

## WHO (WORLD HEALTH ORGANIZATION) GUIDELINES FOR STANDARDIZATION OF HERBAL DRUGS

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### ABSTRACT

Herbal drugs are being used as medicines from ancient period. The increased use of herbal drugs, and concerns over their safety and efficacy have certainly augmented the need of standardization of these herbal drugs. WHO has set up guidelines for standardization of these drugs, which are used as a standard by the majority of countries. The standardization includes the external (macroscopy/microscopy) as well as internal examination/ash values, extractive values and many other parameters to identify, authenticate and study its chemical composition. Standardization of the medicinal plants will ensure indirectly that the plants are conserved for their medicinal and nutritive value. Standardization confirms the safety of the medicinal plant but efficacy has to be judged clinically or in the laboratory. There is a thin line between efficacy and the presence of chemical compounds in the drug. The major hurdle in standardization of the batch to batch variation in the plant compounds. Addition of finer analytical methods of the chemical compounds may help to minimize the variation and give a better resolution of the plant drug. Importance of toxicological examination has increased manifolds as contamination can occur at various stages, from collection, storage, analysis or processing to extraction of active principles. These parameters should be recorded for years together; their database should be generated, recorded and analyzed statistically to see the difference in quality and quantity of the chemical compounds.

**Keywords:** Standardization, herbal drug, botanical, pharmacological, toxicological, parameters

### INTRODUCTION

Medicinal plants are in use for the purpose of treatment of different ailments since centuries. There has been an immense increase in sales of herbal OTC (Over the counter drugs. This is growing to a billion dollar industry. The need for safety and efficacy has also escalated since the western interest has grown. Thus the need for standardization has come into view. The process of evaluation of the quality and purity of

crude drugs by means of various parameters like morphological, microscopical, physical, chemical and biological observations is called standardization.<sup>1</sup>Standardisation of the herbal drug begins from the collection of the herbal drug to its packaging/use as medicine. The impediments in standardization of herbal drugs-

- Variability in the chemical composition of the soil and changes in the climate in-

# Who Guidelines For Standardization Of Herbal Drugs

**C. K. Ong**



## **Who Guidelines For Standardization Of Herbal Drugs:**

*Standardization and Utilization of Herbal Medicines* J. O. Moody, 1999      **Quality Control and Regulatory Compliance for Herbal Medication** Raveesha Peeriga, Krishnaveni Manubolu, 2025-06-30 This comprehensive book provides a detailed framework for the evaluation and standardization of herbal products promoting the safe and effective use of herbal medicines through rigorous testing and compliance with global regulatory requirements. It begins with an overview of the fundamental tests for medicinal plant materials followed by an in depth look at World Health Organization WHO guidelines for quality control and the evaluation of commercial drugs. The book explores quality assurance practices like cGMP, GAP, GMP and GLP with a focus on traditional medicine systems while also examining EU and ICH guidelines, stability testing and the application of chromatographic techniques in product standardization. Additionally, it addresses the preparation of documents for new drug applications, export registration and regulatory requirements as well as providing guidelines on Pharmacovigilance and comparisons between various herbal pharmacopoeias. A valuable reference work for professionals in the pharmaceutical industries as well as researchers and students interested in this topic.      *Medicinal Plants, Their Bioactivity, Screening and Evaluation*, 1998 Papers presented at the International Workshop on Medicinal Plants their Bio activity Screening and Evaluation      Quality Control of Herbal Drugs Pulok K. Mukherjee, 2002      **ASEAN Common Guideline on Research of Traditional Medicine Products (herbal Medicine)**, 2016      *Quality Control and Standardization of Herbal Drugs* Prof. K. N. Rao, Santhosh Illendula, Sudhakar Kommu, 2024-06-13 *Quality Control and Standardization of Herbal Drugs: Principles and Practices* is an essential guide for ensuring the safety and efficacy of herbal medicines. Covering fundamental tests, WHO guidelines, regulatory standards and advanced analytical techniques, this book offers valuable insights through real world case studies and practical examples. It provides a comprehensive resource for students, researchers and industry professionals bridging traditional practices with modern scientific approaches.      **Plant, Health, and Man**, 2008      **Bulletin of the World Health Organization** World Health Organization, 2001      *WHO Global Atlas of Traditional, Complementary, and Alternative Medicine* C. K. Ong, 2005 Through global and regional maps and tables the map volume provides a visual representation of topics such as the popularity of herbal traditional medicine, Ayurveda, Siddha, Unani, traditional Chinese medicine, homeopathy, acupuncture, chiropractic, osteopathy, bone setting, spiritual therapies and others, national legislation and traditional medicine policy, public financing, legal recognition of traditional medicine practitioners by their area of therapy, education and professional regulation, conventional health care practitioners who are entitled to provide various traditional complementary and alternative therapies and many other aspects.      **The Journal of Alternative and Complementary Medicine**, 2009      *Rajya Sabha Committees-- a Profile*, 2006, 2007      *Essentials of Herbal Drug Technology* Shanti Bhushan Mishra, 2019-01-30 *Essentials of Herbal Drug Technology* is a unique attempt to arouse the interest of students in this fast developing branch of pharmacy, i.e. Pharmacognosy and related fields like herbal

medicine natural products and their standardization because increasing interest in the field of herbal medicine and ayurvedic dosage forms their standardization is utmost required The Book provides in depth information about various guidelines of different regulatory bodies that are required in quality control of herbal drugs This book has been written with the object that the new syllabus of the Bachelor in Pharmacy Master in Pharmacy and doctorate in herbal medicines and their pharmacological efficacy as per PCI course curriculum is covered in reasonable detail to provide sound scientific knowledge of quality control and standardization

*Indian Science Abstracts* ,2012-03      **Medicinal & Aromatic Plants Abstracts** ,2007      Studies in History of Medicine and Science ,2002      **Horticultural Abstracts** ,1981      **Quality Standards of Indian Medicinal Plants** A. K. Gupta,Neeraj Tandon,Dr. Madhu Sharma,2003      Indigenous Knowledge and Sustainable Practice Darlina Md. Naim,Mardiana Idayu Ahmad,2017 Indigenous knowledge plays a key role in sustainable practices and has been the fundamental part in many areas including agriculture health care education fisheries food preparation and conservation This book consists of six articles which deal with indigenous knowledge and local wisdom related to natural resources This book mainly discusses the use of natural resources as a source of food and economy and how the local communities use the resources for their survival Another aspect presented in this book is the integration of science and natural resources as well as its usefulness in facilitating human s life Besides presents the interconnectedness and dynamic relationship between humans biodiversity and environment including plants and animals this book also highlights the implementation of an appropriate technology in utilizing the natural resources for sustainable use Indigenous Knowledge and Sustainable Practice is definitely a resource for students researchers and academicians especially from the field of science and those who are interested in knowing and learning the local knowledge in natural sciences and technology with the focus in the Malaysian context Page 4 of cover

**Herbal Medicines** Joanne Barnes,Linda A. Anderson,John David Phillipson,2007 Written by experts in the fields of pharmacognosy phytochemistry phytopharmacy clinical herbal medicines phytopharmacovigilance and regulation of herbal medicinal products Herbal Medicines is an invaluable reference text for pharmacists and other healthcare professionals who require evidence based information on herbal medicines used for treatment and prevention of health problems

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## **Table of Contents Who Guidelines For Standardization Of Herbal Drugs**

1. Understanding the eBook Who Guidelines For Standardization Of Herbal Drugs
  - The Rise of Digital Reading Who Guidelines For Standardization Of Herbal Drugs
  - Advantages of eBooks Over Traditional Books
2. Identifying Who Guidelines For Standardization Of Herbal Drugs
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Who Guidelines For Standardization Of Herbal Drugs
  - User-Friendly Interface
4. Exploring eBook Recommendations from Who Guidelines For Standardization Of Herbal Drugs

- Personalized Recommendations
  - Who Guidelines For Standardization Of Herbal Drugs User Reviews and Ratings
  - Who Guidelines For Standardization Of Herbal Drugs and Bestseller Lists
5. Accessing Who Guidelines For Standardization Of Herbal Drugs Free and Paid eBooks
    - Who Guidelines For Standardization Of Herbal Drugs Public Domain eBooks
    - Who Guidelines For Standardization Of Herbal Drugs eBook Subscription Services
    - Who Guidelines For Standardization Of Herbal Drugs Budget-Friendly Options
  6. Navigating Who Guidelines For Standardization Of Herbal Drugs eBook Formats
    - ePub, PDF, MOBI, and More
    - Who Guidelines For Standardization Of Herbal Drugs Compatibility with Devices
    - Who Guidelines For Standardization Of Herbal Drugs Enhanced eBook Features
  7. Enhancing Your Reading Experience
    - Adjustable Fonts and Text Sizes of Who Guidelines For Standardization Of Herbal Drugs
    - Highlighting and Note-Taking Who Guidelines For Standardization Of Herbal Drugs
    - Interactive Elements Who Guidelines For Standardization Of Herbal Drugs
  8. Staying Engaged with Who Guidelines For Standardization Of Herbal Drugs
    - Joining Online Reading Communities
    - Participating in Virtual Book Clubs
    - Following Authors and Publishers Who Guidelines For Standardization Of Herbal Drugs
  9. Balancing eBooks and Physical Books Who Guidelines For Standardization Of Herbal Drugs
    - Benefits of a Digital Library
    - Creating a Diverse Reading Collection Who Guidelines For Standardization Of Herbal Drugs
  10. Overcoming Reading Challenges
    - Dealing with Digital Eye Strain
    - Minimizing Distractions
    - Managing Screen Time
  11. Cultivating a Reading Routine Who Guidelines For Standardization Of Herbal Drugs
    - Setting Reading Goals Who Guidelines For Standardization Of Herbal Drugs
    - Carving Out Dedicated Reading Time
  12. Sourcing Reliable Information of Who Guidelines For Standardization Of Herbal Drugs

- Fact-Checking eBook Content of Who Guidelines For Standardization Of Herbal Drugs
  - Distinguishing Credible Sources
13. Promoting Lifelong Learning
- Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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