

Specification

Technical Data Sheet

CAS 274901-16-5	STORAGE 2 to 8 &deg;C	MOLECULAR WEIGHT 303.40
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PRODUCT**Vildagliptin**

Product number	34622851
CAS number	274901-16-5
Molecular formula	C17H25N3O2
Molecular weight	303.40 g/mol

PARAMETER	SPECIFICATION
Appearance	White crystalline powder
Assay (HPLC)	98.0% - 102.0%
Acetone	≤5000ppm
Acetonitrile	≤410ppm
Heavy metals	≤20ppm
Identification	Identical to HPLC retention of standard/ Identical to IR specyrum of standard
Impurity A	≤0.15%
Impurity B	≤0.15%
Impurity C	≤0.2%
Impurity D	≤0.15%
Melting Point	148.0°C - 152.0°C
Water	≤1.0%
3-amino-1-adamantanol	≤0.15%
Chloride (Cl-)	≤0.05%
Dimethylformamide	≤880ppm

PARAMETER	SPECIFICATION
Ethanol	≤5000ppm
Ethyl acetate	≤5000ppm
Individual impurity	≤0.1%
Methanol	≤3000ppm
Methyl ethyl ketone	≤5000ppm
R-isomer impurity	≤0.5%
Residue on Ignition	≤0.1%
Solubility	Easy to dissolve in methanol, ethanol, dimethyl sulfoxide, water or 0.01mol/L hydrochloric acid solution, slight soluble in acetonitrile or isopropanol
Toluene	≤890ppm
Total Impurities	≤1.0%
Butyl acetate	≤5000ppm
Impurity G	≤0.15%
Isopropyl Alcohol	≤5000ppm
Methylene chloride	≤600ppm
Sulphates (SO₄)(2-)	≤0.02%

SPECIFICATION STATEMENT	The values stated above represent the standard specification for this product, issued under Molekula Ltd 's quality management system. Batch-specific results are provided on the Certificate of Analysis.
STORAGE	Store as indicated on the product label, away from light, moisture and incompatible materials.

Molekula Ltd would like to thank you for your support of our products and service.
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