

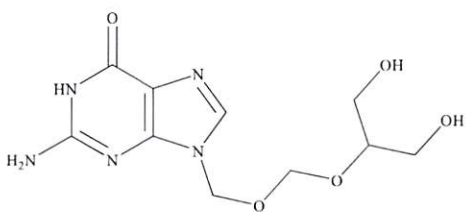
Certificate of Analysis

Certificate No.: **20250919006**



Date: September 19, 2025

Retest date: September 18, 2028

Compound Name: Ganciclovir EP Impurity D	
Synonyms:	2-amino-9-((((1,3-dihydroxypropan-2-yl)oxy)methoxy)methyl)-1,9-dihydro-6H-purin-6-one
TLC Catalogue Number:	G-169
CAS Number:	1346598-14-8
Alternate CAS Number:	N/A
Molecular Weight:	285.26
Molecular Formula:	C ₁₀ H ₁₅ N ₅ O ₅
Source:	TLC Pharmaceutical Standards
Source Lot No.:	7004-059A5
Storage Conditions:	Store at 2-8 °C
Solubility:	Solution of Methanol and Water, 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
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.2%
Impurity (HPLC)	RT 10.37, 0.13%; RT 14.70, 0.20%; RT 19.56, 0.24%	
Water Content (KF)	N/A	0.5%
Residual Solvents (NMR)	1.6% methanol	
Assay (%)	Not less than 90.0%	97.1%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		09/19/2025
Approved by:	Quality Assurance		09/19/2025

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