

CERTIFICATE OF ANALYSIS

(Certificate No. KMV013020-02)

Release Date: 22/10/2024

Re-test Date: 21/10/2027

Vildagliptin Impurity B

Identification

Chemical Name :

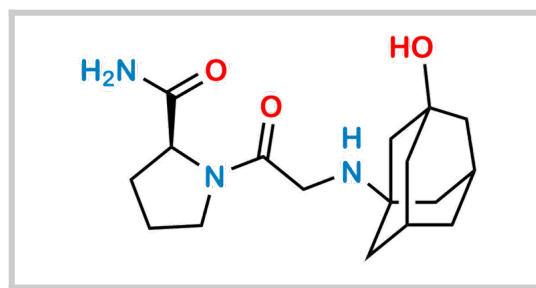
(2S)-1-[2-[(3-Hydroxytricyclo[3.3.1.1^{3,7}]dec-1-yl)amino]acetyl]-2-pyrrolidine carboxamide

CAT No. : KMV013020

CAS No. : 565453-39-6

Molecular Formula : C₁₇H₂₇N₃O₃

Molecular Weight : 321.4



Analytical Information

Batch No. : V013020-073-422

Description : Off White Hygroscopic Solid

HPLC Purity : 95.80 %

Weight Loss By TGA : 0.47 %

% Potency : 95.35 %

Solubility : Water

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 - 0.47(Weight Loss By TGA)] x [95.80(HPLC Purity)]/100 = 95.35 %

-¹³C NMR Analysis added on 27.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/02/2025

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