Lote: 0970517

FARMABIOS
Active Pharmaceutical Ingredients
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CERTIFICATE OF ANALYSIS

Product Name **MEDROXYPROGESTERONE ACETATE MICRONIZED**
According to Ph.Eur. - USP

Batch Nr.	**2172AM0 A0221624**	**Manufacturing Date**	**04/2016**	**Expiration Date**	**04/2021**
Analysis record Nr.	**201602779**	**Net weight**		**Nr. of packages**	

Appearance White to almost-white, crystalline powder. 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.

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR,UV methods)	COMPLIES	COMPLIES	
WATER CONTENT (KF)	0.18	<= 0.5	%
LOSS ON DRYING (after 3 hours at 100° - 105 °C)	0.04	<= 1.0	%
SPECIFIC OPTICAL ROTATION (USP) (c = 1% in Dioxane)	+47.9	+45.0 - +51.0	° o.d.b.
SPECIFIC OPTICAL ROTATION (EP) (c = 1% in Acetone)	+51.2	+47.0 - +53.0	° o.d.b.
SPECIFIC ABSORBANCE (in Ethanol at about 241 nm)	419.1	408.0 - 432.0	A(1%,1cm) o.d.b.
RESIDUE ON IGNITION	NEGLIGIBLE	<= 0.1	%
RELATED SUBSTANCES (HPLC method)			
6ß-Hydroxymedroxyprogesterone Acetate (Imp.A-EP)	0.01	<= 0.1	% Vs Std
17a-alfa-methyl-17-Keto-D-Homo Medroxyprogesterone (Imp.I-EP)	0.12	<= 0.2	% Vs Std
Hydroxyprogesterone Acetate (Imp. H - EP)	N.D.	<= 0.1	% Vs Std
Medroxyprogesterone (Imp.B - EP)	0.08	<= 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
6ß-Methyl Analog (Imp.D - EP)	0.12	<= 0.5	% Vs Std
6-Methylenacetoxyprogesterone (Imp.E - EP)	0.09	<= 0.2	% Vs Std
Largest unspecified impurity	< 0.02	<= 0.10	% Vs Std
Total impurities	0.44	<= 1.0	%
4,5-Dihydro Analog (Imp.F - EP, Imp.A-USP)	0.25	<= 0.5	% Vs Std
ASSAY (HPLC method)	99.6	97.0 - 103.0	% *
ASSAY (Spectrophotometric method)	99.8	97.0 - 103.0	%
MELTING POINT	207.7	205.0 - 209.0	° C
HEAVY METALS	< 10	<= 10	ppm

**** as C24H34O4 on dried basis referred to the Std.***

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
08/07/2016	18/07/2016	MONICA FERRAROTTI	14/07/2016	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.

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TESTS	RESULTS	SPECIFICATIONS	UNITS
RESIDUAL SOLVENTS (GLC methods			
Methanol	N.D.	<= 500	ppm
Acetone	24	<= 500	ppm
Ethanol	N.D.	<= 100	ppm
Methylene Chloride (*)	N.D.	<= 100	ppm
Tetrahydrofuran	N.D.	<= 50	ppm
Dimethylformamide	N.D.	<= 100	ppm
(*)No potential for other "OVIs" USP <467> presence because not used in the process.			
COLOUR OF SOLUTION (at 400 nm) (c=10% in Chloroform)	0.001	<= 0.100	A.U.
PARTICLE SIZE (Laser Scattering method) Particles <=20 µm	99.8	>= 99.0	% of total volume

**** as C24H34O4 on dried basis referred to the Std.***

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