

### 測試報告

報告編號: UP/2017/A0680A-01 日期: 2017年11月13日 頁數:1 of 7

#### 冠泰藥業有限公司

台中市西區民權路185號10F11室

以下測試之樣品係由申請廠商所提供及確認:

產品名稱: Viva 鈣片螯合釋放膜衣錠

申請廠商: 瑞法貿易有限公司

產品型號/批號: ---

生產或供應廠商: VIVA PHARMACEUTICAL INC

樣品狀態: 請參考報告末頁樣品照片

製造日期: --

有效期限: 2021年08月23日 收樣日期: 2017年10月30日

測試日期: 2017年10月30日~2017年11月13日

委託測試項目: 312項常見西藥成份分析

**測試方法:** 本測試參考衛生福利部食品藥物管理署建議方法-中藥及食品中摻加西藥之檢驗方法,以薄

層層析法(TLC)、液相層析離子阱質譜儀(LC/MS/MS)或氣相層析質譜儀(GC/MS)檢測。

測試結果: 此份樣品共檢測312項常見西藥成份(詳附錄),均未檢出。

備註:1.測試報告僅就委託者之委託事項提供測試結果,不對產品合法性做判斷。

2. 本報告不得分離,分離使用無效。

3. 檢測結果若大於方法偵測極限則匯整上表中,本次檢測項目及方法偵測極限分别詳列於附錄中。

Signed for and on behalf

SGS Taiwan Ltd.

Shin-Jyh Chen

台灣檢驗科技股份有限公司

Manager

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## 測試報告

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### 冠泰藥業有限公司

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#### 附 錄

<u>測試項目及MDL匯整表:</u> 單位:ppm(mg/kg)

測試項目及MDL匯登表: 測試項目	平位.ppm(mg/kg 類別	方法偵測 極限	測試項目	類别	方法偵測 極限
Digitoxin	心臟血管類用藥	100	Meperidine	局部麻醉類	10
Dipyridamole	心臟血管類用藥	10	Chloramphenicol	抗生素類	10
Nylidrin	心臟血管類用藥	10	Econazole	抗生素類	10
Papaverine	心臟血管類用藥	100	Griseofulvin	抗生素類	10
Diltiazem	心臟血管類用藥	10	Lomefloxacin	抗生素類	10
Verapamil	心臟血管類用藥	10	Ketoconazole	抗生素類	20
Desacetyl diltiazem	心臟血管類用藥	10	Metronidazole	抗生素類	10
Prazosin	心臟血管類用藥	10	Nalidixic acid	抗生素類	10
Pentoxifylline	心臟血管類用藥	10	Nitrofurantoin	抗生素類	100
Benazepril	心臟血管類用藥	50	Minocycline	抗生素類	20
Bisoprolol Fumarate	心臟血管類用藥	10	Quinine	抗生素類	10
Carvedilol	心臟血管類用藥	250	Sulfaquinoxaline	抗生素類	20
Dihydroergotamine	心臟血管類用藥	250	Sulfamonomethoxine(SMM)	抗生素類	20
Doxazosin	心臟血管類用藥	250	Sulfadiazine	抗生素類	20
Aminophylline	支氣管擴張劑	100	Sulfadimethoxine	抗生素類	10
Theophylline	支氣管擴張劑	100	Sulfamerazine	抗生素類	10
Clenbuterol	支氣管擴張劑	10	Sulfamethazine	抗生素類	10
Dyphylline	支氣管擴張劑	100	Sulfamethizole	抗生素類	100
Fenoterol	支氣管擴張劑	250	Sulfamethoxazole	抗生素類	10
Salbutamol	支氣管擴張劑	20	Sulfamethoxypyridazine	抗生素類	10
Carisoprodol	肌肉鬆弛劑	10	Sulfanilamide	抗生素類	100
Chlormezanone	肌肉鬆弛劑	100	Sulfathiazole	抗生素類	10
Chlorzoxazone	肌肉鬆弛劑	10	Sulfisoxazole	抗生素類	100
Orphenadrine	肌肉鬆弛劑	10	Terbinafine	抗生素類	10
Zolazepam HCl	肌肉鬆弛劑	10	Tinidazole	抗生素類	10
Benzocaine	局部麻醉類	50	Tetracycline	抗生素類	20
Dibucaine	局部麻醉類	10	Trimethoprim	抗生素類	10
Diclofenac	局部麻醉類	30	Benzathine-penicillin	抗生素類	250
Lidocaine	局部麻醉類	10	Clindamycin phosphate	抗生素類	20
Procaine	局部麻醉類	10	Cloxacillin Sodium	抗生素類	20
Tetracaine	局部麻醉類	10	Chlortetracycline	抗生素類	20
Noscapine	局部麻醉類	10	Ciprofloxacin(CFA)	抗生素類	10

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## 測試報告

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### 冠泰藥業有限公司

台中市西區民權路185號10F11室

#### 附 錄

測試項目及MDL匯整表: 單位:ppm(mg/kg)

測試項目	類别	方法偵測 極限	測試項目	類别	方法偵測 極限
Dimetridazole	抗生素類	100	Diethylpropion	其他	10
Enrofloxacin	抗生素類	10	Fenfluramine	其他	10
Lincomycin	抗生素類	10	Finasteride	其他	10
Difloxacin	抗生素類	10	Mazindol	其他	10
Ofloxacin	抗生素類	10	Phentermine	其他	10
Oxytetracycline (OTC)	抗生素類	20	Phentolamine	其他	10
Sulfisomidine	抗生素類	10	Phenylpropanolamine	其他	500
Santonin	抗生素類	50	Yohimbine	其他	10
Ampicillin	抗生素類	20	Nicotine	其他	10
Amoxicillin	抗生素類	100	Fluconazole	其他	25
Clindamycin HCl	抗生素類	10	Naltrexone	其他	10
Cephradine	抗生素類	50	Simvastatin	其他	10
Ceftriaxone	抗生素類	100	Methaqualone	其他	10
Doxycycline	抗生素類	20	Metharbital	其他	500
Erythromycin	抗生素類	10	Clobenzorex	其他	10
Rifampin	抗生素類	10	Salicylic acid	其他	250
Cefotaxime	抗生素類	10	Methimazole	治甲狀腺機能缺陷	100
Nifuroxazide	抗生素類	10	Carbimazole	治甲狀腺機能缺陷	200
Nitrofurazone	抗生素類	25	Liothyronine	治甲狀腺機能缺陷	10
Cefoperazone dihydrate	抗生素類	50	Chlorothiazide	泌尿系統用藥	10
Cefamandole nafate	抗生素類	10	Flavoxate	泌尿系統用藥	20
Brompheniramine	抗組織胺類	10	Furosemide	泌尿系統用藥	10
Carbinoxamine	抗組織胺類	10	Hydrochlorothiazide	泌尿系統用藥	500
Chlorpheniramine	抗組織胺類	10	Phenazopyridine	泌尿系統用藥	10
Diphenhydramine	抗組織胺類	10	Sulfinpyrazone	泌尿系統用藥	10
Terfenadine	抗組織胺類	10	Oxybutynin	泌尿系統用藥	10
Cyproheptadine	抗組織胺類	10	Norfloxacin	泌尿系統用藥	10
Cetirizine	抗組織胺類	10	Bezafibrate	降血脂用藥	10
Triprolidine	抗組織胺類	10	Fluvastatin	降血脂用藥	10
Ketotifen fumarate	抗組織胺類	10	Clofibrate	降血脂用藥	50
Astemizole	抗組織胺類	10	Etofibrate	降血脂用藥	10
Doxylamine	抗組織胺類	10	Fenofibrate	降血脂用藥	10

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## 測試報告

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### 冠泰藥業有限公司

台中市西區民權路185號10F11室

#### 附 錄

<u>測試項目及MDL匯整表:</u> 單位:ppm(mg/kg)

測試項目	類別	方法偵測 極限	測試項目	類别	方法偵測 極限
Gemfibrozil	降血脂用藥	150	Nandrolone	荷爾蒙類	200
Nicametate	降血脂用藥	50	Norethisterone acetate	荷爾蒙類	10
Xanthinol Niacinate	降血脂用藥	10	Oxymetholone	荷爾蒙類	100
Atorvastatin	降血脂用藥	10	Progesterone	荷爾蒙類	10
Atenolol	降血壓用藥	10	Stanozolol	荷爾蒙類	10
Hydralazine	降血壓用藥	100	Testosterone	荷爾蒙類	100
Minoxidil	降血壓用藥	10	Diethylstilbestrol	荷爾蒙類	200
Nifedipine	降血壓用藥	10	Estradiol	荷爾蒙類	200
Propranolol	降血壓用藥	10	Ethinylestradiol	荷爾蒙類	500
Reserpine	降血壓用藥	10	7-Keto dehydroepiandrosterone	減肥	10
Timolol Maleate	降血壓用藥	10	N-Desmethyl sibutramine	減肥	10
Methyl DOPA-Sesquihydrate	降血壓用藥	100	N-Didesmethyl sibutramine	減肥	10
Indapamide	降血壓用藥	50	Orlistat	減肥	10
Amlodipine	降壓、利尿類	10	Rimonabant	減肥	10
Nitrazepam	消化系統用藥	10	Sibutramine	減肥	10
Apomorphine	消化系統用藥	10	Synephrine	減肥	10
Dimenhydrinate	消化系統用藥	20	Cetilistat	減肥	50
Methamphetamine	神經興奮劑類	10	Mephentermine	減肥	-
Morphine	神經興奮劑類	100	Atropine	腸胃類用藥	10
Pentazocine	神經興奮劑類	10	Bisacodyl	腸胃類用藥	10
Phenylephrine	神經興奮劑類	100	Butropium bromide	腸胃類用藥	10
Strychnine	神經興奮劑類	10	Camylofine	腸胃類用藥	10
Theobromine	神經興奮劑類	50	Cimetidine	腸胃類用藥	10
Caffeine	神經興奮劑類	10	Dicyclomine	腸胃類用藥	10
Estriol	荷爾蒙類	100	Glycopyrronium	腸胃類用藥	10
Estrone	荷爾蒙類	50	Homatropine	腸胃類用藥	10
Ethisterone	荷爾蒙類	10	Metoclopramide	腸胃類用藥	250
Ethylestrenol	荷爾蒙類	100	Oxethazaine	腸胃類用藥	10
Fluoxymesterone	荷爾蒙類	10	Oxyphencyclimine	腸胃類用藥	10
Methandriol	荷爾蒙類	100	Phenolphthalein	腸胃類用藥	10
Methandrostenolone	荷爾蒙類	10	Pirenzepine	腸胃類用藥	10
Methyltestosterone	荷爾蒙類	10	Propantheline	腸胃類用藥	10

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## 測試報告

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### 冠泰藥業有限公司

台中市西區民權路185號10F11室

#### 附 錄

<u>測試項目及MDL匯整表:</u> 單位:ppm(mg/kg)

測試項目	類別	方法偵測 極限	測試項目	類别	方法偵測 極限
Ranitidine	腸胃類用藥	10	Acetylvardenafil	補腎滋養	10
Scopolamine N-butyl bromide	腸胃類用藥	10	Acetaminophen	解熱止痛劑	100
Vardenafil analogue(分子量312.37)	補腎滋養	10	Aminopyrine	解熱止痛劑	10
Acetil acid	補腎滋養	10	Benzbromarone	解熱止痛劑	20
Acetildenafil	補腎滋養	10	Bucetin	解熱止痛劑	10
Aminotadalafil	補腎滋養	10	Colchicine	解熱止痛劑	10
Carbodenafil	補腎滋養	10	Ethoxybenzamide	解熱止痛劑	10
Dimethylsildenafil	補腎滋養	10	Flurbiprofen	解熱止痛劑	500
Gendenafil	補腎滋養	10	Ibuprofen	解熱止痛劑	500
Homosildenafil	補腎滋養	10	Indomethacin	解熱止痛劑	10
Hydroxyacetildenafil	補腎滋養	10	Ketoprofen	解熱止痛劑	20
Hydroxyhomosildenafil	補腎滋養	10	Mefenamic acid	解熱止痛劑	50
Hydroxythiohomosildenafil	補腎滋養	10	Naproxen	解熱止痛劑	50
Vardenafil analogue(分子量437.54)	補腎滋養	10	Oxyphenbutazone	解熱止痛劑	10
Pseudovardenafil	補腎滋養	10	Phenylbutazone	解熱止痛劑	10
Sildenafil	補腎滋養	10	Piroxicam	解熱止痛劑	10
Tadalafil	補腎滋養	10	Probenecid	解熱止痛劑	10
Thiodimethylsildenafil	補腎滋養	10	Salicylamide	解熱止痛劑	100
Thiohomosildenafil	補腎滋養	10	Sulindac	解熱止痛劑	10
Thiosildenafil	補腎滋養	10	Acetophenetidin	解熱止痛劑	10
Vardenafil	補腎滋養	10	Benzydamine	解熱止痛劑	10
Noracetildenafil	補腎滋養	10	Bufexamac	解熱止痛劑	100
Nortadalafil	補腎滋養	10	Fenbufen	解熱止痛劑	200
Chloropretadalafil	補腎滋養	10	Flufenamic acid	解熱止痛劑	10
Imidazosagatriazinone	補腎滋養	10	Aspirin	解熱止痛劑	100
Dithio-desmethyl-carbodenafil	補腎滋養	10	Allopurinol	解熱止痛劑	200
Desmethyl sildenafil	補腎滋養	10	Amitriptyline	精神用藥	10
Desmethyl acetildenafil	補腎滋養	10	Amphetamine	精神用藥	200
Hydroxyvardenafil	補腎滋養	10	Benzhexol	精神用藥	10
N-Desethyl vardenafil	補腎滋養	10	Bromisoval	精神用藥	200
Norneosildenafil	補腎滋養	10	Chlordiazepoxide	精神用藥	10

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## 測試報告

報告編號: UP/2017/A0680A-01

日期: 2017年11月13日

頁數:6 of 7

### 冠泰藥業有限公司

台中市西區民權路185號10F11室

#### 附 錄

<u>測試項目及MDL匯整表:</u> 單位:ppm(mg/kg)

測試項目	類别	方法偵測 極限	測試項目	類别	方法偵測 極限
Chlorpromazine	精神用藥	10	Chlorpropamide	糖尿病用藥	10
Cinnarizine	精神用藥	10	Glibenclamide(Glyburide)	糖尿病用藥	10
Cocaine	精神用藥	10	Glipizide	糖尿病用藥	20
Diazepam	精神用藥	10	Metformin	糖尿病用藥	10
Diphenylhydantoin	精神用藥	100	Phenformin	糖尿病用藥	10
Fluoxetine	精神用藥	10	Pioglitazone	糖尿病用藥	10
Lorazepam	精神用藥	25	Tolbutamide	糖尿病用藥	10
Melatonin	精神用藥	20	Rosiglitazone	糖尿病用藥	10
Mephenesin	精神用藥	100	Bromhexine	鎮咳怯痰劑	10
Meprobamate	精神用藥	100	Carbetapentane	鎮咳怯痰劑	10
Phenobarbital	精神用藥	1000	Dextromethorphan	鎮咳怯痰劑	10
Quetiapine	精神用藥	10	Guaiacol Glyceryl Ether(Guaifenesin)	鎮咳怯痰劑	10
Primidone	精神用藥	20	Phenacetin	鎮咳怯痰劑	10
Secobarbital	精神用藥	500	Ambroxol	鎮咳怯痰劑	10
Thioridazine	精神用藥	10	Cloperastine	鎮咳怯痰劑	10
Zolpidem	精神用藥	10	Eprazinone	鎮咳怯痰劑	250
Haloperidol	精神用藥	10	Betamethasone	類固醇類	10
Sulpiride	精神用藥	10	Cortisone	類固醇類	10
Cephalexin	精神用藥	10	Dexamethasone	類固醇類	50
Cefazolin	精神用藥	20	Hydrocortisone	類固醇類	10
Carbamazepine	精神用藥	10	Methylprednisolone	類固醇類	20
Triazolam	精神用藥	10	Prednisolone	類固醇類	20
Imipramine	精神用藥	10	Prednisone	類固醇類	10
Estazolam	精神用藥	10	Triamcinolone	類固醇類	50
Clonazepam	精神用藥	100	Betamethasone 21 Acetate	類固醇類	10
Midazolam	精神用藥	10	Betamethasone Benzoate	類固醇類	10
Buspirone	精神用藥	10	Betamethasone Dipropionate	類固醇類	10
Barbital	精神用藥	200	Betamethasone Valerate	類固醇類	10
Acetohexamide	糖尿病用藥	200	Dexamethasone phosphate	類固醇類	100

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SGS Taiwan Ltd. 台灣檢驗科技股份有限公司



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樣品照片

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