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CERTIFICATE OF ANALYSIS

Analysis Date: Aug 2023

Re-test Date: Jul 2026

Product Name: 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

Synonyms : Sitagliptin 4-Desfluoro Impurity ;
2,5-Difluoro Sitagliptin

CAS Number : 486460-31-5

CAT Number : CP-S3018

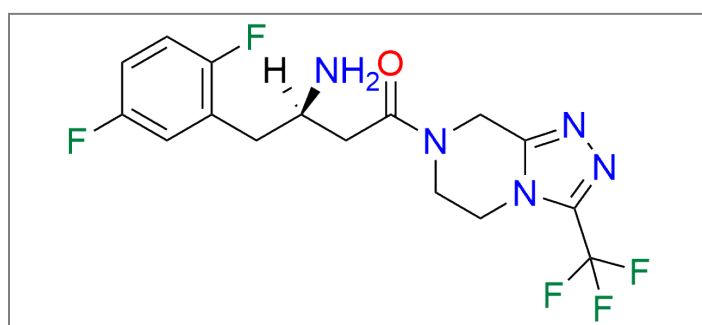
Molecular Formula : C₁₆H₁₆F₅N₅O

Molecular Weight : 389.33

Batch Number : CP-SIT-B-0823

Storage Condition : Tightly closed, Inert atmosphere at 2 to 8° C

Shipping condition : All Products are stable to be shipped at room temperature, if specific condition required it is mention in the COA



Analytical Information:

Sr. No.	Test	Result
1)	Description	White Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	99.34%
5)	H1NMR	Confirm to structure
6)	13CNMR	Confirm to structure
7)	Weight loss by TGA	0.06%
8)	Potency by TGA	99.28%



Prepared and Reviewed By

A handwritten signature in blue ink, appearing to read "Priyanka Salunkhe".

Ms Priyanka Salunkhe
(Manager QC Analytical)

Approved By

A handwritten signature in blue ink, appearing to read "Rohini Gagare".

Ms Rohini Gagare
(QA Head)

Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions.