

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NY1697M**

Manuf. date: **06/2018**

Expiration date: **06/2023**

Tests	Specifications	Results
GENERAL TESTS		
Appearance of the powder	White or almost white crystalline powder	Complies
Solubility	Complies	Complies
Identification IR	Positive	Positive
Identification UV	Positive	Positive
Identification HPLC (EP)	Positive	Positive
Specific optical rotation (EP)	+110° - +117° (anhydrous substance)	+113°
Specific rotation (USP)	+118° - +130° o.d.b.	+124°
Water content	NMT 2.0 %	1,6 %
Loss on drying (USP)	NMT 1.5%	1.10 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99,40 %
IMPURITIES		
Impurity B	NMT 0.20%	N.Q.
Impurity C	NMT 0.15%	N.Q.
Impurity E	NMT 0.15%	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	N.Q.
Any individual impurity (USP)	NMT 0.30%	0.05 %
Total impurities (USP)	NMT 0.80%	0.25 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	90 ppm
Methanol	NMT 900 ppm	223 ppm
Dichloromethane	NMT 400 ppm	N.D.

Complies with cEP and cUSP

Verona, 24/07/2018
NEWCHEM spa www.newchemspa.com

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Approved  by QA Manager

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Tests

PARTICLE SIZE

Particle size
Particle size

Specifications

MT 70% < 5 µm
99% < 10 µm

Results

94 %
100 %

Complies with cEP and cUSP

Verona, 24/07/2018

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