

Certificate Of Analysis

Product Name	Vildagliptin	Batch No.	2310161856
Sample Qty Base	1520.05 KGS	MFG. Date	2023.10.16
Report Date	2023.10.17	EXP. Date	2025.10.15
CAS NO	274901-16-5	Packing	25 KGS / Drum
Item	Standard		Test Results
Appearance	White or off-white crystalline powder		Complies
Solubility	Freely soluble in water, sparingly soluble in butanone, practically insoluble in MTBE		Complies
Identification	A.IR		Complies
	B.HPLC		Complies
Melting Point, °C	148 ~ 152		149.0 ~ 150.5
Specific Rotation, °	-100.0 ~ -104.0		-102.7
pH	9.0 ~ 11.0		9.8
Chloride, %	≤0.01		Complies
Sulfate, %	≤0.02		Complies
Loss on drying, %	≤0.5		0.06
Residue on Ignition, %	≤0.1		0.07
Total Impurities, %	MX20003, %	≤0.10	ND
	MX20005, %	≤0.10	ND
	MX20006, %	≤0.10	ND
	MX20002, %	≤0.10	0.011
	MX20004, %	≤0.10	ND
	MX20007, %	≤0.10	0.033
	MX200074, %	≤0.10	ND
	Any individual unspecified impurity, %	≤0.10	0.057
	Total impurities, %	≤0.50	0.10
Isomer, %	≤0.10		ND
3-Amino-1-Adamantanol, %	≤0.10		0.090
Residual solvent	Methanol, %	≤0.3	ND
	Isobutanol, %	≤0.5	ND
	Ethyl acetate, %	≤0.5	ND
	Isopropanol, %	≤0.5	ND
	Butanone, %	≤0.5	0.049

	MTBE,%	≤0.5	ND
	Acetonitrile,%	≤0.041	ND
	Toluene,%	≤0.089	ND
	Benzene,%	≤0.0002	ND
Heavy Metal,ppm	≤20		Complies
Purity,%	≥99.2		99.95
Storage	Preserve in a tightly closed container and protected from light		Complies
Conclusion	The batch conforms to the IN-HOUSE standard		

Reported By: 张丽川 Checked By: 程雪 QC Manager: 郭毅军 QA Manager: 牛建刚

