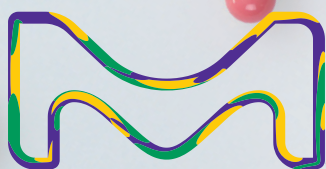


Supelco®
Analytical Products

默克Supelco® 药物二级标准品



扫描二维码
填问卷看COA视频
100%得礼品

在美国和加拿大，默克的生命科学
业务使用MilliporeSigma的名称

MERCK 默克

默克Supelco®标准物质

自2015年默克(Merck)收购西格玛奥德里奇(Sigma-Aldrich)后,经过整合原Sigma-Aldrich、Merck、Supelco等品牌标准品,现已并入默克Supelco品牌旗下。标准物质超过20,000种,涵盖制药、临床和毒理学、刑侦、食品、化妆品、环境、石化等领域内,以及定制服务。商标包括:

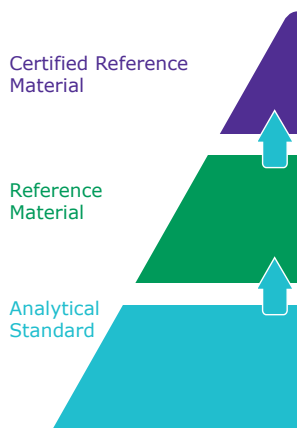
- Pestanal®
- Cerilliant®
- Vetranal™
- TraceCERT®
- Aquastar™
- Certipur®

严格和完善的质量体系,是制造商持续稳定地提供高品质参考物质的保证。ISO 17025 和 ISO 17034 双重认证堪称质量体系的标杆,足以有效保证认证参考物质(CRM)的可靠生产和检测。默克Supelco所有四家参考物质生产基地均通过了此双重认证。

默克生命科学将Merck Millipore与Sigma-Aldrich/Supelco的世界级产品与服务、创新能力及卓越的技术专长完美结合在一起,打造生命科学的全球领导者。

标准物质的质量级别

根据国内外相关法规的定义与要求,不同的生产能力和认证水平,决定着标准物质不同的质量等级,一般分为:认证参考物质(CRM)、参考物质(RM)、分析标准品(Ancalytical Standard)。



认证参考物质 (CRM) (ISO 17034, 17025)

- 提供最高级别的精确度、不确定度和可追溯性(追溯至NMI或国际计量单位SI)
- 其生产通过相关的标准物质生产商认证

参考物质 (RM) (ISO 17034)

- 履行ISO指南的相关要求(低于CRM,无可溯源和不确定性)
- 其生产通过相关的标准物质生产商认证

分析标准品 (Analytical Standard) (ISO 90001)

提供COA证书,但证书涵盖的项目不尽相同。

氨基酸、多肽和蛋白

脂类和脂肪酸

生物标志物和代谢产物

农药

糖、有机酸等

食品和化妆品组分

维生素

环境有机污染物

药典和计量学研究所

物理性质

药物、非法药物和酒精

石化

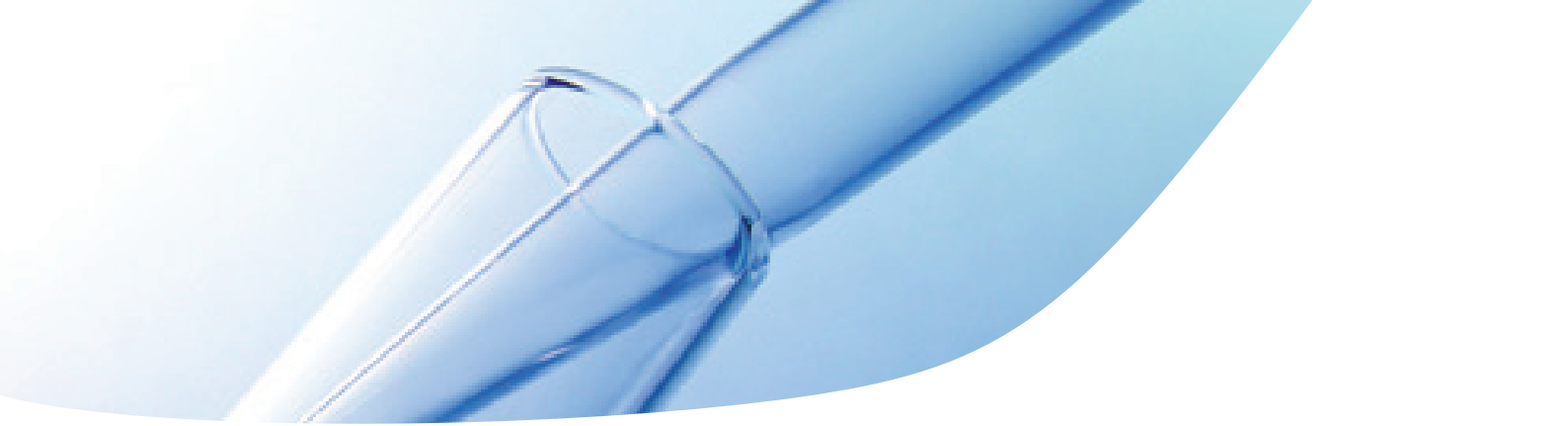
植物提取物

微生物

滴定基准物质

无机元素
(AA/ICP/IC)

确保实验结果精确、
准确与一致性



从药物活性成分 (API) 鉴定, 到元素杂质鉴定, 再到最终产品无菌性测试, 标准物质是制药企业确保生产出安全和高品质药物的关键。默克Supelco®广泛的标准物质产品线, 满足您在药品研究和生产过程中整个分析流程的需要。无论您需要药物一级标准品 (如: EP), 药物二级标准物质CRM, 药物杂质标准物质CRM, 元素杂质、残留溶剂等CRM, 默克Supelco®都是您的合作伙伴, 帮助您实现分析结果的精准性、准确性和一致性, 满足法规及监管要求, 并实现药物及包材的安全性测试。默克Supelco®高品质的标准物质产品线完美匹配您高标准严要求的药物分析。

药物二级标准品CRM

默克Supelco®药物二级标准品专为药物研究和分析所开发, 使用方便, 文件内容齐全, 符合法规相关要求。

美国食品和药物管理局 (FDA)、美国药典 (USP) 和欧洲药典 (EP) 均认可使用可溯源到一级标准品 (如: USP、EP 或 BP) 的二级标准品。

主要产品特性:

- 可追溯至美国药典 (USP) 以及欧洲药典 (EP) 和英国药典 (BP)
- 按照药典规定方法使用 GMP 验证过的设备进行分析
- 根据 ISO 17025 和 ISO Guide 34 通过质量平衡法对标准品进行定值
- 提供符合 ISO Guide 31 规定的全面的标准品分析证书

默克药物二级标准品是在 ISO/IEC 17025 以及 ISO Guide 34 认证设施生产的认证参考物质 (CRM)。随产品一起提供的全面的分析证书提供的数据表明, 可追溯至 USP、EP 以及 BP 一级标准品 (后两种追溯性仅在存在相应一级 CRS 时适用)。

此外, 分析证书还会提供一项独立的认证纯度值, 支持将二级标准品用作定量分析用途的参考物质。

全面的证书

默克药物二级标准品的证书长达 6 页, 包含可追溯性的检测结果、纯度以及分析方法、色谱图等分析数据。登录网站 (sigma-aldrich.com/pharmastandards) 可免费下载分析证书样例。本手册最后附有 6 页布洛芬药物二级标准品 CRM (货号: PHR1004) 分析证书示例。

默克药物标准品的标准品证书可以溯源到药典标准品 (如 USP) 的最新批号。如果有效药典批次发生改变, 则相应默克药物二级标准品也将针对新批次药典重新进行可追溯性认证和分析检测实验, 然后在线提供新证书。正因为这个原因, 建议您在参考物质前, 务必请从网站下载有效的、最新的分析证书。

请注意: 药典机构的参考标准品仅适用于特定的应用或方法。超出限定范围的使用并不受药典支持。默克药物二级标准品证书提供的其他数据仅用于告知信息, 并不支持相应药典应用或方法描述之外的用途。

全面的证书包含以下数据和信息:

- 溯源性分析及谱图 (溯源到 USP、EP 或 BP)
- 有关物质、溶剂残留、水份等杂质分析
- 结构鉴定及谱图 (含 NMR、红外、MS 谱图及熔点、旋光度测定)
- 不确定度、均匀性、稳定性评价

[扫描封面上的二维码, 看视频了解分析证书要点, 100% 得礼品。](#)

可溯源的分析结果

对比分析实验可证明直接溯源至药典标准

- 参比药典标准品(如USP)的可溯源含量值
- 通过质量平衡法计算的纯度(依据 ISO 17025)
- 使用和储存说明
- 分析谱图

节选如下:

1 药典技术要求

2 药典分析方法

3 具体分析条件

4 USP药典标准品批号

5 二级标准品纯度值

6 有关物质测定

7 残留溶剂测定

8 KF水份测定

9 干燥失重

10 质量平衡法定值

11 结构鉴定: 红外光谱

12 质谱图

13 均匀性评价

14 稳定性评价

15 不确定度说明

如下列举部分默克Supelco®药物二级标准品CRM, 并标明其溯源到USP、EP或BP药典标准品的货号。默克Supelco®药物二级标准品CRM, 每年有超过100种新产品上市。

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1256-500MG	Abacavir Sulfate	硫酸阿巴卡韦	1000408		
PHR1266-500MG	Acesulfame Potassium	安赛蜜	1002505	A0070000	
PHR1970-100MG	Acetaminophen Impurity C	对乙酰氨基酚杂质C			
PHR1971-100MG	Acetaminophen Impurity E	对乙酰氨基酚杂质E			
PHR1972-100MG	Acetaminophen Impurity G	对乙酰氨基酚杂质G			
PHR1973-100MG	Acetaminophen Impurity I	对乙酰氨基酚杂质I			
PHR1612-50MG	Acetaminophen Related Compound A	对乙酰氨基酚相关化合物A	1003010		
PHR1642-50MG	Acetaminophen Related Compound B	对乙酰氨基酚相关化合物B	1003027		
PHR1531-200MG	Acetaminophen Related Compound C	对乙酰氨基酚相关化合物C	1003031		
PHR1530-200MG	Acetaminophen Related Compound D	对乙酰氨基酚相关化合物D	1003042		
PHR1150-1G	Acetaminophen Related Compound F	对乙酰氨基酚相关化合物F	1003064		
PHR1149-1G	Acetaminophen Related Compound J	对乙酰氨基酚相关化合物J	1003100		
PHR1148-1G	Acetaminophen Related Compound K	对乙酰氨基酚相关化合物K	1021204		
PHR1086-1G	Acetanilide Melting Point Standard	乙酰苯胺熔点标准品	1004001		
PHR1219-3X1.5ML	Acetone	丙酮	1006801		
PHR1551-3X1.2ML	Acetonitrile	乙腈	1601340		
PHR1546-500MG	Acetylcholine Chloride	氯化乙酰胆碱	1008501	Y0000002	
PHR1156-1G	Acetyltributyl Citrate	乙酰柠檬酸三丁酯	1009901	Y0001055	
PHR1157-1G	Acetyltriethyl Citrate	乙酰柠檬酸三乙酯	1009923		
PHR1523-1G	Acitretin	阿维A	1011007	A0225000	
PHR1254-1G	Acyclovir	阿昔洛韦	1012065	A0220000	
PHR1388-500MG	Adapalene	阿达帕林	1011709	Y0001121	
PHR1383-1G	Adenine	腺嘌呤	1012101	A0230000	
PHR1138-1G	Adenosine	腺苷	1012123	A0230200	
PHR1281-1G	Albendazole	阿苯达唑	1012553	A0325100	763
PHR1967-30MG	Albuterol Related Compound A	沙丁胺醇相关化合物A	1012644		
PHR1599-1G	Alendronate Sodium	阿仑膦酸钠	1012780	Y0001727	
PHR1638-1G	Alfuzosin Hydrochloride	盐酸阿夫唑嗪	1012917	A0325800	
PHR1364-500MG	Allantoin	尿囊素	1012939	A0349000	
PHR1377-1G	Allopurinol	别嘌醇	1013002	A0350000	870

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR2005-50MG	Allopurinol Related Compound A	别嘌醇相关化合物 A	1013024	A0350010	831
PHR2006-50MG	Allopurinol Related Compound B	别嘌醇相关化合物 B			
PHR2007-50MG	Allopurinol Related Compound C	别嘌醇相关化合物 C	1013035	A0350030	843
PHR2008-50MG	Allopurinol Related Compound D	别嘌醇相关化合物 D	1013046	A0350040	844
PHR2009-50MG	Allopurinol Related Compound E	别嘌醇相关化合物 E	1013068	A0350050	845
PHR1981-50MG	Allopurinol Related Compound F	别嘌醇相关化合物 F	1013079		
PHR1711-500MG	Amantadine hydrochloride	盐酸金刚烷胺	1018505	A0363000	530
PHR2063-300MG	Ambroxol Hydrochloride	盐酸氨溴索		A0363700	
PHR1839-1G	Amiloride Hydrochloride	盐酸阿米洛利	1019701	A0370000	8
PHR2061-50MG	Amiloride Related Compound A(Amiloride Impurity A)	阿米洛利相关化合物A	1019712	Y0000020	
PHR1339-500MG	3-Amino-1-propanol	3-氨基-1-丙醇	1570450		
PHR1507-200MG	2-Amino-5-Chlorobenzophenone	2-氨基-5-氯二苯甲酮	1022808		
PHR1719-1G	2-Amino-6-Methoxypurine	6-O-甲基鸟嘌呤			
PHR1747-200MG	4'-Aminoacetophenone	4'-氨基苯乙酮			
PHR1743-200MG	3-Aminobenzoic Acid	3-氨基苯甲酸			
PHR1840-500MG	Aminobenzoic Acid	5-氨基苯甲酸	1019803	Y0000173	
PHR1501-1G	Aminobutanol	氨基丁醇	1020008		
PHR1224-1G	Aminocaproic Acid	氨基己酸	1021000	A0420000	
PHR1745-500MG	4-Aminophenol Hydrochloride	4-氨基苯酚	1021204		
PHR1746-500MG	4-Aminosalicylic Acid	4-氨基水杨酸	1026401		
PHR1164-1G	Amiodarone Hydrochloride	盐酸胺碘酮	1027302	A0575000	532
PHR1646-200MG	Amiodarone Related Compound H	胺碘酮相关化合物 H	1027380		
PHR1384-1G	Amitriptyline Hydrochloride	盐酸阿米替林	1029002	Y0000563	16
PHR1776-50MG	Amitriptyline Related Compound B	阿米替林相关化合物B	1029024		
PHR1185-1G	Amlodipine Besylate	苯磺酸氨氯地平	1029501	Y0000049	
PHR1327-1G	Ammonium Chloride	氯化铵	1029953		
PHR1689-200MG	Ammonium Glycyrhizate	甘草酸铵	1029929	G0460000	
PHR1841-500MG	Amoxapine	阿莫沙平	1031401		
PHR1386-1G	Amylmetacresol	戊间甲酚		Y0001244	
PHR1783-500MG	Anastrozole	阿那曲唑	1034807		
PHR1218-2.2ML	Anethole	反式茴香脑	1035005		
PHR1212-3X1.2ML	Anisole	苯甲醚	1037011		
PHR1677-1G	Anthrakin	地蒽酚	1039006	D2953000	
PHR1454-1G	Arginine Hydrochloride	盐酸精氨酸	1042601	A1271000	694
PHR1784-500MG	Aripiprazole	阿立哌唑	1042634	Y0001649	
PHR1882-100MG	Articaïne	阿替卡因	1042907		
PHR1881-500MG	Articaïne Hydrochloride	盐酸阿替卡因	1042918	Y0000079	
PHR1008-2G	Ascorbic Acid	维生素C	1043003	A1300000	461
PHR1708-30MG	Ascorbic acid Impurity C	维生素C杂质C		Y0001024	
PHR1709-30MG	Ascorbic Acid Impurity D	维生素C杂质D		Y0001170	
PHR1455-2G	Ascorbyl Palmitate	维生素C棕榈酸酯	1043105	Y0000800	
PHR1381-1G	Aspartame	阿司帕坦	1043706	A1320000	
PHR1003-1G	Aspirin	阿司匹林	1044006	A0200000	617
PHR1940-50MG	Aspirin Impurity D	阿司匹林杂质D			
PHR1941-200MG	Aspirin Impurity E	阿司匹林杂质E	1609807		
PHR1942-50MG	Aspirin Impurity F	阿司匹林杂质F			
PHR1909-500MG	Atenolol	阿替洛尔	1044403	A1340000	492
PHR1031-500MG	A-Tocopherol	α-生育酚	1667600	T1550000	882
PHR1030-500MG	A-Tocopheryl Acetate	DL-α-生育酚醋酸酯	1667701	T1600000	
PHR1029-500MG	A-Tocopheryl Acid Succinate	D-α-生育酚琥珀酸酯	1667803	T1610000	
PHR1679-500MG	Atomoxetine Hydrochloride	盐酸托莫西汀			
PHR1422-1G	Atorvastatin Calcium	阿托伐他汀钙	1044516	Y0001327	
PHR1868-30MG	Atorvastatin Related Compound A	阿托伐他汀相关化合物 A	1044527	Y0001328	
PHR1869-30MG	Atorvastatin Related Compound B	阿托伐他汀相关化合物 B	1044538		
PHR1870-30MG	Atorvastatin Related Compound C	阿托伐他汀相关化合物 C	1044549	Y0001330	
PHR1871-30MG	Atorvastatin Related Compound D	阿托伐他汀相关化合物D	1044550	Y0001331	
PHR1872-30MG	Atorvastatin Related Compound E	阿托伐他汀相关化合物 E	1044571	Y0001332	
PHR1873-30MG	Atorvastatin Related Compound H	阿托伐他汀相关化合物 H	1044582		
PHR1874-30MG	Atorvastatin Related Compound I	阿托伐他汀相关化合物 I	1044593		
PHR1591-500MG	Atovaquone	阿托伐醌	1044651	Y0001572	
PHR1073-1G	Avobenzone	阿伏苯宗	1045337		
PHR1911-300MG	Azacitidine	阿扎胞苷	1045520		
PHR1282-1G	Azathioprine	硫唑嘌呤	1046001	A1500000	
PHR1636-1G	Azelastine Hydrochloride	氮萘斯汀	1046158	Y0000326	
PHR1682-1G	Baclofen	巴氯芬			
PHR1912-250MG	Benazepril Hydrochloride	盐酸贝那普利	1048619	Y0001025	
PHR1203-3X1ML	Benzaldehyde	苯甲醛	1050905		
PHR1371-5ML	Benzalkonium Chloride 10% Solution	10%苯扎氯铵标准液	1051001		
PHR1681-1ML	Benzalkonium Chloride 50% Solution	50%苯扎氯铵标准液	1051001		
PHR1310-1G	Benzene	苯	1601146		
PHR1425-1G	Benzethonium Chloride	苄索氯铵	1051500	B0550000	

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1158-1G	Benzocaine	苯佐卡因	1054000	B0600000	
PHR1050-1G	Benzoic Acid	苯甲酸	1055002		
PHR1204-1G	Benzophenone	二苯甲酮		Y0000647	
PHR1028-1G	1,4-Benzoquinone	1,4-对苯醌	1056504		
PHR1192-500MG	Benzothiadiazine Related Compound A	苯并噻二嗪相关化合物A	1057507		
PHR1019-1G	Benzyl Alcohol	苯甲醇	1061901	Y0000167	
PHR1213-5G	Benzyl Benzoate	苯甲酸苄酯	1062008		
PHR1370-1ML	Benzyl Nicotinate	烟酸苄酯			
PHR1349-1G	Beta-Alanine	β-丙氨酸	1012495		
PHR1239-3X100MG	Beta-Carotene	β-胡萝卜素	1065480		
PHR1439-1G	Beta-Cyclodextrin	倍他环糊精	1154569		
PHR2097-500MG	Betahistine Hydrochloride	盐酸倍他司汀	1065618	Y0000391	824
PHR1678-1G	Bicalutamide	比卡鲁胺	1071202	Y0001444	1115
PHR1296-1G	Bifonazole	联苯苄唑		B1110000	
PHR1233-1G	Biotin	生物素	1071508	B1116000	
PHR1456-2X1G	Bis(2-Ethylhexyl)Maleate	马来酸二异辛酯	1075203		
PHR1913-500MG	Bisotrizole	亚甲基双-苯并三唑基四甲基丁基酚	1075677		
PHR1831-200MG	Bromhexine Hydrochloride	溴己新		B1145000	
PHR1864-500MG	Brompheniramine Maleate	马来酸溴苯那敏	1078008	B1153000	
PHR1823-50MG	Budesonide Related Compound L	布地奈德相关化合物L	1078289		
PHR1128-1G	Bupivacaine Hydrochloride	布比卡因	1078507	B1160000	479
PHR1756-20MG	Bupivacaine Impurity B	布比卡因相关化合物B	1078529	Y0000088	
PHR1738-40MG	Bupivacaine Impurity E	布比卡因相关化合物A	1078518	Y0000089	
PHR1730-1G	Bupropion Hydrochloride	安非他酮	1078733		
PHR1752-30MG	Bupropion Hydrochloride Related Compound A	安非他酮相关化合物A	1078744		
PHR1753-30MG	Bupropion Hydrochloride Related Compound B	安非他酮相关化合物B	1078755		
PHR1755-30MG	Bupropion Related Compound F	安非他酮相关化合物F	1078799		
PHR1917-500MG	Buspirone Hydrochloride	盐酸丁螺环酮	1078802	Y0000131	
PHR1209-3X1.2ML	1-Butanol	正丁醇	1081807		
PHR1563-3X1.2ML	2-Butanol	2-丁醇	1081829		
PHR1621-1G	Butoconazole Nitrate	硝酸布康唑	1082300		
PHR1211-3X1.2ML	Butyl Acetate	乙酸丁酯	1082606		
PHR1304-1G	Butylated Hydroxyanisole	丁基羟基茴香醚		B1212000	
PHR1117-1G	Butylated Hydroxytoluene	2,6-二叔丁基-4-甲基苯酚	1082708	B1215000	
PHR1022-1G	Butylparaben	对羟基苯甲酸丁酯	1084000	B1217000	
PHR2038-50MG	Caffeine Impurity B	咖啡因杂质 B	1653037		
PHR1951-30MG	Caffeine Impurity E	咖啡因杂质 E			
PHR2000-50MG	Caffeine Impurity F	咖啡因杂质 F			
PHR1362-5G	Calcium Acetate	乙酸钙	1086334		
PHR1361-500MG	Calcium Ascorbate	抗坏血酸钙	1086356		
PHR1326-5G	Calcium Carbonate	碳酸钙	1086403		
PHR1457-1G	Calcium Lactobionate	乳糖酸钙	1086902		
PHR1232-500MG	Calcium-D-Pantothenate	D-泛酸半钙盐	1087009	C0400000	
PHR1854-200MG	Candesartan Cilexetil	坎地沙坦酯	1087803	Y0001388	
PHR2035-20MG	Candesartan Cilexetil Impurity C	坎地沙坦酯杂质 C			
PHR2036-20MG	Candesartan Cilexetil Impurity E	坎地沙坦酯杂质 E			
PHR2022-20MG	Candesartan Cilexetil Impurity I	坎地沙坦酯杂质I			
PHR2017-20MG	Candesartan Cilexetil Related Compound A	坎地沙坦酯相关化合物A			
PHR2018-20MG	Candesartan Cilexetil Related Compound B	坎地沙坦酯相关化合物B	1087825		
PHR2019-20MG	Candesartan Cilexetil Related Compound D	坎地沙坦酯相关化合物 D			
PHR2020-20MG	Candesartan Cilexetil Related Compound F	坎地沙坦酯相关化合物 F	1087869		
PHR2021-20MG	Candesartan Cilexetil Related Compound G	坎地沙坦酯相关化合物G	1087870		
PHR1405-1G	Capecitabine	卡培他滨	1090706	Y0001642	
PHR1202-1G	Caprylic Acid	正辛酸	1091040	C0426000	
PHR1307-1G	Captopril	卡托普利	1091200	C0430000	538
PHR1511-500MG	Carbachol	卡巴胆碱			
PHR1067-1G	Carbamazepine	卡马西平	1093001	C0450000	
PHR1918-50MG	Carbamazepine Related Compound A	卡马西平相关化合物A	1093012	Y0000033	
PHR1197-500MG	Carbamazepine Related Compound B	卡马西平相关化合物B	1093023		
PHR1655-1G	Carbidopa	卡比多巴	1095506	C0460000	60
PHR1684-1G	Carbimazole	卡比马唑		C0465000	
PHR1452-1G	Carprofen	卡洛芬	1096699	Y0000846	
PHR1564-200MG	Carprofen Related Compound A (Carbazole)	卡洛芬相关化合物A	1096702		
PHR1963-50MG	Catechin	(+)-儿茶素	1096790		
PHR1683-1G	Celecoxib	塞来昔布	1098504	Y0001445	
PHR1656-1G	Cetirizine Dihydrochloride	盐酸西替利嗪	1102929	C0980650	837
PHR1710-40MG	Cetirizine hydrochloride Related Compound A	盐酸西替利嗪相关化合物A			
PHR1133-1G	Cetyl Alcohol	1-十六烷醇	1103003	C0990000	
PHR1166-1G	Cetyl Palmitate	棕榈酸棕榈酯	1103105	Y0000074	
PHR1226-1G	Cetylpyridinium Chloride	西吡氯铵	1104006	C1000000	
PHR1421-1G	Chlorhexidine	氯己定	1111001	C1510000	

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货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1222-500MG	Chlorhexidine Acetate	醋酸氯己定	1111103	C1520000	68
PHR1294-1G	Chlorhexidine Digluconate Solution	氯己定二葡萄糖酸盐			
PHR1459-500MG	Chlorhexidine Hydrochloride	氯己定	1111103	C1540000	
PHR1200-1G	Chlorhexidine Imurity P	氯己定杂质P	1111908		
PHR1665-3X1.2ML	Chlorobenzene	氯苯	1601361		
PHR1545-1G	Chlorobutanol	三氯叔丁醇	1112503		
PHR1258-1G	Chloroquine Phosphate	磷酸氯喹	1118000		
PHR1478-500MG	Chloroxylenol	氯二甲苯酚	1122700		
PHR2004-50MG	Chlorpheniramine Impurity A	氯苯那敏杂质A		Y0000436	
PHR1016-500MG	Chlorpheniramine Maleate	马来酸氯苯那敏	1123000	C1800000	81
PHR1647-200MG	Chlorpheniramine Related Compound B	氯苯那敏相关杂质B			
PHR1688-50MG	Chlorpheniramine Related Compound C	氯苯那敏相关杂质C			
PHR1284-1G	Chlorpropamide	氯磺丙脲	1126009	C1905000	
PHR1919-500MG	Chlorzoxazone	氯唑沙宗	1130505		
PHR1237-500MG	Cholecalciferol	胆钙化醇	1131009	C2100000	787
PHR1533-500MG	Cholesterol	胆固醇	1131960	C2155000	
PHR1460-500MG	Choline Bitartrate	重酒石酸胆碱	1133536		
PHR1251-500MG	Choline Chloride	氯化胆碱	1133547		
PHR1920-500MG	Ciclopirox	环吡酮胺			
PHR1503-1G	Clostazol	西洛他唑	1134153		
PHR1653-100MG	Clostatzol Related Compound B	西洛他唑相关化合物B	1134175		
PHR1676-100MG	Clostatzol Related Compound C	西洛他唑相关化合物C	1134186		
PHR1075-1G	Cimetidine	西咪替丁	1134062	C2175000	475
PHR1089-1G	Cimetidine Hydrochloride	盐酸西咪替丁	1134073	C2175500	
PHR1167-1G	Ciprofloxacin	环丙沙星	1134313	C2190000	
PHR1044-1G	Ciprofloxacin Hydrochloride	盐酸环丙沙星	1134335	Y0000198	
PHR1174-500MG	Ciprofloxacin Impurity A (Fluoroquinolonic Acid)	环丙沙星杂质A	1278302	C2190050	
PHR1910-50MG	Ciprofloxacin Related Compound A	环丙沙星相关化合物A	1134346		
PHR1624-200MG	Cisplatin	顺铂	1134357	C2210000	
PHR1640-1G	Citalopram Hydrobromide	氢溴酸西酞普兰	1134233	Y0001008	
PHR1901-50MG	Citalopram Related Compound A	西酞普兰相关化合物A	1134244		
PHR1902-50MG	Citalopram Related Compound C	西酞普兰相关化合物C	1134266		
PHR1903-30MG	Citalopram Related Compound D	西酞普兰相关化合物D	1134277		
PHR1904-50MG	Citalopram Related Compound E	西酞普兰相关化合物E	1134288		
PHR1863-200MG	Citalopram Related Compound F	西酞普兰相关化合物F	1134299		
PHR1905-25MG	Citalopram Related Compound G	西酞普兰相关化合物G	1134197		
PHR1906-50MG	Citalopram Related Compound H	西酞普兰相关化合物H	1134222		
PHR1071-1G	Citric Acid	柠檬酸	1134368	A1202000	
PHR1720-1G	Clomipramine Hydrochloride	氯米帕明	1140427	C2360000	980
PHR1431-1G	Clopidogrel Bisulfate	硫酸氢氯吡格雷	1140430	Y0001333	
PHR1990-40MG	Clopidogrel Related Compound A	氯吡格雷相关化合物A	1140586	Y0001335	
PHR1991-40MG	Clopidogrel Related Compound B	氯吡格雷相关化合物B			
PHR1992-40MG	Clopidogrel Related Compound C	氯吡格雷相关化合物C			
PHR1058-1G	Clotrimazole	克霉唑	1141002	C2430000	379
PHR1183-500MG	Clotrimazole Impurity E (2-Chlorobenzophenone)	克霉唑杂质E		Y0000279	
PHR1597-1ML	CMIT/MIT	甲基氯异噻唑啉酮/甲基异噻唑啉酮(CMIT/MIT) 混标			
PHR1461-1G	Copper Chlorophyllin	叶绿素铜			
PHR1477-1G	Copper Sulfate	硫酸铜			
PHR1462-1G	Creatinine	肌酐	1150353		
PHR1210-3X1.2ML	Cumene	枯烯	1151709		
PHR1234-1G	Cyanocobalamin	维生素B12	1152009	C3000000	466
PHR1687-3X1.2ML	Cyclohexane	环己烷	1601408		
PHR1404-1G	Cyclophosphamide	环磷酰胺	1157002	C3250000	
PHR1787-500MG	Cytarabine	阿糖胞苷	1162002	C3350000	383
PHR1350-500MG	Cytosine	胞嘧啶	1162148		
PHR1565-500MG	D4 Cyclomethicone	八甲基环四硅氧烷	1154707		
PHR1566-500MG	D5 Cyclomethicone	十甲基环五硅氧烷	1154809		
PHR1924-250MG	Dacarbazine	达卡巴嗪	1162308	Y0000733	100
PHR1858-100MG	Daidzein	黄豆甙元			
PHR1464-1G	Dapsone	氨苯砜	1164008	D0100000	102
PHR1119-1G	D-Camphor	D-樟脑	1087508	C0405000	
PHR1070-5X1.2ML	Dehydrated Alcohol	无水乙醇	1012772		
PHR1582-1G	Dehydroacetic Acid	脱氢乙酸	1166309		
PHR1300-500MG	Dequalinium Chloride	地喹氯铵		D0430000	
PHR2025-50MG	Desbenzyl donepezil hydrochloride	去苄基多奈哌齐盐酸盐			
PHR1723-400MG	Desipramine Hydrochloride	去甲丙米嗪	1172006	D0500000	931
PHR1680-1G	Desloratadine	地氯雷他定			
PHR1228-500MG	Dexpanthenol	D-泛醇	1179504	D0730000	
PHR1975-30MG	Dextromethorphan Impurity C	右美沙芬杂质C			
PHR1974-30MG	Dextrophan tartrate	酒石酸去甲右美沙芬			
PHR1000-1G	Dextrose	葡萄糖	1181302	G0350500	

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货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1956-200MG	D-Glucuronic Acid	D-葡萄糖醛酸	1294319		
PHR1366-1G	Dibutyl Phthalate	邻苯二甲酸二丁酯	1187080	D1010000	
PHR1216-3X1.2ML	Dibutyl Sebacate	癸二酸二正丁酯	1187091		
PHR1144-1G	Diclofenac Sodium	双氯芬酸钠	1188800	S0765000	619
PHR1220-3.2ML	Diethanolamine	二乙醇胺	1192808		
PHR1476-1G	Diethyl Phthalate	邻苯二甲酸二乙酯	1193505	D1410000	
PHR2094-5G	Diethylamino Hydroxybenzoyl Hexyl Benzoate	二乙氨基苯甲酰基苯甲酸己酯			
PHR1045-1G	Diethylene Glycol	二乙二醇	1193265		
PHR1771-300MG	Digoxin	地高辛	1200000	D1900000	
PHR1430-1G	Dihydroxyacetone	二羟基丙酮	1204102		
PHR1309-3G	Dimethyl Sulfoxide	二甲基亚砷	1211006	D2050000	
PHR1553-3X1.2ML	Dimethylformamide	N,N-二甲基甲酰胺	1601500		
PHR1549-3X1.2ML	1,4-Dioxane	二氧六环	1601521		
PHR1015-1G	Diphenhydramine Hydrochloride	盐酸苯海拉明	1218005	D2000000	896
PHR1897-50MG	Diphenhydramine Impurity B	苯海拉明杂质B			
PHR1861-50MG	Diphenhydramine Impurity C	苯海拉明杂质C	1077005		
PHR2071-100MG	Diphenhydramine Impurity D	苯海拉明杂质D	1051602	Y0000887	
PHR1898-50MG	Diphenhydramine N-Oxide HCl	盐酸苯海拉明氧化物	1218050		
PHR1993-50MG	Diphenhydramine Related Compound A	苯海拉明相关化合物A	1218016		
PHR1899-50MG	Diphenhydramine Related Compound B	苯海拉明相关化合物B	1218027		
PHR1514-1G	Disodium Guanylate	鸟苷酸二钠	1221000		
PHR1475-1G	Disodium Inosinate	肌苷酸二钠	1222002		
PHR1690-1G	Disulfiram	二硫化四乙基秋兰姆	1224008	D2950000	132
PHR1358-1ML	Dmdm Hydantoin	DMDM乙内酰脲			
PHR1788-1G	Docosahexaenoic Acid Ethyl Ester	二十二碳六烯酸乙酯	1224620	D2954600	
PHR1584-1G	Donepezil Hydrochloride	盐酸多奈哌齐	1224981		
PHR2023-50MG	Donepezil Related Compound A	多奈哌齐相关化合物A	1224992		
PHR2024-50MG	Donepezil-N-Oxide	多奈哌齐氧化物			
PHR1090-1G	Dopamine Hydrochloride	盐酸多巴胺	1225204	D2690000	468
PHR1925-500MG	Dorzolamide Hydrochloride	盐酸多佐胺	1225281	Y0000726	1069
PHR1420-1G	Doxylamine Succinate	琥珀酸多西拉敏	1227006	Y0001562	
PHR1865-500MG	Duloxetine Hydrochloride	盐酸度洛西汀	1229817	Y0001453	
PHR1849-500MG	Dyclonine Hydrochloride	达克罗宁	1230000		
PHR1510-1G	Edetate Calcium Disodium	乙二胺四乙酸钙二钠	1232006	S0700000	
PHR1068-1G	Edetate Disodium	依地酸盐二钠	1233009	D2900000	
PHR1277-500MG	Edetate Disodium Impurity A	依地酸盐二钠杂质A	1463950		
PHR2072-500MG	Efavirenz	依非韦伦	1234103		
PHR2068-50MG	Efavirenz Related Compound A	依非韦伦相关物质A	1234125		
PHR2069-50MG	Efavirenz Related Compound B	依非韦伦相关物质B	1234147		
PHR2070-50MG	Efavirenz Related Compound C	依非韦伦相关物质C	1234136		
PHR1790-1G	Eicosapentaenoic Acid Ethyl Ester	二十碳五烯酸乙酯	1234307	E0085000	
PHR2120-500MG	Emtricitabine	恩曲他滨			
PHR1289-1G	Enalapril Maleate	马来酸依那普利	1235300	E0109000	
PHR1513-500MG	Enrofloxacin	恩诺沙星	1235900	Y0001259	
PHR1301-1G	Ensulizole	2-苯基苯并咪唑-5-磺酸	1530809		
PHR1333-1G	Epigallocatechin Gallate	(-)-表没食子儿茶素没食子酸酯	1236700		
PHR1766-1G	Eprinomectin	依普菌素	1237752		
PHR1238-500MG	Ergocalciferol	麦角钙化甾醇(维生素D2)	1239005	E0900000	788
PHR1512-200MG	Ergosterol	麦角甾醇	1241007	E1100000	
PHR1479-1G	Erythritol	赤藓糖醇	1241903	Y0000477	
PHR1733-1G	Escitalopram Oxalate	草酸艾司西酞普兰	1249406		
PHR1585-1G	Esomeprazole Magnesium	埃索美拉唑镁	1249789	Y0001028	
PHR1930-500MG	Ethambutol Hydrochloride	乙胺丁醇	1257007	E1850000	
PHR1373-5X1.2ML	Ethanol	乙醇	1012768	E1860100	
PHR1413-1G	Ethosuximide	乙琥胺	1264002	E2150000	146
PHR1550-3X1.2ML	2-Ethoxyethanol	2-乙氧基乙醇	1601543		
PHR1481-3X1.2ML	Ethyl Acetate	乙酸乙酯	1265402	E2195000	
PHR1267-1G	Ethyl Maltol	乙基麦芽酚	1266008		
PHR1268-1G	Ethyl Vanillin	乙基香兰素	1267500		
PHR1229-3X1.2ML	Ethylbenzene	乙苯	1265457		
PHR1046-1G	Ethylene Glycol	乙二醇	1265515		
PHR1295-1.2ML	Ethylene Oxide Stock Solution	环氧乙烷标准储备液			
PHR1914-3X1.2ML	2-Ethylhexanoic Acid	2-乙基己酸			
PHR1011-1G	Ethylparaben	对羟基苯甲酸乙酯	1267000	E2425000	
PHR1828-500MG	Eucalyptol	桉油精	1268900	Y0000176	
PHR1269-1G	Eugenol	丁香酚	1268965	E5000000	
PHR1866-1G	Ezetimibe	依折麦布	1269028		
PHR1696-1G	Famciclovir	泛昔洛韦	1269152		
PHR1055-1G	Famotidine	法莫替丁	1269200	F0050000	653
PHR1832-200MG	Fenbendazole	芬苯达唑			
PHR1246-500MG	Fenofibrate	非诺贝特	1269447	F0048000	

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PHR1482-1G	Ferrous Fumarate	富马酸亚铁			
PHR1644-1G	Ferrous Lactate	乳酸亚铁			
PHR1483-1G	Ferrous Sulfate	硫酸亚铁			
PHR1791-100MG	Ferulic Acid	阿魏酸	1270311	Y0001013	
PHR1685-1G	Fexofenadine Hydrochloride	盐酸非索非那定	1270377	Y0000789	1095
PHR1160-1G	Fluconazole	氟康唑	1271700	Y0000557	
PHR1651-30MG	Fluconazole Related Compound A	氟康唑相关化合物A	1271711	Y0000573	
PHR1862-20MG	Fluconazole Related Compound B	氟康唑相关化合物B	1271722		
PHR1826-20MG	Fluconazole Related Compound C	氟康唑相关化合物C	1271733		
PHR1659-1G	Flucytosine	氟胞嘧啶	1272000	F0175000	
PHR1442-1G	Flunixin Meglumine	氟尼辛葡甲胺	1274607	Y0000443	
PHR1227-500MG	Fluorouracil	氟尿嘧啶	1279000	F0250000	995
PHR1394-1G	Fluoxetine Hydrochloride	氟西汀盐酸盐	1279804	F0253000	797
PHR1952-30MG	Fluoxetine Related Compound A	氟西汀相关化合物A	1279815	F0253030	
PHR1953-30MG	Fluoxetine Related Compound C	氟西汀相关化合物C	1279837		
PHR1792-1G	Fluphenazine Hydrochloride	盐酸氟奋乃静	1282004	F0280000	167
PHR1499-500MG	Flurbiprofen	氟比洛芬	1285750	F0285200	
PHR1846-30MG	Fluticasone Related Compound J	氟替卡松相关化合物J	1285818		
PHR1620-1G	Fluvastatin Sodium	氟伐他汀钠	1285931	Y0001082	
PHR1793-500MG	Fluvoxamine Maleate	马来酸氟伏沙明	1285909	Y0000854	600
PHR1035-1G	Folic Acid	叶酸	1286005	F0300000	
PHR1334-500MG	Folic Acid Impurity A	叶酸杂质A			
PHR2001-20MG	Folic Acid Impurity B	叶酸杂质B			
PHR2002-100MG	Folic Acid Impurity D	叶酸杂质D		Y0001243	
PHR1436-1G	Foscarnet Sodium	膦甲酸钠	1283302	F0389000	623
PHR1002-1G	Fructose	果糖	1286504	F0550000	
PHR1270-1G	Fumaric Acid	富马酸	1286708	F0600000	
PHR1057-1G	Furosemide	呋塞米	1287008	F0700000	547
PHR1817-100MG	Furosemide Related Compound A	呋塞米相关化合物A			
PHR1816-100MG	Furosemide Related Compound B	呋塞米相关化合物B			
PHR1049-1G	Gabapentin	加巴喷丁	1287303		
PHR1979-50MG	Gabapentin Impurity G	加巴喷丁杂质G			
PHR1322-100MG	Gabapentin Related Compound A	加巴喷丁相关物质A	1287325	Y0001281	
PHR2011-100MG	Gabapentin Related Compound B	加巴喷丁相关物质B	1287347	Y0001348	
PHR2012-20MG	Gabapentin Related Compound D	加巴喷丁相关物质D	1287358	Y0001349	
PHR2013-50MG	Gabapentin Related Compound E	加巴喷丁相关化合物E	1287369		
PHR1833-1G	Galactitol	甜醇			
PHR2042-200MG	Galactosamine Hydrochloride	盐酸半乳糖胺	1287722		
PHR1593-1G	Ganciclovir	更昔洛韦	1288306	Y0001129	
PHR1286-1G	Gemfibrozil	吉非罗齐	1288500	Y0000513	
PHR1859-100MG	Genistein	染料木素			
PHR1567-500MG	Gibberellic Acid	赤霉素			
PHR1748-3X1.5ML	Glacial Acetic Acid	乙酸	1005706		
PHR1288-1G	Gliclazide	格列齐特		G0326000	368
PHR1617-1G	Glimepiride	格列美脲	1292303	Y0000515	1144
PHR1725-40MG	Glimepiride Related Compound A (Glimepiride cis-Isomer)	格列美脲相关化合物A	1292314		
PHR1727-40MG	Glimepiride Related Compound C (Glimepiride Urethan-e)	格列美脲相关化合物C	1292336		
PHR1818-1G	Glipizide	格列吡嗪	1292507	G0340000	
PHR1813-50MG	Glipizide Related Compound A	格列吡嗪相关化合物A	1292609	G0342000	
PHR1814-50MG	Glipizide Related Compound B	格列吡嗪相关化合物B	1292610	Y0000643	
PHR1815-50MG	Glipizide Related Compound C	格列吡嗪相关化合物C	1292631		
PHR1199-500MG	Glucosamine Hydrochloride	氨基葡萄糖	1294207	Y0001406	
PHR1359-500MG	Glutathione	谷胱甘肽	1294820	Y0000517	
PHR1287-1G	Glyburide	格列本脲	1295505	G0325000	175
PHR1020-5G	Glycerin	甘油	1295607	G0400000	
PHR1484-1G	Glyceryl Monooleate 40%	甘油酸单油脂	1295753		
PHR1111-1G	Glycine	甘氨酸	1295800	G0450000	
PHR1427-1G	Glycolic Acid	乙醇酸			
PHR1516-200MG	Glycyrrhizic Acid	甘草酸	1295888		
PHR1616-500MG	Granisetron Hydrochloride	格拉司琼	1298106	Y0000396	
PHR1136-1.5G	Guaiacol	愈创木酚	1300004	Y0000619	
PHR1027-1G	Guaifenesin	愈创甘油醚	1301007	G0700000	
PHR1543-50MG	Guaifenesin Impurity B	愈创甘油醚杂质B			
PHR1751-500MG	Guanfacine Hydrochloride	盐酸胍法辛	1302101		
PHR1243-500MG	Guanine	鸟嘌呤	1302156		879
PHR1724-400MG	Haloperidol	氟哌啶醇			
PHR1428-1G	HEPES	HEPES			
PHR1554-3X1.2ML	Heptane	庚烷	1304209		
PHR1794-500MG	Hesperidin	橙皮苷	1304377	Y0001203	
PHR1555-3X1.2ML	Hexane	正己烷	1601601		
PHR1357-500MG	Histamine Dihydrochloride	组胺	1309009	H0600000	

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1085-1G	Homosalate	胡莫柳酯	1311408		
PHR1469-1G	Hydroquinone	对苯二酚	1324002		
PHR1916-3X1.2ML	4-Hydroxy-4-Methyl-2-Pentanone	4-羟基-4-甲基-2-戊酮			
PHR1048-1G	4-Hydroxybenzoic Acid	对羟基苯甲酸	1609013		
PHR1782-1G	Hydroxychloroquine Sulfate	羟氯喹	1327000		1100
PHR1742-200MG	2-Hydroxy-Nitrobenzoic Acid	2-羟基-硝基苯甲酸			
PHR1939-500MG	Hydroxyproline	羟脯氨酸			
PHR1440-1G	Hydroxypropyl Beta Cyclodextrin	羟丙基倍他环糊精	1329709	Y0000186	
PHR1485-1G	Hydroxypropyl Cellulose	羟丙基纤维素	1329800		
PHR1607-1G	Hydroxyzine Dihydrochloride	羟嗪	1333003	H1435000	841
PHR1829-500MG	Hypromellose	羟丙甲纤维素	1330005		
PHR1004-1G	Ibuprofen	布洛芬	1335508	I0020000	539
PHR1933-20MG	Ibuprofen Impurity A	布洛芬杂质A			
PHR1934-20MG	Ibuprofen Impurity B	布洛芬杂质B			
PHR1964-30MG	Ibuprofen Impurity F	布洛芬杂质F			
PHR1965-50MG	Ibuprofen Impurity G	布洛芬杂质G			
PHR2028-50MG	Ibuprofen Impurity H	布洛芬杂质H			
PHR1984-50MG	Ibuprofen Impurity I	布洛芬杂质I			
PHR1935-20MG	Ibuprofen Impurity N	布洛芬杂质N			
PHR1983-30MG	Ibuprofen Impurity O	布洛芬杂质O			
PHR1982-50MG	Ibuprofen Impurity R	布洛芬杂质R			
PHR1146-500MG	Ibuprofen Related Compound C(4-Isobutylacetophenone)	布洛芬相关化合物C(布洛芬杂质E)	1335541		
PHR1978-50MG	Ibuprofen Related Compound J	布洛芬相关化合物J	1335596		
PHR1180-500MG	Imidazole	咪唑	1336580		
PHR1500-1G	Imidurea	咪唑烷基脲	1336806		
PHR1795-100MG	Iminodibenzyl	亚氨基联苄	1337004		
PHR1797-1G	Imipramine Hydrochloride	丙米嗪	1338007	I0100000	932
PHR1247-500MG	Indomethacin	吲哚美辛	1341001	I0200000	
PHR1351-1G	Inositol	肌醇	1340960	Y0000485	
PHR1354-500MG	3-Iodo-2-Propynyl N-Butylcarbamate	3-碘-2-丙炔基N-丁氨基甲酸酯			
PHR1931-1G	Iohexol	碘海醇	1344600	I0320800	
PHR1985-500MG	Iopamidol	碘帕醇	1344702	I0329000	
PHR1443-1G	Irbesartan	厄贝沙坦	1347700	Y0001166	
PHR1958-50MG	Irbesartan Related Compound A	厄贝沙坦相关化合物A	1347711	Y0001156	1122
PHR1999-50MG	Isocaffeine (Caffeine Impurity C)	咖啡因杂质 C			
PHR1932-500MG	Isoniazid	异烟肼	1349706	I0500000	1083
PHR1661-2ML	Isopentane Solution	异戊烷			
PHR1123-1G	Isopropyl Myristate	肉豆蔻酸异丙酯	1350400	I0750000	
PHR1137-1G	Isopropyl Palmitate	棕榈酸异丙酯	1350603	I0725000	
PHR1486-1G	Isosorbide Solution	异山梨醇	1352008		
PHR1188-3X100MG	Isotretinoin	异维A酸	1353500	I0800000	
PHR1834-200MG	Itraconazole	伊曲康唑	1354251	I7000000	
PHR1380-1G	Ivermectin	伊维菌素	1354309	I8000010	864
PHR1385-1G	Ketoconazole	酮康唑	1356508	K0600000	
PHR1375-500MG	Ketoprofen	酮洛芬	1356632	K2000000	668
PHR1140-500MG	Ketorolac Tromethamine	酮咯酸氨丁三醇	1356665	Y0000486	
PHR1215-3X1.5ML	Lactic Acid	乳酸	1356734		
PHR1025-1G	Lactose Anhydrous	乳糖(无水)	1356676	A1206000	
PHR1024-1G	Lactose Monohydrate	乳糖一水合物	1356701	L0100000	
PHR1110-1G	L-Alanine	L-丙氨酸	1012509	A0325000	
PHR1365-1G	Lamivudine	拉米夫定	1356836	Y0000425	802
PHR1392-1G	Lamotrigine	拉莫三嗪	1356756	Y0001030	
PHR1390-1G	Lansoprazole	兰索拉唑	1356916	Y0000773	872
PHR1489-1G	L-Arabinitol	阿拉伯糖醇	1042102	A1269000	
PHR1106-1G	L-Arginine	L-精氨酸	1042500	A1270000	
PHR1104-1G	L-Aspartic Acid	L-天冬氨酸	1043819	A1330000	
PHR1580-1G	Lauric Acid	十二烷酸	1356949	Y0001474	
PHR1102-1G	L-Cysteine Hydrochloride Monohydrate	L-半胱氨酸盐酸盐一水合物	1161509	C3290000	
PHR1323-500MG	L-Cystine	L-胱氨酸	1161586		
PHR1378-1G	Leflunomide	来氟米特	1356960	Y0000654	
PHR1568-200MG	Leflunomide Related Compound A	来氟米特相关化合物A	1357045	Y0000487	
PHR1540-1G	Letrozole	来曲唑	1356971	Y0000685	
PHR1541-1G	Leucovorin Calcium	亚叶酸钙盐	1358004	C0250000	923
PHR1798-250MG	Levamisole Hydrochloride	左旋咪唑	1359302	L0380000	212
PHR1447-1G	Levetiracetam	左乙拉西坦	1359404	Y0001253	
PHR1569-1G	Levocarnitine	左卡尼汀	1359903	L0399000	
PHR1271-500MG	Levodopa	左多巴	1361009	L0400000	
PHR1697-1G	Levofloxacin	左氧氟沙星			
PHR1107-1G	L-Glutamic Acid	L-谷氨酸	1294976	G0355000	
PHR1125-1G	L-Glutamine	L-谷氨酰胺	1294808		
PHR1108-1G	L-Histidine	L-组氨酸	1308505	H0750000	

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1034-1G	Lidocaine	利多卡因	1366002	L0595000	727
PHR1257-500MG	Lidocaine Hydrochloride	盐酸利多卡因		L0600000	214
PHR1977-50MG	Lidocaine Impurity D	利多卡因杂质D			
PHR1994-50MG	Lidocaine Impurity F	利多卡因杂质F			
PHR1995-50MG	Lidocaine Impurity G	利多卡因杂质G			
PHR1669-100MG	Lidocaine Related Compound A	利多卡因相关化合物A			
PHR1670-100MG	Lidocaine Related Compound B	利多卡因相关化合物B			
PHR1671-100MG	Lidocaine Related Compound C	利多卡因相关化合物C			
PHR1672-100MG	Lidocaine Related Compound E	利多卡因相关化合物E			
PHR1673-100MG	Lidocaine Related Compound H	利多卡因相关化合物H	1366080		
PHR1674-100MG	Lidocaine Related Compound I	利多卡因相关化合物I			
PHR1675-100MG	Lidocaine Related Compound J	利多卡因相关化合物J			
PHR1885-500MG	Linezolid	利奈唑胺	1367561		
PHR1143-1G	Lisinopril	赖诺普利	1368609	L0702000	
PHR1099-1G	L-Isoleucine	L-异亮氨酸	1349502	I0460000	
PHR1105-1G	L-Leucine	L-亮氨酸	1357001	L0375000	
PHR1096-1G	L-Lysine Acetate	L-赖氨酸乙酸盐	1371501	Y0000397	
PHR1101-1G	L-Lysine Monohydrochloride	L-赖氨酸单盐酸盐	1372005	L0900000	
PHR1116-1G	L-Menthol	L-薄荷醇	1381709	M0350000	772
PHR1241-1G	L-Methionine	L-甲硫氨酸	1411504	M0960000	
PHR1162-1G	Loperamide Hydrochloride	洛哌丁胺	1370000	L0750000	635
PHR1927-1G	Lopinavir	洛匹那韦	1370101	Y0001498	
PHR1376-1G	Loratadine	氯雷他定	1370270	Y0000688	874
PHR1602-1G	Losartan Potassium	氯沙坦钾	1370462	Y0001062	867
PHR1285-1G	Lovastatin	洛伐他汀	1370600	L0790000	
PHR1100-1G	L-Phenylalanine	L-苯基丙氨酸	1530503	P1150000	
PHR1332-500MG	L-Proline	L-脯氨酸	1568506	P3350000	
PHR1103-1G	L-Serine	L-丝氨酸	1612506	S0450000	
PHR1242-500MG	L-Threonine	L-苏氨酸	1667202	T1340000	
PHR1097-1G	L-Tyrosine	L-酪氨酸	1705006	T2900000	
PHR1699-3X100MG	Lutein	叶黄素	1370804		
PHR1172-1G	L-Valine	L-缬氨酸	1708503	V0030000	
PHR1770-5X100MG	Lycopene	番茄红素	1370860		
PHR1328-5G	Magnesium Carbonate	碳酸镁	1374226		
PHR1363-2.5G	Magnesium Stearate	硬脂酸镁	1374340		
PHR1272-500MG	Maleic Acid	马来酸	1374500		
PHR1273-1G	Malic Acid	苹果酸	1374601	Y0000143	
PHR1497-1G	Maltose Monohydrate	麦芽糖	1375025		
PHR1007-1G	Mannitol	甘露醇	1375105	M0200000	
PHR1705-1G	Mefloquine Hydrochloride	盐酸甲氟喹	1379059	M0253000	
PHR1324-1G	Meglumine	葡甲胺	1379140	Y0001209	
PHR1799-500MG	Meloxicam	美洛昔康	1379401	Y0001080	629
PHR1886-1G	Memantine Hydrochloride	美金刚	1380502		
PHR1411-500MG	Menadione	甲萘醌	1381006	M0300000	
PHR1529-1G	Menthyl Anthranilate	薄荷醇邻氨基苯甲酸酯	1381742		
PHR1955-500MG	Mepivacaine Hydrochloride	盐酸甲哌卡因	1387002	M0370000	699
PHR1611-1G	Mercaptopurine	巯嘌呤			
PHR1060-1G	Mesalamine	氨水杨酸	1392705	Y0000297	
PHR1225-500MG	Mesalazine Impurity B (M-Aminophenol)	美沙拉嗪杂质B	1026004		
PHR1739-200MG	Mesalazine Impurity C(2-Aminophenol)	美沙拉嗪杂质C		Y0001569	
PHR1547-3X1.2ML	Mesityl Oxide	4-甲基-3-戊烯-2-酮			
PHR1570-500MG	Mesna	美司钠	1392807	Y0000337	
PHR1800-100MG	Metamizole Sodium	安乃近		M0600900	
PHR1084-500MG	Metformin Hydrochloride	盐酸二甲双胍	1396309	M0605000	
PHR1274-1G	Metformin Impurity D (Melamine)	二甲双胍杂质D	1379183		
PHR1331-500MG	Metformin Related Compound A	二甲双胍相关物质A	1396310		
PHR1505-50MG	Metformin Related Compound B	二甲双胍相关物质B	1396331		
PHR1506-50MG	Metformin Related Compound C	二甲双胍相关物质C	1396342		
PHR1943-1G	Methacholine Chloride	氯化乙酰甲胆碱			
PHR1372-3X1.5ML	Methanol	甲醇	1424109		
PHR1395-1G	Methocarbamol	甲氧卡巴莫	1412008		
PHR1396-1G	Methotrexate	甲氨蝶呤	1414003	M1000000	
PHR1544-3X1.2ML	2-Methoxyethanol	2-甲氧基乙醇	1601645		
PHR1556-3X1.2ML	Methyl Isobutyl Ketone(MIBK)	甲基异丁酮	1430203		
PHR1835-500MG	Methyl Nicotinate	烟酸甲酯			
PHR1571-1G	Methyl Oleate	油酸甲酯			
PHR1214-3.2ML	Methyl Salicylate	水杨酸甲酯	1437450		
PHR1414-1G	Methyl Stearate	硬脂酸甲酯	1437508	M1770200	
PHR1557-3X1.2ML	Methylene Chloride	二氯甲烷	1601441		
PHR1012-1G	Methylparaben	对羟基苯甲酸甲酯	1432005	M1650000	
PHR1223-500MG	2-Methylpyrazine	2-甲基吡嗪		Y0001376	

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1346-1G	Methylsulfonfylmethane	二甲基砷	1437600		
PHR1132-1G	Metoclopramide Hydrochloride	盐酸甲氧氯普胺	1440808	M1825000	357
PHR1052-1G	Metronidazole	甲硝唑	1442009	M1850000	603
PHR1618-1G	Miconazole	咪康唑	1443409	M1880000	
PHR1163-1G	Miconazole Nitrate	硝酸咪康唑	1443409	M1900000	253
PHR1330-5G	Monobasic Potassium Phosphate	磷酸二氢钾	1551139		
PHR1490-1ML	Monoethanolamine	单乙醇胺	1445925	Y0001184	
PHR1603-1G	Montelukast Sodium	孟鲁司特钠	1446859	Y0001434	
PHR1542-1G	Moxifloxacin Hydrochloride	莫西沙星	1448606	Y0000703	
PHR1313-1G	M-Xylene	间二甲苯	1601849		
PHR1124-1G	Myristic Acid	肉豆蔻酸	1448990		
PHR1135-1G	Myristyl Alcohol	1-十四醇	1449008		
PHR1954-30MG	N-Methyl Omeprazole	N-甲基奥美拉唑			
PHR2110-3X1.2ML	N,N-Dimethylacetamide	N,N-二甲基乙酰胺	1601485		
PHR1432-1G	N-Acetyl Glucosamine	乙酰氨基葡萄糖	1010022		
PHR1098-1G	N-Acetyl-L-Cysteine	N-乙酰基-L-半胱氨酸	1009005	A0150000	
PHR1177-500MG	N-Acetyl-L-Tryptophan	N-乙酰-L-色氨酸	1700523	A0208000	
PHR1173-1G	N-Acetyl-L-Tyrosine	N-乙酰-L-酪氨酸	1010106	A0202000	
PHR1836-500MG	Naphazoline Hydrochloride	萘甲唑啉	1457006	N0080000	
PHR1275-1G	Naphthalene	萘	1457083		
PHR1040-500MG	Naproxen	萘普生	1457301	N0250000	435
PHR1165-1G	Naproxen Sodium	萘普生钠	1457403		
PHR1698-1G	Neotame	纽甜	1460204		
PHR1757-1G	Nevirapine	奈韦拉平	1460703	Y0000520	
PHR1760-50MG	Nevirapine Related Compound A	奈韦拉平相关化合物A	1460725		
PHR1761-50MG	Nevirapine Related Compound B	奈韦拉平相关化合物B	1460736		
PHR1762-50MG	Nevirapine Related Compound C	奈韦拉平相关化合物C	1460747		
PHR1276-1G	Niacin	烟酸(维生素PP)	1461003	N0700000	
PHR1033-1G	Niacinamide	烟酰胺	1462006	N0600000	460
PHR1290-1G	Nifedipine	硝苯地平	1463508	N0750000	462
PHR1336-1G	Nimesulide	尼美舒利		N0845000	
PHR1293-1G	Nimodipine	尼莫地平	1463858	N0850000	651
PHR1731-1G	Nitisinone	尼替西农			
PHR1191-1G	Nitrofurantoin	呋喃妥因	1464001		
PHR1196-1G	Nitrofurazone	呋喃西林	1465004	N0950000	
PHR1352-2G	N-Methylpyrrolidone	N-甲基吡咯烷酮	1437202		
PHR1614-1G	Norfloxacin	诺氟沙星	1471506	N1230000	670
PHR1548-3X1.2ML	N-Propyl Acetate	乙酸丙酯	1576402		
PHR1080-1G	Octinoxate	对甲氧基肉桂酸乙基己酯	1477900		
PHR1081-1G	Octisalate	水杨酸乙基己酯			
PHR1083-1G	Octocrylene	奥克立林	1477411		
PHR1155-1G	Octyldodecanol	2-辛基-1-十二醇	1477808	O0101000	
PHR1168-1G	Ofloxacin	氧氟沙星	1478108	O0120000	
PHR1825-1G	Olanzapine	奥氮平	1478301	Y0001370	1060
PHR1586-1G	Oleic Acid	油酸	1478130	Y0001479	
PHR1851-200MG	Olmesartan Medoxomil	奥美沙坦酯	1478367	Y0001405	1173
PHR2016-40MG	Olmesartan Medoxomil Related Compound A	奥美沙坦酯相关化合物A	1478378		
PHR1059-1G	Omeprazole	奥美拉唑	1478505	O0150000	765
PHR1987-30MG	Omeprazole Impurity B	奥美拉唑杂质B			
PHR1988-30MG	Omeprazole Impurity C	奥美拉唑杂质C			
PHR1989-30MG	Omeprazole Impurity H	奥美拉唑杂质H			
PHR1648-30MG	Omeprazole Related Compound A	奥美拉唑相关化合物A	1478516	O0151000	
PHR1986-30MG	Omeprazole Related Compound B	奥美拉唑相关化合物B	1478480		
PHR1649-30MG	Omeprazole Related Compound E	奥美拉唑相关化合物E	1478527		
PHR1650-30MG	Omeprazole Related Compound I	奥美拉唑相关化合物I	1478561		
PHR1141-1G	Ondansetron Hydrochloride	盐酸昂丹司琼	1478582	Y0000218	
PHR1181-500MG	Ondansetron Impurity F	昂丹司琼杂质F		Y0001320	
PHR1445-1G	Orlistat	奥利司他	1478800		
PHR1777-1G	Orphenadrine Citrate	奥芬那君	1479009	Y0000101	
PHR1781-500MG	Oseltamivir Phosphate	磷酸奥司他韦	1479304	Y0001337	
PHR1473-500MG	O-Toluenesulfonamide	邻甲苯磺酰胺	1672010		
PHR1945-300MG	Quabain	乌本苷		O0200000	
PHR1528-200MG	Oxaliplatin	奥沙利铂	1481204	Y0000271	
PHR1635-1G	Oxcarbazepine	奥卡西平	1483152	Y0001576	
PHR1074-1G	Oxybenzone	二苯酮	1485001		
PHR1312-1G	O-Xylene	邻二甲苯	1601849		
PHR1572-500MG	Oxymetazoline Hydrochloride	盐酸羟甲唑啉	1486004	O0290000	
PHR1355-10G	Padimate O	对二甲氨基苯甲酸异辛酯	1491503		
PHR1120-1G	Palmitic Acid	棕榈酸	1492007	P0090000	
PHR1407-1G	Pamoic Acid	双羟萘酸	1493000		
PHR1465-500MG	Pantolactone	泛酸内酯	1494807		

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1604-1G	Pantoprazole Sodium	泮托拉唑钠	1494895	Y0000835	
PHR1804-500MG	Paroxetine Hydrochloride	帕罗西汀	1500218	Y0000281	1024
PHR1596-500MG	Pemetrexed	培美曲塞		Y0001539	
PHR1217-3X1.2ML	1-Pentanol	正戊醇	1504955		
PHR1887-500MG	Perindopril Erbumine	培哚普利叔丁胺盐	1510889	Y0000238	1073
PHR1573-500MG	Phenformin Hydrochloride	苯乙双胍	1520000		
PHR1047-1G	Phenol	苯酚	1524806		
PHR1402-1G	Phenoxybenzamine Hydrochloride	盐酸酚苄明	1526007		
PHR1121-1.5G	Phenoxyethanol	2-苯氧基乙醇	1526200	P0950000	
PHR1403-1G	Phentolamine Mesylate	酚妥拉明	1530004	Y0001127	520
PHR1152-1G	Phenyl Salicylate Melting Point Standard	水杨酸苯酯熔点标准品	1534209		
PHR1017-500MG	Phenylephrine Hydrochloride	去氧肾上腺素	1533002	P1250000	284
PHR1712-50MG	Phenylephrine Related Compound E (Benzylphenylephrone)	去氧肾上腺素相关化合物E	1533046		
PHR1695-50MG	Phenylephrine Hydrochloride	去氧肾上腺素相关化合物C			
PHR1122-1.5G	Phenylethyl Alcohol	2-苯乙醇	1533250		
PHR1139-1G	Phenytoin	苯妥英	1535008	P1290000	
PHR1574-100MG	Phenytoin Related Compound A	苯妥英相关化合物A	1535019		
PHR1692-100MG	Phenytoin Related Compound B	苯妥英相关化合物B			
PHR1492-1G	Phenytoin Sodium	苯妥英钠	1535507	P1300000	
PHR1297-1G	Phosphated Riboflavin	磷酸化核黄素 (核黄素磷酸钠)	1535700	R0630000	459
PHR1078-1G	Phytonadione	维生素K1	1538006	P1609000	
PHR1632-500MG	Pioglitazone Hydrochloride	吡格列酮	1539905	Y0001520	
PHR1588-200MG	Piroxicam	吡罗昔康	1544508	P2130000	463
PHR1518-1G	Polydimethylsiloxane	聚二甲基硅氧烷	1546300	S0600000	
PHR1329-5G	Potassium Chloride	氯化钾	1548190		
PHR1130-1G	Potassium Gluconate	葡萄糖酸钾	1550001		
PHR1360-5G	Potassium Iodide	碘化钾	1548280		
PHR2203-1G	Potassium Nitrate	硝酸钾			
PHR1278-1G	Potassium Sorbate	山梨酸钾	1548407	P2650000	
PHR1250-500MG	Povidone	聚维酮	1551503	P2660000	
PHR1598-500MG	Pramipexole Dihydrochloride	盐酸普拉克索	1553859	Y0001266	
PHR2010-50MG	Pramipexole Related Compound A	普拉克索杂质A	1553768		
PHR1824-50MG	Pramipexole Related Compound D	盐酸普拉克索杂质D	1553815	Y0001267	
PHR1302-1G	Pramoxine Hydrochloride	盐酸普莫卡因	1554002		
PHR1391-1G	Praziquantel	吡喹酮	1554603	P2670000	
PHR1252-500MG	Procaïnamide Hydrochloride	盐酸普鲁卡因胺	1563502	P3050000	
PHR1161-1G	Procaine Hydrochloride	普鲁卡因	1564006	P3100000	
PHR1713-1G	Proguanil Hydrochloride	盐酸氯胍	1568040		297
PHR1467-1G	Promethazine Hydrochloride	异丙嗪	1570009	P3400000	412
PHR1208-3X1.2ML	1-Propanol	正丙醇	1570406		
PHR1072-3X1.2ML	2-Propanol	2-丙醇	1570428		
PHR1575-500MG	Proprantheline Bromide	溴丙胺太林	1570508		
PHR1663-1ML	Propofol	丙泊酚	1572503	Y0000016	1031
PHR1308-1G	Propranolol Hydrochloride	盐酸普萘洛尔	1576005	P3500000	
PHR1118-1G	Propyl Gallate	没食子酸丙酯	1576800	P3640000	
PHR1051-1.5G	Propylene Glycol	丙二醇	1576708		
PHR1010-1G	Propylparaben	羟苯丙酯	1577008	P3650000	
PHR1389-1G	Propyphenazone	异丙安替比林		P3750000	
PHR1474-500MG	P-Toluenesulfonamide	对甲苯磺酰胺	1672020		
PHR1314-1G	P-Xylene	对二甲苯	1601849		
PHR2082-50MG	Pyrantel Impurity B	双羟萘酸噻嘧啶杂质B			
PHR2083-50MG	Pyrantel Impurity C	双羟萘酸噻嘧啶杂质C			
PHR2081-50MG	Pyrantel Related Compound A	双羟萘酸噻嘧啶相关化合物A	1584014	Y0000403	
PHR1576-500MG	Pyrazinamide	吡嗪酰胺	1585006	P4050000	906
PHR1558-3X1.2ML	Pyridine	吡啶	1601747		
PHR1036-500MG	Pyridoxine Hydrochloride	吡哆素盐酸盐	1587001	P4100000	458
PHR1693-50MG	Pyridoxine Impurity A	吡哆素杂质A		Y0001226	
PHR1694-50MG	Pyridoxine impurity B	吡哆素杂质B			
PHR1340-500MG	Pyrilamine Maleate	吡拉明马来酸	1588004	M0500000	
PHR1740-200MG	1-Vinyl-2-Pyrrolidinone	N-乙烯-2-吡咯烷酮			
PHR1488-1G	Quercetin	槲皮素	1592409	Y0001009	
PHR1856-1G	Quetiapine Fumarate	喹硫平	1592704	Y0001657	
PHR1944-1G	Quinapril Hydrochloride	盐酸喹那普利	1593401	Y0001491	1193
PHR1468-1G	Quinic Acid	奎尼酸	1594506		
PHR1525-1G	Rabeprazole Sodium	雷贝拉唑钠	1598019		
PHR2015-40MG	Raloxifene Related Compound C	雷洛昔芬相关化合物C	1598234		
PHR1446-1G	Ramipril	雷米普利	1598303	R0145000	751
PHR1773-100MG	Ranitidine Related Compound A	雷尼替丁相关化合物A	1598507		
PHR1774-100MG	Ranitidine Related Compound B	雷尼替丁相关化合物B	1598609		
PHR1775-100MG	Ranitidine Related Compound C	雷尼替丁相关化合物C	1598700		
PHR1320-3X1.2ML	Residual Solvent - Acetonitrile	残留溶剂-乙腈	1601340		

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PHR1318-3X1.2ML	Residual Solvent - Benzene	残留溶剂-苯	1601146		
PHR1170-3X1.2ML	Residual Solvent - Methanol	残留溶剂-甲醇	1601623		
PHR1317-3X1.2ML	Residual Solvent - Toluene	残留溶剂-甲苯	1601805		
PHR1319-3X1.2ML	Residual Solvent - Trichloroethylene	残留溶剂-三氯乙烯	1601827		
PHR1063-3X1.2ML	Residual Solvents Mixture - Class I	溶剂残留混标 I	1601102	R0250000	
PHR1064-3X1.2ML	Residual Solvents Mixture - Class Iia	溶剂残留混标 IIA	1601281		
PHR1065-3X1.2ML	Residual Solvents Mixture - Class Iib	残留溶剂混合物-IIB级	1601292		
PHR1066-3X1.2ML	Residual Solvents Mixture - Class Iic	溶剂残留混标 IIC	1601306		
PHR1171-3X1.2ML	Residual Solvent - Methylene Chloride	残留溶剂-二氯甲烷	1601441		
PHR1201-500MG	Resorcinol	间苯二酚	1602003	Y0000767	
PHR1236-1G	Retinyl Acetate	视黄醇乙酸酯	1716002	R0300000	
PHR1235-1G	Retinyl Palmitate	维生素A棕榈酸酯	1602502		
PHR1668-1G	Retinyl Propionate	视黄醇丙酸酯			
PHR1700-1G	Ribavirin	利巴韦林	1602706	Y0000377	593
PHR1054-1G	Riboflavin	核黄素	1603006	R060000	
PHR1936-10MG	Riboflavin Impurity A	核黄素杂质A			
PHR2078-50MG	Risedronate Impurity C	利塞膦酸钠相关化合物C			
PHR2079-50MG	Risedronate Impurity D	利塞膦酸钠相关化合物D			
PHR2075-50MG	Risedronate Related Compound A	利塞膦酸盐相关化合物A	1604621		
PHR2077-50MG	Risedronate Related Compound C	利塞膦酸盐相关化合物C	1604643	Y0001540	
PHR1888-1G	Risedronate Sodium	利塞膦酸钠	1604610	Y0001541	
PHR1631-500MG	Risperidone	利培酮	1604654	R1000600	1137
PHR1615-1G	Ritodrine Hydrochloride	盐酸利托君	1604701		586
PHR1734-1G	Ritonavir	利托那韦	1604803	Y0000714	
PHR2029-30MG	Rivastigmine Related Compound A	卡巴拉汀相关化合物A	1604869		
PHR2030-30MG	Rivastigmine Related Compound B	卡巴拉汀相关化合物B	1604870		
PHR2031-30MG	Rivastigmine Related Compound C	卡巴拉汀相关化合物C	1604811		
PHR2032-100MG	Rivastigmine Related Compound D	卡巴拉汀相关化合物D	1604825		
PHR2033-30MG	Rivastigmine Related Compound E	卡巴拉汀相关化合物E	1604950		
PHR2034-50MG	Rivastigmine Related Compound F	卡巴拉汀相关化合物F	1604961		
PHR1867-1G	Rivastigmine Tartrate	重酒石酸卡巴拉汀	1604858	Y0001516	
PHR1889-500MG	Rizatriptan Benzoate	苯甲酸利扎曲普坦	1604880	Y0001302	1123
PHR1633-200MG	Ropinirole Hydrochloride	盐酸罗匹尼罗	1605205	Y0001773	
PHR1928-1G	Rosuvastatin Calcium	瑞舒伐他汀钙	1606015	Y0001719	
PHR1625-500MG	Rufinamide	卢非酰胺	1606401		
PHR1341-1G	Saccharin	糖精	1607007	S0040000	
PHR1348-500MG	Saccharin Sodium	糖精钠	1607040	S0050000	
PHR1959-50MG	Salbutamol Impurity B	沙丁胺醇杂质B		Y0000030	852
PHR1960-50MG	Salbutamol Impurity D	沙丁胺醇杂质D	1358820	Y0000071	712
PHR1962-20MG	Salbutamol Impurity I	沙丁胺醇杂质I		Y0000032	
PHR1449-1G	Salicylamide	水杨酰胺	1608000		
PHR1013-1G	Salicylic Acid	水杨酸	1609002	S020000	775
PHR1643-200MG	Salicylic Acid Related Compound B	水杨酸相关化合物B	1609024	Y0000405	
PHR1807-500MG	Sildenafil Citrate	西地那非	1612561	Y0001578	
PHR1438-1G	Simvastatin	辛伐他汀	1612700	S0650000	739
PHR1857-1G	Sitagliptin Phosphate	磷酸西格列汀	1612903	Y0001812	
PHR1471-1G	Sodium Alginate	海藻酸钠			
PHR1808-100MG	Sodium Aminosalicilate Dihydrate	对氨基水杨酸钠		Y0001669	
PHR1279-1G	Sodium Ascorbate	L-抗坏血酸钠	1613509	Y0000039	
PHR1231-1G	Sodium Benzoate	苯甲酸钠	1613564		
PHR1948-2G	Sodium Carbonate Anhydrous	碳酸钠	1613757		
PHR1321-5G	Sodium Chloride	氯化钠	1613804		
PHR1416-1G	Sodium Citrate	柠檬酸钠	1613859		
PHR1609-10G	Sodium Dehydroacetic Acid	脱氢乙酸钠	1166309		
PHR1305-1G	Sodium Dodecylbenzenesulfonate	十二烷基苯磺酸钠	1623637		
PHR1408-1G	Sodium Fluoride	氟化钠	1614002		
PHR1645-1G	Sodium Iron Edta	EDTA钠铁盐	1614239		
PHR1113-1G	Sodium Lactate	L-乳酸钠	1614308		
PHR1949-2G	Sodium Lauryl Sulfate	十二烷基硫酸钠	1614363	Y0000620	
PHR1434-1G	Sodium Metabisulfite	焦亚硫酸钠	1614396		
PHR1423-1G	Sodium Nitroprusside	硝普钠	1614501		
PHR1444-1G	Sodium Stearyl Fumarate	硬脂富马酸钠	1614705	S0808000	
PHR1409-4X1G	Sodium Tartrate Dihydrate	二水合酒石酸钠	1614909		
PHR2245-1G	Sodium Tripolyphosphate Hexahydrate	三聚磷酸钠六水合物			
PHR1367-1G	Sorbic Acid	山梨酸	1615956	S0950000	
PHR1006-1G	Sorbitol	D-山梨醇	1617000	S100000	
PHR1417-1G	Squalane	角鲨烷	1619505	Y0000185	
PHR1114-1G	Stearic Acid	硬脂酸	1621008	S1340000	
PHR1115-1G	Stearyl Alcohol	1-十八醇	1622000	S1350000	
PHR1418-1G	Succinic Acid	琥珀酸	1623411		
PHR1342-500MG	Sucralose	三氯蔗糖	1623626	Y0001344	

可追溯至

货号	英文描述	中文描述	USP No.	EP No.	BP No.
PPHR1498-1G	Sulfacetamide	磺乙酰胺	1623808		
PHR1519-1G	Sulfacetamide Sodium	磺胺醋酸钠	1624006	S1700000	
PHR1343-500MG	Sulfadiazine	磺胺嘧啶	1625009	S1800000	
PHR1448-500MG	Sulfadimethoxine	磺胺地索辛	1626001		
PHR1577-1G	Sulfamerazine	磺胺甲噻啉	1628007	S2000000	
PHR1126-1G	Sulfamethoxazole	磺胺甲噁唑	1631001	S2100000	314
PHR1184-5G	Sulfanilamide	磺胺	1632004		
PHR1093-1G	Sulfanilamide Melting Point Standard	磺胺熔点标准品	1633007		
PHR1419-500MG	Sulfanilic Acid	对氨基苯磺酸	1633506		
PHR1087-1G	Sulfapyridine Melting Point Standard	磺胺吡啶熔点标准品	1635002		
PHR1810-500MG	Tadalafil	他达拉非	1642879	Y0001417	
PHR1524-200MG	Tamsulosin Hydrochloride	坦洛新	1643260	Y0000650	876
PHR1667-3X1.2ML	T-Amyl Alcohol	叔戊醇			
PHR1472-1G	Tartaric Acid	酒石酸	1643340		
PHR1109-1G	Taurine	牛磺酸	1643361		
PHR1855-500MG	Telmisartan	替米沙坦	1643419	Y0000648	
PHR1437-1G	Temozolomide	替莫唑胺	1643543		
PHR1592-1G	Tenofovir	替诺福韦	1643601		
PHR1957-500MG	Tenofovir Disoproxil Fumarate	富马酸替诺福韦二吡啶酯	1643656		
PHR1721-1G	Terazosin Hydrochloride	特拉唑嗪			
PHR1298-1G	Terbinafine Hydrochloride	盐酸特比萘芬	1643496	Y0000535	
PHR1560-3X1.2ML	Tert-Butyl Methyl Ether	叔丁基甲基醚	1083303		
PHR1306-500MG	3-Tert-Butyl-4-Hydroxyanisole	3-叔丁基-4-羟基苯甲醚	1083100		
PHR1129-1G	Tetracaine Hydrochloride	盐酸丁卡因	1650006	T0500000	
PHR1561-3X1.2ML	Tetrahydrofuran	四氢呋喃	1601770		
PHR1853-500MG	Tetrahydrozoline Hydrochloride	盐酸四氢唑林	1652001	Y0000460	
PHR1259-500MG	Thiabendazole	噻菌灵	1655000	T1410000	
PHR1037-1G	Thiamine Hydrochloride	硫胺	1656002	Y0000467	
PHR1996-20MG	Thiamine Impurity A	硫胺杂质A			
PHR1997-20MG	Thiamine Impurity B	硫胺杂质B			
PHR1998-20MG	Thiamine Impurity C	硫胺杂质C			
PHR1759-20MG	Thiamine Impurity E	硫胺杂质E			
PHR1337-1G	Thiamine Nitrate	硝酸硫胺			414
PHR1369-500MG	Thiamine Pyrophosphate	焦磷酸硫胺素	1656002		
PHR1587-1G	Thimerosal	硫柳汞	1659000	Y0000109	
PHR1758-200MG	Thiourea	硫脲			
PHR1134-1G	Thymol	百里酚	1667213	T1350000	
PHR1195-500MG	Tinidazole Related Compound A	替硝唑相关化合物A	1667530	Y0000087	
PHR1629-500MG	Tolfenamic Acid	托灭酸		Y0000154	
PHR1778-1G	Tolnaftate	托萘酯	1671006	T1707000	
PHR1891-500MG	Tolterodine Tartrate	托特罗定	1671480	Y0001696	
PHR1311-1G	Toluene	甲苯	1601805		
PHR1600-1G	Topiramate	托吡酯	1672206		
PHR1812-500MG	Tranexamic Acid	氨甲环酸	1672745	T1810000	
PHR1622-3ML	Travoprost	曲伏前列素	1673001		
PHR1344-500MG	Trehalose	海藻糖	1673715	Y0001172	
PHR1187-3X100MG	Tretinoin	维A酸	1674004	T1850000	
PHR1410-1G	Triacetin	三醋酸甘油酯	1675007	G0400010	
PHR2014-100MG	Triamterene Related Compound A	氨苯蝶啶相关化合物A	1680018	N1000000	
PHR1819-100MG	Triamterene Related Compound B	氨苯蝶啶相关化合物B	1680029	Y0000870	
PHR1820-100MG	Triamterene Related Compound C	氨苯蝶啶相关化合物C	1680030		
PHR1154-1G	Tributyl Citrate	柠檬酸三丁酯	1009901		
PHR1205-0.5ML	Tributyl Phosphate	磷酸三丁酯		Y0000279	
PHR1303-500MG	3,4,4'-Trichlorocarbanilide (Triclocarban)	三氯卡班			
PHR1562-3X1.2ML	Trichloroethylene	三氯乙烯	1601827		
PHR1338-1G	Triclosan	三氯生	1682206		
PHR1495-500MG	Trientine Hydrochloride	盐酸曲恩汀	1683504		
PHR1153-1G	Triethyl Citrate	柠檬酸三乙酯	1683606		
PHR1749-1G	Trimeprazine Tartrate	异丁嗪	1689001	Y0001583	415
PHR1056-1G	Trimethoprim	甲氧苄啶	1692505	T2200000	344
PHR1915-3X1.2ML	2,2,4-Trimethylpentane (Isooctane)	2,2,4-三甲基戊烷			
PHR1347-1G	Tromethamine	缓血酸胺	1698002	T2550000	
PHR1176-1G	Tryptophan	色氨酸	1700501	T2610000	
PHR1929-500MG	Ubidecarenone	辅酶Q10	1705301	U0020000	
PHR1429-1G	Undecylenoyl Phenylalanine	十一碳烯酰基苯丙氨酸			
PHR1581-100MG	Uracil	尿嘧啶	1705753	Y0000764	
PHR1406-1G	Urea	尿素	1706698	U0600000	350
PHR1579-500MG	Ursodiol	熊去氧胆酸	1707806	U0800000	
PHR1601-1G	Valacyclovir Hydrochloride	伐昔洛韦	1707839	Y0000834	
PHR1626-1G	Valganciclovir Hydrochloride	盐酸缬更昔洛韦	1708004		
PHR1061-1G	Valproic Acid	丙戊酸	1708707	V0033000	

货号	英文描述	中文描述	可追溯至		
			USP No.	EP No.	BP No.
PHR1652-0.5ML	Valproic Acid Related Compound A	丙戊酸相关化合物A	1708729		
PHR1315-1G	Valsartan	缬沙坦	1708762	Y0001132	
PHR1875-30MG	Valsartan Related Compound A	缬沙坦相关化合物A	1708773		
PHR1876-30MG	Valsartan Related Compound B	缬沙坦相关化合物B	1708784		
PHR1877-30MG	Valsartan Related Compound C	缬沙坦相关化合物C	1708795		
PHR1878-30MG	Valsartan Related Compound E	缬沙坦相关化合物E	1708810		
PHR1245-1G	Vanillin	香草醛	1710006	V0050000	
PHR1091-1G	Vanillin Melting Point Standard	香草醛熔点标准品	1711009		
PHR1627-100MG	Vecuronium Bromide	维库溴铵	1711155	Y0000561	
PHR1736-1G	Venlafaxine Hydrochloride	文拉法辛	1711268	Y0000587	835
PHR1131-1G	Verapamil Hydrochloride	(±)-盐酸维拉帕米	1711202	V0100000	
PHR1194-500MG	Verapamil Related Compound E	维拉帕米相关化合物E	1711439		
PHR1193-500MG	Verapamil Related Compound F	维拉帕米相关化合物F	1711440		
PHR1892-1G	Voriconazole	伏立康唑	1718008	Y0001395	
PHR1435-1G	Warfarin Sodium	华法林钠	1719000	W0100000	672
PHR1280-1G	Xylitol	木糖醇	1720600	X0080000	
PHR2039-500MG	Xylometazoline Hydrochloride	盐酸赛洛唑啉	1721002	X0100000	353
PHR1292-1G	Zidovudine	齐多夫定	1724500	Z1900000	
PHR1345-250MG	Zidovudine Related Compound C	齐多夫定相关化合物C	1724532		
PHR1401-5G	Zinc Pyrithione	吡啶硫酮锌			
PHR1893-1G	Zoledronic Acid	唑来膦酸	1724827		

ICH Q3C残留溶剂标准品CRM

货号	中文名	英文名	包装	备注
PHR1063-3X1.2ML	溶剂残留混标 I	Residual Solvents Mixture - Class I	3X1.2 ml	CRM, 可溯源到USP/ EP或BP
	苯	Benzene		11 mg/mL于二甲亚砜
	四氯化碳	Carbon tetrachloride		20 mg/mL于二甲亚砜
	1,2-二氯乙烷	1,2-Dichloroethane		27 mg/mL于二甲亚砜
	1,1-二氯乙烯	1,1-Dichloroethene		25 mg/mL于二甲亚砜
1,1,1-三氯乙烷	1,1,1-Trichloroethane	50 mg/mL于二甲亚砜		
PHR1065-3X1.2ML	溶剂残留混标 IIB	Residual Solvents Mixture - Class IIB	3X1.2 ml	CRM, 可溯源到USP/ EP或BP
	氯仿	Chloroform		60 ug/mL于二甲亚砜
	1,2-二甲氧基乙烷	1,2-Dimethoxyethane		100 ug/mL于二甲亚砜
	己烷	Hexane		290 ug/mL于二甲亚砜
	3-甲基-2-戊酮	3-Methyl-2-pentanone		50 ug/mL于二甲亚砜
	硝基甲烷	Nitromethane		50 ug/mL于二甲亚砜
	吡啶	Pyridine		200 ug/mL于二甲亚砜
四氯化萘	Tetralin	100 ug/mL于二甲亚砜		
三氯乙烯	Trichloroethylene	80 ug/mL于二甲亚砜		
PHR1066-3X1.2ML	溶剂残留混标 IIC	Residual Solvents Mixture - Class IIC	3X1.2 ml	CRM, 可溯源到USP/ EP或BP
	N,N-二甲基乙酰胺	N,N-Dimethylacetamide		5.45 mg/mL于二甲亚砜
	N,N-二甲基甲酰胺	N,N-Dimethylformamide		4.4 mg/mL于二甲亚砜
	2-乙氧基乙醇	2-Ethoxyethanol		0.8 mg/mL于二甲亚砜
	乙二醇	Ethylene glycol		3.1 mg/mL于二甲亚砜
	甲酰胺	Formamide		1.1 mg/mL于二甲亚砜
	2-甲氧基乙醇	2-Methoxyethanol		0.25 mg/mL于二甲亚砜
	N-甲基吡咯烷酮	N-Methylpyrrolidone		2.65 mg/mL于二甲亚砜
四氢噻吩砜	Sulfolane	0.8 mg/mL于二甲亚砜		

更多关于ICHQ3C残留溶剂的相关单标、混标及应用, 请联系我们索取《ICHQ3C和 ICH Q3D应用方案》

ICH Q3D元素杂质标准品CRM

为了 ICH Q3D 元素杂质分析应用而开发。其中的元素种类与浓度和 ICH Q3D 指南中的 PDE 限值一致。符合 USP<232>、<233> 和 EP 9.3 通则 5.20 和 2.4.20 等元素杂质分析。

- CRM质量级别, 含不确定度和可溯源 (NIST 或BAM)
- 更长的稳定性, 保质期 2-3 年 (氟聚合物瓶 + 气密铝箔袋)
- 由高纯金属制备而成, 适用 ICP 相关仪器分析

货号	口服			注射			吸入			USP<232> 膳食补充	法规未限 定的元素	USP<561> 植物源性物质
	19041	73108	69729	89118	89922	07368	91496	93696	93679	93676	91529	18208
溶剂	12% 硝酸	10% 硝酸	5%硝酸和 <0.5%氢氟酸	12% 硝酸	10% 硝酸	5%硝酸和 <0.5%氢氟酸	12% 硝酸	10% 硝酸	5%硝酸和 <0.5%氢氟酸	12% 硝酸	4.8%硝酸和 <0.5%氢氟酸	12% 硝酸
元素 级别	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L	mg/L
镉 Cd 1	5			2			3			5		5
铅 Pb 1	5			5			5			5		50
砷 As 1	15			15			2			15		20
汞 Hg 1	30			3			1			15		10
钴 Co 2A	50			5			3					
钒 V 2A	100			10			1					
镍 Ni 2A	200			20			5					
铊 Tl 2B	8			8			8					
金 Au 2B		100			100			1				
钯 Pd 2B		100			10			1				
铱 Ir 2B		100			10			1				
锇 Os 2B		100			10			1				
铑 Rh 2B		100			10			1				
钌 Ru 2B		100			10			1				
硒 Se 2B	150			80			130					
银 Ag 2B	150			10			7					
铂 Pt 2B		100			10			1				
锂 Li 3			55			25			25			
锑 Sb 3			120			9			20			
钡 Ba 3			140			70			300			
钼 Mo 3			300			150			10			
铜 Cu 3			300			30			30			
锡 Sn 3			600			60			60			
铬 Cr 3			1100			110			3			
硼 B											100	
钙 Ca											100	
铁 Fe											100	
钾 K											100	
镁 Mg											100	
锰 Mn											100	
钠 Na											100	
铝 Al											100	
钨 W											100	
锌 Zn											100	

* USP法规关于Cd 吸入给药方式的限量在2020年12月1日已更改。因此货号92928已被满足现行法规的91496替换。

更多关于ICHQ3D元素杂质的相关单标、混标及应用, 请联系我们索取《ICHQ3C和 ICH Q3D应用方案》或访问我们网站: SigmaAldrich.com/ICHQ3D。

可提取物与浸出物 (E&L) 标准物质

- 所有组分均可溯源
- 生产过程, 符合 ISO 17034
- 所有相关的组分及测量环节均引入不确定度的计算
- 使用QNMR, LC-UV/MS, GC-MS 多种分析技术, 符合ISO/IEC 17025 要求

货号	产品名称	规格	包装
95636-1mL	可提取物与浸出物筛查混标, 用于HPLC 抗氧剂1010(Irganox 1010) 抗氧剂168氧化物(Irgafos 168-oxide) 双(2-乙基己基)邻苯二甲酸酯(DEHP) 棕榈酸 二苯基胺(DBA) 紫外线吸收剂 UV-P (Dometrizol (Dome)) 双(4-氯苯基)砒(CPS)	21 种组分, 50 µg/mL溶于乙腈 抗氧剂1076 (Irganox 1076) 二丁基羟甲基苯(BHT) 2,4-叔丁基苯酚 硬脂酸 (SA) ε-己内酰胺(CAP) 油酸酰胺(Ole) 2,6-二叔丁基-4-羟甲基苯酚(DBOHP)	1mL 抗氧剂3114 (Irganox 3114) 双酚 A (BPA) 1,3-二叔丁基苯 (DBB) 苯甲酸(BA) 2-乙基己酸(EHA) 芥酸酰胺(Eruca) 2-巯基苯并噻唑(2-MBT)
01829-1mL	可提取物与浸出物筛查混标, 用于GC 抗氧剂1076 (Irganox 1076) 2,4-二叔丁基苯酚 2,6-二叔丁基苯酚 油酸酰胺(Ole)	14 种组分, 50 µg/mL溶于叔丁基甲醚 抗氧剂168氧化物(Irgafos 168-oxide) 双(2-乙基己基)邻苯二甲酸酯(DEHP) ε-己内酰胺(CAP) 棕榈酸 2-巯基苯并噻唑(2-MBT)	1mL 二丁基羟甲基苯(BHT) 双酚 A (BPA) 1,3-二叔丁基苯 (DBB) 芥酸酰胺(Eruca) 硬脂酸 (SA)

另有超过100种可提取物与浸出物单标, 详细信息请访问我们网站: SigmaAldrich.com/extractablesandleachables

药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第1页



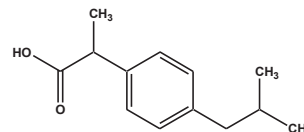
www.sigmaaldrich.com

分析证书 CRM质量级别

Certificate of Analysis – Certified Reference Material

标准物质名称 **IBUPROFEN**

货号 **Product no.:** PHR1004-1G
 批号 **Lot no.:** LRAC0253
 形状描述 **Description of CRM:** White Powder
 有效期 **Expiry date:** 31 December 2023
 存储 **Storage:** Room Temperature
 证书版本 **Certificate version:** LRAC0253.2 (Note: Certificates may be updated due to Pharmacopeial Lot Changes or the availability of new data. Check our website at: www.sigma-aldrich.com for the most current version.)
Chemical formula: C₁₃H₁₈O₂
Molecular mass: 206.29
CAS No.: 15687-27-1



认证的纯度值及不确定度 U

Analyte	Certified Purity ± associated uncertainty U, U=k · u (k=) (Mass Balance/basis)
Ibuprofen	99.8 % U _{crm} = ± 0.3 %, k = 2.1 (as is basis)

计量溯源性

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. Additional traceability to Primary Standards is established through comparative assay determinations. See "Details on metrological traceability" on page 2.

测量方法

Measurement method: Where applicable, the certified value is based on a purity determination by mass balance. See "Certification process details" on page 3.

预期用途

Intended use: Intended for R&D and Analytical Use only. Not for drug, household or other uses.

最小取样量

Minimum sample size: 80 mg

使用说明

Instructions for handling and correct use: Do not dry, use on the as is basis. The internal pressure of the container may be slightly different from the atmospheric pressure at the user's location. Open slowly and carefully to avoid dispersion of the material. Attachment of a 20 mm aluminum crimp seal recommended for unused portions.

健康与安全信息

Health and safety information: All chemical reference materials should be considered potentially hazardous and should be used only by qualified laboratory personnel. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

认证信息

Accreditation: Sigma-Aldrich RTC is accredited by the US accreditation authority ANAB as a registered reference material producer AR-1470 in accordance with ISO 17034.

证书签发日期

Certificate issue date: 31 August 2020

标准物质生产者
ISO 17034 认证标识



标准物质生产者名称和联系信息

Sigma-Aldrich RTC, 2931 Soldier Springs Rd. Laramie, WY 82070, USA;
 Tel. 1 307-742-5452; Fax 1 307-855-831-9211; www.sigmaaldrich.com
 Sigma-Aldrich RTC is a subsidiary of Merck KGaA, Darmstadt, Germany.

标准物质批准人员的姓名及职务

[Andy Ommen; Quality Control]

[Mark Pooler; Quality Assurance]



药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第2页

Packaging: 1G in amber vial

Details on metrological traceability:

计量溯源性详细信息

This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error. Fill volume to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances. Further traceability to a corresponding Primary Standard may be achieved through a direct comparison assay. Where a Primary Standard is available, the assay value will be included in the specified section of the COA.

Associated uncertainty:

不确定度

不确定度值是扩展不确定度, 95% 置信区间。特性值、均匀性、长期稳定性、短期稳定性都是不确定度组成部分。

Uncertainty values in this document are expressed as Expanded Uncertainty (U_{CRM}) corresponding to the 95% confidence interval. U_{CRM} is derived from the combined standard uncertainty multiplied by the coverage factor k , which is obtained from a t -distribution and degrees of freedom. The components of combined standard uncertainty include the uncertainties due to characterization, homogeneity, long term stability, and short term stability (transport). The components due to stability are generally considered to be negligible unless otherwise indicated by stability studies.

溯源性分析

Traceability Assay:

Comparative assay demonstrates direct traceability to Pharmacopeial Standards

METHOD: HPLC (ref.: Ibuprofen; Current Compendial Monographs)

ASSAY vs. USP REFERENCE STANDARD (as is basis)

ASSAY VALUE
100.03 %

vs. USP LOT 溯源到 USP 标准品的批号
R024X0
Labeled Content = 0.998 mg/mg

ASSAY vs. EP CRS (as is basis)

ASSAY VALUE
99.7 %

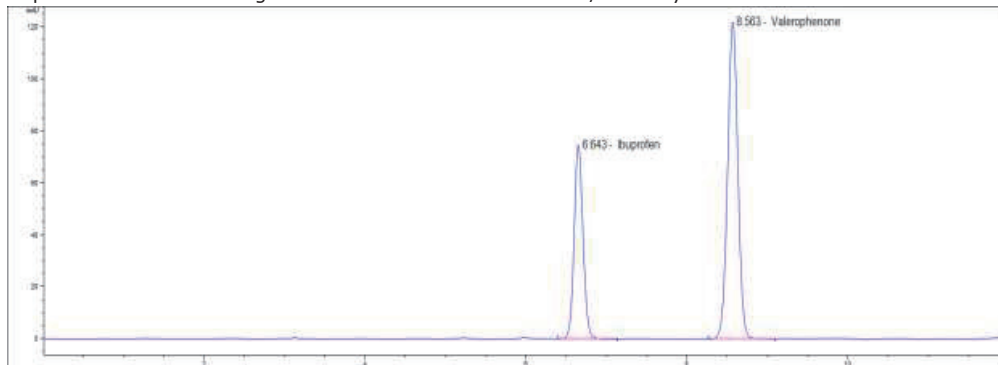
vs. EP BATCH 溯源到 EP 标准品的批号
5.1
Labeled Content = None
Assigned Content = 99.9% *

*The assigned content of the EP CRS was determined by assay against the USP RS and the BP CRS

Column: Ascentis C18, 4.6 x 250 mm, 5 μ m
Mobile Phase: 10g/L Chloroacetic acid in Water (pH: 3.0), Acetonitrile (40:60)
Column Temperature: 30°C
Flow Rate: 1.5 mL/min
Injection: 10 μ L
Detector Wavelength: 254 nm
Internal Standard: Valerophenone

分析条件及谱图

Representative Chromatogram from Lot: LRAC0253 vs. USP/EP Analysis



药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第3页

Method: HPLC (ref.: Ibuprofen, Current Compendial Monographs)

ASSAY vs. BP CRS (as is basis)

ASSAY VALUE

99.9 %

vs. BP BATCH

4105

溯源到 BP 标准品的批号

Labeled Content = 99.9 %

Column: Ascentis C18, 250 mm x 4.6mm, 5µm particle size

Mobile Phase A: (10 g/L Chloroacetic Acid in Water (pH 3.0)): (Acetonitrile)

[分析条件及谱图](#)

Mobile Phase Ratio: 40:60

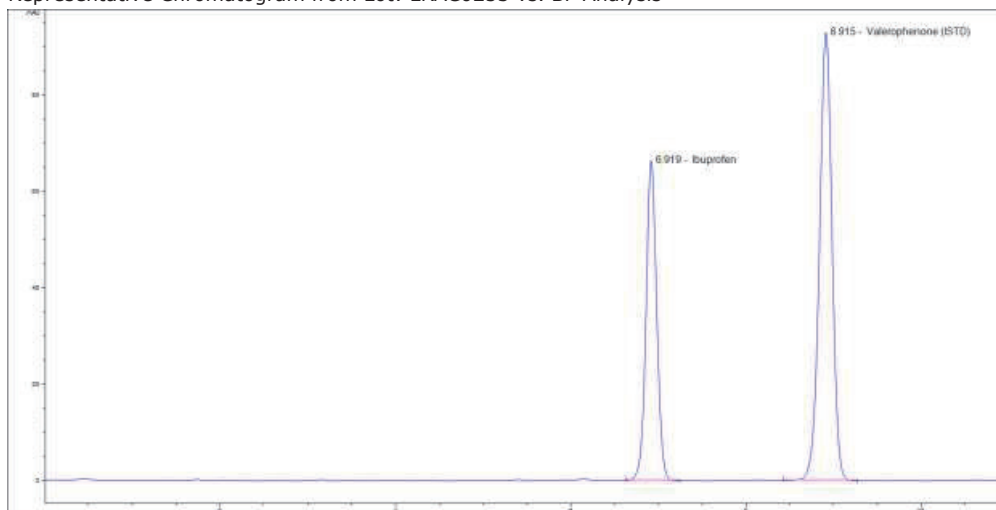
Flow Rate: 1.5 mL/min

Column Temperature: 30 °C

Injection Volume: 10 µL

Detector: DAD, Wavelength: 254 nm

Representative Chromatogram from Lot: LRAC0253 vs. BP Analysis



纯度值认证过程

Certification process details:

The certified purity is determined by mass balance and calculated as

质量平衡法定值公式

$$\%Purity = (100 - ROI - LOD - H_2O - RS) * \left(\frac{100 - TCI}{100}\right)$$

- TCI = Total Chromatographic Impurities
- LOD = Loss on Drying
- H₂O = Water content determined by Karl Fischer analysis
- ROI = Residue on Ignition
- RS = Residual Solvents

Methods for impurity determination may be added or deleted as required. The following techniques are applied:

CHROMATOGRAPHIC IMPURITY ANALYSIS [有关物质色谱分析](#)

METHOD: HPLC (ref.: Ibuprofen, Current Compendial Monographs)

[分析条件及谱图](#)

Column: Ascentis Express C18 4.6 x 50mm, 2.7µm

Mobile Phase A: 0.5mL H₃PO₄, 660mL Water, 340mL Acetonitrile

Mobile Phase B: Acetonitrile

Gradient:

Time (min)	% A	% B
0-10	100	0
10-23	100-15	0-85
23-30	15	85

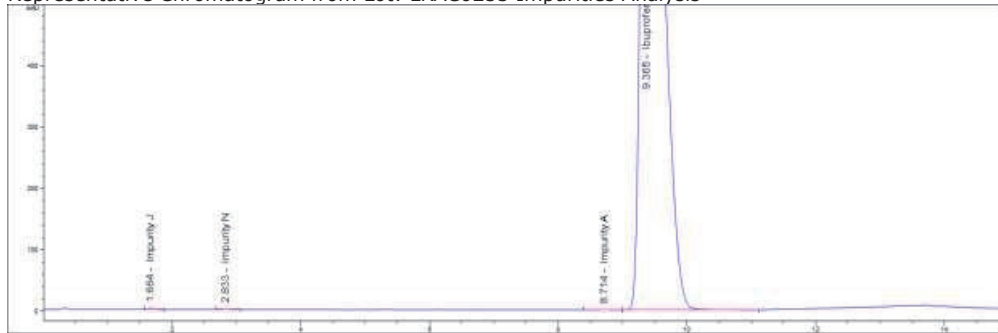
药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第4页

Flow Rate: 1.5 mL/min
Column Temperature: 30 °C
Injection: 10 µL
Detector: 214 nm
Impurities detected:

Impurity J: 0.028% Impurity N: 0.018%
Impurity A: 0.017%

Total Impurities: **0.062%**

Representative Chromatogram from Lot: LRAC0253 Impurities Analysis



RESIDUAL SOLVENTS 杂质-残留溶剂, GC-MS 顶空法测定

Method: GC-MS Headspace (ref.: Adapted from Residual Solvents USP <467>)
Column: SPB-624, 30 m x 0.25 mm, 1.4 mm
Carrier gas: He
Flow: 1.2 mL/min
Split Ratio: 1:5
Injection/Temperature: 1 mL/220 °C
Temperature Program: 40 °C for 5 min, 8 °C/min to 200 °C, hold 5 min

Solvents Detected: **None**

WATER DETERMINATION 杂质-卡尔费休水份测定

Method: Karl Fischer (ref.: Current Compendial Monographs)
Mean of three measurements, Water Content = **0.1 %**

LOSS ON DRYING/VOLATILES 杂质-干燥失重

Method: Dry in vacuum over P₂O₅ (ref.: Current Compendial Monographs)
Mean of three measurements, Loss = **0.0058 %**

RESIDUE ANALYSIS 杂质-灼烧残渣

Method: Sulfated Ash (ref.: Current Compendial Monographs)
Sample Size: ~ 100 mg
Mean of three measurements, Residue = **None**

CERTIFIED PURITY BY MASS BALANCE 质量平衡法定值

99.8 % U_{CRM} = ± 0.3 %, k = 2.1
(as is basis)

Homogeneity assessment: 均匀性评价

Homogeneity was assessed in accordance with ISO Guide 35. Completed units were sampled using a random stratified sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA. Heterogeneity was not detected under the conditions of the ANOVA.

Analytical method: HPLC

Sample size: 80 mg

药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第5页

Stability assessment:

稳定性评价

Significance of the stability assessment will be demonstrated if the analytical result of the study and the range of values represented by the Expanded Uncertainty do not overlap the result of the original assay and the range of its values represented by the Expanded Uncertainty. The method employed will usually be the same method used to characterize the assay value in the initial evaluation.

长期稳定性

Long Term Stability Evaluation - An assessment, or re-test, versus a Compendial Reference Standard may be scheduled, within the 3 year anniversary date of a release of a Secondary Standard. The re-test interval will be determined on a case-by-case basis. Short Term Stability Study - It is useful to assess stability

短期稳定性

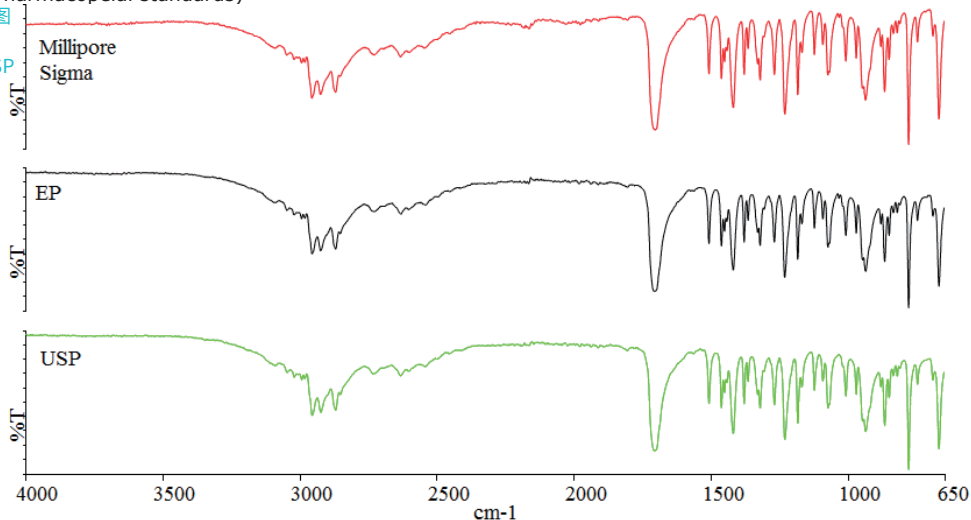
under reasonably anticipated, short term transport conditions by simulating exposure of the product to humidity and temperature stress. This type of study is conducted under controlled conditions of elevated temperature and humidity.

结构鉴定及谱图

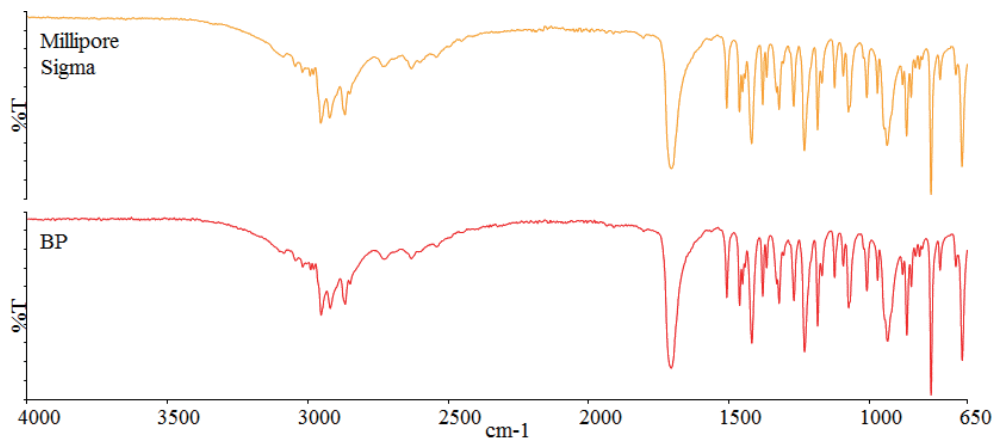
Identification Test:

INFRARED SPECTROPHOTOMETRY (Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)

红外谱图
对比
EP、USP
BP



MilliporeSigma Lot: LRAC0253 vs. EP Batch: 5.1 / USP Lot: R024X0

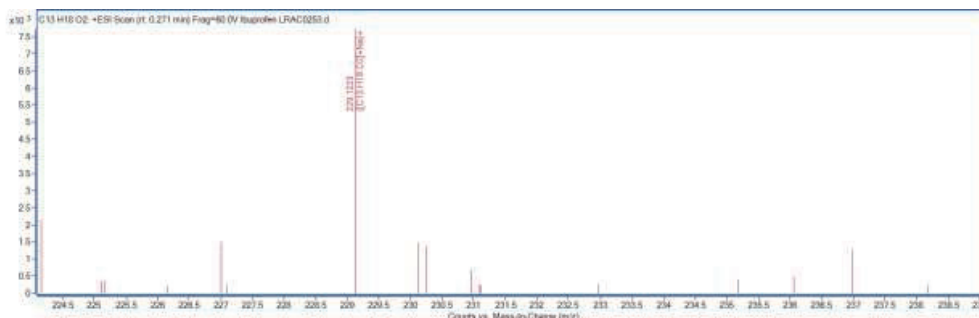


MilliporeSigma Lot: LRAC0253 vs. BP Batch: 4105

药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第6页

质谱 MASS SPECTRUM

Method: HR-QTOF; 4.0 kV ESI+; temperature: 325 °C



Theoretical value: 229.1205 m/z

The signal of the MS spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

熔点 MELTING RANGE

Specification: 75-78°C (EP)

Mettler Toledo FP900 Thermosystem with FP81 Measuring Cell

Mean of three measurements = **74.8-75.9 °C**

旋光度 OPTICAL ROTATION

Specification: -0.005 to 0.005 ° (EP)

Perkin Elmer Polarimeter 343

Wavelength: 589 nm

Concentration: 0.025 g/mL

Cell Path: 100 mm

Mean of three Measurements = **0.0053 °**

分析证书历史版本信息

Certificate of analysis revision history:

Certificate version	Date	Reason for version
LRAC0253.1	01 November 2018	Original Release
LRAC0253.2	31 August 2020	Requalification Test

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