

天津天药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.



Lote: 0100412

Page: 1/1

	The state of the s	TO THE SECOND CO.	1 age: 17 1
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.

Checked by:

2012.4.5

Approved by: 東熱 達 2012.4.5



天津市经济技术开发区西区新业九街19号 No. 19, XINYE 9th Street, West Area of Tianjin Economic-Technological Development Area, Tianjin, 300462, China King York 电话 (Telephone): 86 22 66321554 传真 (FAX): 86 22 66321556

^{*}Calculated on the dried basis