

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NB3485M** **METAPHARMACEUTICAL** Manuf. date: **12/2021**

N DE LOTE:

0240322

Expiration date: **12/2026**

28/03/2022

af

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)	+111°
Specific rotation (USP)	+118° - +130° o.d.b.	+125°
Water content	NMT 2.0 %	1.0 %
Loss on drying (USP)	NMT 1.5%	0.87 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99.50 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	88 ppm
Methanol	NMT 900 ppm	179 ppm
Dichloromethane	NMT 400 ppm	N.D.
IMPURITIES		
Impurity B	NMT 0.20%	N.Q.
Impurity C	NMT 0.15%	0.08 %
Impurity E	NMT 0.15%	0.09 %
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0.17 %
Any individual impurity (USP)	NMT 0.30%	0.06 %
Total impurities (USP)	NMT 0.80%	0.15 %

Complies with cEP and cUSP

NEWCHEM declares that: this batch was produced under GMP condition; the documentation relevant to this process has been reviewed by the Quality Unit

Verona

26/01/2022

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[Signature]
Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at: Via E. De Amicis 47 - 20123 Milano - Italy Tel. +39 02 581516 info@newchemspa.it

Capitale sociale Euro 1.000.000 i.v. R.E.A. MI n. 1559575 iscrizione registro imprese MI - codice fiscale e partita IVA/vat 12437910156

Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co. Ltd.

Stabilimenti/factories:

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PARTICLE SIZE		
Particle size	99% < 10 µm	100 %
Particle size	70% < 5 µm	97 %

Complies with cEP and cUSP

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