

## 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 occurs 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

**Ms. Meena Bandiya, Dr. Sonu Sharma,  
Dr. Prabhat Kumar Upadhyay, Dr.  
Nidhi Saxena, Dr. Rajesh Kumar  
Sharma**

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

TEXT BOOK OF QUALITY CONTROL AND STANDARDIZATION OF HERBALS Dr. Rekha Tarasingh Rajput, Saurabh Khare, Dr. Vivek Srivastava, Dr. Prabhat Kumar Upadhyay, Dr. Shweta S. Saboo, 2025-04-21 The Textbook of Quality Control and Standardization of Herbals is a comprehensive guide covering the principles techniques and regulatory requirements for ensuring the quality and safety of herbal medicines. It provides essential knowledge for students, researchers and professionals in the pharmaceutical and herbal drug industries. The book begins with basic tests for pharmaceutical substances, medicinal plant materials and dosage forms along with WHO guidelines for quality control of herbal drugs. It discusses methods for evaluating commercial crude drugs intended for medicinal use. A key focus is quality assurance detailing the implementation of cGMP, GAP, GMP and GLP in the herbal drug industry. The WHO guidelines on Good Manufacturing Practices cGMP for Herbal Medicines are covered in detail. The book also includes EU and ICH guidelines for the quality control of herbal drugs, safety and efficacy research and stability testing of herbal formulations. It highlights the importance of pharmacovigilance systems for monitoring herbal medicine safety. The role of chromatographic techniques such as HPTLC, HPLC and GC in the standardization of herbal products is thoroughly explored. The book also explains the regulatory requirements for herbal medicines including new drug applications, export registration and GMP compliance. The Herbal Pharmacopoeia section compares various global pharmacopoeias and emphasizes the role of chemical and biological markers in herbal drug standardization. This book serves as a valuable resource for ensuring the authenticity, purity and consistency of herbal medicines worldwide.

*Phytopharmaceuticals and Herbal Drugs* Manju Rawat Singh, Deependra Singh, 2023-07-15 Phytopharmaceuticals and Herbal Drugs: Prospects and Safety Issues in the Delivery of Natural Products explores the delivery aspects of plant based drugs providing insights into formulation constraints associated with plant based drugs, the development of novel delivery systems based on polymers or lipids and how combining natural products with technological advancements in drug delivery is making large strides. Some of the best selling drugs for the treatment of diseases like cancer, ulcers and malaria are either natural products or their derivatives, all of which are covered in this comprehensive resource. This book will be useful to researchers working in plant derived medicines and the development of their delivery systems including sections on their derivatives and analogs that represent over 50% of all drugs in clinical use. Active ingredients originated from plant resources generally exhibit compromised desired effects limited by issues such as stability, solubility, molecular size, bioavailability and toxicity. Includes perspectives from academic and industry research, provides information on the safety, regulatory aspects and clinical aspects related to plant based drugs, introduces developments of new targeted drug delivery systems.

**TEXT BOOK OF HERBAL DRUG TECHNOLOGY** Ms. Meena Bandiya, Dr. Sonu Sharma, Dr. Prabhat Kumar Upadhyay, Dr. Nidhi Saxena, Dr. Rajesh Kumar Sharma, 2025-05-09 The Textbook of Herbal Drug Technology is a detailed and structured guide that explores the science, tradition and modern

applications of herbal medicines It begins by defining herbs herbal drugs and herbal medicinal products while also explaining the selection identification and processing of herbal raw materials The book highlights biodynamic agriculture and good agricultural practices including organic farming and pest management using eco friendly methods It offers insights into the principles of Indian systems of medicine like Ayurveda Siddha Unani and Homeopathy and discusses the preparation and standardization of traditional Ayurvedic formulations The growing field of nutraceuticals is explored with focus on their health benefits in managing diseases like diabetes cardiovascular disorders and gastrointestinal issues Key herbs such as garlic ginger ashwagandha and spirulina are discussed for their therapeutic roles The book also covers herbal drug and herb food interactions emphasizing possible side effects and safety concerns Herbal cosmetics and excipients of natural origin are included showing their applications in personal care products Various herbal formulations and advanced dosage forms like phytosomes are presented Evaluation of herbal drugs based on WHO and ICH guidelines including stability testing is thoroughly discussed The book explores intellectual property rights patenting issues and the global significance of traditional knowledge with case studies on turmeric and neem It also examines regulatory frameworks in India such as ASU DTAB ASU DCC and Schedule Z of the Drugs Cosmetics Act Furthermore it introduces the herbal industry's present scope and future prospects Details on GMP requirements under Schedule T are included covering infrastructure hygiene and documentation practices The book offers a balanced approach combining ancient wisdom with modern science making it a valuable resource for students professionals and researchers in the field of herbal drug technology

*Formulating Pharma-, Nutra-, and Cosmeceutical Products from Herbal Substances* Anupama Singh, Hitesh Kulhari, Vikas Anand Saharan, 2025-08-12 A practical and up to date discussion of the formulation and design of dosage forms and delivery systems containing herbal ingredients In Formulating Pharma Nutra and Cosmeceutical Products from Herbal Substances Dosage Forms and Delivery Systems a team of distinguished researchers delivers a step by step approach to preparing and manufacturing dosage forms and delivery systems Intuitively organized with comprehensive coverage of the fundamentals functional materials manufacturing and marketing of pharmaceutical nutraceutical and cosmeceutical products the book also examines regulatory issues of quality safety and efficacy The authors discuss essential formulation development and delivery information for novel and controlled delivery systems of herbal ingredients Readers will also find A thorough introduction to the basic principles of developing modern pharma nutra and cosmeceutical products from herbal substances Comprehensive explorations of conventional formulations including issues of stability Practical discussions of advanced formulations including chronotherapeutic delivery systems liposome based delivery of phytoconstituents and nanoparticle mediated delivery of herbal actives Complete treatments of regulatory challenges including nonclinical characterization and documentation for marketing authorizations of herbal formulations Perfect for professionals working in the herbal drug natural product and dietary supplement industries Formulating Pharma Nutra and Cosmeceutical Products from Herbal Substances will also

benefit academic researchers and graduate students studying herbal research cosmetics and pharmaceutical sciences

**Role of Herbal Medicines** Amal Kumar Dhara, Subhash C. Mandal, 2024-02-26 Emergence of lifestyle diseases e.g. type II diabetes, cancers, obesity, cardiovascular disorders, liver cirrhosis, etc. are exponentially increasing day by day. Modern drifts toward the utilization of herbal medicines in different healthcare aspects necessitate the replacement of synthetic molecules with phytoconstituents because of their biocompatibility, biodegradability, economic extraction process, and ready availability from the natural source. This book provides a thorough insight into the comprehensive and up-to-date trends of phytomedicines in the management of lifestyle diseases and its mechanisms, modern methods of extraction and purification of phytoconstituents, and chemical characterization as well as standardization of phytoconstituents using modern equipments.

**Evidence Based Validation of Traditional Medicines** Subhash C. Mandal, Raja Chakraborty, Saikat Sen, 2021-01-18

The demand for traditional medicines, herbal health products, herbal pharmaceuticals, nutraceuticals, food supplements, and herbal cosmetics, etc. is increasing globally due to the growing recognition of these products as mainly non-toxic, having lesser side effects, better compatibility with physiological flora, and availability at affordable prices. In the last century, medical science has made incredible advances all over the globe. In spite of global reorganization and a very sound history of traditional uses, the promotion of traditional medicine faces a number of challenges around the globe, primarily in developed nations. Regulation and safety is the high concern for the promotion of traditional medicine. Quality issues and quality control, pharmacovigilance, scientific investigation and validation, intellectual property rights, and biopiracy are some key issues that restrain the advancement of traditional medicine around the globe. This book contains diverse and unique chapters explaining in detail various subsections like phytomolecule drug discovery and modern techniques, standardization and validation of traditional medicine and medicinal plants, safety and regulatory issues of traditional medicine, pharmaceutical excipients from nature plants for future. The contents of the book will be useful for the academicians, researchers, and people working in the area of traditional medicine.

**TEXT BOOK OF ADVANCE PHARMACOGNOSY** Mr. Diwaker Dadwal, Dr. Pankaj Pradhan, Dr. Dipanwita Chaudhuri Sil, Dr. Vasundhara Saxena, Dr. Rajesh Kumar Sharma, 2025-08-25 The Text Book of Advance Pharmacognosy is a comprehensive academic resource that delves into modern developments and specialized topics in the field of pharmacognosy with a particular emphasis on medicinal plants, marine natural products, nutraceuticals, phytopharmaceuticals, and pharmacovigilance. It begins with Plant Drug Cultivation, highlighting the pivotal role of pharmacognosy in the herbal drug industry and covers the contributions of the Indian Council of Agricultural Research (ICAR) along with Current Good Agricultural Cultivation and Collection Practices essential for ensuring quality and sustainability. The section also discusses conservation strategies for medicinal plants both ex situ and in situ to preserve biodiversity. The second chapter explores Marine Natural Products, detailing general methods for isolation and purification, the study of marine toxins, and recent advances in marine drug research. It also addresses challenges such as taxonomical identification and

chemical screening along with their practical solutions. The third chapter on Nutraceuticals examines current trends, future prospects and the therapeutic significance of various classes including inorganic mineral and vitamin supplements, digestive enzymes, dietary fibers, cereals, grains, natural health drinks, antioxidants, polyunsaturated fatty acids and herbs as functional foods. It also provides guidelines for formulation standardization and regulatory compliance under FSSAI norms. A dedicated section elaborates on Nutraceutical Sources listing marker compounds, their chemical nature, medicinal uses and health benefits for key examples like spirulina, soybean, ginseng, garlic, broccoli, green and herbal tea, flax seeds, black cohosh and turmeric. The book then transitions into Phytopharmaceuticals, describing occurrence, isolation techniques, chemical characteristics, pharmacological applications and health benefits of bioactive compounds such as carotenoids, limonoids, saponins, flavonoids, phenolic acids, vitamins, tocotrienols, tocopherols, andrographolide, glycolipids, gugulipids, withanolides, vascine and taxol. The final chapter emphasizes Pharmacovigilance of Natural Drugs, discussing WHO and AYUSH guidelines for safety monitoring, spontaneous reporting schemes for adverse reactions and critical insights into biodrug, drug and biodrug food interactions with relevant examples. Overall, the book blends traditional pharmacognosy principles with cutting-edge research, regulatory frameworks and applied aspects, making it a vital reference for students, researchers and professionals in the pharmaceutical sciences.

**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 **Medicinal & Aromatic Plants Abstracts** ,2007

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