



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

# **SITAGLIPTIN IMPURITY 22**

## **Identification**

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

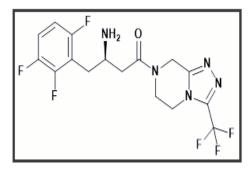
[1,2,4] triazolo [4,3-a] pyrazin-7 (8H)-yl)butan-1-one

**CAT No** : ALL-S04179

**CAS No** : 945261-50-7

Molecular Formula : C16H15F6N5O

Molecular Weight : 407.31



# **Analytical Information**

Batch Code : ALL-S04179 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% 1HNMR : Confirm

**Residue Of Ignition** : 0.578%

# **Additional Information**

 $\label{eq:potency} \mbox{$\%$Potency} = [100 - (Weight Loss By TGA \% + Residue Of Ignition \%) \times Chromatographic Purity\%]/100 = (100 - (Weight Loss By TGA \% + Residue Of Ignition \%)) \times (100 - (Weight Loss By TGA \% + Residue Of Ignition \%)) \times (100 - (Weight Loss By TGA \% + Residue Of Ignition \%)) \times (100 - (Weight Loss By TGA \% + Residue Of Ignition \%)))$ 

 $[100 - (0.620 + 0.578) \times 98.00]/100 = 96.82\%$ 

**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