

Analysis Date: 24-09-2025

Re-test Date: 24-09-2028

SITAGLIPTIN IMPURITY 32

Identification

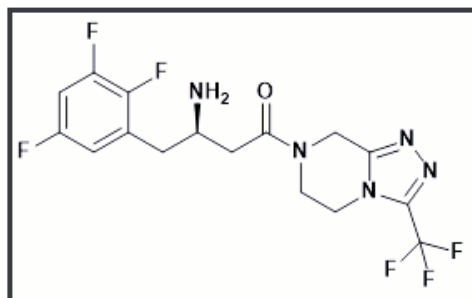
Chemical Name : R-3-amino-4-(2,3,5-trifluorophenyl)-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4] triazolo [4,3-a] pyrazin-7 (8H)-yl)butan-1-one

CAT No : ALL-S04178

CAS No : 945261-49-4

Molecular Formula : C₁₆H₁₅F₆N₅O

Molecular Weight : 407.31



Analytical Information

| | | | |
|------------------------------|-----------------------------------|--------------------------|-----------|
| Batch Code | : ALL-S04178 | HPLC Purity | : 98.00% |
| Solubility | : USP Diluent / EP Diluent (MEOH) | Potency | : 95.87% |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : -20°C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 1.145% | ¹H NMR | : Confirm |
| Residue Of Ignition | : 1.025% | | |

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
[100 - (1.145+1.025) × 98.00]/100 = 95.87%

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

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