

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 40

Identification

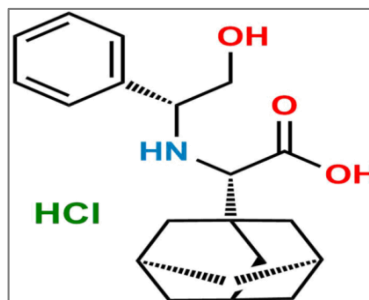
Chemical Name : (S)-2-((3S,5S,7S)-Adamantan-1-yl)-2-(((R)-2-hydroxy-1-phenylethyl)amino)acetic acid hydrochloride

CAT No : ALL-SAX-87

CAS No : 361441-96-5

Molecular Formula : C₂₀H₂₇NO₃ : HCl

Molecular Weight : 329.4 : 36.5



Analytical Information

Batch No.	: ALL-SAX-87	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 97.61%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.248%	¹H NMR	: Confirm
Residue Of Ignition	: 0.144%		

Additional Information

$$\% \text{Potency} = [100 - (\text{Weight Loss By TGA \%} + \text{Residue Of Ignition \%}) \times \text{Chromatographic Purity\%}] / 100 = [100 - (0.248 + 0.144) \times 98.00\%] / 100 = 97.61\%$$

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