STARRY 司太立制药 STARRY PHARMACEUTICAL

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Certificate of Analysis

Product Name	Levofloxacin Hemihydrate	Batch No.	C008-2106608
Quantity	629.34kg	Number of COA	C008-2106-022
Packing	25kg/ drum	Producing Date	2021.06.06
Reporting Date	2021.06.25	Retesting Date	2024.06.05
According To	USP43		

Contents of testing	Specification	Result
Description	Light yellowish-white to yellow-white crystals or crystalline powder..	Conform
Specific Rotation	-92° to -106°	-102°
Identifications		
IR	The IR spectrum of the sample is consistent with that of the reference substance	Conform
HPLC	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	Conform
Water	2.0%-3.0%	2.6%
Residue on ignition	NMT 0.2%	0.03%
Related compounds 1	N-Desmethyl levofloxacin (a) NMT 0.3%	0.05%
	Diamine derivative (b) NMT 0.3%	0.01%
	Levofloxacin N-oxide (c) NMT 0.3%	0.02%
	9-Desfluoro levofloxacin (d) NMT 0.3%	ND
	d-Isomer (e) NMT 0.8%	0.3%
	Any unknown impurity NMT 0.1%	0.009%
	Total impurities NMT 0.5%	0.09%
Related compounds 2	Levofloxacin related compound A (N-Desmethyl levofloxacin)[a] NMT 0.20%	0.05%
	Levofloxacin related compound B[b] NMT 0.13%	ND
	Any other impurity NMT 0.10%	0.06%
	Total impurities NMT 0.50%	0.16%
Related compounds 3	Acceptance critetria: NMT1.0%	0.2%
Assay	Levofloxacin contains not less than 98.0 percent and not more than 102.0 percent of $C_{18}H_{20}FN_3O_4$, calculated on the anhydrous basis.	100.3%

Conclusion：Conform to USP43

Manager：2021.06.25　Checker：2021.06.25　Analyst：2021.06.25