

# 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 ;

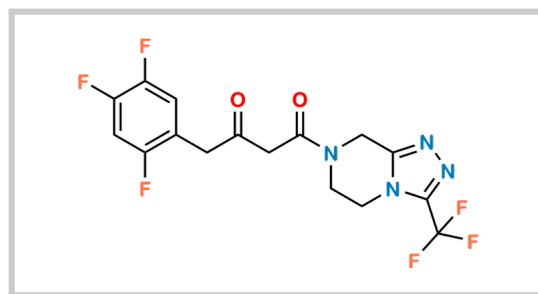
**Alt. Name** : Sitagliptin dioxo impurity

**CAT No.** : KMS010150

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

**Molecular Formula** : C<sub>16</sub>H<sub>12</sub>F<sub>6</sub>N<sub>4</sub>O<sub>2</sub>

**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

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA