

# NEWCHEM

## CERTIFICATE OF ANALYSIS TRIAMCINOLONE ACETONIDE MICRONIZED

Batch: **NE0996M**

Manuf. date: **04/2024**

**METAPHARMACEUTICAL**

Expiration date: **04/2029**

N DE LOTE:

**0121024**

**09/10/2024**

| 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.                     | +121°    |
| Water content                  | NMT 2.0 %                                | 1,6 %    |
| Loss on drying (USP)           | NMT 1.5%                                 | 0,98 %   |
| <b>ASSAY</b>                   |                                          |          |
| Assay HPLC (EP)                | 97.5% - 102.0% (anhydrous substance)     | 100,70 % |
| <b>RESIDUAL SOLVENTS</b>       |                                          |          |
| Acetone                        | NMT 1000 ppm                             | N.Q.     |
| Methanol                       | NMT 900 ppm                              | 38 ppm   |
| Dichloromethane                | NMT 400 ppm                              | N.D.     |
| <b>IMPURITIES</b>              |                                          |          |
| Impurity B                     | NMT 0.20%                                | N.Q.     |
| Impurity C                     | NMT 0.15%                                | N.Q.     |
| Impurity E                     | NMT 0.15%                                | 0,07 %   |
| Each other single impurity     | NMT 0.10 %                               | N.Q.     |
| Total impurities               | NMT 0.50 %                               | 0,07 %   |
| Any individual impurity (USP)  | NMT 0.30%                                | 0,05 %   |
| Total impurities (USP)         | NMT 0.80%                                | 0,11 %   |

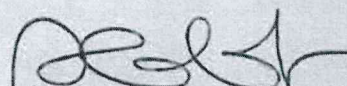
Complies with cEP and cUSP

NEWCHEM declares that: this batch was produced under GMP condition; the documentation relevant to this process has been reviewed by the Quality Unit

Verona

03/06/2024

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Approved by Qualified Person

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

Sede legale/registered at:

Via San Vittore, 39 - 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: [info@newchemspa.it](mailto:info@newchemspa.it) PEC: [newchemspa@legalmail.it](mailto:newchemspa@legalmail.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. IT12437910156

Company subject to direction and coordination of Zhejiang Xianju Pharmaceutical Co. Ltd.

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)

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| Tests                | Specifications | Results |
|----------------------|----------------|---------|
| <b>PARTICLE SIZE</b> |                |         |
| Particle size        | 99% < 10 µm    | 100 %   |
| Particle size        | 70% < 5 µm     | 92 %    |

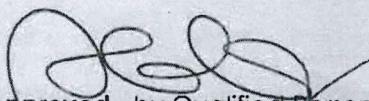
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## CERTIFICATO DI ANALISI GRANULOMETRICA

Analisi # 6 del 13/05/2024

| Informazioni Prodotto   |                         |
|-------------------------|-------------------------|
| Cliente                 | NEWCHEM                 |
| Nome Prodotto           | TRIAMCINOLONE ACETONIDE |
| Numero di lotto cliente | NE0996                  |
| Numero di lotto interno | L24225A1                |
| Data fine produzione    | 13/05/2024              |

| Strumentazione |                  |
|----------------|------------------|
| Marca          | Malvern          |
| Modello        | Mastersizer 3000 |
| Tecnica        | LALLS            |

| Metodo di Analisi     |                |
|-----------------------|----------------|
| Codice                | MGR160TRI031   |
| Mezzo disperdente     | ACQUA DEPURATA |
| Teoria di diffrazione | FRAUNHOFER     |

| Distribuzione Granulometrica |                |
|------------------------------|----------------|
| Specifiche richieste         | Risultati      |
| 99.0 % < 10 µm               | 99.89% < 10 µm |
| 70% < 5 µm                   | 91.86% < 5 µm  |

| Note                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Il lotto sopraindicato e ricevuto dal cliente al solo scopo di essere micronizzato, dal momento dell'arrivo alla fine produzione, è stato processato, analizzato e documentato in base al nostro Sistema Qualità gestito secondo le cGMP<br>Allegato stampato analisi |

| Data          | Firma Laboratorio        |
|---------------|--------------------------|
| 13/05/2024    | S. N.                    |
| Data/Firma QC | Data/Firma QP            |
| 11/05/2024    | 21/05/2024<br>S. Pastori |

Mod. MBR4/ATi



MICROCHEM S.R.L. a socio unico Via Turati 2 I - 29017 Fiorenzuola d'Arda (PC)  
T. +39 0523 98 11 30 F. +39 0523 94 29 35  
microchem@microchem.it www.microchem.it

P.Iva - CF - Reg. Imp 01026710333 R.E.A. PC 122208 Cap. Soc. € 93.600 I.V.  
Soggetta ad attività di direzione e coordinamento di AL.GA. Holding SA

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# Result Analysis Report

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## Measurement Details

Sample Name NEWCHEM TRIAMCINOLONE ACETONIDE  
Lot number NE0996 (L24225A1)  
SOP File Name Triamcinolone acetonide.msop  
Instrument Type Mastersizer3000  
Instrument Serial No. MAL1163532

## Measurement Details

Analysis Date Time 13/05/2024 21:29:11  
Measurement Date Time 13/05/2024 21:29:11  
Result Source Measurement  
Record Number 6  
Operator Name romanini

## Analysis

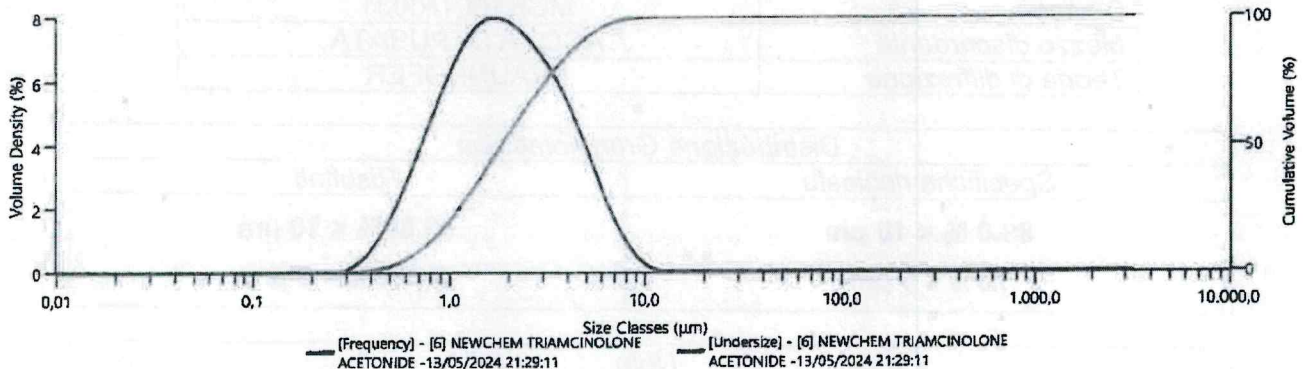
Particle Name Fraunhofer  
Particle Refractive Index 0,000  
Particle Absorption Index 0,000  
Particle Refractive Index Blue 0,000  
Particle Absorption Index Blue 0,000  
Dispersant Name Water  
Dispersant Refractive Index 1,330  
Scattering Model Fraunhofer  
Analysis Model General Purpose  
Background Measurement Time 12,00 s  
Sample Measurement Time 5,00 s  
Manual Stirrer Speed 2000  
Accessory Name Manual Accessory  
Are particles non-spherical? Yes

## Result

Weighted Residual 0,36 %  
Laser Obscuration 13,20 %  
Dv (10) 0,754 µm  
Dv (50) 1,849 µm  
Dv (90) 4,665 µm  
D [4;3] 2,343 µm  
Span 2,115  
Dv (70) 2,770 µm  
Dv (75) 3,099 µm  
Dv (85) 3,991 µm  
Dv (95) 5,745 µm  
Dv (98) 7,044 µm  
Dv (99) 7,909 µm  
Dv (99,9) 10,084 µm  
Dv (100) 11,161 µm

SK

## Frequency (compatible) and Undersize



## Result

| Size (µm) | % Volume Under | Size (µm) | % Volume Under | Size (µm) | % Volume Under | Size (µm) | % Volume Under | Size (µm) | % Volume Under | Size (µm) | % Volume Under | Size (µm) | % Volume Under | Size (µm) | % Volume Under |
|-----------|----------------|-----------|----------------|-----------|----------------|-----------|----------------|-----------|----------------|-----------|----------------|-----------|----------------|-----------|----------------|
| 0.010     | 0.00           | 0.550     | 3.42           | 2.000     | 54.04          | 5.500     | 94.05          | 14.500    | 100.00         | 30.000    | 100.00         | 70.000    | 100.00         | 120.000   | 100.00         |
| 0.020     | 0.00           | 0.600     | 4.75           | 2.200     | 58.88          | 6.000     | 95.82          | 15.000    | 100.00         | 32.500    | 100.00         | 72.000    | 100.00         | 130.000   | 100.00         |
| 0.030     | 0.00           | 0.750     | 9.86           | 2.300     | 61.09          | 7.000     | 97.94          | 16.000    | 100.00         | 35.000    | 100.00         | 74.000    | 100.00         | 135.000   | 100.00         |
| 0.050     | 0.00           | 0.800     | 11.79          | 2.500     | 65.16          | 7.500     | 98.62          | 16.500    | 100.00         | 36.500    | 100.00         | 75.000    | 100.00         | 140.000   | 100.00         |
| 0.060     | 0.00           | 0.900     | 15.76          | 2.600     | 67.01          | 8.000     | 99.07          | 17.000    | 100.00         | 38.000    | 100.00         | 80.000    | 100.00         | 149.000   | 100.00         |
| 0.080     | 0.00           | 1.000     | 19.81          | 2.800     | 70.47          | 9.000     | 99.63          | 18.000    | 100.00         | 40.000    | 100.00         | 85.000    | 100.00         | 150.000   | 100.00         |
| 0.090     | 0.00           | 1.100     | 23.93          | 3.000     | 73.55          | 9.500     | 99.78          | 18.500    | 100.00         | 45.000    | 100.00         | 90.000    | 100.00         | 160.000   | 100.00         |
| 0.100     | 0.00           | 1.200     | 27.98          | 3.300     | 77.62          | 10.000    | 99.89          | 19.000    | 100.00         | 48.000    | 100.00         | 95.000    | 100.00         | 180.000   | 100.00         |
| 0.200     | 0.00           | 1.400     | 35.55          | 3.500     | 80.05          | 10.500    | 99.94          | 20.000    | 100.00         | 50.000    | 100.00         | 96.000    | 100.00         | 190.000   | 100.00         |
| 0.240     | 0.00           | 1.500     | 39.08          | 3.800     | 83.17          | 11.000    | 99.98          | 22.000    | 100.00         | 55.000    | 100.00         | 100.000   | 100.00         | 200.000   | 100.00         |
| 0.380     | 0.40           | 1.700     | 45.60          | 4.000     | 85.08          | 12.000    | 100.00         | 24.000    | 100.00         | 56.000    | 100.00         | 103.000   | 100.00         |           |                |
| 0.450     | 1.27           | 1.800     | 48.59          | 4.500     | 88.94          | 13.000    | 100.00         | 25.000    | 100.00         | 60.000    | 100.00         | 110.000   | 100.00         |           |                |
| 0.500     | 2.24           | 1.900     | 51.40          | 5.000     | 91.86          | 14.000    | 100.00         | 28.000    | 100.00         | 65.000    | 100.00         | 115.000   | 100.00         |           |                |

Operator Notes ANALISI FINALE (2 GOCCE TWEEN 80 + 2' US)



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Mastersizer - v3.81  
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L24225A1 Triamcinolone Ac

Created: 12/03/2019  
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# Result Analysis Report



Signature

Record Number

Sample Name

Signature State

Signatory

Signature Date

6 NEWCHEM TRIAMCINOLONE ACETONIDE

Signed MICROCHEM\yomanini 13/05/2024 21:31:49 +02:00

Locked MICROCHEM\testi 14/05/2024 06:55:18 +02:00



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