

# NEWCHEM

## CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NY1697M**

Manuf. date: **06/2018**

Expiration date: **06/2023**

| Tests                          | Specifications                           | Results  |
|--------------------------------|------------------------------------------|----------|
| <b>GENERAL TESTS</b>           |                                          |          |
| 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.                     | +124°    |
| Water content                  | NMT 2.0 %                                | 1,6 %    |
| Loss on drying (USP)           | NMT 1.5%                                 | 1,10 %   |
| <b>ASSAY</b>                   |                                          |          |
| Assay HPLC (EP)                | 97.5% - 102.0% (anhydrous substance)     | 99,40 %  |
| <b>IMPURITIES</b>              |                                          |          |
| Impurity B                     | NMT 0.20%                                | N.Q.     |
| 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 0.50 %                               | N.Q.     |
| Any individual impurity (USP)  | NMT 0.30%                                | 0,05 %   |
| Total impurities (USP)         | NMT 0.80%                                | 0,25 %   |
| <b>RESIDUAL SOLVENTS</b>       |                                          |          |
| Acetone                        | NMT 1000 ppm                             | 90 ppm   |
| Methanol                       | NMT 900 ppm                              | 223 ppm  |
| Dichloromethane                | NMT 400 ppm                              | N.D.     |

Complies with cEP and cUSP

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| <b>PARTICLE SIZE</b> |                |         |
| Particle size        | MT 70% < 5 µm  | 94 %    |
| Particle size        | 99% < 10 µm    | 100 %   |

Complies with cEP and cUSP

Verona, 24/07/2018

NEWCHEM spa [www.newchemspa.com](http://www.newchemspa.com)

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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](mailto: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](mailto: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](mailto: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](mailto:info@imsmicron.it)

**CERTIFICATO ANALISI N° S18P00353**

|                    |                                          |
|--------------------|------------------------------------------|
| Prodotto:          | TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm |
| Cliente:           | NEWCHEM S.P.A.                           |
| N° lotto:          | NY1697                                   |
| Codice:            | TAM0002N                                 |
| Quantità:          | 72,94 Kg.                                |
| Lavorazione IMS N° | 18S0103                                  |
| Codice IMS         | 420103                                   |
| Metodo di analisi  | SOP-06-L-178-02                          |
| Versione Specifica | 1                                        |
| N° di analisi      | AV180103SF                               |
| Strumento          | LS13320 MLM                              |

| Saggio                             | Specifiche | Risultati |
|------------------------------------|------------|-----------|
| Identificazione (a o b o c)<br>NIR | Positiva   | Positiva  |
| Granulometria<br>%<5µm             | >= 70 %    | 94 %      |
| %<10µm                             | >= 99 %    | 99,99 %   |

**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 - LOTTO APPROVATO**

Il responsabile CQ

Denis Carfora Approvato Data 09/07/2018

Il responsabile QA

Michele Urso Russo Approva Data 09/07/2018

*Il presente certificato è firmato elettronicamente*

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

I.M.S. Micronizzazioni srl

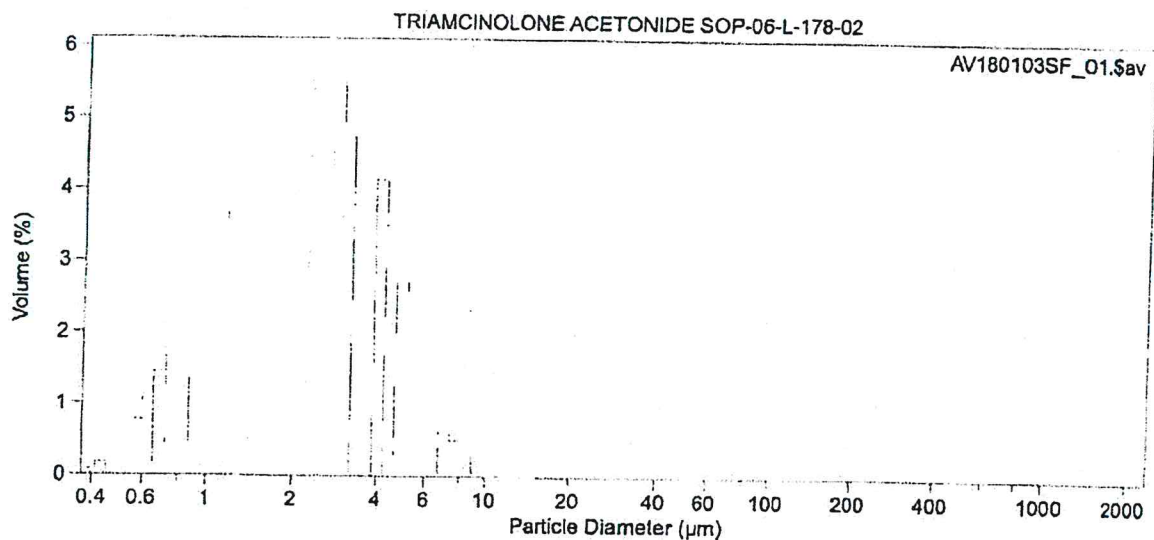
File name: C:\LS13320\samples\CERT\_18\Newchem\Triamcinolone Acetonide\AV180103SF\_01.\$av  
File ID: AV180103SF  
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-02  
Operator: Silvia Mele  
Comment: Prodotto finito  
Sample info: Lotto NY1697 per Newchem in lavorazione 18S0103  
Compliance: CONFORME 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\18010309SF\_01.\$is  
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\18010310SF\_01.\$is  
C:\LS13320\samples\Newchem\Triamcinolone Acetonide\18010311SF\_01.\$is



Volume Statistics (Arithmetic)

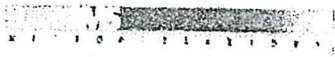
AV180103SF\_01.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%  
Mean: 2.450 µm  
Median: 2.123 µm  
Mode: 2.539 µm

d<sub>10</sub>: 0.911 µmd<sub>50</sub>: 2.123 µmd<sub>90</sub>: 4.431 µm

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2018/7/7



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| Particle<br>Diameter<br>$\mu\text{m}$ | AV180103SF<br>_01.\$av<br>Volume<br>% < |
|---------------------------------------|-----------------------------------------|
| 5                                     | 94.0                                    |
| 8                                     | 99.5                                    |
| 10                                    | 99.99                                   |
| 15                                    | 100                                     |
| 20                                    | 100                                     |
| 45                                    | 100                                     |
| 50                                    | 100                                     |
| 60                                    | 100                                     |
| 100                                   | 100                                     |
| 200                                   | 100                                     |

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2018/07