

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch:

ND3236M

METAPHARMACEUTICAL

N DE LOTE:

0020224

Manuf. date: **11/2023**

Expiration date: **11/2028**

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.	+125°
Water content	NMT 2.0 %	1.1 %
Loss on drying (USP)	NMT 1.5%	1.07 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	101.10 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	74 ppm
Methanol	NMT 900 ppm	80 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%	0.06 %
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%	0.14 %

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

29/11/2023

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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.

Stabilimenti/factories:

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Batch: **ND3236M**

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Tests	Specifications	Results
PARTICLE SIZE		
Particle size	99% < 10 µm	100 %
Particle size	70% < 5 µm	87 %

Complies with cEP and cUSP

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CERTIFICATO ANALISI N° S23P01080

Prodotto:	TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm
Cliente:	NEWCHEM S.P.A.
N° lotto:	TAM0002N ND3236
Codice:	
Quantità:	71,17 Kg.
Lavorazione IMS N°	23S0181
Codice IMS	420103
Metodo di analisi	SOP-06-L-178-04
Versione Specifica	11
N° di analisi	AV230181SF
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 %	86,8 % 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 17/11/2023

Il responsabile QA

Michele Urso Russo Data 20/11/2023

Il presente certificato è firmato elettronicamente

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

I.M.S. Micronizzazioni srl

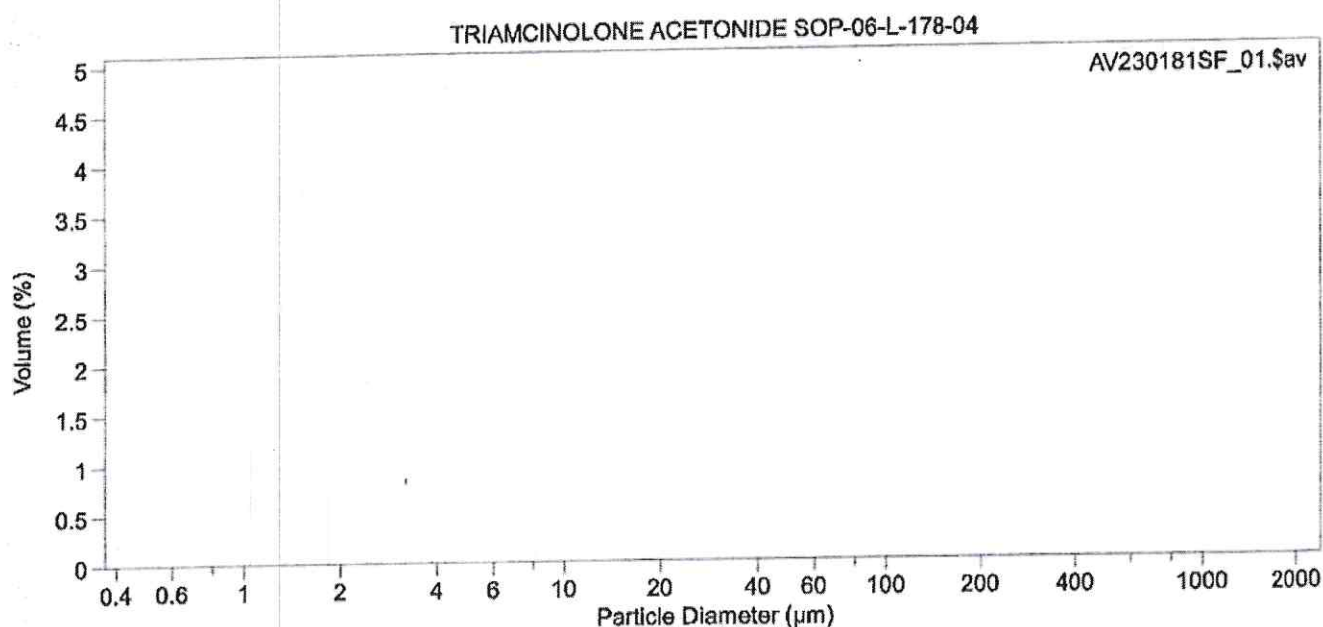
File name: C:\LS13320\samples\Newchem\Triamcinolone Acetonide\AV230181SF_01.\$av
File ID: AV230181SF_01.\$av
Sample ID: AV230181SF
Operator: TRIAMCINOLONE ACETONIDE SOP-06-L-178-04
Comment: Daniele Porceddu
Sample info: Prodotto Finito
Compliance: Lotto TAM0002N ND3236 per Newchem in lavorazione 23S0181
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\23018110SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23018111SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\23018112SF_01.\$ls



Volume Statistics (Arithmetic)

AV230181SF_01.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 2.803 µm
Median: 2.432 µm
Mode: 3.687 µm

d₁₀: 0.870 µmd₅₀: 2.432 µmd₉₀: 5.357 µm

Particle Diameter µm	AV230181SF_01.\$av Volume % <
5	86.8
8	99.8
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100

27/11/23

17 NOV 2023