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

香港中藥材標準
Hong Kong
Chinese Materia Medica
Standards

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

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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

Publication of HKCMMS Reference Standards (Monographs)

Scientific Committee

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

International Advisory Board

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

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Hong Kong Chinese Materia Medica Standards

Progress of HKCMMS

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

Lists of Chinese Materia Medica in HKCMMS https://www.cmro.gov.hk/html/eng/useful_information/hkcmms/cmmlist.html

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

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(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

Medulla Junci (stem pith)

- 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)

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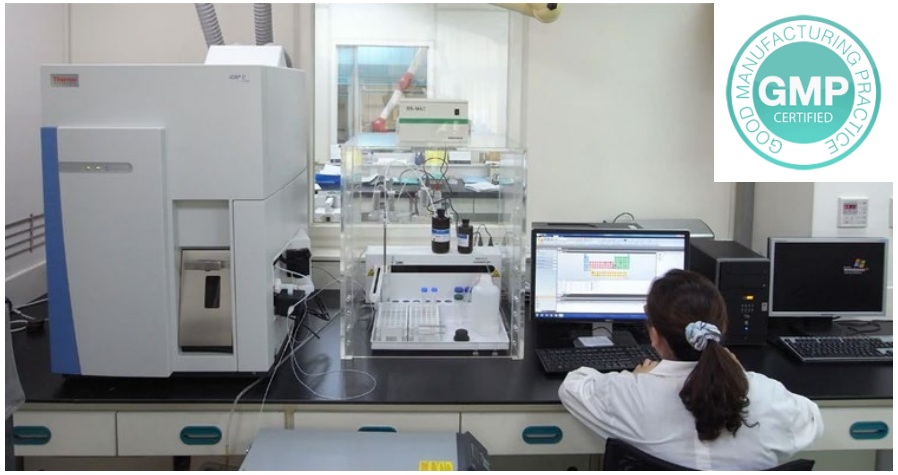
(1) Provide Applicable and Adoptable Reference for CMM Trade

- 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



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(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

醫院管理局
HOSPITAL AUTHORITY

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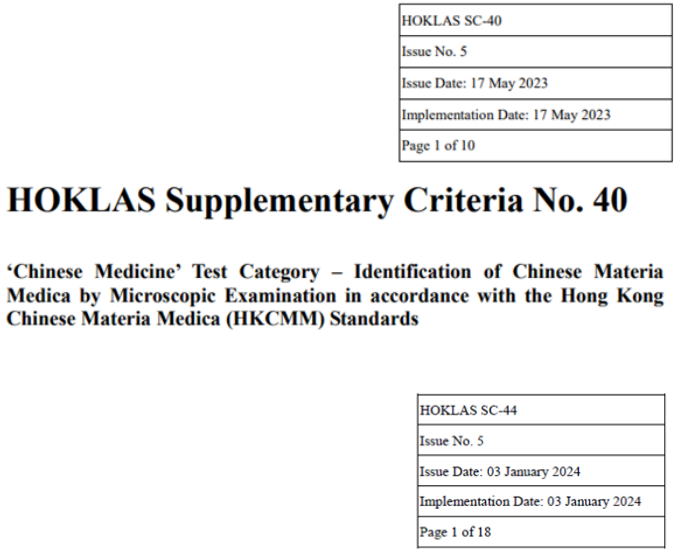
(2) Ensure CMM Safety and Quality in Protection of Public Health

- 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 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
Implementation 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

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Hong Kong Chinese Materia Medica Standards

*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

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(5) Provide Frameworks for References and Research Findings

- 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

American Herbal Pharmacopoeia®

AHP-Verified™ Botanical Reference Material
Macroscopic Certificate of Authenticity

Botanical Nomenclature	*Isatis indigotica*
Standard Common Name	Isatis (ban lan gen)
Plant Part	Root
Material Code	Isa.ind.ro.CHHC.01
Lot Nr.	2761
Quantity	5 gm
Reference(s) Used for Comparison	HKCMMA 2007; PPRC 2000; Wagner et al. 2009; Zhao 2004
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

AHP Verified

Macroscopic Characterization

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: Lynette R. Casper

Released by Roy Upton, RH
Title: AHP Executive Director
Date: 1/19/17
Signature:

Website: www.herbal-ahp.org

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*Website of American Herbal Pharmacopoeia: https://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.	Document Description
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.	Document Description
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

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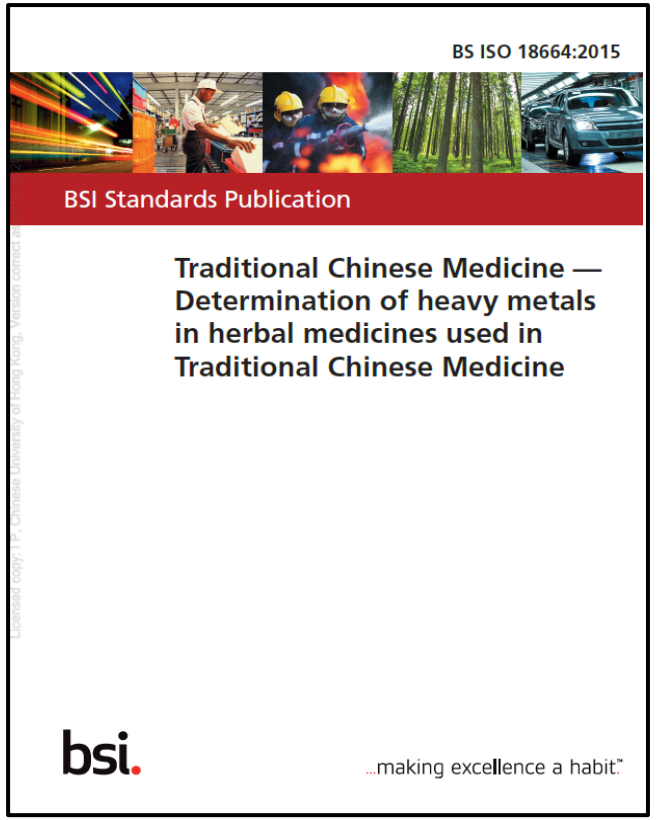
*Website of ISO: https://www.iso.org/home.html (as at 15 Nov 2024)

(5) Provide Frameworks for References and Research Findings

- 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:

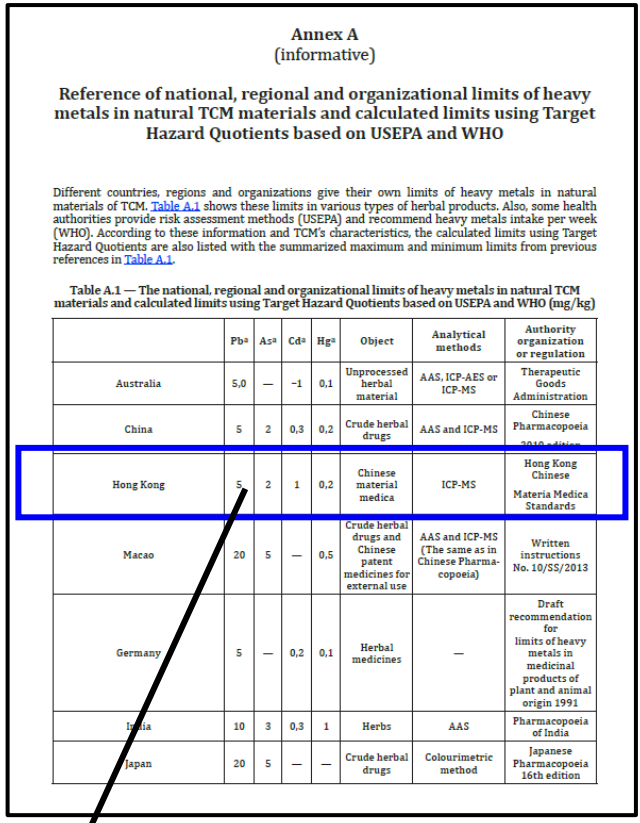
  ✓ Harmonization of the determination of heavy metals in herbal medicines used in TCM
  ✓ Providing the maximum limits of heavy metals in natural materials of TCM in various references


BS ISO 18664:2015

BSI Standards Publication

Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine

bsi. ...making excellence 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 TCM. Table A.1 shows these limits in various types of herbal products. Also, some health authorities provide risk assessment methods (USEPA) and recommend heavy metals intake per week (WHO). According to these information and TCM'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 materials and calculated limits using Target Hazard Quotients based on USEPA and WHO (mg/kg)

	Pb[a]	As[a]	Cd[a]	Hg[a]	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 Pharmacopoeia)	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
India	10	3	0,3	1	Herbs	AAS	Pharmacopoeia of India
Japan	20	5	—	—	Crude herbal drugs	Colourimetric method	Japanese Pharmacopoeia 16th edition

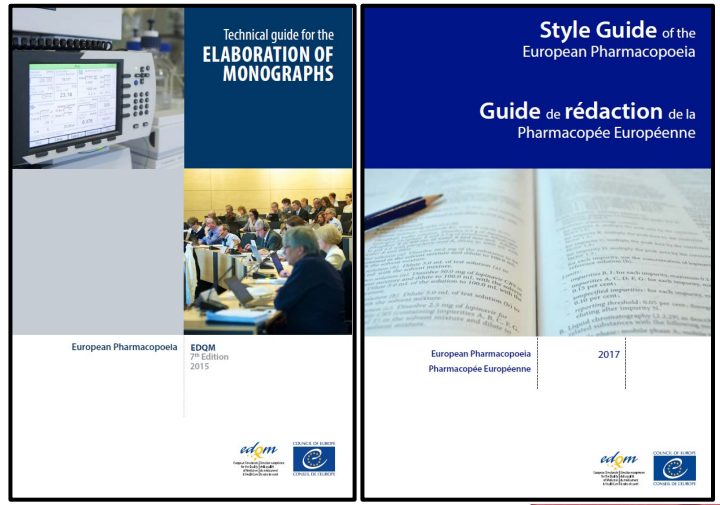
	Pb[a]	As[a]	Cd[a]	Hg[a]	Object	Analytical methods	Authority organization or regulation
Hong Kong	5	2	1	0,2	Chinese material medica	ICP-MS	Hong Kong Chinese Materia Medica Standards

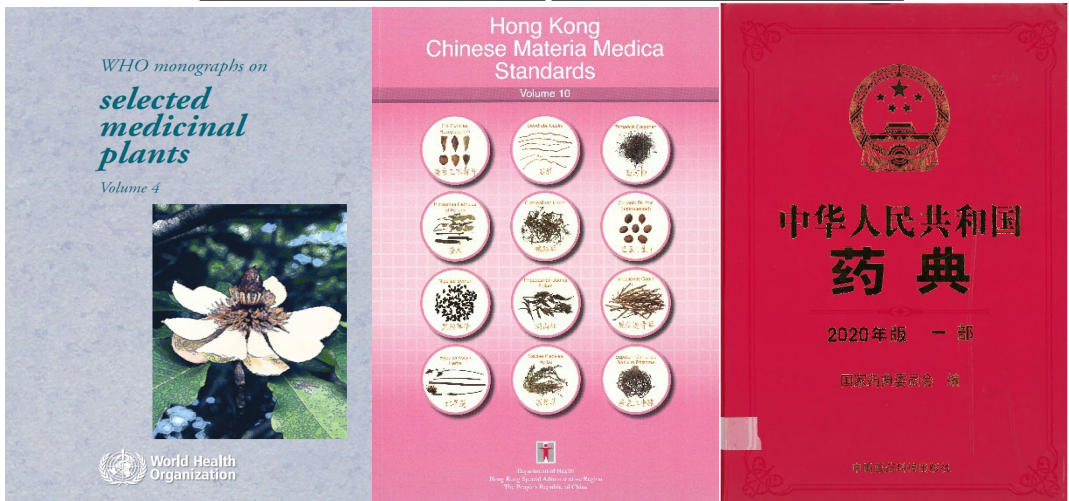
香港中藥材標準
Hong Kong Chinese Materia Medica Standards

(5) Provide Frameworks for References and Research Findings

- TCM herbal drug monographs in the European Pharmacopoeia (EP) must be prepared according to[1]:

  ✓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





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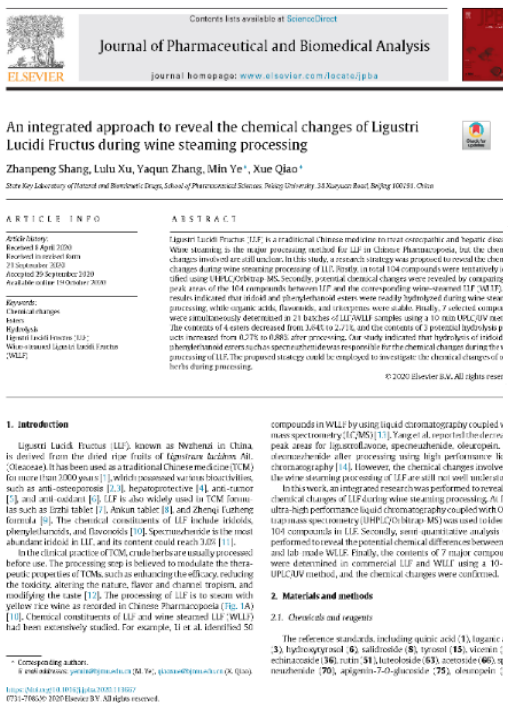
[1]Mei Wang and Gerhard Franz. The Role of the European Pharmacopoeia in Quality Control of Traditional Chinese Herbal Medicine in European Member States. *World Journal of Traditional Chinese Medicines* 2015 1(1):5-15

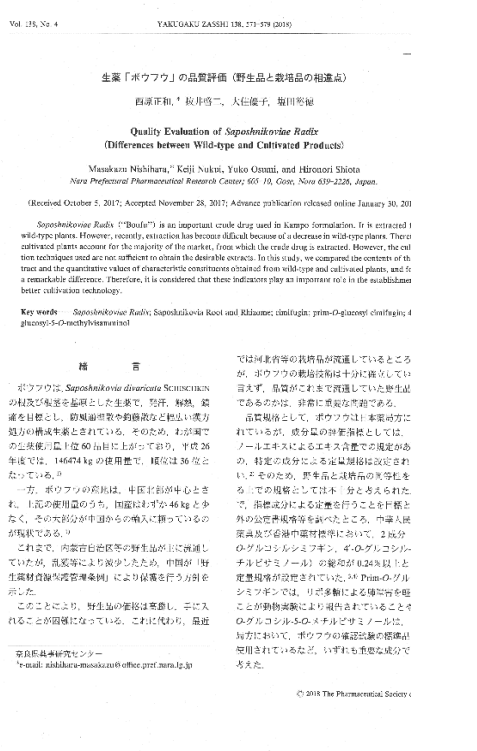
(5) Provide Frameworks for References and Research Findings

- 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

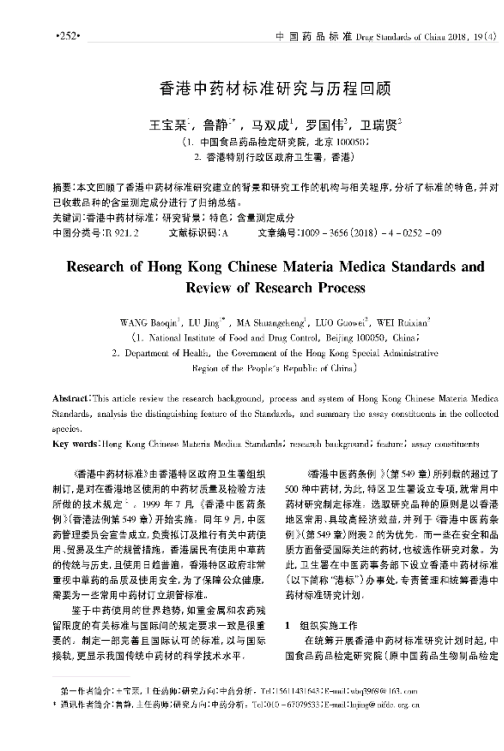

Journal of Pharmaceutical and Biomedical Analysis

An integrated approach to reveal the chemical changes of Ligustri Lucidi Fructus during wine steaming processing

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


生薬「ボウフウ」の品質評価（野生品と栽培品の相違点）

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


ABSTRACT

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

香港中药材标准研究与历程回顾

Research of Hong Kong Chinese Materia Medica Standards and Review of Research Process


“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

(5) Provide Frameworks for References and Research Findings

- 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

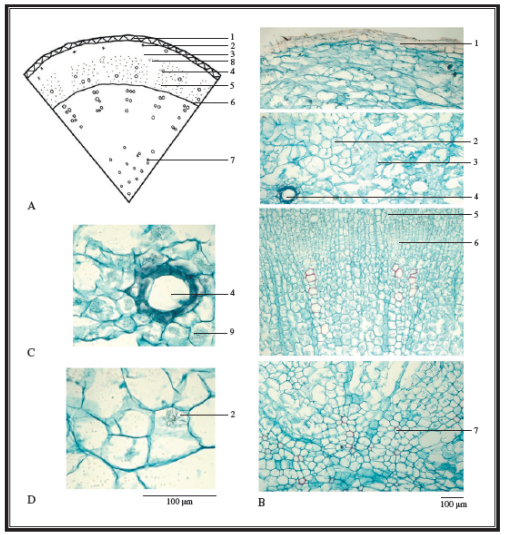


Figure 2 Microscopic features of transverse section of Radix Panacis Quinquefolii

A. Sketch B. Section illustration C. Resin canal D. Cluster of calcium oxalate

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

Radix Panacis Quinquefolii monograph in HKCMMS Volume 3 published in 2010

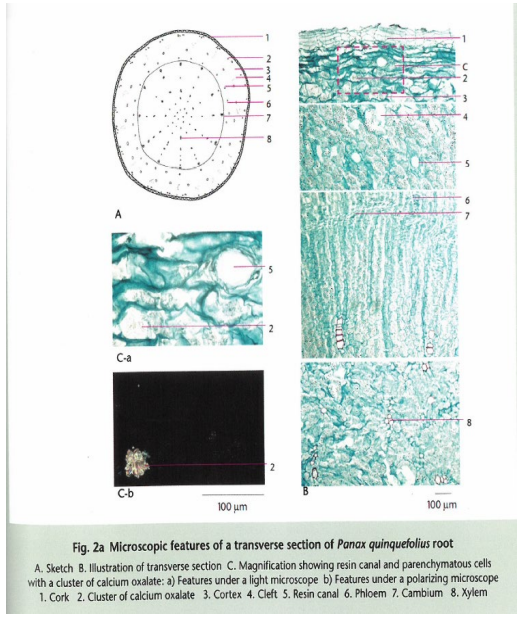


Fig. 2a Microscopic features of a transverse section of *Panax quinquefolius* root

A. Sketch B. Illustration of transverse section C. Magnification showing resin canal and parenchymatous cells with a cluster of calcium oxalate: a) Features under a light microscope b) Features under a polarizing microscope
1. Cork 2. Cluster of calcium oxalate 3. Cortex 4. Cleft 5. Resin canal 6. Phloem 7. Cambium 8. Xylem

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

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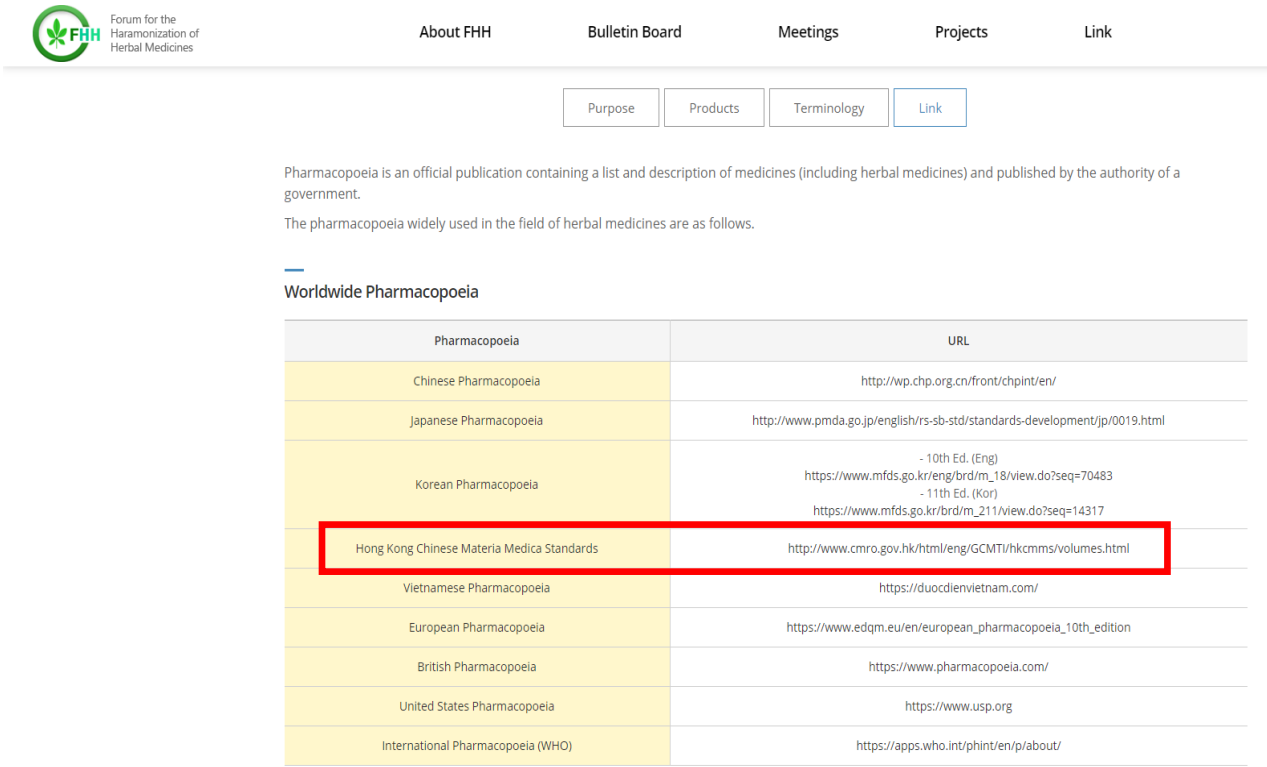
*Website of USP Dietary Supplements Compendium: https://www.usp.org/products/dietary-supplements-compendium

(5) Provide Frameworks for References and Research Findings

- 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



Pharmacopoeia	URL
Chinese Pharmacopoeia	http://wp.chp.org.cn/front/chpint/en/
Japanese Pharmacopoeia	http://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0019.html
Korean Pharmacopoeia	- 10th Ed. (Eng) https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=70483 - 11th Ed. (Kor) https://www.mfds.go.kr/brd/m_211/view.do?seq=14317
Hong Kong Chinese Materia Medica Standards	http://www.cmro.gov.hk/html/eng/GCMTI/hkcmms/volumes.html
Vietnamese Pharmacopoeia	https://duocdienvietnam.com/
European Pharmacopoeia	https://www.edqm.eu/en/european_pharmacopoeia_10th_edition
British Pharmacopoeia	https://www.pharmacopoeia.com/
United States Pharmacopoeia	https://www.usp.org
International Pharmacopoeia (WHO)	https://apps.who.int/phint/en/p/about/

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*Website of FHH: http://www.fhh.or.kr/projects/pharma_link.php

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