



大连汉德姆精细化学品有限公司

DALIAN HANDOM CHEMICALS CO.,LTD.

Certificate of Analysis

Product Name: Vildagliptin

CAS No.: 274901-16-5

Molecular Formula: C₁₇H₂₅N₃O₂

Molecular Weight: 303.4

Batch No.: HDC20230102

Manufacturing Date: Jan 2nd, 2023

Packing: 20Kg/Drum

Batch Quantity: 101.00kg

Report Date: Jan 3rd, 2023

Retest Date: Jan 1st, 2025

Test Item	Specification	Test Result	
Character	White to yellowish white or grayish white powder	Conforms	
Identification	It exhibits most strongest absorption at the wave numbers of about 3293cm ⁻¹ , 2915cm ⁻¹ , 2238cm ⁻¹ , 1659cm ⁻¹ , 1407cm ⁻¹ , 1355cm ⁻¹ and 1151cm ⁻¹	Conforms	
Purity	Heavy Metals	Not more than 10 ppm	Conforms
	Related Substances 1	L-Prolinamide: Not more than 0.10%	Not detected
		AHA: Not more than 0.10%	0.01%
	Related Substances 2	RRt about 0.6 impurity: Not more than 0.10%	0.03%
	Related Substances 3	Maximum impurity: Not more than 0.10%	0.02%
		Total impurities: Not more than 0.50%	0.03%
Enantiomer	RRt about 0.78 impurity: Not more than 0.10%	Not detected	
Water	Not more than 0.5%	0.04%	
Residue on Ignition	Not more than 0.1%	0.06%	
Assay	98.5% ~ 101.0%	100.5%	
Foreign Matter Test	Fatal foreign matter: 0	Conforms	
	Critical foreign matter: Not more than 2	Conforms	
	Minor foreign matter: Not more than 5	Conforms	
Residual Solvents 1	2-Butanone: Not more than 5000 ppm	340 ppm	
Residual Solvents 2	2-Propanol: Not more than 5000 ppm	Not detected	
	Dichloromethane: Not more than 600 ppm	Not detected	
	Triethylamine: Not more than 5000 ppm	Not detected	

Conclusion: The testing results of this batch are complied with the Enterprise Standard.