



## Certificate of Analysis

Certificate No.: 20240103043

Date: January 3, 2024

Retest date: December 22, 2026

<b>Compound Name:</b>	<b>Rivaroxaban Impurity 29 HCl</b>	
<b>Synonyms:</b>	(R)-4-(4-(5-(aminomethyl)-2-oxooxazolidin-3-yl)phenyl)morpholin-3-one, hydrochloride (1:1)	
<b>TLC Catalogue Number:</b>	R-2919	
<b>CAS Number:</b>	1429311-47-6	
<b>Molecular Weight:</b>	291.31 36.46	
<b>Molecular Formula:</b>	C <sub>14</sub> H <sub>17</sub> N <sub>3</sub> O <sub>4</sub> . HCl	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	5864-055A3	
<b>Storage Conditions:</b>	Store at 2-8 °C	
<b>Solubility:</b>	Methanol, DMSO, Water	

Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>99.0%</b>
<b>Impurity (HPLC)</b>	RT 12.09, 0.54%; RT 15.60, 0.11%	
<b>Purity (Chiral HPLC, free base)</b>	Not less than 98.0%	<b>100.0%</b>
<b>Water Content (KF)</b>	N/A	<b>0.2%</b>
<b>Optical Rotation</b>	N/A	$[\alpha]_D^{20.0}(c=0.31, \text{DMSO}): +42.1^\circ$
<b>Residual Solvents (NMR)</b>	0.7% methanol	
<b>Assay (%)</b>	Not less than 90.0%	<b>98.1%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01/03/2024
Approved by:	Quality Assurance		01/03/2024

Attachments: HPLC, IR, MS and NMR spectra.