

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NB2565M**

Manuf. date: **09/2021**

METAPHARMACEUTICAL

13/02/2023

Expiration date: **09/2026**

N DE LOTE:

0180223

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 %	1,2 %
Loss on drying (USP)	NMT 1.5%	1,25 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	100,10 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	69 ppm
Methanol	NMT 900 ppm	87 ppm
Dichloromethane	NMT 400 ppm	N.D.
IMPURITIES		
Impurity B	NMT 0.20%	N.Q.
Impurity C	NMT 0.15%	N.Q.
Impurity E	NMT 0.15%	0,07 %
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0,07 %
Any individual impurity (USP)	NMT 0.30%	0,05 %
Total impurities (USP)	NMT 0.80%	0,11 %

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

20/10/2021

Page 1 of 2

[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:

Via Roveggia 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568 info@newchemspa.it

Via Parco del Ticino 10 - 27028 San Martino Siccomario - Pavia - Italy Tel. +39 0382 521027 Fax +39 0382 490570 info@newchemspa.it

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NB2565M**

Manuf. date: **09/2021**

Expiration date: **09/2026**

Tests	Specifications	Results
PARTICLE SIZE		
Particle size	99% < 10 µm	100 %
Particle size	70% < 5 µm	82 %

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

20/10/2021

Page 2 of 2


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:

Via Roveggia 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568 info@newchemspa.it

Via Parco del Ticino 10 - 27028 San Martino Siccomario - Pavia - Italy Tel. +39 0382 521027 Fax +39 0382 490570 info@newchemspa.it