

NEWCHEM

CERTIFICATE OF ANALYSIS PREDNICARBATE MICRONIZED

Batch:

NT0780M

Manuf. date: 04/2013

Retest date: 05/2016

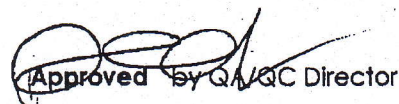
Expiration date: 04/2018

Tests	Specifications	Results
GENERAL TESTS		
Appearance	White or almost white crystalline powder	Complies
Solubility	Complies	Complies
Identification IR	Positive	Positive
Loss on drying (EP)	NMT 0.5 %	0,4 %
Specific rotation	+ 60° - + 66° o.d.b.	+64 °
Water content	NMT 0,5 %	0,3 %
ASSAY		
HPLC assay	97,0 % - 102,0 % o.d.b.	99,1 %
RESIDUAL SOLVENTS		
Dichloromethane	NMT 600 ppm	N.D.
Ethanol	NMT 3000 ppm	1278 ppm
Isopropyl ether	NMT 500 ppm	N.D.
THF	NMT 720 ppm	N.D.
Pyridine	NMT 200 ppm	29 ppm
IMPURITIES		
Imp.A - Prednisolone	NMT 0.5%	N.D.
Imp.B - Prednisolone-17-ethylcarbonate	NMT 0.5%	N.Q.
Imp.C - Prednisolone-21-propanoate	NMT 0.5%	0,05 %
Imp.D - Prednisolone-21-ethylcarbonate	NMT 0.5%	0,14 %
Imp.E - Prednisolone-21-acetate-17-ethylcarbonate	NMT 0.5%	N.Q.
Imp.F - 1,2-dihydroprednicarbate	NMT 1.0%	0,12 %
Imp.I - Prednisolone-17-methylcarbonate-21-prop.	NMT 0.15%	N.D.
Imp.L - Prednisolone-17-propylcarbonate-21-prop.	NMT 0.15%	N.D.
Imp.M - Prednisolone-17-ethylcarbonate-21-butyrate	NMT 0.15%	N.D.
Imp.P - Prednicarbate-11-propionate	NMT 0.15%	N.Q.
Each other unspecified impurities	NMT 0.10%	0,03 %

Complies with CEP

Verona, 21/05/2013

Page 1 of 2


Approved by QA/QC Director

NEWCHEM spa www.newchemspa.com

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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. 12437910156
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Batch: **NT0780M**

Manuf. date: **04/2013**

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Tests	Specifications	Results
IMPURITIES		
Total Impurities	NMT 2,0 %	0,4 %
PARTICLE SIZE		
Particle size	100 % $\leq 20 \mu\text{m}$	100 %
Particle size	NLT 90 % $< 5 \mu\text{m}$	96 %

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

44 67 0068

19/12/14
Director Técnico

Complies with CEP

Verona, 21/05/2013

Page 2 of 2


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