



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 251894

Product:	CYPROTERONE ACETATE
Lot:	251894
Expiry date:	21/02/2030
Reference:	Cumple PhEur11.8
Synonyms:	
Formule:	C ₂₄ H ₂₉ ClO ₄
Poids moléculaire:	416,95 g/mol

Assay	Result	Specification	
Identification	Conform (A)	Test PhEur (A)	
Organoleptic properties	Conform	PhEur	
Melting point	210 ° C	Approx. 210 °C	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+156°	(+152°)-(+157°)	
Loss on drying	0,01 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay	100,1 %	97,0-103,0%	
Impurity B	< 0,05 %	<= 0,15 %	
Impurity C	< 0,05 %	<= 0,15 %	
Impurity G	< 0,05 %	<= 0,15 %	
Impurity E	0,15 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,4 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,15 %	<= 0,5 %	
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Chloroform	< 60 ppm	<= 60 ppm	#
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Pract. insoluble in water, very soluble in methylene chloride, freely soluble in acetone, soluble in methanol, sparingly soluble in anhydrous ethanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 07/11/2025

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F01060 Hubei Gedian Humanwell Pharmaceutical Co. , Ltd

Manufacturer batch: HG-CPAII250201M1

Produit	Nom	Capacité	Lot
1119482	CIPROTERONA ACETATO	5 g	251894-E-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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