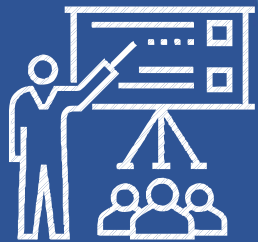


Chinese Medicine Regulatory Office
Department of Health
衛生署中醫藥規管辦公室



Chinese Medicinal Oil for External Use
Workshop cum GCMTI visit
外用中藥藥油工作坊暨參觀
政府中藥檢測中心



內容



方法介紹



標準品及樣本制備



儀器設置及數據分析



參觀政府中藥檢測中心



方法討論

GCMTI RD-1:2019

GCMTI method publications

Determination of α -Pinene, Eucalyptol, Camphor, Menthol and Methyl Salicylate in Chinese Medicinal Oil for External Use by Gas Chromatography

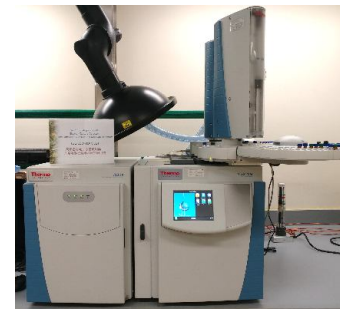
http://www.cmro.gov.hk/html/b5/GCMTI/results_index.html

外用藥油中中藥材指標成分的分析

第一階段

- 儀器 : GC-FID
- 建立及確認定性和定量分析5種指標成分的方法

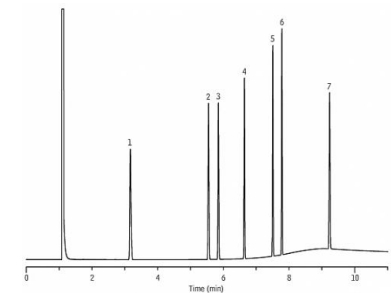
有效成分 Active ingredient	指標成分 Chemical markers
樟腦 Camphor	樟腦 Camphor
桉油 Eucalyptus oil	桉油精 Eucalyptol
薄荷腦 Menthol	薄荷腦 Menthol
冬青油 Methyl Salicylate	水楊酸甲酯 Methyl Salicylate
松節油 Turpentine oil	α -蒎烯 α -Pinene



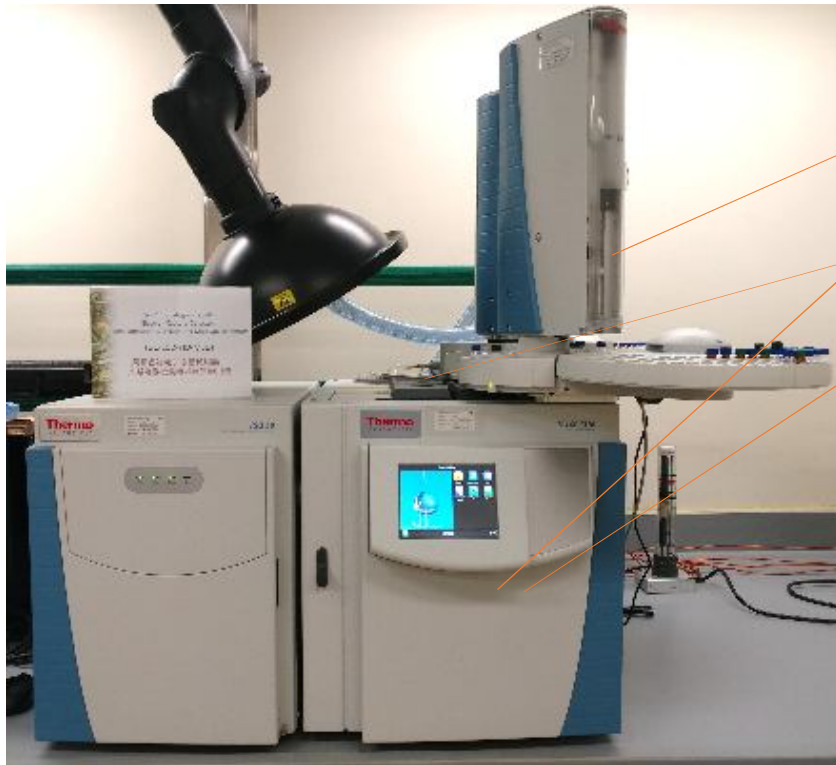
【中成藥註冊】

品質性資料

技術指引



氣相色譜火焰電離檢測器 GC-FID



Components

- Injector
- Oven
- FID
- Column

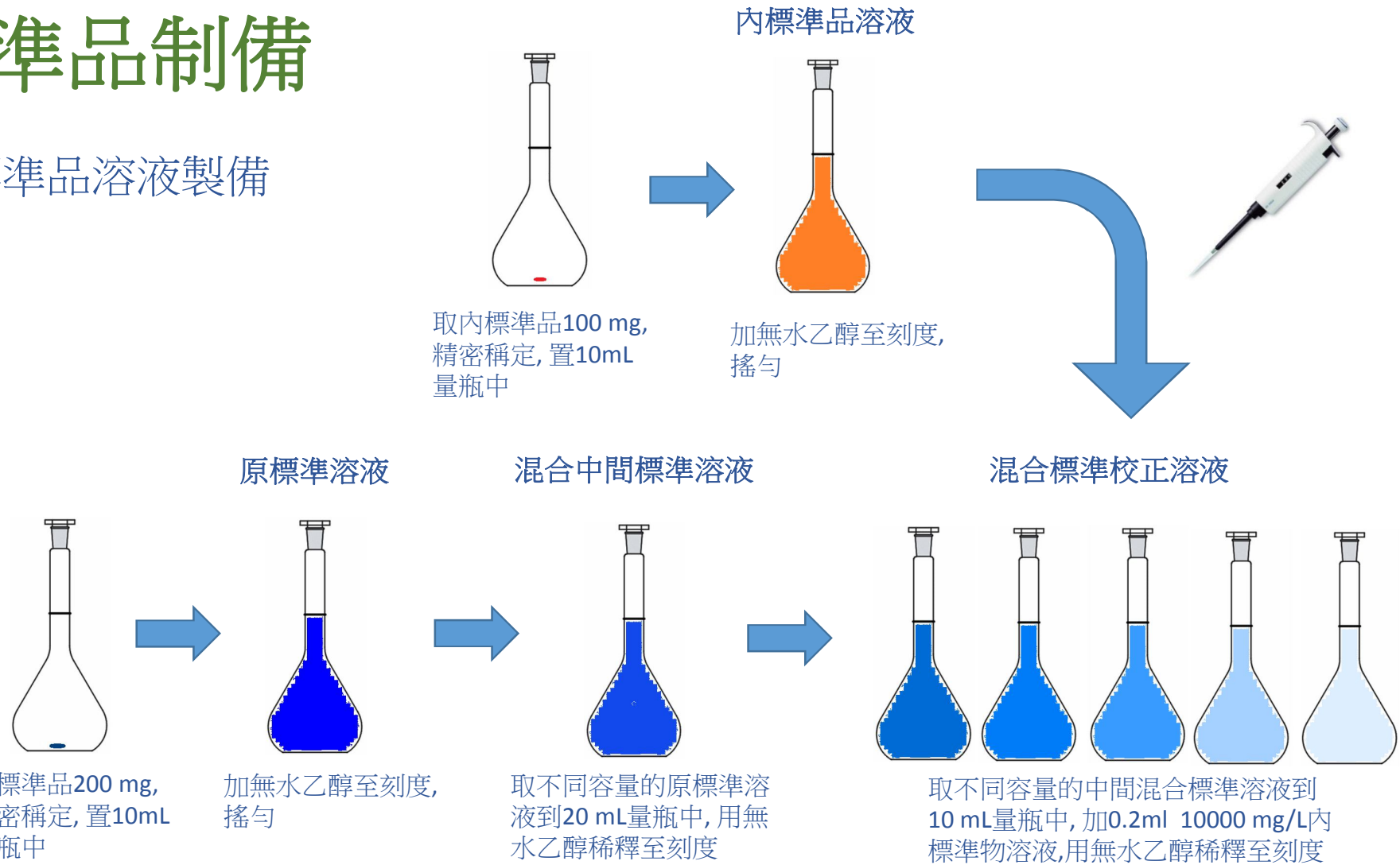
Applications

- Separation and determination of volatile carbon-containing components
- Pharmaceuticals, food, fragrances, environmental.....

[Theory of GC](#)

標準品制備

- 標準品溶液製備

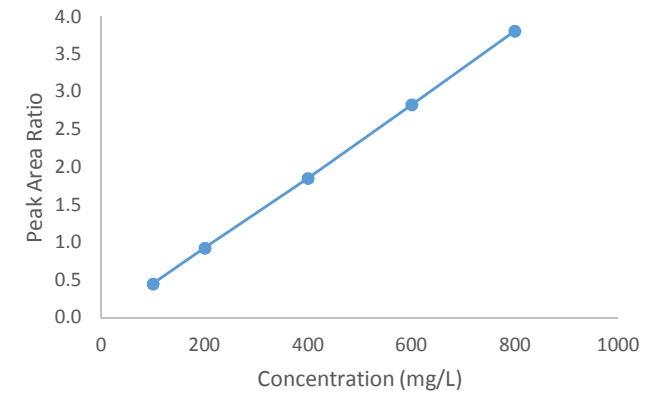


標準品制備

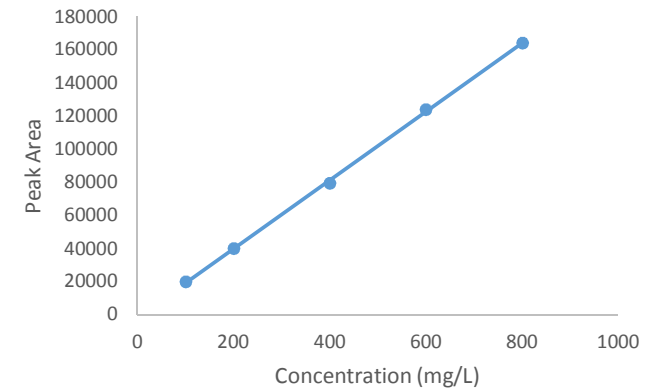
- 標準曲綫

Marker	Concentration (mg/L)				
	Level 1	Level 2	Level 3	Level 4	Level 5
α -Pinene	100	200	400	600	800
Eucalyptol	50	100	200	300	400
Camphor	100	200	400	600	800
Menthol	250	500	1000	1500	2000
Methyl salicylate	250	500	1000	1500	2000

Internal standard calibration

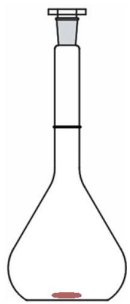


External standard calibration

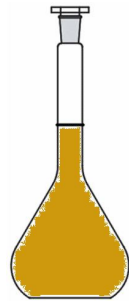
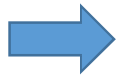


樣品制備

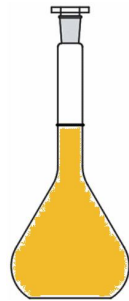
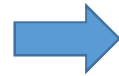
- 樣品溶液製備



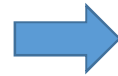
取樣本100 mg, 精密稱定, 置10 mL量瓶中



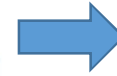
加無水乙醇至刻度, 搖勻



取2 mL 樣品溶液到10 mL量瓶中, 加0.2ml 10000 mg/L 內標準物溶液, 用無水乙醇稀釋至刻度



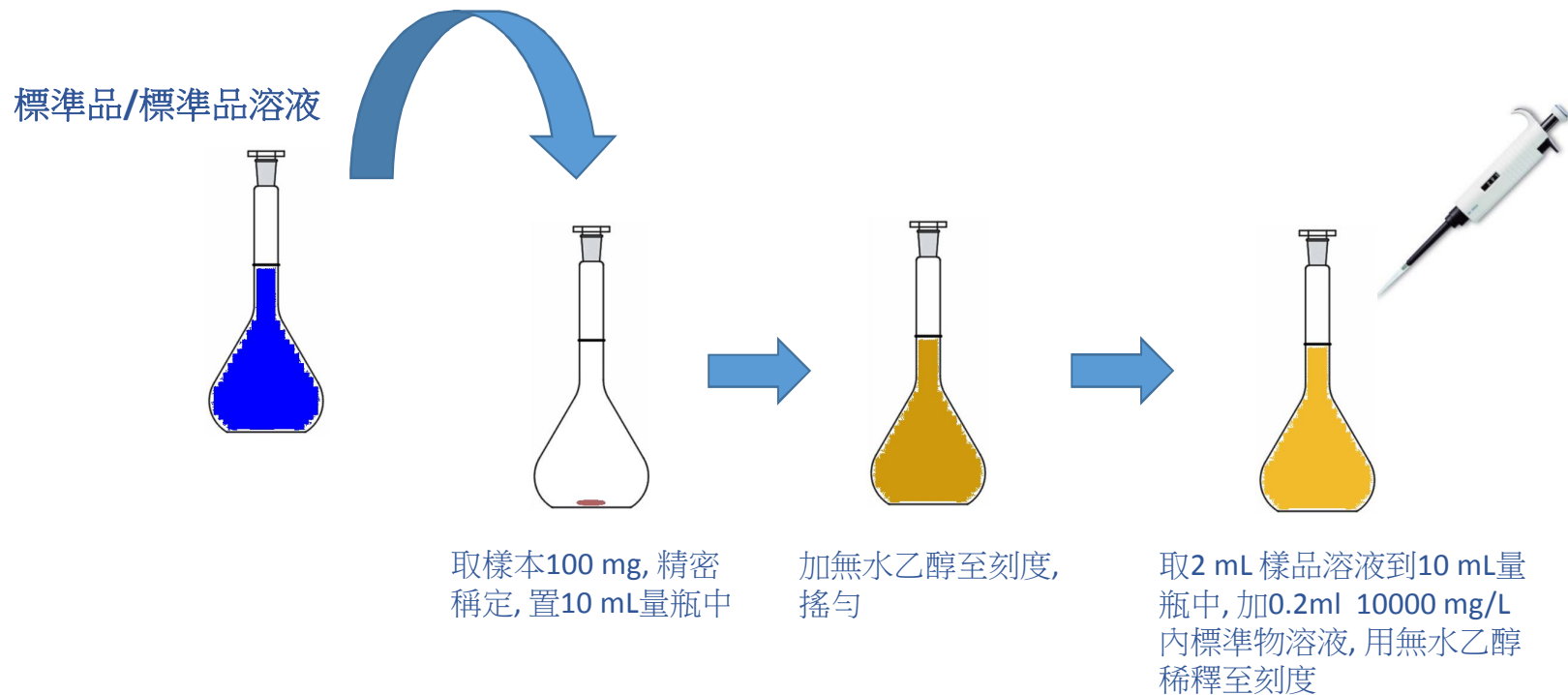
經0.45 μm 微膜過濾至 GC vial



GC-FID 分析

樣品制備

- 樣品加標溶液製備



儀器設置



- 色譜柱

	Column	Dimension	Stationary Phase
1	Restek Stabilwax-MS	0.25 mm ID x 30 m x 0.25 μ m	Polyethylene glycol (PEG)
2	Agilent Technologies HP-5MS	0.25 mm ID x 60 m x 0.25 μ m	5% Phenyl Methylpolysiloxane

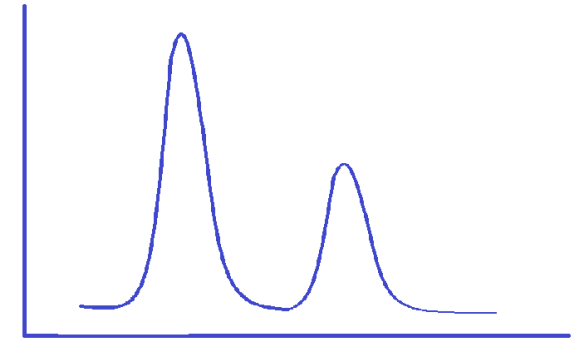
- GC-FID設置

Injection volume	1 μ L	
Injection mode	Split mode, split ratio 50:1	
Column flow rate	1.5 mL/min	
Temperature programme	Column 1: 40°C for 15 min, then 20°C/min to 190°C for 4 min (Total run time 26.5 min)	Column 2: 65°C for 5 min, 1°C/min to 80°C for 0 min, 20°C/min to 190°C for 3 min (Total run time 28.5 min)

數據分析

- 定性分析

$$\text{RRT} = \frac{\text{Retention time (RT) of analyte peak}}{\text{Retention time (RT) of naphthalene peak}}$$



- 定量分析

$$\text{Content (mg/g) of the analyte in sample} = \frac{C \times V \times D}{1000 \times W}$$

