

Analysis Date: 09-10-2025

Re-test Date: 09-10-2028

SAXAGLIPTIN NITROSO IMPURITY 5

Identification

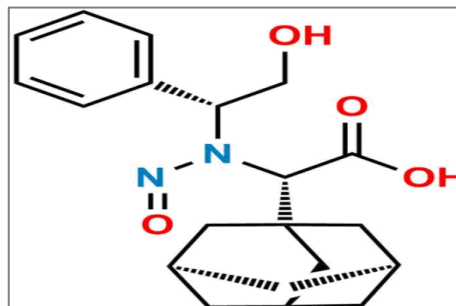
Chemical Name : (S)-2-((3S,5S,7S)-adamantan-1-yl)-2-(((R)-2-hydroxy-1-phenylethyl)(nitroso)amino)acetic acid

CAT No : ALL-SAX-106

CAS No : N.A.

Molecular Formula : C₂₀H₂₆N₂O₄

Molecular Weight : 358.4



Analytical Information

Batch No.	: ALL-SAX-106	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%	¹H NMR	: 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