

Manufacturing Site:

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

CERTIFICATE OF ANALYSIS

Product Name: **MEDROXYPROGESTERONE ACETATE MICRONIZED**

SAP Product Name: MEDROXYPROGESTERONE ACETATE MICRONIZED

According to: Ph. Eur. / USP current edition

Batch Nr: **2172AM0 0572424**

Manufacturing Date: **08-Jul-2024**

Expiration Date **08-Jul-2029**

Analysis Record Nr: **B2407-00354**

Specification: **2172AM0/M1 v1**

TESTS	RESULTS	SPECIFICATION
CHARACTERS		
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
CHARACTERS		
Appearance	COMPLIES	Crystalline powder
Color	COMPLIES	White to almost white
IDENTIFICATION (IR)	COMPLIES	Complies
IDENTIFICATION (IR, UV)		
IR identification	COMPLIES	Complies
UV identification	COMPLIES	Complies
WATER CONTENT	0.09	<= 0.5 %
LOSS ON DRYING (after 3h at 105°C)	0.08	<= 1.0 %
SPECIFIC OPTICAL ROTATION (USP) (c=1% in 1,4-Dioxane)	49.1	+45.0 - +51.0 °o.d.b.
SPECIFIC OPTICAL ROTATION (EP) (c=1% in Acetone)	51.5	+47.0 - +53.0 °o.d.b.
SPECIFIC ABSORBANCE (in Ethanol at about 241 nm)	418.8	408.0 - 432.0 A(1%,1cm)
RESIDUE ON IGNITION	0.01	<= 0.1%
RELATED SUBSTANCES (HPLC method)		
6beta-Hydroxymedroxyprogesterone Acetate (Imp. A - EP)	N.D.	<= 0.1 % Vs Std
17a-alpha-Methyl-17-Keto-D-Homo Medroxyprogesterone (Imp. I - EP)	<0.05	<= 0.2 % Vs Std

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TESTS	RESULTS	SPECIFICATION
Hydroxyprogesterone Acetate (Imp. H - EP)	N.D.	$\leq 0.10\%$ Vs Std
Medroxyprogesterone (Imp. B - EP)	<0.05	$\leq 0.2\%$ Vs Std
D-Homo Medroxyprogesterone Acetate (Imp. C - EP)	<0.05	$\leq 0.1\%$ Vs Std
Megestrol Acetate (Imp. G - EP)	N.D.	$\leq 0.1\%$ Vs Std
6beta-Methyl Analog (Imp. D - EP)	0.09	$\leq 0.5\%$ Vs Std
6-Methylenacetoxypregesterone (Imp. E)	<0.05	$\leq 0.2\%$ Vs Std
Any unspecified impurity	N.D.	$\leq 0.10\%$ Vs Std
Total impurities	0.09	$\leq 1.0\%$
4,5-Dihydro Analog (Imp. F - EP, Imp. A - USP)	0.31	$\leq 0.5\%$ Vs Std
ASSAY o.d.b. (HPLC method)	100.8	97.0 - 103.0 % o.d.b. (*)
ASSAY o.d.b. (UV method)	99.7	97.0 - 103.0 % o.d.b.
MELTING POINT	207.1	205.0 - 209.0 °C
RESIDUAL SOLVENTS (GLC method)		
Methanol	<6	≤ 500 ppm
Acetone	66	≤ 500 ppm
Ethanol	N.D.	≤ 100 ppm
Methylene Chloride (**)	15	≤ 100 ppm
Tetrahydrofuran	N.D.	≤ 50 ppm
Dimethylformamide	N.D.	≤ 100 ppm
COLOUR OF SOLUTION (C= 10% in Chloroform at 400 nm)	0.014	≤ 0.100 A.U.
GRANULOMETRIC DISTRIBUTION (24) Particles $\leq 20\ \mu\text{m}$	99.78	$\geq 99.0\%$ of total volume



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SAP Product Name: MEDROXYPROGESTERONE ACETATE MICRONIZED		
According to: Ph. Eur. / USP current edition		
Batch Nr: 2172AM0 0572424	Manufacturing Date: 08-Jul-2024	Expiration Date 08-Jul-2029
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TESTS	RESULTS	SPECIFICATION
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(*) as C24H34O4 on dried basis referred to the Std.

(**) No potential for other "OVIs" USP <467> presence because not used in the process.

QC Laboratory Manager Bottiroli Viviana	Analytical Release 07-Aug-2024	Qualified Person Abbiati Sabrina	Release Date 28-Aug-2024
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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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