



Certificate of analysis

Productname: Levofloxacin

Cas number: 100986-85-4

Molecular Formula: C₁₈H₂₀FN₃O₄

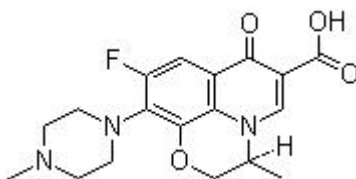
Molecular Weight: 361.37

Date of production: Feb. 18, 2019

Batch NO: 20190218

Exp Date: Feb. 17, 2021

Chemical structure:



Items	Specifications	Results
Appearance	White or yellow light crystalline powder	Complies
Identification	IR, HPLC, H ¹ NMR spectrum	Complies
Optical rotation	-92° ~ -106°	-96.7°
Individual impurity	N-Desmethyllevofloxacin ≤ 0.3%	0.07%
	Diamine derivative ≤ 0.3%	0.05%
	Levofloxacin N-oxide ≤ 0.3%	0.03%
	9-Desfluorolevofloxacin ≤ 0.3%	0.10%
	D-Isomer ≤ 0.8%	0.26%
	Any unknown impurity ≤ 0.1%	Complies
Total impurity (Do not include D-Isomer)	≤ 0.5%	0.30%
Residual solvent	Ethanol ≤ 0.5%	Complies
	Dimethyl Formamide ≤ 0.088%	Complies
	Toluene ≤ 0.089%	Complies
	Dimethyl sulfoxide ≤ 0.5%	Complies
Residue on ignition	≤ 0.2%	0.1%
Heavy metals	≤ 10ppm	Complies
Water	2.1%~2.7%	2.5%
Purity (HPLC)	98.5%~102.0%	99.15%

Conclusion: It complies with the USP34 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F