

NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **NB1943M**

Manuf. date: **06/2021**

METAPHARMACEUTICAL

Expiration date: **02/2026**

N DE LOTE:

0250921

27/02/2021

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.	99,9 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.D.
Methanol	NMT 1000 ppm	N.D.
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 %	N.Q.
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

04/08/2021

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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

Via Parco del Ticino 10 - 27028 San Martino Siccomario - Pavia - Italy Tel. +39 0382 521027 Fax +39 0382 490570 info@newchemspa.it

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IMPURITIES cEP		
Total impurities	NMT 0.50 %	N.Q.
Epimer A	40.0% - 51.0 %	48,5 %
IMPURITIES cUSP		
16 α -hydroxyprednisolone	NMT 0.20 %	N.Q.
Budesonide acetaldehyde acetal (epimers)	NMT 0.10 %	N.D.
D-Homobudesonide	NMT 0.10 %	N.D.
Desonide	NMT 0.10 %	N.D.
21-dehydrobudesonide (epimers)	NMT 0.07 %	N.D.
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.D.
Each other single impurity	NMT 0.10 %	N.Q.
Total specified impurities	NMT 0.40 %	N.Q.
Total unspecified impurities	NMT 0.4 %	N.Q.
Epimer A	40.0 % - 51.0 %	48,5 %
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

Complies with cEP and cUSP

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MICROBIOLOGIC TESTS		
Escherichia Coli	Absent	Absent
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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MICROCHEM
The Micronization since 1978

13 LUG. 2021
MUL. CUPA
16.00.11

CERTIFICATO DI ANALISI GRANULOMETRICA

Analisi # 6 del 08/07/2021

Informazioni Prodotto	
Cliente	NEWCHEM
Nome Prodotto	BUDESONIDE
Numero di lotto cliente	NB1943
Numero di lotto interno	L21429A1
Data fine produzione	08/07/2021

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) = 2.500 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
08/07/2021	<i>Margherita Braga</i>
Data/Firma QC	Data/Firma QP
08/07/2021 <i>F. X. L. Monti</i>	12/07/2021 <i>M. Braga</i> DEPUTY QUALIFIED PERSON Margherita Braga

Mod. MBR4/A71

MICROCHEM S.R.L. a socio unico Via Turati 2 I - 29017 Florenzuola d'Arda (PC)
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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



08/07/21

Result Analysis Report

13 LUG. 2021



Measurement Details

Sample Name NEWCHEM BUDESONIDE
Lot number NB1943 (L21429A1)
SOP File Name Budesonide3.msop
Instrument Type Mastersizer3000
Instrument Serial No. MAL1230885

Measurement Details

Analysis Date Time 08/07/2021 06:25:25
Measurement Date Time 08/07/2021 06:25:25
Result Source Measurement
Record Number 6
Operator Name sommi

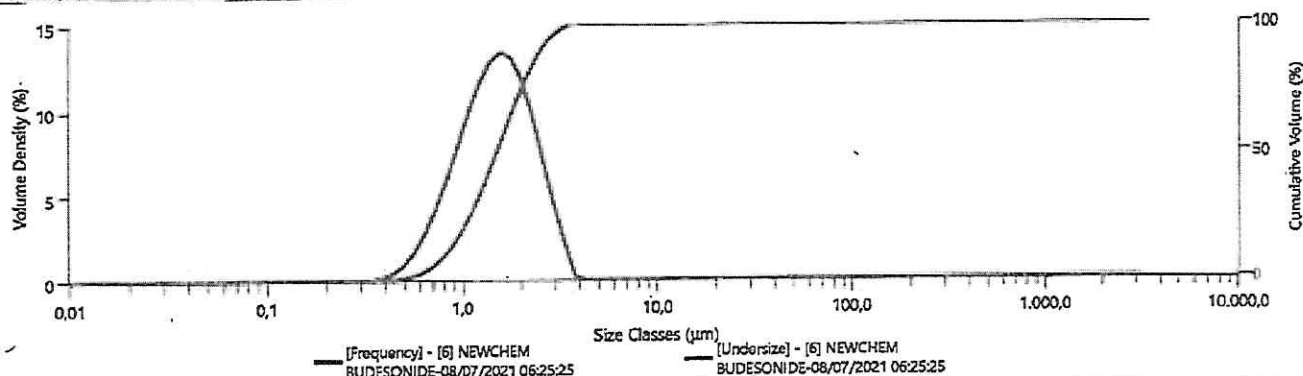
Analysis

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 0,31 %
Laser Obscuration 15,72 %
Dv (10) 0,804 µm
Dv (50) 1,480 µm
Dv (90) 2,500 µm
D [4:3] 1,575 µm
Span 1,146
Dv (70) 1,863 µm
Dv (75) 1,986 µm
Dv (85) 2,290 µm
Dv (95) 2,807 µm
Dv (98) 3,113 µm
Dv (99) 3,321 µm
Dv (99,9) 3,533 µm
Dv (100) 3,949 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	0,590	1,57	2,000	75,53	5,500	100,00	14,500	100,00	30,000	100,00	70,000	100,00	120,000	100,00
0,020	0,00	0,600	2,56	2,200	82,45	6,000	100,00	15,000	100,00	32,500	100,00	72,000	100,00	130,000	100,00
0,030	0,00	0,750	7,55	2,300	85,27	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	9,79	2,500	90,00	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	14,77	2,600	91,81	8,000	100,00	17,000	100,00	36,000	100,00	80,000	100,00	149,000	100,00
0,080	0,00	1,000	20,32	2,800	94,93	8,500	100,00	18,000	100,00	40,000	100,00	85,000	100,00	150,000	100,00
0,090	0,00	1,100	26,44	3,000	96,93	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	32,77	3,300	98,91	10,000	100,00	19,000	100,00	48,000	100,00	95,000	100,00	180,000	100,00
0,200	0,00	1,400	45,22	3,500	99,76	10,500	100,00	20,000	100,00	50,000	100,00	100,000	100,00	190,000	100,00
0,240	0,00	1,500	51,15	3,600	99,99	11,000	100,00	22,000	100,00	55,000	100,00	105,000	100,00	200,000	100,00
0,380	0,04	1,700	62,12	4,000	100,00	12,000	100,00	24,000	100,00	60,000	100,00	110,000	100,00		
0,450	0,30	1,800	67,03	4,500	100,00	13,000	100,00	25,000	100,00	65,000	100,00	115,000	100,00		
0,500	0,50	1,900	71,56	5,000	100,00	14,000	100,00	26,900	100,00						

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



Malvern Instruments Ltd.
www.malvern.com

Mastersizer - v3.81
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20161071 21

L21429A1 Budesonide

Created: 12/03/2019
Printed: 08/07/2021 08:45

Result Analysis Report



Signature				
Record Number	Sample Name	Signature State	Signatory	Signature Date
6	NEWCHEM BUDESONIDE	Signed	MICROCHEM\sommi	08/07/2021 06:26:44 +02:00
		Locked	MICROCHEM\delmatti	08/07/2021 08:45:58 +02:00

