



超微量工業安全實驗室

Ultra Trace Industrial Safety Hygiene

測試報告

報告編號： PUF21B00705

日期： 2021年12月13日

頁數： 1 of 9



冠泰藥業有限公司

403臺中市西區民權路185號10樓 11室

以下測試之樣品係由申請廠商所提供及確認：

產品名稱： 觀萃哲持續釋放膠囊
申請廠商： 冠泰藥業有限公司
申請廠商地址： 403臺中市西區民權路185號10樓 11室
電話/聯絡人： 04-22202275/冠泰藥業有限公司
樣品包裝： 請參考報告末頁樣品照片
數量： 30T*3/包
樣品保存方式： 室溫
產品型號： ---
產品批號： 52002801
製造/國內負責廠商： VIVA PHARMACEUTICAL INC.
製造日期： 2021/10/16
有效期限： 2025/10/16
收樣日期： 2021年11月29日
測試日期： 2021年11月29日 ~ 2021年12月13日
測試結果： -請見下頁-

陳新智

陳新智 經理
台灣檢驗科技股份有限公司
報告簽署人



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測試結果：

測試項目	測試方法	測試結果	定量/偵測極限	單位
365項西藥定性分析	---	---	---	---
本樣品檢測共365項西藥定性分析(項目詳見附錄)	本測試依實驗室內部方法(TESP-UB-0173, TESP-UB-0181, TESP-UB-0182), 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(µg/g)

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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 -

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365項西藥定性分析測試項目及偵測極限(LOD)彙整表：

單位：ppm($\mu\text{g/g}$)

測試項目	CAS NO.	LOD	測試項目	CAS NO.	LOD
2,4-Dinitrophenol	51-28-5	3600	Benzathine-penicillin	41372-02-5	3300
2-Diphenylmethylpyrrolidine	22348-31-8	900	Benzbromarone	3562-84-3	900
7-keto-Dehydroepiandrosterone	566-19-8	3000	Benzhexol	144-11-6	1800
Acetaminophen	103-90-2	300	Benzocaine	94-09-7	300
Acetil acid	147676-78-6	1500	Benzylamine	642-72-8	348
Acetildenafil	831217-01-7	600	Betamethasone	378-44-9	900
Acetohexamide	968-81-0	750	Betamethasone 21 Acetate	987-24-6	4500
Acetophenetidin	62-44-2	3600	Betamethasone Benzoate	22298-29-9	3225
Acetylvardenafil	1261351-28-3	600	Betamethasone Dipropionate	5593-20-4	1050
Acrinol	1837-57-6	2832	Betamethasone Valerate	2152-44-5	108
Allopurinol	315-30-0	600	Bezafibrate	41859-67-0	600
Ambroxol	18683-91-5	600	Bisacodyl	603-50-9	600
Aminophylline	317-34-0	4500	Bisoprolol Fumarate	104344-23-2	60
Aminopyrine	58-15-1	900	Bromhexine	3572-43-8	1200
Aminotadalafil	385769-84-6	900	Bromopride	4093-35-0	60
Amitriptyline	549-18-8	750	Brompheniramine	86-22-6	1800
Amlodipine	88150-42-9	300	Bromvalerylurea	496-67-3	1950
Amoxicillin	26787-78-0	4320	Bucetin	1083-57-4	600
Amphetamine	300-62-9	375	Bufexamac	2438-72-4	1650
Ampicillin	69-53-4	2700	Buspirone	36505-84-7	3600
Apomorphine	58-00-4	600	Butropium	107080-63-7	3000
Aspirin	50-78-2	600	Caffeine	58-08-2	600
Astemizole	68844-77-9	150	Camylofine	54-30-8	3000
Atenolol	29122-68-7	300	Carbamazepine	298-46-4	3600
Atorvastatin	134523-00-5	420	Carbetapentane	77-23-6	150
Atropine	51-55-8	150	Carbimazole	22232-54-8	600
Avanafil	330784-47-9	600	Carbinoxamine	486-16-8	1650
Baclofen	1134-47-0	300	Carbodenafil	944241-52-5	1500
Barbital	57-44-3	750	Carisoprodol	78-44-4	375
Benazepril	86541-75-5	450	Carvedilol	72956-09-3	2400
Benproperine	2156-27-6	600	Cefamandole nafate	42540-40-9	150

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365項西藥定性分析測試項目及偵測極限(LOD)彙整表：

單位：ppm(μg/g)

測試項目	CAS NO.	LOD	測試項目	CAS NO.	LOD
Cefazolin	25953-19-9	1050	Cloperastine	3703-76-2	1500
Cefoperazone dihydrate	113826-44-1	300	Clotrimazole	23593-75-1	3000
Cefotaxime	63527-52-6	150	Cloxacillin Sodium	7081-44-9	4770
Ceftriaxone	73384-59-5	4224	Clozapine	5786-21-0	600
Celecoxib	169590-42-5	900	Cocaine	50-36-2	750
Cephalexin	15686-71-2	75	Colchicine	64-86-8	750
Cephradine	38821-53-3	81	Cortisone	53-06-5	750
Cetilistat	282526-98-1	1500	Cortisone acetate	50-04-4	3600
Cetirizine	83881-51-0	159	Cyproheptadine	129-03-3	1500
Chloramphenicol	56-75-7	1200	Desacetyl bisacodyl	603-41-8	600
Chlordiazepoxide	58-25-3	300	Desacetyl diltiazem	42399-40-6	60
Chlorhexidine	55-56-1	2400	Dexamethasone	50-02-2	1200
Chlormezanone	80-77-3	60	Dexamethasone phosphate	312-93-6	900
Chloropretadalafil	171489-59-1	1500	Dextromethorphan	125-71-3	1500
Chlorothiazide	58-94-6	750	Diazepam	439-14-5	300
Chlorpheniramine	113-92-8	1200	Dibucaine	85-79-0	450
Chlorpromazine	50-53-3	300	Diclofenac	15307-86-5	600
Chlorpropamide	94-20-2	600	Dicyclomine	77-19-0	375
Chlortetracycline	57-62-5	600	Diethylpropion	39648-50-5	450
Chlorzoxazone	95-25-0	1050	Diethylstilbestrol	56-53-1	600
Cimetidine	51481-61-9	1500	Difloxacin	98106-17-3	3000
Cinnarizine	298-57-7	600	Digitoxin	71-63-6	450
Ciprofloxacin(CFA)	85721-33-1	240	Dihydroergotamine	511-12-6	150
Clenbuterol	21898-19-1	900	Diltiazem	42399-41-7	300
Clindamycin HCl	21462-39-5	456	Dimenhydrinate	523-87-5	150
Clindamycin phosphate	24729-96-2	150	Dimethylsildenafil	496835-35-9	3000
Clobenzorex	13364-32-4	375	Dimetridazole	551-92-8	150
Clobetasol Propionate	25122-46-7	2400	Diphenhydramine	58-73-1	375
Clofibrate	637-07-0	1500	Diphenylhydantoin	57-41-0	150
Clonazepam	1622-61-3	150	Diprophylline	479-18-5	900
Clonidine	4205-90-7	300	Dipyridamole	58-32-2	450

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單位：ppm(μg/g)

測試項目	CAS NO.	LOD	測試項目	CAS NO.	LOD
Dipyron	68-89-3	600	Fluocinonide	356-12-7	3600
Dithio-desmethyl-carbodenafil	1333233-46-7	1500	Fluoxetine	54910-89-3	1200
Doxazosin	74191-85-8	2400	Fluoxymesterone	76-43-7	600
Doxycycline	564-25-0	576	Flurbiprofen	5104-49-4	150
Doxylamine	469-21-6	60	Fluvastatin	93957-54-1	1200
Dyclonine Hydrochloride	536-43-6	3600	Furosemide	54-31-9	600
Econazole	27220-47-9	150	Gemfibrozil	25812-30-0	4500
Enrofloxacin	93106-60-6	3090	Gildenafil	147676-66-2	3000
Eprazinone	10402-90-1	300	Glibenclamide	10238-21-8	4800
Erythromycin	114-07-8	240	Glimepiride	93479-97-1	2400
Estazolam	29975-16-4	60	Glipizide	29094-61-9	3000
Estradiol	50-28-2	1200	Glycopyrronium	740028-90-4	900
Estradiol benzoate	50-50-0	600	Griseofulvin	126-07-8	450
Estriol	50-27-1	60	Guaifenesin	93-14-1	2400
Estrone	53-16-7	30	Haloperidol	52-86-8	1620
Ethinyl estradiol	57-63-6	30	Homatropine	87-00-3	150
Ethisterone	434-03-7	600	Homosildenafil	642928-07-2	1350
Ethoxybenzamide	938-73-8	600	Hydralazine	86-54-4	450
Ethylestrenol	965-90-2	30	Hydrochlorothiazide	58-93-5	600
Etodolac	41340-25-4	600	Hydrocortisone	50-23-7	750
Etofibrate	31637-97-5	3000	Hydroxyacetildenafil	147676-56-0	600
Famotidine	76824-35-6	750	Hydroxyhomosildenafil	139755-85-4	1200
Fenbufen	36330-85-5	1875	Hydroxythiohomosildenafil	479073-82-0	1650
Fenfluramine	458-24-2	375	Hydroxywardenafil	224785-98-2	1500
Fenofibrate	49562-28-9	150	Hydroxyzine	2192-20-3	900
Fenoterol	13392-18-2	750	Ibuprofen	15687-27-1	1200
Finasteride (Proscar)	98319-26-7	3000	Imidazosagatriazinone	139756-21-1	1200
Flavoxate	15301-69-6	900	Imipramine	50-49-7	60
Flibanserin	167933-07-5	3600	Indapamide	26807-65-8	2400
Fluconazole	86386-73-4	480	Indomethacin	53-86-1	1200
Flufenamic acid	530-78-9	4050	Isoniazid	54-85-3	302.4

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單位： ppm($\mu\text{g/g}$)

測試項目	CAS NO.	LOD	測試項目	CAS NO.	LOD
Ketoconazole	65277-42-1	300	Metronidazole	443-48-1	900
Ketoprofen	22071-15-4	450	Mexiletine	31828-71-4	1500
Ketotifen fumarate	34580-14-8	60	Midazolam	59467-70-8	60
Lidocaine	137-58-6	60	Minocycline	10118-90-8	750
Lincomycin	154-21-2	1710	Minoxidil	38304-91-5	600
Liothyronine	6893-02-3	3600	Morphine	57-27-2	150
Lomefloxacin	98079-51-7	1500	Nalidixic acid	389-08-2	300
Lorazepam	846-49-1	300	Naloxone	465-65-6	384
Lorcaserin	616202-92-7	900	Naltrexone	16590-41-3	2370
Maprotiline	10262-69-8	150	Nandrolone	434-22-0	750
Mazindol	22232-71-9	1950	Naphazoline Hydrochloride	835-31-4	300
Meclizine	569-65-3	60	Naproxen	22204-53-1	900
Mefenamic acid	61-68-7	900	N-Desethylvaridenafil	448184-46-1	3000
Melatonin	73-31-4	1200	N-Desmethylacetildenafil	147676-55-9	3000
Meloxicam	71125-38-7	4500	N-Desmethylsibutramine	168835-59-4	3000
Meperidine	57-42-1	150	N-Desmethylsildenafil	139755-82-1	3000
Mephenesin	59-47-2	150	N-Didesmethylsibutramine	84467-54-9	3000
Mephentermine	100-92-5	240	Nefopam	13669-70-0	300
Meprobamate	57-53-4	375	Nicametate	3099-52-3	2550
Metformin	657-24-9	300	Nicotine	54-11-5	60
Methamphetamine	537-46-2	750	Nifedipine	21829-25-4	600
Methandriol	521-10-8	2400	Nifuroxazide	965-52-6	540
Methandrostenolone	72-63-9	600	Nitrazepam	146-22-5	600
Methaqualone	72-44-6	900	Nitrofurantoin	67-20-9	450
Metharbital	50-11-3	750	Nitrofurazone	59-87-0	4410
Methimazole	60-56-0	300	Noracetildenafil	949091-38-7	300
Methyl DOPA-Sesquihydrate	41372-08-1	1620	Noraminyprine	519-98-2	2400
Methylprednisolone	83-43-2	750	Norethisterone	68-22-4	600
Methyltestosterone	58-18-4	600	Norfloracin	70458-96-7	300
Metoclopramide	364-62-5	750	Norfludiazepam	2886-65-9	150
Metoprolol	51384-51-1	150	Norgestrel	6533-00-2	600

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單位：ppm(µg/g)

測試項目	CAS NO.	LOD	測試項目	CAS NO.	LOD
Norneosildenafil	371959-09-0	1000	Piperidenafil	224788-34-5	1500
Nortadalafil	171596-36-4	1500	Pirenzepine	28797-61-7	1350
Noscapine	128-62-1	300	Piroxicam	36322-90-4	600
Nylidrin	849-55-8	4500	Prazosin	19216-56-9	300
Ofloxacin	82419-36-1	1920	Prednisolone	50-24-8	1200
Omeprazole	73590-58-6	1200	Prednisone	53-03-2	750
Orlistat	96829-58-2	375	Prilocaine	721-50-6	750
Orphenadrine	83-98-7	300	Primidone	125-33-7	30
Oxeladin	468-61-1	120	Probenecid	57-66-9	900
Oxethazaine	126-27-2	150	Procaine	59-46-1	300
Oxybutynin	5633-20-5	4635	Progesterone	57-83-0	600
Oxymetholone	434-07-1	1050	Promethazine	60-87-7	300
Oxyphenbutazone	129-20-4	450	Propafenone	54063-53-5	2400
Oxyphencyclimine	125-53-1	75	Propranethine	298-50-0	3000
Oxytetracycline (OTC)	79-57-2	960	Propranolol	525-66-6	1350
Papaverine	58-74-2	1560	Propyphenazone	479-92-5	3000
Pentazocine	359-83-1	30	Quetiapine	111974-69-7	2400
Pentobarbital	76-74-4	150	Quinine	130-95-0	300
Pentoxifylline	6493-05-6	2400	Ranitidine	66357-59-3	600
Phenacetin	62-44-2	3600	Reserpine	50-55-5	1200
Phenazopyridine	94-78-0	750	Rifampin	13292-46-1	120
Phenformin	114-86-3	900	Rimonabant	168273-06-1	3000
Phenobarbital	50-06-6	900	Rosiglitazone	122320-73-4	3000
Phenolphthalein	77-09-8	600	Salbutamol	18559-94-9	37.5
Phentermine	122-09-8	1500	Salicylamide	65-45-2	600
Phentolamine	50-60-2	1500	Salicylic acid	69-72-7	900
Phenylbutazone	50-33-9	750	Santonin	481-06-1	450
Phenylephrine	59-42-7	2850	Scopolamine	6533-68-2	150
Phenylpropanolamine	14838-15-4	60	Secobarbital	76-73-3	900
Pioglitazone	111025-46-8	1200	Sibutramine	106650-56-0	1200
Piperiacetildenafil	147676-50-4	3000	Sildenafil	139755-83-2	1200

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SGS Taiwan Ltd., No.38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku District, New Taipei City, 24890, Taiwan/ 新北市五股區新北產業園區五權七路38號
 台灣檢驗科技股份有限公司 t (886-2) 2299-3939 f (886-2) 2298-1338 www.tw.sgs.com

Member of the SGS Group



超微量工業安全實驗室

Ultra Trace Industrial Safety Hygiene

測試報告

報告編號： PUF21B00705

日期：2021年12月13日

頁數：8 of 9



冠泰藥業有限公司

403臺中市西區民權路185號10樓11室

附錄

365項西藥定性分析測試項目及偵測極限(LOD)彙整表：

單位：ppm(μg/g)

測試項目	CAS NO.	LOD	測試項目	CAS NO.	LOD
Simvastatin	79902-63-9	600	Tetracycline	60-54-8	750
Spiroinolactone	52-01-7	300	Tetramethylpyrazine	1124-11-4	2400
Stanozolol	10418-03-8	2100	Theobromine	83-67-0	600
Strychnine	57-24-9	900	Theophylline	58-55-9	600
Sulfadiazine	68-35-9	600	Thiodimethylsildenafil	856190-47-1	450
Sulfadimethoxine	122-11-2	750	Thiohomosildenafil	479073-80-8	450
Sulfamerazine	127-79-7	450	Thioridazine	50-52-2	300
Sulfamethazine	57-68-1	600	Thiosildenafil	479073-79-5	450
Sulfamethizole	144-82-1	600	Tiletamine	14176-49-9	300
Sulfamethoxazole	723-46-6	600	Timolol Maleate	26921-17-5	150
Sulfamethoxypyridazine	80-35-3	450	Tinidazole	19387-91-8	900
Sulfamonomethoxine	1220-83-3	4650	Tolbutamide	64-77-7	375
Sulfanilamide	63-74-1	375	Topiramate	97240-79-4	450
Sulfapyridine	144-83-2	2400	Trazodone hydrochloride	19794-93-5	3000
Sulfaquinolaxaline	59-40-5	4740	Triamcinolone	124-94-7	900
Sulfathiazole	72-14-0	600	Triamcinolone acetonide	76-25-5	4800
Sulfinpyrazone	57-96-5	750	Triazolam	28911-01-5	150
Sulfisomidine	515-64-0	3000	Trimethoprim	738-70-5	1500
Sulfisoxazole	127-69-5	450	Tripolidine	486-12-4	60
Sulindac	38194-50-2	750	Usnic acid	125-46-2	3600
Sulpiride	15676-16-1	1140	Vardenafil	224785-90-4	1800
Synephrine	94-07-5	450	Vardenafil analogue(Molecular weight312.37)	224789-21-3	1800
Tadalafil	171596-29-5	600	Verapamil	152-11-4	60
Terbinafine	91161-71-6	300	Xanthinol Niacinate	437-74-1	1050
Terfenadine	50679-08-8	450	Yohimbine	146-48-5	1500
Testosterone	58-22-0	600	Zolazepam HCl	31352-82-6	60
Testosterone propionate	57-85-2	3000	Zolpidem	82626-48-0	300
Tetracaine	94-24-6	600	--	--	--

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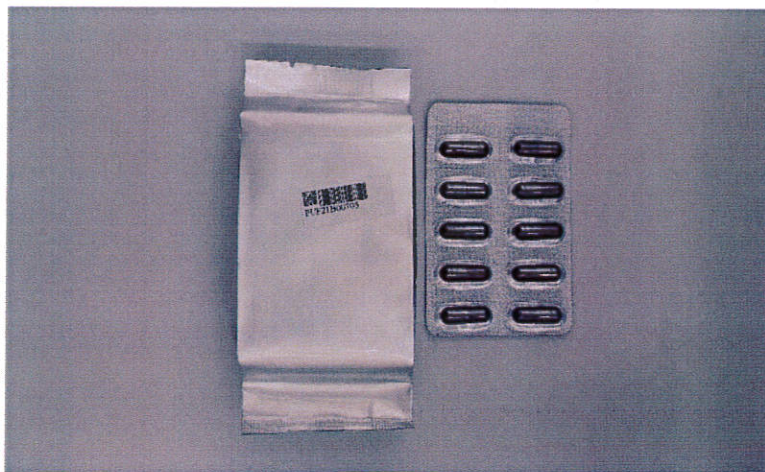
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冠泰藥業有限公司
403臺中市西區民權路185號10樓 11室

樣品照片

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