

EU AND ICH GUIDELINES FOR QUALITY CONTROL OF HERBAL DRUGS

Anshu Pandey *Awan Kumar Pandey

S.N. College of Pharmacy, Lakhauwa, Jaunpur, India.

Article Received: 25 March 2026, Article Revised: 15 April 2026, Published on: 05 May 2026

*Corresponding Author: Awan Kumar Pandey

S.N. College of Pharmacy, Lakhauwa, Jaunpur, India.

DOI: <https://doi-doi.org/101555/ijarp.6167>

ABSTRACT

Because of their medicinal advantages and historical relevance in traditional medical systems, herbal medications are utilized extensively worldwide. However, maintaining consistent quality, safety, and efficacy is extremely difficult due to their complex chemical composition and variability. In order to solve these issues, regulatory frameworks created by the International Council for Harmonization (ICH) and the European Union (EU) are essential. While ICH gives generic pharmaceutical quality standards that apply to herbal formulations, the EU offers particular recommendations designed for herbal medical goods.

The EU and ICH guidelines for quality control, such as raw material standardization, Good Agricultural and Collection Practices (GACP), analytical validation, impurity control, and stability testing, are thoroughly covered in this paper. By incorporating these criteria, harmonization is ensured, global acceptance is increased, and the creation of superior herbal therapeutic products is supported.

1. INTRODUCTION

For centuries, medical systems including Ayurveda, Traditional Chinese Medicine, and Unani have utilized herbal medicines. Due to the belief that they are safer and more natural substitutes for synthetic medications, their popularity has grown around the world in recent decades.

- Herbal medications, however, are very different from traditional pharmaceuticals because •They are made up of intricate combinations of bioactive substances.
- Environmental and genetic factors influence their composition.
- Sometimes the active ingredients are unknown. Because of these difficulties,

quality control is an essential part of developing herbal drugs.

- In order to tackle these concerns, global regulatory organizations like: The European Union (EU)
- Guidelines have been established by the International Council for Harmonization (ICH) to guarantee that herbal medical products fulfill requirements of:
- Excellence
- Security
- Effectiveness

ICH standards offer a more comprehensive framework that applies to all pharmaceuticals, whereas EU guidelines concentrate exclusively on herbal medications.

2. QUALITY CONTROL GOALS FOR HERBAL DRUGS.

The following are the main goals of quality control:

1. Verifying the validity and identification of herbal materials
2. Maintaining consistency in chemical composition
3. Identifying contamination and adulteration
4. Ensuring human consumption is safe
5. Reaching consistency from batch to batch

3. DIFFICULTIES IN HERBAL DRUGS' QUALITY CONTROL

Herbal medication quality control is difficult because of:

3.1 Plant Material Variability

- The composition is influenced by harvesting conditions, soil, and climate.

3.2 Complicated Chemical Makeup

- The presence of several components rather than just one active component.

3.3 Substitution and Adultery

- The deliberate or inadvertent replacement of subpar materials.

3.4 Pollution

- Aflatoxins, microorganisms, pesticides, and heavy metals

3.5 Insufficient Standardization

- The challenge of identifying precise active components

4. EU RULES FOR HERBAL DRUGS QUALITY CONTROL

Through the European Medicines Agency (EMA), the European Union has created a thorough regulatory framework for herbal medical products.

4.1 FRAMEWORK FOR REGULATORY

Important legal and regulatory papers consist of: Directive 2001/83/EC

- The Traditional Herbal Medicinal Products Directive 2004/24/EC The European Pharmacopoeia.

4.2 GACP, or Good Agricultural and Collection Practices

GACP controls the following to guarantee the quality of raw herbal materials:

- Conditions for cultivation
- Time for harvesting
- Storage and drying
- Avoiding contamination

4.3 Herbal Substance Quality Requirements

Tests are specified in EU guidelines for:

Identity • Both macroscopic and microscopic assessment Chromatographic fingerprinting

Purity • Foreign affairs Ash values

- Metals that are heavy
- Remaining pesticide residues Content/Assay
- Determination of active or marker compounds

4.4 Herbal Recipes

Essential oils, tinctures, and extracts are examples of herbal preparations.

Among the standards for quality are:

- Ratio of drug to extract
- Solvent for extraction
- Marker-based standardization

4.5 Methods of Analysis

The EU suggests contemporary analytical techniques like:

- HPLC, or high performance liquid chromatography Gas Chromatography (GC)

- TLC, or thin-layer chromatography Spectroscopic techniques

In order to guarantee consistency, fingerprint profiling is very crucial.

4.6 Testing for Stability

Testing for stability guarantees:

- Determining shelf life
- Preservation of chemical integrity
- The right storage conditions

4.7 Management of Contaminants

There are strict restrictions for:

- Heavy metals, such as cadmium, lead, and mercury Microbiological contamination
- Pesticides Mycotoxins

4.8 Herbal Combination Products

There are particular rules because:

- The intricacy of several herbs
- The challenge of recognizing active components

5. ICH QUALITY CONTROL GUIDELINES

ICH rules offer a uniform framework that can be used wherever in the world.

5.1 ICH Q1: Testing for Stability

- Specifies stability procedures
- Establishes shelf life
- Consists of both long-term and expedited testing.

5.2 Analytical Validation, ICH Q2

Among the validation parameters are:

- Precision
- Accuracy
- Particularity
- Linearity
- Limits of detection

5.3 ICH Q3: Contaminants

Covers:

- Organic contaminants
- Remaining solvents
- Impurities that are elemental

5.4 Good Manufacturing Practices (GMP): ICH Q7

Assures:

- Appropriate production procedures Systems for quality assurance
- Documentation

5.5 Pharmaceutical Development, ICH Q8

focuses on:

- Development of formulations Optimization of processes.

5.6 ICH Q9: Risk Management for Quality

- Identification of risks
- Risk assessment
- Risk management

5.7 Pharmaceutical Quality System, ICH Q10

- A lifecycle approach to quality
- Ongoing development

6. A COMPARATIVE EXAMINATION OF ICH AND EU GUIDELINES

EU Guidelines for Parameters ICH Recommendations Scope: General and Herbal-specific
Emphasis on plant variability and raw materials System-based excellence Fingerprinting
validation using an analytical technique Limited and extensive risk management.

7. WHO GUIDELINES WHO supports the EU and ICH by offering:

- International regulations for herbs
- GACP regulations • Monitoring for safety

8. CURRENT METHODS FOR CONTROLLING HERBAL QUALITY

8.1 Fingerprinting using Chromatography

Guarantees that the chemical composition is consistent.

8.2 Standardization Based on Markers

Used in situations when the active ingredients are uncertain.

8.3 Barcoding DNA

Aids in the identification of plants.

8.4 Chemometrics

Statistical evaluation of complicated data.

9. FUTURE PROSPECTS AND REGULATORY DIFFICULTIES

Obstacles

- The absence of worldwide harmonization
- The diversity of botanical materials
- Insufficient clinical information

Prospective Paths:

- Sophisticated analytical methods
- Harmonization of regulations worldwide
- More investigation and verification.

10. SUMMARY

Together, EU and ICH rules offer a strong foundation for herbal medication quality control. ICH guarantees worldwide uniformity through methodical quality measures, whereas EU standards deal with issues unique to herbs.

The two systems' integration guarantees:

- Superior herbal products
- Enhanced effectiveness and safety
- Worldwide acceptance

Future developments will enhance the standardization of herbal medicine and fortify the regulatory framework even further.

REFERENCES:-

1. The European Medicines Agency is cited. Rules for Herbal Medicinal Product Quality.
2. EMA. Guidelines of the Herbal Medicinal Products Committee (HMPC).
3. Directive 2001/83/EC.
4. Directive 2004/24/EC.
5. Commission on European Pharmacopoeia.
6. EMA GACP Regulations.
7. Guidelines for EMA Quality Control.
8. The World Health Organization's guidelines for good agricultural practices.
9. WHO Herbal Medicine Technical Report Series.
10. ICH Q1A(R2): Testing for Stability.
11. ICH Q2(R1): Analytical Procedure Validation.
12. Impurities in ICH Q3A/B.
13. GMP Guidelines, ICH Q7.
14. Pharmaceutical Development, ICH Q8(R2).
15. Quality Risk Management (ICH Q9).
16. Pharmaceutical Quality System (ICH Q10).
17. Mukherjee PK. Herbal Drug Quality Control.
18. Evans and Trease Pharmacognosy.
19. WHO Medicinal Plant Monographs.
20. Standardization of Herbal Medicines, Kunle OF et al.
21. Herbal Medicine in Clinical Practice, Bent S.
22. Calixto JB. Herbal Medicine's Effectiveness.
23. Heinrich M. Phytotherapy and Pharmacognosy.
24. Commission E Monographs, Blumenthal M.
25. FDA Guidelines for Botanical Drug Development.
26. OECD Guidelines for Herbal Safety.
27. Herbal Monographs published by the European Commission.
28. Indian Pharmacopoeia Herbal Standards.
29. Commission on Chinese Pharmacopoeia.
30. The Herbal Medicines Compendium of the United States Pharmacopoeia (USP).