



## Certificate of analysis

Product name: Linagliptin

Cas number: 668270-12-0

Molecular Formula: C<sub>25</sub>H<sub>28</sub>N<sub>8</sub>O<sub>2</sub>

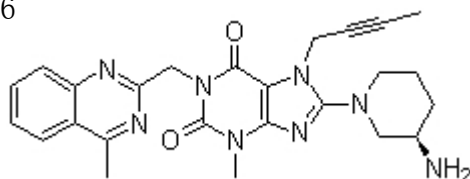
Molecular Weight: 472.54

Date of production: Apr. 22, 2014

Batch NO: 20140422

Exp Date: Apr. 21, 2016

Chemical structure:



Items		Specifications	Results
Appearance		A Off- White to cream coloured Powder	Conforms
Identification	NMR	The sample spectrum corresponds to that of the working standard	Conforms
	HPLC	The retention time of the major peak in the chromatogram of the sample corresponds to that exhibited by the working standard	
Loss on drying		≤0.5%	0.26%
Water		≤1.0%	0.45%
Heavy metals		≤ 20PPM	Conforms
Related substances	Total impurities ≤ 1.0%		0.60%
	Single impurity ≤ 0.5%		0.46%
Assay by HPLC		98%-102% ( on dried basis)	99.4%
Residual solvents		Methanol ≤3000ppm	102ppm
		Methylene chloride ≤ 600ppm	N.D
		MTBE ≤ 5000ppm	N.D
		Acetic acid ≤ 5000ppm	N.D
		Dimethyl formamide ≤880ppm	N.D
		Isopropyl alcohol ≤5000ppm	694ppm
		Methyl Isobutyl Ketone ≤5000ppm	573ppm
		Dimethyl sulphoxide ≤5000ppm	197ppm
Particle size		≤20 μ m	Conforms

**Conclusion: It complies with the Enterprise Standard.**

Analyst: Zhao

Checker: Liu

Q.C Director. Fang