

NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

METAPHARMACEUTICAL

N° DE LOTE:

0080921

Batch: **NB1509M**

Manuf. date: **05/2021**

Expiration date: **05/2026**

03/07/21

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 %	0,12 %
Loss on drying (USP)	NMT 0.3 %	0,12 %
Identification UV (cUSP)	Positive	Positive
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	100,6 %
Assay HPLC (USP)	98.0% - 102.0% o.d.b.	100,3 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.D.
Methanol	NMT 1000 ppm	31 ppm
Isopropyl ether	NMT 500 ppm	N.D.
Butyraldehyde	NMT 170 ppm	N.D.
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 %	N.Q.
Impurity L	NMT 0.2 %	N.Q.
Impurity K	NMT 0.2 %	N.Q.
Unspecified impurities	NMT 0.10 %	N.Q.

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

29/07/2021

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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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IMPURITIES CEP		
Total impurities	NMT 0.50 %	0,12 %
Epimer A	40.0% - 51.0 %	47,7 %
IMPURITIES cUSP		
16 α -hydroxyprednisolone	NMT 0.20 %	0,11 %
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.Q.
Budesonide 21-acetate	NMT 0.10 %	0,06 %
Each other single impurity	NMT 0.10 %	N.Q.
Total specified impurities	NMT 0.40 %	0,17 %
Total unspecified impurities	NMT 0.4 %	N.Q.
Epimer A	40.0 % - 51.0 %	47,7 %
MICROBIOLOGIC TESTS		
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

Complies with cEP and cUSP

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MICROBIOLOGIC TESTS		
Salmonella sp	Absent	Absent
Pseudomonas Aeruginosa	Absent	Absent
Staphylococcus Aureus	Absent	Absent
Clostridia	Absent	Absent
Candida Albicans	Absent	Absent
PARTICLE SIZE		
Particle size	100 % NMT 10 µm	100 %
Particle size	99.5% ≤ 5 µm	100 %

Complies with cEP and cUSP

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CERTIFICATO DI ANALISI GRANULOMETRICA

Analisi # 7 del 28/06/2021

Informazioni Prodotto	
Cliente	NEWCHEM
Nome Prodotto	BUDESONIDE
Numero di lotto cliente	NB1509
Numero di lotto interno	L21409A1
Data fine produzione	28/06/2021

Strumentazione	
Marca	Malvern
Modello	Mastersizer 3000
Tecnica	LALLS

Metodo di Analisi	
Codice	MGR665BUD171
Mezzo disperdente	ACQUA DEPURATA
Teoria di diffrazione	FRAUNHOFER

Distribuzione Granulometrica	
Specifiche richieste	Risultati
100% < 10 μm	100% < 10 μm
99.5% < 5 μm	100% < 5 μm
d(90) $\leq$ 2.8 μm	d(90) = 2.494 μm

Note
Il lotto sopraindicato è 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.
Allegato stampato analisi

Data	Firma Laboratorio
28/06/2021	<i>[Firma]</i>
Data/Firma QC	Data/Firma QP
28/06/2021 <i>[Firma]</i>	06/07/2021 <i>S. Pastori</i> QUALIFIED PERSON Sarah Pastori

Mod. MBR4/A71



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microchem@microchem.it www.microchem.it

P.Iva - CF - Reg. Imp 01026710333 R.E.A. PC 122206 Cap. Soc. € 93.600 i.v.
Soggetta ad attività di direzione e coordinamento di AL.GA. Holding SA



Result Analysis Report

MCH MICROCHEM
The Microanalyst since 1978

Measurement Details

Sample Name NEWCHEM BUDESONIDE
Lot number NB1509 (L21409A1)
SOP File Name Budesonide3.msop
Instrument Type Mastersizer3000
Instrument Serial No. MAL1230885

Measurement Details

Analysis Date Time 28/06/2021 19:30:13
Measurement Date Time 28/06/2021 19:30:13
Result Source Measurement
Record Number 7
Operator Name montanari

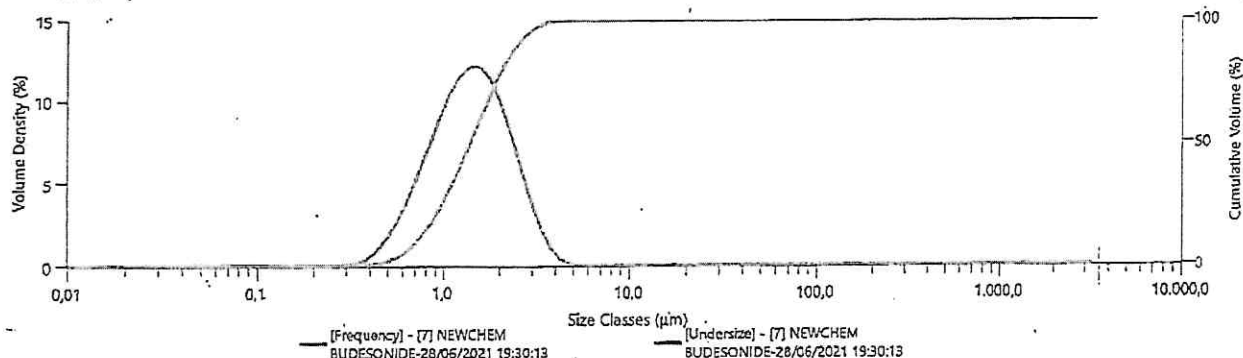
Analysis

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 0,22 %
Laser Obscuration 28,67 %
Dv (10) 0,718 µm
Dv (50) 1,382 µm
Dv (90) 2,494 µm
D [4;3] 1,511 µm
Span 1,285
Dv (70) 1,785 µm
Dv (75) 1,914 µm
Dv (85) 2,253 µm
Dv (95) 2,878 µm
Dv (98) 3,325 µm
Dv (99) 3,583 µm
Dv (99,9) 4,348 µm
Dv (100) 4,572 µm

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	0,530	3,16	2,000	77,89	5,500	100,00	14,500	100,00	38,000	100,00	70,000	100,00	120,000	100,00
0,020	0,00	0,600	4,74	2,200	83,74	6,000	100,00	15,000	100,00	32,500	100,00	72,000	100,00	132,000	100,00
0,030	0,00	0,750	11,54	2,300	86,11	7,000	100,00	16,000	100,00	35,000	100,00	74,000	100,00	135,000	100,00
0,050	0,00	0,800	14,30	2,500	90,09	7,500	100,00	16,500	100,00	35,500	100,00	75,000	100,00	140,000	100,00
0,060	0,00	0,900	20,14	2,600	91,63	8,000	100,00	17,000	100,00	36,000	100,00	76,000	100,00	145,000	100,00
0,080	0,00	1,000	26,31	2,800	94,29	9,000	100,00	18,000	100,00	40,000	100,00	80,000	100,00	150,000	100,00
0,090	0,00	1,100	32,73	3,000	96,06	9,500	100,00	18,500	100,00	45,000	100,00	90,000	100,00	160,000	100,00
0,100	0,00	1,200	39,09	3,300	97,89	10,000	100,00	19,000	100,00	48,000	100,00	95,000	100,00	165,000	100,00
0,150	0,00	1,400	51,05	3,500	98,74	10,500	100,00	20,000	100,00	50,000	100,00	100,000	100,00	170,000	100,00
0,200	0,00	1,500	56,53	3,800	99,38	11,000	100,00	22,000	100,00	55,000	100,00	105,000	100,00	200,000	100,00
0,250	0,00	1,700	66,33	4,000	99,70	12,000	100,00	24,000	100,00	58,000	100,00	108,000	100,00		
0,300	0,00	1,800	70,60	4,500	99,96	13,000	100,00	25,000	100,00	60,000	100,00	110,000	100,00		
0,400	1,25	1,900	74,52	5,000	100,00	14,000	100,00	26,000	100,00	65,000	100,00	115,000	100,00		

Operator Notes ANALISI FINALE (2 GOCCE TWEEN 80 + 3' US)

Malvern

Malvern Instruments Ltd.
www.malvern.com

Mastersizer - v3.81
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L21409A1 Budesonide

Created: 12/03/2019
Printed: 28/06/2021 21:02

Result Analysis Report



Signature				
Record Number	Sample Name	Signature State	Signatory	Signature Date
7	NEWCHEM, BUDESONIDE	Signed	MICROCHEM\montanari	28/06/2021 19:30:31 +02:00
		Locked	MICROCHEM\delmatti	28/06/2021 21:02:19 +02:00



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