

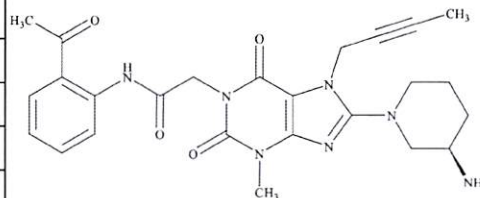
Certificate of Analysis

Certificate No.: **20231031006**



Date: October 31, 2023

Retest date: October 24, 2026

Compound Name: Linagliptin Impurity 7	
Synonyms:	(R)-N-(2-acetylphenyl)-2-(8-(3-aminopiperidin-1-yl)-7-(but-2-yn-1-yl)-3-methyl-2,6-dioxo-2,3,6,7-tetrahydro-1H-purin-1-yl)acetamide
TLC Catalogue Number:	L-4420
CAS Number:	2416949-69-2
Molecular Weight:	491.55
Molecular Formula:	C ₂₅ H ₂₉ N ₇ O ₄
Source:	TLC Pharmaceutical Standards
Source Lot No.:	5933-007A6
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
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	97.6%
Impurity (HPLC)	RT 20.87, 2.26%	
Purity (Chiral HPLC)	Not less than 98.0%	100.0%
Water Content (KF)	N/A	0.7%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.32, CHCl ₃): -18.5°
Residual Solvents (NMR)	0.1% dichloromethane and 1.6% acetonitrile	
Assay (%)	Not less than 90.0%	95.3%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		11 / 01 / 2023
Approved by:	Quality Assurance		11 / 01 / 2023

Attachments: HPLC, IR, MS and NMR spectra.