

CIPROTERONA ACETATO (EUR. PH.)

PRODUCT CODE: 0399	CAS Nº: 427-51-0	ANALYSIS Nº: 229/23
MANUFACTURER BATCH: 2113AM1 B0012135.	CERTIFICATE ID: 39.441	
SUPPLIER BATCH: 22322001	MANUFACTURING DATE: 10/12/2021	
METAPH BATCH: 0120923	EXPIRY DATE: 10/12/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Solubility	Practically insoluble in water, very soluble in methylene chloride, freely soluble in acetone, soluble in methanol, sparingly soluble in anhydrous ethanol	Complies
Melting point	About 210 °C	210.1 °C (*)
Identification A	Complies	Complies (*)
Specific optical rotation	+152.0 / +157.0	+156
Related substances		
Impurity F	=< 0.4 %	< 0.4 %
Impurity E	=< 0.2 %	< 0.05 %
Impurity B	=< 0.15 %	Not Detected
Impurity C	=< 0.15 %	< 0.15 %
Impurity G	=< 0.15 %	No Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.50 %
Loss on drying	=< 0.5 %	0.10 % (*)
Sulfated ash	=< 0.1 %	0.08 % (*)
Assay	97.0 - 103.0 %	101.1 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Cyproterone acetate 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".

(*) Data controlled by Metapharmaceutical Industrial SL.

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 tightly closed, in a dry and cool place and protected from the light.

Analysis date: 22/09/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000236
 FARMABIOS S.p.A. Active Pharmaceutical
 Ingredients
 Via Pavia, 1
 (PV) ITALIA

