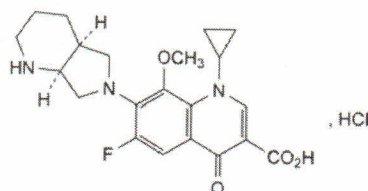


Batch no T20250801
Mf date Aug 05 2025
Exp date Aug 04 2028

Molecular Structure



Molecular Formula $C_{21}H_{25}ClFN_3O_4$
Molecular Weight 437.9
CAS Registry Number 186826-86-8

Aug 22 2025

Tests	Specifications	Results
Appearance	Slightly yellow to yellow powder or crystals	Conforms
Solubility	Sparingly soluble in water & in methanol; slightly soluble in 0.1N hydrochloric acid, in dimethylformamide & in alcohol; practically insoluble in methylene chloride, in acetone, in ethyl acetate & in toluene; insoluble in tert-butyl methyl ether & n-heptane	Conforms
Identification	IR, reaction of chloride	Positive
Residue on ignition	$\leq 0.1\%$	0.02%
Sulfate	$\leq 0.04\%$	$< 0.04\%$
Related substances	Impurity A $\leq 0.1\%$	ND
	Impurity B $\leq 0.1\%$	ND
	Impurity C $\leq 0.1\%$	ND
	Impurity D $\leq 0.1\%$	ND
	Impurity E $\leq 0.1\%$	ND
	Other individual impurity $\leq 0.1\%$	0.06%
	Total impurities $\leq 0.5\%$	0.06%
Enantiomeric purity	$\leq 0.15\%$	ND
pH	3.9 ~ 4.6	4.3
Water	$\leq 4.5\%$	4.0%
Residual solvents	Ethanol ≤ 5000 ppm	ND
	Methanol ≤ 3000 ppm	ND
	Acetic acid ≤ 5000 ppm	ND
	Methylene chloride ≤ 600 ppm	ND
Microbial limit	Total aerobic bacteria count ≤ 1000 cfu/gr	< 10 cfu/gr
	Total combined molds & yeasts count ≤ 100 cfu/gr	< 10 cfu/gr
Assay (oab)	98.0 ~ 102.0% of $C_{21}H_{25}ClFN_3O_4$	99.9%

Packaging & storage	In an airtight container, protected from light
Conclusion	Material complies with USP42