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CERTIFICATE OF ANALYSIS

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Product Name CYPROTERONE ACETATE MICRONIZED**According to** Ph.Eur current edition

Batch Nr.	2113AM1	B0012030	Manufacturing Date	06/2020	Expiration Date	06/2025
Analysis record Nr.	202004724	Net weight	Nr. of packages	CoA Version	3.0	
Appearance	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. It melts at about 210°C.					

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR method)	COMPLIES	COMPLIES	
LOSS ON DRYING (80°C under vacuum for 3 hours)	0.13	<= 0.5	%
SPECIFIC OPTICAL ROTATION (c = 1% in Acetone)	+156.7	+152.0 - +157.0	° o.d.b.
SPECIFIC ABSORBANCE (at about 282 nm)	413.3	402.0 - 426.0	A(1%,1cm) o.d.b.
SULPHATED ASH	0.01	<= 0.1	%
MELTING POINT	210.6	208.0 - 212.0	° C
RELATED SUBSTANCES (HPLC method)			
1,2-CH ₂ -6-Keto Acetoxypregesterone (Imp E Ph.Eur)	0.06	<= 0.10	% Vs Std
Cyproterone (Imp F Ph.Eur)	0.06	<= 0.15	% Vs Std
1,2-CH ₂ -Delta6-Acetoxypregesterone (Imp.A - Ph.Eur)	< 0.05	<= 0.10	% Vs Std
1AlfaCl-CH ₂ -6-Cl-Delta6-Acetoxypregesterone (Imp.C Ph.Eur)	N.D.	<= 0.10	% Vs Std
Any unspecified impurity	< 0.05	<= 0.10	% Vs Std
Total Impurities	0.12	<= 0.5	%
ASSAY (HPLC method)	100.7	98.0 - 102.0	% *
ASSAY (Spectrophotometric method)	99.8	97.0 - 103.0	%
RESIDUAL SOLVENTS (HS-GLC method)			
Methanol	N.D.	<= 1000	ppm
Methylene Chloride (*)	< 6	<= 500	ppm
(*)No potential presence for all the other residual solvents reported in ICH Q3C.			
COLOUR OF SOLUTION (c=10% in Chloroform)	0.028	<= 0.100	A.U.
PARTICLE SIZE - Particle <= 10 µm (Laser Scattering method)	100.0	>= 99.0	% of total volume

* as C₂₄H₂₉ClO₄ on dried basis referred to the Std.

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
31/07/2020	03/08/2020	FABIO VECCHIO	31/07/2020	SABRINA ABBATI

"Certificate of Conformance (CoC)": The Qualified Person hereby confirm that that the API has been manufactured and packaged in compliance with cGMP, the product registration, applicable laws or regulations and tested according to the approved specifications.
This Certificate of analysis has been produced by a electronic validated system and it is valid without a signature.