

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 37

Identification

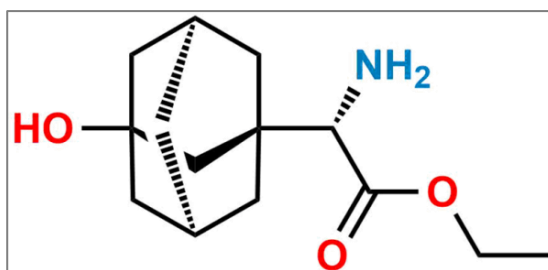
Chemical Name : Ethyl (S)-2-Amino-2-((1r,3R,5R,7S)-3-hydroxyadamantan-1-yl)acetate

CAT No : ALL-SAX-85

CAS No : 1621530-36-6

Molecular Formula : C₁₄H₂₃NO₃

Molecular Weight : 253.3



Analytical Information

| | | | |
|------------------------------|-----------------------------------|-------------------------|-----------|
| Batch No. | : ALL-SAX-85 | 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