

# 安庆沃德化工有限公司

ANQING WORLD CHEMICAL COMPANY LIMITED

## 检验报告单

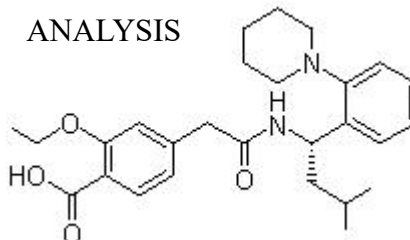
CERTIFICATE OF ANALYSIS

**Product:** Repaglinide

品名: 瑞格列奈

**CAS:** 135062-02-1

**Molecular Structure:**



Batch No. 批号	20170618	Manu. Date 生产日期	2017-06-18
Quantity 批量	20kg	Rep. Date 报告日期	2017-06-19
Source 来源	Workshop 车间	Expiry Date 有效期	24 months
QCS 检验标准	EP 5.2 欧洲药典 5.2		

TETS	STANDARD	RESULTS
Appearance	White or almost white powder	almost white powder
Solubility	Practically insoluble in water, freely soluble in methanol and in methylene chloride.	Complies
Identification by	IR spectrum of sample should be concordant with that of working standard	Complies
	Specific rotation :+6.3° 至+7.3°	+6.7°
Enantiomeric purity	Impurity E ≤0.2%	Undetected
Related substances	Impurity A ≤0.1%	Undetected
	Impurity B ≤0.1%	Undetected
	Impurity C ≤0.1%	Undetected
	Impurity D ≤0.1%	Undetected
	Max individual unknown impurity ≤0.1%	<0.03%
	Total impurity ≤0.5%	<0.03%
Loss of drying	≤0.5%	0.02%
Supplanted ash	≤0.1%	0.03%
HPLC assay	99.0%—101.0%	100.8%
Residual solvents	Methanol ≤3000ppm	41.7 ppm
	Ethanol ≤5000ppm	598.0 ppm
	dichloromethane ≤600ppm	1.0ppm
	toluene ≤890ppm	5.0 ppm
Conclusion: Complies With EP5.2 符合欧洲药典 5.2		

ANALYST:FC

CHECKER:WJ

Q.C.SUPERVISOR:WFF