

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 56

Identification

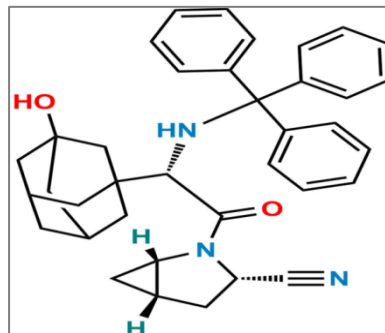
Chemical Name : (1S,3S,5S)-2-((2S)-2-(3-hydroxyadamantan-1-yl)-2-(tritylamino)acetyl)-2-azabicyclo[3.1.0]hexane-3-carbonitrile

CAT No : ALL-SAX-97

CAS No : 1669461-40-8

Molecular Formula : C₃₇H₃₉N₃O₂

Molecular Weight : 557.7



Analytical Information

Batch No.	: ALL-SAX-97	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 97.61%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.248%	¹H NMR	: Confirm
Residue Of Ignition	: 0.144%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.248+0.144) × 98.00%]/100 = 97.61%

Recommendation : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr.Vipul khadase Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

Attachment : HPLC, Mass, ¹H NMR, IR, TGA

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office