

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 57

Identification

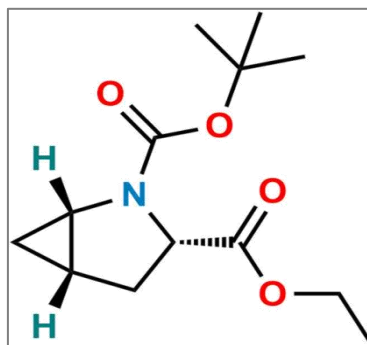
Chemical Name : 2-(Tert-butyl) 3-ethyl (1S,3S,5S)-2-azabicyclo[3.1.0]hexane-2,3-dicarboxylate

CAT No : ALL-SAX-98

CAS No : 214193-11-0

Molecular Formula : C₁₃H₂₁NO₄

Molecular Weight : 255.3



Analytical Information

Batch No.	: ALL-SAX-98	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 96.85%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.516%	¹HNMR	: Confirm
Residue Of Ignition	: 0.648%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.516+0.648) × 98.00]/100 = 96.85%

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