

Kalchem International

Chemicals & Compounding Supplies

报告单编号 (COA NO.) TS-QCSA00109002-Report01-00

检字号 (Serial No.) A1041409087

检品名称 Product	盐酸环丙沙星 Ciprofloxacin Hydrochloride	批号 Batch No.	104-140908-5
包装 Packaging Size	10Kg/桶 (drum)	数量 Quantity	10Kg
生产日期 MFG Date	08/09/2014 (d/m/y)	报告日期 Reporting Date	12/09/2014 (d/m/y)
执行标准 According to	美国药典 (USP37)	复测日期 Retest Date	07/09/2017(d/m/y)

检验项目 (Tests)	标准规定 (Acceptance Criteria)	结果 (Results)
外观 Appearance	微黄色至淡黄色结晶性粉末 Faintly yellowish to light yellow crystalline powder.	微黄色结晶性粉末 Faintly yellowish crystalline powder.
性状 Characters	在水中略溶, 微溶于醋酸和甲醇, 在乙醇中极微溶, 几乎不溶于丙酮、乙腈、乙酸乙酯、正己烷和二氯甲烷。Sparingly soluble in water, slightly soluble in acetic acid and methanol; very slightly soluble in dehydrated alcohol; practically insoluble in acetone, in acetonitrile, in ethyl acetate, in hexane, and in methylene chloride.	
溶解性 Solubility		
鉴别 Identification	(1) IR: 红外光吸收图谱应与对照品的图谱一致 IR: Conforms to the spectrum of Ciprofloxacin Hydrochloride RS. (2) HPLC: 在含量测定项下, 供试品溶液主峰保留时间应与对照品溶液主峰保留时间一致 HPLC: The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. (3) 应显氯化物的鉴别反应 Responds to the tests for chloride.	符合 Conforms
酸度 pH	3.0~4.5 (0.25mg/ml water)	3.6
水分 Water	4.7~6.7%	6.4%
炽灼残渣 Residue on ignition	≤ 0.1%	0.03%
硫酸盐 Sulphate	≤ 0.04%	< 0.04%
重金属 Heavy metals	≤ 0.002%	< 0.002%
氟喹啉酸 (TLC) Limit of fluoroquinolonic acid	≤ 0.2%	< 0.2%
色谱纯度 (HPLC) Chromatographic purity	(1) 乙二胺类环丙沙星 Ciprofloxacin ethylenediamine analog ≤ 0.2% (2) 其它单个杂质 Any other single impurity ≤ 0.2% (3) 所有杂质 The sum of all impurities ≤ 0.5%	0.11% 0.08% 0.27%
含量 (HPLC) Assay	按无水物计算, 含 C ₁₇ H ₁₈ FN ₃ O ₂ · HCL 应为 98.0%~102.0% 98.0%~102.0% (On the anhydrous substance)	99.3%
残留溶剂 Residual solvents	(1) 乙醇 Ethanol ≤ 5000ppm (2) 甲苯 Toluene ≤ 890ppm (3) 异戊醇 Isoamyl alcohol ≤ 2500ppm	170ppm 未检出 Not detected 未检出 Not detected

86 结论: 本品按美国药典 37 版标准检验, 结果符合规定

Conclusion: Conforms to USP 37 specification for ciprofloxacin hydrochloride

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Pharmacopeia (USP), the Food Chemical Codex (FCC) and of Commission Regulation (EU) No. 231/2012. All analytical methods are in accordance with the latest requirements of the Ph. Eur., the USP, the FCC or equivalent methods. Test methods are available on request.

QUALITY ASSURANCE MANAGER
William Jamieson

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