

## Marbofloxacin EP11

Batch no

2412038

Mf date

Dec 24 2024 Dec 23 2029

Retest Batch size

247.5 kg

Molecular Structure

 $Molecular\ Formula\ C_{17}H_{19}FN_4O_4$ 

Molecular Weight 362.4

CAS Registry Number 115550-35-1

Jul 04 2025

Tests	<u>Specifications</u>		Results
Appearance Solubility	Light yellow crystalline powder Slightly soluble in water, sparingly soluble in methylene chloride, very slightly soluble in ethanol 96%		Conforms Conforms
Identification	IR		Positive
Absorbance	≤ 0.2 at 450 nm		0. 04
Loss on drying	≤ 0.5% at 105°C, 4h		0. 05%
Sulfated ash	≤ 0.1%		0. 02%
Heavy metals	≤ 20 ppm		< 20 ppm
Related substance	Impurity A	≤ 0.1%	ND
(HPLC)	Impurity B	≤ 0.1%	ND
	Impurity C	≤ 0.2%	0.01%
	Impurity D	≤ 0.2%	ND
	Impurity E	≤ 0.2%	ND
×	Unspecified impurities $\leq$ 0.2%		0.01%
B	Total impurities	≤ 0.5%	< 0.05%
Residual solvents (GC)	Ethanol	≤ 5000 ppm	232 ppm
	Toluene	≤ 890 ppm	203 ppm
1	Methylene chloride		ND
Assay (odb)	99.0 $^{\sim}$ 101.0% of $C_{17}H_{19}FN_4O_4$		99. 32%
Packaging & storage	Protected from light		
Conclusion	Material complies with EP11		

