

## ESPIRONOLACTONA (EUR. PH.)

PRODUCT CODE: 0614	CAS Nº: 52-01-7	ANALYSIS Nº: 269/22
MANUFACTURER BATCH: SA1630	CERTIFICATE ID: 36.724	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 29/08/2022	
METAPH BATCH: 0081222	RETEST DATE: 28/08/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white powder	White powder
Solubility	Practically insoluble in water, soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Specific optical rotation	-41 / -46	-44
Related substances		
Impurity I	=< 0.5 %	Not Detected
Impurity E	=< 0.3 %	Not Detected
Impurity F	=< 0.3 %	Not Detected
Impurity A	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	Not Detected
Impurity D	=< 0.15 %	0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.7 %	0.05 %
Free thiol compounds	Complies	Complies
Loss on drying	=< 0.5 %	0.06 %
Sulfated ash	=< 0.1 %	< 0.01 %
Assay	97.5 - 102.0 %	100.2 %
Residual solvents		(*) (**)
Methanol	=< 3000 ppm	7 ppm
Tetrahydrofuran	=< 720 ppm	< 0.40 ppm (LoD)
Dimethylformamide	=< 880 ppm	< 43 ppm (LoD)
Particle size	< 20 µm (95 %)	Complies (*)

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

It shows polymorphism (5.9).

Spironolactone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(\*) Data adapted from the manufacturer's certificate of analysis.

(\*\*) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Analysis date: 08/02/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000452

TIANJIN JINJIN PHARMACEUTICAL Co., Ltd.

ZHANGJIAWO TOWN

XIQING DISTRICT

200100 TIANJIN





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METAPH BATCH:	0081222	RETEST DATE:	28/08/2026

### STORAGE

Keep the container tightly closed and protected from light.

Analysis date: 08/02/2023  
Signature: Ferran Gonzalez de Rivera Rier  
Conclusion: Complies  
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