FARMABIOS
Active Pharmaceutical Ingredients
Via Pavia,1 - 27027 Gropello Cairoli PV, Italy
Tel. +39 0382 819.1 - Fax +39 0382 815886

CERTIFICATE OF ANALYSIS

Product Name **CYPROTERONE ACETATE MICRONIZED**

According to **EP**

Batch Nr.	**2113AM1**	**B0011721**	**Manufacturing Date**	**11/2017**	**Expiration Date**	**11/2022**	
Analysis record Nr.	**201705742**	**Net weight**	**Nr. of packages**		**CoA Version**	**1.0**	

Appearance **White or almost-white, crystalline powder. Practically insolubile 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)	0.03	<= 0.5	%
SPECIFIC OPTICAL ROTATION (c = 1% in Acetone)	+152.3	+152.0 - +157.0	° o.d.b.
SPECIFIC ABSORBANCE (at about 282 nm)	413.4	402.0 - 426.0	A(1%,1cm) o.d.b.
SULPHATED ASH	NEGLIGIBLE	<= 0.1	%
MELTING POINT	209.5	208.0 - 212.0	° C
RELATED SUBSTANCES (HPLC method)			
1,2-CH2-6-Keto Acetoxyprogesterone (Imp E Ph.Eur)	0.05	<= 0.10	% Vs Std
Cyproterone (Imp F Ph.Eur)	0.05	<= 0.15	% Vs Std
1,2-CH2-Delta6-Acetoxyprogesterone (Imp.A - Ph.Eur)	0.04	<= 0.10	% Vs Std
1AlfaCl-CH2-6-Cl-Delta6-Acetoxyprogesterone (Imp.C Ph.Eur)	N.D.	<= 0.10	% Vs Std
Any other impurity	0.01	<= 0.10	% Vs Std
Total Impurities	0.15	<= 0.5	%
ASSAY (HPLC method)	100.0	98.0 - 102.0	% *
ASSAY (Spectrophotometric method)	99.9	97.0 - 103.0	%
RESIDUAL SOLVENTS (HS-GLC method)			
Methanol	N.D.	<= 1000	ppm
Acetone	16	<= 1000	ppm
Methylene Chloride (*)	N.D.	<= 500	ppm
Ethyl Acetate	6	<= 1000	ppm
(*)No potential presence for all the other residual solvents reported in ICH Q3C.			
COLOUR OF SOLUTION (c=10% in Chloroform)	0.024	<= 0.100	A.U.
PARTICLE SIZE - Particle <= 10 µm (Laser Scattering method)	99.6	>= 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
11/12/2017	12/12/2017	FABIO VECCHIO	12/12/2017	SABRINA ABBIATI

"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.