

NEWCHEM

CERTIFICATE OF ANALYSIS METHYLPREDNISOLONE

Batch: **NS1227**
Batch Producer: **1209003295**

Manuf. date: **05/2012**
Retest date: **05/2014**

Tests	Specifications	Results
GENERAL TESTS		
Appearance	White or almost white crystalline powder	Complies
Identification	Positive	Positive
Loss on drying	NMT 1.0 %	0.5 %
Sulphated ash	NMT 0.1 %	< 0.10 %
Specific rotation (EP)	+79° - +86° o.d.b.	+84°
Specific rotation (USP)	+79° - +86° o.d.b.	+83°
ASSAY		
UV assay	97.0 % - 103.0 % o.d.b.	98.4 %
HPLC assay	97.0% - 103.0% o.d.b.	100.0 %
RESIDUAL SOLVENTS		
Dichloromethane	NMT 500 ppm	N.D.
Methanol	NMT 1000 ppm	151 ppm
THF	NMT 720 ppm	450 ppm
IMPURITIES		
Prednisolone	NMT 0.5 %	N.Q.
Methylprednisolone acetate	NMT 0.2 %	N.Q.
Methylhydrocortisone	NMT 0.2 %	0.06 %
Methylprednisolone methyl 6 B isomer	NMT 0.2 %	N.Q.
Impurity RRT 0.92	NMT 0.2 %	0.07 %
Impurity RRT 1.83	NMT 0.2 %	N.Q.
Impurity RRT 2.12	NMT 0.2 %	N.Q.
Impurity RRT 2.30	NMT 0.2 %	N.Q.
Impurity RRT 2.39	NMT 0.5 %	0.11 %
Impurity RRT 2.75	NMT 0.2 %	N.Q.
Any other impurity	NMT 0.10%	0.09 %
Total impurities	NMT 2.0%	0.3 %

Producer: **SANOFI CHIMIE**

Verona, 02/07/2012

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Approved by QA/QC Director

NEWCHEM spa www.newchemspa.com

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Batch: **NS1227**
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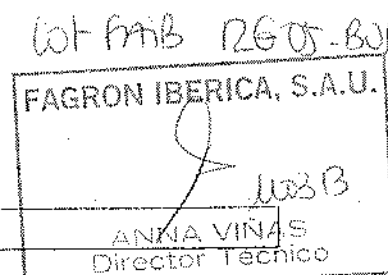
Manuf. date: **05/2012**
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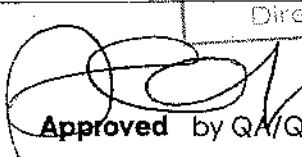
Tests	Specifications	Results
PARTICLE SIZE		
Particle size	NLT 95 % $\leq 15 \mu\text{m}$	99 %
Particle size	100 % $\leq 30 \mu\text{m}$	100 %

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