

Analysis Date: 24-09-2025

Re-test Date: 24-09-2028

## SITAGLIPTIN EP IMPURITY C

### Identification

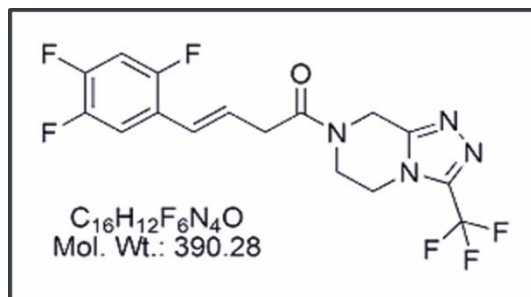
**Chemical Name** : (R)-4-Oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4-difluorophenyl)butan-2-amine

**CAT No** : ALL-SIT-2053

**CAS No** : 1345822-86-7

**Molecular Formula** : C<sub>16</sub>H<sub>12</sub>F<sub>6</sub>N<sub>4</sub>O

**Molecular Weight** : 389.32



### Analytical Information

<b>Batch Code</b>	: ALL-SIT-2053	<b>HPLC Purity</b>	: 99.32 %
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 97.81%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.711%	<b><sup>1</sup>HNMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 0.801%		

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
[100 - (0.711+0.801) × 99.32 %]/100 = 97.81%

**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, <sup>1</sup>H 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