# CERTIFICATE OF ANALYSIS

(Certificate No. KMS010150-02)

**Release Date:** 21/11/2025 **Re-test Date:** 20/11/2028

## 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 ;

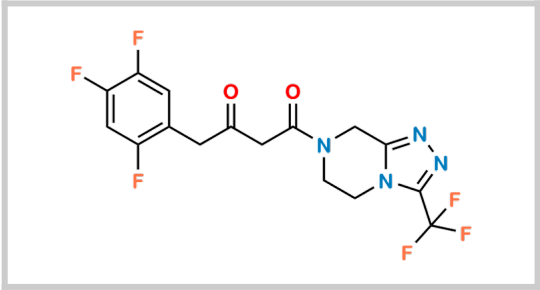
**Alt. Name** : Sitagliptin dioxo impurity

**CAT No.** : KMS010150

**CAS No.** : 764667-65-4

**Molecular Formula** : C16H12F6N4O2

**Molecular Weight** : 406.3



## Analytical Information

**Batch No.** : S010150-114-012

**Description** : Light Yellow Solid

**HPLC Purity** : 96.90 %

**Weight Loss By TGA** : 1.85 %

**% Potency** : 95.11 %

**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 - 1.85(Weight Loss By TGA)] x [96.90(HPLC Purity)]/100 = 95.11 %

**Recommendation** : Released

| | Department | Name | Signature | Date |
|---|---|---|---|---|
| **Prepared By** | Analytical | Jignesh Patel | | 21/11/2025 |
| **Reviewed & Approved By** | Quality Control | Jatin Patel | | 21/11/2025 |

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