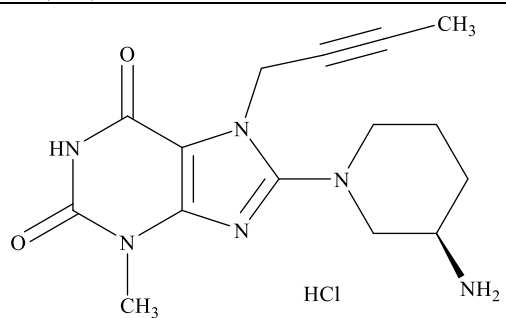


Certificate of Analysis

Certificate No.: 20210715009

Date: July 15, 2021

Retest date: July 1, 2024

Compound Name:	Linagliptin Impurity 90 HCl	
Synonyms:	(R)-8-(3-aminopiperidin-1-yl)-7-(but-2-yn-1-yl)-3-methyl-3,7-dihydro-1H-purine-2,6-dione, hydrochloride (1:1)	
TLC Catalogue Number:	L-44102	
CAS Number:	1791405-13-4 (free base)	
Molecular Weight:	316.37 36.46	
Molecular Formula:	C ₁₅ H ₂₀ N ₆ O ₂ · HCl	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4524-038A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	DMSO, Water, DMF	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.3%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.35, H ₂ O): -24.4°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.7%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.