• “十二五”国家重点图书出版规划项目

中药材

质量专论

• 主审　胡之璧
• 主编　王峥涛　谢培山
• Reviser in-chief　Hu Zhibi
• Editors in-chief　Wang Zhengtao　Xie Peishan

Monographs for Quality Evaluation of Chinese Crude Drugs

上海科学技术出版社
SHANGHAI SCIENTIFIC & TECHNICAL PUBLISHERS

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内容提要 Abstract

本书中英文对照，以60种常用药材为对象，收载其品名、基原、产地、功能与主治、性状、显微鉴别、薄层色谱鉴别、高效液相（气相）特征图谱鉴别、含量测定、述评、参考文献11项。作者将形态、显微鉴别与化学分析相结合，指标成分含量测定与特征指纹图谱分析相结合，化学成分分析与生物活性评价相结合，研究、建立具有专属性鉴别特征的、反映内在品质的质量评价方法，并配以原色照片、图片及图谱，图文并茂，更科学、客观、直观地展现了各品种的现状和特征。

本书内容不论是样品收集、鉴定，还是特征色谱指纹图谱分析、含量测定，均为第一手原创性实验资料，在显微鉴别特征、薄层色谱鉴别图谱方面精益求精，形成了鲜明的特色。在述评部分，多数品种还重点论述了常见的近缘品种、混乱品种及其鉴别特征。本书为这些常用中药的质量控制和标准完善、提升提供了坚实的科学基础和翔实的实验依据，也为其他中药的质量研究提供了参考依据。本书对于如何评价药材的真伪、优劣，确保临床用药的安全有效，可提供重要的参考和借鉴。

This work is edited and refined on the bases of a summary report of a major project of "Monographs for Quality Evaluation of Chinese Crude Drugs", supported by the State Administration of Traditional Chinese Medicine. It contains 60 monographs of the commonly used TCM herbs, each of them involves the following items: definition, location, action and indication, description, microscopic identification, TLC identification, HPLC/GC fingerprint identification (optional), assay, discussion, and references.

This work is featured on the comprehensive evaluation of the individual herbs by integrating the morphology authentication and chemical analysis, quantitative determination of the marker compounds and HPLC characteristic fingerprint, and physi-chemical analysis and bioassay, aimed at establishing quality assessment methods with the specific identification characteristics and representing the intrinsic quality of the tested herbs.

All the contents were written bilingually with primary colored figures and photos, which may afford a scientific, objective, and intuitive assessment and reflect the quality status and the characteristics of each species of herb.

All the contents of the monographs were from the first-hand experimental data such as sample collection, macroscopic and microscopic identification, TLC and HPLC characteristic chromatographic fingerprints, and assay of the target components in the tested samples.

The distinct points of the monographs are mainly embodied in the digital imaged microscopic identification, TLC/HPTLC documentation, and a discussion and comments on the authentic quality differences between the genuine and substitutes available in commercial crude drugs markets.

We hope those monographs will provide a reference of quality assessment for other traditional Chinese medicines.

国家中医药管理局中医药科技重大专项

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编委会 Editorial Committee

序 Preface

中药基原复杂、成分复杂，药效物质不明确，对照品短缺，质量标准不科学，评价体系不健全的问题长期存在，直接影响到临床用药的安全性、有效性，成为制约中医药发展的瓶颈。因此，研究、建立科学、先进、适用的中药质量评价方法和技术标准，对于提升国家中药标准水平，促进中药的现代化、国际化具有十分重要的意义。

由王峥涛教授、谢培山教授领衔研究、编撰的《中药材质量专论》，以《中华人民共和国药典》收载的常用中药材为对象，在全国主要药材市场上收集代表性样品，将形态、显微鉴别与化学分析相结合，指标成分含量测定与特征指纹图谱分析相结合，化学成分分析与生物活性评价相结合，研究、建立具有专属性鉴别特征的、反映内在品质的质量评价方法，编撰了中英文对照、图文并茂的中药材质量研究专论，更科学、客观、直观地展现了各品种的现状和特征。

在研究中作者采用了很多新的技术，如薄层色谱-生物自显影技术、超高效液相色谱-质谱联用技术等。更为难得者，在于首次阐明了多种中药的特征性指标成分，建立了相应的定性、定量分析方法。

该《专论》不论是样品收集、鉴定，还是特征色谱指纹图谱分析、含量测定，均为第一手实验资料，在显微鉴别特征、薄层色谱鉴别图谱方面精益求精，形成了鲜明的特色。在述评部分，多数品种还重点论述了常见的近缘品种、混乱品种及其鉴别特征，为这些常用中药的质量控制和标准完善、提升提供了坚实的科学基础和翔实的实验依据，也为其他中药的质量研究提供了参考依据。

值此《专论》付梓之际，欣然命笔，是为之序。

肖培根

中国工程院院士

中国医学科学院药用植物研究所名誉所长

2012年10月15日

前言 Foreword

中医药在中国已有数千年的应用历史,目前作为补充和替代医学,正逐渐被西方世界接受。中药及其他草药产品的销量在国际医药或健康食品市场上也呈递增趋势。

中药来源于药用植物、动物及矿物。作为天然来源的药物,生态环境、采收和种植条件,甚至干燥、储藏或运输过程都可能极大地影响药材的质量。中药多以复方的形式应用,即便是单方,也含有上百种化学成分,但其中只有一小部分结构明确,且作用机制尚不清楚。此外,因形态相似或资源短缺,导致中药基原复杂,很多中药包含同属多种植物,并时有替代品、混伪品出现。总之,中药的质量评价与科学标准的制订是确保临床用药安全、有效的关键。

随着现代分析仪器和分析技术的发展,各种薄层色谱、高效液相色谱及气相色谱等色谱技术,紫外、红外、质谱、核磁等波谱技术,以及色谱/波谱联用技术,广泛应用于中药的品质评价。中药的国家标准《中华人民共和国药典》)水平也显著提升,促进甚或引领着天然药物的国际标准发展。

毫无疑问,化学分析已经成为中药和天然药物质量控制的主导方向。然而,一方面由于中药化学成分的多样性、复杂性及不确定性,中药材、饮片及成方制剂的现行质量标准仍无法真正反映其内在品质。另一方面,中医药的发展和应用是基于朴素的唯物论和辩证法,着眼于多种成分对机体的整体调控作用。

显然,通过单一或少数指标性成分的测定难以客观评价中药的质量,对于多基原、多产地,以及药效成分不明确的药材,更是如此。

因此,只有综合运用多学科技术手段,形态鉴定与化学分析相结合,定性鉴别与含量测定相结合,理化分

Traditional Chinese Medicine (TCM) has been used for medication in China over thousands of years, and now become more and more accepted as a source of alternative and complementary medicine in western world. The sale of TCMs and other herbal products is increasing in the international medicines or health products markets.

TCM herbs are derived from medicinal plants, as well as animals and minerals. As a source of natural medicines, the ecological environments, the collecting and agricultural practices, even the drying, storage, and shipping processes may greatly affect their quality. TCMs are normally used in formulations which are composed of numerous herbs, and even a single herb may contain hundreds of chemical components, but only a small portion of them has been identified with unclear mechanisms. Furthermore, many TCM herbs are genetically multi-originated or even disordered by adulterants owing to the morphological similarity and resources shortage. All in all, quality evaluation and standards development of TCM herbs are the key point to ensure the safety and effectiveness in clinical application.

With the development of advanced analytical instruments and technologies, chromatographic such as TLC, HPLC, and GC, spectroscopic including UV, IR, MS and NMR, and the hyphenated techniques, are all extensively used in the quality evaluation of TCM herbs. The level of national standards for TCMs has been improved impressively, which have advanced or led the trend in international standards for natural medicines.

There is no doubt that the chemical analysis has become the dominant direction of the quality control system of TCM and natural medicines. Nevertheless, the current standards for crude drugs, decoction slices and formulated preparations of TCMs are still not consummated to effectively monitor the qualified property of the tested herbs due to the diversity, complexity and uncertainty of the chemical compositions in TCM herbs. Moreover, Chinese medicine is practiced based on the hypothesis of simple materialism and dialectics, emphasizing the regulation functions of the whole body by the multi-ingredients existing in the herbs.

Obviously it is difficult to measure their quality for TCM herbs by detecting solely the presence/absence of a single or small number of marker components at very low concentration, especially for the herbs derived from multi-origins and produced from wide localities, as well as those with unknown

principle bioactive components.

From this standpoint, it is necessary to use multidisciplinary technologies, integrating the morphological authentication and chemical analysis, qualitative detection and quantitative determination, and physico-chemical analysis and bioassay, in order to distinguish the authentic herb from the adulterant, the superior from the inferior, and to improve the national standards of TCM herbs.

In addition, monographs illustrated with primary colored photos of the original plants and medicinal parts, diagnostic microscopic pictures, and characteristic TLC and HPLC profiles will help to demonstrate the intuitive and panorama images for the tested TCM herbs, as the diagnostic feathers of many herbs could not be described exactly with poor linguistic expression.

Based on this importance, we edited the monographs of 60 commonly used TCM herbs. All the experimental data were summarized from a major project of "Monographs for Quality Evaluation of Chinese Crude Drugs", supported by the State Administration of Traditional Chinese Medicine, and each monograph involves the following items: definition, location, action and indication, description, microscopic identification, TLC identification, HPLC/GC fingerprint identification (optional), assay, discussion, and references.

This work has been featured on a comprehensive evaluation of the individual herbs aiming to identify the diagnostic characteristics by either chemical or microscopic analyses, or by integrating the morphologic and chemical technologies, based on comparison between the authentic herbs and the substitutes or adulterants, if the latter available in the markets.

All the contents of the monographs were from our first-hand experimental data such as sample collection, macroscopic and microscopic identification, TLC and HPLC characteristic chromatographic fingerprints, assay of the target components, and evidence-based establish of the marker substances for some species.

The representative samples were collected from at least 10 crude drug markets throughout China mainland in order to cover the mainstream commercial crude drugs.

All the contents were written bilingually with primary colored photos and figures, which may afford a scientific, objective, and intuitive assessment and reflect the quality status and the characteristics of each species of herb.

The discussion section of each monograph was addressed on the evidence-based establish of the reference substances and the morphologic and chemical differences between the genuine and substitutes if available in commercial crude drugs markets.

In one word, the ultimate goal of this book is to provide a guidance and reference for how to assess the authenticity, the pros and cons, and to ensure the safety and effectiveness of the clinical use of TCM herbs.

The laboratory research of this project was co-contributed by research fellows from Shanghai University of Traditional Chinese Medicine, Guangdong Provincial Hospital of Traditional

析与生物检定相结合,才能真正判别中药的真伪、优劣,提升中药的国家标准水平。

此外,由于很多药材的鉴别特征只可意会、不可言传,很难仅仅用语言来准确描述,若配以原色原植物和药材照片、显微特征图片及薄层色谱、高效液相谱图,图文并茂,将有助于对药材的品质特征进行更直观、完整的表征。

有鉴于此,我们在承担、完成国家中医药管理局中医药科技重大专项课题"中药材质量评价专论"的基础上,总结其研究成果,编撰了60种常用中药材质量专论。每种药材专论包括以下项目:基原、产地、功能与主治、性状鉴别、显微鉴别、薄层色谱鉴别、高效液相(气相)色谱特征图谱鉴别(部分品种)、含量测定、述评及参考文献。

本专论的特色是对常用中药材进行整体质量评价,通过市场上流通的正品与替代品或伪品的比较,研究、建立其化学或显微鉴别特征,或化学分析与形态鉴别相结合,找到其品质特征。

专论中的所有内容均来自于第一手实验研究数据,如样品收集、性状和显微鉴别、薄层色谱及高效液相色谱特征指纹图谱、含量测定以及部分品种中定性、定量指标成分的研究确定。

每种药材均从全国各地至少10个药材市场采集代表性样品,基本涵盖了主流商品药材。本专论内容为双语(中、英)对照,配以原色照片、图片、图谱,以期提供科学、客观、直观的评判标准,反映其品质特征。

每个专论的述评部分重点阐明对照品的确立依据,商品药材市场流通的正品、混伪品之间的性状和化学差异。总之,本专论的编撰、出版,对于如何评价药材的真伪、优劣,确保临床用药的安全有效可提供重要的参考和借鉴作用。

本项目由谢培山教授、王峥涛教授领衔,由上海中医药大学、广东省中医院、珠海科曼中药研究有限公司、上海中药标准化研究中心、中国药科大学、广州中医药大学等单位通力合作完成。对该项目各合作单位给予的大力支持致以衷心感谢。

毋庸讳言,本专论尚存在很多不足之处,有待于进一步完善。首先,有些品种用于化学分析的指标成分相对较少。虽曾尝试分离、鉴定尽可能多的既具有特

征鉴别意义,又有相关活性的对照品,但终因时间所限,未能如愿。

有些专论中的质量评价和讨论部分受限于所具备的对照品和对照药材。每次尝试为得到多种特征性指标成分而去鉴定薄层色谱的条带和高效液相色谱峰,但是根据植物分类学意义和相关生物活性而准备足够数量的纯净标准品是很困难的。

再者,部分品种的样品代表性仍显不足。虽然已从主要药材市场收集了10批以上的商品药材样品,但是对于一些多基原、存在混伪品的药材,因未能采到全部的对照药材,致使无法在同一鉴定、分析条件下进行正品、混伪品的直接比较。

当然,英文的翻译,特别是述评部分内容的翻译,需要进一步提高。

著 者

2012年10月1日

Chinese Medicine, Chromap Institute of Science & Medicine International Ltd., Shanghai R&D Centre for Standardization of Chinese Medicines, China Pharmaceutical University and Guangzhou University of Traditional Chinese Medicine, directed by Prof. Xie Peishan and Prof. Wang Zhengtao. The supports and assistances from all the participation institutes are sincerely acknowledged.

The quality evaluation and discussion in some of the monographs presented are limited by the reference substances and the authentic samples obtained. Every attempt was made to get multiple specific chemical markers to identify the diagnostic zones in TLC and peaks in HPLC profiles, but it is proven a hard work to prepare enough quantities of the purified reference compounds with phytotaxonomic significance and the related bioactivity.

Although the commercial crude drug samples collected from 10 markets were representative, the authentic species were not available for some multi-originated herbs which led a lack of direct comparison between the authentic and the tested samples. In addition, the English translation, especially in discuss, needs a further improvement.

Authors

2012 - 10 - 01

编写说明 Editorial Notes

1．本专论共收载常用中药材60种,所有实验数据均为第一手研究资料。

2．本专论根据药材基原按植物分类(Engler)系统排序。

3．各药材品种项下收载的内容包括：品名、基原、产地、功能与主治、性状、显微鉴别、薄层色谱鉴别、高效液相/气相色谱特征图谱鉴别、检查、含量测定、述评、参考文献。

4．品名　包括药材中文名、汉语拼音名、拉丁名、英文名。

5．基原　包括科名、植物学名、药用部位及采收加工,附原植物原色照片。

6．产地　记述药材的主产地,如有栽培亦加说明。

7．功能与主治　参照《中华人民共和国药典》2010年版记述药材的功能与主治。

8．性状　按形状、大小、颜色、表面特征、质地、断面、气味等描述,并附药材性状特征照片。

9．显微鉴别　描述特定药用部位的横切面组织构造或粉末显微特征,附显微特征照片。

10．薄层色谱鉴别　包括对照品、对照药材、供试品溶液制备,色谱条件与参数,检识方法与结果表述,附原色薄层色谱照片。

11．高效液相/气相特征图谱鉴别(部分品种)包括对照品、供试品溶液制备,色谱条件与参数,检测方法与结果,附特征指纹图谱与特征峰保留时间表。

12．含量测定　主要采用高效液相色谱法或液相色谱-质谱联用技术测定专属性或活性成分的含量,包括色谱条件与参数,对照品、供试品溶液制备,并附有样品实测数据和高效液相色谱图。与《中华人民共和国药典》2010年版含量测定项指标成分一致者,给出相

1. This work includes 60 monographs of commonly used Chinese Crude Drugs, and all the research data in this book were first-hand materials of the authors.

2. The monographs in this work are arranged according to Engler botanical classification system of the original plants of the crude drugs.

3. The contents of each monographs includes: Nomenclature, Definition, Location, Actions and Indications, Description, Microscopic authentication, TLC identification, HPLC/GC fingerprint identification (optional), Test, Assay, Discussion and Reference.

4. Nomenclature refers to the Chinese name, Chinese phonetic name, Latin name and English name of the crude drug.

5. Definition refers to the source of the plant and its scientific name(s), medicinal organ(s), harvesting and processing procedures, with primary colored photo(s) of the original plant(s).

6. Location refers to the main distribution and/or cultivation areas.

7. Actions and Indications are quoted from the descriptions in *ChP* 2010.

8. Description refers to the macroscopic feathers of the shape, size, color, appearance, texture, cross section, odor and taste, or other physical constants, with primary colored photo(s) of the specified medicinal organ(s) of the crude drug.

9. Microscopic identification refers to the microscopic characters of the cross section or the powdered drugs of the specified medicinal organ(s), with digital image(s) of the microscopic characteristics.

10. TLC identification refers to the preparation of the samples, reference substance(s), and reference drug, TLC condition and parameters, detection method(s) and the result statement, with primary colored TLC photo(s).

11. HPLC/GC fingerprint identification (optional) refers to the preparation of the samples, reference substance(s), chromatographic condition and parameters, detection method and the result statement, with HPLC/GC characteristic fingerprints and table of the relative retention times of the specific peaks.

12. Assay refers to the quantitative determination by HPLC or LC-MS of the specific or bioactive compound(s), including the HPLC condition and parameters, the experimental

data and the HPLC/LC－MS profile. In case of the specified content value of the target analyte (s) is available in *ChP* 2010, the specified value by *ChP* is provided for reference.

13. Discussion deals with the principal chemical constituents and the structures of the representative compounds. The choice of the chemical marker is highlighted. The factors that affect the quality of the crude drug, survey and authentication of the alternatives and adulterants, if available in the markets, were described and discussed as much as possible, and provided with the discriminating approach (s) by morphological, TLC and HPLC technology or by a combination of those methods.

14. Reference lists the literatures which are closely related to the content of each monograph dealing mainly with the chemical constituents and quality evaluation.

15. Index Four cross-referenced indexes to the scientific name of the original plant, the Chinese name, English name and Latin name of the crude drug are provided for reader's convenience.

关规定值。

13. 述评 概述各药材的主要活性成分,重点介绍质量控制指标成分选择的依据,并绘出代表性成分的结构式;对影响药材质量的因素、市场上发现的替代品、混淆品予以讨论,并尽量描述真伪鉴别的方法。

14. 参考文献 列出与专论内容密切相关的化学成分、质量评价相关主要参考文献。

15. 索引 附有植物学名索引、药材中文名索引、药材英文名索引和药材拉丁名索引。

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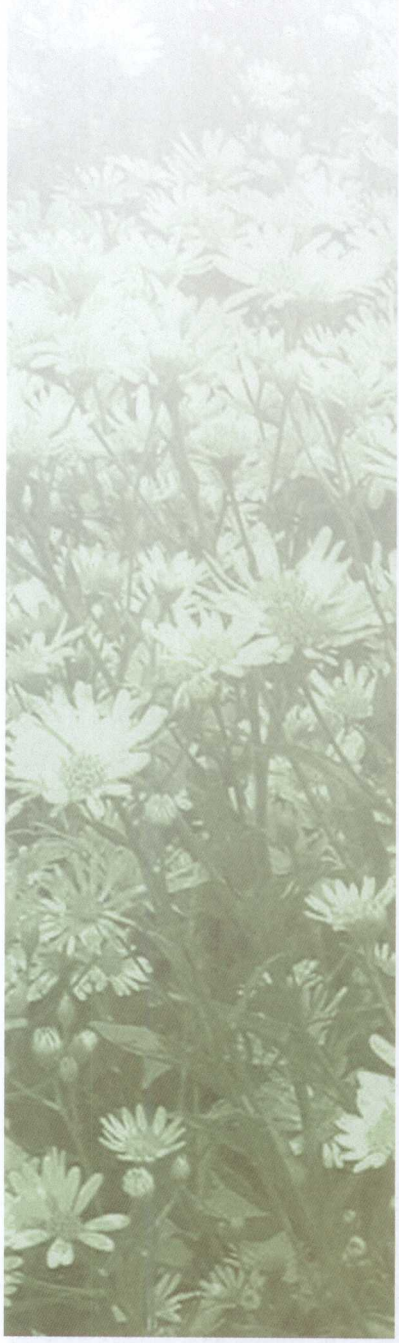

总 论
General

总论 General

Traditional Chinese Medicine (TCM) has been widely used for medication in China over thousands of years, and now become gradually accepted as a source of alternative or complementary medicine in western world. The sale of TCMs and other herbal products is increasing in the international medicines or health food markets.

TCM herbs are derived from medicinal plants, as well as animals and minerals. As a source of natural medicines, the ecological environments, the collecting and agricultural practices, even the drying, processing, storing, and shipping procedures may significantly affect their quality. TCMs are normally used in formulations which are composed of numerous herbs, and even a single herb may contain hundreds of chemical components, but only a small portion of them has been identified, but the bioactive mechanism is almost not yet clear, which made the truly meaningful quality control of TCMs is still harder achieved. On the other hand, some multi-originated herbs and the adulterants increase the confusion in herbs circulation and quality uncertainty. In a word, quality evaluation and standards development of TCMs are the key point to ensure the safety and effectiveness in clinical application. It is, therefore, arduous, and necessary.

Along with the increasing advancement in sciences and technologies, the methodologies for quality evaluation of TCMs have been developed correspondingly. Organoleptic inspection of crude drugs, by virtue of the physical appearance and texture, the odor and taste, initiated from ancient time, have been utilized and not been vanished until now, on the contrary, the accumulated intangible experiences for discrimination of true or false, or merit ranking of the TCMs still exert its irreplaceable role on quality control of TCMs. Following the development of modern physical and chemical applications, morphological identification is also deepened toward from macroscopic to microscopic observation to describe characteristic of the tissues and cells as well as the secondary metabolites (resin, essential oils and oxalic acid crystals), aided by histochemical reactions in the crude drugs unveiled the tiny differences between species. Microscopic identification has become an official identification method since *Chinese Parmacopoeia* (*ChP*, 1997 edition). In the era of chemical analysis technology underdeveloped, it played an important role in the identification of not only crude drugs, but also the formulated preparations. Even now it is still an indispensable technology, especially for the Chinese formulated preparations in which the chemical components are unclear, and whereby powder is directly used in the formulation.

中医药在中国已有数千年的应用历史，目前作为补充和替代医学，正逐渐被西方世界接受。中药及其他草药产品的销量在国际医药或健康食品市场上也呈递增趋势。

中药来源于药用植物、动物及矿物。作为天然来源的药物，生态环境、采收和种植条件，甚至干燥、储藏或运输过程都可能影响药材的质量。中药多以复方的形式应用，即便是单方，也含有上百种化学成分，但其中只有一小部分结构明确，且作用机制尚不清楚，因此，真正的有意义的质量控制仍然难以实现。此外，因形态相似或资源短缺，导致中药基原混乱，很多中药包含同属多种植物，并时有替代品、混伪品出现，增加了有效的质量控制的必要性。总之，中药的质量评价与科学标准的制订是确保临床用药安全、有效的关键，既有难度，又有必要。

中药质量控制的手段随着人们的认识和技术水平的提高而不断提高和改进。自古以来，外观形态及气味、颜色、质地等感官鉴别已经积累了丰富的经验，至今仍然起着不可或缺的作用。随着近代物理、化学的发展，形态鉴别逐渐向微观延伸，如采用显微分析技术观察组织器官乃至细胞内部结构的形态，再辅之以组织化学试验，则能够检测植物代谢产物，如树脂、挥发油、草酸钙晶体等，提高了鉴别的准确性和专属性。显微鉴别从《中华人民共和国药典》(下称《中国药典》)1977年版开始正式成为国家法定的中药鉴别方法，在理化分析尚不发达的时代，对多来源混乱药材品种的鉴别起到重要作用，特别是对于化学成分仍不明确、以粉末直接入药的成方制剂，至今仍是重要技术手段。

色谱技术最早应用于中药质量控制的是纸色谱，