

# CERTIFICATE OF ANALYSIS

(Certificate No. KMV013004-02)

Release Date: 10/09/2024

Re-test Date: 09/09/2027

## N-Nitroso Vildagliptin Methyl Ester Impurity

### Identification

**Chemical Name :**

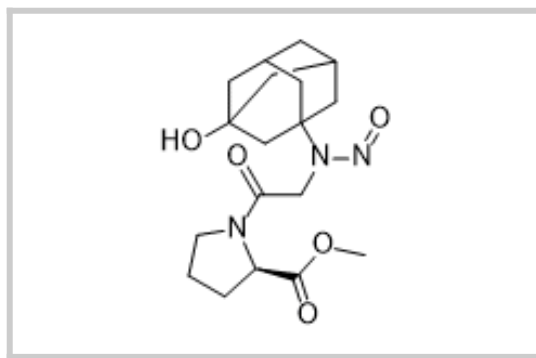
(2R)-methyl 1-(2-((3-hydroxyadamantan-1-yl)(nitroso)amino)acetyl)pyrrolidine-2-carboxylate

CAT No. : KMV013004

CAS No. : Not Available

Molecular Formula : C<sub>18</sub>H<sub>27</sub>N<sub>3</sub>O<sub>5</sub>

Molecular Weight : 365.42



### Analytical Information

Batch No. : V013004-073-372

Description : Brown Solid

HPLC Purity : 96.01 %

Weight Loss By TGA : 0.57 %

% Potency : 95.46 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

<sup>1</sup>H 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 - 0.57(Weight Loss By TGA)] x [96.01(HPLC Purity)]/100 = 95.46 %

Recommendation : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 10/09/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 10/09/2024 |

Attachments : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA