

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NB0600M**

Manuf. date: **02/2021**

Expiration date: **02/2026**

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.	+126 °
Water content	NMT 2.0 %	0,9 %
Loss on drying (USP)	NMT 1.5%	0,51 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99,50 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	82 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%	0,07 %
Impurity E	NMT 0.15%	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0,07 %
Any individual impurity (USP)	NMT 0.30%	0,04 %
Total impurities (USP)	NMT 0.80%	0,17 %

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

07/04/2021

Page 1 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

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NB0600M**

Manuf. date: **02/2021**

Expiration date: **02/2026**

Tests	Specifications	Results
PARTICLE SIZE		
Particle size	99% < 10 µm	100 %
Particle size	70% < 5 µm	94 %

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

07/04/2021

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

**IMS s.r.l. Micronizzazioni**

Via Venezia Giulia 23
20157 Milano
Tel 0239002128
Fax 0239002132
Cap. Soc. €99.000i.v.

C.F. e P.IVA n.00923920151
Aut.Min.Sanità
Reg.Impr.n.151751 Trib.MI
R.E.A. 852403
e-mail:

CERTIFICATO ANALISI N° S21P00263

Prodotto: TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm
Cliente: NEWCHEM S.P.A.
N° lotto: TAM0002N NB0600
Codice:
Quantità: 65,80 Kg.
Lavorazione IMS N° 21S0050
Codice IMS 420103
Metodo di analisi SOP-06-L-178-03
Versione Specifica 10
N° di analisi AV210050SF
Strumento LS13320 MLM

Saggio	Specifiche	Risultati
Identificazione (a o b o c)		
NIR	Positiva	Positiva
Punto di fusione	[274 - 278] ° C	N.A. ° C
Granulometria		
%<5µm	>= 70 %	94,1 %
%<10µm	>= 99 %	100 %

Note: I dati sopra riportati sono stati ottenuti usando il metodo indicato e sono soggetti a possibili variazioni legate a metodo e condizioni analitiche.

CONCLUSIONI: PRODOTTO CONFORME A SPECIFICHE

Il responsabile CQ

Luca Macchi Data 19/03/2021

Il responsabile QA

Michele Urso Russo Data 19/03/2021

Il presente certificato è firmato elettronicamente

MOD-01-L-012-1E in vigore dal 01/03/2018

31

I.M.S. Micronizzazioni srl

File name: C:\LS13320\samples\Cert_21\Newchem\Triamcinolone Aceonide\AV210050SF_ca.\$av
File ID: AV210050SF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-03
Operator: Silvia Mele
Comment: Prodotto finito
Sample info: Lotto TAM0002N-NB0600 per Newchem in lavorazione 21S0050
Compliance: CONFORME NON CONFORME N.A.
Optical model: Fraunhofer.rf780d
LS 13 320 Micro Liquid Module

Run length: 30 seconds

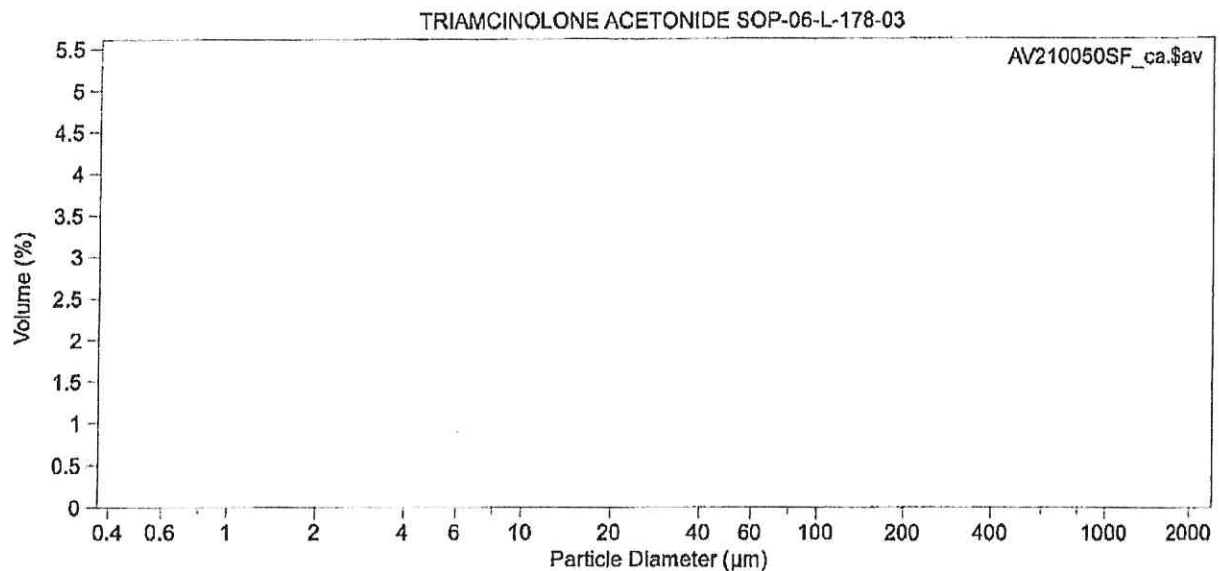
Stirrer speed (Off)
Fluid: Water

Average of 3 files:

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\21005010SF_01.\$ls

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\21005011SF_01.\$ls

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\21005012SF_01.\$ls



Volume Statistics (Arithmetic)

AV210050SF_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 2.497 µm
Median: 2.175 µm
Mode: 1.919 µm

d₁₀: 0.930 µmd₅₀: 2.175 µmd₉₀: 4.600 µm

Particle Diameter µm	AV210050SF_ca.\$av Volume % <
5	94.1
8	100
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100

31 MAR 2021