FARMABIOS
Via Pavia,1 - 27027 Gropello Cairoli PV, Italy
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lde: 0140121

CERTIFICATE OF ANALYSIS



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

| | | | | | |
|---|---|---|---|---|---|
| **Batch Nr.** | **2172AM0 A0351924** | **Manufacturing Date** | **09/2019** | **Expiration Date** | **09/2024** |
| **Analysis record Nr.** | **201906181** | **Net weight** | | **Nr. of packages** | **CoA Version** **2.0** |

**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)*** | 0.04 | <= 0.5 | % |
| ***LOSS ON DRYING (after 3 hours at 100° - 105 °C)*** | 0.26 | <= 1.0 | % |
| ***SPECIFIC OPTICAL ROTATION (USP) (c = 1% in Dioxane)*** | +48.0 | +45.0 - +51.0 | ° o.d.b. |
| ***SPECIFIC OPTICAL ROTATION (EP) (c = 1% in Acetone)*** | +50.6 | +47.0 - +53.0 | ° o.d.b. |
| ***SPECIFIC ABSORBANCE (in Ethanol at about 241 nm)*** | 419.8 | 408.0 - 432.0 | A(1%,1cm) o.d.b. |
| ***RESIDUE ON IGNITION*** | 0.03 | <= 0.1 | % |
| ***RELATED SUBSTANCES (HPLC method)*** | | | |
| *6ß-Hydroxymedroxyprogesterone Acetate (Imp.A-EP)* | N.D. | <= 0.1 | % Vs Std |
| *17a-alfa-methyl-17-Keto-D-Homo Medroxyprogesterone (Imp.I-EP)* | 0.07 | <= 0.2 | % Vs Std |
| *Hydroxyprogesterone Acetate (Imp. H - EP)* | N.D. | <= 0.10 | % Vs Std |
| *Medroxyprogesterone (Imp.B - EP)* | 0.06 | <= 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)* | 0.09 | <= 0.5 | % Vs Std |
| *6-Methylenacetoxyprogesterone (Imp.E - EP)* | 0.05 | <= 0.2 | % Vs Std |
| *Any unspecified impurity* | N.D. | <= 0.10 | % Vs Std |
| *Total impurities* | 0.27 | <= 1.0 | % |
| *4,5-Dihydro Analog (Imp.F - EP, Imp.A-USP)* | 0.47 | <= 0.5 | % Vs Std |
| ***ASSAY (HPLC method)*** | 99.0 | 97.0 - 103.0 | % * |
| ***ASSAY (Spectrophotometric method)*** | 100.0 | 97.0 - 103.0 | % |
| ***MELTING POINT*** | 207.7 | 205.0 - 209.0 | ° C |
| | | | |

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

| Assay Date | Print Date | Q.C. department | Release Date | Qualified Person |
|---|---|---|---|---|
| 28/11/2019 | 06/03/2020 | FABIO VECCHIO | 29/11/2019 | 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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|---|---|---|---|
| ***RESIDUAL SOLVENTS (GLC methods*** | | | |
| *Methanol* | 6 | <= 500 | ppm |
| *Acetone* | 56 | <= 500 | ppm |
| *Ethanol* | 14 | <= 100 | ppm |
| *Methylene Chloride (*)* | 14 | <= 100 | ppm |
| *Tetrahydrofuran* | N.D. | <= 50 | ppm |
| *Dimethylformamide* | 70 | <= 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)*** | 0.004 | <= 0.100 | A.U. |
| ***PARTICLE SIZE (Laser Scattering method) Particles <=20 µm*** | 99.6 | >= 99.0 | % of total volume |

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

| Assay Date | Print Date | Q.C. department | Release Date | Qualified Person |
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