Via Pavia 1 • 27027 Gropello Cairoli PV, Italy
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CERTIFICATE OF ANALYSIS

Product Name: **FLUOCINOLONE ACETONIDE MICRONIZED**

According to: Ph. Eur. - USP

Batch Nr.	2151NM1	B0011323	Manufacturing Date	02/2013	Expiration Date 02/2018
Analysis record Nr.	201301514		Net weight		Nr. of packages

Appearance White to almost white microcrystalline powder. Practically insoluble in water; soluble in Methanol, Ethanol, Chloroform and Acetone; slightly soluble in Ether. It melts at about 270°C, with decomposition.

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR, UV, HPLC methods)	COMPLIES	COMPLIES	
LOSS ON DRYING (after 3 hours at 100 - 105 °C)	0.25	<= 1.0	%
SPECIFIC OPTICAL ROTATION (E.P.) (c = 1% in Ethanol)	+102.3	+100.0 - +104.0	* o.d.b.
SPECIFIC OPTICAL ROTATION (USP) (c = 1% in Methanol)	+103.0	+98.0 - +108.0	* o.d.b.
SPECIFIC ABSORBANCE (at about 238 nm)	354.2	344.0 - 366.0	A(1% 1cm) o.d.b.
RELATED SUBSTANCES (HPLC method)			
17beta-Acid Analog (Imp. B - EP)	N.D.	<= 0.1	% Vs Std
Fluocinolone (Imp. C - EP)	N.D.	<= 0.5	% Vs Std
21-Acid Analog (Imp. A - EP)	0.03	<= 0.1	% Vs Std
21-Aldehyde Analog (Imp. D - EP)	0.06	<= 0.25	% Vs Std
Triamcinolone Acetonide	0.07	<= 0.25	% Vs Std
Delta-14 Fluocinonne Acetonide	< 0.03	<= 0.5	% Vs Std
6alfa-Fluoro, 9,11-Epoxide Prednisolone 16,17 Acetonide (Imp. E - EP)	< 0.02	<= 0.1	% Vs Std
Fluocinonide	N.D.	<= 0.10	% Vs Std
Flurandrenolide 21-Acetate (Imp. G - EP)	N.D.	<= 0.1	% Vs Std
Any unspecified impurity	< 0.02	<= 0.10	% Vs Std
Total impurities	0.24	<= 2.0	%
ASSAY (HPLC method)	100.1	97.0 - 102.0	% *
ASSAY (Spectrophotometric method)	99.8	97.0 - 103.0	%

** as C24H30F2O6 on dried basis referrend to the Std*

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
18/03/2013	22/03/2013	Paola Vecchio	18/03/2013	Giuseppe Pellumbi

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

THE CONNECTING LINK
TRANSO-PHARM HANDELS-GmbH

FARMABIOS
Via Pavia, 1 • 27027 Gropello Cairoli PV, Italy
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TESTS	RESULTS	SPECIFICATIONS	UNITS
RESIDUAL SOLVENTS (HS-GLC method)			
Methanol	21	<= 500	ppm
Acetone	185	<= 1000	ppm
Methylene Chloride (*)	N.D.	<= 500	ppm
(*)No potential for other "OVis" USP <467> presence because not used in the process			
PARTICLE SIZE (Laser Scattering method)			
Particles <= 30 µm	100.0	>= 99.0	% of total volume
Particles <= 15 µm	99.8	>= 95.0	% of total volume
Particles <= 5 µm	83.4	>= 75.0	% of total volume

** as C24H30F2O6 on dried basis referrend to the Std*

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
18/03/2013	22/03/2013	Fabio Vecchio	18/03/2013	Giuseppe Fortunato

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FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
13L30 B35
17/06/15
Director Técnico

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TRANSO-PHARM
HANDELS-GMBH