

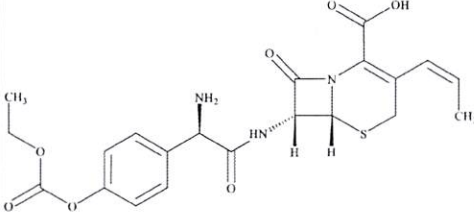


Certificate of Analysis



Certificate No.: 20230627007

Date: June 27, 2023

Retest date: June 26, 2026

Compound Name:	Cefprozil EP Impurity M	
Synonyms:	(6R,7R)-7-((R)-2-amino-2-(4-((ethoxycarbonyloxy)phenyl)acetamido)-8-oxo-3-((Z)-prop-1-en-1-yl)-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid	
TLC Catalogue Number:	C-127011	
CAS Number:	1605314-84-8	
Molecular Weight:	461.49	
Molecular Formula:	C ₂₁ H ₂₃ N ₃ O ₇ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3920-015A8	
Storage Conditions:	Store at -20 °C	
Solubility:	DMSO, Water, DMF	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.6%
Impurity (HPLC)	RT 7.59, 0.50%; RT 11.95, 0.70%	
Water Content (KF)	N/A	2.1%
Optical Rotation	N/A	$[\alpha]_D^{25.0}(c=0.32, H_2O): +47.6^\circ$
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	96.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06 / 28 / 2023
Approved by:	Quality Assurance		06 / 28 / 2023

Attachments: HPLC, IR, MS and NMR spectra.