

Analysis Date: 24-09-2025

Re-test Date: 24-09-2028

SITAGLIPTIN HYDROXY AMIDE IMPURITY

Identification

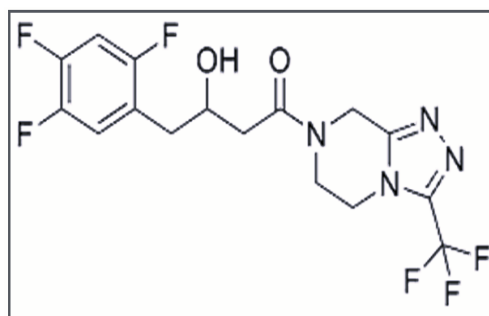
Chemical Name : 3-Hydroxy-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl)-4-(2,4,5-trifluorophenyl)butan-1-one

CAT No : ALL-SIT-2060

CAS No : 1253056-01-7

Molecular Formula : C₁₆H₁₄F₆N₄O₂

Molecular Weight : 408.3



Analytical Information

| | | | |
|------------------------------|-----------------------------------|--------------------------|-----------|
| Batch Code | : ALL-SIT-2060 | HPLC Purity | : 98.00% |
| Solubility | : USP Diluent / EP Diluent (MEOH) | Potency | : 96.82% |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : -20°C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 0.620% | ¹H NMR | : Confirm |
| Residue Of Ignition | : 0.578% | | |

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.620+0.578) × 98.00]/100 = 96.82%

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

Allmpus Laboratories Pvt Ltd 38, Solitaire Industrial Estate, Plot No.TS-1, Near Nandi Palace Hotel, MIDC-Phase 1, Dombivli (E), Mumbai, Maharashtra 421203