

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 53

Identification

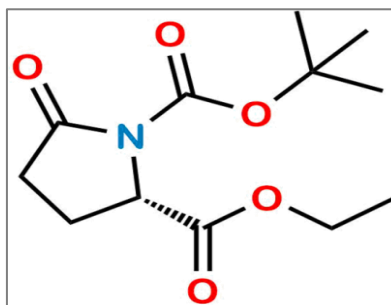
Chemical Name : 1-(Tert-butyl) 2-ethyl (S)-5-oxopyrrolidine-1,2-dicarboxylate

CAT No : ALL-SAX-94

CAS No : 144978-12-1

Molecular Formula : C₁₂H₁₉NO₅

Molecular Weight : 257.3



Analytical Information

Batch No : ALL-SAX-94

HPLC Purity : 98.00%

Solubility : MeOH: ACN

Potency : 96.09%

Appearance of Product : Off White Solid

Mass : Confirm

Long Term Storage : 2-8 °C

IR Analysis : Confirm

Weight Loss By TGA : 1.196%

¹H NMR : Confirm

Residue Of Ignition : 0.744%

Additional Information

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

$$[100 - (1.196 + 0.744) \times 98.00] / 100 = 96.09\%$$

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, TGA.

Shipping Condition : All Product are stable to be shipped at room temperature, unless otherwise specified

Corporate Office