

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

## **SITAGLIPTIN IMPURITY 44**

## **Identification**

Chemical Name: (R)-3-amino-4-(2, 4-difluorophenyl)-1-(3- (trifluoromethyl)-5, 6-dihydro-

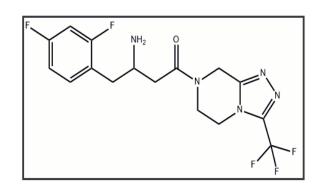
[1, 2, 4] triazolo [4, 3-a] pyrazin- 7(8H)-yl) butan-1-one

**CAT No** : ALL-S03535

**CAS No** : 1334244-28-8

**Molecular Formula** : C16H16F5N5O

**Molecular Weight** : 389.32



# **Analytical Information**

Batch Code : ALL-S03535 HPLC Purity : 98.00%

Solubility: MeOH: ACN Potency: 96.58%

**Appearance of Product**: Off White Solid Mass: Confirm

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

Weight Loss By TGA : 0.223 % 1HNMR : Confirm

**Residue Of Ignition** : 1.214 %

## Additional Information

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

 $[100 - (0.223 + 1.214) \times 98.00]/100 = 96.58\%$ 

**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**