

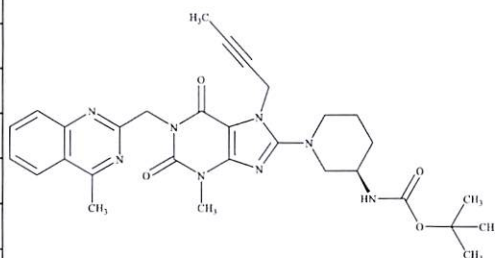
Certificate of Analysis

Certificate No.: **20240226019**



Date: February 26, 2024

Retest date: February 23, 2027

Compound Name: Linagliptin Impurity 43	
Synonyms:	<i>tert</i> -butyl (R)-(1-(7-(but-2-yn-1-yl)-3-methyl-1-((4-methylquinazolin-2-yl)methyl)-2,6-dioxo-2,3,6,7-tetrahydro-1 <i>H</i> -purin-8-yl)piperidin-3-yl)carbamate
TLC Catalogue Number:	L-4437
CAS Number:	668273-75-4
Molecular Weight:	572.67
Molecular Formula:	C ₃₀ H ₃₆ N ₈ O ₄
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3213-088A4
Storage Conditions:	Store at 2-8 °C
Solubility:	DMSO, solution of Methanol and 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
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	1.8%
Optical Rotation	N/A	[α] _D ^{20.0} (c=0.70, CHCl ₃): -1.8°
Residual Solvents (NMR)	0.3% methanol and 0.3% dichloromethane	
Assay (%)	Not less than 90.0%	97.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		02/27/2024
Approved by:	Quality Assurance		02/27/2024

Attachments: HPLC, IR, MS and NMR spectra.