

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 59

Identification

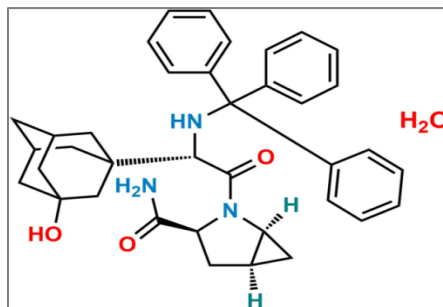
Chemical Name : (S)-1-(tert-butoxycarbonyl)-2,3-dihydro-1H-pyrrole-2-carboxylic acid

CAT No : ALL-SAX-100

CAS No : 90104-21-5

Molecular Formula : C₁₀H₁₅NO₄

Molecular Weight : 213.2



Analytical Information

| | | | |
|------------------------------|----------------------|--------------------------|-----------|
| Batch No. | : ALL-SAX-100 | HPLC Purity | : 98.00% |
| Solubility | : MeOH: ACN | Potency | : 96.03% |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : 2-8 ⁰ C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 0.675 % | ¹H NMR | : Confirm |
| Residue Of Ignition | : 1.334 % | | |

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.675 + 1.334) × 98.00]/100= 96.03%

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