# APPLICATIONS OF "HONG KONG CHINESE MATERIA MEDICA STANDARDS"

**Chinese Medicine Regulatory Office, Department of Health of Hong Kong** 

Hong Kong Chinese Materia Medica Standards (HKCMMS) Section



### **HKCMMS**

### **Background:**

• Launched by Department of Health in 2001, aiming at establishing reference standards for commonly used Chinese Materia Medica (CMM) in Hong Kong

### Aims:

- Promote research of Chinese medicines
- Provide reference standards for CMM trade
- Ensure the safety and quality of CMM
- Promote modernisation and internationalization of Chinese medicines industry in Hong Kong
- Facilitate trade in Chinese medicines



## **Governance & Partnership**

### **Research Institutions (RI)**

- Collect sample and develop research methods
- Collect data and draft standard

### **Government Laboratory**

- Verify the methods provided by RI
- Provide technical support in method development



# Scientific Committee



Publication of HKCMMS
Reference
Standards
(Monographs)





# International Advisory Board

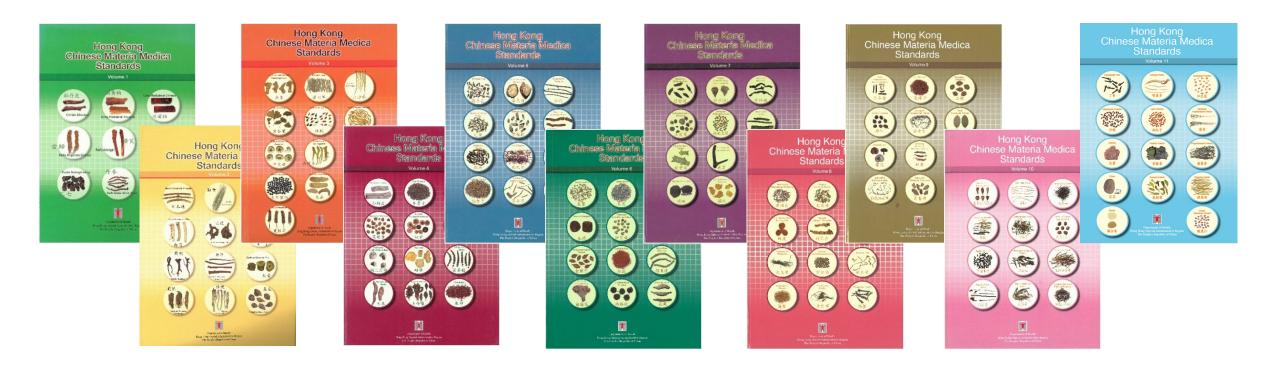
- Evaluate the methods and draft standards provided by RI
- Resolve technical issues and monitor progress

- **Endorse standards**
- Advise on the principles, methodologies, parameters and analytical methods



### **Progress of HKCMMS**

- 11 volumes of HKCMMS were published between 2005-2024
- Total number of CMM standards endorsed: 344





### **Highlights of HKCMMS Applications**

### **Key contributions:**

- 1. Provide the applicable and adoptable reference for CMM trade
- 2. Ensure the safety and quality of CMM in protection of public health
- 3. Facilitate the trade in Chinese medicines
- 4. Promote CM research and developments
- 5. Provide frameworks for references and research findings

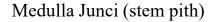


# (1) Provide Applicable and Adoptable Reference for CMM Trade

- Identification of CMM and rectification of medicinal parts used in Hong Kong
  - For instance, the monograph of Medulla Junci specified the correct medicinal part for this CMM

### Morphology of Medulla Junci and Herba Junci





- Correct medicinal part as shown in HKCMMS Volume 3



#### Herba Junci (whole plant)

- Commonly available in market before publication of HKCMMS Volume 3
- Used medicinal part deviated from the Chinese Medicine Ordinance (Cap. 549 Laws of Hong Kong)



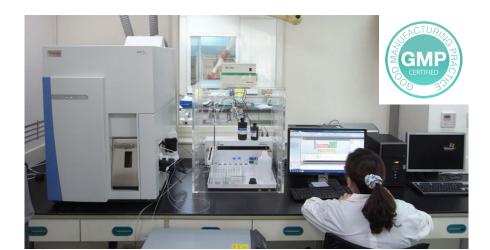
# (1) Provide Applicable and Adoptable Reference for CMM Trade

### • To assist:

- Manufacturers of proprietary Chinese medicines (pCm)
- ✓ Holders of Certificate for Manufacturer (GMP) of pCm
- Applicants of registration of pCm

for establishing raw materials and product specifications









# (1) Provide Applicable and Adoptable Reference for CMM Trade

• A number of Hong Kong manufacturers of proprietary Chinese medicines certified with Good Manufacturing Practice (GMP) and Hospital Authority (HA) have adopted references standards of HKCMMS in the procurement of CMM and establishing quality control standards







# (2) Ensure CMM Safety and Quality in Protection of Public Health

- Provide information for regulatory authorities to strengthen the control:
  - For example, heavy metal content exceed limits for a CMM may warrant drug regulatory authority to conduct related risk assessments and initiate product recall
- Provide updates on the trends and concerns of contaminants in CMM:
  - Conduct regular reviews on limits and developments in order to be consistent with the requirements of various Pharmacopoeias. e.g.
    - ➤ Limit of Cadmium reviewed to harmonize with the European Pharmacopoeia
    - Determination of Sulphur Dioxide residues with limit has been included with reference to latest regulatory control in the Mainland





### (3) Facilitate the Trade in Chinese Medicines

- Serve as standards for accreditation:
  - The Hong Kong Accreditation Service has already launched ISO/IEC 17025 accreditation service to laboratories performing tests according to HKCMMS
  - 4 local laboratories complied with criteria of Hong Kong Laboratory Accreditation Scheme to authenticate the CMM according to the HKCMMS

Accredited Test Items	No. of Accredited Laboratory*
Microscopic Identification	3
Chemical Analysis (including TLC, FP and AS)	2
Heavy Metals	2
Pesticide Residues	1
Aflatoxin	1
Tests (including ash, water content and extractives)	2

HOKLAS SC	40	
Issue No. 5		
Issue Date: 17	May 2023	
Implementation	n Date: 17 May	2023
Page 1 of 10		

#### **HOKLAS Supplementary Criteria No. 40**

'Chinese Medicine' Test Category – Identification of Chinese Materia Medica by Microscopic Examination in accordance with the Hong Kong Chinese Materia Medica (HKCMM) Standards

HOKLAS SC-44					
Issue	No. 5				
Issue	Date: 03 January 2024				
Impl	ementation Date: 03 January 2024				
Page	1 of 18				

### **HOKLAS Supplementary Criteria No. 44**

'Chinese Medicine' Test Category – Chemical and Physicochemical Testing to the Hong Kong Chinese Materia Medica (HKCMM) Standards



<sup>\*</sup>According to the information on the website of Hong Kong Accreditation Service (https://www.itc.gov.hk/en/quality/hkas/accreditation/our accreditation services.html) in Nov 2024

## (4) Promote CM Research & Developments

- Local universities and non-local research institutions participate in the HKCMMS Project
- Expansion of research capacity of research institutions in terms of manpower, analytical equipment and funding, etc







- Cited by overseas reputable authorities
- Serve as reference methods in authenticating the reference herbal materials
  - e.g. American Herbal Pharmacopoeia\* adopts HKCMMS to authenticate Botanical Reference Materials of Eucommiae Cortex, Isatidis Radix, Polygoni Multiflori Radix, Rehmanniae Radix



#### AMP-Verified<sup>TM</sup> Botanical Reference Material Macroscopic Certificate of Authenticity

Botanical Nomenclature	Isatis indigotica	OJCAN H
Standard Common Name	Isatis (ban lan gen)	1/97
Plant Part	Root	AHP
Material Code	Isa.ind.ro.CHHC.01	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Lot Nr.	2761	12
Quantity	5 gm	PALLONS
Reference(s) Used for Comparison	HKCMMA 2007; PPRC 2000; Wagner et al. 2009; Zhao 2004	MACCA
Result	Material conforms with reference data.	_
Certificate Nr.	645	Date: 01/04/2017
Provided For	TCM Healthcare, Unit 705 Sun Cheong Industrial Bldg.	, 1 Cheung Shun St.

Kowloon, Hong Kong



When whole, cylindrical, slightly twisted, 10-20 cm in length, 0.5-1 cm in diameter. External surface pale grayish-yellow or pale brownish-yellow, longitudinally wrinkled, with horizontal lenticels, and rootlets or rootlet scars. Root stock bulges slightly, showing dull green or dull brown remnants of petiole bases and scars arranged in whorls, and dense verruciform (wart-like) protuberances. In transverse section, bark yellowish-white, occupying around ½-¾ of radius, wood (xylem) yellow.

Organoleptic Characterization			
Taste	Sweetish, then bitter and astringent.		
Aroma	Slight.		
Texture	Compact, soft, slightly brittle.		
Fracture	Fairly even.		







Figure 1 Isatis indigotica obliquely sliced root, sample # Isa.ind.ro.CHHC.01.

Figure 2 Isatis indigotica obliquely sliced root close-up view, sample # Isa.ind.ro.CHHC.01.

Figure 3 Isatis indigotica root fracture, sample # Isa.ind.ro.CHHC.01

Compiled by Lynette Casper, B.S.
Title: Quality Assurance
Date: 01/19/17
Signature: Supply X. Casp.

Released by Roy Upton, RH
Title: AHP Executive Director
Date: //?//?

Website: www.herbal-ahp.org



## (5) Provide Frameworks for References and Research Findings • Total 24 ISO documents related to Traditional Chinese Medicine (TCM) cited HKCMMS as reference:

No.	<b>Document Description</b>						
1	ISO 18664:2015 - Determination of Heavy Metals in Herbal Medicines used in Traditional Chinese Medicine						
2	ISO 21314:2019 - Salvia miltiorrhiza Root and Rhizome						
3	ISO 21316:2019 - Isatis indigotica Root						
4	ISO 21317:2019 - Lonicera japonica Flower						
5	ISO 21370:2019 - Dendrobium officinale Stem						
6	ISO 22212:2019 - Gastrodia elata Tuber						
7	ISO 22584:2019 - Angelica sinensis Root						
8	ISO 22988:2019 - Astragalus mongholicus Root						
9	ISO 23191:2020 - Determination of selected Aconitum Alkaloids by High-Performance Liquid Chromatography (HPLC)						
10	ISO/TR 23975:2019 - Priority List of Single Herbal Medicines for Developing Standards						
11	ISO 19609-1:2021 - Quality and Safety of Raw Materials and Finished Products Made with Raw Materials - Part 1: General Requirements						
12	ISO 19609-1:2021 - Quality and Safety of Raw Materials and Finished Products Made with Raw Materials - Part 2 Identity Testing of Constituents of Herbal Origin						

No.	<b>Document Description</b>
13	ISO 23959:2021 - Glehnia littoralis root
14	ISO 22585:2022 - Codonopsis pilosula root
15	ISO 22586:2022 - Paeonia lactiflora root - White peony root
16	ISO 23965:2022 - Bupleurum chinense, Bupleurum scorzonerifolium and Bupleurum falcatum root
17	ISO 4564:2023 - Scutellaria baicalensis root
18	ISO 9306:2023 Traditional Chinese medicine — Ephedra sinica, Ephedra intermedia and Ephedra equisetina herbaceous stem
19	ISO 8071:2024 Traditional Chinese medicine — Ligusticum chuanxiong rhizome
20	ISO 9109:2024 Traditional Chinese medicine — Rehmannia glutinosa root
21	ISO/TR 18986:2024 Traditional Chinese medicine — Report on the global industry and standardization development of Panax ginseng
22	ISO 8959:2024 Traditional Chinese medicine — Eucommia ulmoides stem bark
23	ISO 9299:2024 Traditional Chinese medicine — Curcuma longa rhizome
24	ISO 13615:2024 Traditional Chinese medicine — Atractylodes macrocephala rhizome



- Maximum permitted limits of heavy metals stated in HKCMMS were cited to provide one of reference standards in TCM in BS ISO 18664:2015
- BS ISO 18664 was published in 2015 in response to the worldwide demand for:
  - ✓ Harmonization of the determination of heavy metals in herbal medicines used in TCM
  - ✓ Providing the maximum limits of heavy metals in natural materials of TCM in various references



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...making exce**l**lence a habit."

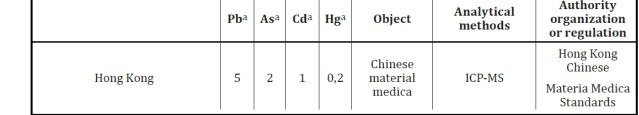
#### Annex A (informative)

Reference of national, regional and organizational limits of heavy metals in natural TCM materials and calculated limits using Target Hazard Quotients based on USEPA and WHO

Different countries, regions and organizations give their own limits of heavy metals in natural materials of TOM. Table A.1 shows these limits in avainus types of herbal products. Also, some healthly authorities provide risk assessment methods (USEPA) and recommend heavy metals intake per week (WHO). According to these information and TOM's characteristics, the calculated limits using Target Hazard Quotients are also listed with the summarized maximum and minimum limits from previous references in Table A.1.

Table A.1 — The national, regional and organizational limits of heavy metals in natural TCM

	Pba	Asa	Cd=	Hga	Object	Analytical methods	Authority organization or regulation
Australia	5,0	-	-1	0,1	Unprocessed herbal material	AAS, ICP-AES or ICP-MS	Therapeutic Goods Administration
China	5	2	0,3	0,2	Crude herbal drugs	AAS and ICP-MS	Chinese Pharmacopoeia
Hong Kong	5	2	1	0,2	Chinese material medica	ICP-MS	Hong Kong Chinese Materia Medica Standards
Macao	20	5	-	0,5	Crude herbal drugs and Chinese patent medicines for external use	AAS and ICP-MS (The same as in Chinese Pharma- copoeia)	Written instructions No. 10/SS/2013
Germany	5	_	0,2	0,1	Herbal medicines	-	Draft recommendation for limits of heavy metals in medicinal products of plant and animal origin 1991
Irdia	10	3	0,3	1	Herbs	AAS	Pharmacopoeia of India
Japan	20	5	_	_	Crude herbal drugs	Colourimetric method	Japanese Pharmacopoeia 16th edition





- TCM herbal drug monographs in the European Pharmacopoeia (EP) must be prepared according to<sup>1</sup>:
  - ✓ The Style Guide of EP
  - ✓ Technical guide for elaboration of Monographs
  - ✓ Chinese Pharmacopoeia as basis
  - ✓ Take into consideration the information from WHO monographs on selected medicinal plants and HKCMMS as well





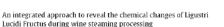


<sup>1</sup>Mei Wang and Gerhard Franz. The Role of the European Pharmacopoeia in Quality Control of Traditional Chinese Herbal Medicine in European Member States. *World Journal of Traditional Chinese Medicines* 2015 1(1):5-15

- As references for scientific research of Chinese medicines
- Out of 344 CMM monographs published in HKCMMS, around 157 of them have been cited as references in more than 390 international journal articles

Contents lists available at ScienceDirect

Journal of Pharmaceutical and Biomedical Analysis



Zhanpeng Shang, Lulu Xu, Yaqun Zhang, Min Ye\*, Xue Qiao\*

State New Laborations of Flattered and Biominusis Drugs, School of Pharmaconical Sciences Points University 34 National Board, Beijing 100/91, Orbin

Keywords: Chemical changes

Ligastri Lucidi Fructus (IJF) is a traditional Chinese medicine to recat estecpathic and hepatic disc Wine steaming is the major processing method for LLF in Chinese Phaemacopoeta, but the chen changes involved are still uncloss. In this study, a research strategy was proposed to reveal the chen changes during wine sesuning processing of ILP. Postly, in rotal 104 compounds were tentatively is ified using UHPLC Orbitrap-MS. Secondly, notential chemical changes were revealed by coneak areas of the 104 compounds between LEF and the corresponding wine-scenned LLF SMLE results indicated that indoid and phenylethanoid esters were readily hydrolyzed during wine stea incressing, while organic acids, flavoroids, and interpenes were stable. Finally, 7 selected comp purcessing, while sugance artist, floorende, and retraptive source adults. Furthly, 3 elected compa-wer annualmental electronal results of LLT WILL STATES and TO MULTI, White and USE of the Company of

Ligustri Lucidi Fructus (LUF), known as Nyzhenzi in China. is derived from the dried ripe fruits of timetrany facilities. Ail. Oleaceae). It has been used as a traditional Chinese medicine (YCM) or more than 2000 years [1], which possessed various bloactivities, [5], and anti-oxidant [6]. LLF is also widely used in TCM formu las such as Erzhi tablet [7]. Ankun tablet [8], and Zhengi Fuzheng formula [9]. The chemical constituents of LLF include indolds, plenylethanoids, and flavonoids [10]. Spectrum/heride is the most abundant iridoid in EIF, and its content could reach 3.0% [11].

in the clinical practice of TCM, crude herbs are usually p hefore use. The processing step is believed to modulate the thera-peutic properties of TCMs, such as enhancing the efficacy, reducing the toxicity, altering the nature, flavor and channel tropism, an modifying the taste [12]. The processing of LLF is to steam with yellow rice wine as recorded in Chinese Pharmacopoeta (Fig. 1A) [10]. Chemical constituents of LLF and wine steamed LLF (WLLF) had been excensively studied. For example, II et al. identified 50

https://doi.org/10.1016/j.jpha.2000.113667 0731-706530 2020 Elsevier B.Y. All rights reserved

compounds in WLF by using tiquid chromatography coupled s mass spectrometry (IC/MS) [1.5]. Yang et al. reported the decres peak areas for ligastroflavone, specneuzhenide, oleuropein. ofermanizemide after processing using high performance is chromatography [14]. However, the chemical changes involve the wine steaming processing of LEF are still not well understo chemical changes of LUF during wine steaming processing. At

ultra-high performance liquid chromatography coupled with C trap mass spectrometry (UHPLC/Orbitrap-MS) was used to ide 104 compounds in LLE Secondly, semi-quantitative analysis performed to reveal the potential chemical differences between and lab made WLLF. Finally, the contents of 7 major compo-were determined in commercial LLF and WLLF using a 10-UPLC/UV method, and the chemical changes were confirmed.

2.1. Chemicals and reasents

The reference standards, including quinic acid (1), logania e-mail: nishihara-masaka.zu@office.pref.nara.lg.jg (3), hydroxytyrosol (6), salidroside (8), tyrosol (15), vicenin echinacoside (36), rutin (51), luteoloside (63), acetoside (66).

生薬「ボウフウ」の品質評価(野生品と栽培品の相違点) 西原正和, \* 按井啓二、大佳優子、塩田彩線

> Quality Evaluation of Saposhnikoviae Radix (Differences between Wild-type and Cultivated Products)

YAKU GAKU ZASSHI 138, 571-579 (2018)

Masakazu Nishihara," Keiji Nukui, Yuko Osumi, and Hironori Shiota Nara Prefectural Pharmaceutical Research Center: 665-19, Gase, Nova 639-2226, Japan

Received October 5, 2017; Accepted November 28, 3017; Advance publication released online January 30, 201

Soposhnikovine Rudix ("Boulu") is an important crude drug used in Kampo formulation. It is extracted to wild-type plants. However, recently, extraction has become difficult because of a decrease in wild-type plants. There entitivated plants account for the majority of the market, from which the crade drug is extracted. However, the cult tion techniques used are not sufficient to obtain the desirable extracts. In this study, we commuted the contents of the truct and the quantitative values of characteristic constituence obtained from wild-true and cultivated where, and for

Key words — Saposhnikoviae Radiv; Saposlutikovia Root and Rhizome; cimifugin; prim-O-glucosyl cimifugin; 4

#117 77 1712 Sanoshnikovia divarionta Schuschkin の相及び相等を基項とした生姜で、発汗、解熱、鎖 確を目標とし、防風消空数や約務節などに広い進力 処方の構成生素とされている そのため おが国で の小林健用品上位 60 毎日に上がっており、平成 26 年度では、146474 kg の使用量で、順位は36位と たっている.D

一方 ボウフウの変化は 中国北部が中心とき れ、上記の使用量のうち、国産はおずか 46 kg と少 なく、その大部分が中国からの輸入に摂っているの が現状であるり

これまで、内蒙古白治医等の野生品が主に深通し ていたが、乱獲等により減少したため、中国が「好 生薬材資源保護管理条例」により保護を行う方針を

このことにより、野生品の価格は高盛し、手に入 れることが困難になっている。これに代わり、最近

奈良県共事研究センター

では河北省等の技熔晶が流運しているところ が、ボウフウの萎燥技能は主分に確立しては 言えず、品質がこれまで流通していた膨生品 であるのかは、非常に重要な問題である。

品質規格として、ボウフウは日本窓局方に れているが、成分量の評価指標としては、 フールエキスによるエキス含量での規定があ の、特定の成分による定量規格は改定され い。こそのため、野生品と栽培品の同等性を る上での規格としては不十分と考えられた。 、指標成分による定量を行うことを円標と 外の公定書規格等を調べたところ、中華人民

菜具及び香港中葉材標準において、2成分 O-グルコシルシミフギン、4-O-グルコシル-チルビサミノール) の総和が 0.24%以上と 定量規格が設定されていた。3.6 Prim-O-グル ことが動物実験により報告されていることも O-グルコシル-S-O-メチルピサミノールは 局力において、ボウフラの確認試験の標準品 使用されているなど、いずれも重要な成分で

C: 2018 The Pharmacratical Society of

대한한방부인과학회지 pISSN 1229-4292 / eISSN 2508-36 J Korean Obstet Gynerol, VOL 33, NO 2 : 001-012 (202 https://doi.org/10.15204/jkobgy.2020.33.2.0

#### 전탕 시간에 따른 매엽의 성분패턴 비교연구

'경희대학교 대학원 임상한의학과, '추원당한의원 <sup>3</sup>겸희대학교 한의과대학 한방부인과교실 유준걸!, 김민선?, 한성민?, 활덩상?, 이지무?, 이상훈?, 장준복

#### ABSTRACT

The Comparative Study on Compositional Pattern Analysis of Decoction of Extracted Artemisia argyi by Different Extraction Time

Jun-Geol Yoon', Mean-Sun Kim², Seong-Min Han², Deok-Sang Hwang³, Jin-Moo Lee³, Chang-Hoon Lee³, Jun-Bock Jang³ 'Dept. of Clinical Korean Medicine, Graduate School, Kyung Hee University Choonwondang Korean Medical Clinic <sup>3</sup>Dept. of Korean Medicine Gynecology, College of Korean Medicine, Kyung Hee University

Objectives: This study was conducted to find out the optimal extraction time or Artemisia argyi.

Methods: The compositional pattern was compared with HPLC (High Performance Liquid Chromatography) and GC (Gas-Chromatography) by decocting Artemisia argyi 10, 60, 120 minutes respectively.

Results: With longer extraction time, the contents of reference compounds were extracted 1.1 times more when 3.4-dicaffeoylquinic acid was extracted for 60 minutes than when extracted for 10 minutes in HPLC test, but the contents were reduced when extracted for 120 minutes compared to 60 minutes extraction time. 3.4-di-O-caffeoylquiniacid, 3,5-di-O-caffeoylquinic acid, 4,5-di-O-caffeoylquinic acid, jaccosidin, and eupatilii showed the largest yield rate when extracted for 10 minutes, and it decreased as timacid, iscensidin, scoparone, and expatilin were detected only in 10 minutes extraction but not in 60 or 120 minutes extraction according to GC test.

Conclusions: The results show that extraction time could affect the physicochemica haracteristic or composition of Artemisia argy extracted. Thus, short extraction time could be useful for decoction of Artemisia argvi.

Key Words: Artemisia Argyi Extraction Time, High Performance Liquid Chromatography

Corresponding author(Jun-Book Jang): Kyung Hee University Korean Medicine Hospital, 23. Kyungheedae-ro, Dongdaemun-gu, Seoul, Republic of Korea 

中国药品标准Drug Standards of China 2018, 19(4)

#### 香港中药材标准研究与历程回顾

王宝栞,鲁静,,马双成,,罗国伟,,卫瑞贤, (1 中国食品药品均定研查院、北京 100050) 2. 香港特別行政区政府卫生署、香港)

摘要:本文回顾了香港中药材标准研究建立的背景和研究工作的机构与相关程序,分析了标准的特色,并对 已收载品种的含量测定成分进行了归纳总结

关键词:香港中药材标准; 研究背景; 特色; 含量测定成分 中国分类号:R 921.2 文献标识码:A 文章编号:1009-3656(2018)-4-0252-09

Research of Hong Kong Chinese Materia Medica Standards and

#### Review of Research Process

WANG Baoqin1, LU Jing19, MA Shuangcheng1, LUO Guowei1, WEI Ruixian (1. National Institute of Food and Drug Control, Beijing 100050, China; 2. Department of Health, the Covernment of the Hong Kong Special Administrative Region of the People's Republic of China)

Abstract: This article review the research background, process and system of Hong Kong Chinese Materia Medica Standards, analysis the distinguishing feature of the Standards, and summary the assay constituents in the collected

Key words: Hong Kong Chinese Materia Medius Standards; research background; feature; assay constituents

《香港中药材标准》由香港特区政府卫生署组织 制订、是对在香港地区使用的中药材质量及检验方法 500 种中药材、为此、特区卫生署设立专项、就常用中 所做的技术规定 , 1999 年 7 月 《香港中医药条 例》(香港法例第549章)开始实施:同年9月,中医 药管理委员会官告成立,负责拟订及推行有关中药使 用、贸易及生产的规管措施,香港居民有使用中草药 的传统与历史, 日使用日趋普遍, 香港特区政府非常 **重视中草药的品质及使用安全**。为了保障公众健康。 需要为一些常用中药材订立规管标准。

鉴于中药使用的世界趋势,如重金属和农药残 留限度的有关标准与国际间的规定要求一致是很重 要的。制定一部完善且国际认可的标准。以与国际 接轨,更显示我国传统中药材的科学技术水平。

药材研究制定标准、选取研究品种的原则是以香港 地区常用、且效高经济劳益、并列干(吞类中医药类 例》(第549章)附表2的为优先。而一些在安全和品 原方面各受国际关注的药材, 也被洗作研究对象。为 此,卫生署在中医药事务部下设立香港中药材标准 (以下简称"洗标") か事处, 专责管理和统筹香港中 药材标准研究计划

《香港中医药条例》(第549章)所列载的超过了

在统筹开展香港中药材标准研究计划时起,中 国食品药品检定研究院(原中国药品生物制品检定

第一作者简介: + 宝莱, 1 任药师: 研究方向: 中药分析, Tel: 1561 1431 643 18-mail: wba3966@ 163. com 通訊作者值介: 會算, 主任药师: 研究方向: 中药分析。Tol:0(0 - 67079933; E-mail: laring@ nifec. orz. on. World Latest Medione Information (Electronic Version) 2017 Vol.17 No.79

#### "香港中药材标准"与《中华人民共和国药典》 在新药筛选中的对比与前景

使用中医疗大学、使用 成图 710046

横一要。中游对是会球或对体发中不可忽似的现实,但是在实际友际对他可能产业许多严重的问题。你见的中游对问题 我这个方料的克格。高州的政策。 电电极的现在,我可以宣称。这些问题会直接收获中方在而外边与内部行为个通汉及 原对后来也是任务的。因此,有种的水色和水化制于全国联系的工作水源是中国有效企业的有效。不是对比"有限" 有《中国人民共和国内景)的内部的对象的概念的变效。 "你也可能是这些人工作可以是这样对关系并有什么会会是。"但是是不

来两种规范的发展简繁。 美健词:基汤:《中华人无达仁斯拉供》,新打笔压 中国分类号: 3.241 文献标识码: B DOI: 10.19613/f-cmbi.1671-3141.3017.79.136

本文引用格式:学验、"各基中药材格准"与《中华人民共和国药典》有著药的选中的对比与发展[月]也尽说新数学能范夫

《中华人民共和国药典》与"香港中药材标准"的意义 不的定用,获得中药材在外别。研制、开发、使用上更有解除 提起中国内地的中药材尔亚化、就不停不要《中华人居共 相对比《中国彩电》、"多类中药排标准"在科技化上中 的国務集),沒今为1.,国的海中药材除绝类有三个。它们分 加先进。以显微镜影测这一项为例。"黄海"中所有药材深渊 · 為見《中华人民共和国的典》,首称《中国的典》,国务院区 一有彩色图片,正《中国的典》是正均改有:薄层色编纂则中。 约卫生行政部门建发的约益标准;有、自治区、直领市部发的。 与附有多类原片以及化学对照品,《中国药典》中 60年的中 药物标准。前二者的国家商品定律,并者都进方项品标准。国 一点材质设有照片的,因为线线材料效用语的温则也对用字:"例 安禄准是一个主体性、主学性和普遍性的标准。加方标准是一一维中药材含有"中、这项技术设有体现在《中国务典》中 P区域排、污染性科学充体的宗帝,《中国资典》在字函意义 外,"否德中运动标准"对于一种中或材资讯,比如重金属。 型度量疑。当主、医疗小专用药物规律性、单类药物名称的第一取药或胃、杂质、水分、灰分的含量等等。但《中国药典》中 乱而造成的许多不必要的问题上就可以看出。如:"五年参" 从而对于环州还制, 开发, 使用产生不可造免的影响。

用口北美、天下方加了美工出方部"亦名数户的港湾。"朱字 与"人名"在名称上的记储、造成过远疗事故和毒融反应。第一3 结论 在新药组制与开发中,某到创革促在丰振资料处方中写"零 一"、显然不够看前。寄生还分为"桑杏生"和"老杏生" 由于处方未将药材明确执定,以设试验中桑奇生与相寄生。 疾方面的发展速度是其代于较1时(初升)的主要以出。故长补惩 多次交替实用,效仿许多工作领劳而无益。

"高粱中药以及治"是由中位人民共和国委员会和行政区 卫生署于 2008年现有,旨在农副与衡量中养材标准化作用的从一学的建设与投资。培育更多优秀的中国药人才,内能中国药场 8、至今已公布 5 册。共包含证 140 种中等别的鉴别。香港县一 个国际经济交流的青年地区、为了中经时间以上广泛的推问国际。 定阻难。其次、学校应该在对于医学生学习目标和职业规划中 司要切布一套结合本程具体指页与国际化的标准<sup>和</sup>。"选择"的 左右, 更加发升了中心排标准化前进的基度与国际认真的影像。 《中华人民共和国药典》与"香港中药材标准"在 新药筛选中的对比

在都会研制与严嵩中,必是温利的结果直接关系到实品的一角身优秀人才,对于福迪发展中医药标准化有着重要意义。 质量与安全性。随着科技的变成,舒整药具(2010 使)核之间度 运用了更多技术支引行茶物发料。首张、杨彬热重论矿物器外科。 建立了薄层系别方法,皆履薄层色谱影别 2049 以,4 这种名别 一知色学拉药剂的品质,保证药品的安全性,在临床就用中产生 方法可以近行药物系反应造成含量的焦定,确保了药品品使约可。 最大严谨的行案,治疗更多的证者。因此,如何不断提弃收回 控性; 再如, 应用 DKa 分子在时中或同品种内, 不是外界环境, 药典的现代化,是一个世界注意的问题。也可以看出,我国务 国式有生物体分音阶段及器直针头系是不影响特征,作为价格等。 对的标准化有着十分广阔的发展前途。 记其行移情品、动物药材、破库药材、除用药材、除仁药材的基 参考文章 動も銀有效。5 歳方法的采用他可以有力地遇犯用状定场及监督 [1] 李老字の日子はフ1.キモ: キモキ川行か ステにミエシエチ 步年的保证债务品的问题。5 無抵弃典里、再次明确了中共饮户 定义, 位为亿层产电大幅增加, 2005年服约其收载的实片层 杨卢华列,基本演员了中国临床拿用次片品种型。这些科学新技

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等。2015年9月20日 2015 [7] 《魏元·中西南新昌展台西南 [7] 三建 : 直線科學技术应提

推復为19個。而劉敬與其第片課權決至 822年。其中 23 年飲井 【3】 考えた。夏孝、馬食、羊、芝をあれ中に示なた[1]。と近中のもた

中华州的区布化对于新药的研制开发、中药材产位世界系

有在重要的意义。因此,还过"奇德中的材深推"与《中国领力》

的时比,取长补法,不难看出。"香香中药材标准"在科技员

《中国药典》也是该能化更新得效方向的内容。滋魂这种现象

第原因我认为有以下几点。首先、国内应该提高对于中医药;

校的变势安徽量和尔力朱之不差。他给我就过且的进行走来

有更高层次的情节,大部分医学生学业之后走回临床,真正步 大学术研究人所占比例法少。也可以分析为特物研究中具有医

病专业评定知识的人才断层<sup>18</sup>。专法国为追继位置相往会职遇。 更容易吸引因的并更未平人才。也是因为这点,如何结合内也

无论是"香罐中药材保证",还是《中国药典》、静在中

長曜前,李守重,李是去,祖全女的姓名及它都为研究中的应用[1] 集化、表介、音道"测量证》"及使少角或或编绘 [7] 长在在的 表 2011 1289:178(1)

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- As a precedent to show microscopic identification features of CMM with high resolution images
- HKCMMS is the first reference standard compendium to illustrate microscopic features of CMM with drawings and photographs
- Set an example to other pharmacopoeias / compendia

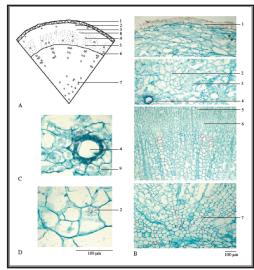
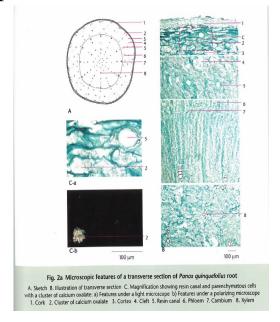


Figure 2 Microscopic features of transverse section of Radix Panacis Quinquefolii
A. Sketch B. Section illustration C. Resin canal D. Cluster of calcium oxalate

Cork 2. Cluster of calcium oxalate 3. Cortex 4. Resin canal
 Phloem 6. Cambium 7. Xylem 8. Cleft 9. Starch granules

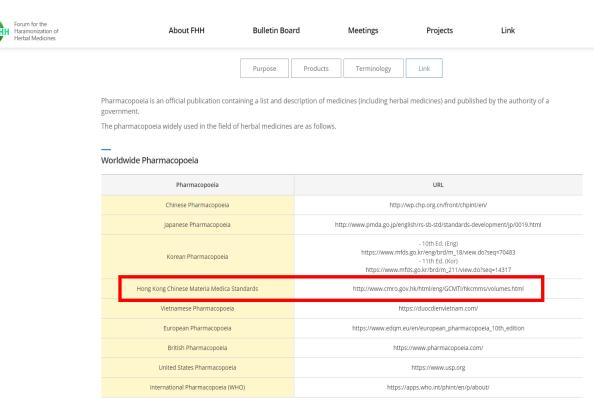
Radix Panacis Quinquefolii monograph in HKCMMS Volume 3 published in 2010



Radix Panacis Quinquefolii monograph in USP's Dietary Supplements Compendium\* published in 2015



- The Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH) is a technical forum with aims to provide technical documents and consensus on technical issues related to the quality, safety and efficacy of herbal medicines
- HKCMMS is cited as one of the pharmacopoeial references in FHH webpage





# THANK YOU

