

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 55

Identification

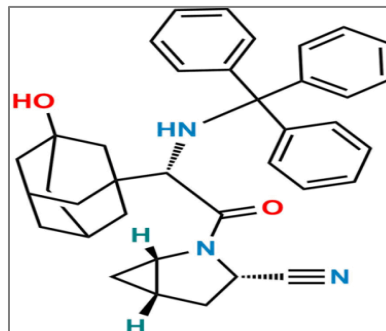
Chemical Name : (1S,3S,5S)-2-((S)-2-(adamantan-1-yl)-2-(tritylamino)acetyl)-2-azabicyclo[3.1.0]hexane-3-carbonitrile

CAT No : ALL-SAX-96

CAS No : N.A.

Molecular Formula : C₃₇H₃₉N₃O

Molecular Weight : 541.7



Analytical Information

Batch No.	: ALL-SAX-96	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 97.26%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.275%	1HNMR	: Confirm
Residue Of Ignition	: 0.476%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.275+0.476) × 98.00]/100 = 97.26%

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