

Analysis Date: 24-09-2025 **Re-test Date:** 24-09-2028

SITAGLIPTIN FP IMPURITY E

Identification

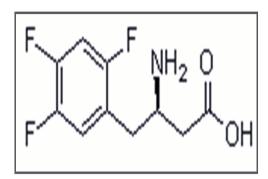
Chemical Name : (3R)-3-Amino-4-(2,4,5-trifluorophenyl)butanoic acid

CAT No : ALL-SIT-2058

CAS No : 936630-57-8

Molecular Formula : C10H10F3NO2

Molecular Weight : 233.19



Analytical Information

Batch Number : ALL-SIT-2058 HPLC Purity : 98.00%

Solubility : MeOH: ACN Potency : 95.71 %

Appearance of Product: Off White Solid Mass: Confirm

Long Term Storage : 2-8 0C **IR Analysis** : Confirm

Weight Loss By TGA : 1.483 % 1HNMR : Confirm

Residue Of Ignition : 0.849 %

Additional Information

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

 $[100 - (1.483 + 0.849) \times 98.00]/100 = 95.71\%$

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