

2004090275



Zhejiang Starry Pharmaceutical Co., Ltd.

http: //www.starrypharm.com

Tel: 0576-87718691; 0576-87718626

Add: No.1 Starry Road of Xianju Modern Industrial Centralization Zone, Xianju, Zhejiang, China

SOR09(04)- A002-01

Certificate of Analysis

Product Name	Levofloxacin Hemihydrate	Batch No.	C018-2003002
Quantity	225.08kg	Number of COA	C018-2003-002
Packing	25kg/ drum	Producing Date	2020.03.12
Reporting Date	2020.03.20	Retesting Date	2023.03.11
According To	USP37		

Contents of testing	Specification	Result
Description	Light yellowish-white to yellow-white crystals or crystalline powder..	Conform
Specific Rotation	-92° to -106°	-103°
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
Solubility	Soluble in dimethylsulfoxide and in acetic acid; sparingly soluble in water, in acetone, and in methanol; practically insoluble in glycerin and in n-octanol	Conform
Water	2.0%-3.0%	2.5%
Residue on ignition	NMT 0.2%	0.02%
Heavy Metals	NMT 10ppm	<10ppm
Related compounds 1	N-Desmethyl levofloxacin (a) NMT 0.3%	0.05%
	Diamine derivative (b) NMT 0.3%	0.02%
	Levofloxacin N-oxide (c) NMT 0.3%	0.01%
	9-Desfluoro levofloxacin (d) NMT 0.3%	ND
	d-Isomer (e) NMT 0.8%	0.07%
	Any unknown impurity NMT 0.1%	ND
	Total impurities NMT 0.5%	0.08%
Related compounds 2	Levofloxacin related compound A (N-Desmethyl levofloxacin) ^a NMT 0.20%	0.06%
	Levofloxacin related compound B ^b NMT 0.13%	ND
	Any other impurity NMT 0.10%	0.02%
	Total impurities NMT 0.50%	0.08%
Related compounds 3	Acceptance criteria: NMT 1.0%	0.02%
Assay	Levofloxacin contains not less than 98.0 percent and not more than 102.0 percent of C ₁₈ H ₂₀ FN ₃ O ₄ , calculated on the anhydrous basis.	99.8%

Conclusion: Conform to USP37

Manager:

2020.03.20

Checker:

2020.03.20

Analyst:

2020.03.20



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Certificate of Analysis

Product Name	Levofloxacin Hemihydrate	Batch No.	C018-2003002
Quantity	225.08kg	Number of COA	C018-2003-002
Packing	25kg/ drum	MFG Date	2020.03.12
Reporting Date	2020.03.24	EXP.Date	2023.03.11
According To	/		

Contents of testing	Specification	Result
Particle size	D (90)	25 μ m
	D (100)	46 μ m
Residual Solvents	Methanol: NMT 3000ppm	ND
	Ethanol: NMT 5000ppm	66ppm
	Chloroform: NMT 60ppm	ND

Conclusion: /

Manager:

[Signature]
2020.03.24

Checker:

[Signature]
2020.03.24

Analyst:

[Signature]
2020.03.24