

METAPHARMACEUTICAL

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15/07/2024

TIANJIN JINJIN PHARMACEUTICAL CO., LTD. CERTIFICATE OF ANALYSIS

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Report No.:	2024-112	2024-05-11	Page 1 of 1
Product Name:	Spironolactone		
Batch No.:	SA2117	Manufacture Date:	2024.04.15
Quantity:	25Kg	Retest Date:	2028.04.14
Package:	drum or carton	Report Date:	2024.05.20

Items	Requirements	Results
Appearance	white or yellowish-white powder	White powder
Solubility(annual)	practically insoluble in water, soluble in ethanol (96 percent)	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	-46° to -41°	-43.5°
Related substances		
Impurity A	not more than 0.2%	BDL
Impurity F	not more than 0.3%	ND
Impurity C	not more than 0.2%	ND
Impurity D	not more than 0.15%	BDL
Impurity E	not more than 0.3%	ND
Impurity I	not more than 0.5%	BDL
unspecified impurities	not more than 0.10%	Complies
Total	not more than 0.7%	0.07%
Free thiol compounds	a blue colour develops	Complies
Loss on drying	maximum 0.5%	0.09%
Sulfated ash	maximum 0.1%	0.00%
Assay	97.5% to 102.0%	99.8%
Residual solvent (In-house)		
Methanol	not more than 3000ppm	9ppm
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.11

Responsible Person :

Checker:

Date:

Date:

2024.06.12

2024.06.12

SRC09-770-03