

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Name **HALCINONIDE MICRONIZED**

According to **USP**

Batch Nr.	21650M0	B0031622	Manufacturing Date	09/2016	Expiration Date	09/2021
Analysis record Nr.	201605286		Net weight		Nr. of packages	

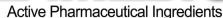
Appearance White to off-white, odorless, crystalline powder. Soluble in Acetone and Chloroform; slightly soluble in Alcohol and in Ethyl Ether; insoluble in Water and in Hexanes.

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR, methods)	COMPLIES	COMPLIES	
LOSS ON DRYING (after 3 hours at 100 °C)	0.29	<= 1.0	%
WATER CONTENT (KF)	0.45	<= 1.0	%
SPECIFIC OPTICAL ROTATION (c = 2% in Chloroform)	+159.2	+150.0 - +160.0	° o.d.b.
RESIDUE ON IGNITION	0.11	<= 0.2	%
RELATED SUBSTANCES (HPLC method)			
1,2-Dihydrotriamcinolone	N.D.	<= 0.15	% Vs Std
1,2-Dihydrotriamcinolone 16,17 Acetonide	< 0.01	<= 0.15	% Vs Std
1,2 Dihydrotriamcinolone 16,17 Acetonide 21 Mesylate	0.04	<= 0.10	% Vs Std
Largest Unknown	0.02	<= 0.10	% Vs Std
Total	0.07	<= 1.5	%
ASSAY (HPLC method)	100.4	97.0 - 102.0	% *
ASSAY (Spectrophotometric method)	99.2	97.0 - 102.0	%
RESIDUAL SOLVENTS (HS-GLC methods)			
Methanol	4	<= 500	ppm
Acetone	4	<= 500	ppm
Methylene Chloride (*)	445	<= 500	ppm
Ethyl Acetate	165	<= 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
04/11/2016	07/11/2016	FABIO VECCHIO	04/11/2016	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.



--

Page 2 of 2

According to USP

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.
------------	---

*** as C₂₄H₃₂ClFO₅ on dried basis refferend to the Std**

"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.