

NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **ND0241M**

Manuf. date: **02/2023**

METAPHARMACEUTICAL

16/01/2024

Expiration date: **02/2028**

N DE LOTE:

0070124

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 %	0,14 %
Loss on drying (USP)	NMT 0.3 %	0,14 %
Identification UV (cUSP)	Positive	Positive
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	100,8 %
Assay HPLC (USP)	98.0% - 102.0% o.d.b.	100,9 %
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 %	0,08 %
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

08/06/2023

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[Signature]
Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

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Capitale sociale Euro 1.000.000 i.v. R.E.A. MI n. 1559575 iscrizione registro imprese MI, codice fiscale e partita IVA/vat it n. IT12437910156

Company subject to direction and coordination of Zhejiang Xianju Pharmaceutical Co. Ltd.

Stabilimenti/factories:

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IMPURITIES cEP		
Total impurities	NMT 0.50 %	0,08 %
Epimer A	40.0 % - 51.0 %	48,1 %
IMPURITIES cUSP		
16 α -hydroxyprednisolone	NMT 0.20 %	0,08 %
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.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.D.
Budesonide 21-acetate	NMT 0.10 %	N.Q.
Each other single impurity	NMT 0.10 %	N.Q.
Total specified impurities	NMT 0.40 %	0,08 %
Total unspecified impurities	NMT 0.4 %	N.Q.
Epimer A	40.0 % - 51.0 %	48,2 %
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

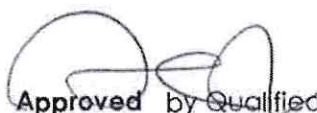
Complies with cEP and cUSP

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MICROBIOLOGIC TESTS		
Salmonella	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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Budesonide

Measurement Details

Operator Name enrico.scarpellini
Sample Name ND0241M
SOP File Name HydroMV.cfg

Measurement Details

Analysis Date Time 26/05/2023 14:31:29
Measurement Date Time 26/05/2023 14:31:29
Result Source Averaged

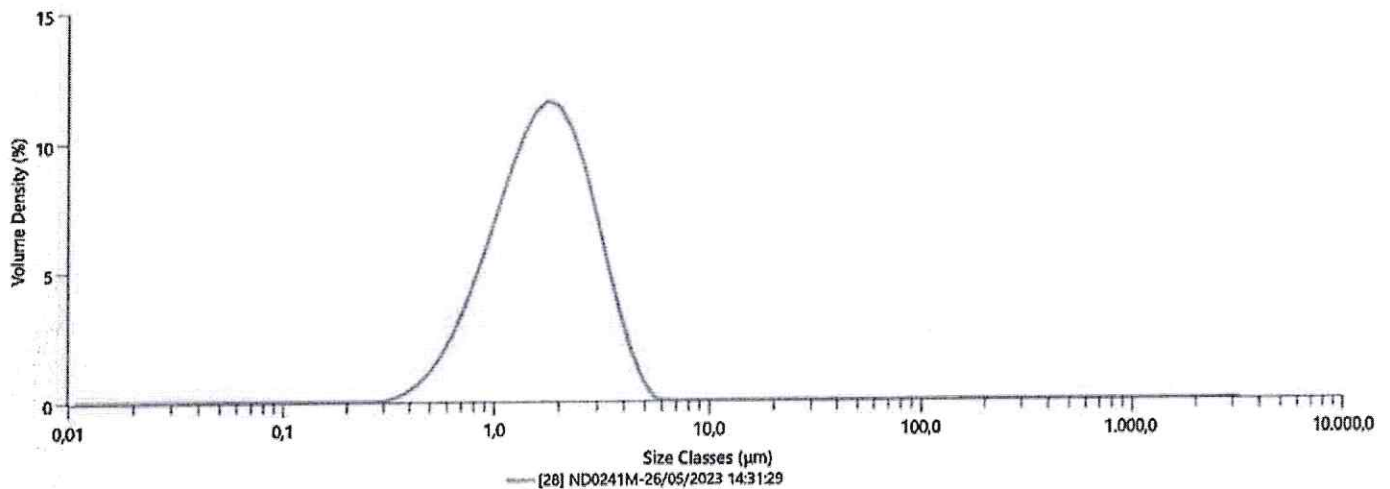
Analysis

Particle Name Default
Particle Refractive Index 0,000
Particle Absorption Index 0,000
Dispersant Name Water
Dispersant Refractive Index 1,330
Scattering Model Fraunhofer
Analysis Model General Purpose
Weighted Residual 0,38 %
Laser Obscuration 12,75 %

Result

Concentration 0,0026 %
Span 1,360
Uniformity 0,420
Specific Surface Area 4239 m²/kg
D [3;2] 1,415 µm
D [4;3] 1,827 µm
Dv (10) 0,811 µm
Dv (50) 1,668 µm
Dv (90) 3,080 µm
Volume Below (10) µm 100,00 %
Volume Below (5) µm 99,80 %

Frequency (compatible)



Result

Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In	Size (µm)	% Volume In
0,010	0,00	0,060	0,00	0,357	0,26	2,131	0,76	12,726	0,00	76,006	0,00	453,960	0,00	2711,357	0,00
0,011	0,00	0,066	0,00	0,403	0,51	2,421	7,55	14,458	0,00	86,335	0,00	515,772	0,00	3080,544	0,00
0,013	0,00	0,077	0,00	0,460	0,89	2,750	6,02	16,427	0,00	98,114	0,00	586,001	0,00	3500,000	0,00
0,015	0,00	0,088	0,00	0,523	1,42	3,125	4,37	18,664	0,00	111,473	0,00	665,793	0,00		
0,017	0,00	0,100	0,00	0,594	2,11	3,550	2,81	21,205	0,00	126,652	0,00	756,449	0,00		
0,019	0,00	0,113	0,00	0,675	2,97	4,034	1,52	24,092	0,00	143,897	0,00	859,450	0,00		
0,022	0,00	0,128	0,00	0,767	3,99	4,583	0,62	27,373	0,00	163,490	0,00	976,475	0,00		
0,024	0,00	0,146	0,00	0,872	5,14	5,207	0,00	31,100	0,00	185,752	0,00	1109,435	0,00		
0,028	0,00	0,166	0,00	0,991	6,35	5,916	0,00	35,335	0,00	211,044	0,00	1260,499	0,00		
0,032	0,00	0,188	0,00	1,125	7,54	6,722	0,00	40,146	0,00	239,780	0,00	1432,133	0,00		
0,036	0,00	0,214	0,00	1,279	8,58	7,637	0,00	45,613	0,00	272,430	0,00	1627,136	0,00		
0,041	0,00	0,243	0,00	1,453	9,33	8,677	0,00	51,823	0,00	309,525	0,00	1848,692	0,00		
0,046	0,00	0,276	0,00	1,651	9,67	9,858	0,00	58,880	0,00	351,670	0,00	2100,416	0,00		
0,053	0,00	0,314	0,11	1,875	9,48	11,201	0,00	66,897	0,00	399,555	0,00	2386,415	0,00		



Malvern Panalytical
www.malvernpanalytical.com

ND0241M

Mastersizer - v3.84

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Instrument Serial No: MAL1243587

21CFR Mode: Active

Record Number: 28

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