

# NEWCHEM

## CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **NC2574M**

Manuf. date: **10/2022**

**METAPHARMACEUTICAL**

N DE LOTE:

**0040723**

Expiration date: **10/2027**

*af 11/01/2023*

| 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 |
| Loss on drying (EP)      | NMT 0.5 %                                | 0,13 %   |
| Loss on drying (USP)     | NMT 0.3 %                                | 0,13 %   |
| Identification UV (cUSP) | Positive                                 | Positive |
| <b>ASSAY</b>             |                                          |          |
| Assay HPLC (EP)          | 97.5% - 102.0% o.d.b.                    | 100,5 %  |
| Assay HPLC (USP)         | 98.0% - 102.0% o.d.b.                    | 99,7 %   |
| <b>RESIDUAL SOLVENTS</b> |                                          |          |
| Acetone                  | NMT 5000 ppm                             | 268 ppm  |
| Methanol                 | NMT 1000 ppm                             | 43 ppm   |
| Isopropyl ether          | NMT 500 ppm                              | N.D.     |
| Butyraldehyde            | NMT 170 ppm                              | N.Q.     |
| Pyridine                 | NMT 200 ppm                              | N.D.     |
| Tetrahydrofuran          | NMT 360 ppm                              | N.D.     |
| <b>IMPURITIES cEP</b>    |                                          |          |
| Impurity A               | NMT 0.2 %                                | 0,10 %   |
| Impurity D               | NMT 0.20 %                               | N.Q.     |
| Impurity L               | NMT 0.2 %                                | N.Q.     |
| Impurity K               | NMT 0.2 %                                | 0,05 %   |
| Unspecified impurities   | NMT 0.10 %                               | N.Q.     |
| Total impurities         | NMT 0.50 %                               | 0,16 %   |

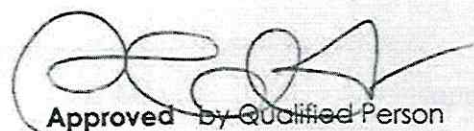
Complies with cEP and cUSP

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

Verona

17/03/2023

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Approved By Qualified Person

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

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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>IMPURITIES cEP</b>                           |                 |            |
| Epimer A                                        | 40.0% - 51.0 %  | 48,5 %     |
| <b>IMPURITIES cUSP</b>                          |                 |            |
| 16 $\alpha$ -hydroxyprednisolone                | NMT 0.20 %      | 0,10 %     |
| Budesonide acetaldehyde acetal (epimers)        | NMT 0.10 %      | N.D.       |
| D-Homobudesonide                                | NMT 0.10 %      | N.D.       |
| Desonide                                        | NMT 0.10 %      | N.Q.       |
| 21-dehydrobudesonide (epimers)                  | NMT 0.07 %      | N.Q.       |
| IMP E (14,15-dehydrobudesonide)                 | NMT 0.10 %      | N.Q.       |
| IMP L (11-ketobudesonide)                       | NMT 0.20 %      | N.Q.       |
| IMP G (1,2-dehydrobudesonide) epimers           | NMT 0.10 %      | N.Q.       |
| Budesonide 21-butyrate                          | NMT 0.10 %      | N.D.       |
| Budesonide 21-acetate                           | NMT 0.10 %      | N.Q.       |
| Each other single impurity                      | NMT 0.10 %      | N.Q.       |
| Total specified impurities                      | NMT 0.40 %      | 0,10 %     |
| Total unspecified impurities                    | NMT 0.4 %       | N.Q.       |
| Epimer A                                        | 40.0 % - 51.0 % | 48,5 %     |
| <b>MICROBIOLOGIC TESTS</b>                      |                 |            |
| TAMC                                            | NMT 1000 cfu/g  | < 10 cfu/g |
| TYMC                                            | NMT 100 cfu/g   | < 10 cfu/g |
| Enterobacteria and other gram-negative bacteria | Absent          | Absent     |
| Escherichia Coli                                | Absent          | Absent     |
| Salmonella                                      | Absent          | Absent     |

Complies with cEP and cUSP

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|----------------------------|-----------------|---------|
| <b>MICROBIOLOGIC TESTS</b> |                 |         |
| Pseudomonas Aeruginosa     | Absent          | Absent  |
| Staphylococcus Aureus      | Absent          | Absent  |
| Clostridia                 | Absent          | Absent  |
| Candida Albicans           | Absent          | Absent  |
| <b>PARTICLE SIZE</b>       |                 |         |
| Particle size              | 100 % NMT 10 µm | 100 %   |
| Particle size              | 99.5% ≤ 5 µm    | 100 %   |

Complies with cEP and cUSP

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## Particle Size Distribution Report

Measurement file name: \\nc-srv-fslab\CQ147-malvern\Measurement Data\CQ\Budesonide\NC2574M\_PF.mea

Measurement date and time : venerdì 10 marzo 2023 15:27:56

Analysis date and time : venerdì 10 marzo 2023 15:27:58

Operator name : alessandro.adami

Name of editor : alessandro.adami

Operator Notes : authorship

Sample Name : Budesonide\_Micro

Sample bulk lot ref : NC2574M

Source type :

Instrument serial number : MAL1039317

Instrument kernel version : 4.01

Instrument firmware version : 2.01

Software version : 5.61

Particle name : Fraunhofer

Particle refractive index : 0.000

Particle absorption index : 0

Particle refractive index - blue : 0.000

Particle absorption index - blue : 0

Dispersant name : Water

Dispersant refractive index : 1.330

Analysis sensitivity : Normal

Analysis model : General purpose

Measurement integration time : 10000

Background integration time : 10000

Obscuration range - lower : 5.0

Obscuration range - upper : 20.0

Accessory name : Hydro 2000µP (A)

Pump speed : 2500

Ultrasonic level : 50

Obscuration : 5.78

Residual - weighted : 0.609

Result source : Averaged

Average result records : "11,12,13,14,15"

Concentration : 0.0023 % Vol

Span : 1.189

Uniformity : 0.365

Beam length : 1.35

Size range: 0.020 to 2000.000 µm

Result transform type :

Specific surface area : 3.88 m²/g

D [3, 2] - Surface weighted mean : 1.545 µm

D [4, 3] - Volume weighted mean : 1.879 µm

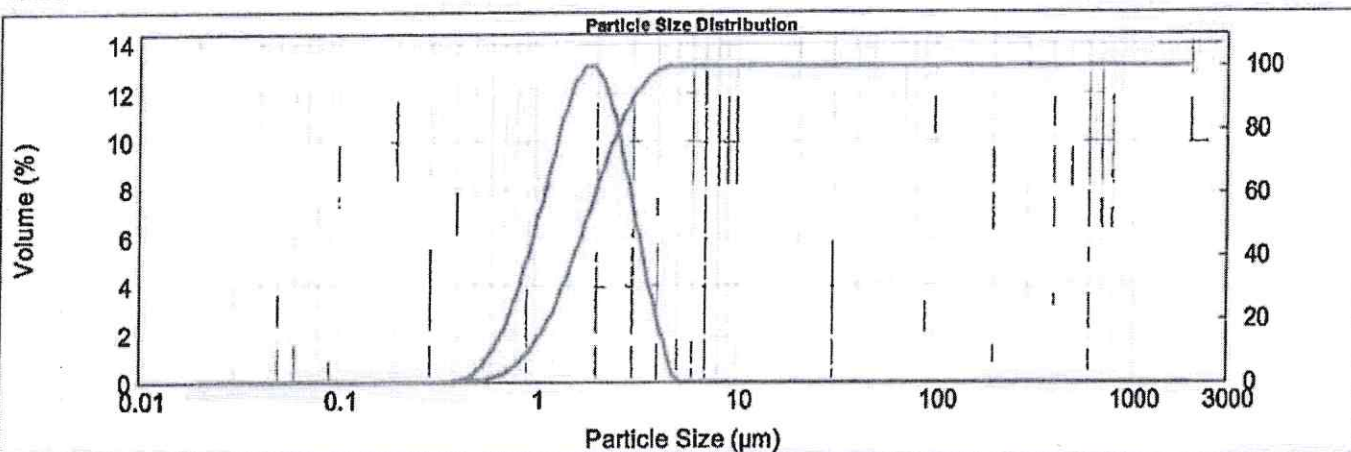
Percentage below  
10.00 µm : 100.00%  
PASS

Percentage below 5.00  
µm : 100.00%  
PASS

D(0.90) : 3.02 µm

D(0.50) : 1.75 µm

D(0.10) : 0.94 µm



Budesonide Micro, venerdì 10 marzo 2023 15:27:56

| Size (µm) | Vol Under % | Size (µm) | Vol Under % | Size (µm) | Vol Under % | Size (µm) | Vol Under % | Size (µm) | Vol Under % | Size (µm) | Vol Under % | Size (µm) | Vol Under % | Size (µm) | Vol Under % |
|-----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|-----------|-------------|
| 1.000     | 12.46       | 15.000    | 100.00      | 29.000    | 100.00      | 43.000    | 100.00      | 57.000    | 100.00      | 71.000    | 100.00      | 85.000    | 100.00      | 100.000   | 100.00      |
| 2.000     | 61.58       | 16.000    | 100.00      | 30.000    | 100.00      | 44.000    | 100.00      | 58.000    | 100.00      | 72.000    | 100.00      | 86.000    | 100.00      | 101.000   | 100.00      |
| 3.000     | 88.75       | 17.000    | 100.00      | 31.000    | 100.00      | 45.000    | 100.00      | 59.000    | 100.00      | 73.000    | 100.00      | 87.000    | 100.00      | 102.000   | 100.00      |
| 4.000     | 98.56       | 18.000    | 100.00      | 32.000    | 100.00      | 46.000    | 100.00      | 60.000    | 100.00      | 74.000    | 100.00      | 88.000    | 100.00      | 103.000   | 100.00      |
| 5.000     | 100.00      | 19.000    | 100.00      | 33.000    | 100.00      | 47.000    | 100.00      | 61.000    | 100.00      | 75.000    | 100.00      | 89.000    | 100.00      | 104.000   | 100.00      |
| 6.000     | 100.00      | 20.000    | 100.00      | 34.000    | 100.00      | 48.000    | 100.00      | 62.000    | 100.00      | 76.000    | 100.00      | 90.000    | 100.00      | 105.000   | 100.00      |
| 7.000     | 100.00      | 21.000    | 100.00      | 35.000    | 100.00      | 49.000    | 100.00      | 63.000    | 100.00      | 77.000    | 100.00      | 91.000    | 100.00      | 106.000   | 100.00      |
| 8.000     | 100.00      | 22.000    | 100.00      | 36.000    | 100.00      | 50.000    | 100.00      | 64.000    | 100.00      | 78.000    | 100.00      | 92.000    | 100.00      | 107.000   | 100.00      |
| 9.000     | 100.00      | 23.000    | 100.00      | 37.000    | 100.00      | 51.000    | 100.00      | 65.000    | 100.00      | 79.000    | 100.00      | 93.000    | 100.00      | 108.000   | 100.00      |
| 10.000    | 100.00      | 24.000    | 100.00      | 38.000    | 100.00      | 52.000    | 100.00      | 66.000    | 100.00      | 80.000    | 100.00      | 94.000    | 100.00      | 109.000   | 100.00      |
| 11.000    | 100.00      | 25.000    | 100.00      | 39.000    | 100.00      | 53.000    | 100.00      | 67.000    | 100.00      | 81.000    | 100.00      | 95.000    | 100.00      | 110.000   | 100.00      |
| 12.000    | 100.00      | 26.000    | 100.00      | 40.000    | 100.00      | 54.000    | 100.00      | 68.000    | 100.00      | 82.000    | 100.00      | 96.000    | 100.00      | 111.000   | 100.00      |
| 13.000    | 100.00      | 27.000    | 100.00      | 41.000    | 100.00      | 55.000    | 100.00      | 69.000    | 100.00      | 83.000    | 100.00      | 97.000    | 100.00      | 112.000   | 100.00      |
| 14.000    | 100.00      | 28.000    | 100.00      | 42.000    | 100.00      | 56.000    | 100.00      | 70.000    | 100.00      | 84.000    | 100.00      | 98.000    | 100.00      | 113.000   | 100.00      |