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CERTIFICATE OF ANALYSIS

产品名称 Product name	培美曲塞二钠 Pemetrexed Disodium	CAS No.	357166-30-4
批号 Batch No.	20120206	有效期 Expiry date	2014.02
报告日期 Report Date	2012.02.12	数量 Quantity	10.6kg

Tests 项目	Specifications 标准	Results 结果
Description 性状	white or almost white powder 白色或类白色粉末	almost white powder 类白色粉末
Clarification&color of solution 溶液颜色和澄清度	The color should not thicker than second standard yellow solution. 溶液澄清, 颜色不得深于黄色二号标准比色液	Complies 符合规定
Identification 鉴别	A: Specific rotation: +10.0° ~+16.0° 比旋度: +10.0° ~+16.0°	+11.4°
	B: By HPLC, The retention time should match with working standard HPLC 图谱主峰保留时间应与对照品一致	Complies 符合规定
	C:Chemical method: should be positive reaction 应为正反应	Complies 符合规定
PH	7.0~8.5	7.52
Heavy metal 重金属	≤20ppm	<20ppm
Chloride 氯化物	≤ 0.02%	Complies 符合规定
Moisture 水分	8.5%~10%	9.52%
Related Substances 有关物质	Each impurity ≤0.1% 任一杂质不得过 0.1%	0.08%
	Total impurity ≤1.0% 总杂质不得过 1.0%	0.29%
Optical isomer 异构体	≤0.5% 不得过 10ppm	Not detected 未检出
Sulfated ash 硫酸灰分	≤0.1%	0.04%
residual solvents 有机残留	Ethanol 乙醇≤0.5%	0.07%
	Dichloromethane 二氯甲烷≤0.06%	Not detected 未检出
	Methanol 甲醇≤0.3%	Not detected 未检出
	THF≤0.072%	Not detected 未检出
	Acetone 丙酮≤0.5%	Not detected 未检出
N,N-DMF≤0.088%	Not detected 未检出	
Assay 含量	≥98.5% (on the anhydrous basis 以干品计)	99.26%
Conclusion 结论: Conforms to enterprise standard 符合企业内部标准		

Analyst: wuhao

Checker: shilijuan

Supervisor :maohongjun

