



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	2025.04.16
Batch No.	LN250703		Report date	2025.07.15
Test criteria	EP11/USP2025		Retest date	2029.04.16
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°	-44°
Related substances	Total impurities $\leq 0.7\%$	<0.05%	Spironolactone related compound B $\leq 0.2\%$	<0.05%
	Impurity A $\leq 0.2\%$	<0.05%	Spironolactone related compound A $\leq 0.2\%$	<0.05%
	Impurity C $\leq 0.2\%$	<0.05%	Spironolactone related compound C $\leq 0.2\%$	<0.05%
	Impurity D $\leq 0.15\%$	<0.05%	Spironolactone related compound D $\leq 0.3\%$	<0.05%
	Impurity E $\leq 0.3\%$	<0.05%	Spironolactone epimers $\leq 0.3\%$	<0.05%
	Impurity F $\leq 0.3\%$	<0.05%	Spironolactone related compound I $\leq 0.1\%$	<0.05%
	Impurity I $\leq 0.5\%$	<0.05%	Any unspecified impurity $\leq 0.10\%$	<0.05%
	Each unspecified impurity $\leq 0.10\%$	<0.05%	Total impurities $\leq 1.0\%$	<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	$\leq 0.5\%$	0.13%	$\leq 0.5\%$	0.13%
Sulphated ash	$\leq 0.1\%$	Conforms	-----	-----
Assay*	97.5% ~ 102.0%	100.7%	97.0% ~ 103.0%	100.3%
Residual solvents	Ethyl acetate ≤ 5000 ppm	ND	Ethyl acetate ≤ 5000 ppm	ND
	Methanol ≤ 3000 ppm	11ppm	Methanol ≤ 3000 ppm	11ppm
Particle size	Thioacetic acid ≤ 1200 ppm	14ppm	Thioacetic acid ≤ 1200 ppm	14ppm
	99% < 30 μ m	Conforms	99% < 30 μ m	Conforms
Batch size	320kg			
Conclusion	The above product conforms to EP11 and USP2025.			

*Calculated on the dried basis

Checked by: Zhang Jinling 张金玲

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November 20, 2025

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