

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

SAXAGLIPTIN IMPURITY 44

Identification

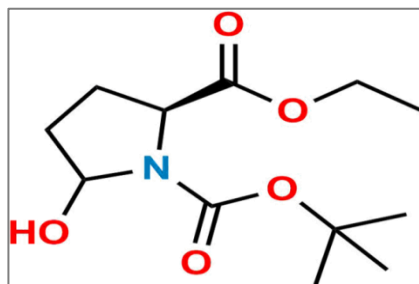
Chemical Name : 1-(Tert-butyl) 2-ethyl (2S)-5-hydroxypyrrolidine-1,2-dicarboxylate

CAT No : ALL-SAX-89

CAS No : 194594-23-5

Molecular Formula : C₁₂H₂₁NO₅

Molecular Weight : 259.3



Analytical Information

Batch No.	: ALL-SAX-89	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.55%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.453%	¹HNMR	: Confirm
Residue Of Ignition	: 1.045%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.453+1.045) × 98.00]/100 = 95.55%

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