

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NA1931M**

Manuf. date: **07/2020**

Expiration date: **07/2025**

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 %	1,4 %
Loss on drying (USP)	NMT 1.5%	1,13 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	98,90 %
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%	0,22 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	111 ppm
Methanol	NMT 900 ppm	148 ppm
Dichloromethane	NMT 400 ppm	N.D.

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

03/08/2020

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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

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PARTICLE SIZE		
Particle size	99% < 10 μ m	100 %
Particle size	70% < 5 μ m	95 %

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

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CERTIFICATO ANALISI N° S20P00671

Prodotto: **TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm**
Cliente: **NEWCHEM S.P.A.**
N° lotto: **TAM002N NA1931**
Codice:
Quantità: **69,03 Kg.**
Lavorazione IMS N° **20S0114**
Codice IMS **420103**
Metodo di analisi **SOP-06-L-178-03**
Versione Specifica **10**
N° di analisi **AV200114SF**
Strumento **LS13320 MLM**

Saggio	Specifiche	Risultati
Identificazione (a o b o c) NIR Punto di fusione	Positiva [274 - 278] ° C	N.A. 275 ° C
Granulometria %<5µm %<10µm	>= 70 % >= 99 %	94,5 % 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 20/07/2020

Il responsabile QA

Michele Urso Russo Data 20/07/2020

Il presente certificato è firmato elettronicamente

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



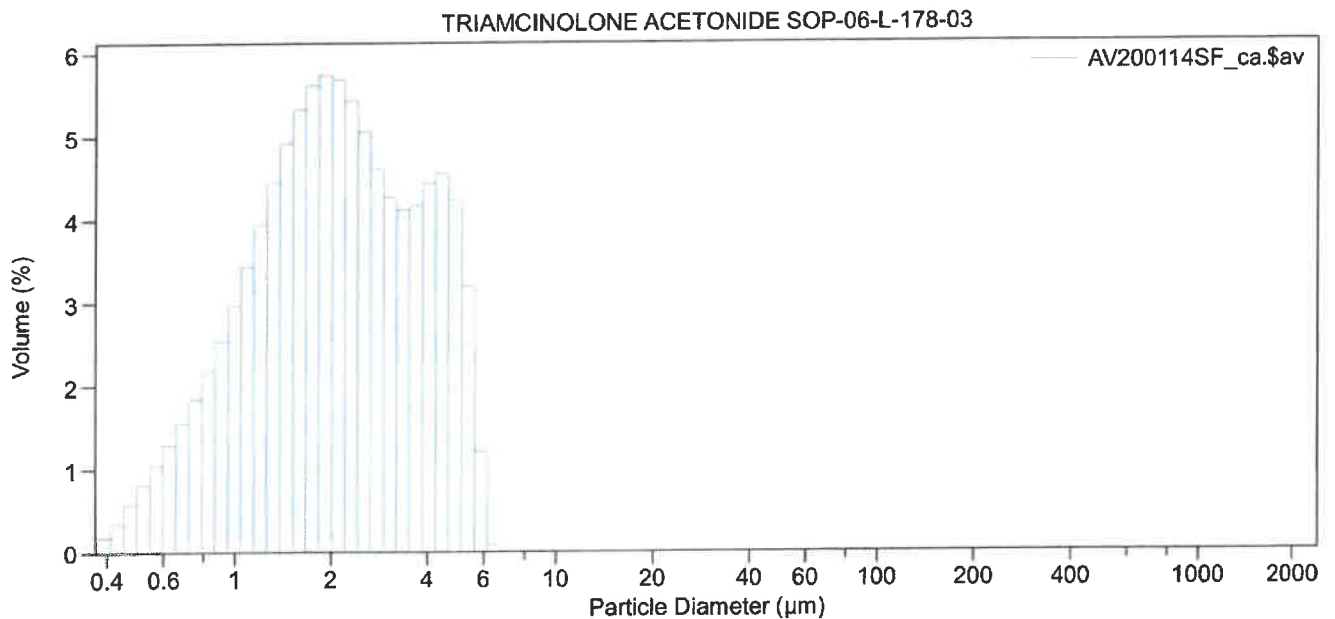
File name: C:\LS13320\samples\CERT_20\Newchem\Triamcinolone Acetonide\AV200114SF_ca.\$av
File ID: AV200114SF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-03
Operator: Silvia Mele
Comment: Prodotto finito
Sample info: Lotto TAM0002N-NA1931 per Newchem in lavorazione 20S0114
Compliance: CONFORME NON CONFORME N.A.
Optical model: Fraunhofer.r780d
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\20011412SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\20011413SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\20011414SF_01.\$ls



Volume Statistics (Arithmetic) AV200114SF_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 2.393 µm
Median: 2.051 µm
Mode: 1.919 µm

d₁₀: 0.873 µm d₅₀: 2.051 µm d₉₀: 4.543 µm

Particle Diameter µm	AV200114SF_ca.\$av Volume % <
5	94.5
8	100
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100

17 JUL 2020