



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 233093**

Product:	CYPROTERONE ACETATE
Lot:	233093
Expiry date:	26/04/2028
Reference:	Cumple PhEur11.2
Synonyms:	
Formula:	C <sub>24</sub> H <sub>29</sub> ClO <sub>4</sub>
Molecular weight:	416,95 g/mol

Assay	Result	Specification	
Identification	Conform (A)	Test PhEur (A)	
Organoleptic properties	Conform	PhEur	
Melting point	209 °C	Approx. 210 °C	
Related substances (HPLC)	Conform	Test PhEur	
Specific rotation	+157°	(+152°)-(+157°)	
Loss on drying	0,08 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99,5 %	97,0-103,0%	
Impurity B	< 0,05 %	<= 0,15 %	
Impurity C	NDT	<= 0,15 %	
Impurity G	NDT	<= 0,15 %	
Impurity E	0,08 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,4 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,14 %	<= 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: 08/09/2023

Responsible: M. Mesa

Technical director: Montserrat Enrique

Judgement:  
APPROVED

Manufacturer: F00024 HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO

Manufacturer batch: EU-CPA230401M

Product	Name	Capacity	Batch
1119481	CIPROTERONA ACETATO (INACTIVO)	1 g	233093-D-1
1119481	CIPROTERONA ACETATO (INACTIVO)	1 g	233093-D-2
1119482	CIPROTERONA ACETATO	5 g	233093-E-1
1119482	CIPROTERONA ACETATO	5 g	233093-E-2
1119482	CIPROTERONA ACETATO	5 g	233093-E-3
1119482	CIPROTERONA ACETATO	5 g	233093-E-4

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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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