

測試報告

報告編號：

UF/2019/10341

日期：2019年01月30日

頁數：1 of 8



沅泰藥業有限公司

台中市北屯區昌平路2段1-19號1樓

以下測試之樣品係由申請廠商所提供及確認：


產品名稱：	新芯樂第二代軟膠囊
申請廠商：	瑞法貿易有限公司
產品型號/批號：	21808122
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：	2022年08月07日
收樣日期：	2019年01月17日
測試日期：	2019年01月17日 ~ 2019年01月30日
委託測試項目：	360項常見西藥定性分析
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-中藥及食品中檢出西藥之檢驗方法，以薄層層析法(TLC)、液相層析離子阱質譜儀(LCMS/MS)或氣相層析質譜儀(GC/MS)檢測。
測試結果：	此份樣品共檢測360項常見西藥(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別詳列於附錄中。

Signed for and on behalf of
SGS Taiwan Ltd.


Shin-Jyh Chen
Manager



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SGS Taiwan Ltd.
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測試報告

報告編號：UF/2019/A0692

日期：2019年11月14日

頁數：2 of 9



瑞法貿易有限公司

台中市南屯區大墩一街57巷7號1樓

測試結果：

測試項目	CAS NO.	測試方法	測試結果	定量/偵測 極限	單位
360項常見西藥	---	---	---	---	---
本樣品檢測共360項 西藥(項目詳見附錄)	---	本測試依實驗室內部方法，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。	N.D.	---	ppm(mg/kg)

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. 本測試報告之所有檢驗內容，均依委託事項執行檢驗，如有不實，願意承擔完全責任。
3. 本報告不得分離，分離使用無效。
4. 若該測試項目屬於定量分析則以「定量極限」表示；若該測試項目屬於定性分析則以「偵測極限」表示。
5. 低於定量極限/偵測極限之測定值以 "N.D." 或 "陰性" 表示。微生物測試低於定量極限以 "<定量極限值" 表示。

- END -

測試報告

報告編號： UF/2019/A0692

日期： 2019年11月14日

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瑞法貿易有限公司

台中市南屯區大墩一街57巷7號1樓

附 錄

360項常見西藥測試項目及LOD彙整表：

單位：ppm(mg/kg)

測試項目	類別	偵測極限	測試項目	類別	偵測極限
Vardenafil analogue(分子量312.37)	補腎滋養	1800	Fenfluramine	減肥	375
7-Keto dehydroepiandrosterone	補腎滋養	3000	Mephentermine	減肥	240
Acetil acid	補腎滋養	1500	N-Desmethysibutramine	減肥	3000
Acetildenafil	補腎滋養	600	N-Didesmethysibutramine	減肥	3000
Aminotadalafil	補腎滋養	900	Orlistat	減肥	375
Carbodenafil	補腎滋養	1500	Rimonabant	減肥	3000
Chloropretadalafil	補腎滋養	1500	Sibutramine	減肥	1200
N-Desmethysildenafil	補腎滋養	3000	Synephrine	減肥	450
N-Desmethylacetildenafil	補腎滋養	3000	Cetilistat	減肥	1500
Dimethysildenafil	補腎滋養	3000	Lorcaserin	減肥	60
Gendenafil	補腎滋養	3000	2,4-Dinitrophenol	減肥	3600
Homosildenafil	補腎滋養	1350	Acetaminophen	解熱止痛劑	300
Hydroxyacetildenafil	補腎滋養	600	Allopurinol	解熱止痛劑	600
Hydroxyhomosildenafil	補腎滋養	1200	Aminopyrine	解熱止痛劑	900
Hydroxythiohomosildenafil	補腎滋養	1650	Aspirin	解熱止痛劑	600
Hydroxyvardenafil	補腎滋養	1500	Benzbromarone	解熱止痛劑	900
Imidazosagatriazinone	補腎滋養	1200	Bucetin	解熱止痛劑	600
N-Desethylvardenafil	補腎滋養	3000	Colchicine	解熱止痛劑	750
Norneosildenafil	補腎滋養	1000	Ethoxybenzamide	解熱止痛劑	600
Piperiacetildenafil	補腎滋養	3000	Flurbiprofen	解熱止痛劑	150
Piperidenafil	補腎滋養	1500	Ibuprofen	解熱止痛劑	1200
Sildenafil	補腎滋養	1200	Indomethacin	解熱止痛劑	1200
Tadalafil	補腎滋養	600	Ketoprofen	解熱止痛劑	450
Thiodimethysildenafil	補腎滋養	450	Mefenamic acid	解熱止痛劑	900
Thiohomosildenafil	補腎滋養	450	Naproxen	解熱止痛劑	900
Thiosildenafil	補腎滋養	450	Oxyphenbutazone	解熱止痛劑	450
Vardenafil	補腎滋養	1800	Phenylbutazone	解熱止痛劑	750
Noracetildenafil	補腎滋養	300	Piroxicam	解熱止痛劑	600
Acetyl vardenafil	補腎滋養	600	Probenecid	解熱止痛劑	900
Nortadalafil	補腎滋養	1500	Salicylamide	解熱止痛劑	600
Dithio-desmethyl-carbodenafil	補腎滋養	1500	Sulindac	解熱止痛劑	750

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測試報告

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日期： 2019年11月14日

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瑞法貿易有限公司

台中市南屯區大墩一街57巷7號1樓

附 錄

360項常見西藥測試項目及LOD彙整表：

單位：ppm(mg/kg)

測試項目	類別	偵測極限	測試項目	類別	偵測極限
Acetophenetidin	解熱止痛劑	3600	Promethazine	抗組織胺類	300
Benzylamine	解熱止痛劑	348	Betamethasone	類固醇類	900
Bufexamac	解熱止痛劑	1650	Cortisone	類固醇類	750
Fenbufen	解熱止痛劑	1875	Dexamethasone	類固醇類	1200
Flufenamic acid	解熱止痛劑	4050	Hydrocortisone	類固醇類	750
Etodolac	解熱止痛劑	600	Methylprednisolone	類固醇類	750
Dipyrone	解熱止痛劑	600	Prednisolone	類固醇類	1200
Propyphenazone	解熱止痛劑	3000	Prednisone	類固醇類	750
Celecoxib	解熱止痛劑	3000	Triamcinolone	類固醇類	900
Noraminopyrine	解熱止痛劑	2400	Betamethasone 21 Acetate	類固醇類	4500
Bromhexine	鎮咳祛痰劑	1200	Betamethasone Benzoate	類固醇類	3225
Carbetapentane	鎮咳祛痰劑	150	Betamethasone Dipropionate	類固醇類	1050
Dextromethorphan	鎮咳祛痰劑	1500	Betamethasone Valerate	類固醇類	108
Guaifenesin	鎮咳祛痰劑	2400	Dexamethasone phosphate	類固醇類	900
Phenacetin	鎮咳祛痰劑	300	Triamcinolone acetonide	類固醇類	4800
Ambroxol	鎮咳祛痰劑	600	Clobetasol Propionate	類固醇類	2400
Cloperastine	鎮咳祛痰劑	1500	Fluocinonide	類固醇類	3600
Eprazinone	鎮咳祛痰劑	300	Cortisone Acetate Crystalline	類固醇類	3600
Benproperine	鎮咳祛痰劑	2400	Carisoprodol	肌肉鬆弛劑	375
Brompheniramine	抗組織胺類	1800	Chlormezanone	肌肉鬆弛劑	1200
Carbinoxamine	抗組織胺類	1650	Chlorzoxazone	肌肉鬆弛劑	1050
Chlorpheniramine	抗組織胺類	1200	Orphenadrine	肌肉鬆弛劑	300
Diphenhydramine	抗組織胺類	375	Zolazepam HCl	肌肉鬆弛劑	60
Terfenadine	抗組織胺類	450	Aminophylline	支氣管擴張劑	4500
Cyproheptadine	抗組織胺類	60	Theophylline	支氣管擴張劑	600
Cetirizine	抗組織胺類	159	Clenbuterol	支氣管擴張劑	900
Tripolidine	抗組織胺類	60	Diprophyllyne	支氣管擴張劑	900
Ketotifen fumarate	抗組織胺類	60	Fenoterol	支氣管擴張劑	750
Astemizole	抗組織胺類	150	Salbutamol	支氣管擴張劑	37.5
Doxylamine	抗組織胺類	60	Oxeladin	支氣管擴張劑	120
Meclizine	抗組織胺類	60	Benzocaine	局部麻醉類	300

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測試報告

報告編號： UF/2019/A0692

日期： 2019年11月14日

頁數： 5 of 9



瑞法貿易有限公司

台中市南屯區大墩一街57巷7號1樓

附 錄

360項常見西藥測試項目及LOD彙整表：

單位：ppm(mg/kg)

測試項目	類別	偵測極限	測試項目	類別	偵測極限
Dibucaine	局部麻醉類	450	Chlorpropamide	糖尿病用藥	600
Diclofenac	局部麻醉類	600	Glibenclamide	糖尿病用藥	4800
Lidocaine	局部麻醉類	60	Metformin	糖尿病用藥	300
Procaine	局部麻醉類	300	Phenformin	糖尿病用藥	900
Tetracaine	局部麻醉類	600	Pioglitazone	糖尿病用藥	1200
Naloxone	局部麻醉類	384	Rosiglitazone	糖尿病用藥	3000
Noscapine	局部麻醉類	300	Tolbutamide	糖尿病用藥	375
Tiletamine	局部麻醉類	300	Glipizide	糖尿病用藥	3000
Meperidine	局部麻醉類	150	Glimepiride	糖尿病用藥	2400
Prilocaine	局部麻醉類	4800	Digitoxin	心臟血管類用藥	450
Atropine	腸胃類用藥	150	Dipyridamole	心臟血管類用藥	450
Bisacodyl	腸胃類用藥	600	Nylidrin	心臟血管類用藥	4500
Butropium	腸胃類用藥	3000	Papaverine	心臟血管類用藥	1560
Camyllofine	腸胃類用藥	3000	Diltiazem	心臟血管類用藥	300
Cimetidine	腸胃類用藥	1500	Metoprolol	心臟血管類用藥	150
Dicyclomine	腸胃類用藥	375	Verapamil	心臟血管類用藥	60
Glycopyrronium	腸胃類用藥	900	Amlodipine	心臟血管類用藥	300
Homatropine	腸胃類用藥	150	Desacetyl diltiazem	心臟血管類用藥	60
Metoclopramide	腸胃類用藥	750	Prazosin	心臟血管類用藥	300
Oxethazaine	腸胃類用藥	150	Tetramethylpyrazine	心臟血管類用藥	2400
Oxyphencyclimine	腸胃類用藥	75	Pentoxifylline	心臟血管類用藥	2400
Phenolphthalein	腸胃類用藥	600	Clonidine	心臟血管類用藥	300
Pirenzepine	腸胃類用藥	1350	Benazepril	心臟血管類用藥	450
Propantheline	腸胃類用藥	3000	Bisoprolol Fumarate	心臟血管類用藥	60
Ranitidine	腸胃類用藥	600	Carvedilol	心臟血管類用藥	2400
Scopolamine	腸胃類用藥	150	Dihydroergotamine	心臟血管類用藥	150
Bromopride	腸胃類用藥	60	Doxazosin	心臟血管類用藥	2400
Dimenhydrinate	腸胃類用藥	150	Mexiletine	心臟血管類用藥	1500
Famotidine	腸胃類用藥	2400	Propafenone	心臟血管類用藥	2400
Omeprazole	腸胃類用藥	2400	Bezafibrate	降血脂用藥	600
Acetohexamide	糖尿病用藥	750	Clofibrate	降血脂用藥	1500

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瑞法貿易有限公司

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附 錄

360項常見西藥測試項目及LOD彙整表：

單位：ppm(mg/kg)

測試項目	類別	偵測極限	測試項目	類別	偵測極限
Etofibrate	降血脂用藥	3000	Ketoconazole	抗生素類	300
Fenofibrate	降血脂用藥	3000	Metronidazole	抗生素類	900
Gemfibrozil	降血脂用藥	4500	Nalidixic acid	抗生素類	300
Nicametate	降血脂用藥	2550	Nitrofurantoin	抗生素類	450
Xanthinol Niacinate	降血脂用藥	1050	Minocycline	抗生素類	750
Atorvastatin	降血脂用藥	420	Quinine	抗生素類	300
Fluvastatin	降血脂用藥	1200	Sulfaquinolaxine	抗生素類	4740
Atenolol	降血壓用藥	300	Sulfamonomethoxine(SMM)	抗生素類	4650
Hydralazine	降血壓用藥	450	Sulfadiazine	抗生素類	600
Minoxidil	降血壓用藥	600	Sulfadimethoxine	抗生素類	750
Nifedipine	降血壓用藥	600	Sulfamerazine	抗生素類	450
Propranolol	降血壓用藥	1350	Sulfamethazine	抗生素類	600
Reserpine	降血壓用藥	1200	Sulfamethizole	抗生素類	600
Timolol Maleate	降血壓用藥	150	Sulfamethoxazole	抗生素類	600
Methyl DOPA-Sesquihydrate	降血壓用藥	1620	Sulfamethoxypyridazine	抗生素類	450
Indapamide	降血壓用藥	2400	Sulfanilamide	抗生素類	375
Carbimazole	治甲狀腺機能缺陷	600	Sulfathiazole	抗生素類	600
Liothyronine	治甲狀腺機能缺陷	3600	Sulfisoxazole	抗生素類	450
Methimazole	治甲狀腺機能缺陷	300	Terbinafine	抗生素類	300
Chlorothiazide	泌尿系統用藥	750	Tinidazole	抗生素類	900
Flavoxate	泌尿系統用藥	900	Tetracycline	抗生素類	750
Furosemide	泌尿系統用藥	600	Trimethoprim	抗生素類	300
Hydrochlorothiazide	泌尿系統用藥	600	Benzathine-penicillin	抗生素類	3300
Norfloxacin	泌尿系統用藥	300	Clindamycin phosphate	抗生素類	150
Phenazopyridine	泌尿系統用藥	750	Cloxacillin Sodium	抗生素類	4770
Sulfapyrazone	泌尿系統用藥	750	Chlortetracycline	抗生素類	600
Oxybutynin	泌尿系統用藥	4635	Ciprofloxacin(CFA)	抗生素類	240
Chloramphenicol	抗生素類	1200	Dimetridazole	抗生素類	150
Econazole	抗生素類	150	Enrofloxacin	抗生素類	3090
Griseofulvin	抗生素類	450	Lincomycin	抗生素類	1710
Lomefloxacin	抗生素類	1500	Difloxacin	抗生素類	3000

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測試報告

報告編號： UF/2019/A0692

日期： 2019年11月14日

頁數： 7 of 9



瑞法貿易有限公司

台中市南屯區大墩一街57巷7號1樓

附 錄

360項常見西藥測試項目及LOD彙整表：

單位：ppm(mg/kg)

測試項目	類別	偵測極限	測試項目	類別	偵測極限
Ofloxacin	抗生素類	1920	Lorazepam	精神用藥	300
Oxytetracycline (OTC)	抗生素類	960	Melatonin	精神用藥	1200
Sulfisomidine	抗生素類	3000	Mephenesin	精神用藥	150
Santonin	抗生素類	450	Meprobamate	精神用藥	375
Ampicillin	抗生素類	2700	Phenobarbital	精神用藥	900
Amoxicillin	抗生素類	4320	Quetiapine	精神用藥	2400
Clindamycin HCl	抗生素類	456	Primidone	精神用藥	1500
Cephalexin	抗生素類	75	Secobarbital	精神用藥	900
Cephadrine	抗生素類	81	Thioridazine	精神用藥	300
Cefazolin	抗生素類	1050	Zolpidem	精神用藥	300
Ceftriaxone	抗生素類	4224	Haloperidol	精神用藥	1620
Doxycycline	抗生素類	576	Sulpiride	精神用藥	1140
Erythromycin	抗生素類	240	Nitrazepam	精神用藥	600
Rifampin	抗生素類	120	Carbamazepine	精神用藥	3600
Cefotaxime	抗生素類	150	Pentobarbital	精神用藥	150
Nifuroxazide	抗生素類	540	Triazolam	精神用藥	150
Nitrofurazone	抗生素類	4410	Imipramine	精神用藥	60
Cefoperazone dihydrate	抗生素類	300	Estazolam	精神用藥	60
Sulfapyridine	抗生素類	2400	Clonazepam	精神用藥	150
Cefamandole nafate	抗生素類	150	Midazolam	精神用藥	60
Amitriptyline	精神用藥	750	Buspirone	精神用藥	3600
Barbital	精神用藥	750	Maprotiline	精神用藥	150
Benzhexol	精神用藥	1800	Trazodone hydrochloride	精神用藥	3000
Bromvalerylurea	精神用藥	1950	Norfludiazepam	精神用藥	150
Chlordiazepoxide	精神用藥	300	Clozapine	精神用藥	3000
Chlorpromazine	精神用藥	300	Clotrimazole	精神用藥	3000
Cinnarizine	精神用藥	600	Amphetamine	神經興奮劑類	375
Cocaine	精神用藥	750	Caffeine	神經興奮劑類	600
Diazepam	精神用藥	300	Methamphetamine	神經興奮劑類	750
Diphenylhydantoin	精神用藥	150	Morphine	神經興奮劑類	150
Fluoxetine	精神用藥	1200	Pentazocine	神經興奮劑類	300

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單位：ppm(mg/kg)

測試項目	類別	偵測極限	測試項目	類別	偵測極限
Phenylephrine	神經興奮劑類	2850	Clobenzorex	其他	375
Strychnine	神經興奮劑類	900	Diethylpropion	其他	450
Theobromine	神經興奮劑類	600	Finasteride	其他	3000
Naphazoline Hydrochloride	神經興奮劑類	300	Mazindol	其他	1950
2-Diphenylmethylpyrrolidine	神經興奮劑類	150	Methaqualone	其他	900
Diethylstilbesterol	荷爾蒙類	600	Metharbital	其他	750
Estradiol	荷爾蒙類	1200	Phentermine	其他	1500
Estriol	荷爾蒙類	60	Phentolamine	其他	1500
Estrone	荷爾蒙類	30	Phenylpropanolamine	其他	60
Ethinylestradiol	荷爾蒙類	30	Salicylic acid	其他	900
Ethisterone	荷爾蒙類	600	Yohimbine	其他	1500
Ethylestrenol	荷爾蒙類	30	Nicotine	其他	60
Fluoxymesterone	荷爾蒙類	600	Acrinol	其他	2832
Methandriol	荷爾蒙類	2400	Apomorphine	其他	600
Methandrostenolone	荷爾蒙類	600	Fluconazole	其他	480
Methyltestosterone	荷爾蒙類	600	Isoniazid	其他	302.4
Nandrolone	荷爾蒙類	750	Naltrexone	其他	2370
Norethisterone	荷爾蒙類	600	Simvastatin	其他	600
Oxymetholone	荷爾蒙類	1050	Chlorhexidine	其他	2400
Progesterone	荷爾蒙類	600	Meloxicam	其他	4500
Stanozolol	荷爾蒙類	2100	Usnic acid	其他	3600
Testosterone	荷爾蒙類	600	Baclofen	其他	300
Testosterone propionate	荷爾蒙類	3000	Dyclonine Hydrochloride	其他	3600
Norgestrel	荷爾蒙類	3000	Nefopam	其他	3600
Estradiol Benzoate	荷爾蒙類	1200	Flibanserin	其他	3600

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