

NEWCHEM

CERTIFICATE OF ANALYSIS DESONIDE MICRONIZED

Batch:

NT2227M

Manuf. date: 11/2013

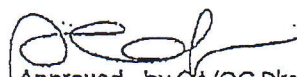
Retest date: 12/2016

Expiration date: 11/2018

Tests	Specifications	Results
GENERAL TESTS		
Solubility	Complies	Complies
Appearance	White or almost white crystalline powder	Complies
Identification IR	Positive	Positive
Identification UV	Positive	Positive
Specific rotation	+103° - +111° o.d.b.	+106°
Water content	NMT 0,5 %	0,1 %
Loss on drying	NMT 1,0 %	0,4 %
Residue on ignition	NMT 0,1 %	N.D.
Melting point	265° C - 275° C	269 °C
Specific absorbance	350 - 370	353 AU
ASSAY		
UV assay	97,0 % - 103,0 % o.d.b.	99,2 %
RESIDUAL SOLVENTS		
Methanol	NMT 3000 ppm	845 ppm
Acetone	NMT 5000 ppm	308 ppm
THF	NMT 720 ppm	24 ppm
Dichloromethane	NMT 100 ppm	N.D.
Isopropyl ether	NMT 500 ppm	N.D.
IMPURITIES		
Desonide 1,2 saturated analogue	LT 0.50%	0,05 %
Desonide Delta 9(11) analogue	LT 0.50%	0,43 %
Any other impurity	NMT 0.10%	0,07 %
Total Impurities	NMT 1,0 %	0,6 %
PARTICLE SIZE		
Particle size	NLT 95 % ≤ 30 µm	100 %
Particle size	NLT 80 % ≤ 15 µm	100 %

Verona, 03/12/2013

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Approved by QA/QC Director

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PARTICLE SIZE		
Particle size	NLT 70 % $\leq$ 5 μ m	95 %

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