Taizhou Crene Biotechnology Co., Ltd.

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Certificate of analysis

Product Name:CIPROFLOXACIN BASE		0 0
Batch/Lot No.:20201215		F OH
CAS Number:85721-33-1	MFG Date:Dec.15,.2020	
Molecular Formula:C17H18FN3O3	Expiry Date:Dec.14,2022	\sim \square
Molecular Weight :331.34	Report Date:Dec.14,2020	-

Tests Item	Specification	Results
Appearance	White to yellowish crystalline powder	Almost white crystaline powder
Solubility	Soluble in acetic acid;very slightly soluble in ethanol and trichloromethane;practically insoluble in water.	Meet the requirements
Identification	 (1) Retention time of main peak obtained from test solution corresponds to that of reference solution (2) IR spectrum obtained from test sample corresponds to that of reference standard 	Meets the requirement
Loss on drying	Not more than 1.0%	0.32%
Residue on ignition	Not more than0. 1%	0.02%
Heavy metals	Not more than 20ppm	<20ppm
Clarity	Solution should be clear or slightly Opalescent	Meet the requirements
Fluoroquinolonic acid	Not more than 0.2%	0.03%
Ciprofloxacin ethylenediamine analog	Not more than 0.2%	0.07%
Any other impurity	Not more than 0.2%	0.06%
Total impurity	Not more than 0.5%	0.24%
Assay(on the dried basis)	Between 98.0% and 102.0% (C17H18FN3O3)	100.0%

Conclusion: It complies with the USP42 Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F