

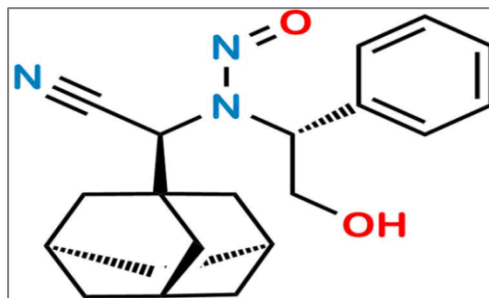
Analysis Date: 09-10-2025

Re-test Date: 09-10-2028

SAXAGLIPTIN NITROSO IMPURITY 3
Identification
Chemical Name : N-((S)-((3S,5S,7S)-adamantan-1-yl)(cyano)methyl)-N-((R)-2-hydroxy-1-phenylethyl)nitroso amide

CAT No : ALL-SAX-105

CAS No : N.A.

Molecular Formula : C₂₀H₂₅N₃O₂
Molecular Weight : 339.4

Analytical Information

Batch No.	: ALL-SAX-105	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.65%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.045%	¹HNMR	: Confirm
Residue Of Ignition	: 1.351%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.045+1.351) × 98.00]/100 = 95.65%

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