



### Product List of API

Product Name	中文名	CEP# & DMFNo.Status	Indication/Type
Tamoxifen Citrate	枸橼酸他莫昔芬	US DMF NO.19284; USP/BP/EP/CP	Antineoplastic 抗肿瘤 乳腺癌
Duloxetine Hydrochloride	盐酸度洛西汀	GMP/CEP	Neuroscience 神经系统
Clopidogrel Bisulfate	硫酸氯吡格雷	GMP/CEP(R0-CEP 2013-290-Rev 00 )	Cardiovascular 心血管药
Clozapine	氯氮平	GMP, EDMF,USDMF,FDA, COS( R1-CEP 2012-006-Rev 00 )	Neuroscience 神经系统
Phloroglucinol Dihydrate /Anhydrate	间苯三酚二水合物	DMF,COS(R1-CEP 2013-099-Rev 00 )	Relieves spastic pain 缓解痉挛性疼痛
Pantoprazole Sodium	泮托拉唑钠	DMF,COS(R0-CEP 2013-350-Rev 01 )	Anti-ulcer 抗溃疡药
Omeprazole	奥美拉唑	COS(R1-CEP 2011-237-Rev 00 ), GMP,EDMF,USDMF,FDA,PMD A	Treatment of peptic ulcer 治疗消化性溃疡
Lansoprazole	兰索拉唑	DMF,COS( R1-CEP 2012-372-Rev 00 )	Digestive system agents 消化系统用药
Omeprazole Magnesium	奥美拉唑镁	DMF,COS( R0-CEP 2015-341-Rev 00)	Treatment of duodenal ulcer, gastric ulcer and reflux esophagitis 治疗十二指肠溃疡、胃溃疡和返流性食管炎
Esomeprazole Magnesium Dihydrate/Trihydrate	埃索美拉唑镁(三水)	DMF,COS(R0-CEP 2016-027-Rev 00 )	Medication for gastroesophageal reflux gastropathy 胃食管反流性胃病用药
Trimethoprim(TMP)	甲氧苄啶	COS(R1-CEP 2005-115-Rev 01 ), GMP,EDMF,USDMF,FDA,COF EPRIS,WHO,TGA	Antibacterial agents 抗菌药物



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Sulfamethoxazole	磺胺甲恶唑	FDA,WHO,GMP,EDMF,USDMF , COS(R1-CEP 2007-332-Rev 01)	Antibacterial agents 抗菌药物
Metformin HCl	盐酸二甲双胍	COS( R1-CEP 2008-043-Rev 04 ); US DMF NO.23273;GMP,EDMF,USDMF ,FDA,EU-GMP,KFDA	Blood sugar regulation 调节血糖
Hydroxychloroquine sulfate	硫酸羟基氯喹	US FDA; DMF # 030825;EU CEP in 2018;GMP	Rheumatoid Arthritis 类风湿性关节炎 红斑 狼疮
Cilostazol JP16/USP38	西洛他唑	JAPAN(PMDA): No.224MF10046&229MF1016 6 RUSSIA: Øc-000505; US DMF NO.22463&25666	Antiplatelet 抗血小板 药
Tropium Chloride	去甲托品醇盐酸盐	GMP;US DMF NO.19284	Bacteriostatics 抑菌
Hydrocortisone Base	氢化可的松	EP/USP/CP,CEP(R0-CEP 2015-033-Rev 01)	Antiviral 抗病毒
Hydrocortisone Acetate	醋酸氢化可的松	EP/USP/CP,CEP(R1-CEP 2008-085-Rev 00 )	Antiviral 抗病毒
Spironolactone	螺内酯	EP/USP/CP,CEP( R1-CEP 2012-185-Rev 00)	Diuretic 利尿剂 泌尿 道系统
Clobetasol propionate	丙酸氯倍他索	GMP Being Prepared/EP,USP,CP	Anti-itch 抗瘙痒 皮肤 用药
Lacosamide	拉考沙胺	US DMF NO.33678;	Epilepsy 抗癫痫药
Levetiracetam	左乙拉西坦	CEP(R0-CEP 2014-139-Rev 02 )/EP	Antiepileptics 抗癫痫 药
Simvastatin	辛伐他汀	CEP(R0-CEP 2017-184-Rev 01 )/EP/USP/ChP	Lowering Cholesterol 降低胆固醇
Lanreotide Acetate	醋酸兰瑞肽	US DMF No.029693	Aeuroendocrine tumours and Acromegaly 神经内分 泌肿瘤和肢端肥大症
Terlipressin Acetate	醋酸特利加压素	Pre-assigned	Vasoactive drug 血管 活性药
Dronedarone	决奈达隆	US DMF No.031221	Cardiovascular 心血管
Isosorbide Mononitrate	单硝酸异山梨酯	US DMF NO.29555; CEP Being Prepared	Cardiovascular 心血管 药



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Gliclazide	格列齐特	CEP(R0-CEP 2012-028-Rev 00)	Diabetes 糖尿病
Gemfibrozil	吉非罗齐	US-DMF, GMP CEP(R1-CEP 2008-118-Rev 00 )	Cardiovascular 心血管药
Atracurium Besylate	苯磺阿曲库铵	USP41,EP9,GMP,CEP( R0-CEP 2013-019-Rev 00 )	Muscle relaxant 肌松剂
Capecitabine	卡培他滨	USP41,GMP, USDMF NO. 26818	Oncology 抗癌药
Valsartan	缬沙坦	CEP(R0-CEP 2018-208-Rev 00 ),US DMF	Cardiovascular 心血管药
Losartan	洛沙坦	CEP(R1-CEP 2010-175-Rev 01 )	Cardiovascular 心血管药
Esomeprazole magnesium dihydrate/Trihydrate	埃索美拉唑镁二水	CEP(R0-CEP 2016-166-Rev 01 )	Digestive system agents 消化系统用 药
Esomeprazole magnesium trihydrate	埃索美拉唑镁三水	CEP(R0-CEP 2018-001-Rev 01),US DMF	Digestive system agents 消化系统用 药
Rosuvastatin calcium	瑞舒伐他汀钙	CEP2019	Cardiovascular 心血管药
Clopidogrel	氯吡格雷	CEP2019,US DMF2019	Cardiovascular 心血管药
Entecavir hydrate	恩替卡韦一水合物	CEP2020	Oncology 抗癌药
Sugammadex sodium	舒更葡糖钠	US:2021, CN2020	Muscle relaxant 肌松拮抗剂
Obeticholic Acid	奥贝胆酸	US: 2022	Liver disease 肝病
Anidulafungin	阿尼芬净	US:2020	Antibacterial agents 抗菌药物
Alvimopan	阿维莫潘	US: 2022	Digestive system agents 消化系统用 药
Posaconazole	泊沙康唑(无定型)	US:2019	Antibacterial agents 抗菌药物
Posaconazole	泊沙康唑(晶型 I )	US: 2020	Antibacterial agents 抗菌药物
Eribulin Mesylate	甲磺酸艾日布林	US:2023,CN2019	Oncology 抗癌药
Everolimus	依维莫司(2.0%BHT)	US: 2019.12.6	Oncology 抗癌药
Telavancin hydrochloride	盐酸特拉万星	US:2027	Anti-infective 抗感 染
FidaxoMicin	非达霉素	US:2027	antibiotic 抗生素



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Daptomycin	达托霉素	CGMP, USFDA(29137 & 29859)	Antibacterial 抗菌
Colistimethate Sodium	粘菌素甲磺酸钠	CGMP, USFDA(28350)	Antibacterial 抗菌
Kanamycin sulfate	单硫酸卡那霉素	GMP,CGMP,WHO,USFDA(28 275)	Antibacterial 抗菌
Gentamycin Sulfate	硫酸庆大霉素	CGMP,USFDA,VMF	Antibacterial 抗菌
Tobramycin sulfate	硫酸妥布霉素	CGMP, USFDA(27841)	Antibacterial 抗菌
Tobramycin Base	妥布霉素	CGMP, USFDA(20724)	Antibacterial 抗菌
Lovastatin	洛伐他汀	GMP,CGMP,USFDA(18539)	Cholesterol lowering 降低胆固醇
APREPITANT	阿瑞匹坦	GMP,CEP Being Prepared	Digestive system agents 消化系统用药
Fingolimod Hydrochloride	盐酸芬戈莫德	US DMF NO.028142;Completeness Assessment Done	Multiple Sclerosis 多发 性硬化症(神经系统疾 病)
Aripiprazole	阿立哌唑	US DMF NO.019982	Schizophrenia 精神分 裂症
Imatinib Mesylate	甲磺酸伊马替尼	US DMF NO.024838	Anti CML and GIST 慢 性髓细胞白血病和胃 肠道间质瘤
Rasagiline Mesylate	甲磺酸雷沙吉兰	US DMF NO.024159	Parkinson 帕金森病
Mefenamic Acid	甲灭酸;甲芬那酸	US DMF NO.020374	Pain and Inflammation 疼痛和炎症
Glycopyrrolate	格隆溴铵	US DMF NO.021326	Peptic Ulcer 胃溃疡
Injectafer	羧麦芽糖铁	US:2024,CN:2023	Digestive system agents 消化系统用药
Vancomycin hydrochloride	盐酸万古霉素	EUGMP, CGMP, CEP(R1-CEP 2012-235-Rev 00 ) USFDA	Antibacterial 抗菌
Teicoplanin	替考拉宁	CEP(R0-CEP 2012-028-Rev 00)	Diabetes 糖尿病
Clozapine	氯氮平	GMP, EDMF,USDMF,FDA,COS	Neuroscience 神经系 统
Anastrozole	阿那曲唑	GMP; DMF	Antineoplastic 抗肿瘤 药
Lenalidomide	来那度胺	GMP; DMF	Antineoplastic 抗肿瘤 药
Dacarbazine	达卡巴嗪	GMP. CEP. DMF	Antineoplastic 抗肿瘤



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Oxaliplatin	奥沙利铂	GMP , DMF	Antineoplastic 抗肿瘤
Pemetrexed disodium	培美曲塞二钠	GMP; DMF	Antineoplastic 抗肿瘤
Palbociclib	哌柏西利/帕布昔利布	GMP; DMF	Antineoplastic 抗肿瘤 乳腺癌
Lenvatinib	乐伐替尼	GMP; DMF	Antineoplastic 抗肿瘤
Bortezomib	硼替佐米	GMP; DMF	Antineoplastic 抗肿瘤
Nedaplatin	奈达铂	GMP; DMF	Antineoplastic 抗肿瘤
Bendamustine	苯达莫司汀	GMP; DMF	Chronic Lymphocytic Leukemia 慢性淋巴细胞性白血病(CLL)
Dexmedetomidine Hydrochloride	盐酸右美托咪定	GMP; DMF	Analgesic 止痛剂
Parecoxib sodium	帕瑞昔布钠	GMP; DMF	Analgesic 止痛剂
Rizatriptan Benzoate	苯甲酸利扎曲坦	GMP; DMF	Analgesic 止痛剂
Ropivacaine Mesylate	甲磺酸罗哌卡因	GMP; DMF	Anesthesia and Analgesia 麻醉和镇痛
Omeprazole	奥美拉唑	GMP,COS,EDMF,USDMF,FDA ,PMDA	Treatment of peptic ulcer 治疗消化性溃疡
Palonosetron Hydrochloride	盐酸帕洛诺司琼	GMP; DMF	Anti-nausea and vomiting 抑制恶心呕吐
Zinc Acexamate	醋氨己酸锌	GMP; DMF	anti-HP 抗胃溃疡
Acyclovir	阿昔洛韦	GMP, DMF, USP/EP/CP	Antiviral 抗病毒
Clindamycin Hydrochloride	盐酸克林霉素	GMP,DMF,USP,EP/ BP,CP,IP	Antiviral 抗病毒
Clindamycin Phosphate	克林霉素磷酸酯	GMP,DMF,USP,EP/ BP,CP,IP	Antiviral 抗病毒
Silver Sulfadiazine	磺胺嘧啶银	GMP, EDMF,USP/BP/EP/CP	Infection of burn wounds 烧伤创面的感染
Trimethoprim(TMP)	甲氧苄啶	GMP,COS,EDMF,USDMF,FDA ,COFEPRIS,WHO,TGA	Antibacterial agents 抗菌药物
Sulfamethoxazole	磺胺甲恶唑	GMP,EDMF,USDMF,COS,FDA ,WHO	Antibacterial agents 抗菌药物
Biapenem	比阿培南	GMP; DMF	Antibacterial agents 抗菌药物
Posaconazole	泊沙康唑	GMP; DMF	Antifungal 抗真菌
Vancomycin hydrochloride	盐酸万古霉素	EUGMP, CGMP, CEP, USFDA	Antibacterial 抗菌
Teicoplanin	替考拉宁	EUGMP, CEP	Antibacterial 抗菌



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Daptomycin	达托霉素	CGMP, USFDA	Antibacterial 抗菌
Colistimethate Sodium	粘菌素甲磺酸钠	CGMP, USFDA	Antibacterial 抗菌
Kanamycin sulfate	单硫酸卡那霉素	GMP,CGMP,WHO,USFDA	Antibacterial 抗菌
Kanamycin Acid Sulphate	硫酸卡那霉素	WHO	Antibacterial 抗菌
Gentamycin Sulfate	硫酸庆大霉素	CGMP,USFDA,VMF	Antibacterial 抗菌
Tobramycin sulfate	硫酸妥布霉素	CGMP, USFDA	Antibacterial 抗菌
Tobramycin Base	妥布霉素	CGMP, USFDA	Antibacterial 抗菌
Luliconazole	卢立康唑	GMP; DMF	Antibacterial 抗菌
Zanamivir	扎那米韦	GMP; DMF	Anti-influenza virus 抗流感病毒
Moxifloxacin hydrochloride	盐酸莫西沙星	GMP; DMF	Antiviral Drug 抗病毒
Voriconazole	伏立康唑	GMP; DMF	Antiviral Drug 抗病毒
Valaciclovir HCl Anhydrous	盐酸伐昔洛韦无水物	GMP, DMF, JDMF,Form I, Form II, EP, USP	Antiviral 抗病毒
Amlodipine maleate	马来酸氨氯地平	GMP; DMF	Anti-hypertension 抗高血压
Acarbose	阿卡波糖	GMP,DMF	Antidiabetic 抗糖尿病
Lovastatin	洛伐他汀	GMP,CGMP,USFDA	Cholesterol lowering 降低胆固醇
Epalrestat	依帕斯他	GMP; DMF	Antidiabetic 抗糖尿病
Vildagliptin	维达列汀	GMP; DMF	Antidiabetic 抗糖尿病
Metformin HCl	盐酸二甲双胍	GMP,COS,EDMF,USDMF,FDA ,EU-GMP,KFDA	Blood sugar regulation 调节血糖
Hydrochlorothiazide	氢氯噻嗪	GMP;CEP;DMF	Anti-hypertension 抗高血压
Edaravone	依达拉奉	GMP; DMF	Brain Protective Agent 脑保护剂
Gemfibrozil	吉非罗齐	GMP,US-DMF, CEP	Hypolipidemic 降血脂
Milrinone	米力农	GMP; DMF	Cardiovascular 心血管药
Indapamide	吲达帕胺	GMP.CEP. DMF	Cardiovascular 心血管药
Zoledronic Acid	唑来膦酸	GMP; DMF	Treatment of osteoporosis 防治骨质疏松症
Risedronate Sodium	利塞膦酸钠	GMP; DMF	Treatment of osteoporosis 骨质疏松



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Rupatadine fumarate	富马酸卢帕他定	GMP; DMF	Treatment of urticaria 治疗荨麻疹
Ritodrine Hcl	盐酸利托君	GMP,DMF	Inhibit contraction of uterine smooth muscle 抑制子宫平滑肌的收缩
Diosmectite Montmorillonite	蒙脱石	EU GMP; DMF	Gastrointestinal System 肠胃系统 腹泻
Aldioxa	尿囊素铝	GMP; DMF	Gastrointestinal System 肠胃系统 胃及 十二指肠溃疡
Iguratimod	艾拉莫德	GMP; DMF	Antirheumatic 抗风湿
Pramipexole	普拉克索	GMP; DMF	Anti Parkinson's disease 抗帕金森病
Tofacitinib	托法替尼	GMP; DMF	Treatment of Rheumatoid Arthritis 类风湿关节炎
Mycophenolate mofetil	霉酚酸酯	GMP,DMF	Treatment of psoriasis 治疗银屑病
Aprepitant	阿瑞吡坦	GMP; DMF, CEP	Treatment of chemotherapy vomiting 治疗化疗呕 吐
Fosaprepitant Dimeglumine	福沙吡坦二甲葡 胺	GMP; DMF	Treatment of chemotherapy vomiting 治疗化疗呕 吐
Gadobutrol	钆布醇	GMP; DMF	Contrast agent 造影剂
Gadoterate meglumine	多它灵	GMP; DMF	Contrast agent 造影剂
Mirabegron	米拉贝隆	GMP; DMF	Urinary System 泌尿系 统 膀胱过度活动症
Varenicline tartrate	酒石酸伐仑克林	GMP; DMF	Smoking cessation drugs 戒烟药
Efinaconazole	艾氟康唑	GMP; DMF	Treatment of onychomycosis 治疗脚 趾甲灰指甲