

CERTIFICATE OF ANALYSIS

(Certificate No. KMS010017-01)

Release Date: 23/12/2024

Re-test Date: 22/12/2027

SITAGLIPITIN WS

Identification

Chemical Name :

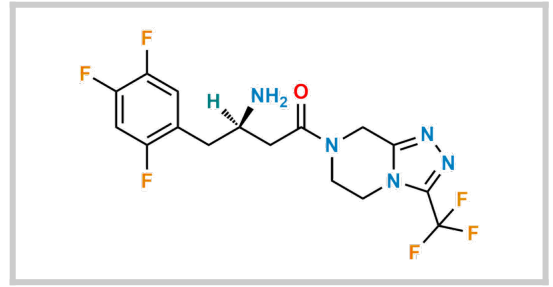
(R)-3-amino-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl)-4-(2,4,5-trifluorophenyl)butan-1-one

CAT No. : KMS010017

CAS No. : 486460-32-6

Molecular Formula : C₁₆H₁₅F₆N₅O

Molecular Weight : 407.3



Analytical Information

Batch No. : S010017-091-095

Description : Off White Solid

HPLC Purity : 100.00 %

Weight Loss By TGA : 0.02 %

% Potency : 99.98 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.02(Weight Loss By TGA)] x [100.00(HPLC Purity)]/100 = 99.98 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|-------------|-----------|------------|
| Prepared By | Analytical | Parag Patel | | 23/12/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 23/12/2024 |

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA