

NEWCHEM

Lot: 0170120

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NZ3279M**

Manuf. date: **12/2019**

Expiration date: **12/2024**

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.	+127°
Water content	NMT 2.0 %	0,9 %
Loss on drying (USP)	NMT 1.5%	0,70 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	101,60 %
IMPURITIES		
Impurity B	NMT 0.20%	0,07 %
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 %	0,07 %
Any individual impurity (USP)	NMT 0.30%	0,07 %
Total impurities (USP)	NMT 0.80%	0,18 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	96 ppm
Methanol	NMT 900 ppm	155 ppm
Dichloromethane	NMT 400 ppm	N.D.
PARTICLE SIZE		
Particle size	MT 70% < 5 µm	93 %

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

NEWCHEM spa www.newchemspa.com

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

Verona, 28/01/2020 Capitale Sociale Euro 1.000.000 i.v. R.E.A. MI n. 1556795030122 Registro imprese MI - codice fiscale 02471470201 P.IVA n. 02471470201

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

[Signature]

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Batch: **NZ3279M**

Manuf. date: **12/2019**

Expiration date: **12/2024**

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

Complies with cEP and cUSP

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Verona 28/01/2020 Page 2 of 2 Approved by Q.A. Manager

Capital Sociale/Euro 1.000.000 i.v. R.E.A. MI n. 155599 - iscrizione registro imprese MI - codice fiscale partita IVA 03040400151
Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co. Ltd.

Stabilimenti/factories:

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IMS Srl - Micronizzazioni

IMS s.r.l. Micronizzazioni

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Cap. Soc. €99.000i.v.

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Reg.Impr.n.151751 Trib.MI
R.E.A. 852403
e-mail: info@msmicron.it

CERTIFICATO ANALISI N° S20P00022

Prodotto:	TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm
Cliente:	NEWCHEM S.P.A.
N° lotto:	NZ3279
Codice:	TAM0002N
Quantità:	76,43 Kg.
Lavorazione IMS N°	20S0002
Codice IMS	420103
Metodo di analisi	SOP-06-L-178-03
Versione Specifica	10
N° di analisi	av200002sf
Strumento	LS13320 MLM

Saggio	Specifiche	Risultati
Identificazione (a o b o c)		
NIR	Positiva	N.A.
Punto di fusione	[274 - 278] ° C	276 ° C
Granulometria		
%<5µm	>= 70 %	93 %
%<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 20/01/2020

Il responsabile QA

Michele Urso Russo Data 20/01/2020

Il presente certificato è firmato elettronicamente

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



I.M.S. Micronizzazioni srl

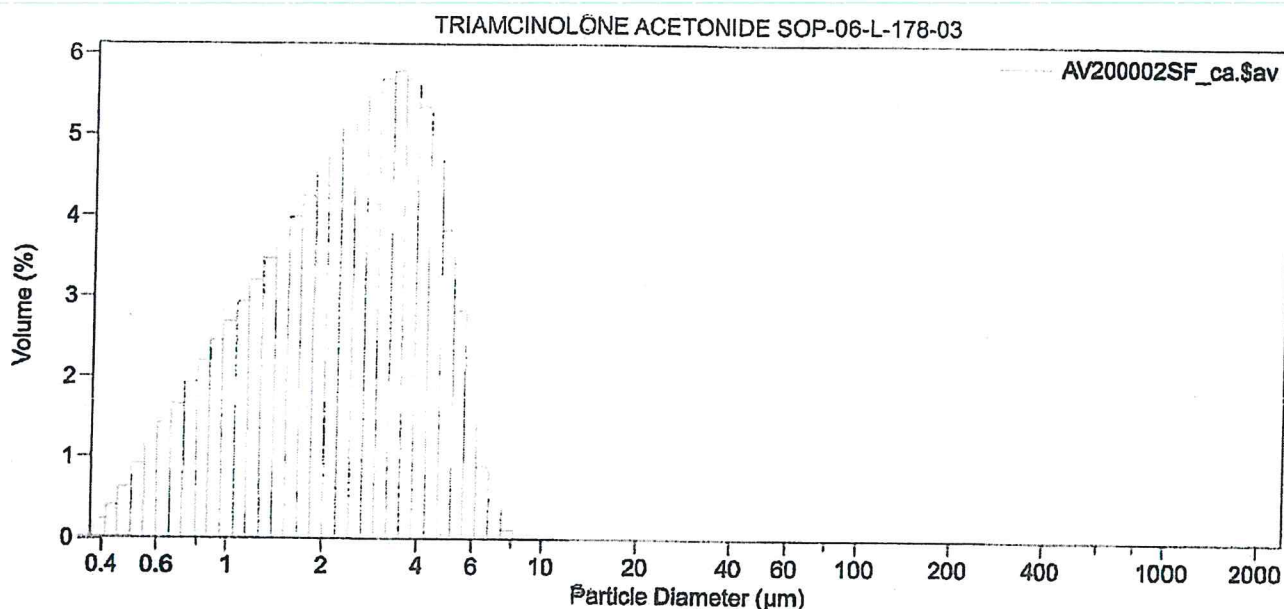
File name: C:\LS13320\samples\CERT_20\Newchem\Triamcinolone Acetonide\AV200002SF_ca.\$av
File ID: AV200002SF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-03
Operator: Fillppo Cinà
Sample info: Lotto NZ3279 per Newchem in lavorazione 20S0002
Compliance: CONFORME X NON CONFORME N.A.
Optical model: Fraunhofer.rf780d
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\20000210SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\20000211SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\20000212SF_01.\$ls



Volume Statistics (Arithmetic)

AV200002SF_ca.\$av

Calculations from 0.375 μm to 2000 μm

Volume: 100%
Mean: 2.576 μm
Median: 2.343 μm
Mode: 3.359 μm

d₁₀: 0.847 μmd₅₀: 2.343 μmd₉₀: 4.647 μm

Particle Diameter μm	AV200002SF_ca.\$av Volume % <
5	93.0
8	99.9
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100

18/01/2020
[Signature]