



TECHNICAL DATA SHEET

0399-TDS-ENG-2023

CIPROTERONA ACETATO (PH.EUR)		
DESCRIPTION DCI: CYPROTERONE ACETATE		DESCRIPTION DOE: CIPROTERONA ACETATO
CAS Nº: 427-51-0	EC Nº: 207-048-3	AEMPS CODE: 602AC
MOL. WEIGHT: 416.95	MOL. FORMULA: C ₂₄ H ₂₉ ClO ₄	ARTICLE CODE: 0399

ATTRIBUTES	SHOULD BE
Appearance	White or almost 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
Melting point	About 210 °C
Identification A	Complies
Specific optical rotation	+152.0 / +157.0
Related substances	
Impurity F	=< 0.4 %
Impurity E	=< 0.2 %
Impurity B	=< 0.15 %
Impurity C	=< 0.15 %
Impurity G	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

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".

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.