

lot: 0050419

天津市津津药业有限公司检验报告单

TIANJIN JINJIN PHARMACEUTICAL CO., LTD. CERTIFICATE OF ANALYSIS


No.8,Jingfu Road, Industrial Zone of Zhangjiawo Town, Xiqing district, Tianjin ,China


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Report No.:	2018-145	Analytical No.:	2018-10-18	Page 1 of 1
Product Name:	Spironolactone	Manufacture Date:	2018.10.17	
Batch No.:	SA0880	Retest Date:	2022.10.16	
Quantity:	10Kg	Report Date:	2018.10.31	
Package:	drum or carton			

Items	Requirements	Results
Appearance(Ph.Eur.)	a white or yellowish-white powder	White powder
Solubility(Ph.Eur.)(annual)	practically insoluble in water,soluble in ethanol(96 per cent)	Complies
Identification		
A.IR -spectrum(Ph.Eur.)	meets the requirement	Complies
A.IR -spectrum(USP)	meets the requirement	Complies
B.TLC(Ph.Eur.)	meets the requirement	Complies
B. UV Absorption(USP)	meets the requirement	Complies
C. Colour Reaction(Ph.Eur.)	meets the requirement	Complies
C.Precipitate reaction(USP)	meets the requirement	Complies
Specific optical rotation		
(Ph.Eur.)	between -41° and -46°	-43.5°
(USP.)	between -41° and -45°	-43.8°
Loss on drying		
(Ph.Eur.)	not more than 0.5%	0.05%
(USP)	not more than 0.5%	0.02%
Sulphated ash(Ph.Eur.)	not more than 0.1 %	0.01%
Related substances(Ph.Eur.)		
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%	0.05%
Impurity E	not more than 0.3%	ND
Impurity I	not more than 0.5%	ND
Any unspecified impurity	not more than 0.10%	ND
Total	not more than 0.7%	0.05%
Ordinary impurities(USP)	not more than 2.0%	Complies
Free thiol compounds(Ph.Eur.)	not more than 0.05ml	Complies
Free mercapto compounds(USP)	not more than 0.10ml	Complies
Chromium(Ph.Eur.)	not more than 50ppm	Complies
Assay		
HPLC (Ph.Eur.)	between 97.5% and 102.0 %	100.6%
HPLC(USP)	between 97.0 % and 103.0 %	99.5%
Residual solvent(In-house)		
Methanol	not more than 3000ppm	8ppm
Tetrahydrofuran	not more than 720ppm	Less than LOD(0.4ppm)
DMF	not more than 880ppm	Less than LOD(43ppm)
Particle size(In-house)	95% not more than 20 microns	Complies

CONCLUSION : THE PRODUCT CONFORMS TO Ph.Eur.9/USP 40

Responsible Person : 
Date: 2019.3.19

Checker: 
Date: 2019.3.19