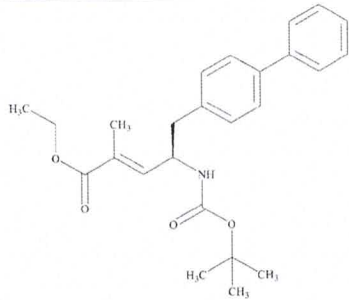


Certificate of Analysis


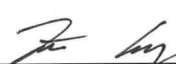
Certificate No.: 20220526018

Date: May 26, 2022

Retest date: May 20, 2025

Compound Name:	Sacubitril Impurity 21	
Synonyms:	ethyl (R,E)-5-([1,1'-biphenyl]-4-yl)-4-((tert-butoxycarbonyl)amino)-2-methylpent-2-enoate	
TLC Catalogue Number:	S-072027	
CAS Number:	1817838-91-7	
Molecular Weight:	409.53	
Molecular Formula:	C ₂₅ H ₃₁ NO ₄	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	5016-001A1	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, Ethanol	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.9%
Impurity (HPLC)	RT 7.74, 1.06%	
Purity (Chiral HPLC)	Not less than 98.0%	99.9%
Water Content (KF)	N/A	0.1%
Optical Rotation	N/A	$[\alpha]_D^{25.0}(c=0.46, \text{CHCl}_3)$: -29.3°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	98.7%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/27/2022
Approved by:	Quality Assurance		05/27/2022

Attachments: HPLC, IR, MS and NMR spectra.