

NEWCHEM

CERTIFICATE OF ANALYSIS

BETAMETHASONE DIPROPIONATE MICRONIZED

Batch: **ND1477M**

Manuf. date: **05/2023**

METAPHARMACEUTICAL

Expiration date: **05/2028**

N DE LOTE:

0510525

30/05/2025

Tests	Specifications	Results
GENERAL TESTS		
Appearance	White or almost white crystalline powder	Complies
Solubility (cEP/cUSP)	Complies	Complies
Identification IR (EP/USP)	Positive	Positive
Loss on drying	NMT 1,0 %	0,4 %
Specific rotation (EP)	+ 84° - + 88° o.d.b.	+85 °
Identification TLC (USP)	Positive	Positive
Specific rotation (USP)	+63° - +70° o.d.b.	+66 °
Residue on ignition	NMT 0,2 %	0,00 %
ASSAY		
HPLC Assay (EP)	to 97.0% from 102.0% o.d.b	98,1 %
Assay HPLC (USP)	97.0% - 103.0% o.d.b.	97,3 %
RESIDUAL SOLVENTS		
Methanol	NMT 300 ppm	N.D.
Acetone	NMT 1500 ppm	125 ppm
Isopropyl ether	NMT 2500 ppm	80 ppm
THF	NMT 72 ppm	N.D.
Pyridine	NMT 200 ppm	N.D.
Dichloromethane	NMT 600 ppm	N.D.
IMPURITIES cEP		
Impurity A	NMT 0.1%	N.D.
Impurity B	NMT 0.3%	0,09 %
Impurity C	NMT 0.5%	N.Q.
Impurity D	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

09/06/2023

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Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

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

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IMPURITIES cEP		
Impurity E	NMT 0.2%	N.Q.
Impurity G	NMT 0.2%	0,07 %
Impurity I	NMT 0.15 %	N.Q.
Impurity H	NMT 0.3%	N.Q.
Any other impurity (EP)	NMT 0.10%	0,06 %
Total impurities	NMT 1.0%	0,2 %
IMPURITIES cUSP		
Each single impurity (USP)	NMT 1.0%	0,09 %
Total impurities (USP)	NMT 2.0%	0,20 %
PARTICLE SIZE		
Particle size	NLT 99 % ≤ 20 µm	100 %

Complies with cEP and cUSP

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