

Analysis Date: 24-09-2025

Re-test Date: 24-09-2028

SITAGLIPTIN 2-DESFLUORO IMPURITY

Identification

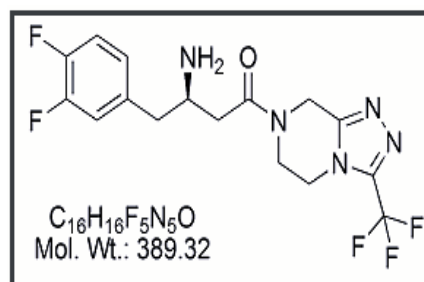
Chemical Name : (3R)-3-Amino-4-(3,4-difluorophenyl)-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl)butan-1-one

CAT No : ALL-S03518

CAS No : 486459-88-5

Molecular Formula : C₁₆H₁₆F₅N₅O

Molecular Weight : 389.3



Analytical Information

Batch Code	: ALL-S03518	HPLC Purity	: 99.11%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 98.36%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.275%	¹H NMR	: Confirm
Residue Of Ignition	: 0.476%		

Additional Information

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

$$[100 - (0.275 + 0.476) \times 99.11] / 100 = 98.36\%$$

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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