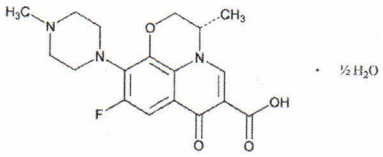
Compounding Chemicals.com.au

Levofloxacin Hemihydrate USPNF2024

Batch no	DK21-32412292
Mf date	Dec 29 2024
Retest date	Dec 28 2029
Batch size	754.18 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

Jan 13 2025

Tests	Specifications		Results
Appearance	Light yellowish-white to yellow-white crystals or crystalline powder		Light 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°		-101.5°
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:0.41)
			0.05% (RRT:1.69)
	Total impurities (except D-isomer)	≤ 0.5%	0.11%
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%	0.03% (RRT:0.44)
			0.06% (RRT:0.77)
			0.04% (RRT:2.54)
	Total impurities	≤ 0.5%	0.13%
Residue on ignition	≤ 0.2%		0.04%
Residual solvents	Chloroform	≤ 60 ppm	24 ppm
	Ethanol	≤ 1000 ppm	418 ppm
	DMSO	≤ 1000 ppm	< 100 ppm (LOD)
Assay (oab)	98.0 ~ 102.0% of $C_{18}H_{20}FN_3O_4$		99.6%

Packaging & storage	Preserve in tight and light-resistant containers. Store at room temperature.
Conclusion	Material complies with USPNF2024

ASTRAL SCIENTIFIC PTY LTD | **T:** (02) 9540 2055
W: www.compoundingchemicals.com.au | **E:** sales@compoundingchemicals.com.au