新 昌 县 九 信 药 业 有 限 公 司

Xinchang JiuXin Pharmaceutical Co.,Ltd

Certificate of analysis

Levofloxacin Hemihydrate

D-QA526-F05-R01 Analysis NO.:DK210-1501032-01

batch no.: DK210-1501032	Quantity:575.00kg	packaging size: 25kg/drum
MFG DATE: 03 JAN.2015	Issuing Date: 14 JAN.2015	Re-test period: 02 JAN.2018
Source:518 workshop	Quality specification:USP35	

Items	specification	results
Characters		
appearance	Light yellowish-white to yellow-white crystalline powder or crystals	Light yellowish-white crystalline powder
identification		
IR	The spectrum obtained from sample consists with that obtained from Levofloxacin RS	complies
HPLC	The retention time of major peak of the sample solution corresponds to that the standard solution, as obtained in the assay	complies
Assay(on the anhydrous basis)	98.5%~102.0% of $C_{18}H_{20}FN_3O_4$	99.7%
IMPURITIES		
Inorganic impurities		
residue on ignition	≤0.2%	0.02%
heavy metals	≤10ppm	＜10ppm
organic impurities		
N-desmethy Levofloxacin	≤0.3%	0.02%
Diamine derivative	≤0.3%	0.01%
Levofloxacin N-oxide	≤0.3%	Not found
9-desfluoro Levofloxacin	≤0.3%	Not found
D-ISOMER	≤0.8%	0.22%
Any unknown impurity	≤0.1%	0.03%(RRT:0.4)
		0.06%(RRT:1.6)
		0.06%(RRT:2.0)
Total impurities(expect the D-isomer)	≤0.5%	0.20%
Optical rotation(at 20℃)	-92°~-106°	-101.5°
water	2.1%~2.7%	2.6%
Residual solvents		
chloroform	≤60ppm	27ppm
ethanol	≤1000ppm	525ppm
DMSO	≤1000ppm	Not found

Conclusion: conforms to USP35.

Reported by: Cai lanlan reviewed by: Pan fangfang approved by: Cai lanlan

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