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CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Name **DESONIDE MICRONIZED**

According to **USP current edition**

Batch Nr. **2187NM0** **B0012123** Manufacturing Date **01/2021** Expiration Date **01/2026**

Analysis record Nr. **202101140** Net weight Nr. of packages CoA Version **2.0**

Appearance White to almost-white, crystalline powder. Insoluble in Water, soluble in Chloroform; sparingly soluble in Ethanol and Acetone.

TESTS	RESULTS	SPECIFICATIONS	UNITS
IDENTIFICATION (IR, HPLC methods)	COMPLIES	COMPLIES	
LOSS ON DRYING (After 3 hours at 105°C)	0.14	<= 0.5	%
WATER CONTENT (KF)	0.10	<= 1.0	%
SPECIFIC OPTICAL ROTATION (c=1% in Dioxane)	+106.9	+104.0 - +110.0	° o.d.b.
RESIDUE ON IGNITION	0.02	<= 0.10	%
MELTING POINT	268.0	265.0 - 275.0	° C
RELATED SUBSTANCES (HPLC method)			
16a-Hydroxyprednisolone (Im. A USP)	0.04	<= 0.15	%
Desonide 21-Aldheyde (Imp. C USP)	0.05	<= 0.3	%
1,2-Dihydrodesonide (Imp. E USP)	0.05	<= 0.25	%
Desonide 9,11-Epoxyde (Imp F USP)	N.D.	<= 0.15	%
sum of DiHydroDesonide and Desonide 9,11Epoxyde	0.05	<= 0.40	%
Delta 9,11-Desonide	< 0.04	<= 0.10	%
Desonide 21-Acetate (Imp. H USP)	0.06	<= 0.15	%
Single unknown	< 0.04	<= 0.10	%
Total impurities	0.20	<= 1.0	%
ASSAY (HPLC method)	100.0	98.0 - 102.0	% *
RESIDUAL SOLVENTS (HS-GLC methods)			
Methanol	67	<= 500	ppm
Acetone	40	<= 250	ppm
Isopropyl Ether	N.D.	<= 500	ppm
Tetrahydrofuran	213	<= 720	ppm
(*)No potential for other "OVIs" USP <467> presence because not used in the process.			

* as C24H32O6 on dried basis referred to the standard

Assay Date	Print Date	Q.C. department	Release Date	Qualified Person
08/03/2021	12/03/2021	MONICA FERRAROTTI	09/03/2021	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 current edition

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* as C₂₄H₃₂O₆ on dried basis referred to the standard

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