

CERTIFICATE OF ANALYSIS

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Product Name **BETAMETHASONE DIPROPIONATE MICRONIZED**

According to Ph. Eur.- USP

Batch Nr.	2109DMO	B0021622	Manufacturing Date	03/2016	Expiration Date	03/2021
Analysis record Nr.	201601562		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)	0.12	<= 1.0	%
WATER CONTENT (KF)	0.40	<= 1.0	%
SPECIFIC OPTICAL ROTATION (c=1% in Ethanol)	+85.6	+84 - +88	* o.d.b.
SPECIFIC OPTICAL ROTATION (c=1% in Dioxane)	+65.4	+63 - +70	* o.d.b.
SPECIFIC ABSORBANCE (at about 240 nm)	302.0	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	N.D.	<= 0.3	% Vs Std
Betamethasone 21-Propionate	0.17	<= 0.5	% Vs Std
Betamethasone 11,17,21-Tripropionate	0.11	<= 0.2	% Vs Std
Single unknown	0.05	<= 0.10	% Vs Std
Total impurities	0.40	<= 1.0	%
ASSAY (HPLC method)	98.9	97.0 - 102.0	%
ASSAY (Spectrophotometric method)	99.0	97.0 - 102.0	%
RESIDUAL SOLVENTS (GLC methods)			
Methanol	N.D.	<= 1000	ppm
Acetone	55	<= 2000	ppm
Methylene Chloride (*)	N.D.	<= 600	ppm
Isopropyl Ether	N.D.	<= 1000	ppm
Tetrahydrofuran	N.D.	<= 720	ppm
Pyridine	N.D.	<= 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
05/04/2016	11/01/2017	FABIO VECCHIO	07/04/2016	SABRINA ABBATI

"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.

