



津药药业股份有限公司

TIANJIN TIANYAO PHARMACEUTICALS CO., LTD.

CERTIFICATE OF ANALYSIS



Rev.07 (250417)

Product	Spironolactone		Manufacturing date	2025.04.07
Batch No.	LN250601		Report date	2025.06.03
Test criteria	EP11/USP2025		Retest date	2029.04.07
Tests	Specifications (EP11)	Results	Specifications(USP2025)	Results
Appearance	White or yellowish-white powder	White powder	Light cream-colored to light tan, crystalline powder	Light cream-colored crystalline powder
Identification	A: IR	Conforms	A: IR B: HPLC	Conforms
Specific optical rotation*	-46~ -41	-43	-41° ~ -45°	-43°
Related substances	Total impurities ≤ 0.7%	<0.05%	Spironolactone related compound B ≤ 0.2%	<0.05%
	Impurity A ≤ 0.2%	<0.05%	Spironolactone related compound A ≤ 0.2%	<0.05%
	Impurity C ≤ 0.2%	<0.05%	Spironolactone related compound C ≤ 0.2%	<0.05%
	Impurity D ≤ 0.15%	<0.05%	Spironolactone related compound D ≤ 0.3%	<0.05%
	Impurity E ≤ 0.3%	<0.05%	Spironolactone related compound D ≤ 0.3%	<0.05%
	Impurity F ≤ 0.3%	<0.05%	Spironolactone epimers ≤ 0.3%	<0.05%
	Impurity I ≤ 0.5%	<0.05%	Spironolactone related compound I ≤ 0.1%	<0.05%
	Each unspecified impurity ≤ 0.10%	<0.05%	Any unspecified impurities ≤ 0.10% Total impurities ≤ 1.0%	<0.05%
Free mercapto compounds	A blue colour develops.	Conforms	-----	-----
Limit of mercapto compounds	-----	-----	Not more than 0.10mL of 0.010N iodine is consumed	Conforms
Loss on drying	≤ 0.5%	0.13%	≤ 0.5%	0.13%
Sulphated ash	≤ 0.1%	Conforms	-----	-----
Assay*	97.5% ~ 102.0%	100.8%	97.0% ~ 103.0%	100.2%
Residual solvents	Ethyl acetate ≤ 5000 ppm	ND	Ethyl acetate ≤ 5000 ppm	ND
	Methanol ≤ 3000 ppm	2ppm	Methanol ≤ 3000 ppm	2ppm
	Thioacetic acid ≤ 1200 ppm	23ppm	Thioacetic acid ≤ 1200 ppm	23ppm
Particle size	99% < 30 μm By microscope	Conforms	99% < 30 μm By microscope	Conforms
Batch size	320kg			
Conclusion	The above product conforms to EP11 and USP2025.			

*Calculated on the dried basis

Checked by: Zhang Jinling 张

Approved by: Jia Yuping 贾

June 3, 2025

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