

# 安庆沃德化工有限公司



ANQING WORLD CHEMICAL COMPANY LIMITED

## 检验报告单

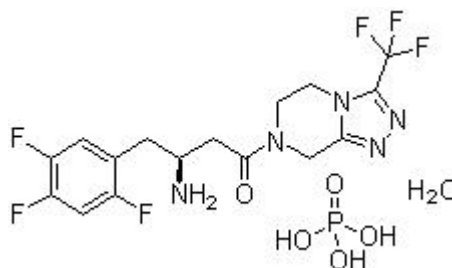
CERTIFICATE OF ANALYSIS

**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	20170208	Manu. Date 生产日期	2017-02-08
Quantity 批量	300.0kg	Rep. Date 报告日期	2017-02-10
Source 来源	Workshop 车间	Expiry Date 有效期	2018-01-07
QCS 检验标准	2015 of Enterprise Standard 企业标准 2015 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%	3.4%
Sulphate	≤0.02%	<0.01%
Chloride	≤0.05%	<0.02%
Phosphate	18.0%~20%	18.2%
Heavy metals	≤20ppm	<10ppm
Residue on ignition	≤0.1%	0.02%
Chiral impurity	No more than 1.0%	0.01%
Specific rotation	-18.0° ~ -23.0° (C=1, water)	-21.1°
	Isopropanol ≤5000ppm	51ppm
	Methanol ≤3000ppm	51ppm

Residual solvents	Toluene $\leq$ 890ppm	31ppm
	DMF $\leq$ 880ppm	32ppm
	Acetonitrile $\leq$ 410ppm	0ppm
Related impurity	Any individual impurity $\leq$ 0.5%	0.08%
	Total impurity no more than 1.0%	0.13%
HPLC assay	98.0% ~ 102.0%	99.8%
Conclusion: Complies With Enterprise Standard 2015 符合企业标准 2015 版		

ANALYST:WJ

CHECKER:WYH

Q.C.SUPERVISOR:YWD