

# 《香港中藥材標準》的應用

香港衛生署中醫藥規管辦公室  
香港中藥材標準組

# 香港中藥材標準

## 背景：

- 由衛生署統籌並於2001年開展，目的為香港常用的中藥材制定參考標準

## 目的：

- 推動中藥研究
- 提供業界參考標準
- 保障中藥材的安全與品質
- 促進本港中藥業現代化及國際化
- 鼓勵中藥貿易

# 管治及夥伴關係

## 科研機構

- ✓ 收集樣本及開發研究方法
- ✓ 收集數據及草擬標準



## 政府化驗所

- ✓ 驗證由科研機構開發的方法
- ✓ 為方法開發提供技術支援



## 出版

## 香港中藥材標準 (《港標》)

## 科學委員會



- ✓ 審核由科研機構開發的方法及草擬標準
- ✓ 解決技術問題並監察進度

## 國際專家委員會



- ✓ 審批標準
- ✓ 對建立標準的原則、方法、參數及分析方法提出意見

# 工作進度

- 《港標》已於 2005-2024 年間出版至第十一冊
- 收載藥材標準總數：344



# 《港標》應用的重點

## 主要應用：

1. 為中藥貿易提供適用及可採用的參考
2. 確保中藥材的安全和品質以保障公眾健康
3. 促進中藥貿易
4. 促進中藥的科研及發展
5. 提供參考和研究結果的框架

# (1) 為中藥貿易提供適用及可採用的參考

- 香港中藥材的鑒定及矯正誤用的藥用部位
  - 如中藥材「燈心草」的專論指出正確的藥用部位

## 「燈心草」與「燈心全草」的形態



莖髓

燈心草 (莖髓)

- 《港標》第三冊顯示正確的藥用部位



全草

花序  
莖皮  
莖髓

燈心全草

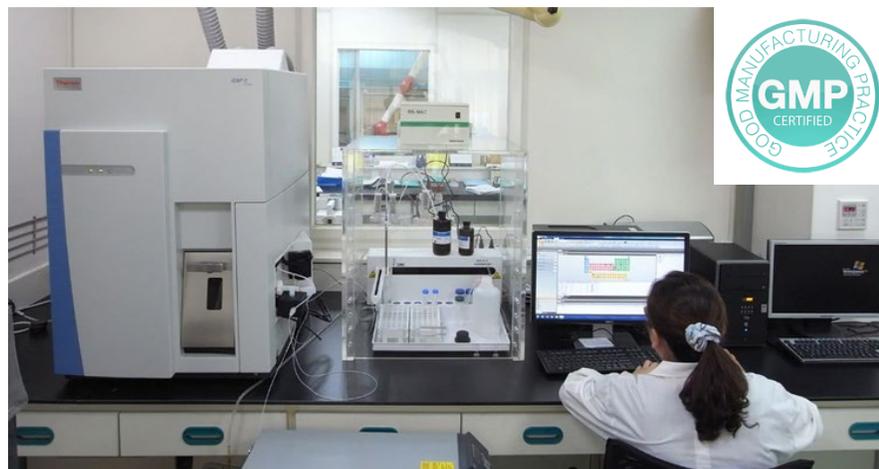
- 《港標》第三冊出版前市場常見的情況
- 與《中醫藥條例》(香港法例第549章)已收載的藥用部位不符

# (1) 為中藥貿易提供適用及可採用的參考

- 協助：

- ✓ 中成藥製造商
- ✓ 中成藥製造證明書（生產質量管理規範，GMP）持有人
- ✓ 中成藥註冊申請人

建立原料及成品的品質標準



## (1) 為中藥貿易提供適用及可採用的參考

- 部分香港持有生產質量管理規範（GMP）證明書的中成藥製造商及醫院管理局在採購中藥材及品質管理工作時亦有應用《港標》的參考標準



醫院管理局  
HOSPITAL  
AUTHORITY



## (2) 確保中藥材的安全和品質以保障公眾健康

- 為監管部門提供資訊以加強控制：
  - 如中藥材的重金屬含量超出限量標準，可能需要藥品監管機構進行相關的風險評估，並啟動產品收回行動
- 提供有關中藥材內污染物的最新發展及關注：
  - 為與各國藥典的要求相符，定期進行有關污染物的限量標準及發展的評估。  
如：
    - 進行「鎘」限量標準的評估，目的為與歐洲藥典的要求一致
    - 參考中國內地的最新規管，納入「二氧化硫殘留」的限量測定及相關標準



## (3) 促進中藥貿易

- 作為認可標準：

- 香港認可處已向根據《港標》進行測試的實驗所推出 ISO/IEC 17025 的認可服務
- 4間符合「香港實驗所認可計劃」標準的本地化驗所可按《港標》認證中藥材

認可的測試項目	認可的實驗所數量*
顯微鑒別	3
化學分析（包括薄層色譜、指紋圖譜及含量測定）	2
重金屬	2
農藥殘留	1
黃曲霉毒素	1
檢查（包括灰分、水分及浸出物）	2

\*根據2024年11月於香港認可處網頁（[https://www.itc.gov.hk/ch/quality/hkas/accreditation/our\\_accreditation\\_services.html](https://www.itc.gov.hk/ch/quality/hkas/accreditation/our_accreditation_services.html)）的資料統計

HOKLAS SC-40
Issue No. 5
Issue Date: 17 May 2023
Implementation Date: 17 May 2023
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### 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

## (4) 促進中藥的科研及發展

- 本地大學及非本地科研機構共同參與《港標》工作
- 科研機構於人力、設備和資金等方面的研發能力均有所提升



## (5) 提供參考和研究結果的框架

- 被海外權威機構引用
- 用作鑑定對照藥材的參考方法
  - 如美國草藥藥典\* (American Herbal Pharmacopoeia) 採用《港標》去認證杜仲、板藍根、何首烏及地黃的對照藥材

  
AMERICAN HERBAL PHARMACOPOEIA®  
AHP-Verified™ Botanical Reference Material  
Macroscopic Certificate of Authenticity

Botanical Nomenclature	<i>Isatis indigotica</i>	
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	

**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 1/2-3/4 of radius, wood (xylem) yellow.

<b>Organoleptic Characterization</b>	
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: 	Released by Roy Upton, RH Title: AHP Executive Director Date: 1/19/17 Signature: 
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Website: www.herbal-ahp.org

## (5) 提供參考和研究結果的框架

- 共24份與中醫藥相關的ISO文件引用《港標》為參考：

序號	文件描述
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

序號	文件描述
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

## (5) 提供參考和研究結果的框架

- 有關中醫藥的ISO文件中，BS ISO 18664：2015引用《港標》規定的重金屬限度為參考標準之一
- BS ISO 18664 於 2015年發布，以回應全球對：
  - ✓ 中藥內重金屬檢測方法的協同要求
  - ✓ 不同參考文獻中，所列載對天然中藥內重金屬限度的要求

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 (µg/kg)

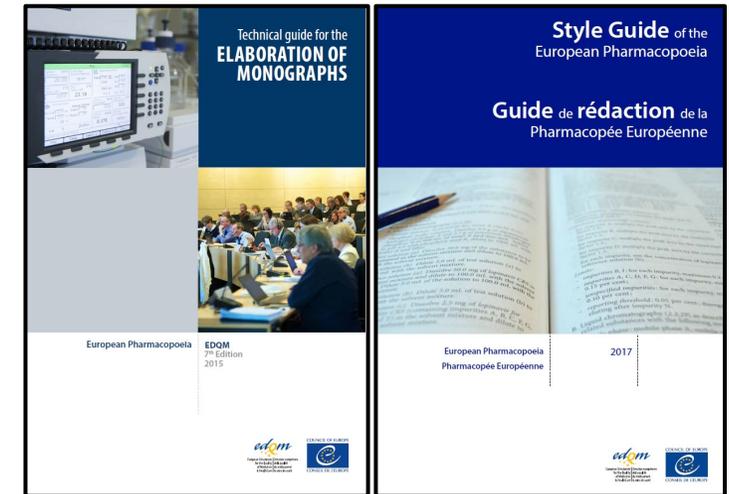
	Pb <sup>a</sup>	As <sup>a</sup>	Cd <sup>a</sup>	Hg <sup>a</sup>	Object	Analytical methods	Authority organization or regulation
Australia	5.0	—	-1	0.1	Unprocessed herbal material	AAS, ICP-AES or ICP-MS	Therapeutic Goods Administration
China	5	2	0.3	0.2	Crude herbal drugs	AAS and ICP-MS	Chinese Pharmacopoeia 2010 edition
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 <sup>a</sup>	As <sup>a</sup>	Cd <sup>a</sup>	Hg <sup>a</sup>	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

## (5) 提供參考和研究結果的框架

- 歐洲藥典中的中草藥專論必須按下列考量點而準備<sup>1</sup>:

- ✓ 歐洲藥典的設計指南 (Style Guide)
- ✓ 編制專論的技術指南 (Technical Guide)
- ✓ 以中華人民共和國藥典為基礎
- ✓ 考慮世界衛生組織選定的藥用植物專論及《港標》的資料



<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



## (5) 提供參考和研究結果的框架

- 以高解像度圖片顯示中藥材的顯微鑒別特徵的先驅
- 《港標》為第一部採用繪圖及照片闡明中藥材顯微特徵的參考標準
- 為其他藥典 / 概論樹立典範

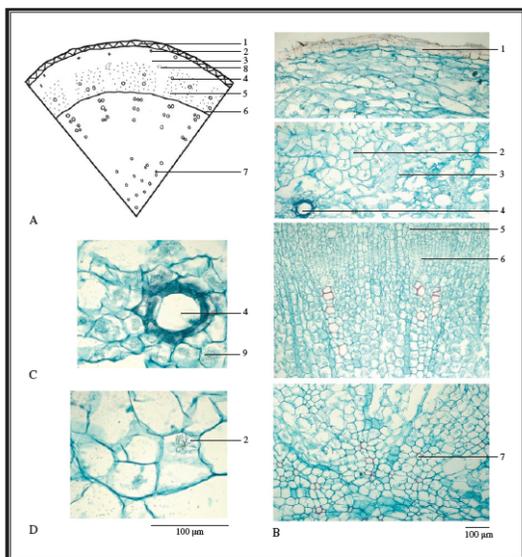


Figure 2 Microscopic features of transverse section of Radix Panacis Quinquefolii

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

2010年出版《港標》第三冊的西洋參專論

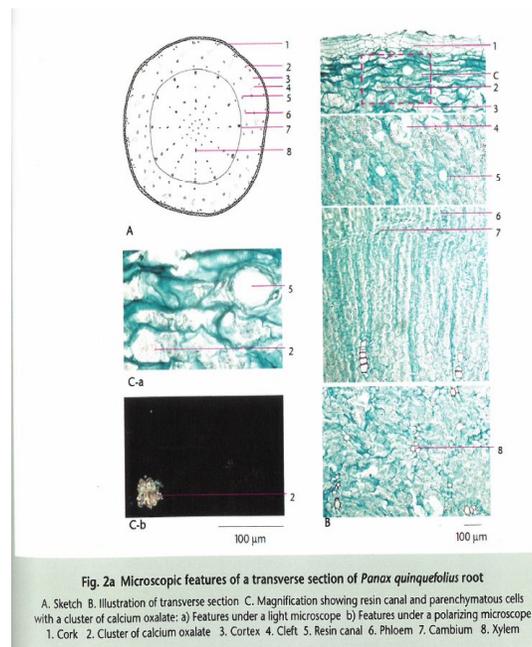


Fig. 2a Microscopic features of a transverse section of *Panax quinquefolius* root

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

2015年出版 USP 膳食補充劑法典\*  
(USP's Dietary Supplements Compendium) 的西洋參專論

## (5) 提供參考和研究結果的框架

- 西太平洋地區草藥協調論壇\*（草藥協調論壇）是一個技術平台，目的就與草藥的品質、安全及成效性問題提供技術文件及共識
- 《港標》被草藥協調論壇網頁引用為藥典參考文獻之一



Forum for the  
Harmonization of  
Herbal Medicines

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Meetings

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Purpose

Products

Terminology

Link

Pharmacopoeia is an official publication containing a list and description of medicines (including herbal medicines) and published by the authority of a government.

The pharmacopoeia widely used in the field of herbal medicines are as follows.

### Worldwide Pharmacopoeia

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

多謝