

Certificate of Analysis

Eflornithine Hcl Monohydrate

CAS No.	96020-91-6	Code	BIOJELF001
Batch No	NDS202407021	Manufacture Date	Jul.31, 2024
Expiry Date	Jul.30, 2027	Quantity	1Kg

Testing Items	Specifications	Results
Description	A white to off-white odourless crystalline powder	Complies
Solubility	Freely soluble in water	Complies
Identification	HPLC test: The retention time of major peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of major peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay
	Reaction for chloride	White precipitate produced
	IR: The infrared absorption spectrum of the potassium bromide dispersion of the sample must be concordant with that of a similar preparation of eflornithine hydrochloride working standard	Concordant with working standard spectrum
Clarity & Colour of 20% solution in water	Clear colourless solution	Complies
pH of 20% solution	3.0~4.0	3.55
Water	6.60%~8.60%	7.60%
Related substances(HPLC)	Any individual impurity $\leq 0.5\%$	0.21%
	L-ornithine hcl $\leq 0.5\%$	0.01%
	Total impurities $\leq 1.0\%$	0.93%
Heavy metals	Not more than 10ppm	Less than 10ppm
Residue on ignition	Not more than 0.10%	0.06%
Assay	97.0%~102.0%(Calculated on the dried basis)	99.3%
Conclusion	This product conforms to In-house standard	

***Storage condition: Store below 25°C, Protect from moisture and light.**