

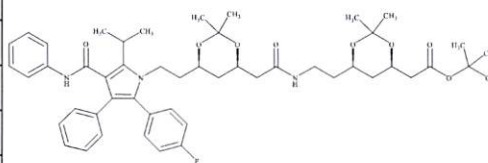
Certificate of Analysis

Certificate No.: **20220627003**



Date: June 27, 2022

Retest date: June 23, 2025

Compound Name: Atorvastatin Impurity 69	
Synonyms:	<i>tert</i> -butyl 2-((4R,6R)-6-(2-(2-((4R,6R)-6-(2-(2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1 <i>H</i> -pyrrol-1-yl)ethyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetamido)ethyl)-2,2-dimethyl-1,3-dioxan-4-yl)acetate
TLC Catalogue Number:	A-12109
CAS Number:	1116118-82-1
Molecular Weight:	854.07
Molecular Formula:	C ₅₀ H ₆₄ FN ₃ O ₈
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3856-035A6
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, 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%	98.8%
Impurity (HPLC)	RT 2.32, 0.43%; RT 7.85, 0.20%; RT 11.69, 0.35%	
Water Content (KF)	N/A	0.5%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.45, CHCl ₃): +3.8°
Residual Solvents (NMR)	1.9% <i>n</i> -hexane	
Assay (%)	Not less than 90.0%	96.4%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06 / 29 / 2022
Approved by:	Quality Assurance		06 / 29 / 2022

Attachments: HPLC, IR, MS and NMR spectra.