

NEWCHEM

METAPHARMACEUTICAL CERTIFICATE OF ANALYSIS

N DE LOTE:

0230624

BUDESONIDE MICRONIZED

Batch:

af
28/06/2024

NE1089M

Manuf. date: 04/2024

Expiration date: 04/2029

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 %	0,08 %
Loss on drying (USP)	NMT 0.3 %	0,08 %
Identification UV (cUSP)	Positive	Positive
ASSAY		
Assay HPLC (EP)	97.5% - 102.0% o.d.b.	100,4 %
Assay HPLC (USP)	98.0% - 102.0% o.d.b.	100,8 %
RESIDUAL SOLVENTS		
Acetone	NMT 5000 ppm	N.D.
Methanol	NMT 1000 ppm	49 ppm
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

22/05/2024

Page 1 of 3

Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

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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 %	N.Q.
Epimer A	40.0% - 51.0 %	46,9 %
IMPURITIES cUSP		
16 α -hydroxyprednisolone	NMT 0.20 %	N.Q.
Budesonide acetaldehyde acetal (epimers)	NMT 0.10 %	N.Q.
D-Homobudesonide	NMT 0.10 %	N.D.
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 %	N.Q.
Budesonide 21-butyrate	NMT 0.10 %	N.Q.
Budesonide 21-acetate	NMT 0.10 %	N.Q.
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 %	46,9 %
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	Absent	Absent
Pseudomonas Aeruginosa	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 1979

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OF ORIGINAL

08 MAR 2024

PO

CERTIFICATO DI ANALISI GRANULOMETRICA

Analisi # 8 del 03/05/2024

Informazioni Prodotto	
Cliente	NEWCHEM
Nome Prodotto	BUDESONIDE BSA
Numero di lotto cliente	NE1089
Numero di lotto interno	L24207A1
Data fine produzione	03/05/2024

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) = 2.675 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
03/05/2024	
Data/Firma QC	Data/Firma QP
03/05/2024 	03/05/2024 QUALIFIED PERSON

Mod. MBR4/A71



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Soggetta ad attività di direzione e coordinamento di AL.GA. Holding SA

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