

**MODERN DEVELOPMENTS IN QUALITY CONTROL OF AYURVEDIC  
FORMULATIONS****\*Dr. Rohit Mehta**

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**INTRODUCTION**

Ayurveda is officially acknowledged as a recognized medical system in India and is also categorized under Traditional Medicine by the World Health Organization. Ensuring the quality of medicinal products is fundamental in any healthcare system. One of the major challenges in promoting Ayurvedic medicines at a global level is the absence of uniform standardization, especially due to adulteration and variability in raw materials.

To maintain authenticity from the stage of raw drug procurement to final product manufacturing, robust quality control measures are essential. Although the foundational principles of Ayurveda remain unchanged as described by the Acharyas, advancements in scientific tools have transformed the methods of evaluation and presentation.

Modern techniques such as DNA fingerprinting and biomarker identification have strengthened the authentication of raw drugs. Advanced instrumentation has also minimized manual dependency and facilitated large-scale production. Therefore, well-defined protocols for assessing various dosage forms are crucial for achieving standardization of Ayurvedic formulations.

**Concept Of Quality Control**

Quality control must begin even before the production process starts. It is not limited to final product testing but must be implemented throughout the entire chain — from collection, processing, storage, and manufacturing to packaging. Standardization refers to defining measurable parameters that establish the identity, purity, safety, and efficacy of a drug. International bodies have emphasized the need to evaluate medicinal plants and formulations using scientific quality assessment methods to ensure consistency and reliability.

**Guidelines For Quality Assessment of Formulations**

The following components are essential during evaluation:

- Examination of crude drugs, processed plant materials, and finished products
- Stability studies and determination of shelf life
- Safety documentation based on traditional evidence and toxicological studies
- Evaluation of therapeutic efficacy through pharmacological and biological investigations

**Major Categories of Ayurvedic Formulations**

Ayurvedic compound preparations are broadly divided into:

1. **Rasaushadhi** (Herbo-mineral and metallic preparations)
2. **Kastaushadhi** (Herbal formulations)

**Rasaushadhi**

Rasaushadhis primarily include processed metals and minerals. These preparations are administered in small doses, act rapidly, and are often claimed to have prolonged shelf stability. They are considered highly effective, particularly in chronic and complex disorders.

The classical preparation methods described in Rasa Shastra involve detoxification and repeated processing to transform metals and minerals into bio-assimilable forms. However, in the present context, scientific

validation and standardization of these herbo-metallic preparations are indispensable.

Common mineral-based products include Shuddha Dravya, Bhasma, Sindura, Parpati, Pottali, Druti, Drava, Satwa, and Kharaliya Rasayana.

#### **Bhasma: Traditional Concept and Modern Validation**

Initially, herbal drugs were predominantly used in therapeutics. Gradually, metals and minerals were incorporated after developing specialized pharmaceutical processes such as:

- **Shodhana** (purification)
- **Marana** (incineration/calcination)
- **Samskara** (specific processing, particularly for mercury)

The preparation of Bhasma requires meticulous execution of purification and incineration steps, sometimes including intermediary processes depending on the material used.

#### **Traditional Testing Parameters**

##### **Physical tests include**

- Rekhapurnatva (fineness)
- Varitaratva (lightness)
- Nishchandratva (absence of metallic shine)

##### **Chemical tests include**

- Apunarbhavatva (irreversibility)
- Nirutthatva (absence of free metal)
- Specific taste-based and reaction-based assessments

Characteristic color observations are also described for different Bhasmas, serving as classical indicators of proper preparation.

While these traditional tests are time-tested and valuable, they rely heavily on practitioner expertise and sensory evaluation, which may lack high sensitivity.

#### **Modern Analytical Methods for Bhasma Evaluation**

Advancements in analytical science have introduced precise and reproducible testing tools such as:

- Metallographic studies
- Spectrophotometry
- Scanning Electron Microscopy (SEM)
- X-Ray Diffraction (XRD)
- Atomic Absorption Spectroscopy (AAS)
- Particle size analysis

These techniques help detect elemental composition, structural changes, presence of toxic metals, and physicochemical properties such as moisture content, ash values, specific gravity, and loss on ignition.

Petrological investigations are also employed to examine structural transformation during different stages — raw, intermediate, and finished product.

#### **Kastaushadhi (Herbal Formulations)**

Herbal formulations have gained widespread therapeutic acceptance. These include preparations such as Kashaya (decoctions), Asava, Arishta, Vati (tablets), and Churna (powders). Each dosage form has defined parameters for assessing quality.

In ancient times, physicians personally prepared medicines following textual guidelines and experiential knowledge. Identification of genuine drugs was based on morphology, sensory attributes, and principles like Rasa Panchaka. Specific signs of proper preparation (Siddhi Lakshana) served as quality indicators.

In the present era, manufacturing is largely handled by pharmaceutical industries. Raw drugs are procured through supply chains, often increasing the risk of substitution, adulteration, or compromised processing standards. Large-scale production sometimes prioritizes quantity over quality, affecting the integrity of formulations.

#### **Modern Quality Parameters For Herbal Drugs**

Contemporary evaluation methods include:

- Particle size determination
- Total ash and acid-insoluble ash values
- Extractive values (water/alcohol soluble)
- Moisture content
- Bulk and tap density
- pH measurement
- Heavy metal analysis
- Microbial load testing
- Chromatographic profiling (TLC, HPTLC, HPLC, GC-MS)
- Detection of pesticide residues
- Testing for specific pathogens and aflatoxins

Advanced techniques such as atomic emission spectrometry assist in detecting trace elements and contaminants.

DNA fingerprinting and biomarker analysis further strengthen raw drug authentication.

#### **Need for Advanced Quality Control Techniques**

Modern quality assessment is essential for:

- Scientific validation of traditional medicines
- Supporting large-scale industrial production
- Ensuring reproducibility and consistency
- Detecting adulteration and contamination
- Establishing global credibility

Integration of traditional knowledge with contemporary scientific methods is necessary to develop reliable Standard Operating Procedures (SOPs).

### **DISCUSSION**

With the increasing global demand for Ayurvedic medicines, mass production has become inevitable. However, expansion must not compromise quality.

Classical guidelines emphasized collection based on geographical region (Desha), season (Ritu), soil type (Bhumi), and timing (Kala), all of which influence drug potency. Understanding shelf life and maintaining storage standards are equally important.

Modern pharmaceutical industries operate in competitive environments, which may increase the risk of quality compromise. Therefore, combining traditional principles with advanced analytical technologies is crucial for maintaining authenticity and safety.

### **CONCLUSION**

Globalization has intensified the necessity for scientifically established standards for Ayurvedic drugs and formulations. Standardization ensures safety, efficacy, and consistency, thereby enhancing international acceptance.

Before any traditional medicine is released for public use, it must undergo thorough quality assessment to eliminate risks of toxicity, adulteration, and contamination. Hence, quality control is not optional but fundamental to the credibility and future growth of Ayurveda.