

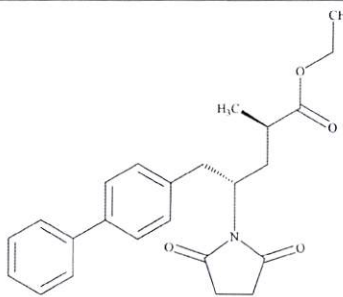
## Certificate of Analysis

Certificate No.: 20241004508



Date: October 4, 2024

Retest date: October 2, 2027

<b>Compound Name:</b> Sacubitril Impurity 2	
<b>Synonyms:</b>	ethyl (2R,4S)-5-([1,1'-biphenyl]-4-yl)-4-(2,5-dioxopyrrolidin-1-yl)-2-methylpentanoate
<b>TLC Catalogue Number:</b>	S-072006
<b>CAS Number:</b>	1038924-97-8
<b>Molecular Weight:</b>	393.48
<b>Molecular Formula:</b>	C <sub>24</sub> H <sub>27</sub> NO <sub>4</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	2505-039A2
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO



Test Description	Specifications	Results
<b>Visual Description</b>	Pale yellow solid	<b>Conforms</b>
<b>Identification</b>		
<b>IR</b>	Conforms to structure	<b>Conforms</b>
<b>MS</b>	Conforms to structure	<b>Conforms</b>
<b><sup>1</sup>H NMR</b>	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>98.7%</b>
<b>Impurity (HPLC)</b>	RT 14.17, 0.44%; RT 18.81, 0.24%	
<b>Water Content (KF)</b>	N/A	<b>0.2%</b>
<b>Optical Rotation</b>	N/A	$[\alpha]_D^{26.0}$ (c=1.04, CHCl <sub>3</sub> ): <b>+59.6°</b>
<b>Residual Solvents (NMR)</b>	0.2% ethyl acetate	
<b>Assay (%)</b>	Not less than 90.0%	<b>98.3%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		10/07/2024
Approved by:	Quality Assurance		10/07/2024

**Attachments:** HPLC, IR, MS and NMR spectra.