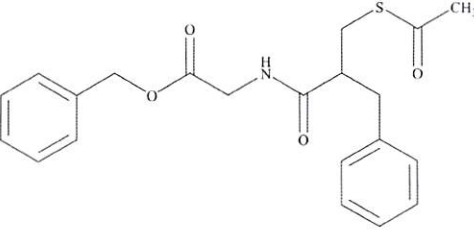


Certificate of Analysis



Certificate No.: 20231026023

Date: October 26, 2023

Retest date: October 23, 2026

Compound Name: Racecadotril		
Synonyms:	benzyl (3-(acetylthio)-2-benzylpropanoyl)glycinate	
TLC Catalogue Number:	R-311	
CAS Number:	81110-73-8	
Molecular Weight:	385.48	
Molecular Formula:	C ₂₁ H ₂₃ NO ₄ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	1169-016A1	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Acetonitrile	

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%	99.9%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.1%
Residue (TGA at 800 °C)	N/A	0.0%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.8%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		10/27/2023
Approved by:	Quality Assurance		10/27/2023

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