

CERTIFICATE OF ANALYSIS

(Certificate No. KMV013002-02)

Release Date: 17/02/2025

Re-test Date: 16/02/2028

N-Nitroso Vildagliptin Amide Impurity

Identification

Chemical Name :

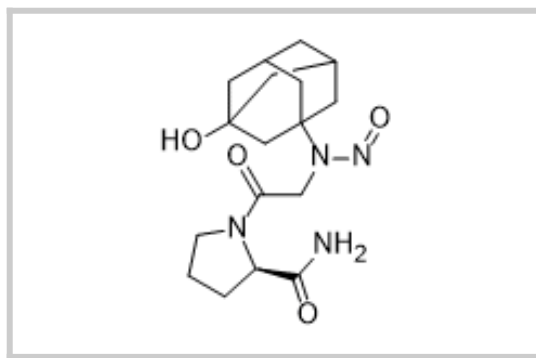
(2R)-1-(2-((3-hydroxyadamantan-1-yl)(nitroso)amino)acetyl) pyrrolidine-2-carboxamide

CAT No. : KMV013002

CAS No. : Not Available

Molecular Formula : C₁₇H₂₆N₄O₄

Molecular Weight : 350.41



Analytical Information

Batch No. : V013002-091-222

Description : Off White Solid

HPLC Purity : 99.69 %

Weight Loss By TGA : 1.87 %

% Potency : 97.83 %

Solubility : ACN : Water (1:1)

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 - 1.87(Weight Loss By TGA)] x [99.69(HPLC Purity)]/100 = 97.83 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		17/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		17/02/2025

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