

NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **NA2911M**Manuf. date: **09/2020**Expiration date: **09/2025**

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 %	0,13 %
Loss on drying (USP)	NMT 0.3 %	0,13 %
Identification UV (USP)	Positive	Positive
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	101,1 %
Assay HPLC (USP)	98.0% - 102.0% o.d.b.	101,0 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.D.
Methanol	NMT 1000 ppm	159 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	100,00 %
IMPURITIES cEP		
Impurity A	NMT 0.2 %	0,12 %
Impurity D	NMT 0.2 %	N.Q.
Impurity L	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

Verona

29/10/2020

Page 1 of 3


 Approved by Qualified Person
NEWCHEM spa www.newchemspa.comSede 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.itVia 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		
Impurity K	NMT 0.2 %	N.Q.
Unspecified impurities	NMT 0.10 %	N.Q.
Total impurities	NMT 0.50 %	0,12 %
Epimer A	40.0 % - 51.0 %	45,6 %
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.Q.
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 %	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 %	0,18 %
Total unspecified impurities	NMT 0.40 %	N.Q.
Epimer A	40.0 % - 51.0 %	45,6 %
MICROBIOLOGIC TESTS cUSP		
TAMC	NMT 1000 UFC/g	< 10 Cfu/g
TYMC	NMT 100 Ufc/g	< 10 Cfu/g

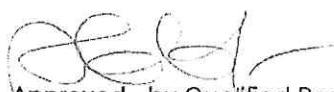
Complies with cEP and cUSP

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MICROBIOLOGIC TESTS cUSP		
Gram negative bacteria	Absent	Absent
Escherichia Coli	Absent	Absent
Salmonella	Absent	Absent
Pseudomonas aeruginosa	Absent	Absent
Staphylococcus Aureus	Absent	Absent
Clostridia	Absent	Absent
Candida Albicans	Absent	Absent

Complies with cEP and cUSP

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19 OTT. 2020

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MICROCHEM
The Micronization since 1978**CERTIFICATO DI ANALISI GRANULOMETRICA****Analisi # 4 del 14/10/2020****Informazioni Prodotto**

Cliente	NEWCHEM
Nome Prodotto	BUDESONIDE
Numero di lotto cliente	NA2911
Numero di lotto interno	L20628A1
Data fine produzione	15/10/2020

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	100% < 5 μm
d(90) $\leq$ 2.8 μm	d(90) = 2.532 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

15/10/2020

Data/Firma QC

15/10/2020

S. Pastori

Firma Laboratorio

S. Pastori

Data/Firma QP

15/10/2020

S. Pastori

QUALIFIED PERSON
Sarah Pastori

Mod. MGR4/A71



MICROCHEM S.R.L. Via Turati 2 I - 29017 Fiorenzuola d'Arda (PC)

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Società a socio unico - Soggetta ad attività di direzione e coordinamento di AL.GA. Holding SA



22 OTT. 2020

Result Analysis Report

19 OTT. 2020
MCH MICROCHEM
The Microchem since 1978

Measurement Details

Sample Name NEWCHEM BUDESONIDE

Lot number NA2911 (L20628A1)

SOP File Name Budesonide3.msop

Instrument Type Mastersizer3000

Instrument Serial No. MAL1230885

Measurement Details

Analysis Date Time 14/10/2020 23:32:36

Measurement Date Time 14/10/2020 23:32:36

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 0,23 %

Laser Obscuration 15,58 %

Dv (10) 0,757 µm

Dv (50) 1,419 µm

Dv (90) 2,532 µm

D [4,3] 1,548 µm

Span 1,251

Dv (70) 1,821 µm

Dv (75) 1,951 µm

Dv (85) 2,288 µm

Dv (95) 2,915 µm

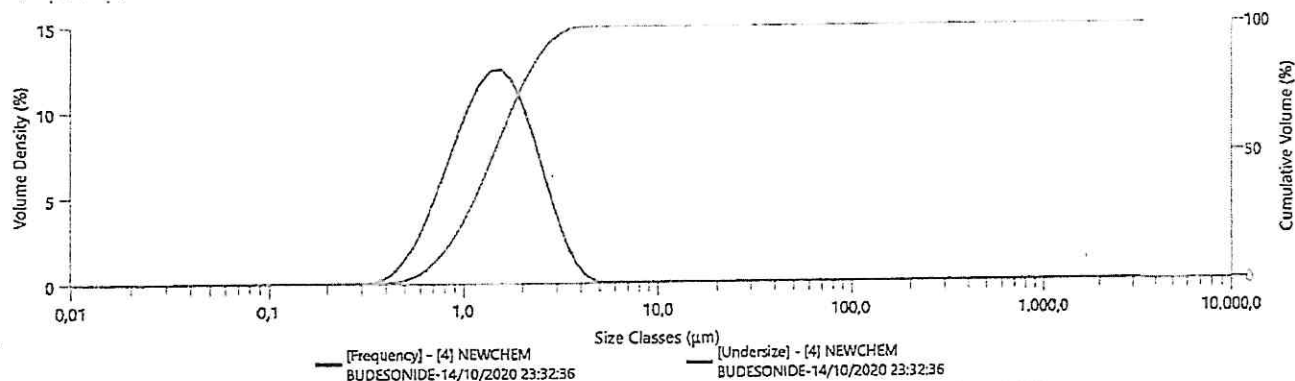
Dv (98) 3,360 µm

Dv (99) 3,630 µm

Dv (99,9) 4,373 µm

Dv (100) 4,574 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	0,550	2,26	2,000	76,69	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	3,57	2,200	82,81	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	9,70	2,300	85,29	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	12,30	2,500	89,48	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	17,91	2,600	91,10	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	23,54	2,800	93,91	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	30,34	3,000	95,78	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	36,74	3,200	97,72	10,000	100,00	19,000	100,00	48,000	100,00	95,000	100,00	165,000	100,00
0,200	0,00	1,400	48,91	3,500	98,63	10,500	100,00	20,000	100,00	50,000	100,00	96,000	100,00	170,000	100,00
0,240	0,00	1,500	54,53	3,800	99,32	11,000	100,00	22,000	100,00	55,000	100,00	100,000	100,00	200,000	100,00
0,380	0,00	1,700	64,66	4,000	99,67	12,000	100,00	24,000	100,00	60,000	100,00	103,000	100,00		
0,450	0,50	1,800	69,03	4,500	99,96	13,000	100,00	25,000	100,00	60,000	100,00	110,000	100,00		
0,500	1,21	1,900	72,17	5,000	100,00	14,000	100,00	28,900	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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L20628A1 Budesonide

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