

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **ND1254M**

Manuf. date: **04/2023**

Expiration date: **04/2028**

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 %	1,4 %
Loss on drying (USP)	NMT 1.5%	0,93 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	100,70 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	69 ppm
Methanol	NMT 900 ppm	119 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%	0,15 %

METAPHARMACEUTICAL

N DE LOTE:

0010623

Complies with cEP and cUSP

6 JUN. 2023

NEWCHEM declares that: this batch was produced under GMP condition; the documentation relevant to this process has been reviewed by the Quality Unit

Verona

24/05/2023

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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 µm	100 %
Particle size	70% < 5 µm	89 %

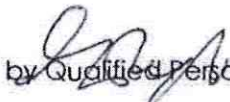
Complies with cEP and cUSP

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CERTIFICATO ANALISI N° S23P00516

Prodotto:	TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm
Cliente:	NEWCHEM S.P.A.
N° lotto:	TAMD002N ND1254
Codice:	
Quantità:	74,25 Kg.
Lavorazione IMS N°	23S0084
Codice IMS	420103
Metodo di analisi	SOP-06-L-178-04
Versione Specifica	11
N° di analisi	AV230084SF
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 %	88,7 %
%<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 12/05/2023

Il responsabile QA

Michele Urso Russo Data 15/05/2023

Il presente certificato è firmato elettronicamente

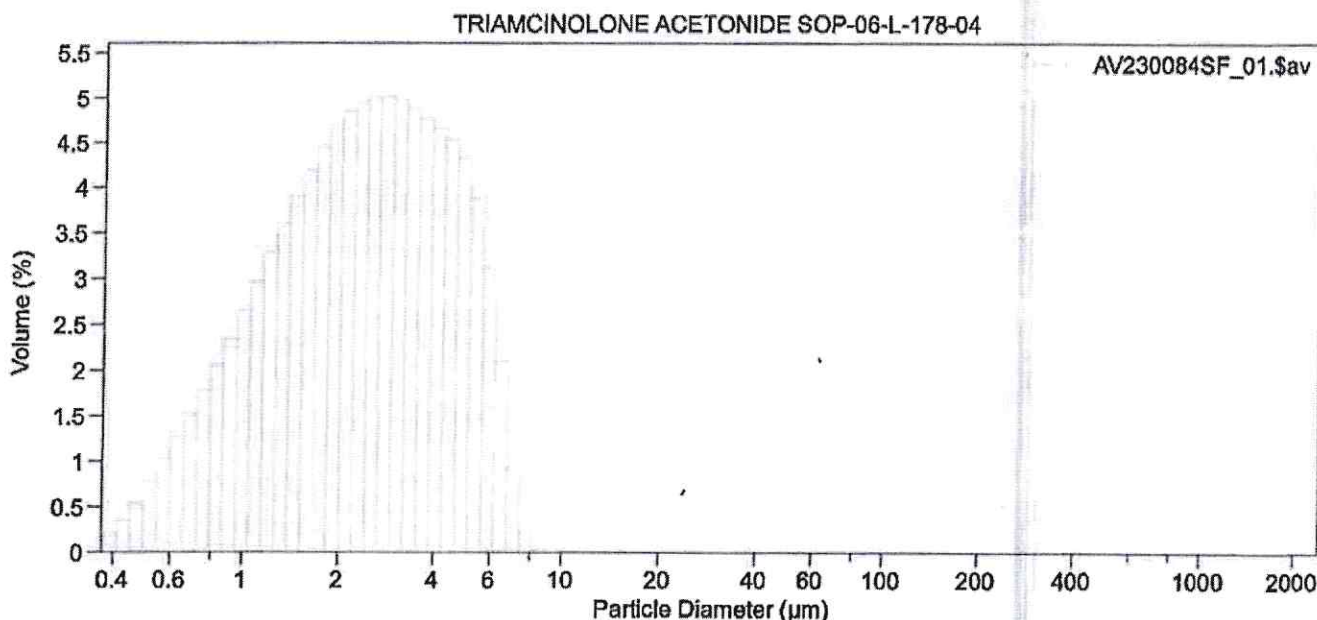
MOD-01-L-012-1E in vigore dal 01/03/2018

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File name: C:\LS13320\samples\Newchem\Triamcinolone Acetonide\AV230084SF_01.\$av
 File ID: AV230084SF
 Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-04
 Operator: Daniele Porceddu
 Comment: Prodotto Finito
 Sample info: Lotto TAM0002N ND1254 per Newchem in lavorazione 23S0084
 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\23008411SF_01.\$ls
 C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23008412SF_01.\$ls
 C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23008413SF_01.\$ls



Volume Statistics (Arithmetic) AV230084SF_01.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
 Mean: 2.715 µm
 Median: 2.360 µm
 Mode: 2.787 µm

d₁₀: 0.886 µm d₅₀: 2.360 µm d₉₀: 5.148 µm

Distib

Particle Diameter µm	AV230084SF _01.\$av Volume % <
5	88.7
8	99.9
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100

12 May 2023