

**Analysis Date:** 08-10-2025

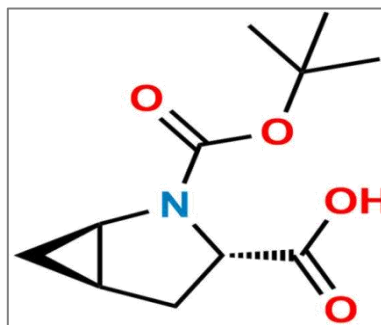
**Re-test Date:** 08-10-2028

**SAXAGLIPTIN IMPURITY 54**
**Identification**
**Chemical Name** : (1S,3S,5S)-2-((2S)-2-(3-hydroxyadamantan-1-yl)-2-(tritylamino)acetyl)-2-azabicyclo[3.1.0]hexane-3-carbonitrile

**CAT No** : ALL-SAX-95

**CAS No** : 197142-34-0

**Molecular Formula** : C37H39N3O2

**Molecular Weight** : 557.7

**Analytical Information**

<b>Batch No.</b>	: ALL-SAX-95	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 95.65%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 1.045%	<b>1HNMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 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**