

Textbook of Herbal Drug Technology

Theory and Practical Course Codes BP603T and BP609P

for **Sixth Semester Bachelor in Pharmacy**

aims to serve as a complete textbook for the sixth semester Bachelor in Pharmacy. This book covers both theoretical and practical parts as per the latest syllabus prescribed by Pharmacy Council of India (Course Codes BP603T and BP609P).

This textbook provides knowledge of basic understanding of the herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, preparation and standardization of Ayurvedic formulations, herbal cosmetics, natural sweeteners, nutraceuticals, etc. It also discusses the good manufacturing practices (GMP), patenting, and regulatory issues of herbal drugs. Upon completion of the study of this book, students will be able to know the WHO and ICH guidelines for the evaluation of raw materials and herbal products. The students will also be able to understand the importance of raw materials as a source of herbal drugs from cultivation to herbal drug products.

This book is a comprehensive treatment of biodynamic agriculture, Indian systems of medicine, herbal drug and herb—food interactions, herbal excipients, herbal formulations, patenting and regulatory requirements of natural products, regulatory issues, general introduction to herbal industry, and good manufacturing practices of Indian systems of medicine. It strikes a balance between essential and advanced areas of knowledge apart from general topics. The subject matter is comprehensive, written in an easy to understand language, carrying well-labeled diagrams and important tables in both the theoretical and practical parts.

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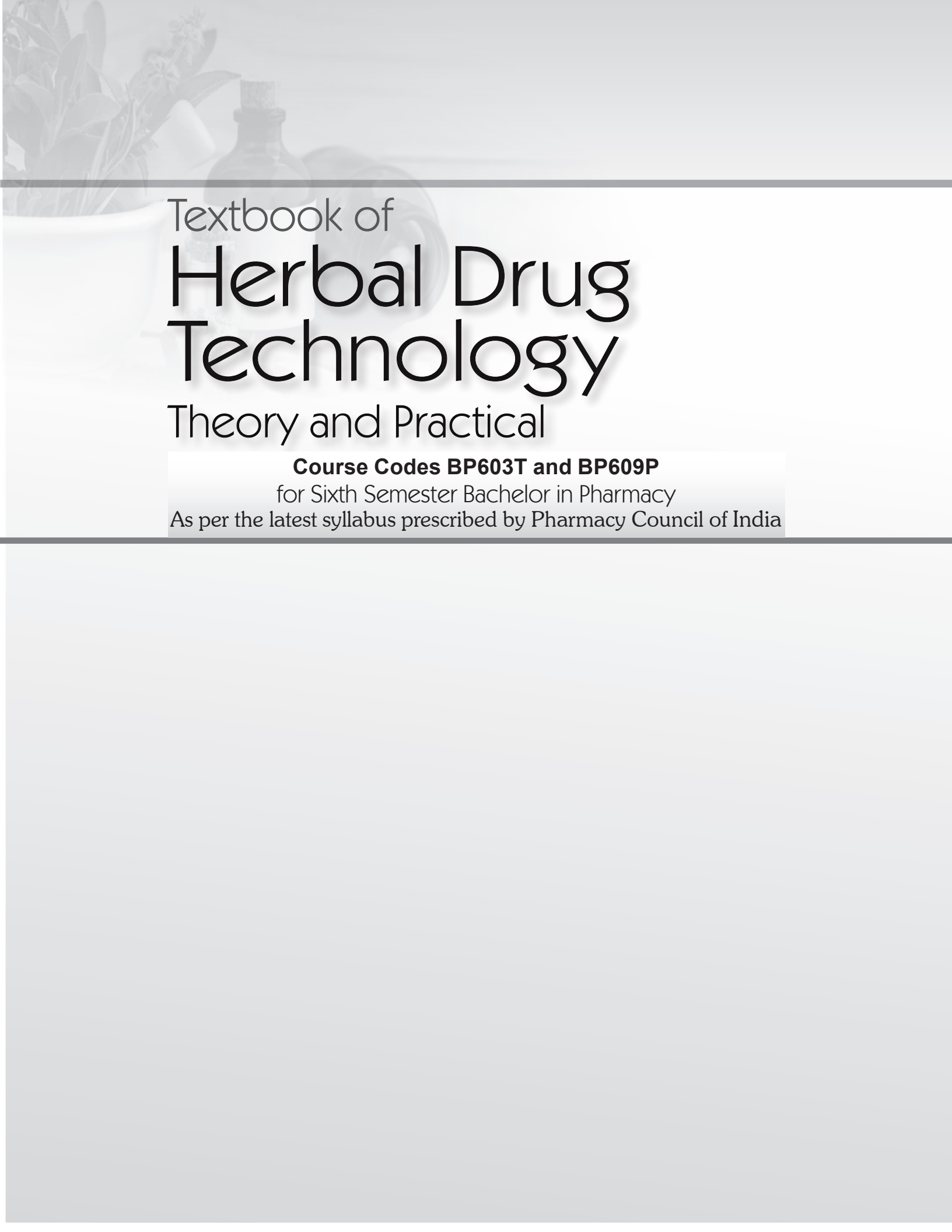
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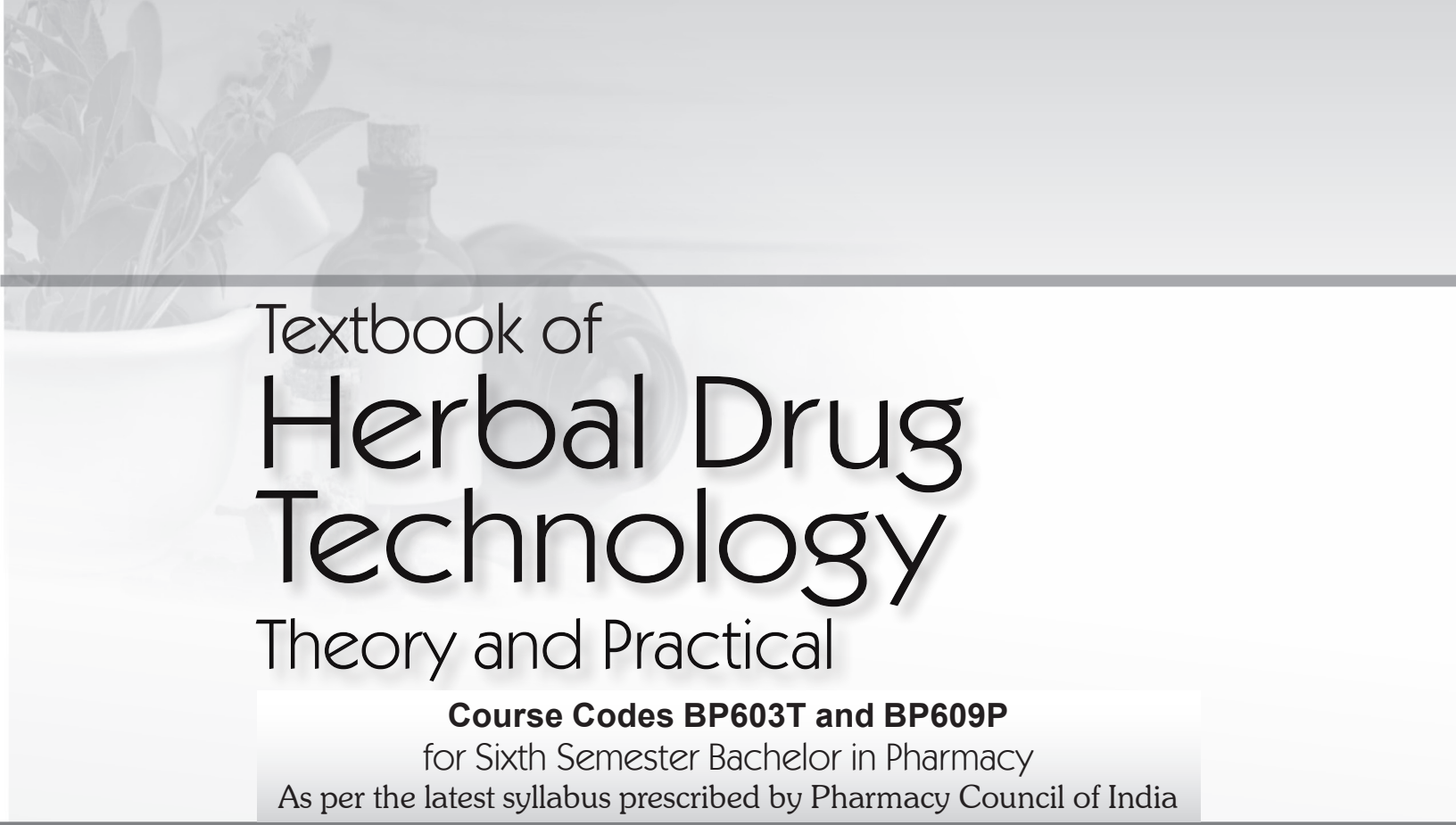


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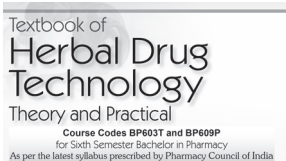


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Preface

It is a pleasure for the students of the 6th semester (3rd year) of B Pharm to get acquainted with the first edition of *Textbook of Herbal Drug Technology* as per the new PCI regulation. This book has both theoretical and practical parts for the convenience of students and teachers.

The theoretical part of this book is designed to provide basic knowledge on the herbal drug industry, the quality of raw material, guidelines for the quality of herbal drugs, herbal cosmetics, natural colorants, binder, natural sweeteners, nutraceuticals, etc. This book will help in understanding the basic concepts of good manufacturing practices (GMP), patenting, and regulatory issues of herbal drugs. In the theoretical part of this book, basic principles involved in Ayurveda, Siddha, Unani, and Homeopathy and the preparation and standardization of ayurvedic formulations are discussed. Conventional herbal formulations like syrups, mixtures, and tablets and novel dosage forms like phytosomes and schedule T—good manufacturing practices of Indian systems of medicine are also discussed in this book.

The experimental part of this book is designed to provide basic practical knowledge on the determination of total phenolic content, total flavonoid content, total alkaloid content, and aldehyde content in the herbal raw materials as well as herbal formulation. Using this book will also help in understanding basic practical knowledge on the determination of alcohol content in arishta and asava. The determination of acid value, saponification value, iodine value, and total solid content are also discussed in the practical part of this book.

The subject matter is illustrated with well-designed diagrams and tables. This book will be beneficial for the students as well as the professors.

Suggestions and criticisms are welcome.

Md Rafiul Haque

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Syllabus

HERBAL DRUG TECHNOLOGY

Theory Course Code BP603T

45 Hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP.

COURSE CONTENT

UNIT I

11 Hours

Herbs as raw materials

- Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs
- Selection, identification and authentication of herbal materials Processing of herbal raw material

Biodynamic agriculture

- Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian systems of medicine

- Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- Preparation and standardization of Ayurvedic formulations viz Arishtas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT II

7 Hours

Nutraceuticals

- General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
- Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina
- **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT III**10 Hours**

- **Herbal cosmetics:** Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.
- **Herbal excipients:** Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.
- **Herbal formulations:** Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT IV**10 Hours**

- **Evaluation of drugs** WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.
- **Patenting and regulatory requirements of natural products:**
 - (a) *Definition of the terms:* Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
 - (b) Patenting aspects of traditional knowledge and Natural Products. Case study of Curcuma & Neem.
- **Regulatory issues:** Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs – Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT V**07 Hours**

- **General introduction to herbal industry**
 - + *Herbal drugs industry:* Present scope and future prospects.
 - + A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.
- **Schedule T:** Good manufacturing practice of Indian systems of medicine
 - + Components of GMP (Schedule T) and its objectives
 - + Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

HERBAL DRUG TECHNOLOGY**Practical Course Code BP609P****4 Hours/week**

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arishta
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids