

安庆沃德化工有限公司

ANQING WORLD CHEMICAL COMPANY LIMITED

检验报告单

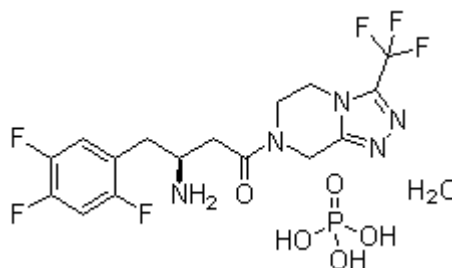
CERTIFICATE OF ANALYSIS

Product: Sitagliptin phosphate monohydrate

品名: 磷酸西他列汀一水合物

CAS: 654671-77-9

Molecular Structure:



Batch No. 批号	20130325	Manu. Date 生产日期	2013-03-25
Quantity 批量	150.0kg	Rep. Date 报告日期	2013-03-27
Source 来源	Workshop 车间	Expiry Date 有效期	24 months
QCS 检验标准	2010 of Enterprise Standard 企业标准 2010 版		

TETS 检验	STANDARD 标准	RESULTS 结果
Appearance	White or almost white powder	white powder
Solubility	Easy to dissolve in the water	Complies
Identification	High-performance liquid chromatograph HPLC	Almost the same
	Infrared absorption	Almost the same
Water	≤3.0-5.0%	3.8%
Sulphate	≤0.02%	<0.02%
Chloride	≤0.05%	<0.05%
Phosphate	18.0%~20%	18.9%
Heavy metals	≤20ppm	<10ppm
Residue on ignition	≤0.1%	0.01%
Chiral impurity	No more than 0.1%	0.01%
Specific rotation	-18.0° ~ -23.0° (C=1, water)	-21.15°
	Isopropanol ≤5000ppm	89ppm
	Methanol ≤3000ppm	23ppm

Residual solvents	Toluene \leq 890ppm	2ppm
	DMF \leq 880ppm	5ppm
	Acetonitrile \leq 410ppm	0ppm
Related impurity	Any individual impurity \leq 0.5%	0.02%
	Total impurity no more than 1.0%	0.1%
HPLC assay	98.0% ~ 102.0%	99.7%
Conclusion: Complies With Enterprise Standard 2010 符合企业标准 2010 版		

ANALYST: Chen.MH

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