

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NX1064M**

Manuf. date: **05/2017**

Expiration date: **05/2022**

Tests	Specifications	Results
GENERAL TESTS		
Appearance	White or almost white crystalline powder	Complies
Solubility	Complies	Complies
Identification IR	Positive	Positive
Identification UV	Positive	Positive
Identification HPLC (EP)	Positive	Positive
Water content (EP)	NMT 2.0%	1.38 %
Loss on drying (USP)	NMT 1.5%	1.12 %
Specific optical rotation (EP)	+110° - +117° (anhydrous substance)	+113°
Specific rotation (USP)	+118° - +130° o.d.b.	+126°
Heavy metals (USP)	NMT 25 ppm	Complies
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99.70 %
IMPURITIES		
Impurity B	NMT 0.2 %	0.07 %
Impurity C	NMT 0.15%	0.06 %
Impurity E	NMT 0.15%	N.Q.
Each other single impurity	NMT 0.10 %	0.06 %
Total Impurities	NMT 0.5 %	0.19 %
Any individual impurity (USP)	NMT 0.3%	0.07 %
Total impurities (USP)	NMT 0.8%	0.36 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	121 ppm
Methanol	NMT 900 ppm	255 ppm
Dichloromethane	NMT 400 ppm	N.D.

Complies with cEP and cUSP

Verona, 28/05/2017
NEWCHEM spa - www.newchemspa.com

Page 1 of 2

Approved by QA Manager

Sede legale/registered at: via E. De Amicis 47 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: 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/val it n. 12437910156
Stabilimenti/factories:
Via Rovaglia 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: **NX1064M**

Manuf. date: **05/2017**

Expiration date: **05/2022**

Tests

PARTICLE SIZE

Particle size

Particle size

Specifications

NLT 70% < 5µm

NLT 99 % < 10 µm

Results

98,20 %

100 %

Complies with cEP and cUSP

Verona 29/05/2017

NEWCHEM spa www.newchemspa.com

Page 2 of 2

Approved  by QA Manager

Sede legale/registered at: via E. De Amicis 47 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: 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 it n. 12437910156

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 s.r.l.
Via Venezia Giulia 23
20157 Milano
Tel 0239002128
Fax 0239002132
Cap. Soc. €99.000 i.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 DI ANALISI

Prodotto TRIAMCINOLONE ACETONIDE
Cliente NEWCHEM S.P.A.
N° lotto NX1064
Codice TAM0002N

Quantità Kg 61,060
Lavorazione IMS N° 17S0056

Codice IMS 420103.01
Versione Specifica 5

N° Bollettino di analisi 11700422
N° Analisi AV170056SF
Metodo di analisi SOP-06-L-178-02
Strumento LS13320 MLM

Analisi	Risultato	Specifica	U.M.
Identificazione NIR	Positiva	Positiva	--
%<10µm	100,00	>= 99,00	%
%<5µm	98,20	>= 70,00	%

Note:

CONCLUSIONI: PRODOTTO CONFORME A SPECIFICHE

Responsabile Controllo Qualità

Data

QA Manager

Data

I dati sopra riportati sono stati ottenuti usando il metodo indicato e sono soggetti a possibili variazioni legate a metodo e condizioni analitiche

MOD-01-L-012-1D Approvato da: Q.A. Manager S.Pagnoncelli

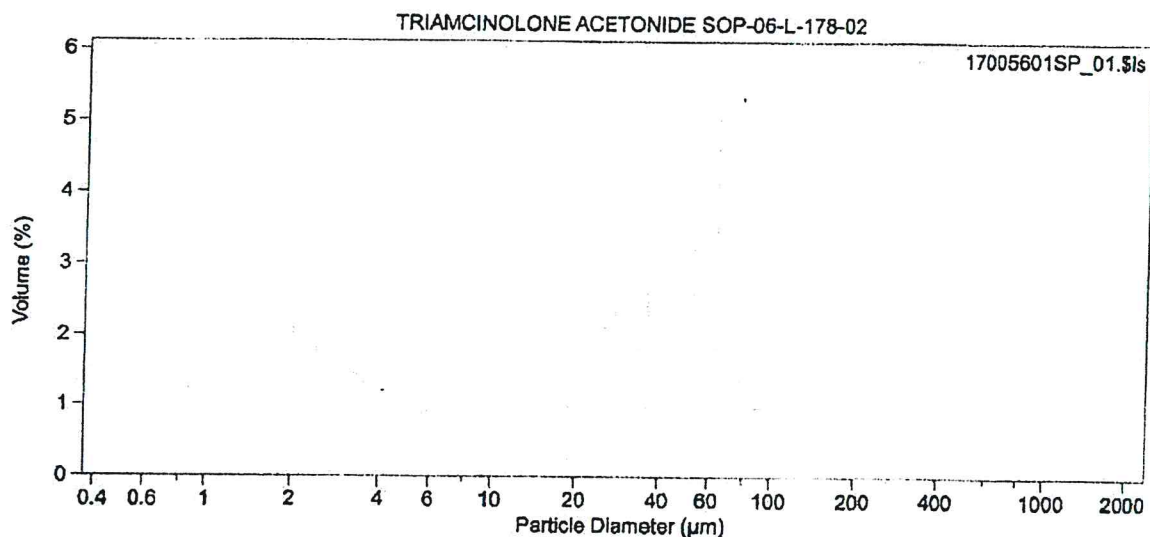
Autorizzato da: Q.P. R.Brusa

In vigore da 01.09.09



I.M.S. Micronizzazioni srl

File name: C:\LS13320\samples\Newchem\Triamcinolone Acetonide\17005601SP_01.\$ls
File ID: 17005601SP
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-02
Operator: Donata Picci
Comment: Materia prima
Run number: 1
Sample info: Lotto NX1064 per Newchem in lavorazione 17S0056
Compliance: CONFORME NON CONFORME N.A.
Optical model: Fraunhofer.r1780d
Residual: 1.47%
LS 13 320 Micro Liquid Module
Start time: 16:07 12 May 2017 Run length: 30 seconds
Stirrer speed: 51
Obscuration: 22%
Fluid: Water
Software: 5.03 Firmware: 2.02



Volume Statistics (Arithmetic) 17005601SP_01.\$ls

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 28.81 µm
Median: 20.36 µm
Mode: 72.94 µm

d₁₀: 1.139 µm d₅₀: 20.36 µm d₉₀: 72.92 µm

Particle Diameter µm	17005601SP_01.\$ls Volume % <
5	38.1
8	42.5
10	44.2
15	46.9
20	49.8
45	69.2
50	72.3
60	79.4
100	99.9
200	100

M 12/05/17

Q 12/05/17

29/05/2017



I.M.S. Micronizzazioni srl

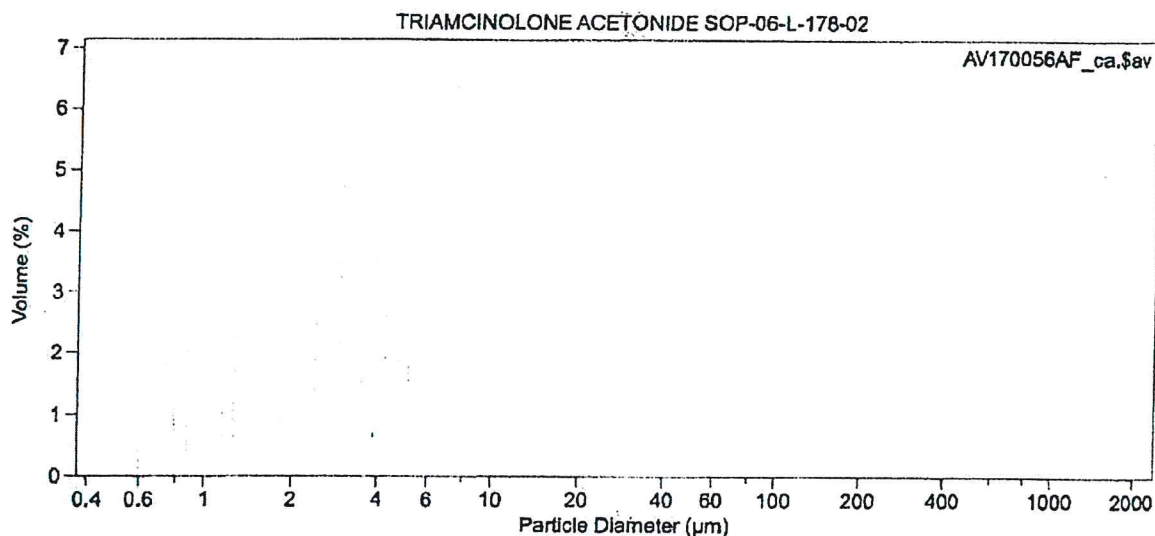
File name: C:\LS13320\samples\CERT_17\Newchem\Triamcinolone Acetonide\AV170056AF_ca.\$av
AV170056AF_ca.\$av
File ID: AV170056AF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-02
Operator: Donata Picci
Comment: Prodotto finito
Sample info: Lotto NX1064 per Newchem in lavorazione 17S0056
Compliance: CONFORME 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\17005608SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\17005609SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\17005610SF_01.\$ls



Volume Statistics (Arithmetic)

AV170056AF_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 2.154 µm
Median: 1.921 µm
Mode: 1.919 µm

d₁₀: 0.890 µmd₅₀: 1.921 µmd₉₀: 3.816 µm*17/05/17**Q (170056)**17/05/17*



Particle Diameter μm	AV170056AF _ca.\$av Volume % <
5	98.2
8	100
10	100
15	100
20	100
45	100
50	100
60	100
100	100
200	100

Chloroform

Q (100%)

19/05/2017