

NEWCHEM

METAPHARMACEUTICAL CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

N DE LOTE:

0111022

Batch: NB2836M

Manuf. date: 10/2021

23/10/2022

Expiration date: 10/2026

Tests	Specifications	Results
GENERAL TESTS		
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 %	0.20 %
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	100,4 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.Q.
Methanol	NMT 1000 ppm	67 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.
IMPURITIES cEP		
Impurity A	NMT 0.2 %	0,12 %
Impurity D	NMT 0.20 %	0,05 %
Impurity L	NMT 0.2 %	0,05 %
Impurity K	NMT 0.2 %	N.Q.
Unspecified impurities	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0,22 %
Epimer A	40.0% - 51.0 %	48,7 %
MICROBIOLOGIC TESTS		
TAMC	NMT 1000 cfu/g	< 10 cfu/g

Complies with cEP

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

Version 02 dated 30/08/2022

Verona

15/06/2022

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Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

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

Stabilimenti/factories:

Via Roveggia 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568 ✉ info@newchemspa.it

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NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **NB2836M**

Manuf. date: **10/2021**

Expiration date: **10/2026**

Tests	Specifications	Results
MICROBIOLOGIC TESTS		
TYMC	NMT 100 cfu/g	< 10 cfu/g
Escherichia Coli	Absent	Absent
Salmonella	Absent	Absent
Pseudomonas Aeruginosa	Absent	Absent
Staphylococcus Aureus	Absent	Absent
Clostridia	Absent	Absent
Candida Albicans	Absent	Absent
Enterobacteria and other gram-negative bacteria	Absent	Absent
PARTICLE SIZE		
Particle size	100 % NMT 10 µm	100 %
Particle size	99.5% ≤ 5 µm	100 %

Complies with cEP

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Particle Size Distribution Report

MASTERSIZER

Measurement file name: \\nc-srv-fs\lab\CQ098-malvern\Measurement Data\CQ\Budesonide\NB2836M.mea

Measurement date and time: lunedì 30 maggio 2022 10:55:32

Analysis date and time: lunedì 30 maggio 2022 10:55:34

Operator name: maria.grillo

Name of editor: maria.grillo

Operator Notes: Authorship

Sample Name: Budesonide BSA Micro

Sample bulk lot ref: NB2836M

Source type: Prodotto finito

Instrument serial number: MAL101392

Instrument kernel version: 1.02

Instrument firmware version: 1.07

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: 8.0

Accessory name: Hydro 2000µP (A)

Pump speed: 2500

Ultrasonic level: 50

Obscuration: 6.80

Residual - weighted: 0.533

Result source: Averaged

Average result records: *30,31,32,33,34*

Concentration: 0.0024 % Vol

Span: 1.171

Uniformity: 0.363

Beam length: 1.35

Size range: 0.020 to 2000.000 µm

Result transform type:

Specific surface area: 4.27 m²/g

D [3, 2] - Surface weighted mean: 1.407 µm

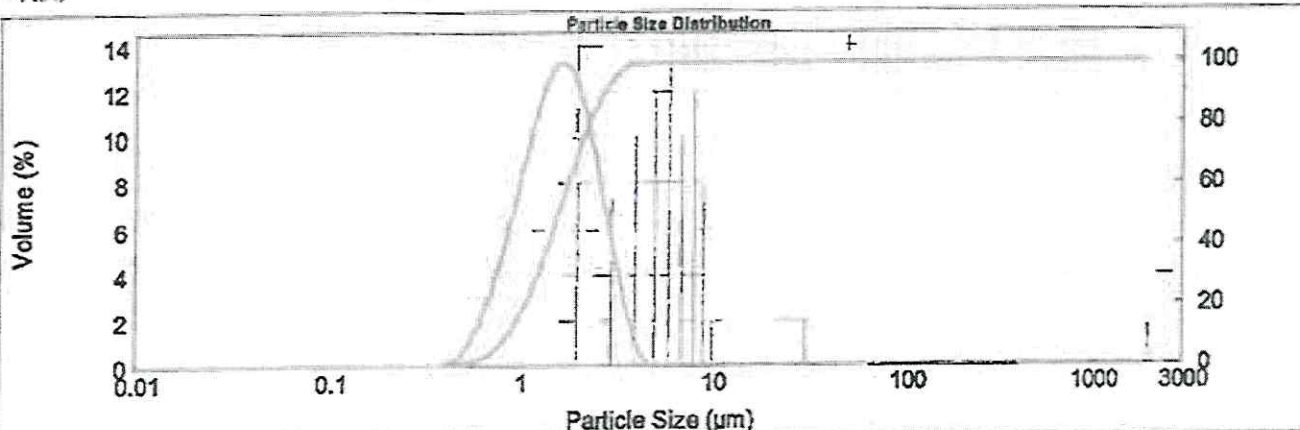
D [4, 3] - Volume weighted mean: 1.697 µm

Percentage below
10.00 µm: 100.00%
PASS

Percentage below 5.00
µm: 100.00%
PASS

D [0.10]: 1.50 µm

D [0.10]: 3.00 µm



Budesonide BSA Micro, lunedì 30 maggio 2022 10:55:32

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	16.00	15.000	100.00	29.000	100.00	43.000	100.00	57.000	100.00	71.000	100.00	85.000	100.00		
2.000	70.19	16.000	100.00	30.000	100.00	44.000	100.00	58.000	100.00	72.000	100.00	86.000	100.00		
3.000	94.19	17.000	100.00	31.000	100.00	45.000	100.00	59.000	100.00	73.000	100.00	87.000	100.00		
4.000	96.73	18.000	100.00	32.000	100.00	46.000	100.00	60.000	100.00	74.000	100.00	88.000	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		
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		
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		
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		
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		
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		
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		
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		
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		
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		