

**SCIENTIFIC AND ANALYTICAL CHALLENGES IN QUALITY CONTROL,
AUTHENTICATION, AND STANDARDIZATION OF MEDICINAL PLANT RAW
MATERIALS UNDER CONDITIONS OF MULTICOMPONENT CHEMICAL
COMPOSITION VARIABILITY**

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1. Introduction. Medicinal plant raw materials represent complex multicomponent systems composed of biologically active and auxiliary compounds belonging to various chemical classes. Their qualitative and quantitative composition varies depending on the botanical species, plant organ, ecological and geographical conditions, growth stage, harvesting time, and processing and storage conditions. Such natural variability poses significant challenges to the authentication of raw materials, the assurance of consistent quality, and the development of scientifically justified standardization criteria.

From the perspective of commodity chemistry, assessing the quality of medicinal plant raw materials solely on the basis of the concentrations of individual bioactive compounds is insufficient. A comprehensive evaluation requires the integrated analysis of chemical profiles, characteristic constituents, their quantitative ratios, physicochemical properties, and safety parameters. Guidelines issued by the World Health Organization (WHO) and the European Medicines Agency (EMA) emphasize the importance of identifying herbal raw materials, conducting appropriate analytical tests, and establishing scientifically justified quality specifications [1, 2].

Recent advances in high-performance liquid chromatography (HPLC), mass spectrometry (LC-MS and GC-MS), and spectroscopic techniques have significantly expanded the possibilities for comprehensive chemical profiling of medicinal plants. Integrating these analytical data with principal component analysis (PCA), hierarchical cluster analysis (HCA), and other chemometric techniques enables the assessment of samples based on chemical similarities, geographical or botanical origin, and compositional differences [3, 4].

However, the identification of numerous chemical constituents does not, in itself, guarantee a reliable assessment of product quality. The selection of analytical indicators should consider their selectivity, reproducibility, stability under natural compositional variability, and ability to discriminate between samples. Furthermore, establishing meaningful relationships between chemical profiles, characteristic constituents, and independently measured physicochemical quality parameters remains an important scientific challenge.

Therefore, the standardization of medicinal plant raw materials requires supplementing conventional approaches based on the quantification of individual compounds with multiparametric chemical analysis, distinguishing natural biological variability from technological variability, and evaluating analytical results according to scientifically established reliability criteria.

The aim of this study is to critically compare existing scientific and analytical approaches to quality control, authentication, and standardization of medicinal plant raw materials under conditions of multicomponent chemical variability, based on international scientific literature, and to identify promising directions for multiparametric quality assessment integrating chemical profiles, characteristic constituents, and physicochemical commodity-quality parameters.

2. Materials and methods. The present study is based on a critical comparative analysis of international scientific literature addressing the chemical composition, quality control, authentication, and standardization of medicinal plant raw materials. The methodological framework involved the systematic organization of scientific sources, comparison of analytical approaches, and evaluation of their relevance to commodity chemistry.

The analysis included scientific publications investigating chemical profiles, characteristic constituents, natural and technological variability, and quality indicators of medicinal plant raw materials, together with relevant methodological guidelines issued by the World Health Organization (WHO) and the European Medicines Agency (EMA) [1–4].

The literature was comparatively evaluated according to the following criteria: selectivity and reproducibility of analytical methods used for chemical characterization; diagnostic significance of characteristic constituents; effects of natural variability on analytical results; discriminatory capabilities of chemical profiling techniques; and the role of physicochemical quality parameters in standardization.

The analytical capabilities of HPLC, LC-MS, GC-MS, and spectroscopic techniques were compared, along with the applications of chemometric approaches such as principal component analysis (PCA), hierarchical cluster analysis (HCA), and partial least squares (PLS), based on findings reported in the scientific literature.

Based on the comparative analysis, the principal challenges associated with quality control were identified and synthesized, and a conceptual framework for multiparametric quality assessment was formulated. No new laboratory experiments were conducted as part of this study; the scientific conclusions presented are derived exclusively from the analytical synthesis of previously published literature.

3. RESULTS 3.1. Effects of Chemical Composition Variability on Quality Control. A comparative analysis of the scientific literature indicates that the chemical composition of medicinal plant raw materials is influenced by biological, ecological, geographical, and technological factors. In particular, botanical species and plant organs play essential roles in determining phytochemical composition, whereas harvesting time, drying, extraction, and storage conditions significantly affect the quantitative distribution of individual constituents [1–4].

Such variability presents two major challenges in quality control: distinguishing natural chemical variations from quality deterioration and establishing reliable acceptance criteria for different production batches. Therefore, chemical composition assessment should consider not only the concentrations of individual constituents but also their quantitative ratios, raw material origin, and physicochemical characteristics.

3.2. Analytical Potential of Characteristic Constituents and Chemical Profiles. In conventional quality control, the quantification of selected characteristic constituents enables the application of analytical methods with high selectivity and reproducibility. However, a high concentration of a particular compound does not necessarily establish its botanical specificity or guarantee its ability to comprehensively represent product quality.

Multicomponent chemical profiles obtained using HPLC and LC-MS provide broader opportunities for assessing compositional similarities and differences among raw material samples. Chemometric techniques, including principal component analysis (PCA) and hierarchical cluster analysis (HCA), facilitate the organization of complex analytical datasets and identification of sample clustering patterns [3, 4].

Nevertheless, classification results derived from chemical profiles should not be directly equated with product quality. Quality-related conclusions must be supported by independently measured physicochemical parameters and appropriate validation procedures.

3.3. Comparative Evaluation of Quality Control and Standardization Approaches

Table 1. Principal Analytical Approaches to Quality Control of Medicinal Plant Raw Materials

Analytical approach	Advantages	Main limitations
Determination of individual characteristic constituents	Facilitates quantitative quality control and analytical method validation	Does not fully characterize complex chemical compositions
HPLC and LC-MS profiling	Enables multicomponent chemical characterization and comparative sample analysis	Depends on sample preparation procedures and instrumental conditions
PCA and HCA	Identifies chemical similarities and sample clustering patterns	Clustering alone does not confirm product quality
Diagnostic quantitative ratios	Enables assessment of relationships among chemical constituents	Requires evaluation of stability under natural compositional variability
Multiparametric quality control	Integrates chemical profiles, physicochemical properties, and safety indicators	Requires extensive analytical data and comprehensive validation

Source: Authors' comparative analytical synthesis based on references [1-4].

The comparative analysis indicates that individual compound determination, chemical profiling, and chemometric techniques represent complementary analytical approaches. Each method serves a specific analytical purpose; however, none can independently encompass all

quality attributes of medicinal plant raw materials. Accordingly, a multiparametric approach integrating chemical profiles, characteristic constituents, diagnostic quantitative ratios, and independently measured physicochemical parameters is proposed for comprehensive quality assessment. A fundamental scientific prerequisite for implementing this approach is the validation of the analytical reliability and quality-discriminating capability of the selected indicators using independent samples.

4. Discussion. A comparative analysis of the scientific literature indicates that the principal challenge in the standardization of medicinal plant raw materials lies not merely in identifying their chemical constituents, but in selecting reliable criteria for assessing product authenticity and quality under conditions of natural compositional variability. Although the quantification of individual characteristic compounds remains an important component of existing analytical approaches, its ability to comprehensively characterize raw material quality is limited [1-4].

Multicomponent chemical profiling partially addresses this limitation. However, similarities between chromatographic or spectral profiles do not necessarily indicate equivalence in product quality. Likewise, clustering patterns identified through principal component analysis (PCA) and hierarchical cluster analysis (HCA) should not be regarded as diagnostic criteria unless they are supported by independently measured quality indicators. From the perspective of commodity chemistry, a promising approach involves integrating chemical profiles and characteristic constituents with moisture content, ash content, extractive matter, storage stability, and relevant safety parameters. In this context, the selectivity, reproducibility, and robustness of analytical indicators against natural compositional variability must be systematically evaluated.

Accordingly, the proposed multiparametric approach provides a theoretical basis for shifting from the characterization of medicinal plant raw materials solely by their chemical composition toward a comprehensive assessment of their authenticity and quality. Nevertheless, the practical effectiveness, acceptance criteria, and predictive performance of this approach require experimental investigation and statistical validation using independent samples.

5. Conclusion

1. A critical review of the scientific literature established that natural and technological variability in the chemical composition of medicinal plant raw materials is an important factor influencing quality control and standardization.

2. The analysis demonstrated that quantification of individual characteristic constituents may not adequately represent the complex chemical composition of herbal raw materials, whereas chemical profiling and chemometric analysis offer broader opportunities for comprehensive quality assessment.

3. A multiparametric quality assessment approach integrating chemical profiles, characteristic constituents, diagnostic quantitative ratios, and independently measured physicochemical quality parameters was proposed.

4. The findings highlight the necessity of validating analytical methods, establishing scientifically justified acceptance ranges that account for natural compositional

variability, and confirming the reliability of the proposed approach using independent samples before its implementation in practical standardization systems.

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