

CERTIFICATE OF ANALYSIS

(Certificate No. KMS010150-01)

Release Date: 17/02/2025

Re-test Date: 16/02/2028

Sitagliptin Ketoamide Impurity

Identification

Chemical Name :

(2Z)-4-Oxo-4-[3-(trifluoromethyl)-5,6-dihydro-[1,2,4] triazolo[4,3-a]pyrazine-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-one ;

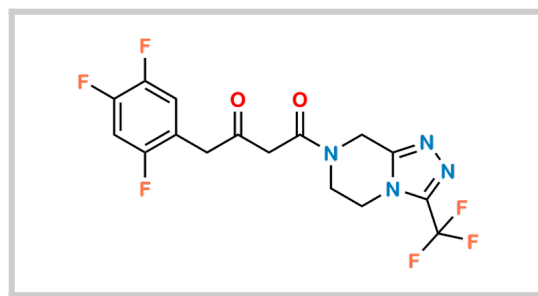
Alt. Name : Sitagliptin dioxo impurity

CAT No. : KMS010150

CAS No. : 764667-65-4

Molecular Formula : C₁₆H₁₂F₆N₄O₂

Molecular Weight : 406.3



Analytical Information

Batch No. : S010150-091-221

Description : Light Yellow Solid

HPLC Purity : 99.51 %

Weight Loss By TGA : 1.76 %

% Potency : 97.76 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C 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 - 1.76(Weight Loss By TGA)] x [99.51(HPLC Purity)]/100 = 97.76 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		18/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		18/02/2025

Attachments : COA, HPLC, MASS, ¹H NMR, ¹³C NMR, IR and TGA