

## 紫草类民族药材的品质评价研究专栏

## [编者按]

紫草为少数民族聚集地常用药材,同时也是常用大宗中药材,目前国内中药材市场上对其年需求量约为1 200吨,但新疆紫草的年产量尚不足100吨。紫草的功能为清热凉血、活血解毒、透疹消斑,可用于血热毒盛、斑疹紫黑、麻疹不透、疮疡、湿疹、水火烫伤。现有可查含紫草的中成药处方122条,中药方剂195条,说明紫草应用广泛且具有重要的药效价值。市场上常见的紫草除药典规定的内蒙紫草和新疆紫草2个品种外,在河北、辽宁和江西等地常用硬紫草,在云南等地常用滇紫草和露蕊滇紫草,在四川等地常用密花滇紫草,在广西和广东等地常用蔷薇科的委陵菜(俗称北紫草)。多地区习用药材与药典收载基原药材不一致,由于药典品种受资源限制,市场供不应求,同时又有进口资源(具体来源尚不明确)混淆于市场中,导致紫草应用的混乱。目前药典收载基原之一的新疆紫草已有人工栽培,但栽培新疆紫草与野生来源新疆紫草的一致性有待考察。因此,扩大紫草药材的资源,填补市场需求的空缺,是一项十分重要与迫切的任务。

2015年,中国食品药品检定研究院中药民族药检定所开展了紫草的全国抽检工作,结论为新疆紫草资源匮乏,内蒙紫草濒临枯竭,目前市场上不合格紫草饮片的占有率较高。故中药民族药检定所启动紫草类药材的专项研究,协助抚育新疆紫草,现已在新疆多地栽培成功并不断扩大栽培面积,以期解决紫草的资源匮乏问题。2022年,中药民族药检定所再次启动紫草的国家药品抽检工作,结果显示紫草饮片的合格率由2015年的43.9%提高到87.5%,合格率大幅度提升。

为深入开展紫草类民族药的质量标准研究,本刊特设“紫草类民族药材的品质评价研究专栏”,“基于2015年和2022年国家药品抽检探讨紫草的质量现状”全面分析了2次紫草抽检工作反映的问题,通过2次抽检工作的研究发现,完善紫草药典标准,建立科学的检验项目,加强质控体系的建设对紫草监管有重要意义;“基于DNA条形码和PCR-RFLP技术的进口紫草ITS2序列特征研究”为市场紫草药材和饮片的质量控制与真伪鉴别提供参考依据;“基于巢式PCR的紫草鉴别引物筛选”可用于高效扩增与鉴别紫草市场样品真伪的特异性引物,为后续紫草类民族药材的鉴定方法研究与开发提供可参考的依据;“基于‘辨色论质’的新疆紫草质量评价研究”对比了新疆紫草的色泽与6个主要紫色素成分含量的相关性,通过药材颜色对紫草的质量进行评价;“紫草市场药材正伪品对小鼠肠道菌群调节作用的比较研究”基于宏基因组测序的方法,比较了紫草市场药材正伪品对小鼠肠道菌群调节作用的异同;“新疆紫草野生品与栽培品的质量比较研究”通过性状对比和化学计量学,对比新疆紫草野生品与3个不同地区栽培品的差异性成分,从而对新疆紫草野生品与栽培品的质量进行比较研究,确立最佳的紫草栽培基地。

希望通过本研究专栏,提供紫草研究的新思路、新方法,在此基础上拓展紫草研究的深度和广度,从而促进紫草类民族药的创新发展。

[特邀栏目主编:郑健]

## Column on Quality Evaluation of *Arnebiae Radix*

### [ Editor's note ]

*Arnebiae Radix* is a common medicinal herb used in ethnic minority areas, and is also a commonly used bulk Chinese medicine. At present, the annual demand for the domestic Chinese herbal medicine market is about 1,200 tons, but the annual output of *Arnebiae Radix* is less than 100 tons. *Arnebiae Radix* functions as clear heat, cool the blood, activate blood, remove toxin, promote eruption and resolve macule, and can be used for exuberant blood heat – toxin, manifested as dark purple macule and papule, unerupted measles, sore and ulcer, eczema, scald and burn. There are 122 Chinese patent medicine prescriptions and 195 Chinese medicine formulas containing *Arnebiae Radix*, indicating that *Arnebiae Radix* is widely used and has important medicinal value. In addition to *Arnebia guttata* Bunge and *Arnebiae Radix* adopted by the *Pharmacopoeia of the People's Republic of China* (ChP), other species of *Arnebiae Radix* are common in the market. *Lithospermum erythrorhizon* is used in Hebei, Liaoning, and Jiangxi, among others. In Yunnan and other places, it is common to use *Onosma paniculatum* and *Onosma exsertum* Hemsl. In Sichuan and other places, it is common to use *Onosma confertum*. *Potentilla chinensis* Ser. (Commonly known as Northern *Arnebiae Radix*) of the *Rosaceae* family is commonly used in Guangxi and Guangdong. The insufficient supply of the species adopted by ChP and the inconsistent species used in local, and the imported species (the exact species are not yet clear) in the market lead to confused application of *Arnebiae Radix*. Currently, *Arnebiae Radix*, one of the species adopted by ChP, has been artificially cultivated. But the consistency between cultivated *Arnebiae Radix* and wild *Arnebiae Radix* needs to be examined. Therefore, it is a very important and urgent task to expand the resources of *Arnebiae Radix* to fill the gap of market demand.

In 2015, Institute for Control of Chinese Traditional Medicine and Ethnic Medicine, National Institutes for Food and Drug Control, carried out a national sampling of *Arnebiae Radix*. It was concluded that the resource of *Arnebiae Radix* were scarce, and that of *Arnebia guttata* Bunge was on the verge of depletion in Inner Mongolia. Besides, a considerable proportion of *Arnebiae Radix* prepared slices from the market were unqualified. Therefore, the Institute for Control of Chinese Traditional Medicine and Ethnic Medicine initiated special research on Boraginaceae herbs and assisted in the cultivation of *Arnebiae Radix*. Now the herb has been successfully cultivated in many parts of the country and continues to expand its cultivation area, intending to solve the problem of the scarcity of resources for *Arnebiae Radix*. In 2022, the Institute for Control of Chinese Traditional Medicine and Ethnic Medicine performed the national drug sampling of *Arnebiae Radix* again, and the results showed that the qualification rate of *Arnebiae Radix* prepared slices increased from 43.9% in 2015 to 87.5%, a substantial increase in qualification rate.

In order to carry out in – depth research on the quality standard of *Arnebiae Radix*, this journal specializes in “Column on Quality Evaluation of *Arnebiae Radix*”. “Discussion on the quality status of *Arnebiae Radix* based on the national drug sampling and testing in 2015 and 2022” comprehensively analyzed the problems reflected in the two sampling tests of *Arnebiae Radix*. The results indicated that it was of great significance to improve the standards of the ChP of *Arnebiae Radix*, to establish scientific test items and to strengthen the construction of the quality control system for the supervision of *Arnebiae Radix*. “The ITS2 sequences’ characters study of imported *Arnebiae Radix* based on DNA barcoding and PCR – RFLP technologies” provided reference basis for quality control and authenticity identification of marketed *Arnebiae Radix* and its prepared slices. “The screening of identification primers for *Arnebiae Ra-*

dix based on nested PCR” could be used to efficiently amplify and identify the specific primers for the authenticity of *Arnebiae Radix* market samples, which provided a referable basis for the subsequent research and development of the identification methods of *Arnebiae Radix*. “Study on quality control of *Arnebiae Radix* based on ‘color discrimination grading’ ” compared the correlation between the color of *Arnebiae Radix* and the contents of six major purple pigment components, and evaluated the quality of *Arnebiae Radix* by the color of herbs. “The comparative study on the regulation effect of authentic and counterfeit *Arnebiae Radix* on intestinal flora in mice” compared the similarities and differences in the regulatory effects of authentic and counterfeit products of *Arnebiae Radix* market herbs on the intestinal flora of mice, relying on the method of macrogenomic sequencing. “Comparative study on the quality of wild and cultivated *Arnebiae Radix*” conducted a comparative study of the quality of wild and cultivated *Arnebiae Radix* by using trait comparisons and chemometrics to compare the dissimilar components of wild and cultivated *Arnebiae Radix* with those of cultivated products from three different regions to establish the optimal *Arnebiae Radix* cultivation site.

Through this research column, the journal hopes to provide new ideas and methods for *Arnebiae Radix* research, on the basis of which the depth and breadth of *Arnebiae Radix* research can be expanded, thus promoting the innovative development of *Arnebiae Radix*.

[Invited Column Editor – in – chief: ZHENG Jian]