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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 **BETAMETHASONE DIPROPIONATE MICRONIZED**

According to Ph. Eur.- USP

Batch Nr.	**2109DM0**	**B0021522**	**Manufacturing Date**	**07/2015**	**Expiration Date** **07/2020**
Analysis record Nr.	**201505991**		**Net weight**		**Nr. of packages**

Appearance **White to almost-white, microcrystalline powder. Practically insoluble in Water; sparingly soluble in Alcohol; freely soluble in Acetone, Methylene Chloride and Chloroform.**

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR-TLC)	COMPLIES	COMPLIES	
LOSS ON DRYING (After 3 hours at 105°C)	0.02	<= 1.0	%
WATER CONTENT (KF)	0.32	<= 1.0	%
SPECIFIC OPTICAL ROTATION (c=1% in Ethanol)	+84.4	+84 - +88	° o.d.b.
SPECIFIC OPTICAL ROTATION (c=1% in Dioxane)	+66.1	+63 - +70	° o.d.b.
SPECIFIC ABSORBANCE (at about 240 nm)	303.8	295.0 - 315.0	A(1%,1cm) o.d.b.
RESIDUE ON IGNITION	0.00	<= 0.2	%
RELATED SUBSTANCES (HPLC method)			
Betamethasone	N.D.	<= 0.10	% Vs Std
Betamethasone 17-Propionate	<0.03	<= 0.3	% Vs Std
Betamethasone 21-Propionate	0.05	<= 0.5	% Vs Std
Betamethasone 11,17,21-Tripropionate	0.04	<= 0.2	% Vs Std
Single unknown	0.06	<= 0.10	% Vs Std
Total impurities	0.22	<= 1.0	%
ASSAY (HPLC method)	98.9	97.0 - 102.0	% *
ASSAY (Spectrophotometric method)	99.6	97.0 - 102.0	%
RESIDUAL SOLVENTS (GLC methods)			
Methanol	N.D.	<= 1000	ppm
Acetone	110	<= 2000	ppm
Methylene Chloride (*)	N.D.	<= 600	ppm
Isopropyl Ether	67	<= 1000	ppm
Tetrahydrofuran	N.D.	<= 720	ppm
Pyridine	134	<= 200	ppm

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

** as C28H37FO7 on dried basis referred to the Std.*

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
06/10/2015	06/04/2016	FABIO VECCHIO	06/10/2015	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
PARTICLE SIZE (Laser Scattering method)			
Particle <= 20 µm	100.0	>= 99.0	% of total volume
Particle <= 10 µm	99.8	>= 90.0	% of total volume
Particle <= 5 µm	97.5	>= 80.0	% of total volume

** as C28H37FO7 on dried basis referred to the Std.*

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
06/10/2015	06/04/2016	FABIO VECCHIO	06/10/2015	SABRINA ABBIATI

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