

Analysis Date: 07-10-2025

Re-test Date: 07-10-2025

SAXAGLIPTIN AMIDE IMPURITY

Identification

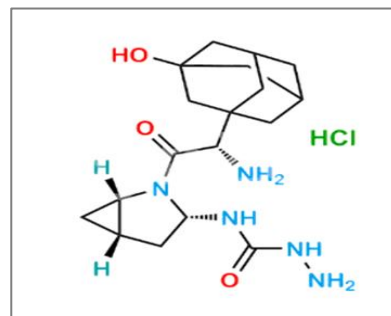
Chemical Name : N-((1S,3S,5S)-2-((2S)-2-amino-2-(3-hydroxyadamantan-1-yl)acetyl)-2-azabicyclo[3.1.0]hexan-3-yl)hydrazinecarboxamide hydrochloride

CAT No : ALL-SAX-72

CAS No : N.A.

Molecular Formula : C₁₈H₂₉N₅O₃ : HCl

Molecular Weight : 363.5 : 36.5



Analytical Information

Batch No.	: ALL-SAX-72	HPLC Purity	: 98.00 %
Solubility	: MeOH: ACN	Potency	: 96.35 %
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: 2-8 ⁰ C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.321 %	¹HNMR	: Confirm
Residue Of Ignition	: 0.361 %		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.321 + 0.361) × 98.00]/100 = 96.35 %

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