



SunRise University

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Syllabus

For

M.Pharm. (Pharmacognosy)

PHARMACOGNOSY

Semester-I

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPA101	Modern Pharmaceutical Analytical Techniques	3	0	0	3	20	10	70	--	--	100
2	MPG101	Advanced Pharmacognosy-I	3	0	0	3	20	10	70	--	--	100
3	MPG102/ MPG203	Phytochemistry/ Indian System of Medicine	3	0	0	3	20	10	70	--	--	100
4	MPG103/ MPG205	Industrial Herbal Drug Technology/ Drug Regulatory Affairs & Intellectual Property Rights	3	0	0	3	20	10	70	--	--	100
5	RPM101	Research Process & Methodology	3	0	0	3	20	10	70	--	--	100
6	MPA105	Modern Pharmaceutical Analytical Techniques Practical	-	-	2	1	--	--	--	20	30	50
7	MPG104	Pharmacognosy Practical-I	-	-	3	2	--	--	--	20	30	50
Total						18						600

Semester-II

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPG201	Medicinal Plant Biotechnology	3	0	0	3	20	10	70	--	--	100
2	MPG202	Advanced Pharmacognosy-II	3	0	0	3	20	10	70	--	--	100
3	MPG203/ MPG102	Indian System of Medicine/ Phytochemistry	3	0	0	3	20	10	70	--	--	100
4	MPG204	Herbal Cosmetics	3	0	0	3	20	10	70	--	--	100
5	MPG205/ MPG103	Drug Regulatory Affairs & Intellectual Property Rights/ Industrial Herbal Drug Technology	3	0	0	3	20	10	70	--	--	100
6	MPG206	Pharmacognosy Practical-II	-	-	2	1	--	--	--	20	30	50
7	MPG207	Seminar-I (Synopsis)	-	-	3	2	--	--	--	50	--	50
Total						18						600

Semester-III

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPG301	Seminar-II	0	0	6	3	--	--	--	100	--	100
2	MPG302	Dissertation (Research Project Audit)	0	0	30	15	--	--	--	200	300	500
Total						18						600

Semester-IV

S.N.	Subject Code	Name of the Subject	Periods			Credit	Evaluation Scheme					Subject Total
			L	T	P		Theory			Practical		
							CT	TA	ESE	TA	ESE	
1	MPG401	Dissertation (Final)	0	0	36	18	--	--	--	200	400	600
Total						18						600

M. Pharm. (Pharmacognosy)

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101)

Unit-I

UV-Visible spectroscopy: Introduction, theory and laws associated with UV-visible spectroscopy, chromophores, auxochromes and their interaction with UV-Vis radiations, choice of solvents and solvent effect. Woodward-Fieser rule and applications of UV-visible spectroscopy.

IR Spectroscopy: Theory, modes of molecular vibrations, factors affecting vibrational frequencies and applications of IR spectroscopy. FT-IR. Interpretation of IR spectra of organic compounds.

Unit-II

Mass spectrometry: Different ionization methods (EI, CI, FAB, ESI, MALDI), analyzers of quadrupole and time of flight. Fragmentation patterns and its rules, relative abundance of ions, molecular ion peak, meta stable ions, isotopic peaks, Mc-Lafferty rearrangement, ring rule. Applications of mass spectrometry.

Flame emission spectroscopy and atomic absorption spectroscopy: Principle, interferences and applications of flame emission spectroscopy and atomic absorption spectroscopy.

Unit-III

NMR Spectroscopy: Principle, chemical shift, factors influencing chemical shift, spin-spin coupling, coupling constant, solvent requirement in NMR, NMR active compounds, free induction decay, relaxation process and NMR signals in various compounds. Applications of NMR spectroscopy.

Unit-IV

Chromatography: Principle, chromatographic parameters, factors affecting and applications of: Thin Layer chromatography, column chromatography, gas chromatography, affinity chromatography, ion exchange chromatography, size exclusion chromatography, high performance liquid chromatography, high performance thin layer chromatography.

Unit-V

Miscellaneous techniques:

Thermal methods of analysis: Introduction, principle, instrumentation and application of TGA, DTA and DSC.

Electron microscopy: Principle, instrumentation and applications of scanning electron microscopy (SEM), transmission electron, microscopy (TEM).

Radioimmuno assay: ELISA.

SUGGESTED BOOKS:

1. Pharmacopoeia of India, Ministry of Health, Govt. of India.
2. Skoog D.A., Holler F.J., Crouch S. R., Instrumental Analysis, Indian Edition, Brooks/Cole, Boston.
3. Willard H.H., Merrit L.L., Dean J.A., Settle P.A., Instrumental Methods of analysis, 7th Edition, CBS Publishers & Distributors New Delhi.
4. Kemp W., Organic Spectroscopy, 3rd Edition, Palgrave, New York.
5. Becket A.H. and Stenlake J.B., Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
6. Pavia D.L., Lampman G.M., and Kriz G.S., Introduction to Spectroscopy, 3rd Edition, Harcourt College Publishers, Philadelphia.

7. Kalsi P.S., Spectroscopy of Organic Compounds, New Age International Publishers, New Delhi.
8. Florey K., Analytical Profile of Drug Substance (All volume), Academic Press, Elsevier,

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Massachusetts.

9. Chatten L.G., A Text Book of Pharmaceutical Chemistry, Vol. I & II, Marcel Dekker, New York.
10. Silverstein R.M., Spectrometric Identification of Organic compounds, 6th Edition, John Wiley & Sons, New Jersey.
11. Obonson J.W.R., Undergraduate Instrumental Analysis, Marcel Dekker Inc, New York.
12. Parikh V.H., Absorption Spectroscopy of Organic Molecules, Addison-Wesley Publishing Co., London.
13. Stahl E., Thin Layer Chromatography: A Laboratory Handbook, Springer, Berlin.

ADVANCED PHARMACOGNOSY-I (MPG101)

Unit-I

Marine pharmacognosy: General methods of isolation and purification of marine natural products, recent advances in research of bioactive agents from marine sources. Study of some marine toxins with its chemistry and uses.

Unit-II

Nutraceutical: Present scenario and future scope of nutraceuticals, formulation and standardization of nutraceuticals in reference to natural health drinks, vitamin and mineral supplements and antioxidants. FSSAI guidelines and regulatory aspects.

Unit-III

Adulteration and evaluation of natural products: Type of adulteration, cause and measures of adulterations, study of DNA finger printing, pesticide residues and microbial contamination for evaluation of natural drugs. Study of quantitative microscopic methods- Leaf constants and *Lycopodium* spore method.

Unit-IV

Plant drug cultivation: Scope and limitations of plant drugs cultivation, factors influencing quality of plant and animal drugs cultivation, importance of pharmacognosy in herbal drug industry, current good agricultural practices (CGAP), current good cultivation practices (CGCP) pest management, use and scope of environment friendly pesticides.

Unit-V

Herbal remedies: Herbals vs. conventional drugs, conservation of medicinal plants- *Ex-situ* and *In-situ*, efficacy of herbal medicine products, toxicity and therapy, validation of herbal therapies.

SUGGESTED BOOKS:

1. Scheupr, P.J., Chemistry of Marine Natural Products, Chemical and Biological Perspectives, Vol. I-III, Academic Press, London.
2. Kokate, C.K., Purohit A.P., Ghokhale, S.B., Text Book of Pharmacognosy, Nirali Prakashan, Pune.
3. Mukarjee., P. K., Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publisher, New Delhi.
4. Rangari V. D., Text book of Pharmacognosy and Phytochemistry, Part I and II, Career Publication, Nasik, India.
5. Rajpal V., Standardization of Botanicals. Testing and Extraction Methods of Medicinal Herbs, Vol. I, Eastern Publisher, New Delhi.

6. Evans V.C., Trease and Evans Pharmacognosy, Harcourt Publishers Ltd., Sydney.
7. Tyler V.E., Brady L.R., Robbers J.E., Pharmacognosy, Lea and Febiger.
8. PDR for Nutritional Supplements, Thomson PDR.

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PHYTOCHEMISTRY (MPG102/MPG203)

Unit-I

Phytochemical studies: Study of advanced methods of extractions and isolation with successive and exhaustive extraction and other methods of extraction, choice of solvent for extraction Super critical fluid extraction, microwave assisted extraction, different methods of fractionation.

Unit-II

Methods of investigation of biosynthetic pathways, tracer techniques and autoradiography. General methods of purification and characterizations with some examples of natural compounds.

Unit-III

Isolation and analytical profiles of herbal drugs: Occurrence, isolation and analytical profile (HPTLC and LCMS/GCMS) of following drugs: *Andrographis paniculata*, *Boswellia serata*, *Withania somnifera*, *Glycyrrhiza glabra*, *Emblica officinalis*.

Unit-IV

Drug constituents and biosynthetic pathways: Study of biosynthesis and isolation of following phyto-pharmaceuticals containing drugs:

a) **Alkaloids:** Quinine, Morphine, Atropine, Ephedrine and Reserpine.

b) **Glycosides:** Sennosides, Glycyrrhizin and Digitoxin.

c) **Steroids:** Diosgenin, Hecogenin and Withanolides

Unit-V

Drug constituents and biosynthetic pathways: Study of biosynthesis and isolation of following phyto-pharmaceuticals containing drugs:

a) **Flavanoids:** Quercetin and Rutin.

b) **Carotenoids:** Lycopene and β -Carotene.

c) **Terpenoids:** Menthol and Eugenol

d) **Antibiotics:** Penicillin and Tetracycline

SUGGESTED BOOKS:

1. Evans V.C., Trease and Evans Pharmacognosy, Harcourt Publishers Ltd., Sydney.
2. Harbone J.B., Phytochemical Dictionary, Handbook of Bioactive Compounds from Plants, Taylor and Francis Ltd, Oxfordshire.
3. Wagner H., Plant Drug Analysis, Springer, Berlin.
4. Zhang L., Demain A.L., Natural Products, Drug Discovery and Therapeutic Medicines, Human Press, New York.
5. Kokate, C.K, Purohit A.P., Ghokhale S.B., Text book of Pharmacognosy, Nirali Prakashan, Pune.
6. Rangari V.D., Text book of Pharmacognosy and Phytochemistry, Part I and II, Career Publication, Nasik.
7. Rajpal V., Standardization of Botanicals: Testing and Extraction Methods of Medicinal Herbs, Vol. I, Eastern Publisher, New Delhi.
8. Indian Herbal Pharmacopoeia, Indian Drug Manufacturers Association and Regional Research Laboratory, Jammu.
9. Agarwal O.P., Organic Chemistry, Natural Products, Krishna Prakashan Media (P) Ltd., Meerut.
10. Jarald E.E. and Jarald S.E., Textbook of Pharmacognosy and Phytochemistry, CBS Publishers and Distributors Pvt. Ltd., New Delhi.
11. Cutler S. J. and Cutler H. G., Biologically Active Natural Products: Pharmaceuticals, CRC Press New York.

INDUSTRIAL HERBAL DRUG TECHNOLOGY (MPG103/MPG205)

Unit-I

Cultivation and management of medicinal plants: Dioscorea, Hyoscyamus, Geranium, Cinchona, Opium, Senna, Isabgol, Mentha, Rauwolfia, Lemmon Grass, Basil.

WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants.

Unit-II

Regulatory requirements: Definition, regulatory requirements in crude drug standardization, importance of biomarkers. Assessment procedures and efficacy and safety requirements for herbal products as per USFDA. Regulatory requirements for setting herbal drug industry, Utilization of waste product of herbal industries.

Unit-III

Herbal drug industry: Herbal drug industry and their standard production. Infra-structural requirements, working space, storage area, machinery and equipments, standard operating procedures for herbal drug industry, challenges in upgrading and standardization of herbal formulations.

Unit-IV

Patents: Indian and international patent laws as applicable to herbal/natural products and process. Copyright, patentable subject matters, procedure for Indian patent filing, patent processing, grant of patents, rights of patents, patent search and literature.

Unit-V

Monographs of herbal drugs: Study of monographs of herbal and Natural drugs.

Comparative study of various pharmacopoeia like- Ayurvedic Pharmacopoeia, American Herbal Pharmacopoeia, British Herbal Pharmacopoeia and Indian Herbal Pharmacopoeia for Testing of natural products and drugs. Indian and international patent law as applicable in herbal drugs and natural products.

SUGGESTED BOOKS:

1. Farooqui, A.A., Sreeramu B.S., Cultivation of Medicinal and Aromatic Crops, University Press, Oxford.
2. Chaudhary R.D., Herbal Drug Industry, Eastern Publisher, New Delhi.
3. Atal C.K., Kapoor B.M., Cultivation and Utilization of Aromatic Plants, Regional Research Laboratory and CSIR, Jammu.
4. Mukharjee, P.K., GMP for Botanicals- Regulatory and Quality Issues on Phytomedicine, Business Horizons, New Delhi.
5. Mukharjee P.K., Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publisher, New Delhi.
6. Indian Herbal Pharmacopoeia, Revised Edition, IDMA, Mumbai.
7. Blumenthal M., Herbal Medicine. Expanded Commission E Monographs, Integrative Medicine Communications.
8. Sharma P.P., How to Practice GMP, Vandana Publications, Agra.
9. Willig H., Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Vol. 52, Marcel Dekker Series, Sidney.
10. WHO guidelines on GACP, GLP and GMP for Medicinal Plants.
11. The Ayurvedic Pharmacopoeia of India, Published by Govt. of India.

RESEARCH PROCESS & METHODOLOGY (RPM101)

Unit-I

Fundamentals of research: Meaning, objective and importance of research methodology, types of research (basic, applied and patent oriented), defining research problem, research design including various methods, research process and steps involved. Literature survey and documentation.

Unit-II

Data collection, analysis and hypothesis testing: Classification of data, methods of data collection, sample size, sampling procedure and methods. Data processing and graphical representation of data. Statistical inference and hypothesis: Types of hypothesis (experimental and non-experimental), hypothesis testing (Parametric and non-parametric tests), generalization and interpretation of results. Use of statistical softwares/ packages in data analysis (SPSS, Graph Pad Prism).

Unit-III

Multivariate analysis: Introduction to multivariate analysis (Linear and non linear methods) and their validation methods (Statistical parameters).

Research ethics, plagiarism and impact of research: Research ethics, responsibility and accountability of the researchers, ethical consideration during animal experimentation including CPCSEA guidelines. Plagiarism and use of plagiarism detection softwares such as-VIPER. Impact of research on environment and society, commercialization of research, intellectual ownership.

Unit-IV

Technical writing and reporting of research: Types of research report: Dissertation and thesis, research paper, review article, short communication, conference presentation, meeting report etc. Structure and organization of research reports: Title, abstract, key words, introduction, methodology, results, discussion, conclusion, acknowledgement, references, footnotes, tables and illustrations. Impact factor, rating, indexing and citation of journals. Detailed study of 'Instruction to Authors' of any research journal, a thorough understanding of steps involved in submitting articles electronically to any research journal (Registration, new article submission, tracking process, submitting revised articles).

Unit-V

Funding agencies and research grants: Introduction to various research funding agencies such as-DST, DBT, AICTE, UGC, CSIR, ICMR, AAYUSH, and DRDO along with their function in India. Writing a research project and procurement of research grant. Project cost analysis.

SUGGESTED BOOKS:

1. Kothari C.R., Research Methodology Methods and Techniques, Wishwa Prakashan, New Delhi.
2. Lokesh K., Methodology of Educational research, Vikash Publishing House Pvt. Ltd., New Delhi.
3. Kumar R., Research Methodology, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
4. Rao G.N., Research Methodology and Qualitative Methods, B.S. Publications, Hyderabad.
5. Saunders M., Lewis P. and Thornhill A., Research Methods for Business Students, Dorling Kindersley (India) Pvt. Ltd., New Delhi.
6. Bolton S. and Bon C., Pharmaceutical Statistics: Practical and Clinical Applications, Marcel Dekker, New York.
7. Garg, B.L., Karadia, R., Agarwal, F. and Agarwal, An introduction to Research Methodology, RBSA Publishers, Jaipur.
8. Fisher R.A. Statistical Methods for Research Works, Oliver and Boyd, Edinburgh.
9. Chow S.S. and Liu J.P., Statistical Design and Analysis in Pharmaceutical Sciences, Marcel Dekker, New York.

10. Buncher C.R., Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

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MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES PRACTICAL (MPA105)

1. Determination of the wavelength of maximum absorbance (λ max) of given compounds by UV-Visible spectrophotometry.
2. Quantitative estimation of Pharmacopoeial compounds by UV-Visible spectrophotometry.
3. UV-Vis spectrophotometric assay of pharmaceutical formulations containing Pharmacopoeial compounds as active ingredients.
4. Simultaneous estimation of multi component containing formulations by UV-Visible spectrophotometry.
5. Quantitative estimation of caffeine in beverages using UV-Vis spectrophotometer.
6. Study and interpretation of the FT-IR/IR spectra of given compounds.
7. Separation of the organic compounds from given mixture by thin layer chromatography (TLC).
8. Isolation of the organic compounds from given mixture by two-dimensional thin layer chromatography (2D-TLC).
9. Separation and quantitative estimation of organic compounds in the given mixture by thin layer chromatography (Preparative TLC).
10. Column packing and separation of organic compounds with the help of column chromatography.
11. Simultaneous estimation of any marketed formulation using RP-HPLC method.
12. Stability studies of marketed formulation by RP-HPLC method as per ICH guidelines.
13. Estimation of Sodium/ Potassium by flame photometry.

PHARMACOGNOSY PRACTICAL-I (MPG104)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Determination of various leaf constants like stomatal number, stomatal index, vein islet number, vein termination number etc.
2. Determination of size of particles, plant fibres, trichome, and starch grains with the help of camera lucida and *Lycopodium* spore method.
3. Isolation of curcumin from *Curcuma longa* rhizomes
4. Isolation of caffeine from tea leaves.
5. Isolation of ammonium Glycyrrhizinate from Liquorice.
6. Isolation of piperine from *Piper longum*.
7. Study of methods of extraction.
8. Phytochemical screening of selected plants as per text.
9. Thin layer chromatography of plant extracts.
10. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV-Visible spectrophotometer
11. Analysis of recorded spectra of simple phytoconstituents.
12. Demonstration of HPLC with some extracts of natural products.
13. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by HPTLC method.
14. Estimation of aldehyde/ phenolic content in herbal raw materials.
15. Estimation of alkaloid content in herbal raw materials.
16. Estimation of flavonoid content in herbal raw materials.
17. Estimation of pesticidal residue in natural products with different analytical methods.

18. *In vitro* antidiabetic screening of plant extract/natural compounds.
19. *In vivo* anti-inflammatory screening of plant extracts/natural compounds.
20. Isolation of nucleic acid from cauliflower heads.

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21. Isolation of RNA from yeast
22. Quantitative estimation of DNA.
23. Immobilization of whole cell.
24. Establishment of callus culture.
25. Establishment of suspension culture.
26. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary.
27. Preparation of certain aromatherapy formulations.
28. Formulation of herbal cosmetics such as- lip balm, lipstick, facial cream, herbal hair and nail care products.
29. Evaluation of herbal tablets and capsules.
30. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction.
31. Formulation of cough syrup.
32. Monograph analysis of clove oil.
33. Monograph analysis of castor oil.
34. Identification of bioactive constituents from plant extracts.
35. Formulation using qualitative and quantitative methods

Second Semester

MEDICINAL PLANT BIOTECHNOLOGY (MPG201)

Unit-I

Introduction: Introduction and applications of mutation, polyploidy and hybridization in modern pharmacognosy, role of plant growth regulators on secondary metabolites, chemical races.

Unit-II

Plant biotechnology: Scope and application of plant biotechnology, genetic and molecular biology in pharmacognosy, recombinant DNA technology, genetic code and DNA and RNA replication.

Unit-III

Plant tissue culture: Introduction and scope of plant tissue culture, type of culture, factors affecting the cell culture. Applications of plant tissue culture in modern pharmacognosy.

Immobilized cell techniques, protoplast fusion, hairy root cultures.

Unit-IV

Biotransformation and transgenesis: Introduction of biotransformation, bioreactors and its application, transgenic plants, methods used in gene identification and sequencing of genes. Application of PCR in plant biotechnology.

Unit-V

Fermentation technology: Introduction and scope of fermentation technology, production of alkaloids and enzymes of pharmaceutical interest. Application of fermentation technology in phyto-pharmaceuticals.

SUGGESTED BOOKS:

1. Singh B.D., Biotechnology: Expanding Horizons, Kalyani Prakashan, New Delhi.
2. Vyas S.P., Dixit V.K., Pharmaceutical Biotechnology, CBS Publishers and Distributors, New Delhi.
3. Vandamme E.J., Biotechnology of Industrial Antibiotics, Marcel Dekker, New York.
4. Trevan M.D., Boffey K.H., Stanbury P.F., Goulding K.H., Biotechnology: The Biological Principles, Tata McGraw Hill Publishing Company Ltd., New Delhi.
5. Lodish H., Berk A., Kaiser C.A., Molecular Cell Biology, W.H. Freeman and Company, New York.
6. Pandey A., Webb C., Soccol C.R., Larroche C., Enzyme Technology, Asiatech Publishers New Delhi.
7. Old R.W., Primrose S.B., Principles of Gene Manipulating, Blackwell Scientific Publications, New Jersey.
8. Lodish H., Baltimore D., Berk A., Lawrence S., Molecular Cell Biology, W.H. Freeman and Company, New York.
9. Primrose S.B., Modern Biotechnology, Blackwell Science Ltd., New Jersey.
10. Murray E.T., Methods in Molecular Biology: Gene Transfer and Expression Protocols, Vol. VII, Springer, Berlin.
11. Lewin B., Genes VIII, Pearson, New York.
12. Asubel F.M., Current Protocols in Molecular Biology, Vol. I and II, John Wiley and Sons, New Jersey.
13. Perkins F.T., Hennesen W., Standardization and Control of Biologicals Produced by Recombinant DNA Technology, International Association of Biological Standardization, Geneva.

ADVANCED PHARMACOGNOSY-II (MPG202)

Unit-I

Phytopharmaceuticals: Occurrence, chemical nature, medicinal uses and health benefits of following-

- a) Saponins: Diosgenins and Shatavarins.
- b) Flavonoids: Rutin, Hesperidin and Quercetin.
- c) Carotenoids: Carotene (α and β) and Xanthophyll (Lutein).
- d) Limonoids: Limonene and α -Terpineol.
- e) Vitamins - Cholecalciferol and Tocopherols.
- f) Gugulipids, Withanolides and Vascine.

Unit-II

Ethnobotany and ethnopharmacology: Impact of ethnobotany in traditional medicine, bioprospecting tools for drug discovery, role of ethnobotany and ethnopharmacology in drug evaluation.

Unit-II

Testing of natural products and drugs: Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. Standardization of market herbal formulation. Stability testing of natural products and their protocols.

Unit-III

Phytopharmacological screening: Introduction of advanced screening methods, toxicity studies as per OECD guidelines and study of phytopharmacological screening for following categories of drugs: Anti-inflammatory, antiulcer, antifertility, anticancer, antidiabetics and antihepatotoxic.

Unit-V

Pharmacovigilance of natural drugs: WHO and AYUSH guidelines for safety monitoring of natural drugs, spontaneous reporting schemes for bio-drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples.

SUGGESTED BOOKS:

1. Brain K.R. and Turner T.D., The Practical Evaluation of Phytopharmaceutical, Wright, Bristol.
2. Stahl E., Thin Layer Chromatography: A Laboratory Hand Book, Springer International Edition, New York.
3. Harborne J.B., Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis, Springer (India) Pvt. Ltd., New Delhi.
4. Cutler S.J. and Cutler H.G., Biologically Active Natural Products: Pharmaceuticals, CRC Press, London.
5. Finar I.L., Organic Chemistry, Volume II: Stereochemistry and the Chemistry of Natural Products, Pearson Education, New Jersey.
6. Indian Herbal Pharmacopoeia, Indian Drug Manufacturers Association and Regional Research Laboratory, Jammu.
7. Agarwal O.P., Organic Chemistry, Natural Products, Krishna Prakashan Media (P) Ltd., Meerut.
8. Evans V.C., Trease and Evans Pharmacognosy, Harcourt Publishers Ltd., Sydney.
9. Jarald E.E. and Jarald S.E., Textbook of Pharmacognosy and Phytochemistry, CBS Publishers and Distributors Pvt. Ltd., New Delhi.
10. Tyler V.E., Pharmacognosy, Lea and Febiger, Philadelphia.
11. Deore S.L., Khadabadi S.S., Baviskar B.A., Pharmacognosy and Phytochemistry: A Comprehensive Approach, PharmaMed Press, Hyderabad.
12. Ramawat K.G., Merillon J.M., Bioactive Molecules and Medicinal Plants, Springer, Berlin.

13. Vogel H.G., Drug Discovery and Evaluation, Springer, Berlin.
14. WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems, Geneva.
15. Wagner H., Bladt S., Plant Drug Analysis, Springer, Berlin.

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16. Rajpal V., Standardization of Botanicals. Testing and Extraction Methods of Medicinal Herbs, Vol. I, Eastern Publisher, New Delhi.
17. Blumenthal M., Herbal Medicine, Expanded Commission E Monographs.

INDIAN SYSTEMS OF MEDICINE (MPG203/MPG102)

Unit-I

Fundamental concepts of Ayurveda, Siddha, Unani, and Homoeopathy systems of medicine: Chronological development of Charak Samhita, and Sushrut Samhita.

Analysis of ayurvedic formulations and crude drugs with references to: Identity, purity and quality of crude drugs. Different dosage forms of the Ayurveda.

Unit-II

Naturopathy, Yoga and Aromatherapy practices:

- a) **Naturopathy:** Introduction, basic principles and treatment modalities.
- b) **Yoga:** Introduction and streams of Yoga. Asanas, pranayama, meditations and relaxation techniques.
- c) **Aromatherapy:** Introduction, aroma oils for common problems, carrier oils.

Unit-III

Formulation development of various systems of medicine: Formulations, standardization, shelf life and stability studies of Ayurveda, Siddha, Homeopathy and Unani formulations as per texts.

Unit-IV

Schedule T: Good manufacturing practice of Indian systems of medicine: Components of GMP (Schedule-T) and its objectives, infrastructural requirements, equipments, standard operating procedures, documentation and records. Quality assurance in herbal drug industry of GAP in traditional system of medicine. Preparation of documents for new drug application and export registration. Challenges in monitoring the safety of herbal medicines.

Unit-V

Traditional knowledge digital library (TKDL), geographical indication skill. Government skills in AYUSH, ISM, CCRAS, CCRS, CCRH, CCRU.

SUGGESTED BOOKS:

1. Ayurvedic Pharmacopoeia, Govt. of India, New Delhi.
2. Panda H., Hand Book on Ayurvedic Medicines., National Institute of Industrial Research, New Delhi.
3. Sengupta K.N., Ayurvedic System of Medicine, Sri Satguru Publications, New Delhi.
4. Ayurvedic Pharmacopoeia, Formulary of Ayurvedic Medicines, IMCOPS, Chennai.
5. Homeopathic Pharmacopoeia, Formulary of Homeopathic Medicines, IMCOPS, Chennai.
6. Kayne S.B., Homeopathic Pharmacy an introduction and Hand Book, Churchill Livingstone, New York.
7. British Herbal Pharmacopoeia, British Herbal Medicine Association, UK.
8. Mukharjee P.K., GMP for Botanicals: Regulatory and Quality Issues on Phytomedicine Business Horizons, New Delhi.
9. Indian System of Medicine and Homeopathy in India, Planning and Evaluation, Govt. of India, New Delhi.
10. Swaminathan M., Essential of Food and Nutrition, Bappco Publication, Bangalore.
11. Antia F.P., Clinical Dietitics and Nutrition, Oxford University Press, Delhi.

12. Yoga V.K., Yoga: The Science of Holistic Living, Vivekananda Yoga Publishing, Bangalore.

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HERBAL COSMETICS (MPG204)

Unit-I

Introduction: Herbal cosmetics, advantages and disadvantages of herbal cosmetics, manufacturing and marketing of herbal cosmetics. Preservatives, surfactants, humectants, oils and other additives from natural origins.

Unit-II

Herbal cosmetics for the skin: Physiology and chemistry of skin methods of preparation of herbal cosmetics for skin and hairs, cleansing cream, lotions, vanishing and foundation creams, anti-sunburn preparations, moisturizing cream, deodorants, face powders, face packs, lipsticks, bath products, soaps and baby product.

Unit-III

Cosmetics of natural origins: Preparation and standardization of herbal shampoos, hair growth formulations, conditioners, tonic, bleaches, colorants, depilatories and hair oils, dentifrices and mouth washes and tooth pastes, cosmetics for nails.

Unit-IV

Analysis of herbal cosmetics: Quality control and toxicity studies, determination of shelf life of raw drugs, powdered drugs, extracts, fractions and finished herbal cosmetics products, pre-formulation studies, regulation and dispensing of herbal cosmetics, stability testing of herbal cosmetics, interactions between chemicals and herbs.

Unit-V

Regulatory provisions: Regulatory Provisions relation to manufacture of herbal cosmetics like -license, offences and penalties, import and export of herbal cosmetics, economic aspects involved in the production of herbal cosmetics. CGMP of herbal cosmetics as per the regulatory authorities.

SUGGESTED BOOKS:

1. Sharma, P.P., Cosmetics: Formulation, Manufacture and Quality Control, Vandana Publications, Agra.
2. Barel A.O., Paye M., Maibach H.I., Handbook of Cosmetic science and Technology, CRC Press, London.
3. Pande H., Herbal Cosmetics, Asia Pacific Business Press Inc., New Delhi.
4. The complete Technology Book on Herbal Perfumes and Cosmetics, National Institute of Industrial Research, Delhi.
5. Chattopadhyay P.K., Herbal Cosmetics and Ayurvedic Medicines (EOU), National Institute of Industrial Research, Delhi.
6. Balsam M.S., Edward S., Cosmetics Science and Technology, Vol-II, Wiley Interscience, New York.
7. Harry's M.M., Cosmeticology, Chemical Publishing Company, New York.
8. Technology of Herbal Cosmetics and Toiletries Products with Formulae Published by Engineers India Research Institute, New Delhi.
9. Trivedi P.C., Medicinal Plants Traditional Knowledge, I.K. International Publishing House Pvt. Ltd., New Delhi
10. Bisset N.G., Wichtl M., Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a scientific Basis, Medpharm Scientific Publication, Centurion.
11. Yaniv Z., Bachrach U., Handbook of medicinal Plants, CBS Publishers and Distributors, New Delhi.

DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS (MPG205/MPG103)

Unit-I

Documentation in pharmaceutical industry: SOP and development of SOPs, master formula record, drug master file (DMF), distribution records, chemistry manufacturing and control (CMC), common technical document (CTD) and electronic common technical document (ECTD) format, investigation medicinal products dossier (IMPD) and investigator brochure (IB), introduction to generic drugs product development, outsourcing of bioavailability (BA) and bioequivalence (BE) to contract research organization (CRO).

Unit-II

Regulatory requirement for product approval: Hatch- Waxman act and amendments, code of federal regulation (CFR), post approval regulatory affairs, regulation for combination products and medical devices, industry and FDA liaison, regulatory requirements of EU, MHRA, USFDA.

Unit-III

Process of product approval: Introduction to API, biologics and novel material of approval, process for obtaining IND, NDA, ANDA for new drugs and generic drugs, US registration for foreign drugs.

Unit-IV

Intellectual property rights: Introduction and different mechanism of protection of IPR (patents, copyrights, trademarks, industrial design, geographical indications, registration of plant varieties and trade secrets).

Recent amendments to Indian Patent Act 1970.

Unit-V

Schedule M and Y of Drugs and cosmetics Act 1940 and rules 1945.

Introduction to ICH guidelines: Q, S, E, M (quality, safety, efficacy and multidisciplinary guidelines).

SUGGESTED BOOKS:

1. Shargel L., Kaufer I., Generic Drug Product Development, Solid Oral Dosage Forms, Vol.143, Marcel Dekker series.
2. Berry I.R., Martin R.P., The Pharmaceutical Regulatory Process, Vol. 185, Drugs and the Pharmaceutical Sciences, Informa Healthcare Publishers, London.
3. Richard A., Guarino M.D., New Drug Approval Process: Accelerating Global Registrations Vol. 190, Drugs and the Pharmaceutical Sciences, CRC, Florida.
4. Douglas J. P., Mantus D., FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, CRC Press, Florida.
5. Douglas J.P., Mantus D., Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance.
6. Malik V., Drugs and Cosmetics Act 1940 and Rules 1945.
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>
11. <https://www.ipindia.nic.in>
12. Willing S.W., Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, New York.
13. Guarino R. A., New Drug Approval Process, Marcel Dekker, New York.
14. Bansal P., IPR Guidelines for Pharm Students and Researchers, Pharma Med Press.
15. Pisano, FDA Regulatory Affairs.

PHARMACOGNOSY PRACTICAL-II (MPG206)

The practicals may be chosen from the following suggested list of experiments based on the subjects opted in that particular semester-

1. Determination of various leaf constants like stomatal number, stomatal index, vein islet number, vein termination number etc.
2. Determination of size of particles, plant fibres, trichome, and starch grains with the help of camera lucida and *Lycopodium* spore method.
3. Isolation of curcumin from *Curcuma longa* rhizomes
4. Isolation of caffeine from tea leaves.
5. Isolation of ammonium Glycyrrhizinate from Liquorice.
6. Isolation of piperine from *Piper longum*.
7. Study of methods of extraction.
8. Phytochemical screening of selected plants as per text.
9. Thin layer chromatography of plant extracts.
10. Analysis of Pharmacopoeial compounds of natural origin and their formulations by UV-Visible spectrophotometer
11. Analysis of recorded spectra of simple phytoconstituents.
12. Demonstration of HPLC with some extracts of natural products.
13. Development of fingerprint of selected medicinal plant extracts commonly used in herbal drug industry viz. Ashwagandha, Tulsi, Bael, Amla, Ginger, Aloe, Vidang, Senna, Lawsonia by HPTLC method.
14. Estimation of aldehyde/ phenolic content in herbal raw materials.
15. Estimation of alkaloid content in herbal raw materials.
16. Estimation of flavonoid content in herbal raw materials.
17. Estimation of pesticidal residue in natural products with different analytical methods.
18. *In vitro* antidiabetic screening of plant extract/natural compounds.
19. *In vivo* anti-inflammatory screening of plant extracts/natural compounds.
20. Isolation of nucleic acid from cauliflower heads.
21. Isolation of RNA from yeast
22. Quantitative estimation of DNA.
23. Immobilization of whole cell.
24. Establishment of callus culture.
25. Establishment of suspension culture.
26. Preparation and standardization of various simple dosage forms from Ayurvedic, Siddha, Homoeopathy and Unani formulary.
27. Preparation of certain aromatherapy formulations.
28. Formulation of herbal cosmetics such as- lip balm, lipstick, facial cream, herbal hair and nail care products.
29. Evaluation of herbal tablets and capsules.
30. Dermatological preparation like sunscreen, UV protection cream, skin care formulations for fungal and dermato reaction.
31. Formulation of cough syrup.
32. Monograph analysis of clove oil.
33. Monograph analysis of castor oil.
34. Identification of bioactive constituents from plant extracts.
35. Formulation using qualitative and quantitative methods.

SYNOPSIS (SEMINAR-I) (MPG207)

SunRise University