

Imatinib Mesilate EP11.0

Batch no Mf date

C001025051201

Retest

May 12 2025 May 11 2027

 $Molecular\ Formula\ C_{29}H_{31}N_70\cdot CH_4O_3S$

Molecular Weight 589.71

CAS Registry Number 220127-57-1

Form Alpha

Jul 08 2025

Tests	Specifications		Results
Appearance	White or almost white, slightly brownish Almost white powder or yellowish powder; yellow or pale yellow		
Identification	IR	and part yourself	Positive
Solubility	Freely soluble in water, slightly soluble in Conforms ethanol (96%), practically insoluble in		
W	methylene chloride		
Water	≤ 3.0%		0. 48%
Sulfated ash	≤ 0.1%		0.04%
Related substances	Impurity A	≤ 0. 15%	ND
	Impurity B	≤ 0.15%	ND
	Impurity C	≤ 0.3%	ND
	Impurity D	≤ 0. 2%	ND
	Impurity F	≤ 20 ppm	4 ppm
	Impurity H	≤ 0.02%	ND
	Unspecified impurities	≤ 0.1%	0.01%
	Total impurities	≤ 0.8%	0. 05%
Assay (HPLC)	98.0% ~ 102.0%		100.0%

Packaging and storage	Protected from light	-
Conclusion	Material complies with EP11.0	

