

Lot - 0020718

NEWCHEM

CERTIFICATE OF ANALYSIS BUDESONIDE MICRONIZED

Batch: **NY1307M**

Manuf. date: **05/2018**
Retest date: **06/2022**
Expiration date: **05/2023**

Tests	Specifications	Results
IMPURITIES cEP		
Unspecified impurities	NMT 0.10 %	0,06 %
Total impurities	NMT 0.50 %	0,24 %
Epimer A	40.0 % - 51.0 %	48,4 %
IMPURITIES cUSP		
16 α -Hydroxyprednisolone	NMT 0.20 %	0,07 %
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 %	0,08 %
Budesonide 21-acetate (epimeres)	NMT 0.10 %	N.Q.
Budesonide 21-butyrate	NMT 0.10 %	N.D.
Each other single impurity	NMT 0.10 %	N.Q.
Total specified impurities	NMT 0.40 %	0,15 %
Total unspecified impurities	NMT 0.40 %	N.Q.
Epimer A	40.0 % - 51.0 %	48,5 %
MICROBIOLOGIC TESTS cUSP		
TAMC	NMT 1000 UFC/g	10 Clu/g
TYMC	NMT 100 Ufc/g	< 10 Clu/g
Gram negative bacteria	Absent	Absent
Escherichia Coli	Absent	Absent
Salmonella	Absent	Absent

Complies with cEP and cUSP


Approved by QA Manager

Verona 12/06/2018
NEWCHEM spa www.newchemspa.com

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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 %	0,17 %
Loss on drying (USP)	NMT 0.3 %	0,17 %
Identification UV (USP)	Positive	Positive
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	100,3 %
Assay HPLC (USP)	98.0% - 102.0% o.d.b.	100,1 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.Q.
Methanol	NMT 1000 ppm	40 ppm
Isopropyl ether	NMT 500 ppm	N.D.
Bulfinic 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 %	0,06 %
Impurity L	NMT 0.2 %	N.Q.
Impurity K	NMT 0.2 %	N.Q.

Complies with cEP and cUSP


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Struttura produttiva:
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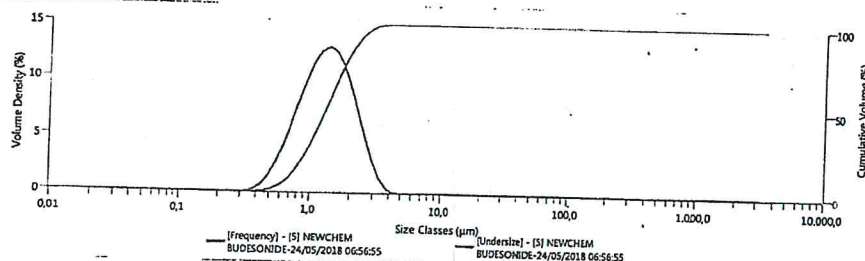
Measurement Details

Analysis Date Time 24/05/2018 06:56:55
Measurement Date Time 24/05/2018 06:56:55
Result Source Measurement
Record Number 5
Operator Name scapuzzi

Result

Weighted Residual 0.22 %
Laser Obscuration 21.80 %

Dv (10)	0,717 µm
Dv (50)	1,314 µm
Dv (90)	2,308 µm
D [4;3]	1,427 µm
Span	1,211
Dv (70)	1,674 µm
Dv (75)	1,791 µm
Dv (85)	2,087 µm
Dv (95)	2,641 µm
Dv (98)	3,022 µm
Dv (99)	3,272 µm
Dv (100)	4,027 µm



BUDESONIDE-24/05/2018 06:56:55

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Operator Notes ANALISI FINALE (2 gocce tween 80 + 3' US)

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Tests

MICROBIOLOGIC TESTS cUSP

Pseudomonas aeruginosa
Staphylococcus Aureus
Clostridia
Candida Albicans

Specifications

Absent
Absent
Absent
Absent

Results

Absent
Absent
Absent
Absent

Complies with cEP and cUSP

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