中藥及食品中摻加西藥成分定性(214 項)認證檢驗範圍偵測極限評估指引

修訂日期：108.07.02

1 目的：

為使「中藥及食品中摻加西藥成分定性(214 項)」認證檢驗範圍偵測極限評估有所依循，特定此文件，本文所稱之偵測極限非學理上之偵測極限，為考量認證實驗室儀器感度及參考文獻資料所得之值。

2 方法：

2.1 配製適當標準溶液，分別以紫外光吸收法、薄層層析法(呈色劑呈色)、氣相層析質譜儀或液相層析串聯質譜儀評估其偵測極限，表一為各方法之偵測極限，方法偵測極限濃度較高者訂為該藥物之偵測極限。

2.2 結果判定：標準品與空白試驗可明確鑑別之濃度訂為偵測極限。

2.3 Estradiol 及 Orlistat 之氣相層析質譜及液相層析串聯質譜儀之參考分析參數如表二及表三。

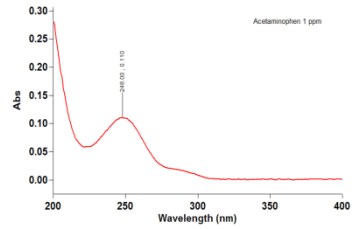
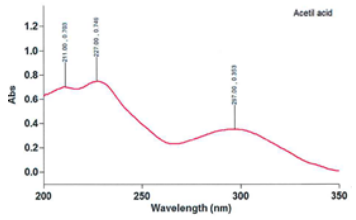
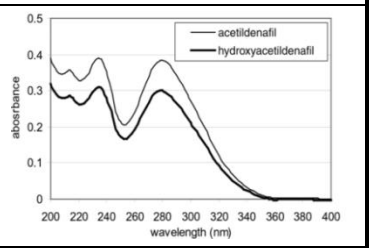
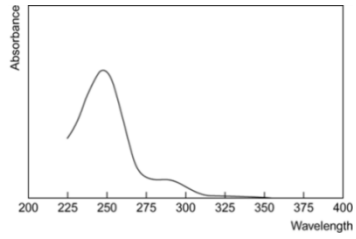
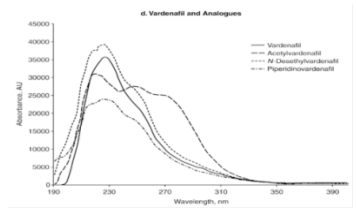
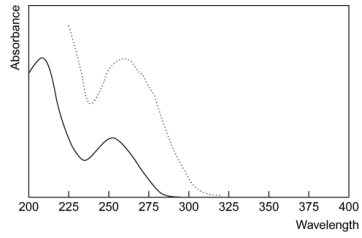
2.4 UV：假設檢體取 5 g，加入 15 mL 溶劑溶解，點注檢液 10 µL 在薄層層析板上，刮下斑點，加入 1 mL 溶劑溶解，稀釋倍數為 300 倍，評估濃度乘上 300 倍為 UV 方法之偵測極限。

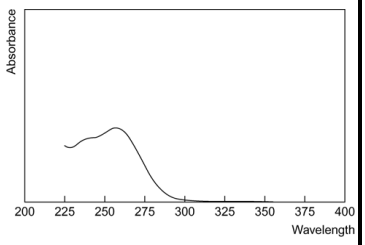
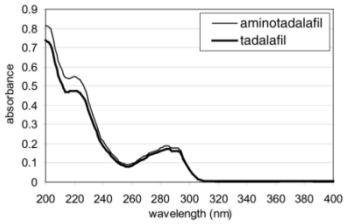
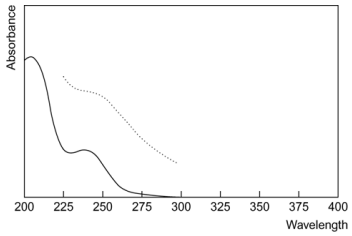
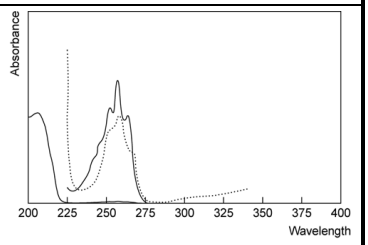
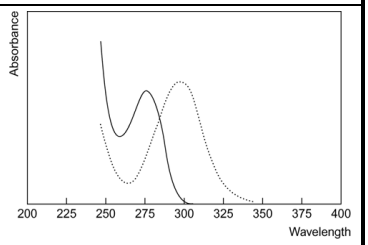
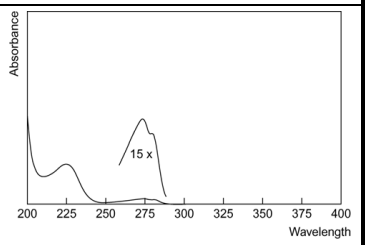
2.5 TLC 呈色法、GC/MS 或 LC/MS/MS：假設檢體取 5 g，加入 15 mL 溶劑溶解，稀釋倍數為 3 倍，評估濃度乘上 3 倍為各方法之偵測極限。

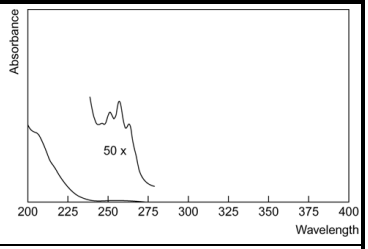
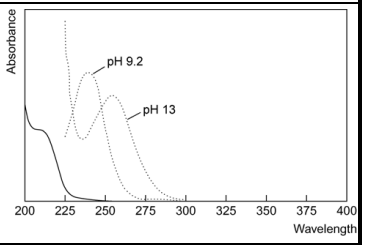
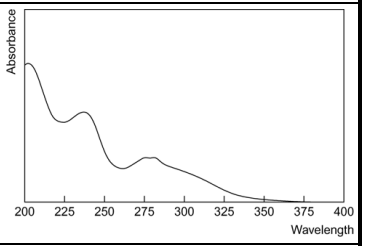
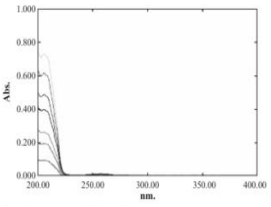
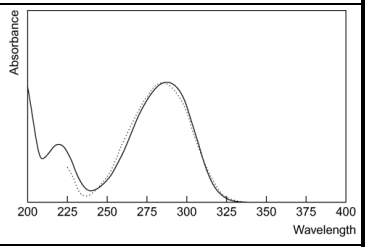
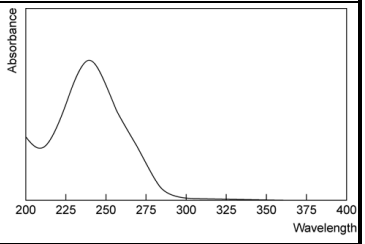
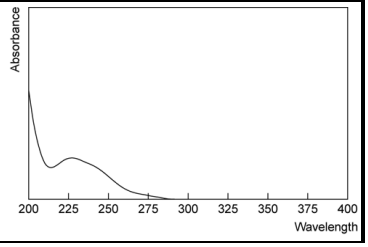
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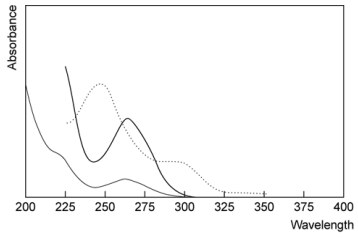
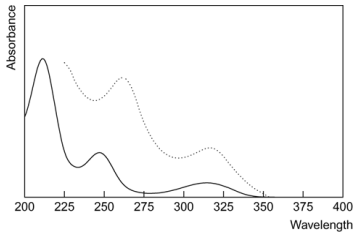
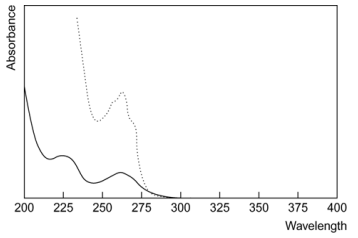
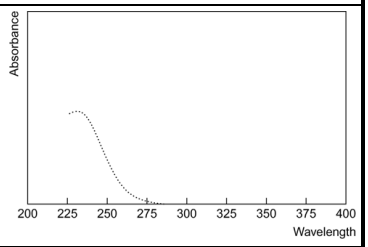
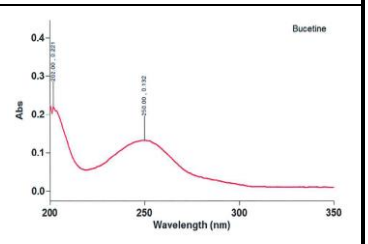
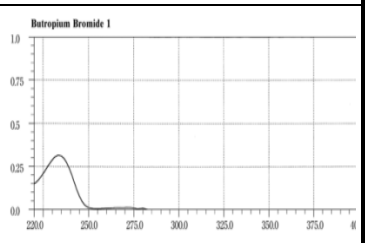
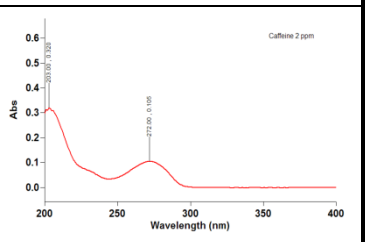
3.1 檢驗結果之判定應依表一之偵測極限，以薄層層析法(紫外光吸收或呈色劑呈色)與質譜法(GC/MS 或 LC/MS/MS)二種原理均有檢出時，方可認定為檢出。

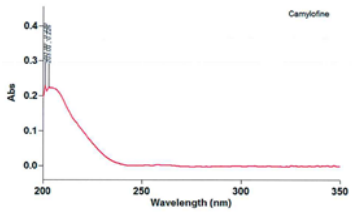
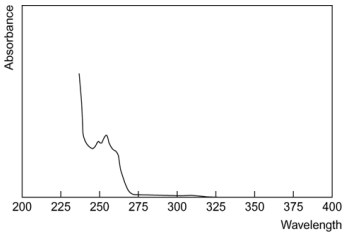
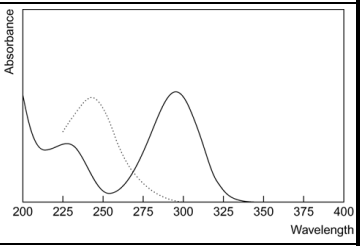
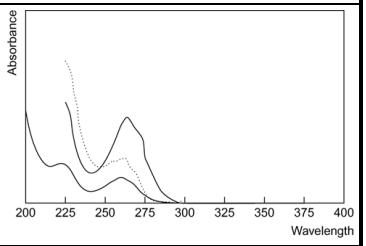
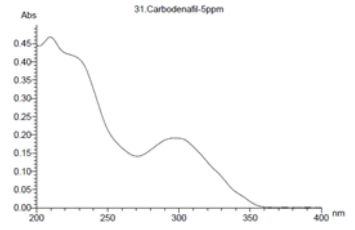
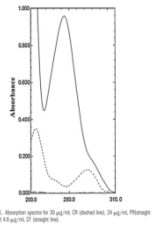
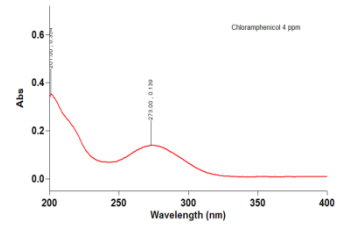
表一、中藥及食品中摻加西藥成分 214 項之偵測極限

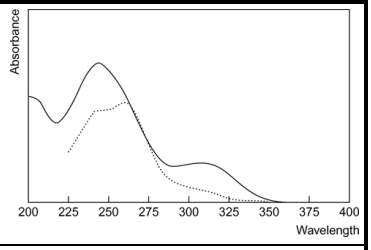
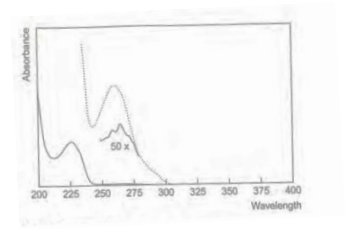
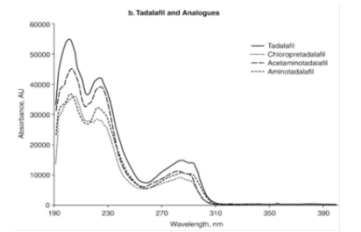
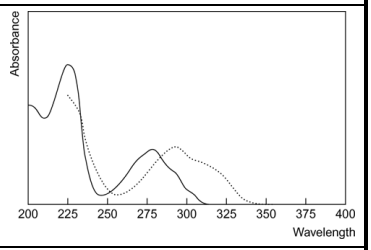
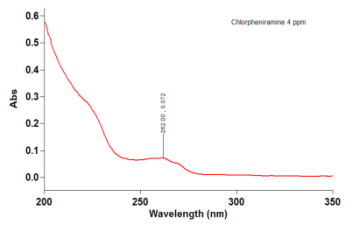
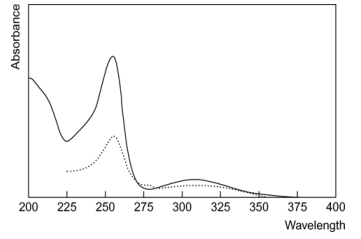
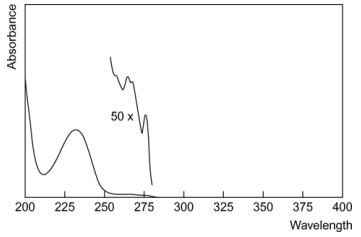
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
1	Acetaminophen	300	1.0	100	100	10	
2	Acetil acid	1500	5.0	500	–	10	
3	Acetildenafil	600	2.0	200	200	10	
4	Acetohexamide	750	2.5	250	250	10	
5	Acetylvardenafil	600	2.0	200	–	10	
6	Allopurinol	600	2.0	200	200	10	

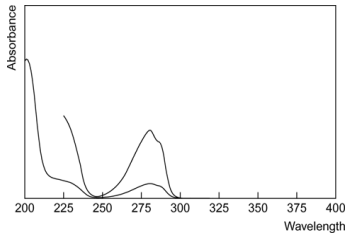
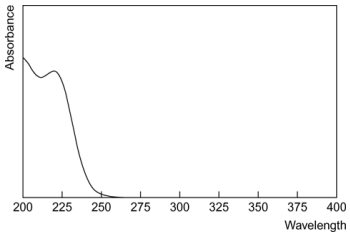
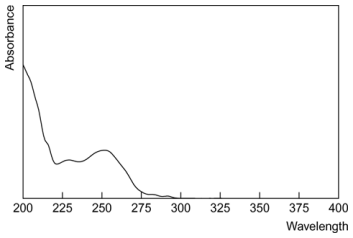
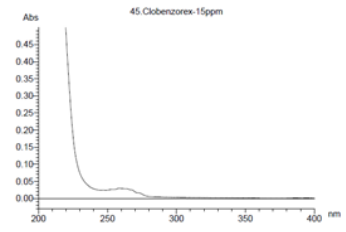
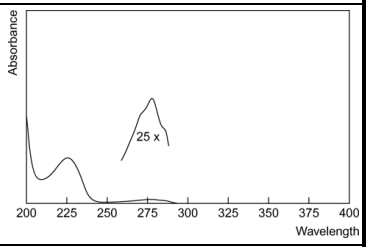
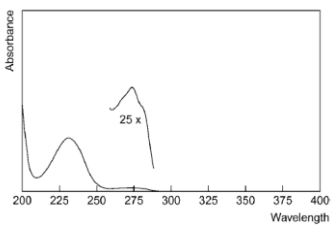
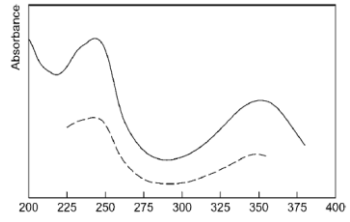
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
7	Aminopyrine	900	3.0	300	300	10	
8	Aminotadalafil	900	3.0	300	300	10	
9	Amitriptyline	750	2.5	250	250	10	
10	Amphetamine	375	–	125	20	10	
11	Aspirin	600	2.0	200	200	10	
12	Atenolol	300	–	100	100	10	

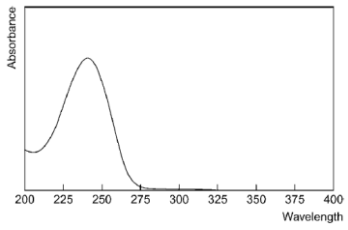
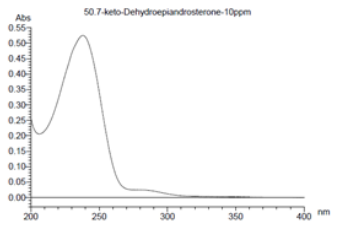
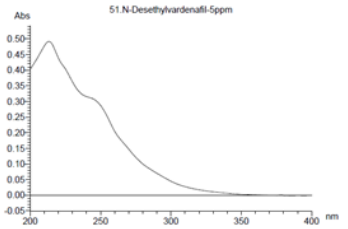
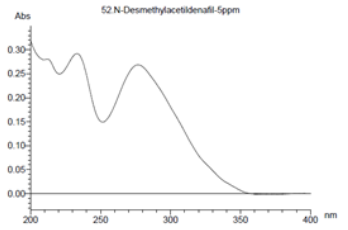
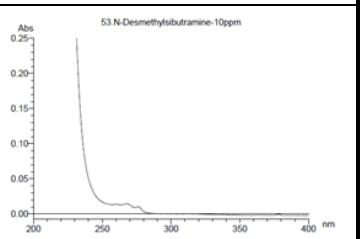
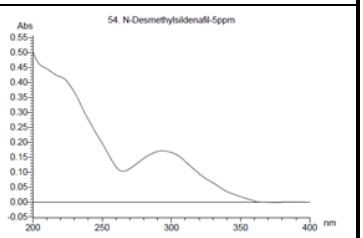
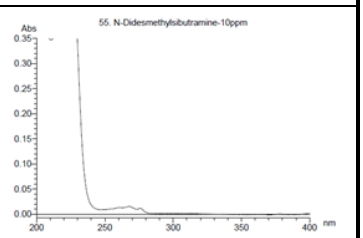
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
13	Atropine	150	–	50	10	10	
14	Barbital	750	2.5	250	250	10	
15	Benzbromarone	900	3.0	300	300	10	
16	Benzhexol	1800	–	600	–	10	 Fig. 2: Overlain spectra of THP in the concentration range 4 - 35 µg/mL
17	Benzocaine	300	1.0	100	100	10	
18	Betamethasone	900	3.0	300	300	10	
19	Bezafibrate	600	2.0	200	200	10	

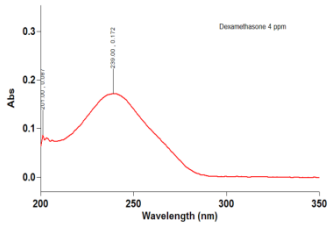
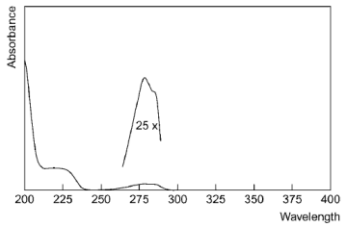
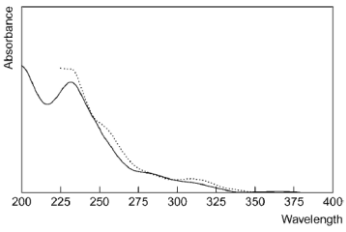
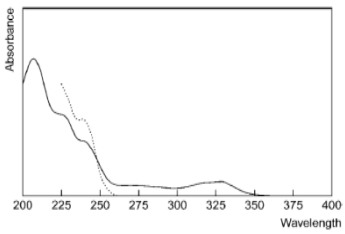
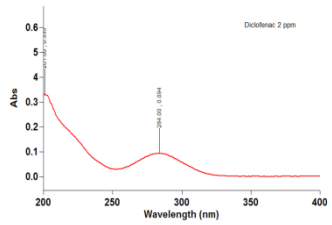
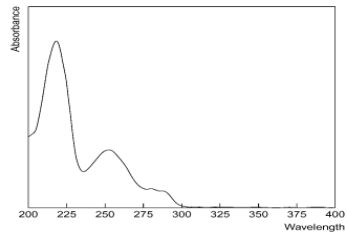
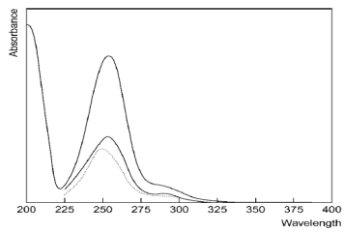
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
20	Bisacodyl	600	2.0	200	200	10	
21	Bromhexine	1200	4.0	400	400	10	
22	Brompheniramine	1800	6.0	600	600	10	
23	Bromvalerylurea	1950	6.5	650	650	10	
24	Bucetin	600	2.0	200	200	10	
25	Butropium	3000	10.0	1000	–	10	
26	Caffeine	600	2.0	200	200	10	

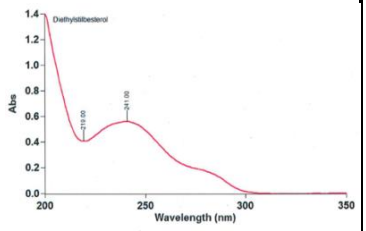
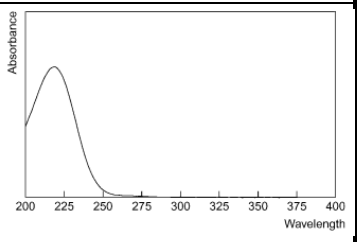
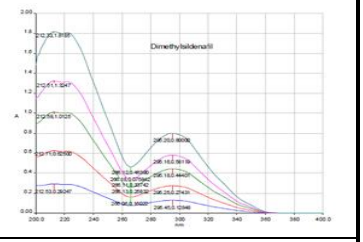
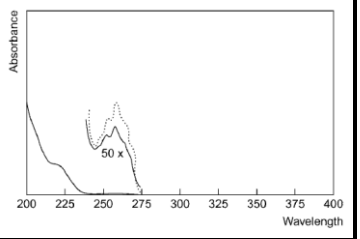
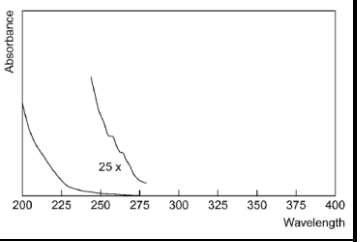
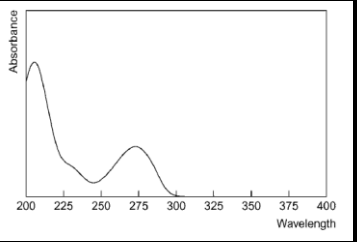
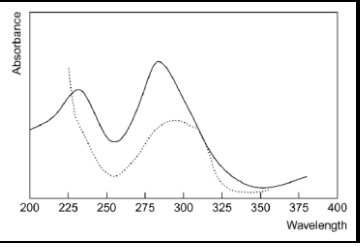
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
27	Camylofine	3000	10.0	1000	–	10	
28	Carbetapentane	150	–	50	10	10	
29	Carbimazole	600	2.0	200	200	10	
30	Carbinoxamine	1650	5.5	550	550	10	
31	Carbodenafil	1500	5.0	500	500	10	
32	Carisoprodol	375	–	125	20	10	
33	Chloramphenicol	1200	4.0	400	400	10	

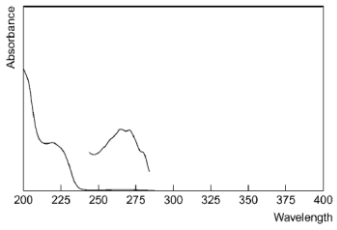
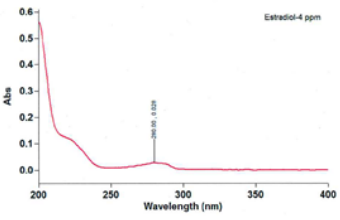
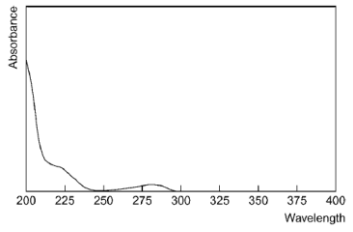
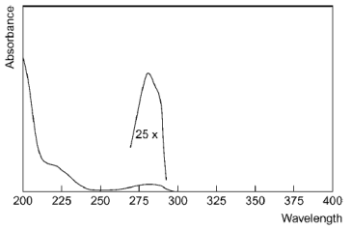
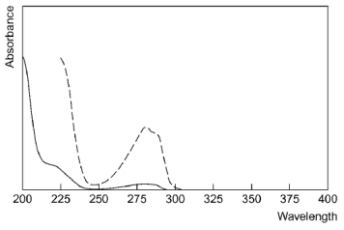
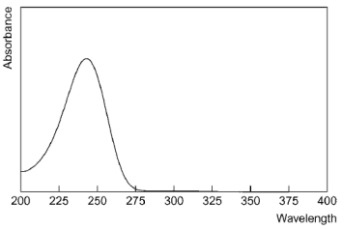
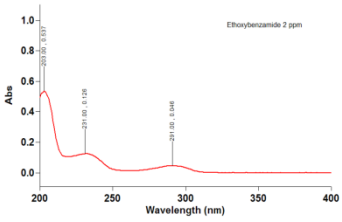
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
34	Chlordiazepoxide	300	1.0	100	100	10	
35	Chlormezanone	1200	–	400	20	10	
36	Chloropretadalafil	1500	5.0	500	–	10	
37	Chlorothiazide	750	2.5	250	–	10	
38	Chlorpheniramine	1200	4.0	400	400	10	
39	Chlorpromazine	300	1.0	100	100	10	
40	Chlorpropamide	600	2.0	200	200	10	

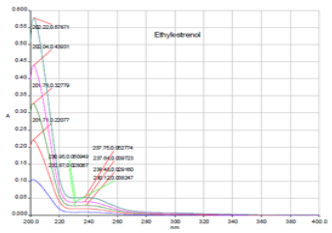
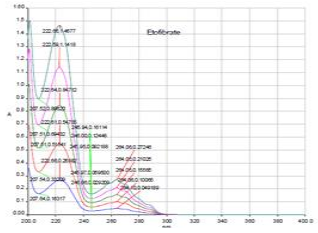
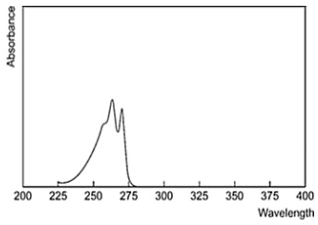
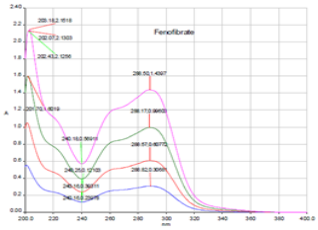
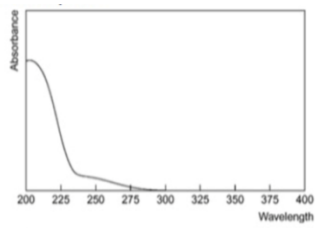
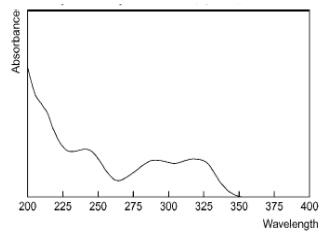
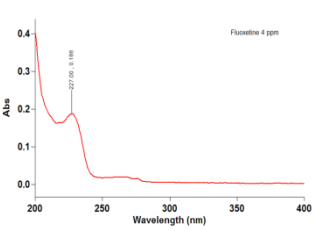
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
41	Chlorzoxazone	1050	3.5	350	350	10	
42	Cimetidine	1500	5.0	500	500	10	
43	Cinnarizine	600	2.0	200	200	10	
44	Clobenzorex	375	–	125	10	10	
45	Clofibrate	1500	5.0	500	500	10	
46	Cocaine	750	2.5	250	250	10	
47	Colchicine	750	2.5	250	250	10	

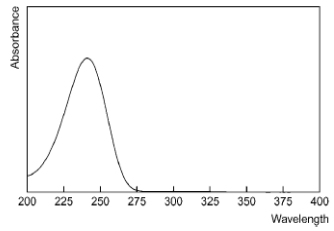
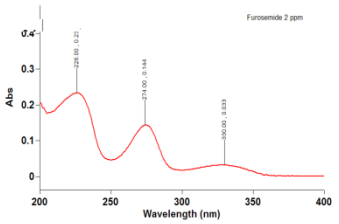
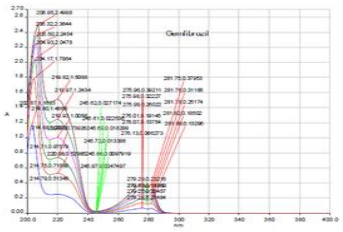
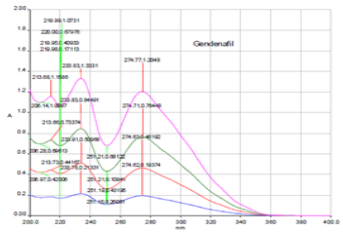
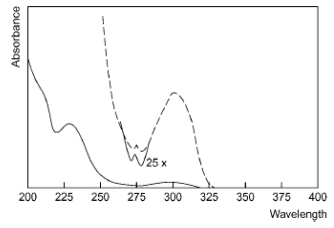
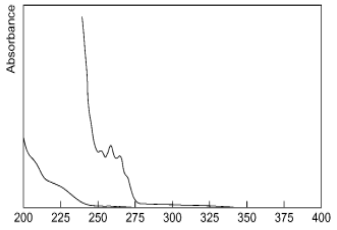
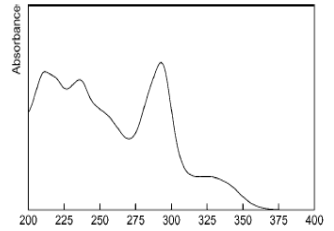
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			紫外光吸收法	呈色劑呈色			
48	Cortisone	750	2.5	250	250	10	
49	7-keto-Dehydroepiandrosterone	3000	10.0	1000	1000	10	
50	N-Desethylvardenafil	3000	10.0	1000	–	10	
51	N-Desmethylacetildenafil	3000	10.0	1000	–	10	
52	N-Desmethylsibutramine	3000	10.0	1000	1000	10	
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54	N-Didesmethylsibutramine	3000	10.0	1000	1000	10	

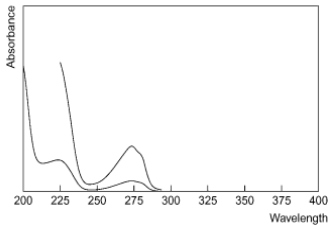
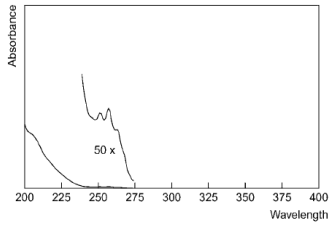
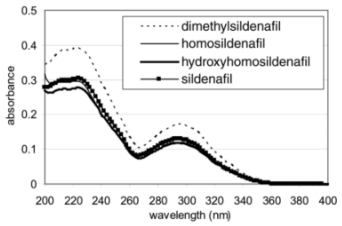
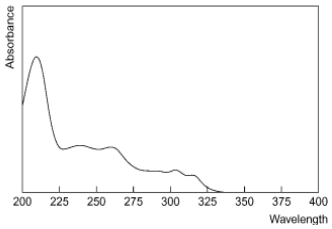
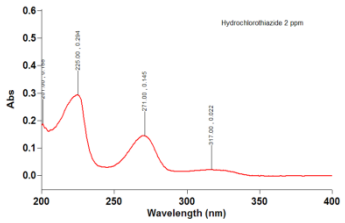
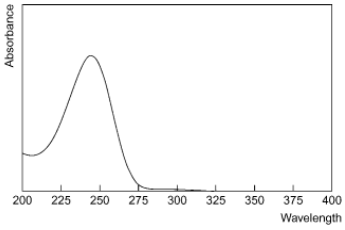
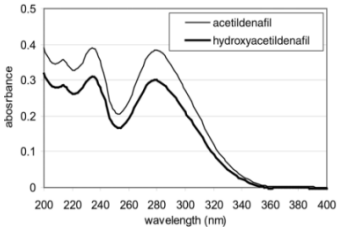
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
55	Dexamethasone	1200	4.0	400	400	10	
56	Dextromethorphan	1500	5.0	500	500	10	
57	Diazepam	300	1.0	100	100	10	
58	Dibucaine	450	1.5	150	150	10	
59	Diclofenac	600	2.0	200	200	10	
60	Dicyclomine	375	–	125	10	10	
61	Diethylpropion	450	1.5	150	150	10	

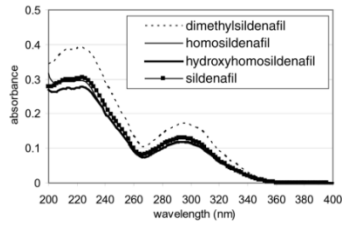
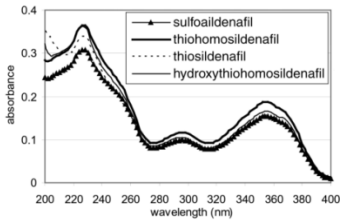
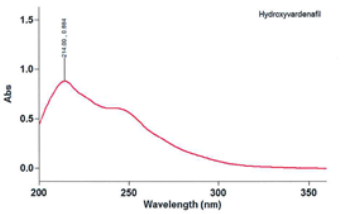
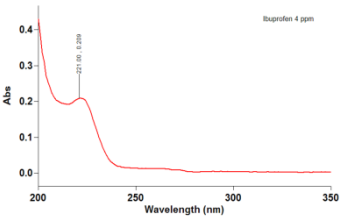
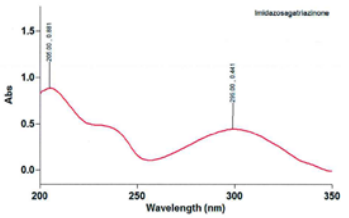
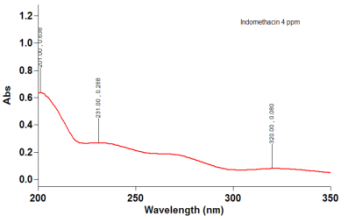
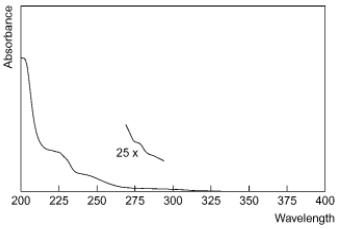
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
62	Diethylstilbestrol	600	2.0	200	200	10	
63	Digitoxin	450	–	150	–	10	
64	Dimethylsildenafil	3000	10.0	1000	1000	10	
65	Diphenhydramine	375	–	125	10	10	
66	Diphenylhydantoin	150	–	50	50	10	
67	Diprophylline	900	3.0	300	300	10	
68	Dipyridamole	450	1.5	150	–	10	

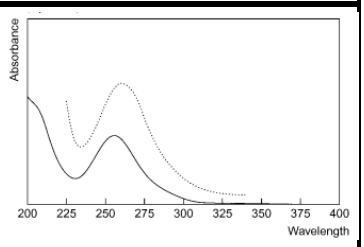
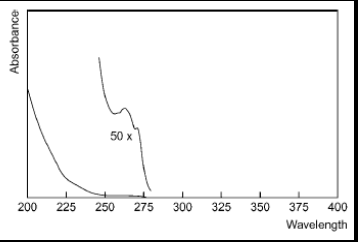
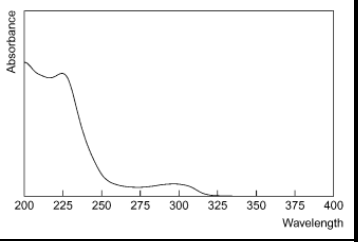
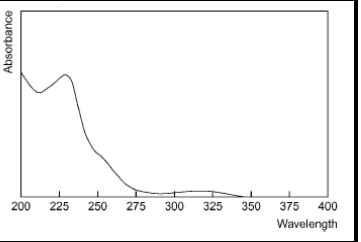
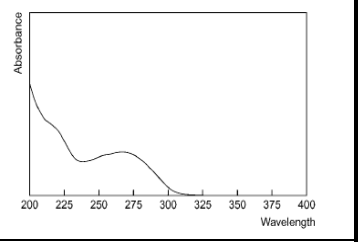
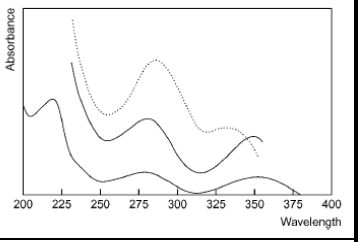
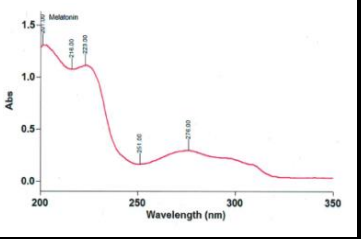
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
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			紫外光吸收法	呈色劑呈色			
69	Econazole	150	–	50	20	10	
70	Estradiol	1200	4.0	400	400	10	
71	Estriol	60	–	20	20	10	
72	Estrone	30	–	10	10	10	
73	Ethinylestradiol	30	–	10	10	10	
74	Ethisterone	600	2.0	200	200	10	
75	Ethoxybenzamide	600	2.0	200	200	10	

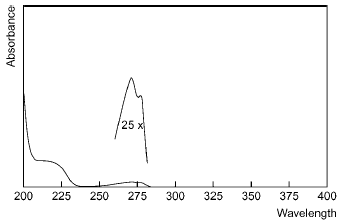
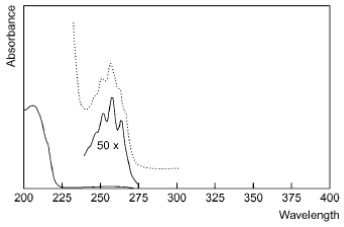
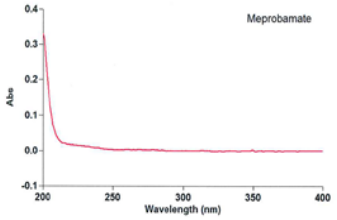
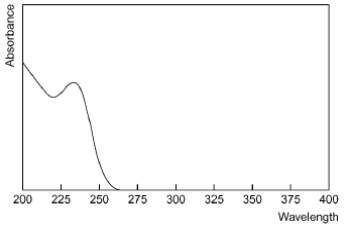
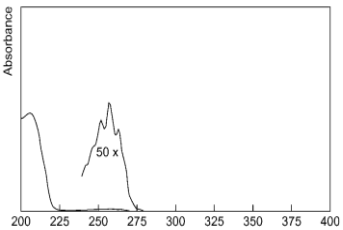
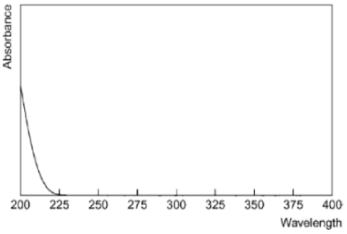
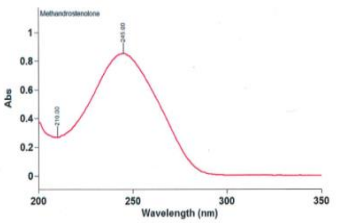
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			紫外光吸收法	呈色劑呈色			
76	Ethylestrenol	30	–	10	10	10	
77	Etofibrate	3000	10	100	–	10	
78	Fenfluramine	375	–	125	10	10	
79	Fenofibrate	3000	10.0	1000	–	10	
80	Finasteride (Proscar)	3000	10.0	1000	1000	10	
81	Flavoxate	900	3.0	300	300	10	
82	Fluoxetine	1200	4.0	400	400	10	

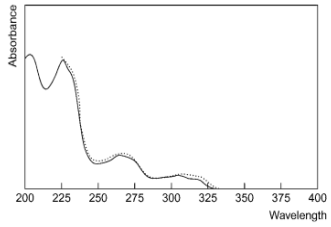
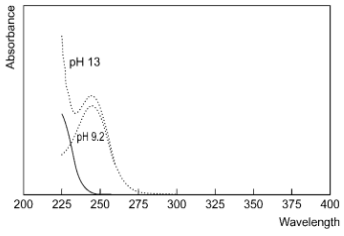
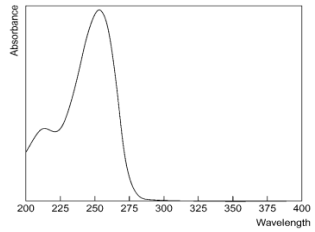
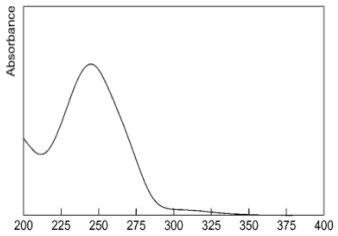
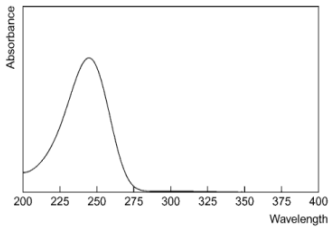
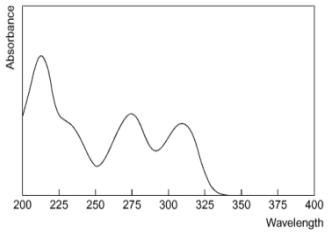
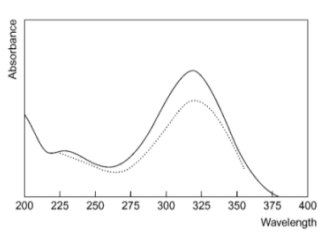
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			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
83	Fluoxymesterone	600	2.0	200	200	10	
84	Furosemide	600	2.0	200	–	10	
85	Gemfibrozil	4500	15.0	1500	1500	10	
86	Gendenafil	3000	10.0	1000	1000	10	
87	Glibenclamide	4800	16.0	1600	–	10	
88	Glycopyrronium	900	–	300	–	10	
89	Griseofulvin	450	1.5	150	150	10	

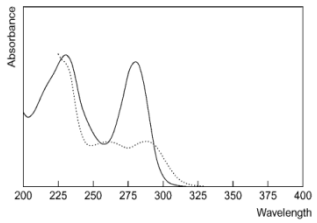
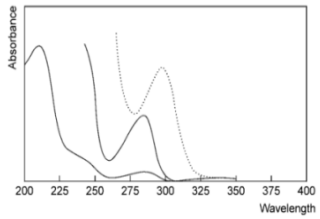
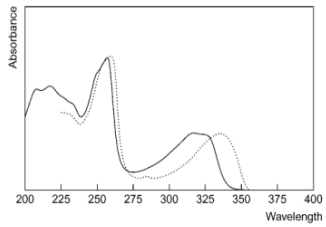
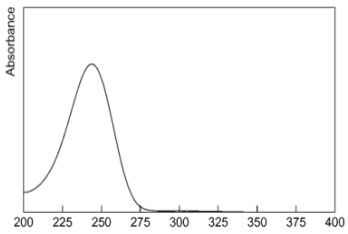
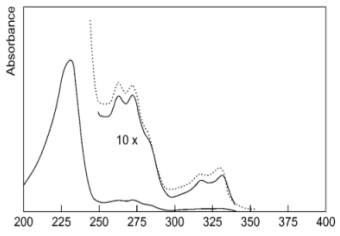
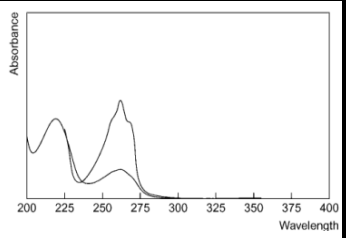
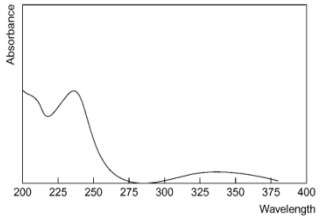
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			紫外光吸收法	呈色劑呈色			
90	Guaifenesin	2400	8.0	800	800	10	
91	Homatropine	150	–	50	20	10	
92	Homosildenafil	1350	4.5	450	450	10	
93	Hydralazine	450	1.5	150	150	10	
94	Hydrochlorothiazide	600	2.0	200	–	10	
95	Hydrocortisone	750	2.5	250	250	10	
96	Hydroxyacetildenafil	600	2.0	200	–	10	

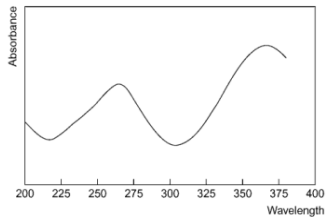
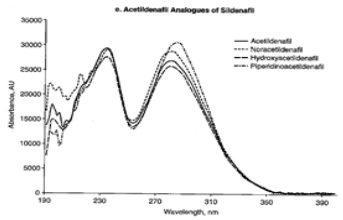
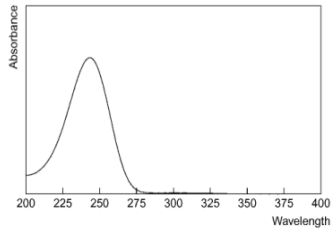
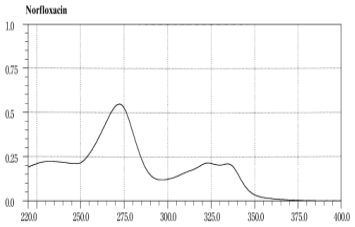
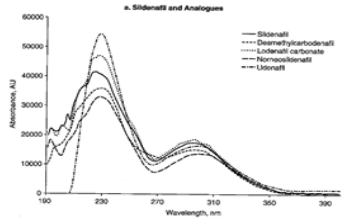
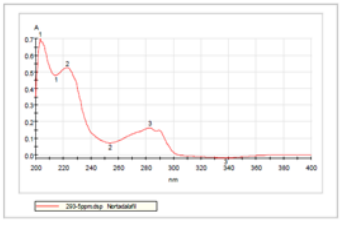
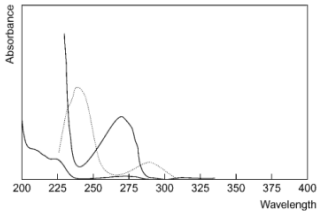
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
97	Hydroxyhomosildenafil	1200	4.0	400	–	10	
98	Hydroxythiohomosildenafil	1650	5.5	550	–	10	
99	Hydroxyvardenafil	1500	5.0	500	–	10	
100	Ibuprofen	1200	4.0	400	400	10	
101	Imidazosagatriazinone	1200	4.0	400	400	10	
102	Indomethacin	1200	4.0	400	400	10	
103	Ketoconazole	300	–	100	–	10	

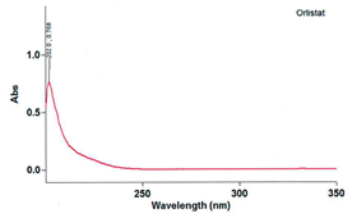
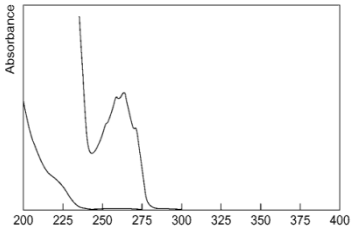
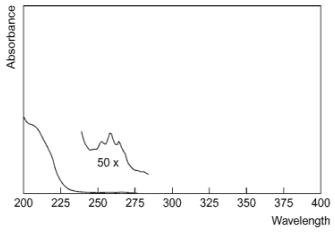
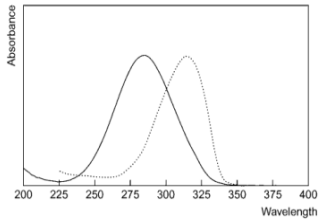
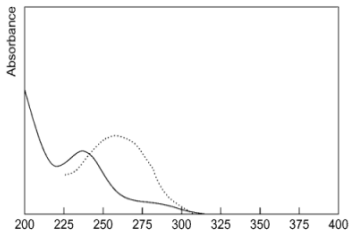
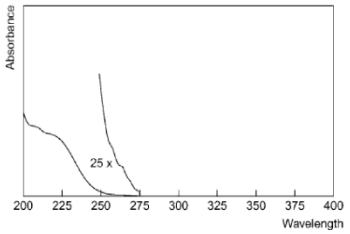
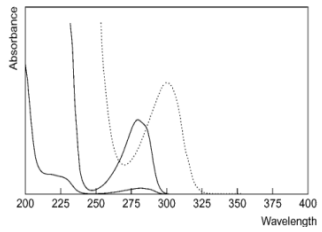
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
104	Ketoprofen	450	1.5	150	150	10	
105	Lidocaine	60	–	20	10	10	
106	Liothyronine	3600	12	1200	–	10	
107	Lorazepam	300	1.0	100	100	10	
108	Mazindol	1950	6.5	650	650	10	
109	Mefenamic acid	900	3.0	300	300	10	
110	Melatonin	1200	4.0	400	400	10	

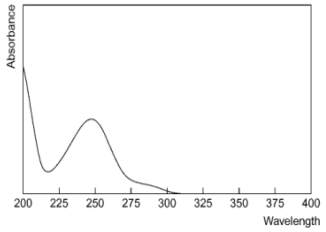
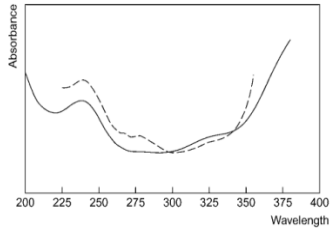
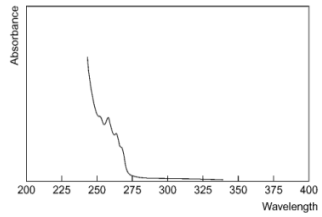
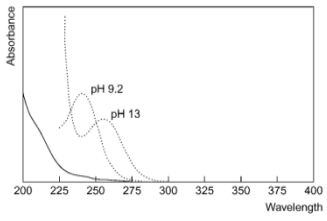
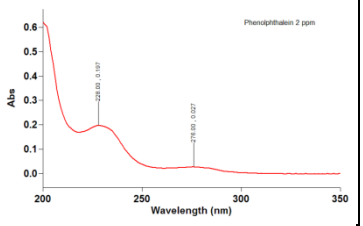
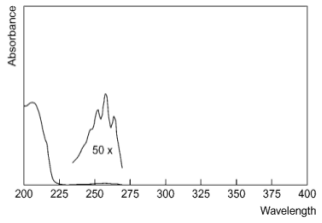
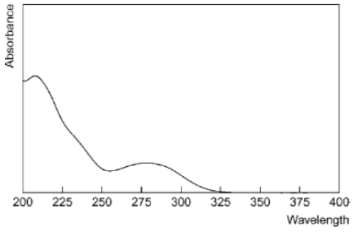
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
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			紫外光吸收法	呈色劑呈色			
111	Mephenesin	150	–	50	50	10	
112	Mephentermine	240	–	80	20	10	
113	Meprobamate	375	–	125	50	10	
114	Metformin	300	1.0	100	–	10	
115	Methamphetamine	750	–	250	20	10	
116	Methandriol	2400	8.0	800	800	10	
117	Methandrostenolone	600	2.0	200	200	10	

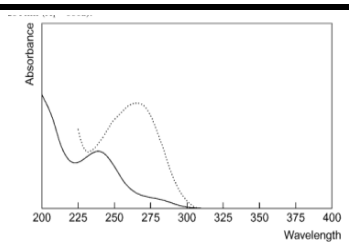
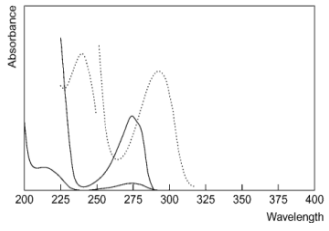
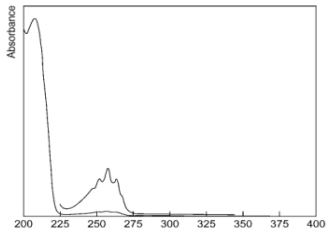
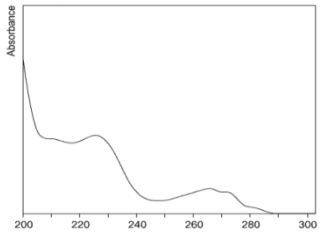
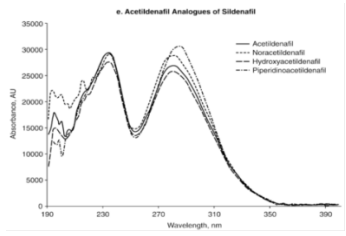
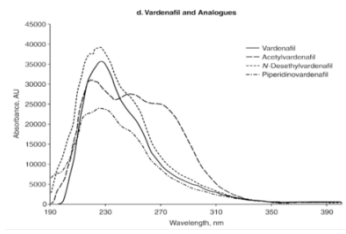
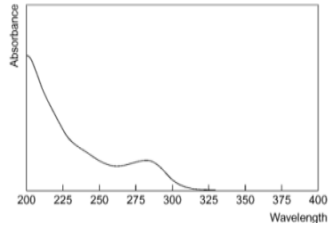
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
118	Methaqualone	900	3.0	300	300	10	
119	Metharbital	750	2.5	250	250	10	
120	Methimazole	300	1.0	100	100	10	
121	Methylprednisolone	750	2.5	250	250	10	
122	Methyltestosterone	600	2.0	200	200	10	
123	Metoclopramide	750	2.5	250	250	10	
124	Metronidazole	900	3.0	300	300	10	

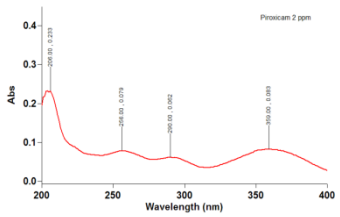
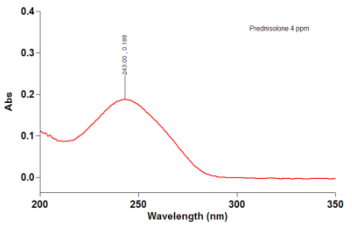
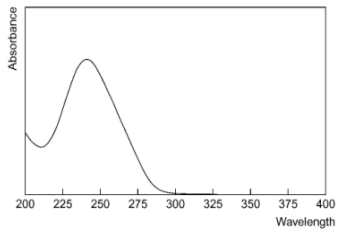
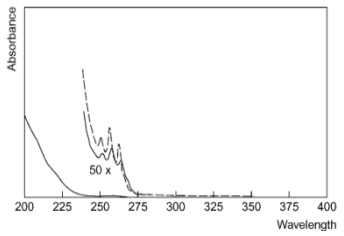
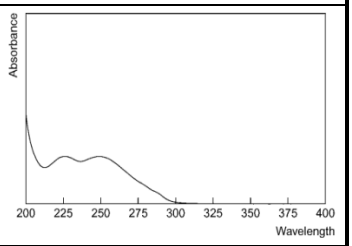
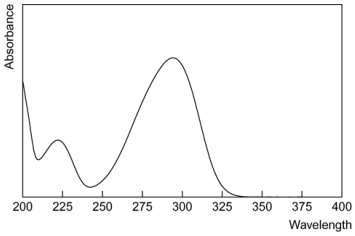
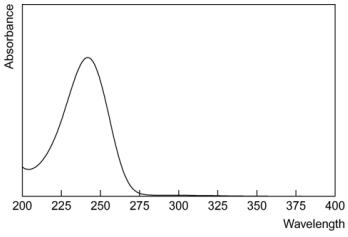
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
125	Minoxidil	600	2.0	200	200	10	
126	Morphine	150	–	50	50	10	
127	Nalidixic acid	300	1.0	100	100	10	
128	Nandrolone	750	2.5	250	250	10	
129	Naproxen	900	–	300	300	10	
130	Nicametate	2550	8.5	850	–	10	
131	Nifedipine	600	2.0	200	200	10	

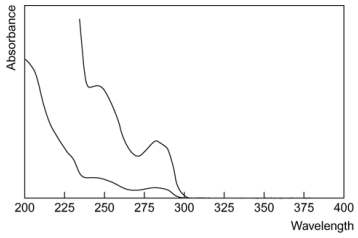
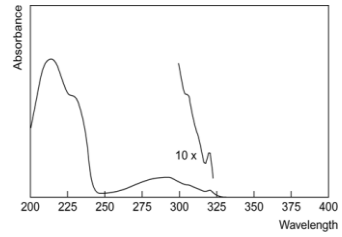
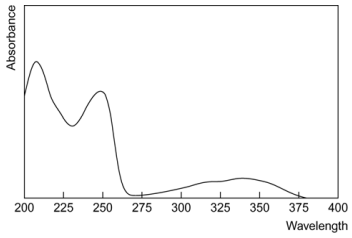
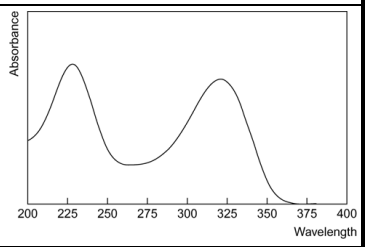
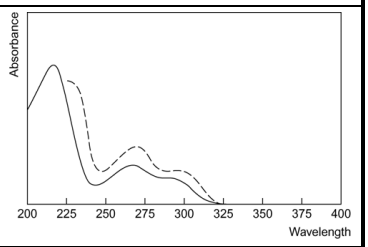
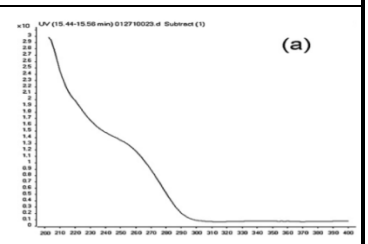
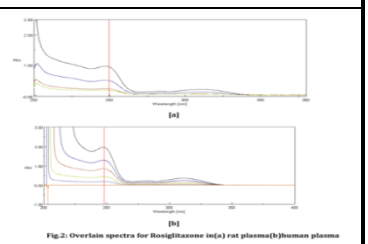
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
132	Nitrofurantoin	450	1.5	150	–	10	
133	Noracetildenafil	300	–	100	100	10	
134	Norethisterone	600	2.0	200	200	10	
135	Norfloxacin	300	1.0	100	–	10	
136	Norneosildenafil	1000	3.3	330	–	10	
137	Nortadalafil	1500	5.0	500	–	10	
138	Nylidrin	4500	15	1500	–	10	

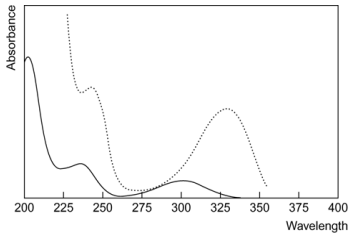
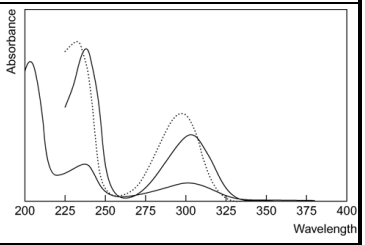
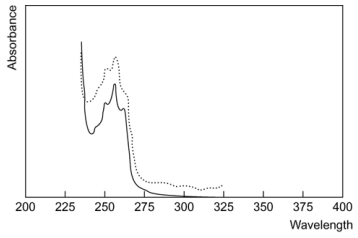
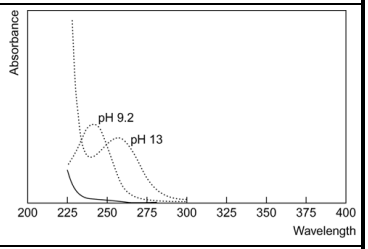
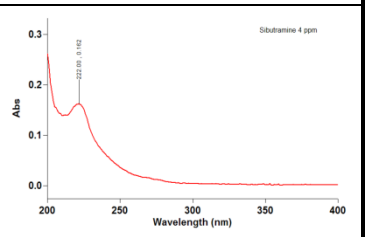
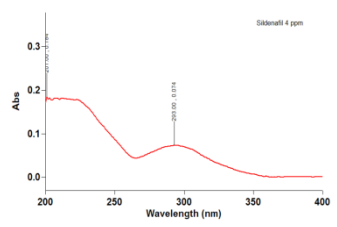
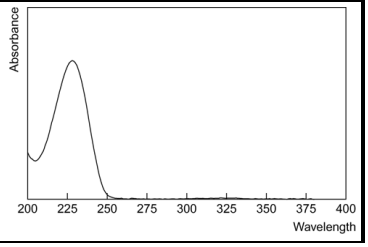
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
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			紫外光吸收法	呈色劑呈色			
139	Orlistat	375	–	125	10	10	
140	Orphenadrine	300	–	100	10	10	
141	Oxethazaine	150	–	50	50	10	
142	Oxymetholone	1050	3.5	350	350	10	
143	Oxyphenbutazone	450	1.5	150	150	10	
144	Oxyphencyclimine	75	–	25.0	–	10	
145	Pentazocine	300	–	100	10	10	

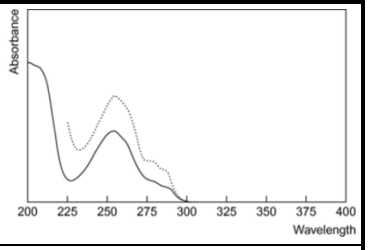
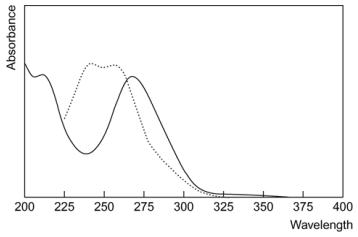
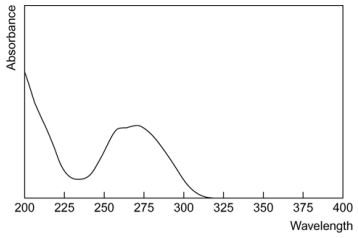
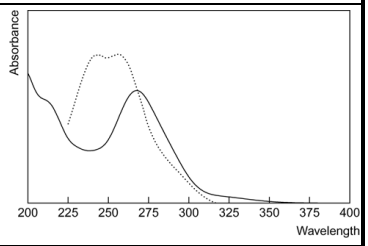
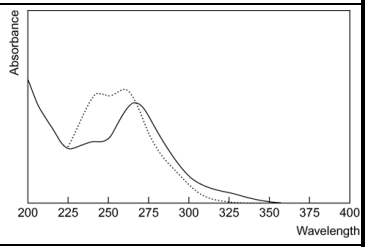
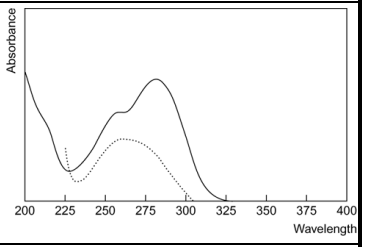
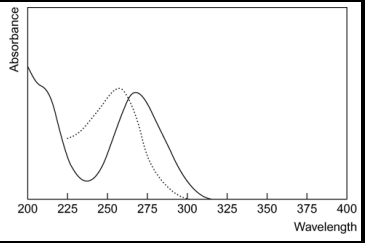
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			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
146	Phenacetin	300	1.0	100	100	10	
147	Phenazopyridine	750	2.5	250	250	10	
148	Phenformin	900	–	300	100	10	
149	Phenobarbital	900	3.0	300	300	10	
150	Phenolphthalein	600	2.0	200	200	10	
151	Phentermine	1500	–	500	20	10	
152	Phentolamine	1500	–	500	500	10	

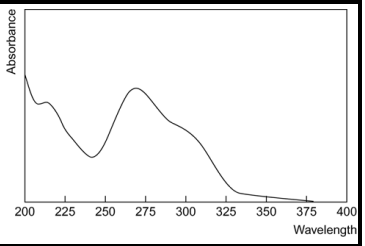
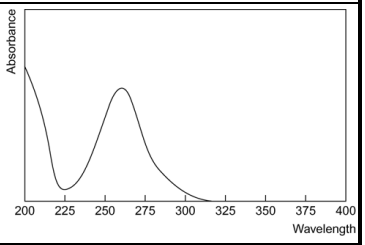
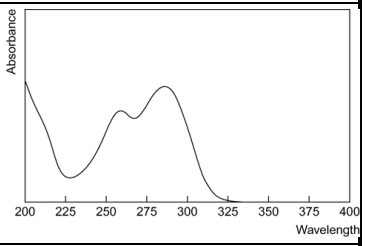
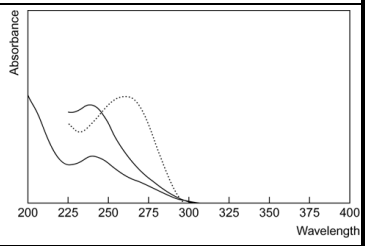
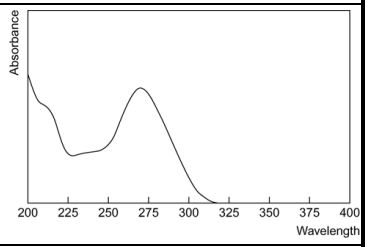
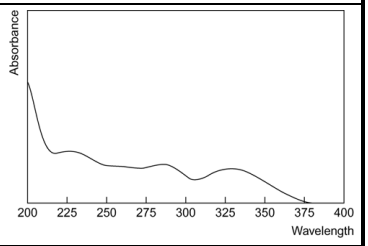
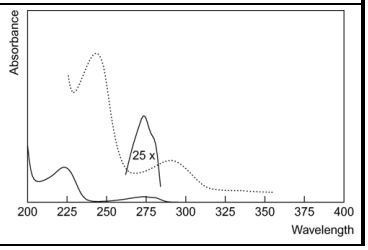
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			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
153	Phenylbutazone	750	2.5	250	250	10	
154	Phenylephrine	2850	9.5	950	950	10	
155	Phenylpropanolamine	60	–	20	20	10	
156	Pioglitazone	1200	4.0	400	–	10	
157	Piperiacetildenafil	3000	10.0	1000	–	10	
158	Piperidenafil	1500	5.0	500	500	10	
159	Pirenzepine	1350	4.5	450	450	10	

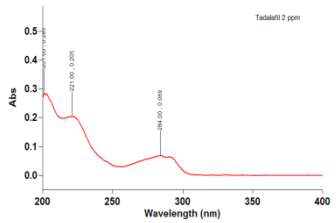
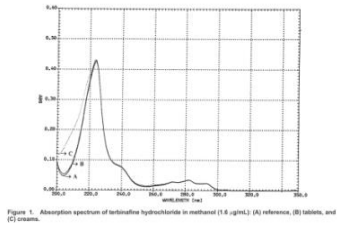
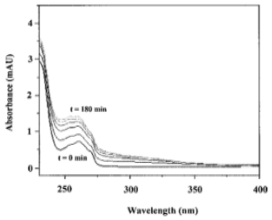
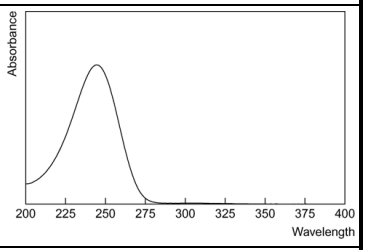
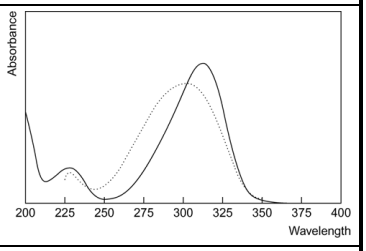
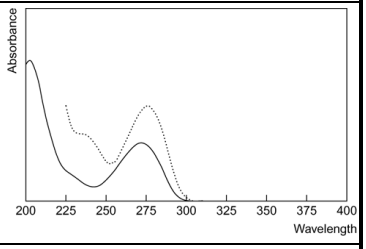
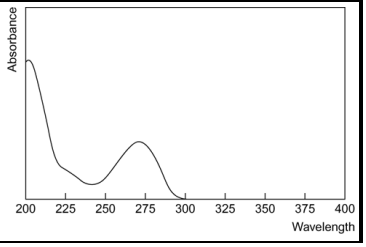
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
160	Piroxicam	600	2.0	200	200	10	
161	Prednisolone	1200	4.0	400	400	10	
162	Prednisone	750	2.5	250	250	10	
163	Primidone	1500	–	500	10	10	
164	Probenecid	900	3.0	300	300	10	
165	Procaine	300	1.0	100	100	10	
166	Progesterone	600	2.0	200	200	10	

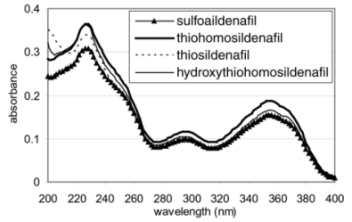
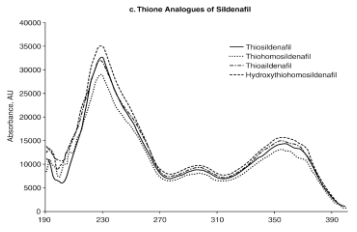
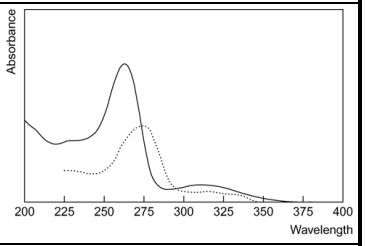
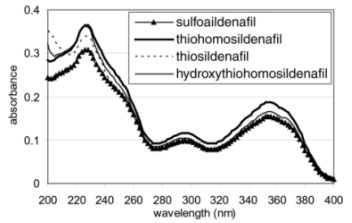
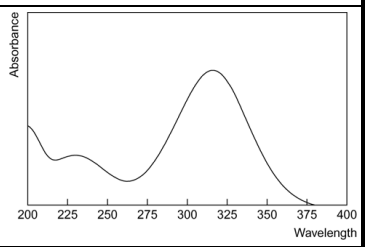
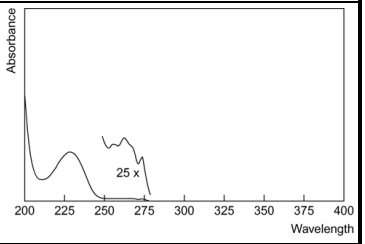
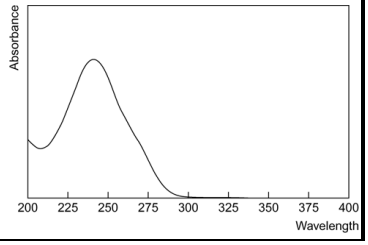
編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
167	Propantheline	3000	10.0	1000	1000	10	
168	Propranolol	1350	4.5	450	450	10	
169	Quinine	300	1.0	100	100	10	
170	Ranitidine	600	2.0	200	200	10	
171	Reserpine	1200	4.0	400	–	10	
172	Rimonabant	3000	10.0	1000	1000	10	
173	Rosiglitazone	3000	10.0	1000	–	10	

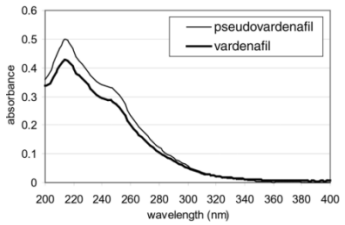
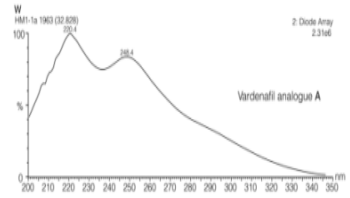
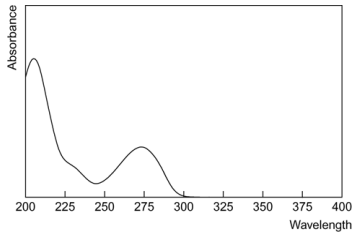
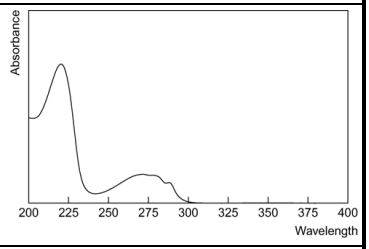
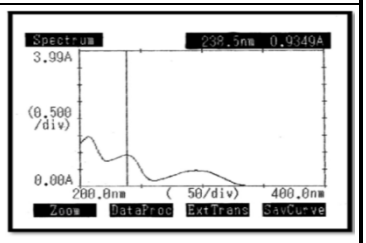
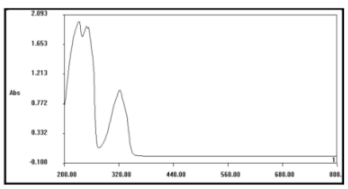
編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
174	Salicylamide	600	2.0	200	200	10	
175	Salicylic acid	900	3.0	300	300	10	
176	Scopolamine	150	–	50	50	10	
177	Secobarbital	900	3.0	300	300	10	
178	Sibutramine	1200	4.0	400	400	10	
179	Sildenafil	1200	4.0	400	400	10	
180	Stanozolol	2100	7.0	700	700	10	

編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
181	Strychnine	900	3.0	300	300	10	
182	Sulfadiazine	600	2.0	200	200	10	
183	Sulfadimethoxine	750	2.5	250	250	10	
184	Sulfamerazine	450	1.5	150	150	10	
185	Sulfamethazine	600	2.0	200	200	10	
186	Sulfamethizole	600	2.0	200	–	10	
187	Sulfamethoxazole	600	2.0	200	200	10	

編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
188	Sulfamethoxypyridazine	450	1.5	150	150	10	
189	Sulfanilamide	375	–	125	100	10	
190	Sulfathiazole	600	2.0	200	–	10	
191	Sulfinpyrazone	750	2.5	250	250	10	
192	Sulfisoxazole	450	1.5	150	–	10	
193	Sulindac	750	2.5	250	250	10	
194	Synephrine	450	1.5	150	150	10	

編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
195	Tadalafil	600	2.0	200	200	10	
196	Terbinafine	300	1.0	100	100	10	
197	Terfenadine	450	1.5	150	–	10	
198	Testosterone	600	2.0	200	200	10	
199	Tetracaine	600	2.0	200	200	10	
200	Theobromine	600	2.0	200	200	10	
201	Theophylline	600	2.0	200	200	10	

編號	名稱	偵測極限 (µg/g)	評估方法及濃度(µg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
202	Thiodimethylsildenafil	450	1.5	150	150	10	
203	Thiohomosildenafil	450	1.5	150	150	10	
204	Thioridazine	300	1.0	100	100	10	
205	Thiosildenafil	450	1.5	150	150	10	
206	Tinidazole	900	3.0	300	300	10	
207	Tolbutamide	375	–	125	50	10	
208	Triamcinolone	900	3.0	300	–	10	

編號	名稱	偵測極限 (μg/g)	評估方法及濃度(μg/ml)				備註 (UV 圖譜僅供參考，因溶劑不同，可能有所差異。
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀	
			紫外光吸收法	呈色劑呈色			
209	Vardenafil	1800	6.0	600	–	10	
210	Vardenafil analogue	1800	6.0	600	600	10	 Figure 9. UV spectra of vardenafil and vardenafil analogue A.
211	Xanthinol Niacinate	1050	3.5	350	–	10	
212	Yohimbine	1500	5.0	500	500	10	
213	Zolpidem	300	1.0	100	100	10	
214	Cetilistat	1500	5.0	500	500	–	 Figure 3: Wavelength of maximum absorption of cetilistat

註：1. *Estradiol Benzoate 主要用於針劑，修正為常用於口服劑型如錠劑、膠囊之 Estradiol。

2. 「－」表示該西藥成分無法以此方法評估偵測極限。

3. 評估方法濃度加底線者，表示檢驗範圍偵測極限由該檢測方法換算而得。

表二、Estradiol 及 Orlistat 西藥成分之氣相層析質譜分析參數

編號	名稱	分子式	分子量	鑑別離子
70	Estradiol	$C_{18}H_{24}O_2$	272	272, 146, 160, 145, 159, 213, 172
139	Orlistat	$C_{29}H_{53}NO_5$	495	292, 114, 69, 96, 55, 82

註：1. 離子化模式：電子撞擊游離(EI)。

2. 碰撞能量：70eV。

3. 以上參數不適時，依所使用之儀器，設定適合之參數。

表三、Estradiol 及 Orlistat 西藥成分之液相層析串聯質譜分析參數

編號	名稱	分子式	分子量	離子化模式	進樣錐電壓(V)	碰撞能量(eV)	前驅離子(m/z)	產物離子(m/z)
70	Estradiol	$C_{18}H_{24}O_2$	272	ESI-	30	40	271	145, 183, 239
139	Orlistat	$C_{29}H_{53}NO_5$	495	ESI-	40	14	494	158, 140, 266, 451

註：1. 毛細管電壓均為 3kV。

2. 以上參數不適時，依所使用之儀器，設定適合之參數。

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「中藥及食品中摻加西藥成分定性(214項)認證檢驗範圍偵測極限評估」指引修正總說明

為使「中藥及食品中摻加西藥成分定性(214項)」認證檢驗範圍偵測極限評估有所依循，特定此指引，本指引所稱之偵測極限非學理上之偵測極限，為考量認證實驗室儀器感度及參考文獻資料所得之值，另整合認證實驗室依其儀器所評估出之偵測極限，做部分調整變動，其修正要點如下：

一、將原備註中UV及TLC呈色法等實驗操作敘述移至2.方法中修訂為2.4 UV及2.5 TLC呈色法、GC/MS或LC/MS/MS。

二、增列3.判定原則：3.1檢驗結果之判定應依表一之偵測極限，以薄層層析法(紫外光吸收或呈色劑呈色)與質譜法(GC/MS或LC/MS/MS)二種原理均有檢出時，方可認定為檢出。

三、「附表」修正23項西藥之薄層層析法(呈色劑呈色)濃度、最終偵測極限及Aspirin薄層層析法(呈色劑呈色)濃度及氣相層析質譜儀濃度之誤植之情形。

西藥成分定性(214項)偵測極限修正對照表

修正指引	現行指引	說明
1 目的： 為使「中藥及食品中摻加西藥成分定性(214項)」認證檢驗範圍偵測極限評估有所依循，特定此文件，本文所稱之偵測極限非學理上之偵測極限，為考量認證實驗室儀器感度及參考文獻資料所得之值。 2 方法： 2.1 配製適當標準溶液，分別以紫外光吸收法、薄層層析法(呈色劑呈色)、氣相層析質譜儀或液相層析串聯質譜儀評估其偵測極限，表一為各方法之偵測極限，方法偵測極限濃度較高者訂為該藥物之偵測極限。 2.2 結果判定：標準品與空白試驗可明確鑑別之濃度訂為偵測極限。 2.3 Estradiol及Orlistat之氣相層析質譜及液相層析串聯質譜儀之參考分析參數如表二及表三。 2.4 UV：假設檢體取5 g，加入15 mL溶劑溶解，點注檢液10 μL在薄層層析板上，刮下斑點，加入1 mL溶劑溶解，稀釋倍數為300倍，評估濃度乘上300倍為UV方法之偵測極限。 2.5 TLC呈色法、GC/MS或LC/MS/MS：假設檢體取5 g，加入15 mL溶劑溶解，稀釋倍數為3倍，評估濃度乘上3倍為各方法之偵測極限。 3 判定原則： 3.1 檢驗結果之判定應依表一之偵測極限，以薄層層析法(紫外光吸收或呈色劑呈色)與質譜法(GC/MS或LC/MS/MS)二種原理均有檢出時，方可認定為檢出。	1 目的： 為使「中藥及食品中摻加西藥成分定性(214項)」認證檢驗範圍偵測極限評估有所依循，特定此文件，本文所稱之偵測極限非學理上之偵測極限，為考量認證實驗室儀器感度及參考文獻資料所得之值。 2 方法： 2.1 配製適當標準溶液，分別以紫外光吸收法、薄層層析法(呈色劑呈色)、氣相層析質譜儀或液相層析串聯質譜儀評估其偵測極限，表一為各方法之偵測極限，方法偵測極限濃度較高者訂為該藥物之偵測極限。 2.2 結果判定：標準品與空白試驗可明確鑑別之濃度訂為偵測極限。 2.3 Estradiol及Orlistat之氣相層析質譜及液相層析串聯質譜儀之參考分析參數如表二及表三。	1. 由原備註處移入2 方法，修訂為2.4 UV及2.5 TLC呈色法、GC/MS或LC/MS/MS。 2. 增列3 判定原則: 3.1敘述。

西藥成分定性(214項)偵測極限修正對照表

修正指引	現行指引	說明

表一、中藥及食品中摻加西藥成分214項之偵測極限

編號	名稱	偵測極限(μg/g)	評估方法及濃度(μg/ml)			
			薄層層析法		氣相層析質譜儀	液相層析串聯質譜儀
			紫外光吸收	呈色劑呈色		
10	Amphetamine	375	-	125	20	10
11	Aspirin	600	2.0	200	200	10
13	Atropine	150	-	50	10	10
28	Carbetapentane	150	-	150	10	10
32	Carisoprodol	375	-	125	20	10
35	Chlormezanone	1200	-	400	20	10
44	Clobenzorex	375	-	125	10	10
60	Dicyclomine	375	-	125	10	10
65	Diphenhydramine	375	-	125	10	10
69	Econazole	150	-	50	20	10
78	Fenfluramine	375	-	125	10	10
91	Homatropine	150	-	50	20	10
105	Lidocaine	60	-	20	10	10
112	Mephentermine	240	-	80	20	10
113	Meprobamate	375	-	125	50	10
115	Methamphetamine	750	-	250	20	10
139	Orlistat	375	-	125	10	10
140	Orphenadrine	300	-	100	10	10
145	Pentazocine	300	-	100	10	10
148	Phenformin	900	-	300	100	10
151	Phentermine	1500	-	500	20	10
163	Primidone	1500	-	500	10	10
189	Sulfanilamide	375	-	125	100	10
207	Tolbutamide	375	-	125	50	10

表一、中藥及食品中摻加西藥成分214項之偵測極限

編號	名稱	偵測極限(μg/g)	評估方法及濃度(μg/ml)			
			紫外光吸收	薄層層析法呈色劑呈色	氣相層析質譜儀	液相層析串聯質譜儀
10	Amphetamine	60	-	20	20	10
11	Aspirin	600	2.0	300	300	10
13	Atropine	30	-	10	10	10
28	Carbetapentane	30	-	10	10	10
32	Carisoprodol	60	-	20	20	10
35	Chlormezanone	60	-	20	20	10
44	Clobenzorex	30	-	10	10	10
60	Dicyclomine	30	-	10	10	10
65	Diphenhydramine	30	-	10	10	10
69	Econazole	60	-	20	20	10
78	Fenfluramine	30	-	10	10	10
91	Homatropine	60	-	20	20	10
105	Lidocaine	30	-	10	10	10
112	Mephentermine	60	-	20	20	10
113	Meprobamate	150	-	50	50	10
115	Methamphetamine	60	-	20	20	10
139	Orlistat	30	-	10	10	10
140	Orphenadrine	30	-	10	10	10
145	Pentazocine	30	-	10	10	10
148	Phenformin	300	-	100	100	10
151	Phentermine	60	-	20	20	10
163	Primidone	30	-	10	10	10
189	Sulfanilamide	300	-	100	100	10
207	Tolbutamide	150	-	50	50	10

修正方法標示及24項西藥偵測極限數值之調整。

西藥成分定性(214項)偵測極限修正對照表

修正指引	現行指引	說明
註：1. *Estradiol Benzoate主要用於針劑，修正為常用於口服劑型如錠劑、膠囊之Estradiol。 2.「–」表示該西藥成分無法以此方法評估偵測極限。 3. 評估方法濃度加底線者，表示檢驗範圍偵測極限由該檢測方法換算而得。 ~~UV：假設檢體取5 g，加入15 mL溶劑溶解，點注檢液10 μL在薄層層析板上，刮下斑點，加入1 mL溶劑溶解，稀釋倍數為300倍，評估濃度乘上300倍為UV方法之偵測極限。~~ ~~TLC呈色法、GC/MS或LC/MS/MS：假設檢體取5 g，加入15 mL溶劑溶解，稀釋倍數為3倍，評估濃度乘上3倍為各方法之偵測極限。~~	註：1. *Estradiol Benzoate主要用於針劑，修正為常用於口服劑型如錠劑、膠囊之Estradiol。 2.「–」表示該西藥成分無法以此方法評估偵測極限。 3. 評估方法濃度加底線者，表示檢驗範圍偵測極限由該檢測方法換算而得。 UV：假設檢體取5 g，加入15 mL溶劑溶解，點注檢液10 μL在薄層層析板上，刮下斑點，加入1 mL溶劑溶解，稀釋倍數為300倍，評估濃度乘上300倍為UV方法之偵測極限。 TLC呈色法、GC/MS或LC/MS/MS：假設檢體取5 g，加入15 mL溶劑溶解，稀釋倍數為3倍，評估濃度乘上3倍為各方法之偵測極限。	調整說明移至2.4及2.5。