

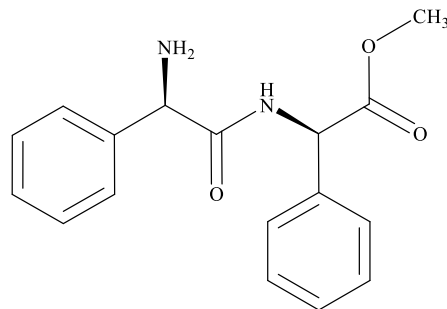
Certificate of Analysis

Certificate No.: 20200619025

Date: June 19, 2020

Retest date: June 18, 2023

Compound Name: Cefaclor Impurity 2	
Synonyms:	methyl (R)-2-((R)-2-amino-2-phenylacetamido)-2-phenylacetate
TLC Catalogue Number:	C-6610
CAS Number:	722547-49-1
Molecular Weight:	298.34
Molecular Formula:	C ₁₇ H ₁₈ N ₂ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3951-022A5
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, DMF



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 15.83, 0.55%; RT 19.15, 0.55%	
Water Content (KF)	N/A	0.3%
Optical Rotation	[α] _D ^{N/A} (c=1.00, CH ₃ OH): -144.5°	[α] _D ^{25.0} (c=0.34, CH ₃ OH): -135.6°
Residual Solvents (NMR)	1.3% ethyl acetate	
Assay (%)	Not less than 90.0%	97.3%
Recommendation:	Released.	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.