

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Name **HALCINONIDE MICRONIZED**

According to USP

Batch Nr. **21650M0 0011122**

Manufacturing Date **11/2011**

Expiration Date **11/2016**

Analysis record Nr. **201106156**

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)	0.22	<= 1.0	%
WATER CONTENT (KF)	0.36	<= 1.0	%
SPECIFIC OPTICAL ROTATION (c = 2% in Chloroform)	+158.5	+150.0 - +160.0	° o.d.b.
RESIDUE ON IGNITION	0.01	<= 0.2	%
RELATED SUBSTANCES (HPLC method)			
1,2-Dihydrotriamcinolone	N.D.	<= 0.15	% Vs Std
1,2-Dihydrotriamcinolone 16,17 Acetonide	0.02	<= 0.15	% Vs Std
1,2 Dihydrotriamcinolone 16,17 Acetonide 21 Mesylate	0.06	<= 0.10	% Vs Std
Largest Unknown	0.07	<= 0.10	% Vs Std
Total	0.31	<= 1.5	%
ASSAY (HPLC method)	98.9	97.0 - 102.0	% *
ASSAY (Spectrophotometric method)	99.8	97.0 - 102.0	%
RESIDUAL SOLVENTS (HS-GLC methods)			
Methanol	159	<= 500	ppm
Acetone	N.D.	<= 500	ppm
Methylene Chloride (*)	355	<= 500	ppm
Ethyl Acetate	130	<= 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	Print Date	Q.C. department	Release Date	Qualified Person
29/11/2011	24/10/2012	Fabio Vecchio	30/11/2011	Giuseppe Fortunato

"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.



Page 2 of 2

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