

Certificate of Analysis

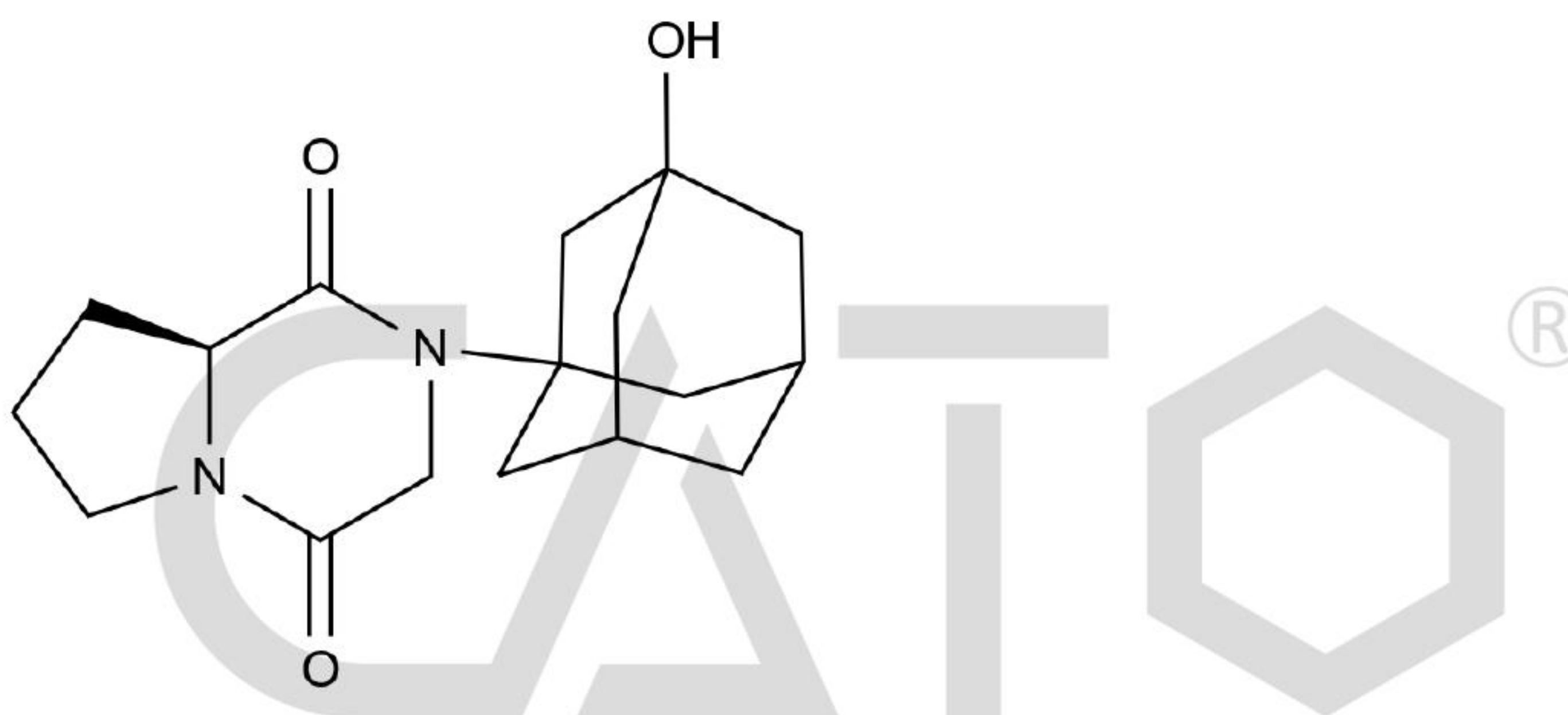
Reference Material & Standard

Product Name:	Vildagliptin Dione Impurity	Catalogue Number:	C1426343
Synonyms:	N/A	Lot Number:	1212-RG-0096
CAS Number:	1844894-70-7	Expiry Date:	May 16, 2028
Molecular Formula:	C ₁₇ H ₂₄ N ₂ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	304.38	Shipping Condition:	Shipping at Room Temperature

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	99.984%
Water Content	Karl Fischer	0.62%
Residual Solvents	NMR	0.31% methanol
Assay		99.1%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

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Approved by General Manager:

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Date: Dec 15, 2025

Date: Dec 16, 2025

Date: Dec 16, 2025



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