

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **ND3236M**

METAPHARMACEUTICAL

N DE LOTE:

0120324

Manuf. date: **11/2023**

Expiration date: **11/2028**

07/03/2024

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.	+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

Page 1 of 2

Approved by *[Signature]*

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

Via San Vittore, 39 - 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: info@newchemspa.it PEC: newchemspa@legalmail.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 it n. IT12437910156

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

Stabilimenti/factories:

Via Roveggia, 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568 E-mail: info@newchemspa.it,

Via Parco del Ticino, 10 - 27028 San Martino Siccomario Pavia - Italy Tel. +39 0382 521027 Fax +39 0382 490570 Email: info@newchemspa.it

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **ND3236M**

Manuf. date: **11/2023**

Expiration date: **11/2028**

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

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

Page 2 of 2

Approved by Qualified Person 

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

Via San Vittore, 39 - 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: info@newchemspa.it PEC: newchemspa@legalmail.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 it n. IT12437910156

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

Stabilimenti/factories:

Via Roveggia, 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568 E-mail: info@newchemspa.it,

Via Parco del Ticino, 10 - 27028 San Martino Siccomario Pavia - Italy Tel. +39 0382 521027 Fax +39 0382 490570 Email: info@newchemspa.it



IMS Srl - Micronizzazioni

IMS s.r.l. Micronizzazioni

Via Venezia Giulia 23
20157 Milano
Tel 0239002128
Fax 0239002132
Cap. Soc. €99.000i.v.

C.F. e P.IVA n.00923920151
Aut.Min.Sanità
Reg.Impr.n.151751 Trib.MI
R.E.A. 852403
e-mail: info@imsmicron.it

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 é firmato elettronicamente

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

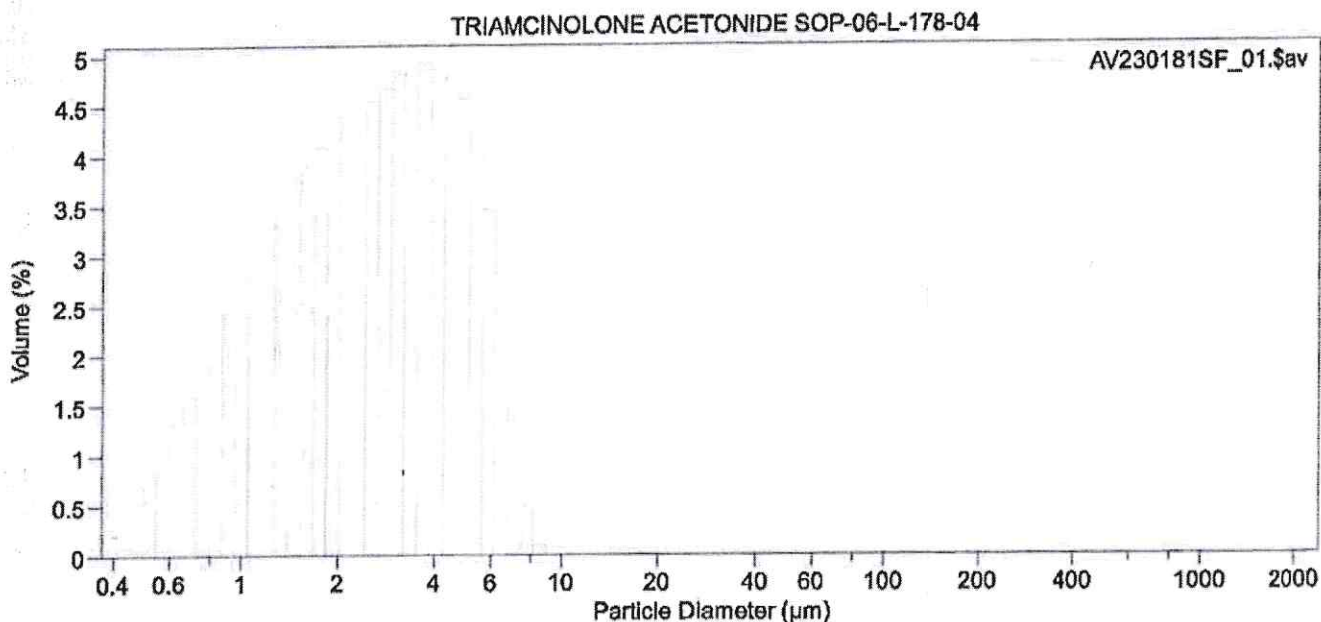
File name: C:\LS13320\samples\Newchem\Triamcinolone Acetonide\AV230181SF_01.\$av
 File ID: AV230181SF
 Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-04
 Operator: Daniele Porceddu
 Comment: Prodotto Finito
 Sample info: Lotto TAM0002N ND3236 per Newchem in lavorazione 23S0181
 Compliance: CONFORME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

d₅₀: 2.432 µm

d₉₀: 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