

## Cyproterone Acetate EP11

Batch no

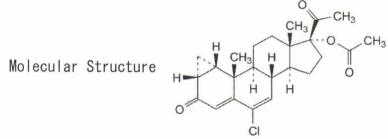
6010-250404

Mf date

May 16 2025

Retest

May 15 2030



Molecular Formula

 $C_{24}H_{29}C\,I\,O_4$ 

Molecular Weight

416.9

CAS Registry Number

427-51-0

Jul 28 2025

<u>Tests</u>	<u>Specifications</u>		Results
Appearance Solubility	White or almost white crystalline powder Practically insoluble in water, very soluble in methylene chloride, freely soluble in acetone, soluble in methanol, sparingly soluble in ethanol		Conforms Conforms
Identification	IR		Positive
Melting point	About 210°C		210 ~ 211°C
Specific optical rotation	+152 ~ +157°		+155°
Loss on drying	≤ 0.5%		0.1%
Related substances	Impurity E	≤ 0.2%	ND
	Impurity G	≤ 0.15%	ND
	Impurity F	≤ 0.4%	0.03%
	Impurity B	≤ 0.15%	ND
	Impurity C	≤ 0.15%	ND
	Unspecified impurity	≤ 0.1%	0.06%
**	Total impurities	≤ 0.5%	0. 15%
Residual solvents	Chloroform	≤ 60 ppm	< 28 ppm
	Methanol	≤ 3000 ppm	ND
	Ethyl acetate	≤ 5000 ppm	< 5 ppm
	Methylene chloride	≤ 600 ppm	ND
Sulfated ash	≤ 0.1%		0. 07%
Assay (odb)	97.0 ~ 103.0%		100.6%

Packaging & storage	Protected from light	
Conclusion	Material complies with EP11	1

