

# NEWCHEM

## CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NW2748M**

Manuf. date: **11/2016**

Expiration date: **11/2021**

| Tests                          | Specifications                           | Results  |
|--------------------------------|------------------------------------------|----------|
| <b>GENERAL TESTS</b>           |                                          |          |
| 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%                                 | 1.12 %   |
| Loss on drying (USP)           | NMT 1.5%                                 | 1.33 %   |
| Specific optical rotation (EP) | +110° - +117° (anhydrous substance)      | +112°    |
| Specific rotation (USP)        | +118° - +130° o.d.b.                     | +127°    |
| Heavy metals (USP)             | NMT 25 ppm                               | Complies |
| <b>ASSAY</b>                   |                                          |          |
| Assay HPLC (EP)                | 97.5% - 102.0% (anhydrous substance)     | 98.50 %  |
| <b>IMPURITIES</b>              |                                          |          |
| Impurity B                     | NMT 0.2 %                                | 0.08 %   |
| Impurity C                     | NMT 0.15%                                | 0.07 %   |
| Impurity E                     | NMT 0.15%                                | 0.08 %   |
| Each other single impurity     | NMT 0.10 %                               | N.Q.     |
| Total impurities               | NMT 0.5 %                                | 0.22 %   |
| Any individual impurity (USP)  | NMT 0.3%                                 | 0.07 %   |
| Total impurities (USP)         | NMT 0.8%                                 | 0.35 %   |
| <b>RESIDUAL SOLVENTS</b>       |                                          |          |
| Acetone                        | NMT 1000 ppm                             | 152 ppm  |
| Methanol                       | NMT 900 ppm                              | 311 ppm  |
| Dichloromethane                | NMT 400 ppm                              | N.D.     |

Complies with cEP and cUSP

Verona 18/12/2016  
NEWCHEM spa [www.newchemspa.com](http://www.newchemspa.com)

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Approved by QA Manager

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|----------------------|------------------|---------|
| <b>PARTICLE SIZE</b> |                  |         |
| Particle size        | NLT 70% < 5µm    | 88,30 % |
| Particle size        | NLT 99 % < 10 µm | 100 %   |

Complies with cEP and cUSP

Verona 19/12/2016

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## CERTIFICATO DI ANALISI

**Prodotto** TRIAMCINOLONE ACETONIDE  
**Cliente** NEWCHEM S.P.A.  
**N° lotto** NW2748  
**Codice** TAM0002N

**Quantità** Kg 62,460  
**Lavorazione IMS N°** 16S0105

**Codice IMS** 420103.01  
**Versione Specifica** 5

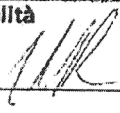
**N° Bollettino di analisi** 11601029  
**N° Analisi** AV160105SF  
**Metodo di analisi** SOP-06-L-178-02  
**Strumento** LS13320 MLM

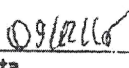
| Analisi             | Risultato | Specifica | U.M. |
|---------------------|-----------|-----------|------|
| Identificazione NIR | Positiva  | Positiva  | --   |
| %<10µm              | 100,00    | >= 99,00  | %    |
| %<5µm               | 88,30     | >= 70,00  | %    |

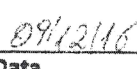
Note:

### 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



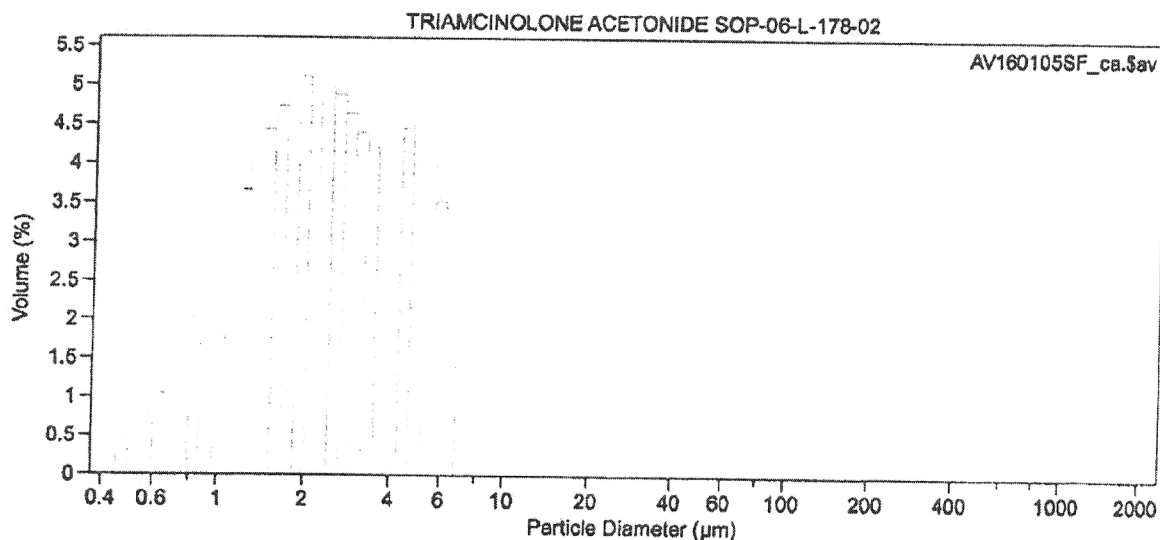


I.M.S. Micronizzazioni srl

File name: C:\LS13320\samples\CERT\_16\Newchem\Triamcinolone Acetonide\AV160105SF\_ca.\$av  
File ID: AV160105SF  
Sample ID: TRIAMCINOLONE ACETONIDE SOP-06-L-178-02  
Operator: Silvia Mele  
Comment: Prodotto finito  
Sample info: Lotto NW2748 per Newchem in lavorazione 16S0105  
Compliance: CONFORME / NON CONFORME N.A.  
Optical model: Fraunhofer.r780d  
LS 13 320 Micro Liquid Module  
Stirrer speed (Off)  
Fluid: Water

Average of 3 files:

C:\LS13320\samples\Newchem\Triamcinolone acetonide\16010509SF\_01.\$is  
C:\LS13320\samples\Newchem\Triamcinolone acetonide\16010510SF\_01.\$is  
C:\LS13320\samples\Newchem\Triamcinolone acetonide\16010511SF\_01.\$is



Volume Statistics (Arithmetic)

AV160105SF\_ca.\$av

Calculations from 0.375 µm to 2000 µm

Volume: 100%  
Mean: 2.686 µm  
Median: 2.261 µm  
Mode: 2.107 µm

d<sub>10</sub>: 0.935 µmd<sub>50</sub>: 2.261 µmd<sub>90</sub>: 5.176 µm

| Particle Diameter µm | AV160105SF_ca.\$av Volume % < |
|----------------------|-------------------------------|
| 5                    | 88.3                          |
| 8                    | 99.99                         |
| 10                   | 100                           |
| 15                   | 100                           |
| 20                   | 100                           |
| 45                   | 100                           |
| 50                   | 100                           |
| 60                   | 100                           |
| 100                  | 100                           |
| 200                  | 100                           |

*Roberto*  
*Desiderio*