



CERTIFICATE OF ANALYSIS

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Product	Spironolactone	Manufacturing date	2011.10.08
Batch No.	ULN 111001	Report date	2011.11.14
Test criteria	Current EP	Retest date	2013.10.08
	Specifications		Result
Appearance	A white or yellowish-white powder		White powder
Identification	A(IR)		Positive
Specific optical rotation	-41° ~ -46° (on the dried substance)		-44°
Related substances	Total impurities ≤ 0.7%		0.14%
	Impurity A ≤ 0.1%		<0.05%
	Impurity C ≤ 0.1%		<0.05%
	Impurity D ≤ 0.1%		<0.05%
	Impurity E ≤ 0.1%		<0.05%
	Impurity F ≤ 0.3%		<0.05%
	Impurity I ≤ 0.1%		0.06%
	Each unspecified impurity ≤ 0.10%		Max: 0.08%
Free thiol compounds	A blue colour develops.		Conforms
Chromium	≤ 50 ppm		Conforms
Loss on drying	≤ 0.5%		0.20%
Sulfated ash	≤ 0.1%		Conforms
Assay*	97.5% ~ 102.0% (Calculated on the dried basis)		100.0%
Residual solvents	Ethyl acetate ≤ 5000 ppm		11ppm
	Methanol ≤ 3000 ppm		21ppm
	Thioacetic acid ≤ 100 ppm		25ppm
Batch size	211 kg		
Quantity	5 kg		
Conclusion	The above product conforms to current EP		

*Storage conditions: Kept in an airtight container and protected from light.

*Calculated on the dried basis

Checked by:

36
2012.4.5

Approved by:

贾晓洋 2012.4.5

