

**Certificate of Analysis**

Product Name	Edoxaban tosylate monohydrate		
Batch No.	20230327	CAS No.	1229194-11-9
Quantity	5kg	Reference	In house
Manufacture Date	Dec. 17. 2023	Retest Date	Dec. 16. 2025

Items	Specifications	Test Results
Appearance	Off-white or white crystalline powder	white crystalline powder
Identification	HPLC: the retention time of the major peak in the chromatogram of the assay, preparation corresponds to that of the standard preparation as obtained in the assay	Conform
Solubility	Soluble in Methanol, Slightly soluble in water	Conform
Related substances	Single impurity: $\leq 0.20\%$	0.026%
	Total impurity: $\leq 0.5\%$	0.13%
Isomer	$\leq 0.15\%$	0.07%
Water	2.0%~3.5%	2.3%
Specific Optical	-89°~ -99°	-96.2°
Residue on ignition	$\leq 0.1\%$	0.04%
Heavy metals	<20ppm	<20ppm
Purity	99.0%	99.87 %
Residual solvents	Methanol $\leq 3000$ ppm	300ppm
	Acetonitrile $\leq 410$ ppm	undetected
	Dichloromethane $\leq 600$ ppm	undetected
	Hexane $\leq 290$ ppm	undetected
	Tetrahydrofuran $\leq 720$ ppm	undetected
	Toluene $\leq 890$ ppm	undetected

**Conclusion:** The material complies with in-house standard.