



Quality Control, Standardization, and Regulatory Perspectives in Herbal Medicines

As per PCI regulations year 2017 for B. Pharm. Students

Pankaj A. Jadhav
Sachin S.Mali
Satwashila S. Kadam
Sarang S. Mahamuni
Ravindra G. Gaikwad

Quality Control, Standardization, and Regulatory Perspectives in Herbal Medicines

As per PCI regulations year 2017 for B. Pharm. Students

Pankaj A. Jadhav

Shivajirao Kadam College of Pharmacy, Kasabe Digraj, Sangli
416 305, India

Sachin S. Mali

Bharati Vidyapeeth college of Pharmacy, Kolhapur 416 013,
India

Satwashila S. Kadam

J. J. Magdum Pharmacy College, Jaysingpur 416 101, India

Sarang S. Mahamuni

KCT's Krishna College of Pharmacy, Karad 415 539, India

Ravindra G. Gaikwad

Bharati Vidyapeeth College of Pharmacy, Palus 416 310, India



Published, marketed, and distributed by:

Deep Science Publishing, 2025
USA | UK | India | Turkey
Reg. No. MH-33-0523625
www.deepscienceresearch.com
editor@deepscienceresearch.com
WhatsApp: +91 7977171947

ISBN: 978-93-7185-723-9

E-ISBN: 978-93-7185-631-7

<https://doi.org/10.70593/978-93-7185-631-7>

Copyright © Pankaj A. Jadhav, Sachin Suryakant Mali , Satwashila S. Kadam, Sarang S. Mahamuni, Ravindra G. Gaikwad , 2025.

Citation: Jadhav, P. A., Mali, S. S., Kadam, S. S., Mahamuni, S. S., Gaikwad, R. G. (2025) *Quality Control, Standardization, and Regulatory Perspectives in Herbal Medicines*. Deep Science Publishing. <https://doi.org/10.70593/978-93-7185-631-7>

This book is published online under a fully open access program and is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License (CC BY-NC 4.0). This open access license allows third parties to copy and redistribute the material in any medium or format, provided that proper attribution is given to the author(s) and the published source. The publishers, authors, and editors are not responsible for errors or omissions, or for any consequences arising from the application of the information presented in this book, and make no warranty, express or implied, regarding the content of this publication. Although the publisher, authors, and editors have made every effort to ensure that the content is not misleading or false, they do not represent or warrant that the information-particularly regarding verification by third parties-has been verified. The publisher is neutral with regard to jurisdictional claims in published maps and institutional affiliations. The authors and publishers have made every effort to contact all copyright holders of the material reproduced in this publication and apologize to anyone we may have been unable to reach. If any copyright material has not been acknowledged, please write to us so we can correct it in a future reprint.

Preface

Herbal remedies are at the forefront of health care around the world today and will continue to be, so long as there continues to be a growing demand for herbal-based drugs. As a result of this growth in demand, there needs to be greater adherence to quality control and standardization for herbal based products. In order to build trust among consumers and meet regulatory requirements, the effectiveness, safety and quality of herbal products need to be guaranteed. This book has been written to give students, researchers, and professionals alike a thorough understanding of the methods, guidelines and regulations that govern the assessment and standardization of herbal drugs. In addition to providing a comprehensive overview of the methods used for assessing and standardizing herbal drugs, the book provides an in-depth look at the International Standards for Quality Assurance in the Herbal Drug Industry, Current Good Manufacturing Practices (cGMP), Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), and Good Laboratory Practices (GLP). These practices are essential to ensuring quality in traditional medicine systems.

One of the primary focuses of the book is the regulatory framework for standardizing herbal drugs. This includes EU and ICH guidelines for the standardization of herbal drugs, as well as research protocols for evaluating the safety and efficacy of these drugs. In addition, the book provides an in-depth examination of the importance of stability testing for herbal drugs and how chromatographic techniques can be used for standardizing herbal drugs. The book also provides detailed information regarding the documentation required for new drug applications and export registrations.

In addition to the documentation process, the book emphasizes the importance of Pharmacovigilance and Regulatory Compliance. The book includes the World Health Organization's (WHO) guidelines on Safety Monitoring of Herbal Medicines. Finally, the book examines the differences between the herbal pharmacopeias of various countries and the use of chemical and biological markers for standardizing herbal drugs. This book was designed to be a reference source for students who are studying Pharmaceutical Sciences and for professionals working in the field of herbal drug research and development. With its unique blend of theoretical and practical knowledge, we believe the book will help to close the gap between traditional knowledge and modern scientific validation, thus contributing to the advancement of the standardization of herbal medicine.

We also hope this book will act as a guide for everyone involved in developing and regulating the production of herbal drugs to strive for excellence in quality.

Warmest regards,
EDITORS

Table of Contents

Chapter. No.	Name	Page No.
UNIT I		
1.	Basic Tests for Pharmaceutical Substances	1
2.	Basic Tests for Medicinal Plant Materials	20
3.	Basic Tests for Dosage Forms	24
4.	WHO guidelines for quality control of herbal drugs	27
5.	Evaluation of commercial crude drugs intended for use	36
UNIT II		
6.	Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine	52
7.	WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines	55
8.	WHO Guidelines on GACP for Medicinal Plants	60
UNIT III		
9.	EU and ICH guidelines for quality control of herbal drugs	65
10.	Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	68
UNIT IV		
11.	Stability testing of herbal medicines	72
12.	Application of various chromatographic techniques in standardization of herbal products	75
13.	Preparation of documents for new drug application and export registration	77
14.	GMP requirements and Drugs & Cosmetics Act provisions	80
UNIT V		
15.	Regulatory requirements for herbal medicines	83
16.	WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems	87
17.	Comparison of various Herbal Pharmacopoeias	89
18.	Role of chemical and biological markers in standardization of herbal products	91