

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NY0131M**

Manuf. date: **01/2018**

Expiration date: **01/2023**

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.	+125°
Water content	NMT 2.0 %	1.2 %
Loss on drying (USP)	NMT 1.5%	1.10 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99.50 %
IMPURITIES		
Impurity B	NMT 0.20%	0.05 %
Impurity C	NMT 0.15%	0.05 %
Impurity E	NMT 0.15%	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0.11 %
Any individual impurity (USP)	NMT 0.30%	0.05 %
Total impurities (USP)	NMT 0.80%	0.14 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	56 ppm
Methanol	NMT 900 ppm	96 ppm
Dichloromethane	NMT 400 ppm	N.D.
PARTICLE SIZE		
Particle size	MT 70% < 5 µm	99 %

Complies with cEP and cUSP

Verona 18/02/2018

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Approved by QA Manager

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PARTICLE SIZE

Particle size

Specifications

99% < 10 μ m

Results

100 %

Complies with cEP and cUSP

Verona 19/02/2018

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