

CERTIFICATE OF ANALYSIS

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Product Name **HALCINONIDE MICRONIZED**

According to **USP**

Batch Nr. **21650M0**

B0021322

Manufacturing Date **11/2013**

Expiration Date **11/2018**

Analysis record Nr. **201306705**

Net weight

Nr. of packages

Appearance White to off-white, odorless, crystalline powder. Soluble in Acetone and Chloroform; slightly soluble in Alcohol and in Ethyl Ether; insoluble in Water and in Hexanes.

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR, methods)	COMPLIES	COMPLIES	
LOSS ON DRYING (after 3 hours at 100 °C)	0.04	<= 1.0	%
WATER CONTENT (KF)	0.23	<= 1.0	%
SPECIFIC OPTICAL ROTATION (c = 2% in Chloroform)	+158.6	+150.0 - +160.0	° o.d.b.
RESIDUE ON IGNITION	0.00	<= 0.2	%
RELATED SUBSTANCES (HPLC method)			
1,2-Dihydrotriamecinolone	N.D.	<= 0.15	% Vs Std
1,2-Dihydrotriamecinolone 16,17 Acetonide	N.D.	<= 0.15	% Vs Std
1,2 Dihydrotriamecinolone 16,17 Acetonide 21 Mesylate	0.08	<= 0.10	% Vs Std
Largest Unknown	0.05	<= 0.10	% Vs Std
Total	0.23	<= 1.5	%
ASSAY (HPLC method)	99.7	97.0 - 102.0	% *
ASSAY (Spectrophotometric method)	100.5	97.0 - 102.0	%
RESIDUAL SOLVENTS (HS-GLC methods)			
Methanol	70	<= 500	ppm
Acetone	13	<= 500	ppm
Methylene Chloride (*)	455	<= 500	ppm
Ethyl Acetate	193	<= 500	ppm
Pyridine	N.D.	<= 100	ppm
Dimethylformamide	N.D.	<= 100	ppm
(*)No potential for other "OVIs" USP <467> presence because not used in the process.			

* as C24H32ClFO5 on dried basis referend to the Std

Assay Date 04/12/2013	Print Date 06/12/2013	Q.C. department Fabio Vecchio	Release Date 05/12/2013	Qualified Person Giuseppe Fortunato
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"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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According to USP

Expiration Date 11/2018

Nr. of packages

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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	99.5	>= 95.0	% of total volume
Particle <= 5 µm	93.6	>= 85.0	% of total volume

* as C₂₄H₃₂ClFO₅ on dried basis refferend to the Std

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
04/12/2013	06/12/2013	Fabio Vecchio	05/12/2013	Giuseppe Fortunato

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