

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **ND3099M**

Manuf. date: **10/2023**

METAPHARMACEUTICAL

N DE LOTE:

0110324

07/03/2024

Expiration date: **10/2028**

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 %	1.2 %
Loss on drying (USP)	NMT 1.5%	0.70 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99.90 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	74 ppm
Methanol	NMT 900 ppm	84 ppm
Dichloromethane	NMT 400 ppm	N.D.
IMPURITIES		
Impurity B	NMT 0.20%	N.Q.
Impurity C	NMT 0.15%	0.06 %
Impurity E	NMT 0.15%	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0.06 %
Any individual impurity (USP)	NMT 0.30%	0.04 %
Total impurities (USP)	NMT 0.80%	0.13 %

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

24/11/2023

Page 1 of 2

[Signature]
Approved By Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

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Capitale sociale Euro 1.000.000 i.v. R.E.A. MI n. 1559575 iscrizione registro imprese MI, codice fiscale e partita IVA/vat it n. IT12437910156

Company subject to direction and coordination of Zhejiang Xianju Pharmaceutical Co. Ltd.

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Tests	Specifications	Results
PARTICLE SIZE		
Particle size	99% < 10 μ m	100 %
Particle size	70% < 5 μ m	85 %

Complies with cEP and cUSP

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CERTIFICATO ANALISI N° S23P01064

Prodotto:	TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm
Cliente:	NEWCHEM S.P.A.
N° lotto:	TAMD002N ND3099
Codice:	
Quantità:	67,29 Kg.
Lavorazione IMS N°	23S0180
Codice IMS	420103
Metodo di analisi	SOP-06-L-178-04
Versione Specifica	11
N° di analisi	AV230180SF
Strumento	LS13320 MLM

Saggio	Specifiche	Risultati
Identificazione (a o b o c) NIR Punto di fusione	Positiva [274 - 278] ° C	Positiva N.A. ° C
Granulometria %<5µm %<10µm	>= 70 % >= 99 %	85,3 % 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 16/11/2023

Il responsabile QA

Michele Urso Russo Data 16/11/2023

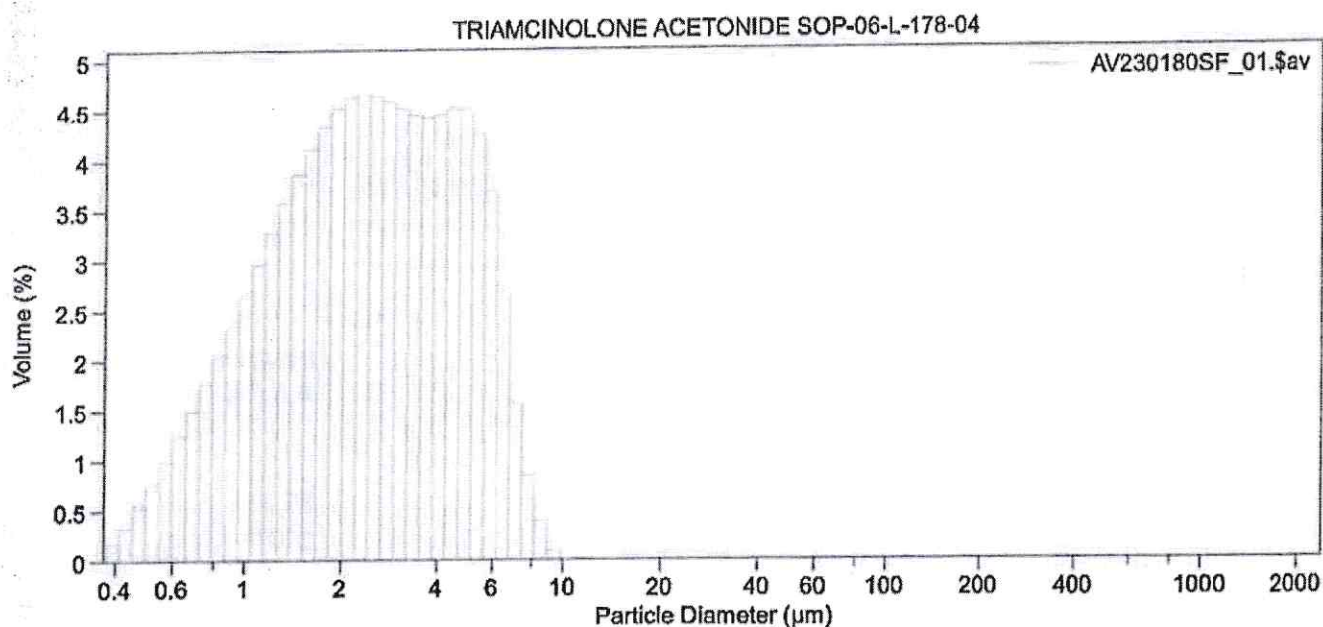
Il presente certificato è firmato elettronicamente
MOD-01-L-012-1E in vigore dal 01/03/2018



File name: C:\LS13320\samples\Newchem\Triamcinolone Acetonide\AV230180SF_01.\$av
AV230180SF_01.\$av
File ID: AV230180SF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-04
Operator: Daniele Porceddu
Comment: Prodotto Finito
Sample info: Lotto TAM0002N ND3099 per Newchem in lavorazione 23S0180
Compliance: CONFORME > NON CONFORME N.A.
Optical model: Fraunhofer.rf780d
LS 13 320 Micro Liquid Module
Stirrer speed (Off)
Fluid: Water

Average of 3 files:

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23018010SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23018011SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23018012SF_01.\$ls



Volume Statistics (Arithmetic) AV230180SF_01.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 2.857 µm
Median: 2.408 µm
Mode: 2.313 µm

d₁₀: 0.891 µm d₅₀: 2.408 µm d₉₀: 5.528 µm

Pistule

Particle Diameter µm	AV230180SF_01.\$av Volume % <
5	85.3
8	99.3
10	99.996
15	100
20	100
45	100
50	100
60	100
100	100
200	100

[Signature]

15 NOV 2023