

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 31

Identification

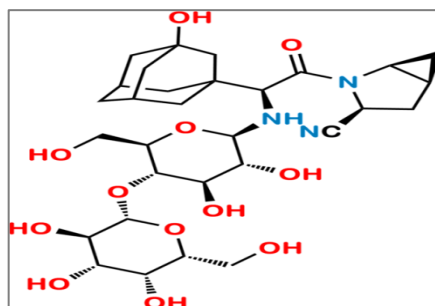
Chemical Name : (1S,3S,5S)-2-((2S)-2-(((3R,4R,6R)-3,4-Dihydroxy-6-(hydroxymethyl)-5-(((3R,4S,5R,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)oxy)tetrahydro-2H-pyran-2-yl)amino)-2-((3R,5R,7S)-3-hydroxyadamantan-1-yl)acetyl)-2-azabicyclo[3.1.0]hexane-3-carbonitrile

CAT No : ALL-SAX-81

CAS No : N.A.

Molecular Formula : C₃₀H₄₅N₃O₁₂

Molecular Weight : 639.7


Analytical Information

Batch No.	: ALL-SAX-81	HPLC Purity	: 98.00%
Solubility	: MeOH: ACN	Potency	: 95.14%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: 2-8 ^o C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.256 %	¹HNMR	: Confirm
Residue Of Ignition	: 1.658 %		

Additional Information

%Potency = [100 -(Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 – (1.256 + 1.658) × 98.00]/100= 95.14%

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