

Analysis Date: 24-09-2025

Re-test Date: 24-09-2028

SITAGLIPTIN EP IMPURITY B

Identification

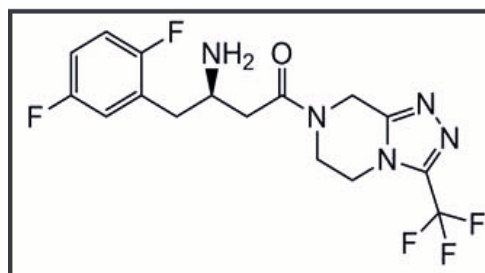
Chemical Name : R-3-amino-4-(2,5-difluorophenyl)-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4] triazolo [4,3-a] pyrazin-7 (8H)-yl)butan-1-one

CAT No : ALL-S03534

CAS No : 486460-31-5

Molecular Formula : C₁₆H₁₆F₅N₅O

Molecular Weight : 389.3



Analytical Information

Batch Code	: ALL-S03534	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.87%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.145%	¹H NMR	: Confirm
Residue Of Ignition	: 1.025%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.145+1.025) × 98.00]/100 = 95.87%

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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