



天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

lot: 0111214

## CERTIFICATE OF ANALYSIS

Page: 1 / 1

Product	Spironolactone	Manufacturing date	2014.02.11
Batch No.	ELN 140201	Report date	2014.02.24
Test criteria	Current EP	Retest date	2016.02.11
	Specifications		Result
Appearance	A white or yellowish-white powder		White powder
Identification	A(IR)		Positive
Specific optical rotation	-41° ~ -46° (on the dried substance)		-41°
Related substances	Total impurities ≤ 0.7%		0.05%
	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%		<0.05%
	Each unspecified impurity ≤ 0.10%		Max: 0.05%
Free thiol compounds	A blue colour develops.		Conforms
Chromium	≤ 50 ppm		Conforms
Loss on drying	≤ 0.5%		0.26%
Sulfated ash	≤ 0.1%		Conforms
Assay*	97.5% ~ 102.0% (Calculated on the dried basis)		99.5%
Residual solvents	Ethyl acetate ≤ 5000 ppm		ND
	Methanol ≤ 3000 ppm		48ppm
	Thioacetic acid ≤ 100 ppm		54ppm
Batch size	212 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: 3457 2014.12.4

Approved by: 贾锐萍 2014.12.4



天津市经济技术开发区西区新业九街19号

邮编: 300462

No. 19, XINYE 9th Street, West Area of Tianjin Economic-Technological Development Area, Tianjin, 300462, China

电话 (Telephone): 86 22 66321554

传真 (FAX): 86 22 66321556