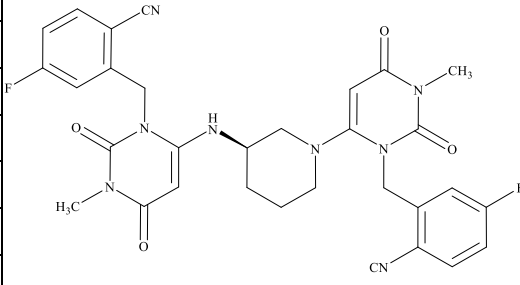


Certificate of Analysis

Certificate No.: 20210726008

Date: July 26, 2021

Retest date: July 21, 2024

Compound Name:	Trelagliptin Impurity 16	
Synonyms:	(R)-2-((6-(3-((3-(2-cyano-5-fluorobenzyl)-1-methyl-2,6-dioxo-1,2,3,6-tetrahydropyrimidin-4-yl)amino)piperidin-1-yl)-3-methyl-2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)methyl)-4-fluorobenzonitrile	
TLC Catalogue Number:	T-155016	
CAS Number:	1917324-13-0	
Molecular Weight:	614.61	
Molecular Formula:	C ₃₁ H ₂₈ F ₂ N ₈ O ₄	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4554-026A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	DMSO, DMF, 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
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.0%
Impurity (HPLC)	RT 10.44, 0.37%; RT 12.34, 0.38%	
Water Content (KF)	N/A	0.5%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.37, DMSO): +18.6°
Residual Solvents (NMR)	1.3% methanol	
Assay (%)	Not less than 90.0%	97.2%
Recommendation:	Release.	

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

Attachments: HPLC, IR, MS and NMR spectra.