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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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Analytical No. 15

化检专用章

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Report No.:	2020-031	2020-03-04
Product Name:	Spironolactone	
Batch No.:	SA1101	2020.2.16
Quantity:	25Kg	2024.2.15
Package:	drum or carton	2020.3.12

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 -46° and -41°	-43.5°
(USP)	between -41° and -45°	-42.9°
Loss on drying		
(Ph.Eur.)	not more than 0.5%	0.05%
(USP)	not more than 0.5%	0.09%
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%	ND
Impurity E	not more than 0.3%	ND
Impurity I	not more than 0.5%	ND
Any unspecified impurity	not more than 0.10%	Complies
Total	not more than 0.7%	0.06%
Ordinary impurities(USP)	not more than 2.0%	Complies
Free thiol compounds(Ph.Eur.)	a blue colour develops	Complies
Free mercapto compounds(USP)	not more than 0.10ml	Complies
Assay		
HPLC (Ph.Eur.)	between 97.5 % and 102.0 %	100.3%
HPLC (USP)	between 97.0 % and 103.0 %	99.4%
Residual solvent(In-house)		
Methanol	not more than 3000ppm	10ppm
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.9.8/USP 40

Responsible Person: 张银杰

Checker: 张银杰

Date: 2020.3.13

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