



# Accreditation Services for Testing and Identification of Chinese Medicines

中藥測試及鑒別的相關認可服務

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Hong Kong Accreditation Service



## What is Hong Kong Accreditation Service 香港認可處 (HKAS)?

- ✦ HKAS is part of Innovation and Technology Commission of the Hong Kong Special Administration Region (HKSAR) Government.
- ✦ 香港認可處是香港特別行政區政府創新科技署屬下工作組別



香港特別行政區政府  
創新科技署

- ✦ It was set up in 1998 (previously known as HOKLAS since 1985)
- ✦ It is the official accreditation body (認可機構) in Hong Kong
- ✦ It provides independent and impartial accreditation services



- ✦ HKAS provides accreditation (認可) services to testing laboratories, certification bodies and inspection bodies under 3 schemes:



- HOKLAS (香港實驗所認可計劃)
- HKCAS (香港認證機構認可計劃)
- HKIAS (香港檢驗機構認可計劃)

- ✦ Participation in the 3 schemes is voluntary

- ✦ The schemes are operated in accordance with the requirements of the international standard ISO/IEC 17011 and criteria set by relevant international and regional cooperations of accreditation bodies, e.g. ILAC, IAF, APLAC & PAC

# Chinese Medicine Testing Services

- Chinese medicines are mainly tested for safety and quality (安全性和品質性測試)
- Safety tests include:
  - Heavy metals and toxic elements (重金屬及有毒元素含量), e.g. cadmium, lead, mercury, arsenic, etc.
  - Pesticide residues (農藥殘留量), e.g. organochlorine pesticides
  - Microbiological examination (微生物檢查), e.g. aerobic bacterial count, yeast and mould count, Salmonella, etc.

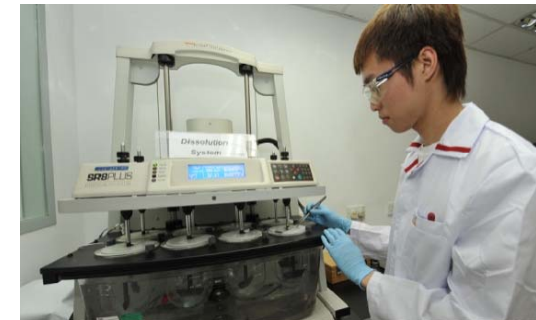


# Chinese Medicine Testing Services

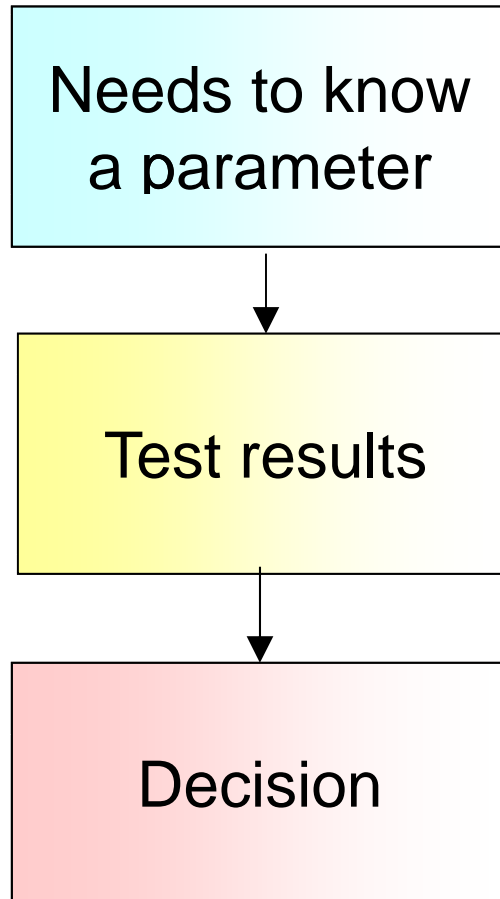
- **Quality tests can include:**
  - **Testing of Chinese Materia Medica (CMM)(中藥材) to standards such as the Hong Kong Chinese Materia Medica Standard 《香港中藥材標準》 or the Pharmacopoeia of the PRC 《中國藥典》**
  - **Identification of CMM (中藥材鑒別) e.g. by chemical means (化學方法) or microscopic examination (顯微觀察)**

# Chinese Medicine Testing Services

- **Quality tests (con't):**
  - Testing of proprietary Chinese medicines (pCm)(中成藥) to standards e.g. Pharmacopoeia of the PRC 《中國藥典》
- **Other tests:**
  - Stability test (穩定性測試) for pCm registration
  - Testing to product specifications (產品規範)



# Use of Test Results



To support decisions on health, safety, regulations, research, trade, manufacturing, etc.

Are the results accurate and reliable?

Inaccurate or unreliable results can reduce the quality of decision

# Value of Accreditation

Assess the competence of a laboratory to perform specific tests

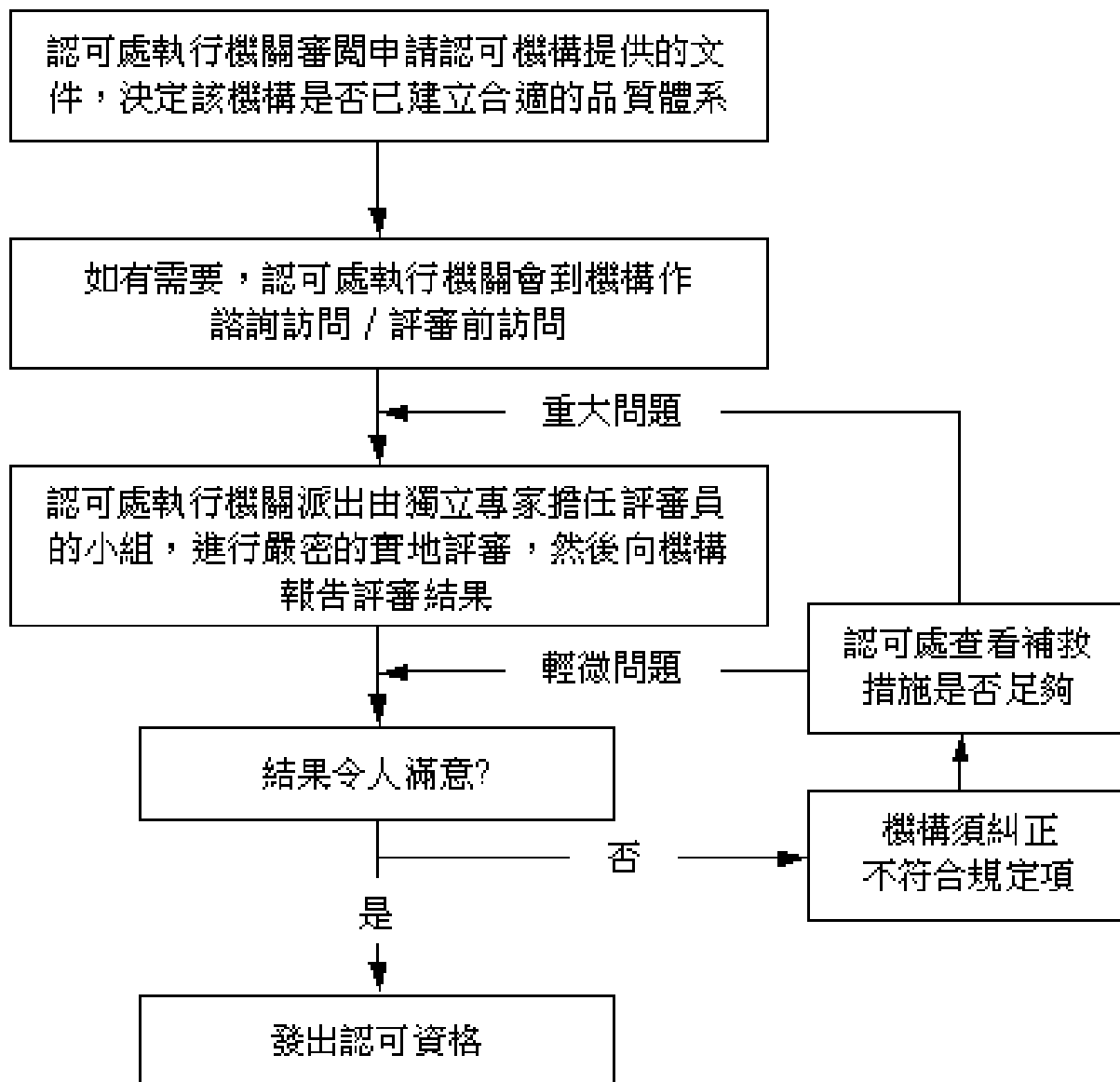
Basis:  
International Standards,  
e.g. ISO/IEC 17025,  
ISO 15189

Grant accreditation to the competent laboratory for the specified tests

Effect:  
Declare to the public that the laboratory is competent in performing the specified tests. The quality and reliability of the test results produced can be assured.



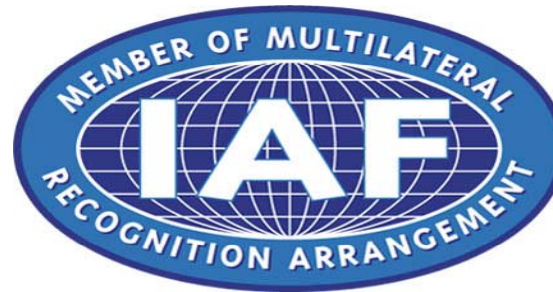
# Accreditation Process 認可程序



# Accreditation Recognised Internationally

## 認可資格獲國際承認

- ✦ HKAS is a signatory member to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) 香港認可處 (HKAS) 是國際實驗室認可合作組織 (ILAC) 及國際認可論壇等 (IAF) 的相互承認協議成員
- ✦ Accreditation status of specific scope recognised by **over 86 accreditation bodies in 70 economies** in the world 所發出的認可資格能獲世界上70經濟體系共86個認可機構互認



# Endorsed Reports and Certificates under HKAS Accreditation Schemes

香港認可處認可計劃認許測試報告及證書



# Endorsed Reports and Certificates under HKAS Accreditation Schemes

## 香港認可處認可計劃認許測試報告及證書

- ✦ Unless otherwise approved and specified, only results of accredited activities can be shown in HOKLAS endorsed reports and certificates

除非經批准及清楚註明，否則獲認可實驗室只可就獲得認可資格的測試工作發出實驗室認可計劃的認許測試報告及證書。

- ✦ Since the competence of the accredited activities has been assessed, the reliability of results in endorsed reports and certificates can be assured

由於獲認可實驗室在獲得認可資格的測試工作上其能力曾經接受嚴謹的評審，認許測試報告及證書上的結果會更可靠。

## Accreditation Services for Testing and Identification of Chinese Medicines 與中藥測試及鑒別有關的認可服務

- Microbiological examination and quality testing of pCm to the Pharmacopoeia of the PRC, e.g. microbial limit test, general requirements for preparations, etc.

根據《中國藥典》對中成藥進行的微生物檢查及品質性測試，例如微生物限度檢查法、製劑通則等。

## Accreditation Services for Testing and Identification of Chinese Medicines 與中藥測試及鑒別有關的認可服務

- Testing of pCm and CMM for heavy metals, toxic elements and pesticide residues.

測試中成藥及中藥材中的重金屬、有毒元素及農藥殘留含量。

## Accreditation Services for Testing and Identification of Chinese Medicines 與中藥測試及鑒別有關的認可服務

- Safety, chemical and physicochemical testing of CMM to the HKCMMS, e.g. aflatoxins, assay, ash, water content, extractives, etc.

根據《香港中藥材標準》對中藥材進行的安全性、化學及理化測試，例如黃曲霉毒素測試、含量測定、灰分、水分、浸出物等。

## Accreditation Services for Testing and Identification of Chinese Medicines 與中藥測試及鑒別有關的認可服務

- Physicochemical and chromatographic identification of CMM to the HKCMMS.  
根據《香港中藥材標準》對中藥材進行的理化及色譜鑒別。
- Microscopic identification of CMM to the HKCMMS.  
根據《香港中藥材標準》對中藥材進行的顯微鑒別。



## Accreditation Services for Testing and Identification of Chinese Medicines 與中藥測試及鑒別有關的認可服務

- Accreditation service may be provided to laboratories performing individual tests given that the relevant accreditation criteria are fulfilled, e.g. assay of specific chemical markers in pCm

認可處亦會就個別測試項目向實驗所提供認可服務 (例如在中成藥中個別化學物標誌物的含量測定)，條件是實驗所要符合有關的認可準則。

## 獲香港認可處認可的中藥測試實驗室 (截至2012年7月 [www.hkas.gov.hk](http://www.hkas.gov.hk))

- 下列機構為公眾提供一項或多項獲認可的中藥測試服務，詳情請向有關測試機構查詢。

機構名稱	電話
ALS Technichem (HK) Pty Ltd.*	2610 1044
Bureau Veritas Hong Kong Ltd 立德國際公證香港有限公司	2331 0888
Castco Testing Centre Ltd. 佳力高試驗中心有限公司	2677 2032
CMA Industrial Development Foundation Ltd. * 香港中華廠商聯合會工業發展基金有限公司	2698 8198

## 獲香港認可處認可的中藥測試實驗室 (截至2012年7月 [www.hkas.gov.hk](http://www.hkas.gov.hk))

機構名稱	電話
Euopharm Laboratories Company Limited – Q. C. Laboratory * 歐化藥業有限公司 – 品質控制實驗室	2662 2433
Hong Kong Productivity Council - Environment and Product Innovation Laboratory 香港生產力促進局 – 環境及產品創新化驗室	2788 5628
Institute for the Advancement of Chinese Medicine (IACM) Ltd. 浸大中醫藥研究所有限公司	3411 5308
Intertek Testing Services Hong Kong Ltd. 天祥公證行有限公司	2173 8888
SGS Hong Kong Limited * 香港通用公證行有限公司	2334 4481
The Hong Kong Standards and Testing Centre Ltd.* 香港標準及檢定中心有限公司	2666 1888
Wellab Limited* 匯力實驗室有限公司	2829 7388

## 中成藥測試實驗所

- ✦ 在中成藥註冊時，香港中醫藥管理委員會中藥組會接納獲認可的中成藥測試實驗所發出的認許測試報告。
  - 如果實驗所同時已獲取測試中成藥中有毒元素、農藥殘留及按《中國藥典》進行的微生物檢查的認可資格，中藥組亦會考慮接納該實驗所發出有關中成藥註冊的其他測試項目(例如穩定性測試)的測試報告。

## 總結

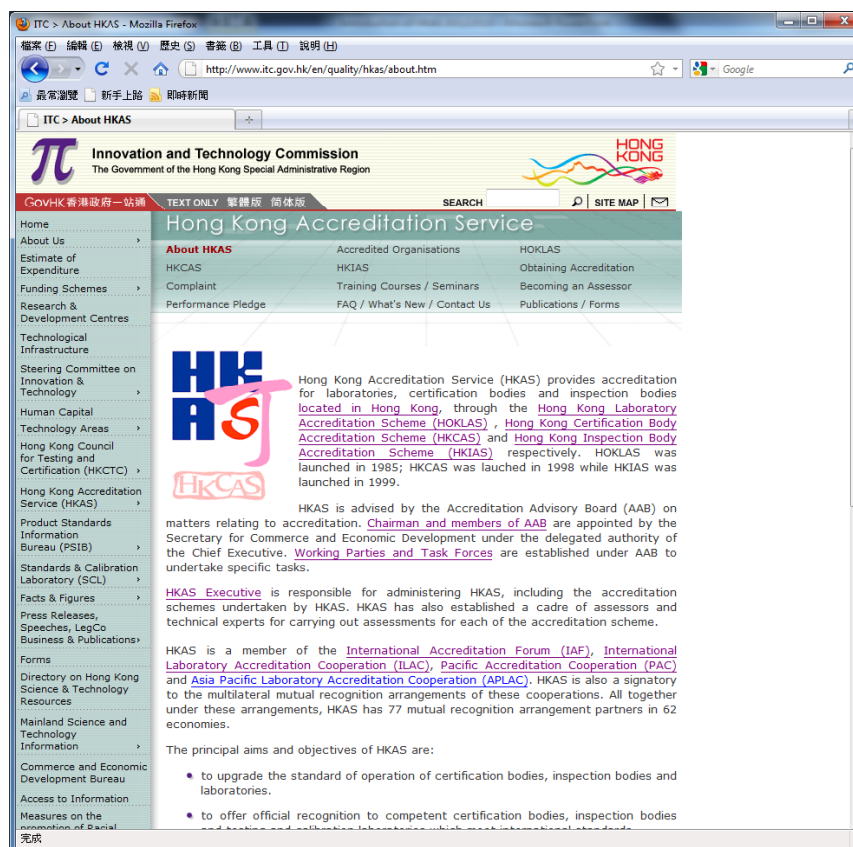
- ✦ 香港實驗所擁有優良的中藥研究和測試技術。中藥測試可幫助中藥從業人員及使用者辨別優質產品及提供安全保證，有助減少購入一些造假、受摻雜、受污染或處理不當的產品。對中藥生產商及貿易商而言，則可加強顧客的信心，有助增加產品的銷量及減低產品因不達法例要求而須回收的風險。長遠而言，中藥測試可促進中藥業的發展，以及鞏固香港作為一個中藥貿易中心的地位。

## 總結

- ✦ 香港認可處向本地實驗所提供認可服務，為已申請認可的中藥測試實驗所進行嚴格評審，以確保其測試能力及運作體系符合國際標準、測試服務及結果更為可靠。

For more information, please visit our website at [www.hkas.gov.hk](http://www.hkas.gov.hk)

詳情請瀏覽香港認可處網頁  
[www.hkas.gov.hk](http://www.hkas.gov.hk)





*Thank you*

