

武义家园医药原料有限公司

Wuyi Jiayuan Pharmaceutical Materials CO.,Ltd

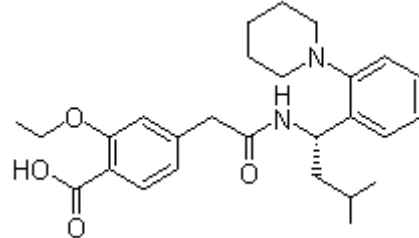
检验报告单

Certificate of Analysis

Product: Repaglinide

品名: 瑞格列奈

CAS: 135062-02-1 **Molecular Structure:**



Batch No. 批号	20110302	Manu. Date 生产日期	2011-03-02
Quantity 批量	20kg	Rep. Date 报告日期	2010-03-03
Bource 来源	Workshop 车间	Expiry Date 有效期	24 months
QCS 检验标准	2010 of 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°	+6.5°
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%	<0.05%
	Total impurity ≤0.5%	<0.05%
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	21.6 ppm
	Ethanol ≤5000ppm	390.1 ppm
	dichloromethane ≤600ppm	1.5 ppm
	toluene ≤890ppm	0.3 ppm
Package: Closed packing with moisture-proof plastic bag inside, packing with Aluminum Drum outside. (3kg-25Kg), moisture-proof plastic bag inside, packing with aluminum foil bag outside. (<3kg)		
Conclusion: Complies With EP5.2 符合欧洲药典 5.2		

ANAL.YIST:Chen.MH

CHECKER:Zhu.JD

Q.C.SUPEDRVISOR:Zhen.FZ

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