



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- D627-00

Certificate of Analysis

Product Name	Levofloxacin Hemihydrate	Batch No.	C018-1812003
Quantity	197.75kg	Number of COA	1812047
Packing	25kg/ drum	MFG Date	2018.12.09
Reporting Date	2018.12.17	EXP Date	2021.12.08
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°	-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
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%	2.4%
Residue on ignition	NMT 0.2%	0.02%
Heavy Metals	NMT 10ppm	<10ppm
Related compounds 1	N-Desmethyl levofloxacin (a) NMT 0.3%	0.01%
	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%	0.04%
	Any unknown impurity NMT 0.1%	ND
	Total impurities NMT 0.5%	0.04%
Related compounds 2	Levofloxacin related compound A (N-Desmethyl levofloxacin)* NMT 0.20%	0.05%
	Levofloxacin related compound B ^b NMT 0.13%	ND
	Any other impurity NMT 0.10%	0.03%
	Total impurities NMT 0.50%	0.17%
Related compounds 3	Acceptance criteria: NMT 1.0%	0.008%
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.	100.0%

Conclusion: Conform to USP37

Manager:

[Signature]
2018.12.17

Checker:

[Signature]
2018.12.17

Analyst:

[Signature]
2018.12.17



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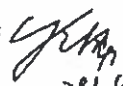
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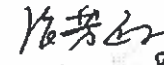
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According To	/		

Contents of testing	Specification	Result
Residual Solvents	Methanol: NMT 3000ppm	ND
	Ethanol: NMT 5000ppm	72ppm
	Chloroform: NMT 60ppm	ND
Particle size	D90	23 μ m
	D100	46 μ m

Conclusion: /

Manager: 

2018.12.19

Checker: 

2018.12.19

Analyst: 

2018.12.19



Version No. :001

LEVOFLOXACIN HEMIHYDRATE

Batch No.: C018-1812003

Manufacturing Date: DEC. 9, 2018

Expiry Date: DEC. 8, 2021

Gross Weight: 28KGS

Net Weight: 25KGS

Storage.: Preserve in light - resistant, tight container.

Manufactured by.: Zhejiang Starry Pharmaceutical Co.,Ltd.

Address.: No.1 Starry Road of Xianju Modern Industrial Centralization Zone,
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Version No. :001

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