

# NEWCHEM

Lot: 0059920

## CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NA1931M**

Manuf. date: **07/2020**

Expiration date: **07/2025**

| 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.                     | +126°    |
| Water content                  | NMT 2.0 %                                | 1,4 %    |
| Loss on drying (USP)           | NMT 1.5%                                 | 1,13 %   |
| <b>ASSAY</b>                   |                                          |          |
| Assay HPLC (EP)                | 97.5% - 102.0% (anhydrous substance)     | 98,90 %  |
| <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%                                | 0,22 %   |
| <b>RESIDUAL SOLVENTS</b>       |                                          |          |
| Acetone                        | NMT 1000 ppm                             | 111 ppm  |
| Methanol                       | NMT 900 ppm                              | 148 ppm  |
| Dichloromethane                | NMT 400 ppm                              | N.D.     |

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

03/08/2020

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**Approved** by Qualified Person

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

Sede legale/registered at: Via E. De Amicis 47 - 20123 Milano - Italy Tel. +39 02 581516 [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 12437910156

Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co. Ltd.

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| Tests                | Specifications | Results |
|----------------------|----------------|---------|
| <b>PARTICLE SIZE</b> |                |         |
| Particle size        | 99% < 10 µm    | 100 %   |
| Particle size        | 70% < 5 µm     | 95 %    |

Complies with cEP and cUSP

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**CERTIFICATO ANALISI N° S20P00671**

Prodotto: TRIAMCINOLONE ACETONIDE 99%<10µm-70%<5µm  
Cliente: NEWCHEM S.P.A.  
N° lotto: TAM0002N NA1931  
Codice:  
Quantità: 69,03 Kg.  
Lavorazione IMS N° 20S0114  
Codice IMS 420103  
Metodo di analisi SOP-06-L-178-03  
Versione Specifica 10  
N° di analisi AV200114SF  
Strumento LS13320 MLM

| Saggio                             | Specifiche      | Risultati |
|------------------------------------|-----------------|-----------|
| <b>Identificazione (a o b o c)</b> |                 |           |
| NIR                                | Positiva        | N.A.      |
| Punto di fusione                   | [274 - 278] ° C | 275 ° C   |
| <b>Granulometria</b>               |                 |           |
| %<5µm                              | >= 70 %         | 94,5 %    |
| %<10µm                             | >= 99 %         | 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 20/07/2020

Il responsabile QA

Michele Urso Russo Data 20/07/2020

*Il presente certificato è firmato elettronicamente*

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



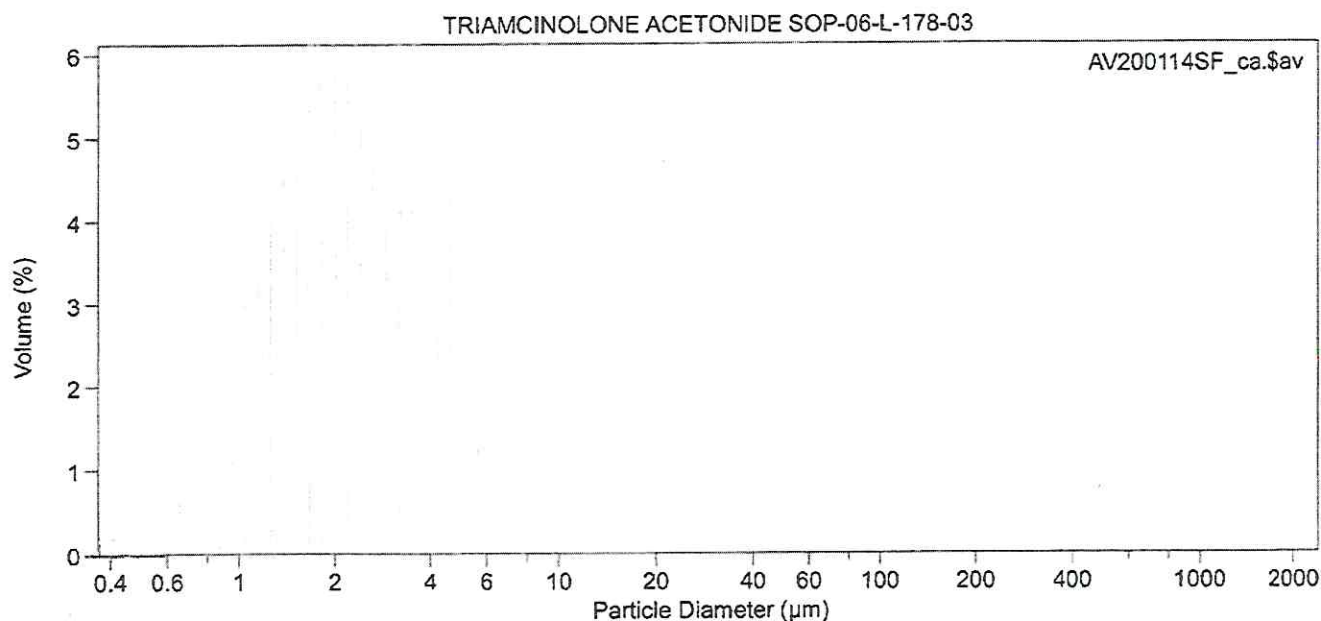
File name: C:\LS13320\samples\CERT\_20\Newchem\Triamcinolone Acetonide\AV200114SF\_ca.\$av  
 File ID: AV200114SF  
 Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-03  
 Operator: Silvia Mele  
 Comment: Prodotto finito  
 Sample info: Lotto TAM0002N-NA1931 per Newchem in lavorazione 20S0114  
 Compliance: 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\20011412SF\_01.\$ls  
 C:\LS13320\samples\Newchem\Triamcinolone Acetonide\20011413SF\_01.\$ls  
 C:\LS13320\samples\Newchem\Triamcinolone Acetonide\20011414SF\_01.\$ls



Volume Statistics (Arithmetic) AV200114SF\_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%  
 Mean: 2.393 µm  
 Median: 2.051 µm  
 Mode: 1.919 µm

d<sub>10</sub>: 0.873 µm d<sub>50</sub>: 2.051 µm d<sub>90</sub>: 4.543 µm

| Particle Diameter µm | AV200114SF_ca.\$av Volume % < |
|----------------------|-------------------------------|
| 5                    | 94.5                          |
| 8                    | 100                           |
| 10                   | 100                           |
| 15                   | 100                           |
| 20                   | 100                           |
| 45                   | 100                           |
| 50                   | 100                           |
| 60                   | 100                           |
| 100                  | 100                           |
| 200                  | 100                           |

17 AUG. 2020

*[Signature]*

*[Signature]*