

# 检 验 报 告 单

## CERTIFICATE OF ANALYSIS

Product name 产品名称	VALSARTAN 缬沙坦		
批号 Batch No.	20100401	生产日期 Manufacture date	2010.04.04
数量 Quantity	100g	检验日期 Report date	2010.04.05
包装 Packing	100g	保质期 Re-test date	2013.04.03
质量标准 Basis of Quality Standard	USP31		

Item 项目	Specification 检测标准	Analytical Results 结果
Appearance 外观	White to off white crystalline powder	complies
Solubility 溶解度	Very soluble in methanol and ethanol, sparingly soluble in chloroform practically insoluble in water.	complies
Identification 鉴别 IR HPLC	Similar to standard Similar to standard	complies complies
Absorbance 吸收	NMT0.02 at 420nm(1/20 in methanol)	complies
Water 水份	NMT2.00%	0.89%
Residue on Ignition 炽灼残渣	NMT0.1%	0.05%
Heavy metals 重金属	NMT 0.001%	complies
Related compounds Compound A Compound B Compound C Any other individual impurity Total impurities	NMT1.0% NMT0.2% NMT0.1% NMT0.1% NMT0.3%	0.10% 0.03% N.D 0.07% 0.25%
Assay (HPLC) 含量	NLT98.0% and NMT 102.0% Calculated on the anhydrous basis	99.5%

Residual solvents by GC		
Hexanes	NMT 290ppm	126ppm
Ethylacetate	NMT 5000ppm	1890ppm
Melhylenchloride	NMT 600ppm	59ppm
Xylene(mixture)	NMT 2170ppm	159ppm
Conclusion: <b>It complies with all the requirements of USP 31</b>		

检验员：侯星文  
Analyst:Hou Xingwen

复核员：陈为选  
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