

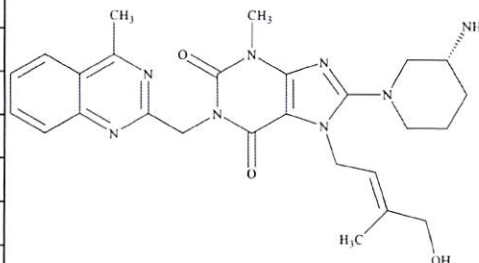
Certificate of Analysis

Certificate No.: 20240716503



Date: July 16, 2024

Retest date: July 12, 2027

Compound Name: Linagliptin Impurity 93	
Synonyms:	(R,E)-8-(3-aminopiperidin-1-yl)-7-(4-hydroxy-3-methylbut-2-en-1-yl)-3-methyl-1-((4-methylquinazolin-2-yl)methyl)-3,7-dihydro-1H-purine-2,6-dione
TLC Catalogue Number:	L-44105
CAS Number:	N/A
Molecular Weight:	504.60
Molecular Formula:	C ₂₆ H ₃₂ N ₈ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	4305-012A15
Storage Conditions:	Store at 2-8 °C
Solubility:	DMSO, solution of Methanol and Acetonitrile



Test Description	Specifications	Results
Visual Description	Yellow 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%	97.1%
Impurity (HPLC)	RT 10.64, 2.25%; RT 13.25, 0.30%; RT 15.09, 0.10%	
Water Content (KF)	N/A	2.9%
Optical Rotation	N/A	$[\alpha]_D^{25.0}$ (c=0.37, CHCl ₃): -11.0°
Residual Solvents (NMR)	0.4% diethyl ether	
Assay (%)	Not less than 90.0%	93.9%
Recommendation:	Release. The compound contains 2.3% isomeric impurity (RT 10.64) according to its HPLC and LC-MS.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/17/2024
Approved by:	Quality Assurance		07/17/2024

Attachments: HPLC, IR, MS and NMR spectra.