

NEWCHEM

CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NX0389M**Manuf. date: **02/2017**Expiration date: **02/2022**

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%	1.25 %
Loss on drying (USP)	NMT 1.5%	0.75 %
Specific optical rotation (EP)	+110° - +117° (anhydrous substance)	+114 °
Specific rotation (USP)	+118° - +130° o.d.b.	+127 °
Heavy metals (USP)	NMT 25 ppm	Complies
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% (anhydrous substance)	99.40 %
IMPURITIES		
Impurity B	NMT 0.2 %	0.06 %
Impurity C	NMT 0.15%	N.Q.
Impurity E	NMT 0.15%	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total impurities	NMT 0.5 %	0.06 %
Any individual impurity (USP)	NMT 0.3%	0.07 %
Total impurities (USP)	NMT 0.8%	0.26 %
RESIDUAL SOLVENTS		
Acetone	NMT 1000 ppm	138 ppm
Methanol	NMT 900 ppm	176 ppm
Dichloromethane	NMT 400 ppm	N.D.

Complies with cEP and cUSP

Verona 10/03/2017
NEWCHEM spa www.newchemspa.com

Page 1 of 2


 Approved by QA Manager

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Batch: **NX0389M**

Manuf. date: **02/2017**

Expiration date: **02/2022**

Tests	Specifications	Results
PARTICLE SIZE		
Particle size	NLT 70% < 5µm	82,20 %
Particle size	NLT 99 % < 10 µm	100 %

Complies with cEP and cUSP

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Page 2 of 2

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IMS
Micronizzazioni

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20157 Milano
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Cap. Soc. €99.000i.v.

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

CERTIFICATO DI ANALISI

Prodotto TRIAMCINOLONE ACETONIDE
Cliente NEWCHEM S.P.A.
N° lotto NX0389
Codice TAM0002N

Quantità Kg 61,000
Lavorazione IMS N° 17S0021

Codice IMS 420103.01
Versione Specifica 5

N° Bollettino di analisi 11700183
N° Analisi AV170021SF
Metodo di analisi SOP-06-L-178-02
Strumento LS13320 MLM

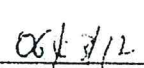
Analisi	Risultato	Specifica	U.M.
Identificazione NIR	Positiva	Positiva	--
%<10µm	99,98	>= 99,00	%
%<5µm	82,20	>= 70,00	%

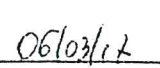
Note:

CONCLUSIONI: PRODOTTO CONFORME A SPECIFICHE


Responsabile Controllo Qualità


QA Manager


Data

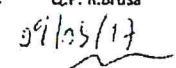

Data

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

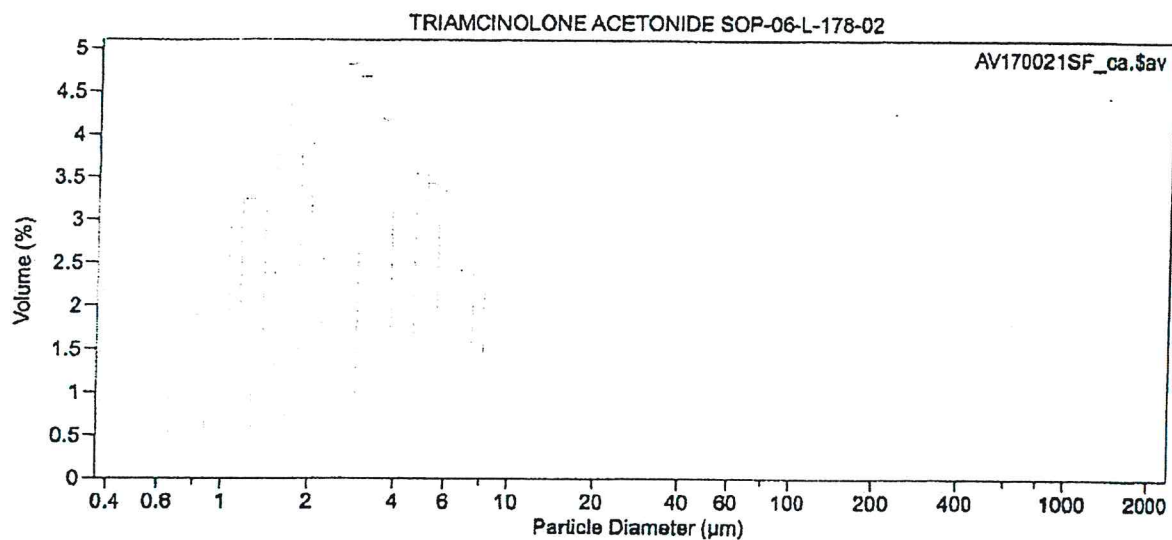
File name: C:\LS13320\samples\CERT_17\Newchem\Triamcinolone Acetonide\AV170021SF_ca.\$av
File ID: AV170021SF
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-02
Operator: Silvia Mele
Comment: Prodotto finito
Sample info: Lotto NX0389 per Newchem in lavorazione 17S0021
Compliance: CONFORME NON CONFORME N.A.
Optical model: Fraunhofer.r780d
LS 13 320 Micro Liquid Module

Stirrer speed (Off)
Fluid: Water

Run length: 30 seconds

Average of 3 files:

C:\LS13320\samples\Newchem\Triamcinolone Acetonide\17002108SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\17002109SF_01.\$ls
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\17002110SF_01.\$ls



Volume Statistics (Arithmetic)

AV170021SF_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%
Mean: 3.042 µm
Median: 2.478 µm
Mode: 2.539 µm

d₁₀: 0.952 µmd₅₀: 2.478 µmd₉₀: 6.194 µm

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06/03/17 hch-0817



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Particle Diameter μm	AV170021SF _ca.\$av Volume % <
5	82.2
8	87.8
10	99.98
15	100
20	100
45	100
50	100
60	100
100	100
200	100

09/07/17

09/07/17