

NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **NA1554M**

Manuf. date: **05/2020**

Expiration date: **05/2025**

Tests	Specifications	Results
GENERAL TESTS		
Appearance of the powder	White or almost white crystalline powder	Complies
Solubility	Complies	Complies
Identification IR (EP/USP)	Positive	Positive
Loss on drying (EP)	NMT 0.5 %	0.05 %
Loss on drying (USP)	NMT 0.3 %	0.05 %
Identification UV (USP)	Positive	Positive
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	100.2 %
Assay HPLC (USP)	98.0% - 102.0% o.d.b.	100.1 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.D.
Methanol	NMT 1000 ppm	47 ppm
Isopropyl ether	NMT 500 ppm	N.D.
Butiric aldehyde	NMT 170 ppm	N.Q.
Pyridine	NMT 200 ppm	N.D.
Tetrahydrofuran	NMT 360 ppm	N.D.
PARTICLE SIZE		
Particle size	100 % NMT 10 µm	100 %
Particle size	NLT 99.5% ≤ 5 µm	99.98 %
IMPURITIES cEP		
Impurity A	NMT 0.2 %	0.14 %
Impurity D	NMT 0.2 %	N.Q.
Impurity L	NMT 0.2 %	N.Q.
Impurity K	NMT 0.2 %	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

NEWCHEM spa www.newchemspa.com

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

Capitale sociale Euro 1.000.000 I.v. R.E.A. Mi n. 1559675 - iscrizione registro imprese MI - codice fiscale 02477040968

Veron. 15/07/2020

Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co., Ltd.

Stabilimenti/factories:

Via Roveggla 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568

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

info@newchemspa.it

Approved by QA Manager

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Tests	Specifications	Results
IMPURITIES cEP		
Unspecified impurities	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0.14 %
Epimer A	40.0 % - 51.0 %	46.6 %
IMPURITIES cUSP		
16 α -Hydroxyprednisolone	NMT 0.20 %	0.14 %
Budesonide acetaldehyde acetal (epimers)	NMT 0.10 %	N.D.
D-Homobudesonide	NMT 0.10 %	N.Q.
Desonide	NMT 0.10 %	N.D.
21-dehydrobudesonide (epimers)	NMT 0.07 %	N.D.
IMP E (11,15-dehydrobudesonide)	NMT 0.10 %	N.Q.
IMP L (11-ketobudesonide)	NMT 0.20 %	N.Q.
IMP G (1,2-dehydrobudesonide) epimers	NMT 0.10 %	0.06 %
Budesonide 21-acetate (epimeres)	NMT 0.10 %	N.Q.
Budesonide 21-butyrate	NMT 0.10 %	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total specified impurities	NMT 0.40 %	0.20 %
Total unspecified impurities	NMT 0.40 %	N.Q.
Epimer A	40.0 % - 51.0 %	46.5 %
MICROBIOLOGIC TESTS cUSP		
TAMC	NMT 1000 UFC/g	< 10 Cfu/g
TYMC	NMT 100 Ufc/g	< 10 Cfu/g
Gram negative bacteria	Absent	Absent
Escherichia Coli	Absent	Absent

Complies with cEP and cUSP

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NEWCHEM spa www.newchemspa.com

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

Capital registered: Euro 1,000,000 i.v. R.E.A. MI n. 1559575 - iscrizione registro imprese MI - codice fiscale 04744740158

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 8201563 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

Verona 05/2020

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Tests

MICROBIOLOGIC TESTS cUSP

	Specifications	Results
Salmonella	Absent	Absent
Pseudomonas aeruginosa	Absent	Absent
Staphylococcus Aureus	Absent	Absent
Clostridia	Absent	Absent
Candida Albicans	Absent	Absent

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

NEWCHEM spa www.newchemspa.com

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

Capital 767.500.000 I.v. R.E.A. MI n. 1559975 - Iscritta al Registro Imprese MI - cod. fiscale 07675000968
Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co. Ltd.

Stabilimenti/factories:

Via Rovaglia 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



MICROCHEM
The Microtechnology 1978

26 GIU. 2020
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CERTIFICATO DI ANALISI GRANULOMETRICA

Analisi # 4 del 23/06/2020

Informazioni Prodotto	
Cliente	NEWCHEM
Nome Prodotto	BUDESONIDE
Numero di lotto cliente	NA1554
Numero di lotto interno	L20383A1
Data fine produzione	23/06/2020

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	99.98% < 5 µm
d(90) ≤ 2.8 µm	d(90) = 2.571 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.

Allegato stampato analisi

Data	Firma Laboratorio
23.06.2020	
Data/Firma QC	Data/Firma QP
23/06/2020 	23/06/2020
	QUALIFIED PERSON Sarah Pastori

Mod. MCH/A71



MICROCHEM S.R.L. Via Turchi 2 I - 29017 Fiorenzuola d'Arda (PC)
T. +39 0523 98 11 30 F. +39 0523 94 29 35

P.Iva - CF - Reg. Imp 0126710333 R.E.A. PC 122208 Cap. Soc. € 93.800 I.v.

microchem@microchem.it www.microchem.it

Società a socio unico - Soggetta ad attività di direzione e coordinamento di ALGA, Holding SA



Result Analysis Report

26 GIU. 2020
CCPV

MCH MICROCHEM
The Micronisation since 1976

Measurement Details

Sample Name NEWCHEM BUDESONIDE
Lot number NA1554 (L20383A1)
SOP File Name Budesonide3.msop
Instrument Type Mastersizer3000
Instrument Serial No. MALI230885

Measurement Details

Analysis Date Time 23/06/2020 13:36:21
Measurement Date Time 23/06/2020 13:36:21
Result Source Measurement
Record Number 4
Operator Name montanari

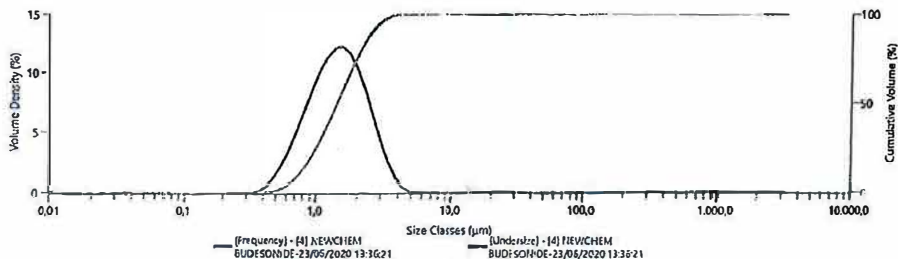
Analysis

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 0,28 %
Laser Obscuration 18,82 %
Dv (10) 0,745 µm
Dv (50) 1,420 µm
Dv (90) 2,571 µm
D [4:3] 1,557 µm
Span 1,286
Dv (70) 1,833 µm
Dv (75) 1,968 µm
Dv (85) 2,315 µm
Dv (95) 2,970 µm
Dv (98) 3,434 µm
Dv (99) 3,754 µm
Dv (99,9) 4,525 µm
Dv (100) 5,162 µm

Frequency (compatible) and Undersize



Result

Size (µm)	N Volume Under	Size (µm)	N Volume Under	Size (µm)	N Volume Under	Size (µm)	N Volume Under	Size (µm)	N Volume Under	Size (µm)	N Volume Under	Size (µm)	N Volume Under	Size (µm)	N Volume Under
0.010	0.00	0.150	2.55	1.000	76.10	5.500	100.00	1.4500	100.00	332.00	100.00	1000.00	100.00	3162.00	100.00
0.030	0.00	0.300	8.94	1.250	82.18	6.500	100.00	1.5849	100.00	354.81	100.00	1122.02	100.00	3548.10	100.00
0.050	0.00	0.450	19.78	1.500	86.63	7.000	100.00	1.7083	100.00	380.18	100.00	1197.93	100.00	3801.80	100.00
0.070	0.00	0.600	32.85	1.750	89.83	7.500	100.00	1.8183	100.00	408.91	100.00	1258.93	100.00	4089.10	100.00
0.100	0.00	0.800	48.85	2.000	92.47	8.000	100.00	1.9053	100.00	436.51	100.00	1333.54	100.00	4365.10	100.00
0.150	0.00	1.000	56.43	2.250	93.95	8.500	100.00	1.9778	100.00	464.16	100.00	1412.54	100.00	4641.60	100.00
0.200	0.00	1.500	67.10	2.500	95.24	9.000	100.00	2.0463	100.00	492.88	100.00	1497.53	100.00	4928.80	100.00
0.300	0.00	2.000	75.00	3.000	96.84	10.000	100.00	2.1544	100.00	531.44	100.00	1600.00	100.00	5314.40	100.00
0.400	0.00	2.500	80.00	3.500	97.59	10.500	100.00	2.2543	100.00	571.76	100.00	1718.28	100.00	5717.60	100.00
0.500	0.00	3.000	83.85	4.000	98.09	11.000	100.00	2.3470	100.00	613.10	100.00	1842.03	100.00	6131.00	100.00
0.600	0.00	3.500	86.63	4.500	98.49	11.500	100.00	2.4328	100.00	655.50	100.00	1971.48	100.00	6555.00	100.00
0.700	0.00	4.000	88.66	5.000	98.79	12.000	100.00	2.5119	100.00	700.00	100.00	2118.75	100.00	7000.00	100.00
0.800	0.00	4.500	89.83	5.500	98.99	12.500	100.00	2.5843	100.00	746.41	100.00	2283.86	100.00	7464.10	100.00
0.900	0.00	5.000	90.83	6.000	99.10	13.000	100.00	2.6509	100.00	794.93	100.00	2467.38	100.00	7949.30	100.00
1.000	0.00	5.500	91.63	6.500	99.19	13.500	100.00	2.7120	100.00	845.60	100.00	2669.90	100.00	8456.00	100.00
1.200	0.00	6.500	93.95	7.500	99.32	14.500	100.00	2.8184	100.00	909.29	100.00	2894.80	100.00	9092.90	100.00
1.500	0.00	8.000	95.24	8.500	99.40	15.500	100.00	2.9243	100.00	977.00	100.00	3144.33	100.00	9770.00	100.00
1.800	0.00	9.000	96.09	9.500	99.45	16.500	100.00	3.0298	100.00	1048.58	100.00	3414.35	100.00	10485.80	100.00
2.000	0.00	10.000	96.49	10.500	99.48	17.000	100.00	3.1259	100.00	1123.59	100.00	3707.40	100.00	11235.90	100.00
2.500	0.00	12.500	97.59	12.500	99.55	18.500	100.00	3.2619	100.00	1214.84	100.00	4033.86	100.00	12148.40	100.00
3.000	0.00	15.000	98.09	15.000	99.59	20.000	100.00	3.3884	100.00	1313.54	100.00	4404.13	100.00	13135.40	100.00
3.500	0.00	17.500	98.49	17.500	99.62	22.000	100.00	3.5091	100.00	1420.45	100.00	4820.74	100.00	14204.50	100.00
4.000	0.00	20.000	98.79	20.000	99.64	24.000	100.00	3.6244	100.00	1536.20	100.00	5285.41	100.00	15362.00	100.00
4.500	0.00	22.500	98.99	22.500	99.66	26.000	100.00	3.7347	100.00	1661.26	100.00	5800.76	100.00	16612.60	100.00
5.000	0.00	25.000	99.10	25.000	99.67	28.000	100.00	3.8400	100.00	1796.00	100.00	6369.31	100.00	17960.00	100.00
5.500	0.00	27.500	99.19	27.500	99.68	30.000	100.00	3.9413	100.00	1940.80	100.00	7003.44	100.00	19408.00	100.00
6.000	0.00	30.000	99.28	30.000	99.69	32.000	100.00	4.0388	100.00	2096.00	100.00	7707.76	100.00	20960.00	100.00
6.500	0.00	32.500	99.32	32.500	99.70	34.000	100.00	4.1326	100.00	2262.00	100.00	8486.88	100.00	22620.00	100.00
7.000	0.00	35.000	99.36	35.000	99.71	36.000	100.00	4.2229	100.00	2438.40	100.00	9345.60	100.00	24384.00	100.00
7.500	0.00	37.500	99.39	37.500	99.72	38.000	100.00	4.3098	100.00	2625.60	100.00	10298.56	100.00	26256.00	100.00
8.000	0.00	40.000	99.41	40.000	99.73	40.000	100.00	4.3934	100.00	2823.20	100.00	11350.56	100.00	28232.00	100.00
8.500	0.00	42.500	99.43	42.500	99.74	42.000	100.00	4.4738	100.00	3031.60	100.00	12506.56	100.00	30316.00	100.00
9.000	0.00	45.000	99.45	45.000	99.75	44.000	100.00	4.5511	100.00	3251.20	100.00	13772.64	100.00	32512.00	100.00
9.500	0.00	47.500	99.46	47.500	99.76	46.000	100.00	4.6254	100.00	3482.40	100.00	15154.56	100.00	34824.00	100.00
10.000	0.00	50.000	99.47	50.000	99.77	48.000	100.00	4.6968	100.00	3734.80	100.00	16658.24	100.00	37348.00	100.00
11.000	0.00	55.000	99.50	55.000	99.78	52.000	100.00	4.8194	100.00	4098.40	100.00	18398.08	100.00	40984.00	100.00
12.000	0.00	60.000	99.52	60.000	99.79	56.000	100.00	4.9384	100.00	4484.80	100.00	20384.64	100.00	44848.00	100.00
13.000	0.00	65.000	99.54	65.000	99.80	60.000	100.00	5.0540	100.00	4894.40	100.00	22634.24	100.00	48944.00	100.00
14.000	0.00	70.000	99.56	70.000	99.81	64.000	100.00	5.1663	100.00	5328.00	100.00	25064.64	100.00	53280.00	100.00
15.000	0.00	75.000	99.57	75.000	99.82	68.000	100.00	5.2755	100.00	5786.40	100.00	27682.56	100.00	57864.00	100.00
16.000	0.00	80.000	99.58	80.000	99.83	72.000	100.00	5.3817	100.00	6270.40	100.00	30494.40	100.00	62704.00	100.00
17.000	0.00	85.000	99.59	85.000	99.84	76.000	100.00	5.4850	100.00	6780.80	100.00	33506.24	100.00	67808.00	100.00
18.000	0.00	90.000	99.60	90.000	99.85	80.000	100.00	5.5855	100.00	7318.40	100.00	36734.72	100.00	73184.00	100.00
19.000	0.00	95.000	99.61	95.000	99.86	84.000	100.00	5.6833	100.00	7883.20	100.00	40195.84	100.00	78832.00	100.00
20.000	0.00	100.000	99.62	100.000	99.87	88.000	100.00	5.7785	100.00	8476.00	100.00	43904.64	100.00	84760.00	100.00

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



Malvern Instruments Ltd.
www.malvern.com

Mastersizer - v3.81
Page 1 of 2

L20383A1 Budesonide

Created: 12/03/2019
Printed: 23/06/2020 15:41

Result Analysis Report



Signature

Record Number	Sample Name	Signature State	Signatory	Signature Date
4	NEWCHEM BUDESONIDE	Signed	MICROCHEM\montanari	23/06/2020 13:36:41 +02:00
		Locked	MICROCHEM\pallastrelli	23/06/2020 15:40:08 +02:00

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Page 2 of 2

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