


Manufacturing Site:

Farmabios SPA Via Pavia,1 - 27027 Gropello Cairoli (PV), Italy Tel. +39 0382 819.1 Fax +39 0382 815886

 03/05/2023

## CERTIFICATE OF ANALYSIS

Product Name: **MEDROXYPROGESTERONE ACETATE MICRONIZED**

According to: Ph. Eur. / USP current edition

Batch Nr: **2172AM0 - 0832224**

Manufacturing Date: **14-Dec-2022**

Expiration Date: **14-Dec-2027**

Analysis Record Nr: **B2302-00187**

Specification: **2172AM0 (24) v1**

TESTS	RESULTS	SPECIFICATION
<b>CHARACTERS</b>		
Appearance	COMPLIES	Crystalline powder
Color	COMPLIES	White to almost white
Solubility	COMPLIES	Insoluble in Water, freely soluble in Chloroform and Methylene Chloride, soluble in Acetone and Dioxane, sparingly soluble in Alcohol and Methanol, slightly soluble in Ether
<b>CHARACTERS</b>		
Appearance	COMPLIES	Crystalline powder
Color	COMPLIES	White to almost white
<b>IDENTIFICATION (IR)</b>	COMPLIES	Complies
<b>IDENTIFICATION (IR, UV)</b>		
IR identification	COMPLIES	Complies
UV identification	COMPLIES	Complies
<b>WATER CONTENT</b>	0.09	<= 0.5 %
<b>LOSS ON DRYING (after 3h at 105°C)</b>	0.14	<= 1.0 %
<b>SPECIFIC OPTICAL ROTATION (USP) (c=1% in 1,4-Dioxane)</b>	48.1	+45.0 - +51.0 °o.d.b.
<b>SPECIFIC OPTICAL ROTATION (EP) (c=1% in Acetone)</b>	50.4	+47.0 - +53.0 °o.d.b.
<b>SPECIFIC ABSORBANCE (in Ethanol at about 241 nm)</b>	419.4	408.0 - 432.0 A(1%,1cm)
<b>RESIDUE ON IGNITION</b>	0.01	<= 0.1%
<b>RELATED SUBSTANCES (HPLC method)</b>		
6beta-Hydroxymedroxyprogesterone Acetate (Imp. A - EP)	N.D.	<= 0.1 % Vs Std
17a-alpha-Methyl-17-Keto-D-Homo Medroxyprogesterone (Imp. I - EP)	N.D.	<= 0.2 % Vs Std
Hydroxyprogesterone Acetate (Imp. H - EP)	N.D.	<= 0.10 % Vs Std

Legal Entity:

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Medroxyprogesterone (Imp. B - EP)	N.D.	<= 0.2 % Vs Std
D-Homo Medroxyprogesterone Acetate (Imp. C - EP)	N.D.	<= 0.1 % Vs Std
Megestrol Acetate (Imp. G - EP)	N.D.	<= 0.1 % Vs Std
6beta-Methyl Analog (Imp. D - EP)	0.08	<= 0.5 % Vs Std
6-Methylenacetoxypregesterone (Imp. E)	<0.05	<= 0.2 % Vs Std
Any unspecified impurity	N.D.	<= 0.10 % Vs Std
Total impurities	0.08	<= 1.0 %
4,5-Dihydro Analog (Imp. F - EP, Imp. A - USP)	0.25	<= 0.5 % Vs Std
ASSAY o.d.b. (HPLC method)	100.0	97.0 - 103.0 % o.d.b. (*)
ASSAY o.d.b. (UV method)	99.9	97.0 - 103.0 % o.d.b.
MELTING POINT	207.0	205.0 - 209.0 °C
RESIDUAL SOLVENTS (GLC method)		
Methanol	21	<= 500 ppm
Acetone	44	<= 500 ppm
Ethanol	N.D.	<= 100 ppm
Methylene Chloride (**)	N.D.	<= 100 ppm
Tetrahydrofuran	N.D.	<= 50 ppm
Dimethylformamide	N.D.	<= 100 ppm
COLOUR OF SOLUTION (C= 10% in Chloroform at 400 nm)	0.015	<= 0.100 A.U.
GRANULOMETRIC DISTRIBUTION (24) Particles <=20 µm	100.00	>= 99.0 % of total volume
MICROBIAL CONTAMINATION		
TAMC	<1	<= 100 CFU/g
TYMC	<1	<= 10 CFU/g
Salmonella	ABSENT/10g	Absent
Pseudomonas Aeruginosa	ABSENT/g	Absent
E. Coli	ABSENT/g	Absent
Staphylococcus Aureus	ABSENT/g	Absent

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&lt;1.0

&lt;= 1.0 CFU/g

(\*) as C24H34O4 on dried basis referred to the Std.

(\*\*) No potential for other "OVIs" USP &lt;467&gt; presence because not used in the process.

QC Laboratory Manager  
Curti MatteoAnalytical Release  
13-Mar-2023Qualified Person  
Abbiati SabrinaRelease Date  
14-Mar-2023

Certificate of Conformance (CoC): The Qualified Person hereby confirm 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.

The certificate of analysis has been produced by an electronic validated system and it is valid without a signature.

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