

Industrial Pharmacognosy (Theory)

BP502T

B.Pharm Semester V

As per the new PCI syllabus 2026 (NEP 2020)

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Preface

This book is a complete course text for BP502T, Industrial Pharmacognosy, the theory paper of the fifth semester of the Bachelor of Pharmacy programme. It is written to the prescribed syllabus, and every topic that syllabus names is developed here to the depth at which it is examined.

What separates this book from the course texts already in circulation is a single decision about how the subject is organised. It teaches the herbal industry as an industry. One continuous chain runs through the eleven chapters: from a hectare of *Withania somnifera* in the field, to the extraction plant that turns the root into a concentrate, to the validated assay that fixes a withanolide percentage on the label, to the monograph that the percentage must satisfy, and finally to the regulator who will read that label in another jurisdiction. Most books present the analytical techniques and the regulations as separate silos, a chapter of instruments followed by a chapter of statutes. Here every analytical technique is introduced against a real botanical problem, and every regulation is introduced against the manufacturing decision it constrains. The consequence is that a student who has finished Chapter 7 knows not only how a high-performance liquid chromatograph works but why the batch in front of them cannot be released without one.

The chapters map onto the five units of the syllabus. Chapters 1 and 2 cover Unit I: the trade and bioeconomy of medicinal and aromatic plants, the institutions that support them, and the emerging therapeutic and cosmeceutical categories. Chapters 3, 4 and 5 cover Unit II: the quality systems under which herbal products are made, the commercial production and standardization of extracts and volatile oils, and the preparation and standardization of the AYUSH dosage forms. Chapters 6 and 7 cover Unit III, the spectroscopic and chromatographic methods by which botanicals are analysed. Chapters 8 and 9 cover Unit IV, the isolation, characterization and commercial production of the six prescribed phytoconstituents. Chapters 10 and 11 cover Unit V: the global regulatory frameworks, the harmonization problem, pharmacovigilance, and the pharmacopoeial monographs of the Indian Pharmacopoeia, the United States Pharmacopoeia, the Ayurvedic Pharmacopoeia of India and the Unani Pharmacopoeia of India.

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Course Objectives

The objectives of this course are to:

1. Introduce students to the industrial, commercial, and economic aspects of herbal drugs in national and global markets.
2. Knowledge of commercial production, quality assurance, and standardization of herbal extracts, volatile oils, and traditional AYUSH formulations.
3. Train students in modern analytical techniques for the identification, characterization, and quality evaluation of plant-based drugs and herbal products.
4. Develop skills in isolation, characterization, commercial production, and analysis of bioactive phytoconstituents.
5. Familiarize students with national and international regulatory frameworks, pharmacopoeial standards, and safety, efficacy, and pharmacovigilance requirements governing herbal medicinal products.

Course Outcomes (CO)

Upon successful completion of this course, the students will be able to:

CO No.	Outcome
CO1	Describe the economic significance, trade potential, emerging therapeutic categories, and institutional support for medicinal and aromatic plant-based industries at national and international levels.
CO2	Explain the principles of commercial production, standardization, and quality control of herbal extracts, volatile oils, cosmeceuticals, and traditional formulations in compliance with AYUSH, WHO-GMP, and global regulatory norms.
CO3	Demonstrate analytical competence in evaluating herbal drugs and botanicals using modern spectroscopic and chromatographic techniques such as UV, IR, NMR, MS, HPTLC, HPLC, UPLC, and GC.
CO4	Describe the process to isolate, characterize, identify, and analyze important phytoconstituents used in pharmaceutical, nutraceutical industries.
CO5	Interpret and apply international regulatory guidelines, pharmacopoeial monographs, and safety, efficacy, and pharmacovigilance requirements for herbal and traditional medicinal products.

Syllabus

Unit	Topics	Hours
I. General Introduction to Herbal Industries, institutions and trade status of herbals	(a) Role of medicinal and aromatic plants trade in national economy of a country and introduction of Current trade status and potential of some commercially important medicinal plants/natural products like Ashwagandha, Turmeric, Ginseng, Amla and essential oils. (b) A brief account of bioeconomy, biodiversity hot spots and plant-based industries and institutions involved in research work on medicinal and aromatic plants in India. (c) Emerging therapeutic categories of Herbal Medicinal Products available in market, their composition with rationale for Aphrodisiac, Antistress, anti-diabetics, antihyperlipidemic, immunomodulator, hepatoprotective and kidney disorders. (d) Emerging Herbal cosmeceuticals: Anti-Aging, Depigmenting, anti-acne, sunscreen, detoxifying, anti-irritant, nutricosmetics.	8
II. Commercial Production and Standardization of botanicals	Significance of AYUSH/ WHO-GMP, GLP and USFDA compliant facility in production of quality herbal products. Commercial production of standardized herbal extracts with clinical relevance: Coleus, Amla, Turmeric, Ashwagandha and Senna. Commercial production and standardization of volatile oils: Eucalyptus oils, Lavender oil and Peppermint oil, Rosemary oil. Preparation and standardization of Ayush formulations viz Aristas and Asawas, Ghutika/Habb, Churna/ Shafoof Arq, Sharbat, Tincture and Bhasma.	10
III. Modern methods of analysis of Plants and Plant-based products	Basic principles and applications in analysis of botanicals: Spectroscopic methods: UV-Visible spectroscopy, IR Spectroscopy, NMR spectroscopy and Mass spectroscopy, Atomic Absorption Spectroscopy. Chromatographic methods: HPTLC, HPLC, UPLC, GC.	12
IV. Isolation, Characterization, Commercial Production and analysis of bioactive phytoconstituents	Isolation, characterization with commercial production, identification and analysis of bioactive phytoconstituents: Artemisinin, Sennosides, Withanolids, Boswellic acid, Atropine, and Lycopene.	08
V. International Regulatory Perspectives	(a) Overview of global regulations for herbal products (e.g., World Health Organization, United States Food and Drug Administration - Dietary Supplement Health and Education Act, European Medicines Agency, TGA-ARG Therapeutic Goods Administration - Australian Regulatory Guidelines for Complementary Medicines, Natural Health Products (Canada) (b) Harmonization challenges and mutual recognition of traditional medicine (c) Importance of safety, efficacy and pharmacovigilance in herbal product regulation (d) Study of Monographs on herbal drugs and botanicals related to Indian Pharmacopoeia, United States Pharmacopoeia Herbal Medicine and Dietary Supplement, Ayurvedic Pharmacopoeia of India and Unani Pharmacopoeia of India.	07
	Total	45

Abbreviations

Abbreviation	Expansion
AAS	Atomic absorption spectroscopy
ABA	3-O-Acetyl-beta-boswellic acid
ACT	Artemisinin-based combination therapy
ADR	Adverse drug reaction
AKBA	3-O-Acetyl-11-keto-beta-boswellic acid
AMC	Adverse Drug Reaction Monitoring Centre
APhI	Ayurvedic Pharmacopoeia of India. Standing rule of this book: APhI, never API (see API below)
API	Active pharmaceutical ingredient. In this book API carries this meaning only; the Ayurvedic Pharmacopoeia of India is always APhI
ARGCM	Australian Regulatory Guidelines for Complementary Medicines
ARTG	Australian Register of Therapeutic Goods
ASU	Ayurvedic, Siddha and Unani (drugs)
ATR	Attenuated total reflectance (infrared sampling)
AUST L / AUST R	Australian listed / registered medicine number
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
BA	Beta-boswellic acid
BMR	Batch manufacturing record
BPR	Batch packing record
BSI	Botanical Survey of India
CAD	Charged aerosol detector
CDRI	CSIR-Central Drug Research Institute, Lucknow
CDSCO	Central Drugs Standard Control Organisation
CFR	Code of Federal Regulations (United States)
CIMAP	CSIR-Central Institute of Medicinal and Aromatic Plants, Lucknow
CoA	Certificate of analysis
CoPP	Certificate of Pharmaceutical Product
CSIR	Council of Scientific and Industrial Research
DER	Drug:extract ratio
DMAPR	ICAR-Directorate of Medicinal and Aromatic Plants Research, Anand
DQ	Design qualification
DSC	Dietary Supplements Compendium (USP)
DSHEA	Dietary Supplement Health and Education Act, 1994 (United States)
EDQM	European Directorate for the Quality of Medicines and HealthCare

Abbreviation	Expansion
EI	Electron ionisation
ELSD	Evaporative light scattering detector
EMA	European Medicines Agency
ESI	Electrospray ionisation
FID	Flame ionisation detector
FSSAI	Food Safety and Standards Authority of India
FTIR	Fourier-transform infrared spectroscopy
GACP	Good Agricultural and Collection Practices
GC	Gas chromatography
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HMC	Herbal Medicines Compendium (USP)
HMPC	Committee on Herbal Medicinal Products (EMA)
HPLC	High-performance liquid chromatography
HPTLC	High-performance thin-layer chromatography
HRMS	High-resolution mass spectrometry
ICAR	Indian Council of Agricultural Research
ICH	International Council for Harmonisation
ICP-MS	Inductively coupled plasma mass spectrometry
IIIM	CSIR-Indian Institute of Integrative Medicine, Jammu
IP	Indian Pharmacopoeia
IPC	Indian Pharmacopoeia Commission, Ghaziabad
IQ	Installation qualification
IR	Infrared (spectroscopy)
ISO	International Organization for Standardization
KBA	11-Keto-beta-boswellic acid
LC-MS	Liquid chromatography-mass spectrometry
LOD	Limit of detection (detection limit)
LOQ	Limit of quantitation (quantitation limit)
MAD	Mutual Acceptance of Data (OECD)
MAP	Medicinal and aromatic plant
MFR	Master formula record
MS	Mass spectrometry

Abbreviation	Expansion
NBPGR	ICAR-National Bureau of Plant Genetic Resources
NCC	National Coordination Centre (pharmacovigilance)
NDI	New dietary ingredient (United States)
NGCMA	National GLP Compliance Monitoring Authority, Department of Science and Technology
NHPD / NNHPD	Natural and Non-prescription Health Products Directorate, Health Canada
NLT	Not less than
NMPB	National Medicinal Plants Board
NMR	Nuclear magnetic resonance (spectroscopy)
NPN	Natural Product Number (Canada)
OECD	Organisation for Economic Co-operation and Development
OQ	Operational qualification
PDA	Photodiode array (detector)
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PLIM	Pharmacopoeial Laboratory for Indian Medicine, Ghaziabad
PQ	Performance qualification
PvPI	Pharmacovigilance Programme of India
QA	Quality assurance
QC	Quality control
R _f	Retardation factor (TLC and HPTLC)
R _s	Resolution (chromatography)
RSD	Relative standard deviation
SMF	Site Master File
SOP	Standard operating procedure
SPF	Sun protection factor
TGA	Therapeutic Goods Administration (Australia)
THMP	Traditional herbal medicinal product (European Union)
TKDL	Traditional Knowledge Digital Library
TLC	Thin-layer chromatography
UPI	Unani Pharmacopoeia of India
UPLC	Ultra-performance liquid chromatography
USFDA	United States Food and Drug Administration
USP	United States Pharmacopeia
USP-NF	United States Pharmacopeia and National Formulary
UV	Ultraviolet

Abbreviation	Expansion
WEU	Well-established use (European Union marketing authorisation route)
WHO	World Health Organization
WHO-UMC	WHO Uppsala Monitoring Centre
XRD	X-ray diffraction

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