

济南健丰化工有限公司
JINAN JIANFENG CHEMICAL CO.LTD.

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CERTIFICATE OF ANALYSIS

Product name: Sitagliptin Phosphate		
Batch No. : 20111202		
Report Date: 2011.12.15		
Perform standard: 2010 of Enterprise Standard		
Item of analysis	Standard	Result of analysis
Appearance	White or almost White powder	White powder
Solubility	Easy to dissolve in the water	Complies
Identification	High -performance liquid chromatograph	Almost the same
	HPLC	
	Infrared absorption	Almost the same
Melting point	203.0-205.0℃	204.0~205.0℃
Chiral impurity:	≤1.0%	0.4%
Related Impurities:	Total Impurities ≤1.0%	0.63%
Water	≤1.0%	0.6%
Heavy metals	≤20ppm	<20ppm
Residue on ignition	≤0.1%	0.01 %
Specific Rotation	Between -18.0° and -23.0°	-21.05°
HPLC Assay	98.0% ~ 102.0%	99.5%
Conclusion: Conforming to Enterprise Standard 2010		
Exam	Analyst	Checker