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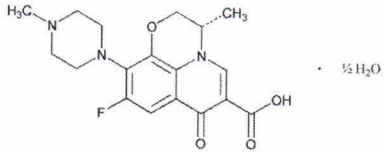
Levofloxacin Hemihydrate USPNF2023

Batch no	DK26-2308281
Mf date	Aug 28 2023
Retest date	Aug 27 2028
Batch size	705.00 kg

Molecular Structure



Molecular Formula $C_{18}H_{20}FN_3O_4 \cdot \frac{1}{2}H_2O$

Molecular Weight 370.38

CAS Registry Number 138199-71-0

Nov 08 2023

Tests	Specifications		Results
Appearance	Light yellowish-white to yellow-white crystals or crystalline powder		Yellowish-white crystalline powder
Solubility	Soluble in dimethylsulfoxide & in acetic acid; sparingly soluble in water, in acetone & in methanol; practically insoluble in glycerine & in n-octanol		Conforms
Identification	IR, HPLC		Positive
Optical rotation (at 20℃)	-92 ~ -106°		-101.9°
Water	2.0 ~ 3.0%		2.5%
Organic impurities			
Procedure 1 (by HPLC)	N-Desmethyl levofloxacin	≤ 0.3%	< 0.02%
	Diamine derivative	≤ 0.3%	< 0.02%
	Levofloxacin N-oxide	≤ 0.3%	< 0.02%
	9-Desfluoro levofloxacin	≤ 0.3%	< 0.02%
	D-Isomer	≤ 0.8%	0.2%
	Any unknown impurity	≤ 0.1%	0.06% (RRT:0.4)
			0.04% (RRT:1.7)
			0.05% (RRT:2.0)
	Total impurities (except D-isomer)	≤ 0.5%	0.15%
Procedure 2 (by HPLC)	Levofloxacin related compound A (N-Desmethyl levofloxacin)	≤ 0.2%	< 0.03%
	Levofloxacin related compound B	≤ 0.13%	< 0.03%
	Any other impurity	≤ 0.10%	0.02% (RRT:0.4)
			0.04% (RRT:0.8)
			0.03% (RRT:2.5)
	Total impurities	≤ 0.5%	0.1%
Residue on ignition	≤ 0.2%		0.02%
Residual solvents	Chloroform	≤ 60 ppm	5 ppm
	Ethanol	≤ 1000 ppm	143 ppm
	DMSO	≤ 1000 ppm	< 200 ppm (LOQ)
Assay (oab)	98.0 ~ 102.0% of $C_{18}H_{20}FN_3O_4$		99.4%

Packaging & storage	Preserve in tight and light-resistant containers. Store at room temperature.
Conclusion	Material complies with USPNF2023

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