

天津市津津药业有限公司检验报告单

TIANJIN JINJIN PHARMACEUTICAL CO., LTD. CERTIFICATE OF ANALYSIS

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化驗專用章

Report No.:	2017-035	Analytical No.:	2017-4-14 Page 1 of 1
Product Name:	Spironolactone		
Batch No.:	SA0599	Manuf. Date:	2017.4.2
Quantity:	5Kg	Retest Date:	2021.4.1
Package:	drum or carton	Report Date:	2017.4.26

Items	Requirements	Results
Appearance	a white or yellowish-white powder	White powder
Solubility(annual)	practically insoluble in water, soluble in ethanol(96percent)	Complies
Identification		
A. IR -spectrum	meets the requirement	Complies
B. TLC	meets the requirement	Complies
C. Colour Reaction	meets the requirement	Complies
Specific optical rotation	between -41° and -46°	-43.4
Related substances		
Impurity A	not more than 0.2%	ND
Impurity F	not more than 0.3%	ND
Impurity C	not more than 0.2%	ND
Impurity D	not more than 0.15%	ND
Impurity E	not more than 0.3%	ND
Impurity I	not more than 0.5%	0.05%
Any unspecified impurity	not more than 0.10%	<0.10%
Total	not more than 0.7%	0.13%
Free thiol compounds	not more than 0.05ml	Complies
Chromium	not more than 50ppm	Complies
Loss on drying	not more than 0.5 %	0.02%
Sulphated ash	not more than 0.1 %	0.00%
Assay	between 97.5 % and 102.0 %	99.6%
Residual solvent(In-house)		
Methanol	not more than 3000ppm	Less than LOD(0.6ppm)
Particle size(In-house)	95% not more than 20 microns	Complies

CONCLUSION : THE PRODUCT CONFORMS TO Ph.Eur.9(R0-CEP 2012-185-Rev 00)

Responsible Person :

Checker:

Date:

Date:

2017.5.27

2017.5.27