methods of isolation and purification. Recent developments in natural product chemistry of plant and microbial sources of marine origin.	12

5.	**Introduction to herbal cosmetics** Classification and economic aspect, herbal cosmetic industry: present scope and future prospects	6
6.	**Herbal cosmetics** Physiology and chemistry of skin and pigmentation, hairs,scalp,lips and nail, cleansing cream,lotions,face powders,face packs, lipsticks, bath products, soaps and baby products, preparation and standardization of the following: Tonic,Bleaches, Dentifrices, Mouth washes, tooth pastes, cosmetics for nails.	8

References:

1. Agarwal O. P., Chemistry of Organic Natural Products vol.1, Krishna Prakashan, Merrut, 2004. ISBN: 81-85842-98-1.

2. Agarwal O. P., Chemistry of Organic Natural Products vol.2, Krishna Prakashan, Merrut, 2005. ISBN: 81-85842-98-1.

3. Atherden, L.M., Bently and Driver's Textbook of Pharmaceutical Chemistry, 8thEd., Oxford University Press, 2004. ISBN: 9780195609639.

4. Bruneton Jean, Caroline K. Hatton, Pharmacognosy, Phytochemistry, Medicinal plants. Lavoisier, 1999. ISBN 1898298637.

5. Chatwal G.R., Organic Chemistry of Natural Products by vol. I and II. Himalaya Publishing House, 2010.ISBN-14: 09789350246441.

6. Evans W. C., Trease G. E., Trease and Evan's Pharmacognosy. W.B. Saunders,2002. 16th Ed. ISBN-10: 0702029335.

7. Finar I.L., Organic Chemistry: Stereochemistry & the Chemistry of Natural Products, Vol.II., Pearson Education India, 5th Ed. ISBN: 81-7758-541-X.

8. Gokhale S.B., Gaud R.S., Surana S.J., Natural Excipients, Nirali Publications, 2008.ISBN 978-81-85790-60-2.

9. Hanson J.R., Natural Products: The Secondary Metabolites, Royal Society of Chemistry, UK, 2003. ISBN 0-85404-490-6.

10. Kokate C. K., Gokhale S.B. and Purohit A.P., Textbook of Pharmacognosy, Nirali Prakashan, Pune, 2008, ISBN: 8185790094.

11. Mukherjee Pulok K., Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons, 2002. ISBN 8190078844.

12. Rajpal V. &Kohli D. P. S., Herbal Drug Industry, Riddhi International, 2nd Ed.,2009. ISBN: 9788190646727.

13. Rangari V.D., Pharmacognosy & Phytochemistry (Vol I), Career Pub., Nashik,2009, ISBN: 978-81-88739-45-5.
14. Rangari V.D., Pharmacognosy & Phytochemistry (Vol II), Career Pub., Nashik,2009, ISBN: 978-81-88739-65-3.
15. Tadeusz F. Molinski, Doralyn S. Dalisay, Sarah L. Lievens and Jonel P. Saludes, Drug development from marine natural products, Nature Reviews: Drug Discovery,8,69-84, 2009.

MPM103T - TRADITIONAL MEDICINES AND ALLIED PLANT BASED THERAPIES

Sr. No.	Chapters & Content	Hours
1.	**Different traditional (alternative) systems of medicine**	8

	Ayurveda, Siddha, Homeopathic medicine, Chinese traditional medicine, Unani Medicines. Concepts, ancient texts, authentic text and popular plants/medicines and formulations thereof. Contribution of alternative medicines to modern medicines	
2.	**Ayurveda** Definition, therapeutic classification, aims, contents and types of Ayurveda. Fundamental principles of Ayurveda. Ayurvedic ethics in present scenario. Importance of Ayurvedic system and its practice in India. Concept of Bhesaja examination: Pharmacology and pharmaceutical knowledge according to Ayurveda. Ten points for examination that is and their utility and application in pharmacy.	8
3.	**Study of different Ayurvedic formulations and preparations belonging to three broad classes** Solids, semi-solids and liquids such as tablets/pills, capsules, churna, taila, ghrita, Avaleha, Asava/Arishta, bhasma etc. Study of various pharmaceutical processes used in Ayurveda: This includes extraction of drugs and fermentation of vegetable drugs. Salient features of the techniques of preparation of some of the important class of Formulations as per Ayurveda.	12
4.	**Quality control parameters of Ayurvedic formulations and introduction to different Ayurvedic formulations:** Bhasma, Sindhura, Mandura, Rasayoga, and Lauha, Arka, Asava / Arista, Avachurnana yoga, Avaleha, Churna, Netrabindu, Karnabindu & Anjana, Lepa / Malahara, Vati / Varti, Pishti, Sneha, Vati / Gutika / Modaka, Shaarkara **Quality control parameters:** As per AYUSH guidelines	12
5.	**General Guidelines for Drug Development of Ayurvedic Formulations** General Guidelines for Drug Development of Ayurvedic Formulations by CCRAS, Emergence of Traditional Chinese Medicines development and its translation according to modern science. Comparison of TCM with Ayurveda	12
6.	**Ethnobotany and Ethnopharmacology** Ethnobotany in herbal drug evaluation, Impact of Ethnobotany in traditional medicine, new development in herbals, Bio-prospecting tools for drug	8

	discovery, Role of Ethnopharmacology in drug evaluation, Reverse Pharmacology, TKDL, Geographical indication Bill	

References:

1. Herbal Medicine in India Indigenous Knowledge, Practice, Innovation and its Value Editors: Sen, Saikat, Chakraborty, Raja (Eds.). 2021, Springer
2. Charak Samhita (Second Revised Edition), translated by A. Chandra Kaviratna & P. Sharma
3. Sarngadhara Samhita, translated by Prof. K.R. Srikantha Murthy Banglore
4. Bhaishajya Ratnavali translated by Dr. Kanjiv Lochan
5. Ayurvedic Pharmacy (Bhaishajya Kalpana) by Dr. Anil K. Mehta and Dr. Raghunandan Sharma
6. Ayurvedic Pharmacopoeia of India (API) Govt. of India, Part I volume I to VII, Part II volume I & II
7. Ayurvedic Formulary of India (AFI), Govt. of India, Part I & II.
8. General Guidelines for Drug Development of Ayurvedic Formulations by CCRAS
9. Recent research/review articles related to emergence of Traditional Chinese Medicines

MPM104T - TQM, PATENT REGULATION AND VALIDATION

Sr. No.	Chapters & Content	Hours

1.	**Basic principles of total quality management and quality audits:** Concept of Total Quality Management, Four M's responsible for Quality variation in pharmaceutical products. Concepts of GMP, GLP and GCP, Quality control laboratory responsibilities, routine controls on instruments and reagents. Standard test procedures, non-clinical testing, controls on animal house, Data generation and storage. Documentation and its importance, Manufacturing documents, Standard Operating Procedures, Finished product release documentation.	10
2.	Quality Audits: Auditing of manufacturing processes and facilities, Quality Review, Compliance reports and handling of Non –compliance. ICH guidelines: Q1-Q10, Guidelines with special reference to quality by design and risk management.	10
3.	**Validation of processes and equipment:** Qualification, validation and calibration of equipment. Validation of processes like mixing, granulation, drying, compression, filtration, filling, etc. Validation of sterilization methods and equipment, dry heat sterilization, autoclaving, membrane filtration. Validation of manufacturing processes, Equipment, Environment and Water supply systems and analytical methods.	12
4.	**Validation and audits of analytical procedures** such as HPLC, UV, GC, HPTLC. Validation of personnel handling the analytical instruments	8
5.	**Regulatory aspects of herbal pharmaceuticals and IPR:** Regulatory aspects of herbal pharmaceuticals in India, US, Europe and other countries, US-FDA and WHO Approval, Clinical trial approval, dossier preparation for herbals. Intellectual Property Rights, Patent search and awareness, Patent applications and filling procedures in India and in other countries	12

	International treaties and conventions on IPR - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO. Patent infringement, exploitation of patent, abuse of patent. Brief introduction to CDSCO. EMEA, TGA, MHRA, MCC, ANVISA Regulatory requirements for contract research organization. Regulations for Biosimilars	
6.	**Regulatory requirements for setting herbal drug industry:** Schedule T, Global marketing management. Indian and international patent law as applicable herbal drugs and natural products.	8

References:

1. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, Inc., New York

2. S. Weinberg, Ed. Marcel Dekker, Good Laboratory PracticeRegulations.4th Edition, New York, 2007

3. Andrew A. Signore and Terry Jacobs Good Design Practices for GMP Pharmaceutical Facilities Informa Healthcare 2005

4. ICH Guidelines available at: http://www.ich.org

5. Carlton F, Agallaco J, "Validation of aseptic Pharmaceutical Processes ", 1st edition, New York, Marcel Dekker.

6. Loftus, B. T., Nash, R. A., ed. Pharmaceutical Process Validation. vol. 57. New York: Marcel Dekker (993.

7. Malik, V, Drugs and Cosmetics Act, 1940, Eastern Book Co.

M. Pharm Practicals

SEMESTER: I

Subject Name: Phytopharmacy and Phytomedicine Practical I
Subject Code:

Scope: This subject deals with the practical aspects of various analytical, extraction, separation and structure elucidation techniques useful for Phytochemicals.

Objectives:

Upon completion of this course the student should be able to

1. Use various modern analytical technique instruments for analysis of phytochemicals
2. Evaluate a traditional medicinal product based on pharmacopeial standards
3. Design and apply techniques for standardization of herbal product
4. Apply chemical and spectrophotometric techniques for structure elucidation of phytochemicals.

Part A

1. Standardization study of Herbal drugs/Medicinal plant materials/formulations by following the 'WHO guidelines' and 'The Ayurvedic Pharmacopoeia of India' such as (indicative list)
    a. Determination of Ash content (acid insoluble, water soluble etc.)
    b. Determination of Extractives (water soluble, alcohol soluble, ether soluble)
    c. Determination of Moisture content
    d. Determination of Volatile oil
    e. Determination of Bitterness value, swelling index, foaming index, haemolytic activity etc.
    f. Determination Pesticide residue, heavy metal etc.
    g. Determination of Loss on Drying.
    h. Determination of total phenolic content/ total flavonoid content/ total tannin content.
2. Preparation of Ayurvedic traditional formulation eg. Asava/Arishtha/ Vati/and its evaluation.
3. Preparation of Ayurvedic traditional formulation eg. Ghrita/Lepa/Bhasma and its evaluation.

Part B

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

SEMESTER II

MPM201T - Phytopharmaceutical product development

Sr. No.	Chapters & Content	Hours
1.	**Dosage form consideration:** **preformulation studies** for solid, liquid, topical and other herbal formulations etc. Challenges in phytopharmaceuticals product development compared to modern medicines.	6
2.	**Preformulation studies with respect to herbal pharmaceuticals:** Molecular level, particulate level and bulk level properties of herbs and additives, solubilization techniques, drug – excipients compatibility studies, protocol for preformulation studies.	8
3.	**Solid dosage forms:** Recent advances in design of different solid dosage forms like tablet ,capsule, pellets, granules etc like double compression, direct compression, capsule filling machine. **Coating of solid dosage forms** **Recent advances in functional coating**	10
4.	Natural products used as pharmaceutical excipients & of allied industrial utility: Excipient types, Pharmaceutical Excipients of Herbal Origin: starch, agar, alginates, carrageenan, guar gum, acacia gum, xanthan gum, gelatin, pectin, tragacanth, numerous coloring, flavoring and sweetening agents binding agents, sustaining agents, thickening agents, gelling agents, stabilizers, and coating materials. Polymer type and their functionalities & role in herbal formulation development. Study of procedures like granulation, compression, coating, fluidization, lyophilization etc in context of herbal formulation and critical factors.	12
5.	**Concepts and systems design for controlled delivery:** **Targeted drug delivery:** General concepts of active and passive targeting different organs like skin, brain, eye, lung, stomach etc.	12

	Design of different types of controlled release therapeutic systems, safety & toxicity evaluation.	
6.	**Herbal Novel Drug Delivery Systems:** Novel herbal formulations like microspheres, liposomes, phytosomes, niosomes, proniosomes, transferosomes, nanogels, emulgels, nanosuspensions, herbasomes, ethosomes, plant vaccines. Formulation and characterization studies. Preparation and evaluation of topical preparations containing actives of herbal and natural origin.	12

References:

1. Herbal Drugs Industry by R.D. Chaudhary
2. Novel drug delivery systems by Y W Chein
3. Controlled and novel drug delivery by N K Jain
4. Control drug delivery – concepts and advances by S P Vyas, and R K khar
5. Pharmaceutical Formulation the Science and Technology of Dosage Forms Edited by Geoffrey D. Tovey
6. Pharmaceutical Dosage Forms and Drug Delivery Third Edition: Revised and Expanded, by Ram I. Mahato and Ajit S. Narang, CRC press
7. Essentials of Pharmaceutical Preformulation by Simon Gaisford and Mark Saunders
8. Handbook of Preformulation Chemical, Biological, and Botanical Drugs Sarfaraz K. Niaz

MPM102T – NUTRACEUTICALS AND HERBAL HEALTH SUPPLEMENTS

Sr. No.	Chapters & Content	Hours
1.	**Nutraceuticals and Dietary Supplements** Introduction, Functional food, Nutraceuticals, Dietary supplement, Classification of nutraceuticals, Health benefits of nutraceuticals, Use of nutraceuticals in the treatment of different diseases, Public health nutrition, Maternal and child nutrition, Nutrition, Nutrition education community, Types of nutraceuticals,Spirulina, Soybean,Ginseng, Garlic, Broccoli, Gingko, Flaxseed	10
2.	**Phytochemicals As Nutraceuticals** Carotenoids, ß-carotene, a-carotene, Carotenoids and their medicinal properties, Lycopene, an-thophylls, Lutein, Sulphides, Diallyl sulphides and diallyitrisulfide, Polyphenolics, Resveratrol, Flavonoids, Rutin, Naringin, Quercetin, Anthocyanidines, Catechins, Flavones, Prebiotics /probiotics, Fructooligosaccharides, Probiotics, Phyto estrogens, Isoflavones, Lignans, Tocopherol, Benefits of tocopherols, Functional food, Proteins, Vitamins, Minerals, Cereals, Vegetables and beverages as functional foods	12
3.	**Free radicals in Various disease prevention** Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defense, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. Functional foods for chronic disease prevention.	12
4.	**Free Radicals, Dietary Fibres and Complex Ingredients** Introduction, Free radicals and reactive oxygen,Oxygen radicals, Biological effects of reactive oxygen, Reactive oxygen species (ROS) and reactive nitrogen species (RNS), Generation of free radicals, Properties of some free radicals Sources of free radicals, Molecular targets of free radicals Effects of dietary fibre on human health and diseases, Carbohydrates	10

5.	**Cosmeceuticals of herbal and natural origin** Hair growth formulations, Shampoos, Conditioners, colorants, & hair oils, Fairness formulation, vanishing and foundation cream, anti sun-burn preparations, moisturizing creams, deodorants	8
6.	**Pharmacopoeial Specifications and Regulatory Aspects for Nutraceuticals** Effects of processing and storage on food and various environmental factors, History of food regulations in India, FSSAI, FDA, FPO, MPO, AGMARK, GMP, Pharmaceutical specifications for dietary suppliments and nutraceuticals	8

References:

1. Dietetics by Sri Lakshmi

2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPublication.

3. Advanced Nutritional Therapies by Cooper. K.A.,(1996).

4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd.,(1988).

5. Prescription for Nutritional Healing by James F.Balchand Phyllis A.Balch2ndEdn., Avery Publishing Group, NY(1997).

6. G. Gibson and C.williams Editors 2000 Functional foods Woodhead Publ. Co.London.

7. Goldberg, I. Functional Foods. 1994. Chapman and Hall, NewYork.

8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods M.K. Sachmidl and T.P. Labuza eds. AspenPress.

9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)

10. Shils, ME, Olson, JA, Shike, M. 1994 Modern Nutrition in Health and Disease. Eighth edition. Lea andFebiger

11. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

12. B.A.Baviskar, S.L.Deore, Dr.S.S.Khadbadi : Experimental Phytopharmacognosy, Nirali Publication

13. Various Reviews and Research Papers

MPM203T - STANDARDIZATION AND VALIDATION OF PHYTOPHARMACEUTICALS

Sr. No.	Chapters & Content	Hours
1.	**Factors affecting quality of plant drugs:** Safe and economical methods for documentation and preservation of herbs and herbal products, detection of common adulterants, microbial contamination, toxic trace metals, pesticides and insect infestation in whole and powdered drugs, substitution and misidentification, Need for standardization, issues related to herbal medicines.	10
2.	**Microscopic evaluation of plant drugs:** T.S./L.S./Surface views of selected Plant drugs - Use of microtome and preparation of histological slides, Quantitative microscopy, vein islet number, vein termination number, stomatal number, stomatal index, palisade ratio. Micrometry, measurement of fibers, trichomes, starch grains and calcium oxalate crystals. Lycopodium spore analysis. Fluorescence analysis	08
3.	**Determination of physical parameters:** Procedures, total ash, acid insoluble ash, water- soluble ash, extractive values of herbal drugs, moisture content determination and loss on drying of herbal drugs, determination of bitterness value, haemolytic activity, and foaming index, swelling index of gum and mucilage containing drugs. **Oil content:** Determination of volatile oil content herbal drugs, procedure apparatus, methods, estimation of fixed oils and lipids of herbal drugs. **Phytochemical assays:** Estimation of tannins, phenols and flavanoids, glycosides and vitamins in herbal drugs with methods and examples. **Limit tests:** Heavy metals in herbal drugs, microbial contamination of crude drugs and its detection, pesticide residues, aflatoxin. Elemental analysis	10
4.	**Quantitative assays for extraction efficiency:** Active component analysis of carbohydrates, peptides & proteins, glycosides and lipids. Purity determination using UV, GC, HPLC and electrophoretic methods. Quality control of various types of official formulations including Ayurvedic preparations. HPTLC & HPLC fingerprint identification of crude drugs/raw material or congeners or their single or multi-component preparations, recognition and evaluation of fingerprints. **Markers and biomarkers:** Concept and their importance in standardization of	10

	herbal drugs, analytical method development and estimation of alkaloids, steroids, carbohydrates, polypeptides/ proteins of herbal drugs.	
5.	**Potency assays:** pharmacological tests, cell line-derived assays, in-vitro biochemical tests **Stability testing of natural products:** Procedures, predictable chemical & galenical changes, technical limitations, testing methods, combination products. **Bioavailability and pharmacokinetics aspects** of herbal drugs with examples of well-known documented clinically used herbal drugs.	10
6.	**Importance of monographs on standards of medicinal plants and their parts:** Comparative study of British Herbal Pharmacopoeia (BHP), Ayurvedic Pharmacopoeia of India (API), Chinese, Japanese and European Pharmacopoeias, US Formulary. WHO, EMEA and ESCOP guidelines for herbal medicinal products. Preparation of Drug Master File (DMF)for herbal medicines.	12

References:

1. Quality Control Methods for Medicinal Plant Materials by World Health Organization (WHO) Publication, Geneva; 1998.

3. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, WHO Publication, Geneva; 2003.

4. National Policy on Traditional Medicine and Regulation of Herbal Medicines, A WHO Publication, Geneva; 2005.

5. Ayurvedic Pharmacopoeias of India, Latest editions

6. Quality Standards of Indian Medicinal Plants, Indian Council of Medical Research, New Delhi

7. Herbal monographs in Indian Pharamcopoeia

8. Ayurvedic Formulary of India

9. Drugs and Cosmetics Act 1940 and rules there under,

10. Quality control of herbal drugs by Pulok K Mukarjee (2002), Business Horizons Pharmaceutical Publisher, New Delhi.

11. ICH guidelines for stability testing

12. Indian Herbal Pharmacopoeia

13. Research and Review articles published in UGC –CARE approved journals regarding standardization/quality control and other aspects

MPM204T - PLANT BIOTECHNOLOGY AND BIOASSAY OF PHYTOMEDICINES

Sr. No.	Chapters & Content	Hours
1.	**Introduction to Plant biotechnology:** Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Concept of genome, genes and gene expression; genome sequencing and sequence comparison methods (microarray) **Plant drug collection and cultivation with plant growth regulators:** Transgenic plants, and approaches for production of transgenic plants. genetic manipulations and plant genetic engineering. Cultivation technology for commercial production of some selected medicinal and aromatic plants. **Biopharmaceuticals:** Concepts of upstream and downstream Processing techniques, Biotechnology of propagation and production of antibiotic and non-antibiotic drugs from lower plants.	10
2.	**Plant Cell and Tissue Culture:** Introduction to plant cell, media & laboratory requirements for tissue culture Types of cultures: - Callus, suspension, meristem, root-tip, hairy root, haploid cultures, anther cultures /Pollen grains (Introduction, methodology & applications of above types) Protoplast culture & protoplast fusion application introduction, Method, Application) Germplasm storage & cryopreservation	12
3.	**Applications of Medicinal Plant Tissue Culture in Pharmacognosy:** Cultivation of Medicinal Plant Cells Production of Secondary Metabolites Bioconversions Using Plant Cells Plant Cell Immobilization Genetic manipulation: Mutation. Polyploidy, Hybridisation, Chemodemes, Transgenic plants, Conservation of Endangered species through micropropagation.	10
4.	**Basic definition and types of toxicology** Regulatory guidelines for conducting toxicity studies in animals: OECD, ICH, EPA and Schedule Y	8

5.	**Different in vivo methods for pharmacological evaluation of botanical/herbal drugs.** Discuss atleast 3 animal models for evaluations for analgesic, antiinflammatory, anxiolytic, antidepressant, anticonvulsant, nootropic, antiparkinsonian, anti-diabetic, antiasthmatic, aphrodisiac, antiulcer and hepatoprotective activity.	10
6.	**Different in vivo methods for pharmacological evaluation of botanical/herbal drugs.** Discuss atleast 3 animal models for evaluations for antihypertensive, antiarrhythmic, antianginal, cardiotonic, diuretic, antiatherosclerotic & antihyperlipidemic activity. An introduction to various in silico methods and alternative methods to animal testing.	10

References:

1.Olive Kaiser, Rainer Muller, Pharmaceutical Biotechnology: Drug Discovery and Clinical Application, Wiley VCH publisher, 2004

2. Peter J. Russel, Genetics 5 th Edition, The Benjamin Cummins Publishing California;1998

3. Watson WH Freeman and company N.Y. Recombinant DNA 2 nd edition Holtzbrinck Publishers 1992

4. Gliek, Molecular biotechnology 3 rd edition ASM press Washington, USA 2003 61

5. Vyas and Dixit Pharmaceutical Biotechnology, 1 st CBS Publisher New Delhi, 1991

6. Dr. S. Iganacimuthu, Basic Biotechnology – Tata McGraw Hill Publishers

7. P. K. Gupta, Elements of Biotechnology, Rastogi Publication, 10 th edition, 2004

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M. Pharm
SEMESTER II

Subject Name: Phytopharmacy and Phytomedicine Practical II
Subject Code:

Scope: This subject deals with the practical aspects of various analytical, extraction, separation and structure elucidation techniques useful for Phytochemicals.

Objectives:

Upon completion of this course the student should be able to

1. Apply basic cell culture and molecular biology techniques in development of phytopharmaceuticals
2. Apply various techniques for extraction of phytochemicals
3. Design and apply techniques for separation of phytochemicals
4. Apply preformulation techniques in formulation and development of phytomedicines
5. Design and evaluate a phytopharmaceutical product in context to traditional and novel drug delivery systems.

Practicals :

1. Preparation of sequential extracts of a plant material and its TLC finger printing.
2. Extraction and isolation of terpene curcumin from Curcuma longa by column chromatography and its characterization.
3. Extraction and isolation of alkaloid (e.g. quinine from Cinchona bark) using CC Chromatography and its characterization.
4. Extraction and isolation of sterol (e.g. β-sitosterol) using CC Chromatography and its characterization.
5. Extraction and isolation of saponin (e.g. glycyrrhizin) using CC Chromatography and its characterization.
6. Extraction and isolation of volatile oil and its characterization.
7. Standardization of a plant extract or herbal formulation using biomarker (e.g. curcumin, berberine, rutin etc.) using HPTLC technique.
8. Standardization of a Plant extract or herbal formulation using biomarker (e.g. curcumin, berberine, rutin etc.) using HPLC technique
9. Standardization of volatile oil or herbal formulation thereof using biomarker (e.g. thymol, menthol etc.) using GC technique
10. Preformulation study of a herbal extract/powder for solid oral dosage form
11. Preparation of a tablet of plant powder/extract (e.g. triphala) and its evaluation.
12. Preparation of a controlled drug delivery formulation of a given phytomedicine.
13. Preparation of nanosuspension/emulsion of phytochemical e.g. curcumin, quercetin, rutin etc.
14. Animal handling: Introduction to various routes of drug administration, blood sampling techniques, anesthesia and euthanasia of experimental animals.

15. Evaluation of anxiolytic/anticonvulsant and analgesic / anti-inflammatory activity of plant extract/phytochemical.
16. In silico / alternative to animal model (zebra fish/ fruit fly/ C. elegan) for pharmacological evaluation of plant extract/phytochemical.