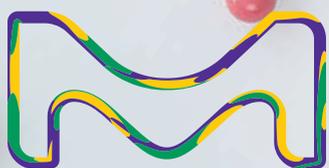


Supelco®
Analytical Products

默克Supelco® 药物二级标准品



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:

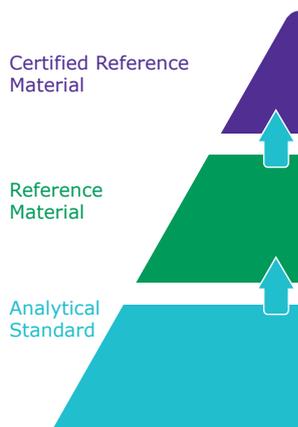
- Pestanal®
- Cerilliant®
- Vetranal™
- TraceCERT®
- Aquastar™
- Certipur®

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(A analytical 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

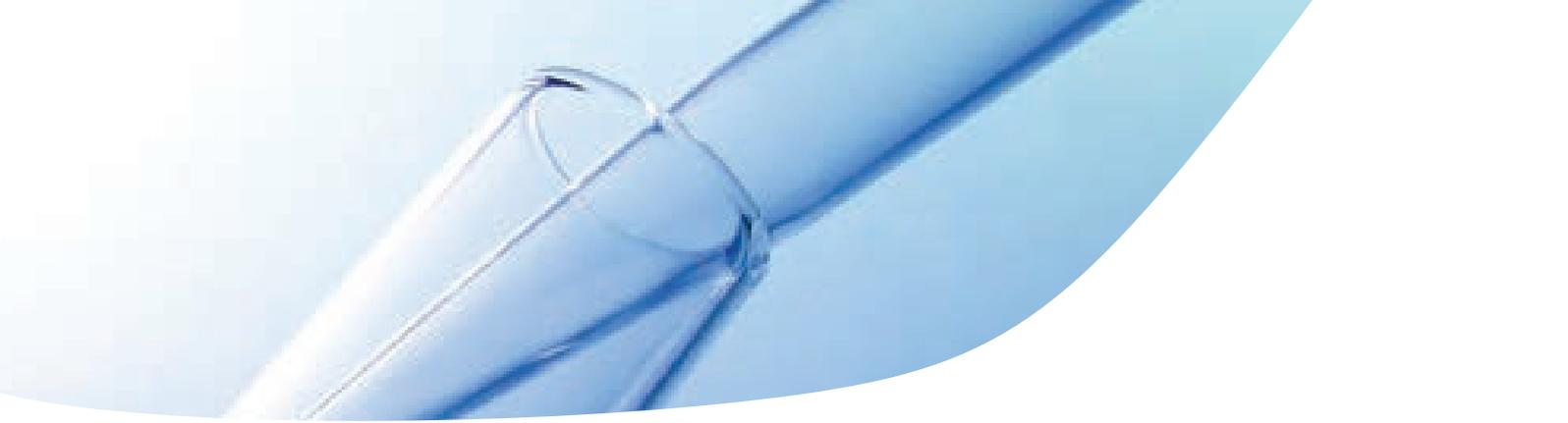
植物提取物

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

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:

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. | 可追溯至 |
|-----------------|------------------------------------|--------------|---------|----------|--------|------|
| 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 | Anthrakinone | 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 | Buspiron 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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| 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 | Clostazol Related Compound B | 西洛他唑相关化合物B | 1134175 | | |
| PHR1676-100MG | Clostazol 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 | 氨苯砞 | 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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| 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 | |

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|-----------------|--|-------------------|---------|----------|--------|
| 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 | |

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|-----------------|---------------------------------------|---------------|---------|----------|--------|
| 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 | |

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| 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 | | |

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| 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 | | |

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| 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 | Y100000 | |
| PHR1417-1G | Squalane | 角鲨烷 | 1619505 | S0000185 | |
| 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 | |

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| 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 | 磺胺甲噻唑 | 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) 二丁基羟基甲苯(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 二丁基羟基甲苯(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

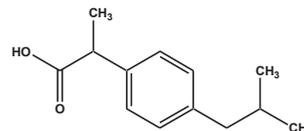



分析证书 CRM质量级别

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 %

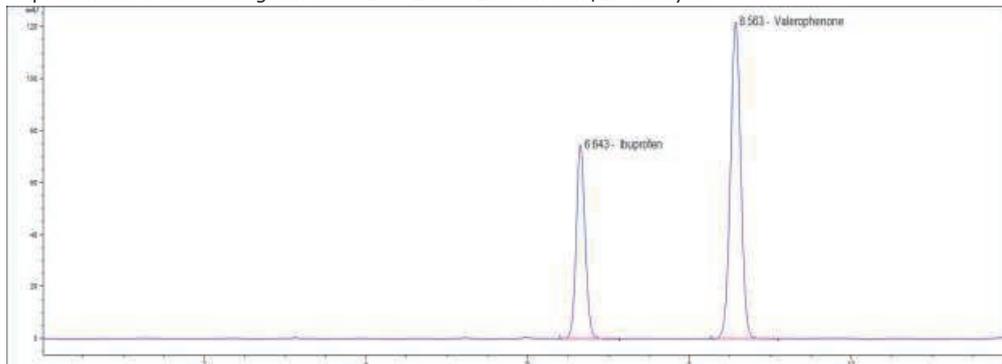
vs. EP BATCH 溯源到 EP 标准品的批号
5.1
Labeled Content = None
Assigned Content = 99.9% *

*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

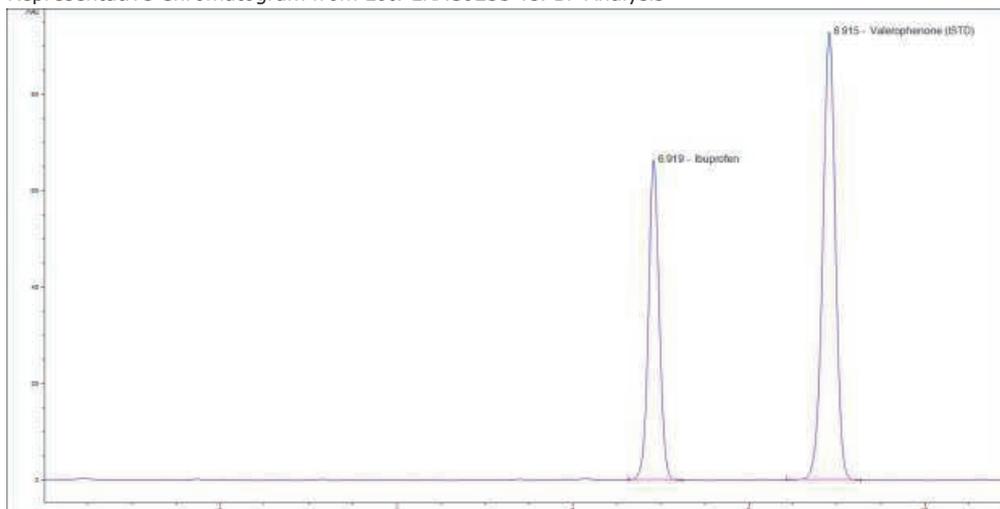
Flow Rate: 1.5 mL/min

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 |

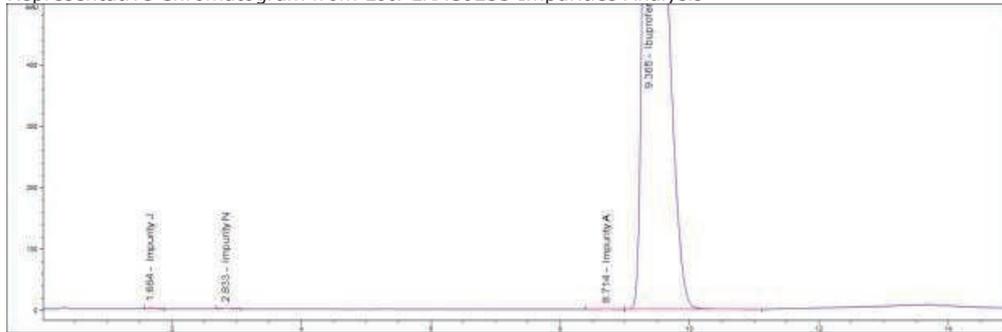
药物二级标准品CRM (布洛芬 货号: PHR1004) 分析证书举例 第4页

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

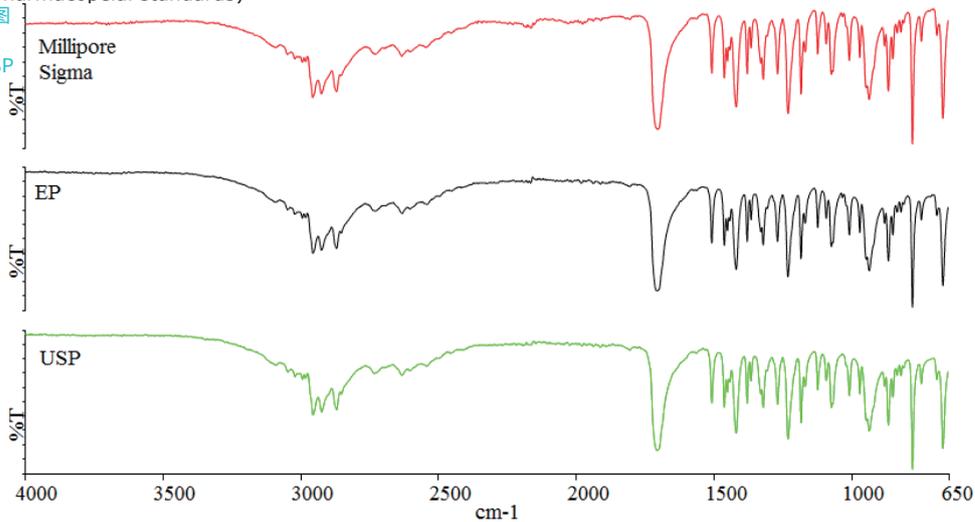
under reasonably anticipated, short term transport conditions by simulating exposure of the product to humidity and temperature stress. This type of study is conducted under controlled conditions of elevated temperature and humidity.

结构鉴定及谱图

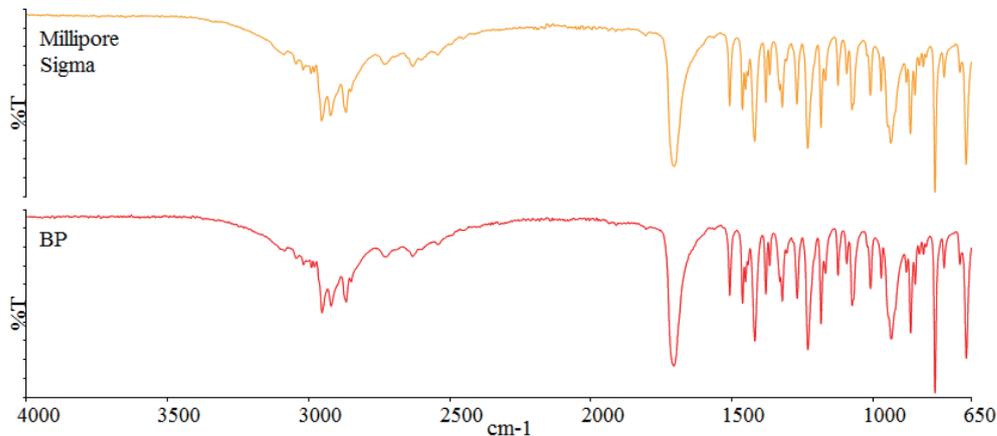
Identification Test:

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

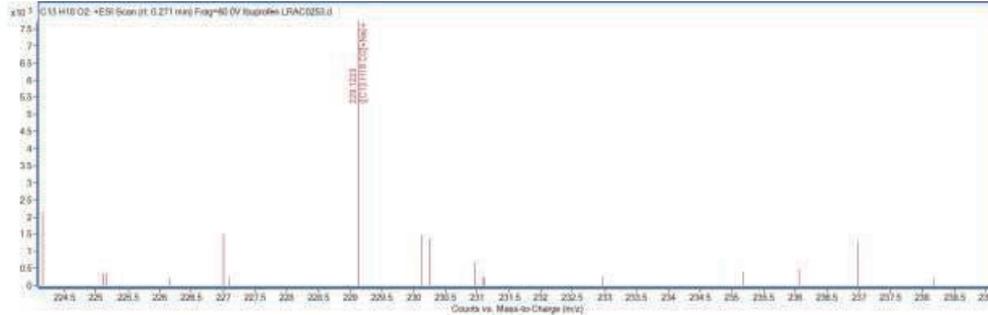


MilliporeSigma Lot: LRAC0253 vs. BP Batch: 4105

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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