

安 庆 沃 德 化 工 有 限 公 司

ANQING WORLD CHEMICAL COMPANY LIMITED

检 验 报 告 单

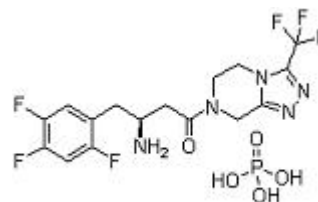
CERTIFICATE OF ANALYSIS

Product: Sitagliptin phosphate

品名: 磷酸西他列汀

CAS: 654671-78-0

Molecular Structure:



Batch No. 批号	20161101	Manu. Date 生产日期	2016-11-01
Quantity 批量	250.0kg	Rep. Date 报告日期	2016-11-03
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
Melting metals:	202.0~204.0℃	203.0-203.1℃
Specific rotation	-18.0° ~ -23.0° (C=1,water)	-21.2°
Heavy metals	≤20ppm	<20ppm
Residue on ignition	≤0.1%	0.02%
Water	≤1.0%	0.7%
Bulk Density	0.3-0.5g/ml	0.33g/ml
Chiral impurity	No more than 1.0%	0.03%
Residual solvents	Ethyl acetate < 5,000 ppm	60ppm
Related impurity	Any individual impurity ≤0.5%	0.07%
	Total impurity no more than 1.0%	0.09%
HPLC assay	98.0%~102.0%	99.8%
Conclusion: Complies With Enterprise Standard 2010 符合企业标准 2010 版		

ANALYST: Wu

CHECKER: Yao.WD

Q.C.SUPERVISOR: Yao.WD