METAPHARMACEUTICAL IND SL
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ESPIRONOLACTONA (EUR. PH.)

PRODUCT CODE: 0614	CAS Nº: 52-01-7	ANALYSIS Nº: 187/24	
MANUFACTURER BATCH:	SA2117	CERTIFICATE ID:	42.968
SUPPLIER BATCH:	----	MANUFACTURING DATE:	15/04/2024
METAPH BATCH:	0100724	RETEST DATE:	14/04/2028

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 %	< 0.05 %
Impurity E	=< 0.3 %	< 0.05 %
Impurity F	=< 0.3 %	< 0.05 %
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 %	0.1 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	97.5 - 102.0 %	99.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

It shows polymorphism.

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Spironolactone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

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.

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.

STORAGE

Keep the container tightly closed and protected from light.

Analysis date: 29/08/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000452
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