

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NB0601M**

Manuf. date: **02/2021**

METAPHARMACEUTICAL

N DE LOTE:

0090222

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)	+112°
Specific rotation (USP)	+118° - +130° o.d.b.	+126°
Water content	NMT 2.0 %	1.0 %
Loss on drying (USP)	NMT 1.5%	0.59 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99.70 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	79 ppm
Methanol	NMT 900 ppm	190 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%	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%	0.15 %

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

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:

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Batch: **NB0601M**

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

Complies with cEP and cUSP

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IMS s.r.l. Micronizzazioni

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C.F. e P.IVA n.00923920151
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R.E.A. 852403
e-mail: info@imsi.org.it

CERTIFICATO ANALISI N° S21P00272

Prodotto:	TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm
Cliente:	NEWCHEM S.P.A.
N° lotto:	TAMD002N NB0601
Codice:	
Quantità:	66,64 Kg.
Lavorazione IMS N°	21S0051
Codice IMS	420103
Metodo di analisi	SOP-06-L-178-03
Versione Specifica	10
N° di analisi	AV210051SF
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 %	93,5 %
%<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 22/03/2021

Il responsabile QA

Michele Urso Russo Data 23/03/2021

Il presente certificato è firmato elettronicamente

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

31 MAR 2021
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I.M.S. Micronizzazioni srl

File name: C:\LS13320\samples\Cert_21\Newchem\Triamcinolone Aceonide\AV210051SF_ca.\$av
File ID: AV210051SF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-03
Operator: Silvia Mele
Comment: Prodotto finito
Sample info: Lotto TAM0002N-NB0601 per Newchem in lavorazione 21S0051
Compliance: CONFORME NON CONFORME N.A.
Optical model: Fraunhofer.rf780d
LS 13 320 Micro Liquid Module

Run length: 30 seconds

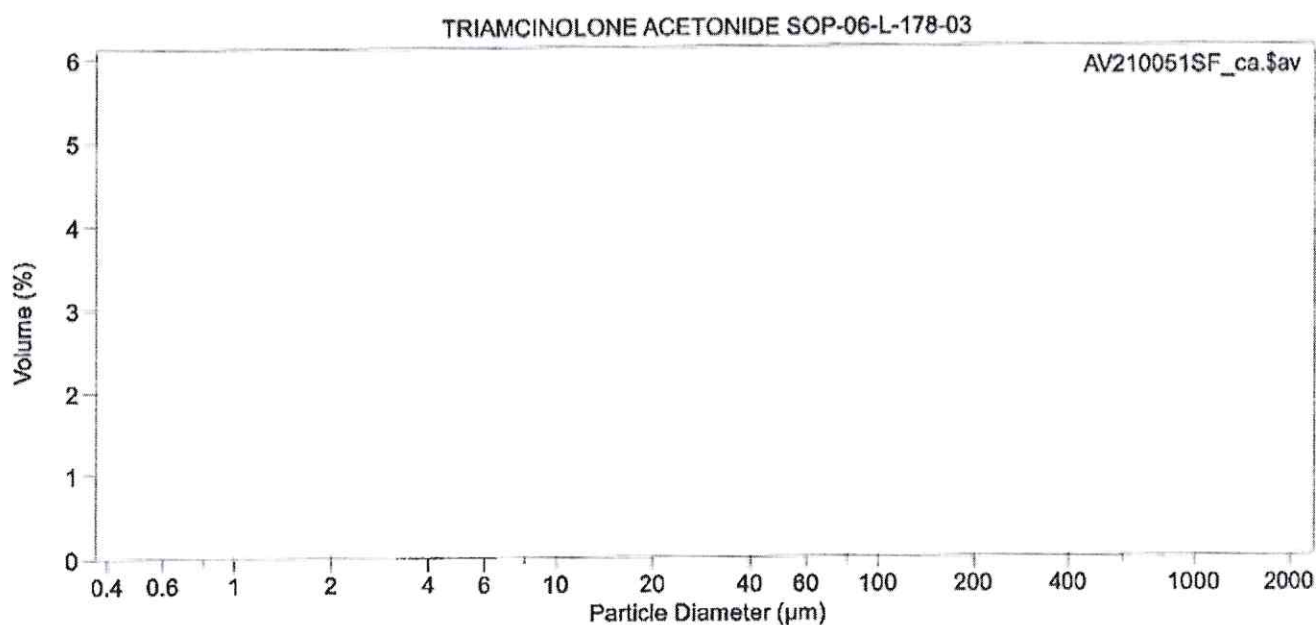
Stirrer speed (Off)
Fluid: Water

Average of 3 files:

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\21005109SF_01.\$ls

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\21005110SF_01.\$ls

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\21005111SF_01.\$ls



Volume Statistics (Arithmetic)

AV210051SF_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 2.416 µm
Median: 2.063 µm
Mode: 1.919 µm

d₁₀: 0.901 µm d₅₀: 2.063 µm d₉₀: 4.591 µm

Particle Diameter µm	AV210051SF _ca.\$av Volume % <
5	93.5
8	100
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100