

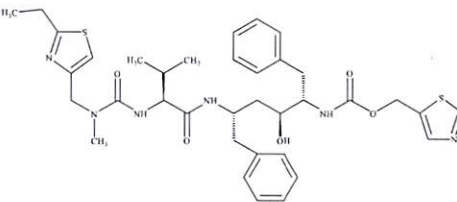
Certificate of Analysis

Certificate No.: **20260428016**



Date: April 28, 2026

Retest date: April 27, 2029

Compound Name: Ritonavir EP Impurity I	
Synonyms:	thiazol-5-ylmethyl ((2S,3S,5S)-5-((S)-2-(3-((2-ethylthiazol-4-yl)methyl)-3-methylureido)-3-methylbutanamido)-3-hydroxy-1,6-diphenylhexan-2-yl) carbamate
TLC Catalogue Number:	R-2721
CAS Number:	165315-26-4
Alternate CAS Number:	N/A
Molecular Weight:	706.92
Molecular Formula:	C ₃₆ H ₄₆ N ₆ O ₅ S ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	4085-007A8
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Acetonitrile, Ethanol



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
Purity (HPLC)	Not less than 95.0%	97.3%
Impurity (HPLC)	RT 5.26, 0.55%; RT 6.86, 1.17%; RT 7.13, 0.40%	
Water Content (KF)	N/A	2.4%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.66, CH ₃ OH): +9.0°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	95.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		04/28/2026
Approved by:	Quality Assurance		04/28/2026

Attachments: Peak Attribution Table, Assay Calculation, HPLC, IR, MS and NMR spectra.