

Certificate of Analysis

Ripasudil Hydrochloride Dihydrate (K115 Hcl Dihydrate)

CAS No.	887375-67-9	Code	BIOJRIP001
Batch No	CVC18-20260601	Manufacture Date	Jun.04, 2026
Retest Date	Jun.03, 2028	Quantity	20G

Testing Items	Specifications	Results
Appearance	White to off-white crystalline powder	White crystalline powder
Solubility	Soluble in methanol and water, very slightly soluble in ethyl acetate and ethyl ether, and practically insoluble in hexane	Conform
IR (KBr)	The infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from working standard or reference	Conform
HPLC	The relative retention time (RRT) in testing sample matches with the RRT or WS	Corresponds
Purity (HPLC)	$\geq 99.0\%$	99.9%
Related substances	Impurity A $\leq 0.15\%$ Impurity B $\leq 0.15\%$ Impurity C $\leq 0.15\%$ Impurity D $\leq 0.15\%$ Any unspecified impurity $\leq 0.10\%$ each Total impurities $\leq 1.0\%$	Not detected Not detected Not detected Not detected $\leq 0.04\%$ 0.1%
Optical purity (EE Value)	$\geq 99.0\%$	100.0%
Water content	8.5% ~ 11.0%	8.8%
Hydrochloride content	8.2% ~ 10.2%	9.0%
Residual on ignition	$\leq 0.2\%$	0.1%
Heavy metal	$\leq 20\text{ppm}$	0.4ppm

Residual solvents	DCM $\leq$ 600ppm Methanol $\leq$ 3000ppm Ethanol $\leq$ 5000ppm Acetonitrile $\leq$ 410ppm Tetrahydrofuran $\leq$ 720ppm Ethyl acetate $\leq$ 5000ppm N-Heptane $\leq$ 5000ppm Acetone $\leq$ 5000ppm	Not detected Not detected Not detected Not detected Not detected Not detected Not detected 598ppm
Assay (Anhydrous basis)	97.0%~103.0%	100.3%
Conclusion	This product conforms to In-house standard	

***Storage conditions:**

Stability studies demonstrate the material remains stable at 25 °C; ambient shipment permitted.

Long-term storage recommended at –20 °C.